

**TDMS No.** 20007 - 06  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
**CAS Number:** 9000-38-8

**Date Report Requested:** 04/13/2009  
**Time Report Requested:** 08:27:00  
**First Dose M/F:** 08/24/04 / 08/23/04  
**Lab:** BAT

F\_M3

**C Number:** C20007  
**Lock Date:** 05/10/2007  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 2.1.0

TDMS No. 20007 - 06  
Test Type: CHRONIC  
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First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	1	TMT:	1	SEX:	Male	DAY ON TEST:	731
		DOSE:	0 G/KG	DISP:	Terminal Sacrifice	HISTO:	0601901

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ORGAN AND ACCOUNTABLE SITE STATUS

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NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Kidney	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Pituitary Gland	* Preputial Gland	* Prostate	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thyroid Gland
* Trachea	* Urinary Bladder		

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MISSING

* Mammary Gland	* Parathyroid Gland	* Thymus
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OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Marked
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Intestine Small, Duodenum		Adenoma	
	[ Adenoma TGLs = 4-10 ]		
* Islets, Pancreatic		Hyperplasia	Moderate
* Liver		Fatty Change	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
	[ Mixed Cell Focus TGLs = 2,3-11+12+13 ]		
Mesentery	Fat	Necrosis	Mild
	[ Necrosis TGLs = 1-11 ]		
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Seminal Vesicle		Fibrosis	Mild
		Inflammation	Minimal
* Spleen		Hematopoietic Cell Proliferation	Mild

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Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 2      **TMT:** 1      **SEX:** Male      **DAY ON TEST:** 732  
**DOSE:** 0 G/KG      **DISP:** Terminal Sacrifice      **HISTO:** 0601902

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Pancreas                 |
| * Parathyroid Gland       | * Pituitary Gland           | * Preputial Gland        | * Seminal Vesicle          |
| * Skin                    | * Stomach, Forestomach      | * Stomach, Glandular     | * Testes                   |
| * Thyroid Gland           | * Trachea                   | * Urinary Bladder        |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |   |   |                                       |
|----------------------|---|---|---------------------------------------|
| * Adrenal Cortex     | Subcapsular<br>Zona Reticul   | Hyperplasia<br>Hyperplasia                                      | Mild<br>Mild                          |
| * Harderian Gland    |   | Hyperplasia<br>Infiltration Cellular                            | Mild<br>Mononuclear CI, Minimal       |
| * Islets, Pancreatic |   | Hyperplasia   | Moderate                              |
| * Kidney             | Renal Tubule  | Mineralization<br>Nephropathy                                   | Minimal<br>Mild                       |
| * Liver              |   | Eosinophilic Focus<br>Infiltration Cellular<br>Mixed Cell Focus | Mononuclear CI, Minimal               |
|                      | [ Eosinophilic Focus TGLs = 2,3,4-10+11 ]<br>[ Mixed Cell Focus TGLs = 1-11 ] |   |                                       |
| * Nose               | Nasolacrim Dct  | Inflammation<br>Inflammation                                    | Suppurative, Mild<br>Chronic, Minimal |
| * Prostate           |   | Infiltration Cellular   | Mononuclear CI, Minimal               |
| * Salivary Glands    |   | Infiltration Cellular   | Mononuclear CI, Minimal               |
| * Spleen             |   | Lymphoma Malignant  |                                       |
| * Thymus             |   | Hyperplasia   | Histiocytic, Moderate                 |
| Tooth                |   | Dysplasia   | Moderate                              |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 3 TMT: 1 SEX: Male DAY ON TEST: 732  
 DOSE: 0 G/KG DISP: Terminal Sacrifice HISTO: 0601903

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Harderian Gland           | * Heart                  | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lymph Node, Mandibular  |
| * Lymph Node, Mesenteric    | * Nose                   | * Pancreas                 | * Pituitary Gland         |
| * Preputial Gland           | * Prostate               | * Skin                     | * Spleen                  |
| * Stomach, Forestomach      | * Stomach, Glandular     | * Testes                   | * Thyroid Gland           |
| * Trachea                   | * Urinary Bladder        |                            |                           |

**MISSING**

- |                 |                     |
|-----------------|---------------------|
| * Mammary Gland | * Parathyroid Gland |
|-----------------|---------------------|

**OBSERVATIONS**

- |                          |                                       |   |                                    |
|--------------------------|---------------------------------------|---|------------------------------------|
| * Adrenal Cortex         | Subcapsular                           | Hyperplasia<br>Infiltration Cellular  | Mild<br>Mononuclear CI, Minimal    |
| * Epididymis             |                                       | Infiltration Cellular   | Mononuclear CI, Minimal            |
| * Intestine Large, Cecum | Serosa                                | Inflammation  | Granulomatous, Mild                |
|                          | [ Inflammation TGLs = 3-11 ]          |   |                                    |
| * Islets, Pancreatic     |                                       | Hyperplasia   | Moderate                           |
| * Kidney                 | Renal Tubule                          | Mineralization<br>Nephropathy   | Minimal<br>Minimal                 |
| * Liver                  |                                       | Clear Cell Focus<br>Fatty Change<br>Infiltration Cellular<br>Mixed Cell Focus | Minimal<br>Mononuclear CI, Minimal |
|                          | [ Clear Cell Focus TGLs = 4-11 ]      |   |                                    |
|                          | [ Mixed Cell Focus TGLs = 5-12 ]      |   |                                    |
| * Lung                   | Alveolus                              | Infiltration Cellular   | Histiocyte, Minimal                |
|                          | [ Infiltration Cellular TGLs = 2-10 ] |   |                                    |
| * Salivary Glands        |                                       | Infiltration Cellular   | Mononuclear CI, Mild               |
| * Seminal Vesicle        |                                       | Fibrosis<br>Inflammation  | Minimal<br>Minimal                 |
|                          | [ Inflammation TGLs = 1-7 ]           |   |                                    |
| * Thymus                 |                                       | Atrophy   | Minimal                            |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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ANIMAL NUM: 3

TMT: 1  
DOSE: 0 G/KG

SEX: Male  
DISP: Terminal Sacrifice

DAY ON TEST: 732  
HISTO: 0601903

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ORGAN AND ACCOUNTABLE SITE STATUS

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Tooth

Dysplasia

Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 4      **TMT:** 1      **SEX:** Male      **DAY ON TEST:** 579  
**DOSE:** 0 G/KG      **DISP:** Natural Death      **HISTO:** 0601904

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     |
| * Pancreas                | * Pituitary Gland           | * Preputial Gland        | * Salivary Glands          |
| * Skin                    | * Stomach, Forestomach      | * Stomach, Glandular     | * Testes                   |
| * Trachea                 |                             |                          |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |   |                        |                         |
|----------------------|---|------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                                 | Hyperplasia            | Mild                    |
| * Harderian Gland    |   | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Islets, Pancreatic |   | Hyperplasia            | Minimal                 |
| * Kidney             | Renal Tubule                                | Hydronephrosis         | Mild                    |
|                      | Renal Tubule                                | Hyperplasia            | Minimal                 |
|                      | Cortex, Medulla                             | Mineralization         | Mild                    |
|                      |   | Necrosis               | Moderate                |
| * Liver              |   | Basophilic Focus       |                         |
|                      |   | Fatty Change           | Mild                    |
|                      |   | Hepatocellular Adenoma | Multiple                |
|                      |   | Infiltration Cellular  | Mononuclear CI, Minimal |
|                      | [ Hepatocellular Adenoma TGLs = 1,2-10+11 ] |                        |                         |
| * Parathyroid Gland  |   | Cyst                   | Minimal                 |
| * Prostate           |   | Inflammation           | Minimal                 |
| * Seminal Vesicle    |   | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Spleen             | Lymph Follic                                | Atrophy                | Moderate                |
| * Thymus             |   | Atrophy                | Moderate                |
| * Thyroid Gland      |   | Cyst                   | Mild                    |
| Tooth                |   | Dysplasia              | Marked                  |
| * Urinary Bladder    |   | Inflammation           | Minimal                 |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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<b>ANIMAL NUM:</b>	4	<b>TMT:</b>	1	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	579
		<b>DOSE:</b>	0 G/KG	<b>DISP:</b>	Natural Death	<b>HISTO:</b>	0601904

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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PRIMARY CAUSE OF DEATH      - Kidney Cortex Medulla Necrosis

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TDMS No. 20007 - 06  
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 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
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 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 5      **TMT:** 1      **SEX:** Male      **DAY ON TEST:** 570  
**DOSE:** 0 G/KG      **DISP:** Natural Death      **HISTO:** 0601905

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Epididymis             | * Esophagus                | * Eye                     |
| * Gallbladder               | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lymph Node, Mandibular  |
| * Lymph Node, Mesenteric    | * Nose                   | * Pancreas                 | * Parathyroid Gland       |
| * Pituitary Gland           | * Preputial Gland        | * Seminal Vesicle          | * Skin                    |
| * Stomach, Forestomach      | * Stomach, Glandular     | * Testes                   | * Trachea                 |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |  |                              |                         |
|----------------------|--|------------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                            | Hyperplasia                  | Mild                    |
| * Harderian Gland    |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Heart              | Myocardium                             | Mineralization               | Mild                    |
| * Islets, Pancreatic |  | Hyperplasia                  | Moderate                |
| * Kidney             | Renal Tubule                           | Hydronephrosis               | Mild                    |
|                      | Cortex, Medulla                        | Mineralization               | Mild                    |
|                      | [ Necrosis TGLs = 3-4 ]                | Necrosis                     | Moderate                |
| * Liver              |  | Basophilic Focus             |                         |
|                      |  | Clear Cell Focus             |                         |
|                      |  | Fatty Change                 | Mild                    |
|                      |  | Hepatocellular Adenoma       |                         |
|                      |  | Infiltration Cellular        | Mononuclear CI, Minimal |
|                      | [ Clear Cell Focus TGLs = 1-10 ]       |                              |                         |
|                      | [ Hepatocellular Adenoma TGLs = 2-11 ] |                              |                         |
| * Lung               |  | Alveolar/Bronchiolar Adenoma |                         |
| * Prostate           |  | Inflammation                 | Mild                    |
| * Salivary Glands    |  | Infiltration Cellular        | Mononuclear CI, Mild    |
| * Spleen             | Lymph Follic                           | Atrophy                      | Mild                    |
| * Thymus             |  | Atrophy                      | Marked                  |
| * Thyroid Gland      |  | Cyst                         | Mild                    |

\* PROTOCOL REQUIRED TISSUE



TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	5	<b>TMT:</b>	1	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	570
		<b>DOSE:</b>	0 G/KG	<b>DISP:</b>	Natural Death	<b>HISTO:</b>	0601905

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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Tooth	Dysplasia	Mild
Urethra	Inflammation	Moderate
* Urinary Bladder	Inflammation	Minimal

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PRIMARY CAUSE OF DEATH - Kidney Cortex Medulla Necrosis

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 6      TMT: 1      SEX: Male      DAY ON TEST: 668  
 DOSE: 0 G/KG      DISP: Natural Death      HISTO: 0601906

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Epididymis	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mandibular
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Skin	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Bone Marrow		Hemangiosarcoma	
* Harderian Gland		Adenoma	
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Adenoma TGLs = 1-9 ]		
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney		Hydronephrosis	Moderate
	Renal Tubule	Inflammation	Moderate
	Cortex, Medulla	Mineralization	Minimal
		Necrosis	Moderate
* Liver		Eosinophilic Focus	
		Hemangiosarcoma	
		Hepatocellular Adenoma	
		Hepatocellular Carcinoma	
		Infiltration Cellular	Mononuclear CI, Minimal
		Necrosis	Mild
	[ Hemangiosarcoma TGLs = 2,3,4,5-10+11+12+13 ]		
	[ Hepatocellular Adenoma TGLs = 3-11 ]		
	[ Hepatocellular Carcinoma TGLs = 5-13 ]		
* Lung		Hemangiosarcoma	Metastatic (Liver)
	Alveolus	Infiltration Cellular	Histiocyte, Mild
	[ Hemangiosarcoma TGLs = 6,8-14 ]		
* Lymph Node, Mesenteric		Atrophy	Moderate
Mesentery		Inflammation	Chronic, Moderate
* Prostate		Inflammation	Moderate

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	6	<b>TMT:</b>	1	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	668
		<b>DOSE:</b>	0 G/KG	<b>DISP:</b>	Natural Death	<b>HISTO:</b>	0601906

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Seminal Vesicle		Inflammation	Minimal
* Spleen	Lymph Follic	Atrophy Hematopoietic Cell Proliferation	Marked Moderate
* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation Necrosis Squamous Cell Papilloma	Moderate Chronic, Moderate Moderate
	[ Squamous Cell Papilloma TGLs = 7-15 ]		
* Thymus		Atrophy	Marked
Tooth		Dysplasia	Mild
* Urinary Bladder		Inflammation	Moderate

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PRIMARY CAUSE OF DEATH - Kidney Inflammation

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TDMS No. 20007 - 06  
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 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
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 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 7 TMT: 1 SEX: Male DAY ON TEST: 652  
 DOSE: 0 G/KG DISP: Natural Death HISTO: 0601907

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lymph Node, Mandibular  |
| * Lymph Node, Mesenteric    | * Nose                   | * Pancreas                 | * Parathyroid Gland       |
| * Pituitary Gland           | * Seminal Vesicle        | * Skin                     | * Spleen                  |
| * Stomach, Glandular        | * Testes                 | * Thyroid Gland            | * Trachea                 |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |   |                          |                         |
|------------------------|---|--------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                                 | Hyperplasia              | Minimal                 |
| * Epididymis           |   | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Harderian Gland      |   | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Islets, Pancreatic   |   | Hyperplasia              | Minimal                 |
| * Kidney               |   | Nephropathy              | Minimal                 |
| * Liver                |   | Eosinophilic Focus       |                         |
|                        |   | Fatty Change             | Mild                    |
|                        |   | Hepatocellular Adenoma   | Multiple                |
|                        |   | Hepatocellular Carcinoma |                         |
|                        |   | Infiltration Cellular    | Mononuclear CI, Minimal |
|                        | [ Eosinophilic Focus TGLs = 4-13 ]          |                          |                         |
|                        | [ Hepatocellular Adenoma TGLs = 2,3-11+12 ] |                          |                         |
|                        | [ Hepatocellular Carcinoma TGLs = 1-10 ]    |                          |                         |
| * Lung                 | Bronchus                                    | Hyperplasia              | Mild                    |
| * Preputial Gland      |   | Inflammation             | Minimal                 |
| * Prostate             |   | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Salivary Glands      |   | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Stomach, Forestomach | Epithelium                                  | Hyperplasia              | Moderate                |
|                        |   | Inflammation             | Chronic, Moderate       |
|                        |   | Necrosis                 | Moderate                |
|                        |   | Squamous Cell Papilloma  |                         |
|                        | [ Necrosis TGLs = 5-14 ]                    |                          |                         |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

ANIMAL NUM: 7

TMT: 1

DOSE: 0 G/KG

SEX: Male

DISP: Natural Death

DAY ON TEST: 652

HISTO: 0601907

ORGAN AND ACCOUNTABLE SITE STATUS

[ Squamous Cell Papilloma TGLs = 5-14 ]

\* Thymus

Atrophy

Mild

Tooth

Dysplasia

Minimal

\* Urinary Bladder

Infiltration Cellular

Mononuclear CI, Minimal

PRIMARY CAUSE OF DEATH - Liver Hepatocellular Carcinoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 8 TMT: 1 SEX: Male DAY ON TEST: 732  
 DOSE: 0 G/KG DISP: Terminal Sacrifice HISTO: 0601908

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular Zona Reticul	Hyperplasia Hyperplasia	Mild Mild
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Adenoma	
* Heart	Artery	Cardiomyopathy Infiltration Cellular	Minimal Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney	Renal Tubule	Mineralization Nephropathy	Minimal Minimal
* Liver		Clear Cell Focus Eosinophilic Focus Fatty Change Hepatocellular Adenoma Infiltration Cellular Mixed Cell Focus	Minimal Multiple Mononuclear CI, Minimal
	[ Eosinophilic Focus TGLs = 4-4 ] [ Hepatocellular Adenoma TGLs = 1,2-10+11 ] [ Mixed Cell Focus TGLs = 3,6-5+12 ]		
* Lung	[ Alveolar/Bronchiolar Carcinoma TGLs = 5-13 ]	Alveolar/Bronchiolar Carcinoma	
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	8	<b>TMT:</b>	1	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	732
		<b>DOSE:</b>	0 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0601908

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Thymus	Atrophy	Minimal
Tooth	Dysplasia	Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 9 TMT: 1 SEX: Male DAY ON TEST: 668  
 DOSE: 0 G/KG DISP: Moribund Sacrifice HISTO: 0601909

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Esophagus	* Eye
* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Kidney
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Seminal Vesicle	* Skin
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Epididymis	Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland	Infiltration Cellular	Mononuclear CI, Minimal
* Heart	Cardiomyopathy	Minimal
	Hepatocholangiocarcinoma	Metastatic (Liver)
* Islets, Pancreatic	Hyperplasia	Minimal
* Liver	Hepatocholangiocarcinoma	
	Infiltration Cellular	Mononuclear CI, Minimal
[ Hepatocholangiocarcinoma TGLs = 1-10 ]		
* Lung	Hepatocholangiocarcinoma	Metastatic (Liver)
[ Hepatocholangiocarcinoma TGLs = 2-11 ]		
* Preputial Gland	Inflammation	Minimal
* Prostate	Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands	Infiltration Cellular	Mononuclear CI, Minimal
* Spleen	Hematopoietic Cell Proliferation	Mild
* Stomach, Forestomach	Squamous Cell Papilloma	
[ Squamous Cell Papilloma TGLs = 3-12 ]		
* Thymus	Atrophy	Marked
	Hepatocholangiocarcinoma	Metastatic (Liver)
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

PRIMARY CAUSE OF DEATH - Liver Hepatocholangiocarcinoma

\* PROTOCOL REQUIRED TISSUE



TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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ANIMAL NUM: 9

TMT: 1

DOSE: 0 G/KG

SEX: Male

DISP: Moribund Sacrifice

DAY ON TEST: 668

HISTO: 0601909

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ORGAN AND ACCOUNTABLE SITE STATUS

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 10 TMT: 1 SEX: Male DAY ON TEST: 731  
 DOSE: 0 G/KG DISP: Terminal Sacrifice HISTO: 0601910

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- \* Adrenal Medulla
- \* Brain
- \* Gallbladder
- \* Intestine Large, Rectum
- \* Lung
- \* Pancreas
- \* Prostate
- \* Stomach, Forestomach
- \* Trachea
- Blood Vessel
- \* Epididymis
- \* Heart
- \* Intestine Small, Duodenum
- \* Lymph Node, Mandibular
- \* Parathyroid Gland
- \* Seminal Vesicle
- \* Stomach, Glandular
- \* Bone
- \* Esophagus
- \* Intestine Large, Cecum
- \* Intestine Small, Jejunum
- \* Lymph Node, Mesenteric
- \* Pituitary Gland
- \* Skin
- \* Testes
- \* Bone Marrow
- \* Eye
- \* Intestine Large, Colon
- \* Islets, Pancreatic
- \* Nose
- \* Preputial Gland
- \* Spleen
- \* Thyroid Gland

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |   |   |   |   |
|---|---|---|---|
| <ul style="list-style-type: none"> <li>* Adrenal Cortex</li> <li>* Harderian Gland</li> <li>* Intestine Small, Ileum</li> <li>* Kidney</li> <li>* Liver</li> </ul>  | <ul style="list-style-type: none"> <li>Subcapsular</li> <li>Epithelium</li> <li>Renal Tubule</li> </ul> | <ul style="list-style-type: none"> <li>Hyperplasia</li> <li>Infiltration Cellular</li> <li>Hyperplasia</li> <li>Inflammation</li> <li>Mineralization</li> <li>Clear Cell Focus</li> <li>Eosinophilic Focus</li> <li>Hemangiosarcoma</li> <li>Hepatocellular Adenoma</li> <li>Infiltration Cellular</li> <li>Mixed Cell Focus</li> <li>Necrosis</li> </ul> | <ul style="list-style-type: none"> <li>Minimal</li> <li>Mononuclear CI, Minimal</li> <li>Mild</li> <li>Chronic, Mild</li> <li>Minimal</li> <li>Multiple</li> <li>Mononuclear CI, Minimal</li> <li>Mild</li> </ul> |
| <ul style="list-style-type: none"> <li>[ Clear Cell Focus TGLs = 6-12 ]</li> <li>[ Hemangiosarcoma TGLs = 2,5-11+13 ]</li> <li>[ Hepatocellular Adenoma TGLs = 1,2,3-4+10+13 ]</li> <li>[ Mixed Cell Focus TGLs = 4-10 ]</li> </ul> |   |   |   |
| <ul style="list-style-type: none"> <li>* Salivary Glands</li> <li>* Thymus</li> <li>Tooth</li> <li>* Urinary Bladder</li> </ul>   |   | <ul style="list-style-type: none"> <li>Infiltration Cellular</li> <li>Atrophy</li> <li>Dysplasia</li> <li>Infiltration Cellular</li> </ul>  | <ul style="list-style-type: none"> <li>Mononuclear CI, Minimal</li> <li>Mild</li> <li>Marked</li> <li>Mononuclear CI, Minimal</li> </ul>  |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 11 TMT: 1 SEX: Male DAY ON TEST: 731  
 DOSE: 0 G/KG DISP: Terminal Sacrifice HISTO: 0601911

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Kidney	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Testes	* Thyroid Gland
* Trachea	* Urinary Bladder		

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Intestine Small, Jejunum		Adenoma	
	[ Adenoma TGLs = 8-17 ]		
* Islets, Pancreatic		Hyperplasia	Mild
* Liver		Eosinophilic Focus	
		Hepatocellular Adenoma	Multiple
		Hepatocellular Carcinoma	
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Hepatocellular Adenoma TGLs = 2,3,4,5-11+12+13+14 ]		
	[ Hepatocellular Carcinoma TGLs = 1-10 ]		
* Lung		Hepatocellular Carcinoma	Metastatic (Liver)
	[ Hepatocellular Carcinoma TGLs = 6,7-15+16 ]		
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen	Lymph Follic	Atrophy	Mild
		Hematopoietic Cell Proliferation	Moderate
* Stomach, Glandular	Epithelium	Hyperplasia	Mild
* Thymus		Atrophy	Marked

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 12    TMT: 1    SEX: Male    DAY ON TEST: 587  
 DOSE: 0 G/KG    DISP: Natural Death    HISTO: 0601912

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Preputial Gland	* Prostate	* Seminal Vesicle
* Skin	* Spleen	* Testes	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

\* Mammary Gland                      \* Pituitary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hepatocholangiocarcinoma Hyperplasia	Metastatic (Liver) Minimal
* Harderian Gland		Hyperplasia Infiltration Cellular	Minimal Mononuclear CI, Minimal
* Heart	[ Hepatocholangiocarcinoma TGLs = 2-12 ]	Hepatocholangiocarcinoma	Metastatic (Liver)
* Kidney	Renal Tubule	Hepatocholangiocarcinoma Mineralization Nephropathy	Metastatic (Liver) Minimal Minimal
* Liver	[ Hepatocholangiocarcinoma TGLs = 1-11 ]	Fatty Change Hepatocholangiocarcinoma Mineralization	Minimal Minimal
* Lung	[ Hepatocholangiocarcinoma TGLs = 3,4-13+14 ]	Hepatocholangiocarcinoma	Metastatic (Liver)
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
Skeletal Muscle	[ Hepatocholangiocarcinoma TGLs = 5-10 ]	Hepatocholangiocarcinoma	Metastatic (Liver)
* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation Necrosis	Mild Chronic, Mild Mild

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	12	<b>TMT:</b>	1	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	587
		<b>DOSE:</b>	0 G/KG	<b>DISP:</b>	Natural Death	<b>HISTO:</b>	0601912

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Stomach, Glandular	Ulcer	Mild
* Thymus	Atrophy	Marked
Tooth	Dysplasia	Mild

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PRIMARY CAUSE OF DEATH - Liver Hepatocholangiocarcinoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 13	<b>TMT:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0601913

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex          | * Adrenal Medulla           | Blood Vessel             | * Bone                     |
| * Bone Marrow             | * Brain                     | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Pancreas                 |
| * Parathyroid Gland       | * Pituitary Gland           | * Seminal Vesicle        | * Spleen                   |
| * Stomach, Glandular      | * Testes                    | * Thyroid Gland          | * Trachea                  |
| * Urinary Bladder         |                             |                          |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |   |   |                         |
|------------------------|---|---|-------------------------|
| * Epididymis           |   | Infiltration Cellular                       | Mononuclear CI, Minimal |
| * Eye                  |   |   |                         |
|                        | Note: Both optic nerves were missing    |   |                         |
| * Harderian Gland      |   | Infiltration Cellular                       | Mononuclear CI, Minimal |
| * Kidney               | Renal Tubule                            | Mineralization<br>Nephropathy               | Minimal<br>Minimal      |
| * Liver                |   | Eosinophilic Focus<br>Infiltration Cellular | Mononuclear CI, Minimal |
|                        | [ Eosinophilic Focus TGLs = 1-11 ]      |   |                         |
| * Lung                 |   | Alveolar/Bronchiolar Adenoma                |                         |
| * Nose                 | Respirat Epith                          | Hyperplasia                                 | Mild                    |
| * Preputial Gland      |   | Inflammation                                | Minimal                 |
| * Prostate             |   | Infiltration Cellular                       | Mononuclear CI, Minimal |
| * Salivary Glands      |   | Infiltration Cellular                       | Mononuclear CI, Minimal |
| * Skin                 | Subcut Tiss                             | Hemangiosarcoma                             |                         |
|                        | [ Hemangiosarcoma TGLs = 2-10 ]         |   |                         |
| * Stomach, Forestomach |   | Squamous Cell Papilloma                     |                         |
|                        | [ Squamous Cell Papilloma TGLs = 3-12 ] |   |                         |
| * Thymus               |   | Atrophy                                     | Moderate                |
| Tooth                  |   | Dysplasia                                   | Moderate                |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 14 TMT: 1 SEX: Male DAY ON TEST: 730  
 DOSE: 0 G/KG DISP: Terminal Sacrifice HISTO: 0601914

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla        | Blood Vessel               | * Bone                    | * Brain                     |
| * Epididymis             | * Esophagus                | * Eye                     | * Gallbladder               |
| * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      | * Lymph Node, Mandibular    |
| * Lymph Node, Mesenteric | * Pancreas                 | * Parathyroid Gland       | * Seminal Vesicle           |
| * Skin                   | * Testes                   | * Thyroid Gland           | * Trachea                   |
| * Urinary Bladder        |                            |                           |                             |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                   |  |                          |                         |
|-------------------|--|--------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                              | Hyperplasia              | Minimal                 |
| * Bone Marrow     |  | Hemangioma               |                         |
| * Harderian Gland |  | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Heart           |  | Cardiomyopathy           | Mild                    |
| * Kidney          | Renal Tubule                             | Mineralization           | Minimal                 |
|                   |  | Nephropathy              | Mild                    |
| * Liver           |  | Degeneration             | Cystic, Minimal         |
|                   |  | Eosinophilic Focus       |                         |
|                   |  | Hepatocellular Carcinoma |                         |
|                   |  | Infiltration Cellular    | Mononuclear CI, Minimal |
|                   | [ Eosinophilic Focus TGLs = 3,6-10+12 ]  |                          |                         |
|                   | [ Hepatocellular Carcinoma TGLs = 4-11 ] |                          |                         |
| * Lung            |  | Hepatocellular Carcinoma | Metastatic (Liver)      |
| * Nose            |  | Inflammation             | Chronic, Minimal        |
| * Pituitary Gland | Pars Intermed                            | Adenoma                  |                         |
|                   | [ Adenoma TGLs = 5-6 ]                   |                          |                         |
| * Preputial Gland |  | Cyst                     | Mild                    |
|                   |  | Inflammation             | Mild                    |
|                   | [ Cyst TGLs = 1-8 ]                      |                          |                         |
| * Prostate        |  | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Salivary Glands |  | Infiltration Cellular    | Mononuclear CI, Minimal |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	14	TMT:	1	SEX:	Male	DAY ON TEST:	730
		DOSE:	0 G/KG	DISP:	Terminal Sacrifice	HISTO:	0601914

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ORGAN AND ACCOUNTABLE SITE STATUS

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* Spleen [ Hematopoietic Cell Proliferation TGLs = 2-4 ]	Hematopoietic Cell Proliferation	Moderate
* Stomach, Forestomach [ Squamous Cell Carcinoma TGLs = 7-13 ]	Inflammation Squamous Cell Carcinoma	Chronic, Mild
* Stomach, Glandular Epithelium	Hyperplasia	Mild
* Thymus	Atrophy	Marked



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 15    TMT: 1    SEX: Male    DAY ON TEST: 455  
 DOSE: 0 G/KG    DISP: Natural Death    HISTO: 0601915

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     |
| * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        | * Prostate                 |
| * Seminal Vesicle         | * Skin                      | * Spleen                 | * Stomach, Forestomach     |
| * Stomach, Glandular      | * Testes                    | * Thyroid Gland          | * Trachea                  |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |  |                          |                         |
|----------------------|--|--------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                              | Hyperplasia              | Minimal                 |
| * Harderian Gland    |  | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Islets, Pancreatic |  | Hyperplasia              | Minimal                 |
| * Kidney             | Renal Tubule                             | Mineralization           | Minimal                 |
| * Liver              |  | Fatty Change             | Minimal                 |
|                      |  | Hepatocellular Carcinoma |                         |
|                      |  | Infiltration Cellular    | Mononuclear CI, Minimal |
|                      | [ Hepatocellular Carcinoma TGLs = 1-10 ] |                          |                         |
| * Preputial Gland    |  | Cyst                     | Mild                    |
|                      | [ Cyst TGLs = 2-8 ]                      |                          |                         |
| * Salivary Glands    |  | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Thymus             |  | Atrophy                  | Minimal                 |
| * Urinary Bladder    |  | Infiltration Cellular    | Mononuclear CI, Minimal |

PRIMARY CAUSE OF DEATH - Liver Hepatocellular Carcinoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 16    **TMT:** 1    **SEX:** Male    **DAY ON TEST:** 644  
**DOSE:** 0 G/KG    **DISP:** Natural Death    **HISTO:** 0601916

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          |
| * Prostate                | * Seminal Vesicle           | * Skin                   | * Spleen                   |
| * Stomach, Forestomach    | * Stomach, Glandular        | * Testes                 | * Thymus                   |
| * Thyroid Gland           | * Trachea                   |                          |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                   |  |                          |                         |
|-------------------|--|--------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                              | Hyperplasia              | Minimal                 |
| * Harderian Gland |  | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Kidney          | Cortex, Medulla                          | Necrosis                 | Moderate                |
| * Liver           |  | Hepatocellular Carcinoma |                         |
|                   | [ Hepatocellular Carcinoma TGLs = 1-10 ] | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Nose            |  | Inflammation             | Chronic, Minimal        |
| * Salivary Glands |  | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Urinary Bladder |  | Infiltration Cellular    | Mononuclear CI, Minimal |

PRIMARY CAUSE OF DEATH - Liver Hepatocellular Carcinoma  
 CONTRIBUTORY CAUSE OF DEATH - Kidney Cortex Medulla Necrosis

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

ANIMAL NUM: 17 TMT: 1 SEX: Male DAY ON TEST: 647  
DOSE: 0 G/KG DISP: Natural Death HISTO: 0601917

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Seminal Vesicle	* Skin
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Moderate
* Kidney		Nephropathy	Minimal
* Liver		Fatty Change	Mild
		Hepatocellular Carcinoma	
	[ Hepatocellular Carcinoma TGLs = 1-10 ]	Infiltration Cellular	Mononuclear CI, Minimal
* Preputial Gland		Inflammation	Minimal
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Chronic, Minimal
	[ Hyperplasia TGLs = 2-11 ]		
* Thymus		Atrophy	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

PRIMARY CAUSE OF DEATH - Liver Hepatocellular Carcinoma

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 18    TMT: 1    SEX: Male    DAY ON TEST: 732  
 DOSE: 0 G/KG    DISP: Terminal Sacrifice    HISTO: 0601918

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla        | Blood Vessel               | * Bone                    | * Bone Marrow               |
| * Brain                  | * Esophagus                | * Eye                     | * Gallbladder               |
| * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    | * Lymph Node, Mandibular    |
| * Lymph Node, Mesenteric | * Nose                     | * Pancreas                | * Parathyroid Gland         |
| * Pituitary Gland        | * Preputial Gland          | * Salivary Glands         | * Seminal Vesicle           |
| * Skin                   | * Spleen                   | * Stomach, Forestomach    | * Stomach, Glandular        |
| * Testes                 | * Thymus                   | * Thyroid Gland           | * Trachea                   |
| * Urinary Bladder        |                            |                           |                             |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |   |                        |                         |
|----------------------|---|------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                               | Hyperplasia            | Mild                    |
| * Epididymis         |   | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Harderian Gland    |   | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Heart              |   | Cardiomyopathy         | Minimal                 |
| * Islets, Pancreatic |   | Hyperplasia            | Moderate                |
| * Kidney             | Renal Tubule                              | Hyperplasia            | Minimal                 |
|                      | Renal Tubule                              | Mineralization         | Minimal                 |
|                      |   | Mineralization         | Minimal                 |
|                      |   | Nephropathy            | Minimal                 |
| * Liver              |   | Clear Cell Focus       |                         |
|                      |   | Eosinophilic Focus     |                         |
|                      |   | Fatty Change           | Minimal                 |
|                      |   | Hepatocellular Adenoma | Multiple                |
|                      |   | Infiltration Cellular  | Mononuclear CI, Minimal |
|                      |   | Mixed Cell Focus       |                         |
|                      | [ Eosinophilic Focus    TGLs = 2-11 ]     |                        |                         |
|                      | [ Hepatocellular Adenoma    TGLs = 1-10 ] |                        |                         |
| * Prostate           |   | Infiltration Cellular  | Mononuclear CI, Minimal |
| Tooth                |   | Dysplasia              | Marked                  |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 19    **TMT:** 1    **SEX:** Male    **DAY ON TEST:** 703  
**DOSE:** 0 G/KG    **DISP:** Natural Death    **HISTO:** 0601919

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla        | Blood Vessel               | * Bone                    | * Bone Marrow               |
| * Brain                  | * Esophagus                | * Eye                     | * Gallbladder               |
| * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    | * Lymph Node, Mandibular    |
| * Lymph Node, Mesenteric | * Nose                     | * Pancreas                | * Parathyroid Gland         |
| * Pituitary Gland        | * Preputial Gland          | * Seminal Vesicle         | * Skin                      |
| * Stomach, Forestomach   | * Stomach, Glandular       | * Testes                  | * Trachea                   |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |              |  |                         |
|----------------------|--------------|--|-------------------------|
| * Adrenal Cortex     | Subcapsular  | Hyperplasia                              | Minimal                 |
| * Epididymis         |              | Infiltration Cellular                    | Mononuclear CI, Minimal |
| * Harderian Gland    |              | Infiltration Cellular                    | Mononuclear CI, Minimal |
| * Heart              |              | Cardiomyopathy                           | Mild                    |
| * Islets, Pancreatic |              | Hyperplasia                              | Mild                    |
| * Kidney             | Renal Tubule | Mineralization                           | Minimal                 |
| * Liver              |              | Clear Cell Focus                         |                         |
|                      |              | Eosinophilic Focus                       |                         |
|                      |              | Hemangiosarcoma                          |                         |
|                      |              | Hepatocellular Carcinoma                 |                         |
|                      |              | Infiltration Cellular                    | Mononuclear CI, Minimal |
|                      |              | Mixed Cell Focus                         |                         |
|                      |              | [ Eosinophilic Focus TGLs = 3-12 ]       |                         |
|                      |              | [ Hemangiosarcoma TGLs = 1-10 ]          |                         |
|                      |              | [ Hepatocellular Carcinoma TGLs = 2-11 ] |                         |
| * Prostate           |              | Infiltration Cellular                    | Mononuclear CI, Minimal |
| * Salivary Glands    |              | Infiltration Cellular                    | Mononuclear CI, Minimal |
| * Spleen             |              | Hematopoietic Cell Proliferation         | Moderate                |
| * Thymus             |              | Atrophy                                  | Mild                    |
| * Thyroid Gland      |              | Cyst                                     | Mild                    |
| Tooth                |              | Dysplasia                                | Moderate                |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	19	<b>TMT:</b>	1	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	703
		<b>DOSE:</b>	0 G/KG	<b>DISP:</b>	Natural Death	<b>HISTO:</b>	0601919

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* Urinary Bladder

Infiltration Cellular

Mononuclear CI, Minimal

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PRIMARY CAUSE OF DEATH - Liver Hemangiosarcoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 20    TMT: 1    SEX: Male    DAY ON TEST: 731  
 DOSE: 0 G/KG    DISP: Terminal Sacrifice    HISTO: 0601920

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney	Capsule	Hemangioma	
	[ Hemangioma TGLs = 3-11 ]	Nephropathy	Minimal
* Liver		Eosinophilic Focus	
	[ Hepatocellular Adenoma TGLs = 2-10 ]	Fatty Change	Minimal
	[ Mixed Cell Focus TGLs = 4-12 ]	Hepatocellular Adenoma	
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
* Lung		Alveolar/Bronchiolar Adenoma	
* Preputial Gland		Cyst	Mild
	[ Cyst TGLs = 1-8 ]	Inflammation	Mild
* Prostate		Hyperplasia	Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Thymus		Lymphoma Malignant	
Tooth		Dysplasia	Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 21    TMT: 1    SEX: Male    DAY ON TEST: 730  
 DOSE: 0 G/KG    DISP: Terminal Sacrifice    HISTO: 0601921

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Esophagus                 | * Eye                    | * Gallbladder              |
| * Harderian Gland         | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lymph Node, Mandibular  | * Lymph Node, Mesenteric    | * Parathyroid Gland      | * Pituitary Gland          |
| * Preputial Gland         | * Seminal Vesicle           | * Skin                   | * Spleen                   |
| * Stomach, Glandular      | * Testes                    | * Thyroid Gland          | * Trachea                  |
| * Urinary Bladder         |                             |                          |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |  |                              |                         |
|------------------------|--|------------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                                  | Hyperplasia                  | Minimal                 |
| * Epididymis           |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Islets, Pancreatic   |  | Hyperplasia                  | Mild                    |
| * Kidney               | Renal Tubule                                 | Adenoma                      | Minimal                 |
|                        | Renal Tubule                                 | Hyperplasia                  | Minimal                 |
|                        | Renal Tubule                                 | Mineralization               | Minimal                 |
|                        |  | Nephropathy                  | Minimal                 |
|                        | [ Adenoma TGLs = 1-10 ]                      |                              |                         |
| * Liver                |  | Eosinophilic Focus           | Minimal                 |
|                        |  | Fatty Change                 | Minimal                 |
|                        |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Lung                 |  | Alveolar/Bronchiolar Adenoma |                         |
|                        | [ Alveolar/Bronchiolar Adenoma TGLs = 2-11 ] |                              |                         |
| * Nose                 |  | Inflammation                 | Chronic, Minimal        |
| * Pancreas             | Acinus                                       | Atrophy                      | Marked                  |
| * Prostate             |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Salivary Glands      |  | Infiltration Cellular        | Mononuclear CI, Mild    |
| * Stomach, Forestomach | Epithelium                                   | Hyperplasia                  | Mild                    |
|                        |  | Inflammation                 | Chronic, Minimal        |
|                        | [ Hyperplasia TGLs = 3-12 ]                  |                              |                         |
| * Thymus               |  | Atrophy                      | Mild                    |

\* PROTOCOL REQUIRED TISSUE



TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	21	<b>TMT:</b>	1	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	730
		<b>DOSE:</b>	0 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0601921

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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Tooth

Dysplasia

Moderate

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 22 TMT: 1 SEX: Male DAY ON TEST: 369  
 DOSE: 0 G/KG DISP: Natural Death HISTO: 0601922

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Harderian Gland           | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     |
| * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          |
| * Prostate                | * Salivary Glands           | * Seminal Vesicle        | * Spleen                   |
| * Stomach, Forestomach    | * Stomach, Glandular        | * Testes                 | * Thymus                   |
| * Thyroid Gland           | * Trachea                   |                          |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |  |   |                       |                         |
|--|---|-----------------------|-------------------------|
| * Adrenal Cortex   | Subcapsular                                   | Hyperplasia           | Minimal                 |
| * Epididymis   |   |                       |                         |
| Note: Part of epididymis was missing   |   |                       |                         |
| * Heart  |   | Osteosarcoma          | Metastatic (Skin)       |
| * Kidney   |   | Mineralization        | Minimal                 |
|  | Renal Tubule                                  | Mineralization        | Minimal                 |
| * Liver  |   | Fatty Change          | Minimal                 |
|  |   | Infiltration Cellular | Mononuclear CI, Minimal |
|  |   | Osteosarcoma          | Metastatic (Skin)       |
|  | [ Osteosarcoma TGLs = 2,3,4,5,6-11+12+13+14 ] |                       |                         |
| * Lung   |   | Osteosarcoma          | Metastatic (Skin)       |
|  | [ Osteosarcoma TGLs = 1-10 ]                  |                       |                         |
| * Skin   | Subcut Tiss                                   | Osteosarcoma          |                         |
| Note: Based on histology and search of wet tissues the nodules identified at necropsy as being on the ribs were dermal nodules |   |                       |                         |
|  | [ Osteosarcoma TGLs = 7-15 ]                  |                       |                         |
| * Urinary Bladder  |   | Infiltration Cellular | Mononuclear CI, Minimal |

PRIMARY CAUSE OF DEATH - Skin Subcut Tiss Osteosarcoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 23    **TMT:** 1    **SEX:** Male    **DAY ON TEST:** 648  
**DOSE:** 0 G/KG    **DISP:** Natural Death    **HISTO:** 0601923

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea

**MISSING**

\* Mammary Gland                      \* Thymus

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Cardiomyopathy	Minimal
* Liver		Fatty Change	Minimal
		Hepatocellular Carcinoma	
		Infiltration Cellular	Mononuclear CI, Mild
	[ Hepatocellular Carcinoma    TGLs = 2-11 ]		
* Lung		Alveolar/Bronchiolar Adenoma	
	[ Alveolar/Bronchiolar Adenoma    TGLs = 1-10 ]		
* Salivary Glands	Parotid GI	Atrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Chronic, Mild
		Necrosis	Minimal
		Squamous Cell Papilloma	
	[ Squamous Cell Papilloma    TGLs = 3-12 ]		
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

**PRIMARY CAUSE OF DEATH**    - Liver    Hepatocellular Carcinoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 24    **TMT:** 1    **SEX:** Male    **DAY ON TEST:** 732  
**DOSE:** 0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0601924

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lymph Node, Mandibular  |
| * Lymph Node, Mesenteric    | * Pancreas               | * Parathyroid Gland        | * Pituitary Gland         |
| * Preputial Gland           | * Seminal Vesicle        | * Skin                     | * Stomach, Glandular      |
| * Testes                    | * Thyroid Gland          | * Trachea                  | * Urinary Bladder         |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |  |                              |                         |
|------------------------|--|------------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                                  | Hyperplasia                  | Minimal                 |
| * Epididymis           |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Harderian Gland      |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Islets, Pancreatic   |  | Hyperplasia                  | Mild                    |
| * Kidney               | Renal Tubule                                 | Mineralization               | Minimal                 |
|                        |  | Nephropathy                  | Minimal                 |
| * Liver                |  | Fatty Change                 | Mild                    |
|                        |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Lung                 |  | Alveolar/Bronchiolar Adenoma |                         |
|                        | [ Alveolar/Bronchiolar Adenoma TGLs = 1-10 ] |                              |                         |
| * Nose                 |  | Inflammation                 | Chronic, Minimal        |
| * Prostate             |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Salivary Glands      |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Spleen               |  | Hyperplasia                  | Lymphoid, Mild          |
| * Stomach, Forestomach | Epithelium                                   | Hyperplasia                  | Moderate                |
|                        |  | Inflammation                 | Chronic, Mild           |
|                        | [ Squamous Cell Papilloma TGLs = 2-11 ]      | Squamous Cell Papilloma      |                         |
| * Thymus               |  | Atrophy                      | Mild                    |
| Tooth                  |  | Dysplasia                    | Minimal                 |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 25    **TMT:** 1    **SEX:** Male    **DAY ON TEST:** 731  
**DOSE:** 0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0601925

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Gallbladder	* Harderian Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney	Renal Tubule	Mineralization Nephropathy	Minimal Minimal
* Liver		Clear Cell Focus Eosinophilic Focus Fatty Change Hepatocellular Adenoma Infiltration Cellular Tension Lipidosis	Minimal Multiple Mononuclear CI, Minimal
	[ Eosinophilic Focus TGLs = 4-12 ] [ Hepatocellular Adenoma TGLs = 1,2,3-10+11+12 ]		
* Lung	Alveolar Epith	Alveolar/Bronchiolar Adenoma Hyperplasia	Minimal
* Nose		Inflammation	Suppurative, Mild
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation	Mild Chronic, Minimal
	[ Hyperplasia TGLs = 5-13 ]		
* Thymus		Atrophy	Marked
Tooth		Dysplasia	Marked

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 26    **TMT:** 1    **SEX:** Male    **DAY ON TEST:** 732  
**DOSE:** 0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0601926

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Cortex           | * Adrenal Medulla         | Blood Vessel                | * Bone                   |
| * Bone Marrow              | * Brain                   | * Epididymis                | * Esophagus              |
| * Eye                      | * Gallbladder             | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric |
| * Nose                     | * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        |
| * Preputial Gland          | * Seminal Vesicle         | * Skin                      | * Spleen                 |
| * Stomach, Forestomach     | * Stomach, Glandular      | * Testes                    | * Thyroid Gland          |
| * Trachea                  | * Urinary Bladder         |                             |                          |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |  |                        |                         |
|----------------------|--|------------------------|-------------------------|
| * Harderian Gland    |  | Adenoma                |                         |
|                      | [ Adenoma TGLs = 4-9 ]                 |                        |                         |
| * Islets, Pancreatic |  | Hyperplasia            | Mild                    |
| * Kidney             | Renal Tubule                           | Mineralization         | Minimal                 |
| * Liver              |  | Angiectasis            | Minimal                 |
|                      |  | Fatty Change           | Mild                    |
|                      |  | Hepatocellular Adenoma |                         |
|                      |  | Infiltration Cellular  | Mononuclear CI, Minimal |
|                      |  | Mixed Cell Focus       |                         |
|                      |  | Tension Lipidosis      |                         |
|                      | [ Hepatocellular Adenoma TGLs = 2-11 ] |                        |                         |
|                      | [ Mixed Cell Focus TGLs = 1,3-10+12 ]  |                        |                         |
| * Prostate           |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Salivary Glands    |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Thymus             |  | Atrophy                | Minimal                 |
| Tooth                |  | Dysplasia              | Minimal                 |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 27	<b>TMT:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 732
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0601927

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                    | * Epididymis              | * Esophagus                 | * Eye                    |
| * Gallbladder              | * Harderian Gland         | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Lymph Node, Mandibular  | * Lymph Node, Mesenteric    | * Nose                   |
| * Parathyroid Gland        | * Pituitary Gland         | * Preputial Gland           | * Seminal Vesicle        |
| * Skin                     | * Stomach, Glandular      | * Testes                    | * Trachea                |
| * Urinary Bladder          |                           |                             |                          |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |   |                                  |                         |
|------------------------|---|----------------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                                   | Hyperplasia                      | Minimal                 |
| * Islets, Pancreatic   |   | Hyperplasia                      | Minimal                 |
| * Kidney               |   | Nephropathy                      | Minimal                 |
| * Liver                |   | Eosinophilic Focus               |                         |
|                        |   | Fatty Change                     | Minimal                 |
|                        |   | Hepatocellular Adenoma           | Multiple                |
|                        |   | Hepatocellular Carcinoma         | Multiple                |
|                        |   | Infiltration Cellular            | Mononuclear CI, Mild    |
|                        | [ Eosinophilic Focus TGLs = 5-12 ]            |                                  |                         |
|                        | [ Hepatocellular Adenoma TGLs = 2,4-10+12 ]   |                                  |                         |
|                        | [ Hepatocellular Carcinoma TGLs = 1,3-10+11 ] |                                  |                         |
| * Lung                 |   | Hepatocellular Carcinoma         | Metastatic (Liver)      |
| * Pancreas             | Acinus  | Hypertrophy                      | Mild                    |
| * Prostate             |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Salivary Glands      |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen               |   | Hematopoietic Cell Proliferation | Minimal                 |
| * Stomach, Forestomach | Epithelium                                    | Hyperplasia                      | Moderate                |
|                        |   | Inflammation                     | Chronic, Mild           |
|                        | [ Hyperplasia TGLs = 6-13 ]                   |                                  |                         |
| * Thymus               |   | Atrophy                          | Marked                  |
| * Thyroid Gland        | Follicle                                      | Hyperplasia                      | Mild                    |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 28    TMT: 1    SEX: Male    DAY ON TEST: 730  
 DOSE: 0 G/KG    DISP: Terminal Sacrifice    HISTO: 0601928

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    |
| * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     | * Pancreas                |
| * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          | * Skin                    |
| * Spleen                    | * Stomach, Forestomach   | * Stomach, Glandular       | * Testes                  |
| * Thymus                    | * Thyroid Gland          | * Trachea                  | * Urinary Bladder         |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |   |                        |                         |
|----------------------|---|------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                               | Hyperplasia            | Minimal                 |
| * Epididymis         |   | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Harderian Gland    |   | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Islets, Pancreatic |   | Hyperplasia            | Mild                    |
| * Kidney             | Renal Tubule                              | Mineralization         | Minimal                 |
|                      |   | Nephropathy            | Minimal                 |
| * Liver              |   | Clear Cell Focus       |                         |
|                      |   | Fatty Change           | Minimal                 |
|                      |   | Hepatocellular Adenoma |                         |
|                      |   | Infiltration Cellular  | Mononuclear CI, Minimal |
|                      | [ Hepatocellular Adenoma    TGLs = 2-10 ] |                        |                         |
| * Prostate           |   | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Salivary Glands    |   | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Seminal Vesicle    |   | Inflammation           | Minimal                 |
|                      | [ Inflammation    TGLs = 1-7 ]            |                        |                         |
| Tooth                |   | Dysplasia              | Minimal                 |



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 29    TMT: 1    SEX: Male    DAY ON TEST: 731  
 DOSE: 0 G/KG    DISP: Terminal Sacrifice    HISTO: 0601929

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    |
| * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     | * Pancreas                |
| * Pituitary Gland           | * Preputial Gland        | * Salivary Glands          | * Seminal Vesicle         |
| * Skin                      | * Spleen                 | * Stomach, Forestomach     | * Stomach, Glandular      |
| * Testes                    | * Thyroid Gland          | * Trachea                  | * Urinary Bladder         |

**MISSING**

- |                 |                     |
|-----------------|---------------------|
| * Mammary Gland | * Parathyroid Gland |
|-----------------|---------------------|

**OBSERVATIONS**

- |                      |  |                        |                         |
|----------------------|--|------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                                    | Hyperplasia            | Minimal                 |
| * Epididymis         |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Harderian Gland    |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Islets, Pancreatic |  | Hyperplasia            | Mild                    |
| * Kidney             | Renal Tubule                                   | Mineralization         | Minimal                 |
|                      |  | Nephropathy            | Minimal                 |
| * Liver              |  | Clear Cell Focus       |                         |
|                      |  | Eosinophilic Focus     |                         |
|                      |  | Fatty Change           | Minimal                 |
|                      |  | Hepatocellular Adenoma | Multiple                |
|                      |  | Infiltration Cellular  | Mononuclear CI, Minimal |
|                      | [ Eosinophilic Focus    TGLs = 1,4-10+11 ]     |                        |                         |
|                      | [ Hepatocellular Adenoma    TGLs = 2,3-11+12 ] |                        |                         |
| * Prostate           |  | Infiltration Cellular  | Mononuclear CI, Mild    |
| * Thymus             |  | Atrophy                | Mild                    |
| Tooth                |  | Dysplasia              | Mild                    |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 30    TMT: 1    SEX: Male    DAY ON TEST: 730  
 DOSE: 0 G/KG    DISP: Terminal Sacrifice    HISTO: 0601930

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- \* Adrenal Cortex
- \* Adrenal Medulla
- \* Bone Marrow
- \* Brain
- \* Gallbladder
- \* Heart
- \* Intestine Large, Rectum
- \* Intestine Small, Duodenum
- \* Lung
- \* Lymph Node, Mandibular
- \* Pancreas
- \* Parathyroid Gland
- \* Skin
- \* Spleen
- \* Thyroid Gland
- \* Trachea
- Blood Vessel
- \* Esophagus
- \* Intestine Large, Cecum
- \* Intestine Small, Ileum
- \* Lymph Node, Mesenteric
- \* Pituitary Gland
- \* Stomach, Glandular
- \* Urinary Bladder
- \* Bone
- \* Eye
- \* Intestine Large, Colon
- \* Intestine Small, Jejunum
- \* Nose
- \* Seminal Vesicle
- \* Testes

MISSING

- \* Mammary Gland

OBSERVATIONS

- |  |   |   |   |
|--|---|---|---|
| <ul style="list-style-type: none"> <li>* Epididymis</li> <li>* Harderian Gland</li> <li>* Islets, Pancreatic</li> <li>* Kidney</li> <li>* Liver</li> </ul> | <p style="text-align: center;">Papilla</p> <p>[ Eosinophilic Focus    TGLs = 5-5 ]<br/>         [ Hepatocellular Adenoma    TGLs = 2,3,4-11+12 ]<br/>         [ Hepatocellular Carcinoma    TGLs = 1-10 ]</p> | <ul style="list-style-type: none"> <li>Infiltration Cellular</li> <li>Hyperplasia</li> <li>Infiltration Cellular</li> <li>Hyperplasia</li> <li>Hydronephrosis</li> <li>Necrosis</li> <li>Nephropathy</li> <li>Clear Cell Focus</li> <li>Eosinophilic Focus</li> <li>Fatty Change</li> <li>Hepatocellular Adenoma</li> <li>Hepatocellular Carcinoma</li> <li>Infiltration Cellular</li> <li>Mixed Cell Focus</li> <li>Cyst</li> <li>Infiltration Cellular</li> <li>Infiltration Cellular</li> <li>Hyperplasia</li> <li>Inflammation</li> </ul> | <ul style="list-style-type: none"> <li>Mononuclear CI, Minimal</li> <li>Mild</li> <li>Mononuclear CI, Minimal</li> <li>Moderate</li> <li>Mild</li> <li>Mild</li> <li>Moderate</li> <li>Minimal</li> <li>Multiple</li> <li>Mononuclear CI, Minimal</li> <li>Mild</li> <li>Mononuclear CI, Minimal</li> <li>Mononuclear CI, Minimal</li> <li>Minimal</li> <li>Chronic, Minimal</li> </ul> |
|--|---|---|---|

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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<b>ANIMAL NUM:</b>	30	<b>TMT:</b>	1	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	730
		<b>DOSE:</b>	0 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0601930

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Thymus	Atrophy	Minimal
Tooth	Dysplasia	Minimal

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

ANIMAL NUM: 31 TMT: 1 SEX: Male DAY ON TEST: 732  
DOSE: 0 G/KG DISP: Terminal Sacrifice HISTO: 0601931

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Esophagus	* Eye	* Gallbladder	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
Note: One adrenal gland was missing			
* Adren Medulla			
Note: One adrenal gland was missing			
* Bone Marrow		Hemangiosarcoma	
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Cardiomyopathy	Minimal
* Islets, Pancreatic		Hyperplasia	Moderate
* Kidney	Renal Tubule	Nephropathy	Mild
		Pigmentation	Lipofuscin, Mild
* Liver		Eosinophilic Focus	
		Fatty Change	Minimal
		Hemangiosarcoma	
		Hematopoietic Cell Proliferation	Mild
		Hepatocellular Adenoma	
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Hemangiosarcoma TGLs = 4-4 ]		
	[ Hepatocellular Adenoma TGLs = 3-12 ]		
* Preputial Gland		Inflammation	Moderate
Skeletal Muscle		Hemangiosarcoma	
	[ Hemangiosarcoma TGLs = 5-10+11 ]		

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	31	TMT:	1	SEX:	Male	DAY ON TEST:	732
		DOSE:	0 G/KG	DISP:	Terminal Sacrifice	HISTO:	0601931

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ORGAN AND ACCOUNTABLE SITE STATUS

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* Spleen		Hemangiosarcoma	
		Hematopoietic Cell Proliferation	Marked
	[ Hemangiosarcoma TGLs = 1,2-4+14 ]		
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Chronic, Mild
		Necrosis	Mild
	[ Necrosis TGLs = 6-13 ]		
* Thymus		Atrophy	Marked
Tooth		Dysplasia	Marked
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 32    TMT: 1    SEX: Male    DAY ON TEST: 617  
 DOSE: 0 G/KG    DISP: Moribund Sacrifice    HISTO: 0601932

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     |
| * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          |
| * Prostate                | * Seminal Vesicle           | * Skin                   | * Stomach, Forestomach     |
| * Stomach, Glandular      | * Testes                    | * Thyroid Gland          | * Trachea                  |
| * Urinary Bladder         |                             |                          |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                   |  |   |                         |
|-------------------|--|---|-------------------------|
| * Adrenal Cortex  | Subcapsular  | Hyperplasia   | Minimal                 |
| * Harderian Gland |  | Infiltration Cellular   | Mononuclear CI, Minimal |
| * Kidney          | Renal Tubule   | Hyperplasia<br>Nephropathy  | Mild<br>Mild            |
| * Liver           |  | Eosinophilic Focus<br>Hepatocellular Carcinoma<br>Infiltration Cellular | Mononuclear CI, Minimal |
|                   | [ Eosinophilic Focus TGLs = 5-11 ]<br>[ Hepatocellular Carcinoma TGLs = 1-10 ] |   |                         |
| * Lung            | [ Hepatocellular Carcinoma TGLs = 2,3,4-11+12+13 ]                             | Hepatocellular Carcinoma  | Metastatic (Liver)      |
| * Salivary Glands |  | Infiltration Cellular   | Mononuclear CI, Mild    |
| * Spleen          |  | Hematopoietic Cell Proliferation  | Moderate                |
| * Thymus          |  | Atrophy   | Marked                  |

PRIMARY CAUSE OF DEATH    - Liver    Hepatocellular Carcinoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 33    TMT: 1    SEX: Male    DAY ON TEST: 732  
 DOSE: 0 G/KG    DISP: Terminal Sacrifice    HISTO: 0601933

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Seminal Vesicle
* Skin	* Stomach, Glandular	* Thyroid Gland	* Trachea

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Moderate
* Kidney		Hydronephrosis	Mild
* Liver		Eosinophilic Focus	
		Hepatocellular Adenoma	
		Hepatocellular Carcinoma	
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Eosinophilic Focus    TGLs = 4,5-4+13 ]		
	[ Hepatocellular Adenoma    TGLs = 2-11 ]		
	[ Hepatocellular Carcinoma    TGLs = 1-12 ]		
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hyperplasia	Lymphoid, Mild
* Stomach, Forestomach	Epithelium	Hyperplasia	Moderate
		Inflammation	Chronic, Mild
		Necrosis	Minimal
		Squamous Cell Papilloma	
	[ Squamous Cell Papilloma    TGLs = 3-10 ]		
* Testes	Interstitial Cell	Adenoma	
* Thymus		Atrophy	Mild

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	33	<b>TMT:</b>	1	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	732
		<b>DOSE:</b>	0 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0601933

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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Tooth	Dysplasia	Mild
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 34    **TMT:** 1    **SEX:** Male    **DAY ON TEST:** 732  
**DOSE:** 0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0601934

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla        | Blood Vessel               | * Bone                    | * Bone Marrow               |
| * Brain                  | * Esophagus                | * Eye                     | * Gallbladder               |
| * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    | * Lymph Node, Mandibular    |
| * Lymph Node, Mesenteric | * Pancreas                 | * Parathyroid Gland       | * Pituitary Gland           |
| * Preputial Gland        | * Seminal Vesicle          | * Skin                    | * Spleen                    |
| * Stomach, Forestomach   | * Stomach, Glandular       | * Thyroid Gland           | * Trachea                   |
| * Urinary Bladder        |                            |                           |                             |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |   |   |  |
|----------------------|---|---|--|
| * Adrenal Cortex     | Subcapsular<br>Zona Reticul   | Hyperplasia<br>Hyperplasia  | Minimal<br>Mild                                |
| * Epididymis         |   | Infiltration Cellular   | Mononuclear CI, Minimal                        |
| * Harderian Gland    |   | Adenoma<br>Infiltration Cellular  | Mononuclear CI, Minimal                        |
|                      | [ Adenoma TGLs = 4-9 ]  |   |  |
| * Heart              |   | Cardiomyopathy  | Minimal  |
| * Islets, Pancreatic |   | Hyperplasia   | Minimal  |
| * Kidney             |   | Nephropathy   | Minimal  |
| * Liver              |   | Fatty Change<br>Hepatocellular Adenoma<br>Hepatocholangiocarcinoma<br>Infiltration Cellular | Minimal<br>Multiple<br>Mononuclear CI, Minimal |
|                      | [ Hepatocellular Adenoma TGLs = 2,3-5 ]<br>[ Hepatocholangiocarcinoma TGLs = 1-10 ] |   |  |
| * Nose               |   | Inflammation  | Chronic, Minimal                               |
| * Prostate           |   | Infiltration Cellular   | Mononuclear CI, Minimal                        |
| * Salivary Glands    |   | Infiltration Cellular   | Mononuclear CI, Minimal                        |
| * Testes             |   | Mineralization  | Minimal  |
| * Thymus             |   | Atrophy   | Marked   |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	34	<b>TMT:</b>	1	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	732
		<b>DOSE:</b>	0 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0601934

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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Tooth

Dysplasia

Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 35    TMT: 1    SEX: Male    DAY ON TEST: 731  
 DOSE: 0 G/KG    DISP: Terminal Sacrifice    HISTO: 0601935

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia Vacuolization Cytoplasmic	Minimal Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney	Renal Tubule	Mineralization Nephropathy	Minimal Minimal
* Liver		Eosinophilic Focus Fatty Change Hepatocellular Adenoma Infiltration Cellular	Mild Multiple Mononuclear CI, Minimal
		[ Eosinophilic Focus TGLs = 3,4,5-11+12 ] [ Hepatocellular Adenoma TGLs = 1-10,2-11 ]	
* Lung		Alveolar/Bronchiolar Adenoma	
		[ Alveolar/Bronchiolar Adenoma TGLs = 6-13 ]	
* Pancreas	Acinus	Hypertrophy	Minimal
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Seminal Vesicle		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Mild
* Thymus		Atrophy	Mild

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 36	<b>TMT:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0601936

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                          |
|---------------------------|-----------------------------|--------------------------|--------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow            |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                    |
| * Gallbladder             | * Harderian Gland           | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Lung                   |
| * Lymph Node, Mandibular  | * Lymph Node, Mesenteric    | * Pancreas               | * Parathyroid Gland      |
| * Pituitary Gland         | * Preputial Gland           | * Prostate               | * Seminal Vesicle        |
| * Stomach, Glandular      | * Testes                    | * Trachea                |                          |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                            |  |                                  |                         |
|----------------------------|--|----------------------------------|-------------------------|
| * Adrenal Cortex           | Subcapsular                                | Hyperplasia                      | Mild                    |
| * Heart                    |  | Cardiomyopathy                   | Minimal                 |
| * Intestine Small, Jejunum |  | Carcinoma                        |                         |
|                            | [ Carcinoma TGLs = 2-11 ]                  |                                  |                         |
| * Islets, Pancreatic       |  | Hyperplasia                      | Mild                    |
| * Kidney                   | Renal Tubule                               | Mineralization                   | Minimal                 |
| * Liver                    |  | Angiectasis                      | Minimal                 |
|                            |  | Clear Cell Focus                 |                         |
|                            |  | Fatty Change                     | Minimal                 |
|                            |  | Hepatocellular Adenoma           |                         |
|                            |  | Infiltration Cellular            | Mononuclear CI, Minimal |
|                            | [ Hepatocellular Adenoma TGLs = 1-10 ]     |                                  |                         |
| * Nose                     |  | Inflammation                     | Chronic, Minimal        |
| * Salivary Glands          |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Skin                     | Subcut Tiss                                | Granular Cell Tumor Benign       |                         |
|                            | [ Granular Cell Tumor Benign TGLs = 3-10 ] |                                  |                         |
| * Spleen                   |  | Hematopoietic Cell Proliferation | Moderate                |
| * Stomach, Forestomach     | Epithelium                                 | Hyperplasia                      | Mild                    |
|                            |  | Inflammation                     | Chronic, Minimal        |
|                            | [ Hyperplasia TGLs = 4-11 ]                |                                  |                         |
| * Thymus                   |  | Atrophy                          | Mild                    |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	36	<b>TMT:</b>	1	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	731
		<b>DOSE:</b>	0 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0601936

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Thyroid Gland	Cyst	Minimal
Tooth	Dysplasia	Marked
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 37    TMT: 1    SEX: Male    DAY ON TEST: 731  
 DOSE: 0 G/KG    DISP: Terminal Sacrifice    HISTO: 0601937

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Kidney                  | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Nose                    | * Pancreas                  | * Parathyroid Gland      | * Pituitary Gland          |
| * Preputial Gland         | * Seminal Vesicle           | * Skin                   | * Spleen                   |
| * Stomach, Forestomach    | * Stomach, Glandular        | * Testes                 | * Thyroid Gland            |
| * Trachea                 | * Urinary Bladder           |                          |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |   |   |  |
|----------------------|---|---|--|
| * Adrenal Cortex     | Subcapsular<br>Zona Reticul   | Hyperplasia<br>Hyperplasia  | Minimal<br>Mild                              |
| * Harderian Gland    |   | Fibrosis<br>Hyperplasia<br>Infiltration Cellular  | Mild<br>Moderate<br>Mononuclear CI, Moderate |
| * Islets, Pancreatic |   | Hyperplasia   | Mild   |
| * Liver              |   | Clear Cell Focus<br>Fatty Change<br>Hepatocellular Adenoma<br>Infiltration Cellular<br>Mixed Cell Focus | Minimal<br>Mononuclear CI, Minimal           |
|                      | [ Clear Cell Focus    TGLs = 2,4-11+13 ]<br>[ Hepatocellular Adenoma    TGLs = 1-10 ]<br>[ Mixed Cell Focus    TGLs = 2,3-11+12 ] |   |  |
| * Prostate           |   | Infiltration Cellular   | Mononuclear CI, Minimal                      |
| * Salivary Glands    |   | Infiltration Cellular   | Mononuclear CI, Minimal                      |
| * Thymus             |   | Atrophy   | Mild   |
| Tooth                |   | Dysplasia   | Mild   |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 38    TMT: 1    SEX: Male    DAY ON TEST: 732  
 DOSE: 0 G/KG    DISP: Terminal Sacrifice    HISTO: 0601938

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Esophagus	* Eye	* Gallbladder	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Pancreas	* Pituitary Gland	* Preputial Gland	* Prostate
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone	Cranium	Hyperostosis	Mild
	[ Hyperostosis    TGLs = 2-10 ]		
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Cardiomyopathy	Minimal
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney	Renal Tubule	Hyperplasia	Minimal
	Renal Tubule	Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Angiectasis	Minimal
		Eosinophilic Focus	
		Fatty Change	Minimal
		Fibrosis	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
		Tension Lipidosis	
	[ Eosinophilic Focus    TGLs = 1-11 ]		
	[ Fibrosis    TGLs = 3-12 ]		
* Nose		Inflammation	Chronic, Minimal
* Parathyroid Gland		Infiltration Cellular	Mononuclear CI, Mild
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Seminal Vesicle		Infiltration Cellular	Mononuclear CI, Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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<b>ANIMAL NUM:</b>	38	<b>TMT:</b>	1	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	732
		<b>DOSE:</b>	0 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0601938

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**ORGAN AND ACCOUNTABLE SITE STATUS**

---

\* Spleen  
\* Thymus

Hyperplasia  
Atrophy

Lymphoid, Mild  
Mild



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 39    TMT: 1    SEX: Male    DAY ON TEST: 731  
 DOSE: 0 G/KG    DISP: Natural Death    HISTO: 0601939

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla        | Blood Vessel               | * Bone                    | * Bone Marrow               |
| * Brain                  | * Esophagus                | * Eye                     | * Gallbladder               |
| * Harderian Gland        | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    | * Lymph Node, Mandibular    |
| * Lymph Node, Mesenteric | * Nose                     | * Pancreas                | * Parathyroid Gland         |
| * Pituitary Gland        | * Preputial Gland          | * Skin                    | * Stomach, Forestomach      |
| * Stomach, Glandular     | * Thyroid Gland            | * Trachea                 |                             |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                          |                 |                          |                         |
|--------------------------|-----------------|--------------------------|-------------------------|
| * Adrenal Cortex         | Subcapsular     | Hyperplasia              | Minimal                 |
| * Epididymis             |                 | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Heart                  |                 | Cardiomyopathy           | Minimal                 |
| * Intestine Large, Cecum |                 | Amyloid Deposition       | Mild                    |
| * Islets, Pancreatic     |                 | Hyperplasia              | Minimal                 |
| * Kidney                 | Renal Tubule    | Inflammation             | Moderate                |
|                          | Cortex, Medulla | Mineralization           | Minimal                 |
|                          |                 | Necrosis                 | Moderate                |
| * Liver                  |                 | Clear Cell Focus         |                         |
|                          |                 | Eosinophilic Focus       |                         |
|                          |                 | Hepatocellular Adenoma   |                         |
|                          |                 | Hepatocellular Carcinoma |                         |
|                          |                 | Infiltration Cellular    | Mononuclear CI, Minimal |
|                          |                 | Necrosis                 | Minimal                 |

Note: No corresponding lesion found for gross pale foci of median lobe (TGL 4)

- [ Eosinophilic Focus TGLs = 2,3-11+12 ]
- [ Hepatocellular Adenoma TGLs = 6-15 ]
- [ Hepatocellular Carcinoma TGLs = 7-16 ]

- |           |                          |          |      |
|-----------|--------------------------|----------|------|
| Mesentery | Fat                      | Necrosis | Mild |
|           | [ Necrosis TGLs = 1-10 ] |          |      |

- \* Prostate    Infiltration Cellular    Mononuclear CI, Minimal

Note: The coagulum with polymorphs in it on the prostate slide is interpreted to be the urinary bladder contents; it is not really part of the prostate.

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	39	TMT:	1	SEX:	Male	DAY ON TEST:	731
		DOSE:	0 G/KG	DISP:	Natural Death	HISTO:	0601939

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ORGAN AND ACCOUNTABLE SITE STATUS

---

* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Seminal Vesicle		Inflammation	Minimal
* Spleen	Lymph Follic	Atrophy	Moderate
* Testes		Inflammation	Mild
* Thymus		Atrophy	Marked
Tooth		Dysplasia	Moderate
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
		Inflammation	Moderate

---

PRIMARY CAUSE OF DEATH - Kidney Inflammation

---

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 40    **TMT:** 1    **SEX:** Male    **DAY ON TEST:** 730  
**DOSE:** 0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0601940

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                    | * Esophagus               | * Eye                       | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular |
| * Lymph Node, Mesenteric   | * Nose                    | * Pancreas                  | * Parathyroid Gland      |
| * Pituitary Gland          | * Preputial Gland         | * Seminal Vesicle           | * Skin                   |
| * Stomach, Forestomach     | * Stomach, Glandular      | * Testes                    | * Thyroid Gland          |
| * Trachea                  |                           |                             |                          |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                   |                                    |                                  |                         |
|-------------------|------------------------------------|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                        | Hyperplasia                      | Minimal                 |
| * Epididymis      |                                    | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Gallbladder     |                                    | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Harderian Gland |                                    | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Heart           |                                    | Cardiomyopathy                   | Minimal                 |
| * Kidney          | Renal Tubule                       | Mineralization                   | Minimal                 |
|                   |                                    | Nephropathy                      | Minimal                 |
| * Liver           |                                    | Clear Cell Focus                 |                         |
|                   |                                    | Eosinophilic Focus               |                         |
|                   |                                    | Infiltration Cellular            | Mononuclear CI, Minimal |
|                   |                                    | Mixed Cell Focus                 |                         |
|                   | [ Eosinophilic Focus TGLs = 1-10 ] |                                  |                         |
|                   | [ Mixed Cell Focus TGLs = 1-10 ]   |                                  |                         |
| * Prostate        |                                    | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Salivary Glands |                                    | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen          |                                    | Hematopoietic Cell Proliferation | Minimal                 |
| * Thymus          |                                    | Atrophy                          | Moderate                |
| Tooth             |                                    | Dysplasia                        | Minimal                 |
| * Urinary Bladder |                                    | Infiltration Cellular            | Mononuclear CI, Minimal |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 41    **TMT:** 1    **SEX:** Male    **DAY ON TEST:** 513  
**DOSE:** 0 G/KG    **DISP:** Natural Death    **HISTO:** 0601941

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                    | * Epididymis              | * Esophagus                 | * Eye                    |
| * Gallbladder              | * Harderian Gland         | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular |
| * Lymph Node, Mesenteric   | * Nose                    | * Pancreas                  | * Parathyroid Gland      |
| * Pituitary Gland          | * Preputial Gland         | * Prostate                  | * Seminal Vesicle        |
| * Skin                     | * Stomach, Forestomach    | * Stomach, Glandular        | * Testes                 |
| * Thyroid Gland            | * Trachea                 | * Urinary Bladder           |                          |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                   |   |                                  |                         |
|-------------------|---|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                                   | Hyperplasia                      | Minimal                 |
| * Kidney          |   | Nephropathy                      | Minimal                 |
| * Liver           |   | Fatty Change                     | Minimal                 |
|                   |   | Hemangiosarcoma                  |                         |
|                   |   | Hepatocellular Carcinoma         | Multiple                |
|                   |   | Infiltration Cellular            | Mononuclear CI, Minimal |
|                   | [ Fatty Change TGLs = 2-3+5+11+12+13+14 ]     |                                  |                         |
|                   | [ Hemangiosarcoma TGLs = 4,5-12+13 ]          |                                  |                         |
|                   | [ Hepatocellular Carcinoma TGLs = 3,6-11+14 ] |                                  |                         |
| * Salivary Glands |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen          |   | Hemangiosarcoma                  |                         |
|                   |   | Hematopoietic Cell Proliferation | Moderate                |
|                   | [ Hemangiosarcoma TGLs = 1-10 ]               |                                  |                         |
| * Thymus          |   | Atrophy                          | Mild                    |

**PRIMARY CAUSE OF DEATH** - Liver Hepatocellular Carcinoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 42    **TMT:** 1    **SEX:** Male    **DAY ON TEST:** 732  
**DOSE:** 0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0601942

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Esophagus                 | * Eye                    | * Gallbladder              |
| * Harderian Gland         | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lymph Node, Mandibular  | * Lymph Node, Mesenteric    | * Nose                   | * Pancreas                 |
| * Parathyroid Gland       | * Preputial Gland           | * Salivary Glands        | * Seminal Vesicle          |
| * Skin                    | * Spleen                    | * Stomach, Forestomach   | * Testes                   |
| * Thyroid Gland           | * Trachea                   |                          |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |  |                        |                         |
|----------------------|--|------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                            | Hyperplasia            | Minimal                 |
| * Epididymis         |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Islets, Pancreatic |  | Hyperplasia            | Mild                    |
| * Kidney             | Renal Tubule                           | Mineralization         | Minimal                 |
| * Liver              |  | Clear Cell Focus       |                         |
|                      |  | Fatty Change           | Minimal                 |
|                      |  | Hepatocellular Adenoma |                         |
|                      |  | Infiltration Cellular  | Mononuclear CI, Minimal |
|                      |  | Tension Lipidosis      |                         |
|                      | [ Clear Cell Focus TGLs = 2-11 ]       |                        |                         |
|                      | [ Hepatocellular Adenoma TGLs = 1-10 ] |                        |                         |
| * Lung               | Alveolar Epith                         | Hyperplasia            | Mild                    |
| * Pituitary Gland    |  | Cyst                   | Minimal                 |
| * Prostate           |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Stomach, Glandular |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Thymus             |  | Atrophy                | Moderate                |
| Tooth                |  | Dysplasia              | Marked                  |
| * Urinary Bladder    |  | Infiltration Cellular  | Mononuclear CI, Minimal |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 43    **TMT:** 1    **SEX:** Male    **DAY ON TEST:** 732  
**DOSE:** 0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0601943

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart	Artery	Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Fatty Change	Minimal
		Hepatocellular Carcinoma	
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Hepatocellular Carcinoma TGLs = 1-10 ]		
* Lung		Hepatocellular Carcinoma	Metastatic (Liver)
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Chronic, Mild
		Necrosis	Mild
* Thymus		Atrophy	Moderate
Tooth		Dysplasia	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 44    **TMT:** 1    **SEX:** Male    **DAY ON TEST:** 732  
**DOSE:** 0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0601944

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex          | * Adrenal Medulla           | Blood Vessel             | * Bone                     |
| * Bone Marrow             | * Brain                     | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lymph Node, Mandibular  | * Lymph Node, Mesenteric    | * Nose                   | * Pancreas                 |
| * Parathyroid Gland       | * Pituitary Gland           | * Preputial Gland        | * Seminal Vesicle          |
| * Skin                    | * Spleen                    | * Testes                 | * Thymus                   |
| * Thyroid Gland           | * Trachea                   | * Urinary Bladder        |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |   |                        |                         |
|------------------------|---|------------------------|-------------------------|
| * Epididymis           |   | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Harderian Gland      |   | Adenoma                |                         |
|                        | [ Adenoma TGLs = 1-9 ]                      |                        |                         |
| * Islets, Pancreatic   |   | Hyperplasia            | Mild                    |
| * Kidney               | Renal Tubule                                | Mineralization         | Minimal                 |
|                        |   | Nephropathy            | Minimal                 |
| * Liver                |   | Clear Cell Focus       |                         |
|                        |   | Eosinophilic Focus     |                         |
|                        |   | Fatty Change           | Mild                    |
|                        |   | Hepatocellular Adenoma | Multiple                |
|                        |   | Infiltration Cellular  | Mononuclear CI, Minimal |
|                        |   | Mixed Cell Focus       |                         |
|                        | [ Clear Cell Focus TGLs = 3,5-11+13 ]       |                        |                         |
|                        | [ Eosinophilic Focus TGLs = 3-11 ]          |                        |                         |
|                        | [ Hepatocellular Adenoma TGLs = 2,4-10+12 ] |                        |                         |
|                        | [ Mixed Cell Focus TGLs = 3-11 ]            |                        |                         |
| * Lung                 | Bronchus                                    | Hyperplasia            | Mild                    |
| * Prostate             |   | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Salivary Glands      |   | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Stomach, Forestomach | Epithelium                                  | Hyperplasia            | Moderate                |
|                        |   | Inflammation           | Chronic, Minimal        |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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ANIMAL NUM: 44    TMT: 1  
DOSE: 0 G/KG

SEX: Male  
DISP: Terminal Sacrifice

DAY ON TEST: 732  
HISTO: 0601944

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ORGAN AND ACCOUNTABLE SITE STATUS

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[ Hyperplasia TGLs = 6-14 ]

\* Stomach, Glandular

Infiltration Cellular

Mononuclear CI, Minimal



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 45    **TMT:** 1    **SEX:** Male    **DAY ON TEST:** 626  
**DOSE:** 0 G/KG    **DISP:** Natural Death    **HISTO:** 0601945

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     |
| * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          |
| * Skin                    | * Stomach, Forestomach      | * Stomach, Glandular     | * Testes                   |
| * Thyroid Gland           | * Trachea                   | * Urinary Bladder        |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |  |                        |                         |
|----------------------|--|------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                            | Hyperplasia            | Minimal                 |
| * Harderian Gland    |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Islets, Pancreatic |  | Hyperplasia            | Moderate                |
| * Kidney             | Renal Tubule                           | Hyperplasia            | Mild                    |
|                      | Renal Tubule                           | Mineralization         | Minimal                 |
|                      | Cortex, Medulla                        | Mineralization         | Minimal                 |
|                      |  | Necrosis               | Marked                  |
|                      |  | Nephropathy            | Minimal                 |
| * Liver              |  | Clear Cell Focus       |                         |
|                      |  | Fatty Change           | Minimal                 |
|                      |  | Hepatocellular Adenoma |                         |
|                      |  | Infiltration Cellular  | Mononuclear CI, Minimal |
|                      |  | Mixed Cell Focus       |                         |
|                      | [ Hepatocellular Adenoma TGLs = 1-10 ] |                        |                         |
| * Prostate           |  | Inflammation           | Mild                    |
| * Salivary Glands    |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Seminal Vesicle    |  | Inflammation           | Minimal                 |
| * Spleen             | Lymph Follic                           | Atrophy                | Mild                    |
| * Thymus             |  | Atrophy                | Moderate                |
| Tooth                |  | Dysplasia              | Moderate                |
| Urethra              |  | Inflammation           | Mild                    |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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<b>ANIMAL NUM:</b>	45	<b>TMT:</b>	1	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	626
		<b>DOSE:</b>	0 G/KG	<b>DISP:</b>	Natural Death	<b>HISTO:</b>	0601945

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ORGAN AND ACCOUNTABLE SITE STATUS

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PRIMARY CAUSE OF DEATH - Kidney Cortex Medulla Necrosis

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 46    TMT: 1    SEX: Male    DAY ON TEST: 732  
 DOSE: 0 G/KG    DISP: Terminal Sacrifice    HISTO: 0601946

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Harderian Gland           | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    |
| * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Pancreas                 | * Parathyroid Gland       |
| * Pituitary Gland           | * Prostate               | * Spleen                   | * Stomach, Glandular      |
| * Thyroid Gland             | * Trachea                | * Urinary Bladder          |                           |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |              |  |                         |
|----------------------|--------------|--|-------------------------|
| * Adrenal Cortex     | Subcapsular  | Hyperplasia  | Mild                    |
| * Epididymis         |              | Granuloma Sperm                                    | Moderate                |
| * Heart              |              | Cardiomyopathy                                     | Minimal                 |
| * Islets, Pancreatic |              | Hyperplasia  | Minimal                 |
| * Kidney             | Renal Tubule | Mineralization                                     | Minimal                 |
|                      |              | Nephropathy  | Minimal                 |
| * Liver              |              | Eosinophilic Focus                                 |                         |
|                      |              | Hepatocellular Adenoma                             |                         |
|                      |              | Hepatocellular Carcinoma                           | Multiple                |
|                      |              | Infiltration Cellular                              | Mononuclear CI, Minimal |
|                      |              | Mixed Cell Focus                                   |                         |
|                      |              | [ Eosinophilic Focus TGLs = 4,8-12+15 ]            |                         |
|                      |              | [ Hepatocellular Adenoma TGLs = 6-14 ]             |                         |
|                      |              | [ Hepatocellular Carcinoma TGLs = 3,5,7-12+13+14 ] |                         |
| * Nose               |              | Inflammation                                       | Chronic, Minimal        |
| * Preputial Gland    |              | Inflammation                                       | Marked                  |
|                      |              | [ Inflammation TGLs = 2-11 ]                       |                         |
| * Salivary Glands    |              | Infiltration Cellular                              | Mononuclear CI, Minimal |
| * Seminal Vesicle    |              | Infiltration Cellular                              | Mononuclear CI, Minimal |
| * Skin               |              | Inflammation                                       | Chronic, Mild           |
|                      |              | Ulcer  | Moderate                |
|                      |              | [ Ulcer TGLs = 1-10 ]                              |                         |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	46	TMT:	1	SEX:	Male	DAY ON TEST:	732
		DOSE:	0 G/KG	DISP:	Terminal Sacrifice	HISTO:	0601946

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ORGAN AND ACCOUNTABLE SITE STATUS

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* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation Squamous Cell Papilloma	Moderate Chronic, Minimal
	[ Hyperplasia TGLs = 9-16 ] [ Squamous Cell Papilloma TGLs = 9-16 ]		
* Testes	Germinal Epith	Atrophy	Mild
* Thymus		Atrophy	Mild

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b> 47	<b>TMT:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0601947

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ORGAN AND ACCOUNTABLE SITE STATUS

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**NORMAL**

* Adrenal Cortex	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Thyroid Gland	* Trachea	

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**MISSING**

* Gallbladder	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Medulla	Hyperplasia	Mild
* Epididymis	Granuloma Sperm Infiltration Cellular	Mild Mononuclear CI, Minimal
* Harderian Gland	Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic	Hyperplasia	Minimal
* Kidney	Nephropathy	Marked
* Liver	Hepatocellular Carcinoma Infiltration Cellular	Mononuclear CI, Minimal
	[ Hepatocellular Carcinoma TGLs = 1-10 ]	
* Prostate	Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands	Infiltration Cellular	Mononuclear CI, Minimal
* Spleen	Hematopoietic Cell Proliferation	Mild
* Stomach, Glandular	Glands Ectasia	Minimal
* Testes	Germinal Epith Atrophy	Mild
* Thymus	Atrophy	Marked
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 48    TMT: 1    SEX: Male    DAY ON TEST: 730  
 DOSE: 0 G/KG    DISP: Terminal Sacrifice    HISTO: 0601948

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    |
| * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     | * Pancreas                |
| * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          | * Seminal Vesicle         |
| * Skin                      | * Spleen                 | * Stomach, Forestomach     | * Stomach, Glandular      |
| * Testes                    | * Trachea                |                            |                           |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |                         |   |                                     |
|----------------------|-------------------------|---|-------------------------------------|
| * Adrenal Cortex     | Subcapsular             | Hyperplasia<br>Vacuolization Cytoplasmic  | Mild<br>Mild                        |
| * Epididymis         |                         | Infiltration Cellular   | Mononuclear CI, Minimal             |
| * Harderian Gland    |                         | Infiltration Cellular   | Mononuclear CI, Minimal             |
| * Islets, Pancreatic |                         | Hyperplasia   | Minimal                             |
| * Kidney             | Renal Tubule<br>Papilla | Hydronephrosis<br>Mineralization<br>Necrosis<br>Nephropathy   | Mild<br>Minimal<br>Mild<br>Moderate |
| * Liver              |                         | Eosinophilic Focus<br>Hepatocellular Carcinoma<br>Infiltration Cellular                             | Multiple<br>Mononuclear CI, Minimal |
|                      |                         | [ Eosinophilic Focus    TGLs = 3,4,5-11+12+13 ]<br>[ Hepatocellular Carcinoma    TGLs = 1,2-10+11 ] |                                     |
| * Prostate           |                         | Infiltration Cellular   | Mononuclear CI, Minimal             |
| * Salivary Glands    |                         | Infiltration Cellular   | Mononuclear CI, Minimal             |
| * Thymus             |                         | Atrophy   | Moderate                            |
| * Thyroid Gland      |                         | Atrophy   | Moderate                            |
| Tooth                |                         | Dysplasia   | Moderate                            |
| * Urinary Bladder    |                         | Infiltration Cellular   | Mononuclear CI, Minimal             |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 49	<b>TMT:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0601949

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     |
| * Pancreas                | * Parathyroid Gland         | * Seminal Vesicle        | * Skin                     |
| * Spleen                  | * Stomach, Glandular        | * Testes                 | * Thyroid Gland            |
| * Trachea                 |                             |                          |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |  |   |                               |
|------------------------|--|---|-------------------------------|
| * Adrenal Cortex       | Subcapsular<br>Zona Reticul                  | Hyperplasia<br>Hyperplasia  | Minimal<br>Mild               |
| * Harderian Gland      |  | Infiltration Cellular   | Mononuclear CI, Minimal       |
| * Kidney               | Papilla                                      | Necrosis<br>Nephropathy   | Mild<br>Mild                  |
| * Liver                |  | Eosinophilic Focus<br>Hepatocellular Adenoma<br>Hepatocellular Carcinoma<br>Infiltration Cellular | Mononuclear CI, Minimal       |
|                        | [ Hepatocellular Carcinoma TGLs = 2-10 ]     |   |                               |
| * Lung                 |  | Alveolar/Bronchiolar Adenoma  |                               |
|                        | [ Alveolar/Bronchiolar Adenoma TGLs = 4-12 ] |   |                               |
| * Pituitary Gland      | Pars Distalis                                | Hyperplasia   | Mild                          |
| * Preputial Gland      |  | Inflammation  | Moderate                      |
|                        | [ Inflammation TGLs = 1-8 ]                  |   |                               |
| * Prostate             |  | Infiltration Cellular   | Mononuclear CI, Minimal       |
| * Salivary Glands      |  | Infiltration Cellular   | Mononuclear CI, Minimal       |
| * Stomach, Forestomach | Epithelium                                   | Hyperplasia<br>Inflammation<br>Necrosis   | Mild<br>Chronic, Mild<br>Mild |
|                        | [ Necrosis TGLs = 3-11 ]                     |   |                               |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	49	<b>TMT:</b>	1	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	730
		<b>DOSE:</b>	0 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0601949

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Thymus	Atrophy	Mild
Tooth	Dysplasia	Minimal
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 50    **TMT:** 1    **SEX:** Male    **DAY ON TEST:** 683  
**DOSE:** 0 G/KG    **DISP:** Moribund Sacrifice    **HISTO:** 0601950

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla        | Blood Vessel               | * Bone                    | * Bone Marrow               |
| * Brain                  | * Esophagus                | * Eye                     | * Gallbladder               |
| * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      | * Lymph Node, Mandibular    |
| * Lymph Node, Mesenteric | * Nose                     | * Pancreas                | * Parathyroid Gland         |
| * Pituitary Gland        | * Seminal Vesicle          | * Skin                    | * Testes                    |
| * Thyroid Gland          | * Trachea                  |                           |                             |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |  |   |                          |
|------------------------|--|---|--------------------------|
| * Adrenal Cortex       | Subcapsular                                    | Hyperplasia<br>Hypertrophy  | Minimal<br>Minimal       |
| * Epididymis           |  | Infiltration Cellular   | Mononuclear CI, Minimal  |
| * Harderian Gland      |  | Infiltration Cellular   | Mononuclear CI, Minimal  |
| * Heart                |  | Cardiomyopathy  | Mild                     |
| * Kidney               | Renal Tubule                                   | Mineralization<br>Nephropathy   | Minimal<br>Mild          |
| * Liver                |  | Eosinophilic Focus<br>Hepatocholangiocarcinoma<br>Infiltration Cellular | Mononuclear CI, Minimal  |
|                        | [ Eosinophilic Focus TGLs = 3,4-11+12 ]        |   |                          |
|                        | [ Hepatocholangiocarcinoma TGLs = 2-10 ]       |   |                          |
| * Lung                 | [ Alveolar/Bronchiolar Carcinoma TGLs = 5-13 ] | Alveolar/Bronchiolar Carcinoma  |                          |
| * Preputial Gland      | [ Inflammation TGLs = 1-8 ]                    | Inflammation  | Moderate                 |
| * Prostate             |  | Infiltration Cellular   | Mononuclear CI, Minimal  |
| * Salivary Glands      |  | Infiltration Cellular   | Mononuclear CI, Minimal  |
| * Spleen               |  | Hematopoietic Cell Proliferation  | Mild                     |
| * Stomach, Forestomach | Epithelium                                     | Hyperplasia<br>Inflammation   | Mild<br>Chronic, Minimal |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	50	TMT:	1	SEX:	Male	DAY ON TEST:	683
		DOSE:	0 G/KG	DISP:	Moribund Sacrifice	HISTO:	0601950

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ORGAN AND ACCOUNTABLE SITE STATUS

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[ Hyperplasia	TGLs = 6-14 ]		
* Stomach, Glandular	Glands	Ectasia	Minimal
* Thymus		Atrophy	Marked
Tooth		Dysplasia	Moderate
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

---

PRIMARY CAUSE OF DEATH - Liver Hepatocholangiocarcinoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 51    **TMT:** 3    **SEX:** Male    **DAY ON TEST:** 546  
**DOSE:** 0.25 G/KG    **DISP:** Natural Death    **HISTO:** 0601951

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                    | * Epididymis              | * Esophagus                 | * Eye                    |
| * Gallbladder              | * Harderian Gland         | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric |
| * Nose                     | * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        |
| * Preputial Gland          | * Salivary Glands         | * Skin                      | * Stomach, Glandular     |
| * Testes                   | * Thyroid Gland           | * Trachea                   |                          |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |  |                        |                         |
|------------------------|--|------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                            | Hyperplasia            | Minimal                 |
| * Islets, Pancreatic   |  | Hyperplasia            | Moderate                |
| * Kidney               | Renal Tubule                           | Hydronephrosis         | Moderate                |
|                        |  | Mineralization         | Minimal                 |
| * Liver                |  | Eosinophilic Focus     |                         |
|                        |  | Fatty Change           | Minimal                 |
|                        |  | Hepatocellular Adenoma |                         |
|                        |  | Infiltration Cellular  | Mononuclear CI, Minimal |
|                        | [ Hepatocellular Adenoma TGLs = 2-10 ] |                        |                         |
| * Prostate             |  | Inflammation           | Moderate                |
| * Seminal Vesicle      |  | Inflammation           | Mild                    |
| * Spleen               |  | Hemangiosarcoma        |                         |
|                        | [ Hemangiosarcoma TGLs = 1-10 ]        |                        |                         |
| * Stomach, Forestomach | Epithelium                             | Hyperplasia            | Minimal                 |
|                        |  | Inflammation           | Chronic, Mild           |
|                        |  | Necrosis               | Minimal                 |
| * Thymus               |  | Hemangiosarcoma        | Metastatic (Spleen)     |
| Urethra                |  | Cyst                   | Moderate                |
|                        |  | Inflammation           | Moderate                |
| * Urinary Bladder      |  | Inflammation           | Minimal                 |

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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<b>ANIMAL NUM:</b>	51	<b>TMT:</b>	3	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	546
		<b>DOSE:</b>	0.25 G/KG	<b>DISP:</b>	Natural Death	<b>HISTO:</b>	0601951

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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PRIMARY CAUSE OF DEATH - Kidney Hydronephrosis

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 52    **TMT:** 3    **SEX:** Male    **DAY ON TEST:** 437  
**DOSE:** 0.25 G/KG    **DISP:** Moribund Sacrifice    **HISTO:** 0601952

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Epididymis             | * Esophagus                | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Nose                    |
| * Pancreas                  | * Parathyroid Gland      | * Pituitary Gland          | * Preputial Gland         |
| * Prostate                  | * Salivary Glands        | * Seminal Vesicle          | * Skin                    |
| * Spleen                    | * Stomach, Forestomach   | * Stomach, Glandular       | * Testes                  |
| * Thymus                    | * Thyroid Gland          | * Trachea                  | * Urinary Bladder         |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                   |   |                        |                      |
|-------------------|---|------------------------|----------------------|
| * Adrenal Cortex  | Subcapsular                                 | Hyperplasia            | Mild                 |
| * Eye             | Cornea                                      | Inflammation           | Chronic, Moderate    |
|                   | [ Inflammation TGLs = 1-9 ]                 |                        |                      |
| * Harderian Gland |   | Adenoma                |                      |
|                   | [ Adenoma TGLs = 2-9 ]                      |                        |                      |
| * Kidney          | Renal Tubule                                | Mineralization         | Minimal              |
| * Liver           |   | Fatty Change           | Mild                 |
|                   | Centrilobular                               | Hepatocellular Adenoma | Multiple             |
|                   |   | Hypertrophy            | Minimal              |
|                   | [ Hepatocellular Adenoma TGLs = 3,4-10+11 ] | Infiltration Cellular  | Mononuclear CI, Mild |

**PRIMARY CAUSE OF DEATH**    - Eye Cornea Inflammation

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 53    **TMT:** 3    **SEX:** Male    **DAY ON TEST:** 731  
**DOSE:** 0.25 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0601953

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                    | * Epididymis              | * Esophagus                 | * Eye                    |
| * Gallbladder              | * Harderian Gland         | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric |
| * Nose                     | * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        |
| * Seminal Vesicle          | * Skin                    | * Spleen                    | * Stomach, Forestomach   |
| * Stomach, Glandular       | * Testes                  | * Thyroid Gland             | * Trachea                |
| * Urinary Bladder          |                           |                             |                          |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |  |                        |                         |
|----------------------|--|------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                                      | Hyperplasia            | Mild                    |
| * Islets, Pancreatic |  | Hyperplasia            | Mild                    |
| * Kidney             | Renal Tubule                                     | Hyperplasia            | Minimal                 |
|                      | Renal Tubule                                     | Mineralization         | Minimal                 |
|                      |  | Nephropathy            | Mild                    |
| * Liver              |  | Clear Cell Focus       |                         |
|                      |  | Eosinophilic Focus     |                         |
|                      | Centrilobular                                    | Hepatocellular Adenoma |                         |
|                      |  | Hypertrophy            | Minimal                 |
|                      |  | Infiltration Cellular  | Mononuclear CI, Minimal |
|                      | [ Eosinophilic Focus TGLs = 2,3,4,5-4+10+11+12 ] |                        |                         |
|                      | [ Hepatocellular Adenoma TGLs = 1-5 ]            |                        |                         |
| Mesentery            | Fat  | Necrosis               | Mild                    |
|                      | [ Necrosis TGLs = 6-13 ]                         |                        |                         |
| * Preputial Gland    |  | Inflammation           | Minimal                 |
| * Prostate           |  | Infiltration Cellular  | Mononuclear CI, Minimal |
|                      |  | Inflammation           | Minimal                 |
| * Salivary Glands    |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Thymus             |  | Atrophy                | Moderate                |
| Tooth                |  | Dysplasia              | Mild                    |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 54	<b>TMT:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 693
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 0601954

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Harderian Gland           | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lung                    | * Lymph Node, Mandibular    | * Pancreas               | * Pituitary Gland          |
| * Preputial Gland         | * Salivary Glands           | * Seminal Vesicle        | * Skin                     |
| * Stomach, Forestomach    | * Stomach, Glandular        | * Testes                 | * Thyroid Gland            |
| * Trachea                 |                             |                          |                            |

**MISSING**

- |                 |                     |
|-----------------|---------------------|
| * Mammary Gland | * Parathyroid Gland |
|-----------------|---------------------|

**OBSERVATIONS**

- |  |              |   |   |
|--|--------------|---|---|
| * Adrenal Cortex   | Subcapsular  | Hyperplasia   | Minimal   |
| * Heart  |              | Cardiomyopathy<br>Inflammation  | Minimal<br>Suppurative, Mild                      |
| Note: Heart has numerous bacterial colonies              |              |   |   |
| * Islets, Pancreatic                                     |              | Hyperplasia   | Mild  |
| * Kidney   | Renal Tubule | Dilatation<br>Inflammation  | Mild<br>Moderate                                  |
|  | Renal Tubule | Mineralization<br>Thrombosis  | Minimal<br>Mild                                   |
| Note: Bacterial colonies in kidneys                      |              |   |   |
| * Liver  |              | Fatty Change<br>Infiltration Cellular<br>Mixed Cell Focus<br>Necrosis | Minimal<br>Mononuclear CI, Minimal<br><br>Minimal |
| [ Mixed Cell Focus TGLs = 1-10 ]                         |              |   |   |
| * Lymph Node, Mesenteric                                 |              | Hyperplasia   | Lymphoid, Moderate                                |
| Note: Bacterial colonies in/around mesenteric lymph node |              |   |   |
| [ Hyperplasia TGLs = 2-5 ]                               |              |   |   |
| * Nose   |              | Inflammation  | Chronic, Minimal                                  |
| * Prostate   |              | Inflammation  | Moderate  |
| * Sem Ves  |              |   |   |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	54	TMT:	3	SEX:	Male	DAY ON TEST:	693
		DOSE:	0.25 G/KG	DISP:	Natural Death	HISTO:	0601954

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ORGAN AND ACCOUNTABLE SITE STATUS

---

Note: Bacterial colonies in seminal vesicles

* Spleen	Lymph Follic	Atrophy	Mild
* Thymus		Atrophy	Moderate
Tooth		Dysplasia	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

Note: Urinary bladder has bacterial colonies

---

PRIMARY CAUSE OF DEATH - Kidney Inflammation  
CONTRIBUTORY CAUSE OF DEATH - Heart Inflammation

---



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 55    TMT: 3    SEX: Male    DAY ON TEST: 732  
 DOSE: 0.25 G/KG    DISP: Terminal Sacrifice    HISTO: 0601955

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Esophagus                 | * Eye                    | * Gallbladder              |
| * Harderian Gland         | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Pancreas                 |
| * Parathyroid Gland       | * Pituitary Gland           | * Preputial Gland        | * Prostate                 |
| * Salivary Glands         | * Seminal Vesicle           | * Skin                   | * Spleen                   |
| * Stomach, Forestomach    | * Stomach, Glandular        | * Testes                 | * Thymus                   |
| * Thyroid Gland           | * Trachea                   | * Urinary Bladder        |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |               |   |                         |
|----------------------|---------------|---|-------------------------|
| * Adrenal Cortex     | Subcapsular   | Hyperplasia                                 | Mild                    |
| * Epididymis         |               | Infiltration Cellular                       | Mononuclear CI, Minimal |
| * Islets, Pancreatic |               | Hyperplasia                                 | Minimal                 |
| * Kidney             | Renal Tubule  | Mineralization                              | Minimal                 |
|                      |               | Nephropathy                                 | Minimal                 |
| * Liver              |               | Angiectasis                                 | Minimal                 |
|                      |               | Fatty Change                                | Minimal                 |
|                      | Centrilobular | Hepatocellular Adenoma                      | Multiple                |
|                      |               | Hypertrophy                                 | Minimal                 |
|                      |               | Infiltration Cellular                       | Mononuclear CI, Minimal |
|                      |               | Mixed Cell Focus                            |                         |
|                      |               | [ Hepatocellular Adenoma TGLs = 1,2-10+11 ] |                         |
|                      |               | [ Mixed Cell Focus TGLs = 3-12 ]            |                         |
| * Nose               |               | Polyp, Inflammatory                         | Mild                    |
| Tooth                |               | Dysplasia                                   | Marked                  |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 56    **TMT:** 3    **SEX:** Male    **DAY ON TEST:** 732  
**DOSE:** 0.25 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0601956

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     |
| * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        | * Salivary Glands          |
| * Seminal Vesicle         | * Skin                      | * Spleen                 | * Stomach, Forestomach     |
| * Stomach, Glandular      | * Testes                    | * Thyroid Gland          | * Trachea                  |
| * Urinary Bladder         |                             |                          |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |   |   |   |
|----------------------|---|---|---|
| * Adrenal Cortex     | Subcapsular<br>Zona Reticul   | Hyperplasia<br>Hyperplasia  | Minimal<br>Mild   |
| * Harderian Gland    |   | Infiltration Cellular   | Mononuclear CI, Minimal                                   |
| * Islets, Pancreatic |   | Hyperplasia   | Mild  |
| * Kidney             |   | Nephropathy   | Minimal   |
| * Liver              |   | Angiectasis<br>Clear Cell Focus<br>Eosinophilic Focus<br>Fatty Change<br>Hepatocellular Adenoma<br>Hypertrophy<br>Infiltration Cellular<br>Mixed Cell Focus | Minimal<br>Multiple<br>Minimal<br>Mononuclear CI, Minimal |
|                      | Centrilobular   |   |   |
|                      | [ Eosinophilic Focus TGLs = 3-11 ]<br>[ Hepatocellular Adenoma TGLs = 2,4-10+12 ]<br>[ Mixed Cell Focus TGLs = 5-13 ] |   |   |
| * Preputial Gland    |   | Cyst  | Mild  |
|                      | [ Cyst TGLs = 1-8 ]   |   |   |
| * Prostate           |   | Infiltration Cellular   | Mononuclear CI, Minimal                                   |
| * Thymus             |   | Atrophy   | Moderate  |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	56	<b>TMT:</b>	3	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	732
		<b>DOSE:</b>	0.25 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0601956

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**ORGAN AND ACCOUNTABLE SITE STATUS**

---

Tooth

Dysplasia

Moderate

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 57    TMT: 3    SEX: Male    DAY ON TEST: 707  
 DOSE: 0.25 G/KG    DISP: Moribund Sacrifice    HISTO: 0601957

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex            | * Adrenal Medulla        | Blood Vessel               | * Bone                    |
| * Bone Marrow               | * Brain                  | * Esophagus                | * Eye                     |
| * Gallbladder               | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lymph Node, Mandibular  |
| * Lymph Node, Mesenteric    | * Pancreas               | * Parathyroid Gland        | * Pituitary Gland         |
| * Preputial Gland           | * Seminal Vesicle        | * Skin                     | * Stomach, Glandular      |
| * Testes                    | * Thyroid Gland          | * Trachea                  |                           |

**MISSING**

- |                 |          |
|-----------------|----------|
| * Mammary Gland | * Thymus |
|-----------------|----------|

**OBSERVATIONS**

- |                        |  |                                  |                         |
|------------------------|--|----------------------------------|-------------------------|
| * Epididymis           |  | Inflammation                     | Chronic, Mild           |
| * Harderian Gland      |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Heart                |  | Cardiomyopathy                   | Minimal                 |
| * Islets, Pancreatic   |  | Hyperplasia                      | Minimal                 |
| * Kidney               | Renal Tubule                             | Mineralization                   | Minimal                 |
| * Liver                |  | Fatty Change                     | Mild                    |
|                        |  | Hematopoietic Cell Proliferation | Marked                  |
|                        |  | Hepatocellular Carcinoma         |                         |
|                        |  | Histiocytic Sarcoma              |                         |
|                        | [ Hepatocellular Carcinoma TGLs = 2-11 ] |                                  |                         |
|                        | [ Histiocytic Sarcoma TGLs = 3-12 ]      |                                  |                         |
| * Lung                 |  | Hepatocellular Carcinoma         | Metastatic (Liver)      |
|                        |  | Histiocytic Sarcoma              |                         |
| * Nose                 | Nasolacrim Dct                           | Inflammation                     | Suppurative, Mild       |
| * Prostate             |  | Inflammation                     | Mild                    |
| * Salivary Glands      | Submandibul Gl                           | Atrophy                          | Mild                    |
| * Spleen               |  | Hematopoietic Cell Proliferation | Moderate                |
| * Stomach, Forestomach | Epithelium                               | Hyperplasia                      | Mild                    |
|                        |  | Inflammation                     | Chronic, Minimal        |
| Tooth                  |  | Dysplasia                        | Moderate                |
| * Urinary Bladder      | Transit Epithe                           | Hyperplasia                      | Marked                  |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	57	TMT:	3	SEX:	Male	DAY ON TEST:	707
		DOSE:	0.25 G/KG	DISP:	Moribund Sacrifice	HISTO:	0601957

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ORGAN AND ACCOUNTABLE SITE STATUS

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[ Hyperplasia TGLs = 1-10 ]	Infiltration Cellular Inflammation	Mononuclear CI, Moderate Marked
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PRIMARY CAUSE OF DEATH - Liver Histiocytic Sarcoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 58    TMT: 3    SEX: Male    DAY ON TEST: 720  
 DOSE: 0.25 G/KG    DISP: Natural Death    HISTO: 0601958

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla        | Blood Vessel               | * Bone                    | * Bone Marrow               |
| * Brain                  | * Esophagus                | * Eye                     | * Gallbladder               |
| * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      | * Kidney                    |
| * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Nose                    | * Pancreas                  |
| * Parathyroid Gland      | * Pituitary Gland          | * Preputial Gland         | * Prostate                  |
| * Salivary Glands        | * Seminal Vesicle          | * Skin                    | * Stomach, Forestomach      |
| * Stomach, Glandular     | * Testes                   | * Thyroid Gland           | * Trachea                   |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                   |   |                                  |                         |
|-------------------|---|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                                   | Hyperplasia                      | Minimal                 |
| * Epididymis      |   | Infiltration Cellular            | Mononuclear CI, Mild    |
| * Harderian Gland |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Heart           |   | Cardiomyopathy                   | Moderate                |
|                   | Myocardium                                    | Inflammation                     | Chronic, Moderate       |
|                   |   | Mineralization                   | Minimal                 |
| * Liver           |   | Eosinophilic Focus               |                         |
|                   |   | Hepatocellular Adenoma           | Multiple                |
|                   |   | Hepatocellular Carcinoma         | Multiple                |
|                   |   | Infiltration Cellular            | Mononuclear CI, Minimal |
|                   | [ Hepatocellular Adenoma TGLs = 3,4-12+13 ]   |                                  |                         |
|                   | [ Hepatocellular Carcinoma TGLs = 1,2-10+11 ] |                                  |                         |
| * Lung            |   | Hepatocellular Carcinoma         | Metastatic (Liver)      |
| * Spleen          |   | Hematopoietic Cell Proliferation | Moderate                |
| * Thymus          |   | Atrophy                          | Marked                  |
| * Urinary Bladder |   | Infiltration Cellular            | Mononuclear CI, Minimal |

PRIMARY CAUSE OF DEATH - Liver Hepatocellular Carcinoma  
 CONTRIBUTORY CAUSE OF DEATH - Heart Inflammation

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 59	<b>TMT:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0601959

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart	Artery	Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Moderate
* Kidney	Renal Tubule	Hyperplasia	Minimal
	Renal Tubule	Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
		Fatty Change	Minimal
		Hepatocellular Adenoma	
		Hepatocellular Carcinoma	
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
	[ Hepatocellular Adenoma TGLs = 2-11 ]		
	[ Hepatocellular Carcinoma TGLs = 1-10 ]		
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Thymus		Atrophy	Mild
Tooth		Dysplasia	Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 60	<b>TMT:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0601960

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                    | * Epididymis              | * Esophagus                 | * Eye                    |
| * Gallbladder              | * Harderian Gland         | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Lymph Node, Mandibular  | * Lymph Node, Mesenteric    | * Nose                   |
| * Pancreas                 | * Parathyroid Gland       | * Pituitary Gland           | * Preputial Gland        |
| * Seminal Vesicle          | * Skin                    | * Stomach, Forestomach      | * Stomach, Glandular     |
| * Testes                   | * Thyroid Gland           | * Trachea                   |                          |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |                          |                              |                         |
|----------------------|--------------------------|------------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular              | Hyperplasia                  | Minimal                 |
| * Islets, Pancreatic |                          | Hyperplasia                  | Mild                    |
| * Kidney             | Renal Tubule             | Mineralization               | Minimal                 |
|                      |                          | Nephropathy                  | Minimal                 |
| * Liver              |                          | Eosinophilic Focus           |                         |
|                      |                          | Fatty Change                 | Minimal                 |
|                      | Centrilobular            | Hypertrophy                  | Minimal                 |
|                      |                          | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Lung               |                          | Alveolar/Bronchiolar Adenoma |                         |
| Mesentery            | Fat                      | Necrosis                     | Mild                    |
|                      | [ Necrosis TGLs = 1-10 ] |                              |                         |
| * Prostate           |                          | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Salivary Glands    |                          | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Spleen             |                          | Hyperplasia                  | Lymphoid, Mild          |
| * Thymus             |                          | Atrophy                      | Mild                    |
| Tooth                |                          | Dysplasia                    | Mild                    |
| * Urinary Bladder    |                          | Infiltration Cellular        | Mononuclear CI, Minimal |



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 61    **TMT:** 3    **SEX:** Male    **DAY ON TEST:** 732  
**DOSE:** 0.25 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0601961

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lymph Node, Mandibular  |
| * Lymph Node, Mesenteric    | * Nose                   | * Pancreas                 | * Parathyroid Gland       |
| * Pituitary Gland           | * Preputial Gland        | * Seminal Vesicle          | * Skin                    |
| * Spleen                    | * Stomach, Forestomach   | * Stomach, Glandular       | * Testes                  |
| * Thyroid Gland             | * Trachea                |                            |                           |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |                                  |                       |                         |
|----------------------|----------------------------------|-----------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                      | Hyperplasia           | Minimal                 |
| * Epididymis         |                                  | Infiltration Cellular | Mononuclear CI, Minimal |
| * Harderian Gland    |                                  | Adenoma               |                         |
|                      | [ Adenoma TGLs = 1-9 ]           |                       |                         |
| * Islets, Pancreatic |                                  | Hyperplasia           | Mild                    |
| * Kidney             | Renal Tubule                     | Adenoma               | Minimal                 |
|                      | Renal Tubule                     | Mineralization        | Minimal                 |
|                      | [ Adenoma TGLs = 3-11 ]          | Nephropathy           |                         |
| * Liver              |                                  | Infiltration Cellular | Mononuclear CI, Minimal |
|                      | [ Mixed Cell Focus TGLs = 2-10 ] | Mixed Cell Focus      |                         |
| * Lung               | Bronchus                         | Hyperplasia           | Minimal                 |
|                      | Alveolus                         | Infiltration Cellular | Histiocyte, Minimal     |
| * Prostate           |                                  | Infiltration Cellular | Mononuclear CI, Minimal |
| * Salivary Glands    |                                  | Infiltration Cellular | Mononuclear CI, Minimal |
| * Thymus             |                                  | Atrophy               | Mild                    |
| * Urinary Bladder    |                                  | Infiltration Cellular | Mononuclear CI, Minimal |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 62    **TMT:** 3    **SEX:** Male    **DAY ON TEST:** 431  
**DOSE:** 0.25 G/KG    **DISP:** Moribund Sacrifice    **HISTO:** 0601962

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     |
| * Pancreas                | * Pituitary Gland           | * Preputial Gland        | * Prostate                 |
| * Seminal Vesicle         | * Skin                      | * Spleen                 | * Stomach, Forestomach     |
| * Stomach, Glandular      | * Testes                    | * Thymus                 | * Thyroid Gland            |
| * Trachea                 | * Urinary Bladder           |                          |                            |

**MISSING**

- |                 |                     |
|-----------------|---------------------|
| * Mammary Gland | * Parathyroid Gland |
|-----------------|---------------------|

**OBSERVATIONS**

- |                   |  |                          |                         |
|-------------------|--|--------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                              | Hyperplasia              | Minimal                 |
| * Harderian Gland |  | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Kidney          | Renal Tubule                             | Hyperplasia              | Minimal                 |
|                   | Renal Tubule                             | Mineralization           | Minimal                 |
|                   |  | Nephropathy              | Minimal                 |
| * Liver           |  | Clear Cell Focus         |                         |
|                   |  | Fatty Change             | Minimal                 |
|                   |  | Hepatocellular Adenoma   |                         |
|                   | Centrilobular                            | Hepatocellular Carcinoma |                         |
|                   |  | Hypertrophy              | Minimal                 |
|                   |  | Infiltration Cellular    | Mononuclear CI, Minimal |
|                   | [ Clear Cell Focus TGLs = 3-12 ]         |                          |                         |
|                   | [ Hepatocellular Adenoma TGLs = 2-11 ]   |                          |                         |
|                   | [ Hepatocellular Carcinoma TGLs = 1-10 ] |                          |                         |
| * Lung            | Alveolus                                 | Infiltration Cellular    | Histiocyte, Minimal     |
| * Salivary Glands |  | Infiltration Cellular    | Mononuclear CI, Minimal |

**PRIMARY CAUSE OF DEATH**    - Liver    Hepatocellular Carcinoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 63    **TMT:** 3    **SEX:** Male    **DAY ON TEST:** 664  
**DOSE:** 0.25 G/KG    **DISP:** Moribund Sacrifice    **HISTO:** 0601963

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Epididymis                | * Esophagus              | * Eye                      | * Gallbladder             |
| * Harderian Gland           | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    |
| * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     | * Pancreas                |
| * Pituitary Gland           | * Preputial Gland        | * Prostate                 | * Seminal Vesicle         |
| * Skin                      | * Stomach, Glandular     | * Testes                   | * Thyroid Gland           |
| * Trachea                   | * Urinary Bladder        |                            |                           |

**MISSING**

- |                 |                     |
|-----------------|---------------------|
| * Mammary Gland | * Parathyroid Gland |
|-----------------|---------------------|

**OBSERVATIONS**

- |                        |                                     |                                  |                         |
|------------------------|-------------------------------------|----------------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                         | Hyperplasia                      | Mild                    |
| * Brain                |                                     | Hemorrhage                       | Moderate                |
| * Heart                | Myocardium                          | Mineralization                   | Minimal                 |
| * Islets, Pancreatic   |                                     | Hyperplasia                      | Mild                    |
| * Kidney               | Renal Tubule                        | Mineralization                   | Minimal                 |
| * Liver                | Centrilobular                       | Eosinophilic Focus               |                         |
|                        |                                     | Hypertrophy                      | Minimal                 |
|                        |                                     | Mixed Cell Focus                 |                         |
|                        | [ Mixed Cell Focus    TGLs = 1-10 ] |                                  |                         |
| * Salivary Glands      |                                     | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen               |                                     | Hematopoietic Cell Proliferation | Mild                    |
| * Stomach, Forestomach | Epithelium                          | Hyperplasia                      | Minimal                 |
|                        |                                     | Inflammation                     | Chronic, Minimal        |
|                        | [ Hyperplasia    TGLs = 2-11 ]      |                                  |                         |
| * Thymus               |                                     | Atrophy                          | Marked                  |
| Tooth                  |                                     | Dysplasia                        | Marked                  |

PRIMARY CAUSE OF DEATH    - UNCERTAIN

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 64    TMT: 3    SEX: Male    DAY ON TEST: 731  
 DOSE: 0.25 G/KG    DISP: Terminal Sacrifice    HISTO: 0601964

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Skin	* Spleen
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
Coagulating Gland		Hyperplasia	Mild
	[ Hyperplasia TGLs = 2-7 ]		
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney	Renal Tubule	Adenoma	Minimal
	Renal Tubule	Hyperplasia	Minimal
	Renal Tubule	Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
		Fatty Change	Minimal
		Hemangioma	
	Centrilobular	Hepatocellular Adenoma	Multiple
		Hypertrophy	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
	[ Eosinophilic Focus TGLs = 6-13 ]		
	[ Hepatocellular Adenoma TGLs = 3,4,5-10+11+12 ]		
* Preputial Gland		Cyst	Mild
	[ Cyst TGLs = 1-8 ]		
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	64	TMT:	3	SEX:	Male	DAY ON TEST:	731
		DOSE:	0.25 G/KG	DISP:	Terminal Sacrifice	HISTO:	0601964

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ORGAN AND ACCOUNTABLE SITE STATUS

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* Salivary Glands	Mineralization	Minimal
* Seminal Vesicle	Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Infiltration Cellular	Mononuclear CI, Minimal
[ Squamous Cell Papilloma TGLs = 7-14 ]	Squamous Cell Papilloma	
* Thymus	Atrophy	Mild
	Ectopic Thyroid	Minimal
Note: This ectopic tissue resembles pituitary (alternatively, salivary gland) more than thyroid, but pituitary is not a choice in present system		
Tooth	Dysplasia	Mild
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 65	<b>TMT:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0601965

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney	Renal Tubule Renal Tubule	Hyperplasia Mineralization Nephropathy	Minimal Minimal Mild
* Liver		Clear Cell Focus Eosinophilic Focus Fatty Change Hepatocellular Carcinoma Infarct Infiltration Cellular Mixed Cell Focus Necrosis	Minimal Moderate Mononuclear CI, Minimal Moderate
	[ Hepatocellular Carcinoma TGLs = 2-11 ] [ Infarct TGLs = 1,3-12 ] [ Mixed Cell Focus TGLs = 4-13 ]		
* Lung	[ Alveolar/Bronchiolar Carcinoma TGLs = 5-14 ]	Alveolar/Bronchiolar Carcinoma	
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	65	<b>TMT:</b>	3	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	731
		<b>DOSE:</b>	0.25 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0601965

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Thymus	Atrophy	Marked
Tooth	Dysplasia	Moderate
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 66	<b>TMT:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 732
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0601966

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Lung
* Lymph Node, Mandibular	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Seminal Vesicle	* Skin
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Intestine Small, Jejunum	Peyers Patch	Lymphoma Malignant	
	[ Lymphoma Malignant TGLs = 3-11 ]		
* Islets, Pancreatic		Hyperplasia	Moderate
* Kidney	Renal Tubule	Hyperplasia	Minimal
	Renal Tubule	Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Fatty Change	Minimal
		Hepatocellular Adenoma	Multiple
	Centrilobular	Hypertrophy	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
		Tension Lipidosis	
	[ Eosinophilic Focus TGLs = 6-13 ]		
	[ Hepatocellular Adenoma TGLs = 4,5,7,8-11+12+14 ]		
* Lymph Node, Mesenteric		Lymphoma Malignant	
	[ Lymphoma Malignant TGLs = 2-10 ]		
Mesentery	Fat	Necrosis	Mild
	[ Necrosis TGLs = 9-15 ]		

\* PROTOCOL REQUIRED TISSUE



TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b> 66	<b>TMT:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 732
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0601966

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ORGAN AND ACCOUNTABLE SITE STATUS

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* Nose	Inflammation	Chronic, Minimal
* Salivary Glands	Infiltration Cellular	Mononuclear CI, Minimal
* Spleen	Lymphoma Malignant	
[ Lymphoma Malignant TGLs = 1-10 ]		
* Stomach, Forestomach Epithelium	Hyperplasia Inflammation	Minimal Chronic, Minimal
* Thymus	Atrophy	Mild
Tooth	Dysplasia	Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 67    **TMT:** 3    **SEX:** Male    **DAY ON TEST:** 732  
**DOSE:** 0.25 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0601967

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                    | * Epididymis              | * Esophagus                 | * Eye                    |
| * Gallbladder              | * Harderian Gland         | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric |
| * Nose                     | * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        |
| * Preputial Gland          | * Salivary Glands         | * Seminal Vesicle           | * Skin                   |
| * Spleen                   | * Stomach, Forestomach    | * Stomach, Glandular        | * Testes                 |
| * Thyroid Gland            | * Trachea                 | * Urinary Bladder           |                          |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |   |                        |                         |
|----------------------|---|------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                                 | Hyperplasia            | Mild                    |
| * Islets, Pancreatic |   | Hyperplasia            | Minimal                 |
| * Kidney             | Renal Tubule                                | Hyperplasia            | Minimal                 |
|                      | Renal Tubule                                | Mineralization         | Minimal                 |
|                      |   | Nephropathy            | Minimal                 |
| * Liver              |   | Fatty Change           | Mild                    |
|                      | Centrilobular                               | Hepatocellular Adenoma | Multiple                |
|                      | [ Hepatocellular Adenoma TGLs = 1,2-10+11 ] | Hypertrophy            | Minimal                 |
| * Prostate           |   | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Thymus             |   | Atrophy                | Minimal                 |
| Tooth                |   | Dysplasia              | Minimal                 |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 68    TMT: 3    SEX: Male    DAY ON TEST: 553  
 DOSE: 0.25 G/KG    DISP: Natural Death    HISTO: 0601968

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Cortex            | * Adrenal Medulla        | Blood Vessel               | * Bone Marrow             |
| * Brain                     | * Epididymis             | * Esophagus                | * Eye                     |
| * Gallbladder               | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     | * Pancreas                |
| * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          | * Salivary Glands         |
| * Skin                      | * Stomach, Glandular     | * Testes                   | * Thymus                  |
| * Thyroid Gland             | * Trachea                |                            |                           |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |   |                                  |                         |
|------------------------|---|----------------------------------|-------------------------|
| * Bone                 |   | Alveolar/Bronchiolar Carcinoma   | Metastatic (Lung)       |
|                        | [ Alveolar/Bronchiolar Carcinoma    TGLs = 2-11 ]           |                                  |                         |
| * Harderian Gland      |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Heart                |   | Cardiomyopathy                   | Minimal                 |
| * Kidney               | Renal Tubule  | Mineralization                   | Minimal                 |
| * Liver                |   | Eosinophilic Focus               |                         |
|                        |   | Fatty Change                     | Minimal                 |
|                        | Centrilobular   | Hepatocellular Carcinoma         |                         |
|                        |   | Hypertrophy                      | Minimal                 |
|                        |   | Infiltration Cellular            | Mononuclear CI, Minimal |
|                        |   | Necrosis                         | Mild                    |
|                        | [ Hepatocellular Carcinoma    TGLs = 1-10 ]                 |                                  |                         |
| * Lung                 |   | Alveolar/Bronchiolar Carcinoma   | Multiple                |
|                        |   | Hepatocellular Carcinoma         | Metastatic (Liver)      |
|                        | [ Alveolar/Bronchiolar Carcinoma    TGLs = 3,4,5-12+13+14 ] |                                  |                         |
| * Prostate             |   | Inflammation                     | Mild                    |
| * Seminal Vesicle      |   | Inflammation                     | Minimal                 |
| * Spleen               |   | Hematopoietic Cell Proliferation | Mild                    |
| * Stomach, Forestomach | Epithelium  | Hyperplasia                      | Minimal                 |
|                        |   | Inflammation                     | Chronic, Minimal        |
| Urethra                |   | Inflammation                     | Mild                    |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b> 68	<b>TMT:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 553
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 0601968

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal
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PRIMARY CAUSE OF DEATH	- Lung	Alveolar/Bronchiolar Carcinoma
CONTRIBUTORY CAUSE OF DEATH	- Liver	Hepatocellular Carcinoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 69    TMT: 3    SEX: Male    DAY ON TEST: 623  
 DOSE: 0.25 G/KG    DISP: Moribund Sacrifice    HISTO: 0601969

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex          | * Adrenal Medulla           | Blood Vessel             | * Bone                     |
| * Bone Marrow             | * Brain                     | * Epididymis             | * Esophagus                |
| * Eye                     | * Gallbladder               | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     |
| * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          |
| * Skin                    | * Stomach, Forestomach      | * Stomach, Glandular     | * Testes                   |
| * Thyroid Gland           | * Trachea                   |                          |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |                                       |                        |                         |
|----------------------|---------------------------------------|------------------------|-------------------------|
| * Harderian Gland    |                                       | Hyperplasia            | Moderate                |
|                      |                                       | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Heart              |                                       | Cardiomyopathy         | Minimal                 |
| * Islets, Pancreatic |                                       | Hyperplasia            | Mild                    |
| * Kidney             | Renal Tubule                          | Mineralization         | Minimal                 |
| * Liver              |                                       | Fatty Change           | Mild                    |
|                      | Centrilobular                         | Hepatocellular Adenoma |                         |
|                      |                                       | Hypertrophy            | Minimal                 |
|                      |                                       | Infiltration Cellular  | Mononuclear CI, Minimal |
|                      |                                       | Necrosis               | Mild                    |
|                      | [ Necrosis TGLs = 2-11 ]              |                        |                         |
| Penis                |                                       | Infiltration Cellular  | Polymorphnuclr, Minimal |
|                      | [ Infiltration Cellular TGLs = 3-12 ] |                        |                         |
| * Prostate           |                                       | Inflammation           | Mild                    |
| * Salivary Glands    |                                       | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Seminal Vesicle    |                                       | Inflammation           | Mild                    |
| * Spleen             | Lymph Follic                          | Atrophy                | Marked                  |
| * Thymus             |                                       | Atrophy                | Moderate                |
| Tooth                |                                       | Dysplasia              | Moderate                |
| Urethra              |                                       | Inflammation           | Mild                    |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

ANIMAL NUM: 69 TMT: 3  
DOSE: 0.25 G/KG

SEX: Male  
DISP: Moribund Sacrifice

DAY ON TEST: 623  
HISTO: 0601969

ORGAN AND ACCOUNTABLE SITE STATUS

[ Inflammation TGLs = 1-10 ]

\* Urinary Bladder

Infiltration Cellular

Mononuclear CI, Minimal

PRIMARY CAUSE OF DEATH - Urethra Inflammation

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM:	70	TMT:	3	SEX:	Male	DAY ON TEST:	732
		DOSE:	0.25 G/KG	DISP:	Terminal Sacrifice	HISTO:	0601970

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Seminal Vesicle	* Skin	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
		Hepatocellular Adenoma	Multiple
		Hepatocellular Carcinoma	
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Hepatocellular Adenoma TGLs = 1,2,3-10+11+12 ]		
	[ Hepatocellular Carcinoma TGLs = 4-13 ]		
* Lung	Alveolar Epith	Hepatocellular Carcinoma	Metastatic (Liver)
		Hyperplasia	Minimal
* Lymph Node, Mandibular		Hyperplasia	Lymphoid, Moderate
* Nose		Inflammation	Chronic, Minimal
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Mild
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
		Inflammation	Chronic, Minimal
* Thymus		Atrophy	Mild
Tooth		Dysplasia	Mild

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	70	<b>TMT:</b>	3	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	732
		<b>DOSE:</b>	0.25 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0601970

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Urinary Bladder	Inflammation Infiltration Cellular	Suppurative, Moderate Mononuclear CI, Minimal
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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 71    **TMT:** 3    **SEX:** Male    **DAY ON TEST:** 732  
**DOSE:** 0.25 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0601971

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Cortex          | * Adrenal Medulla           | Blood Vessel             | * Bone                     |
| * Bone Marrow             | * Brain                     | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lymph Node, Mandibular  | * Lymph Node, Mesenteric    | * Nose                   | * Pancreas                 |
| * Pituitary Gland         | * Preputial Gland           | * Seminal Vesicle        | * Skin                     |
| * Stomach, Glandular      | * Testes                    | * Thyroid Gland          | * Trachea                  |
| * Urinary Bladder         |                             |                          |                            |

**MISSING**

- |                 |                     |
|-----------------|---------------------|
| * Mammary Gland | * Parathyroid Gland |
|-----------------|---------------------|

**OBSERVATIONS**

- |                        |   |                                  |                         |
|------------------------|---|----------------------------------|-------------------------|
| * Epididymis           |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Harderian Gland      |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Islets, Pancreatic   |   | Hyperplasia                      | Minimal                 |
| * Kidney               | Renal Tubule                                  | Mineralization                   | Minimal                 |
|                        |   | Nephropathy                      | Minimal                 |
| * Liver                | Centrilobular                                 | Eosinophilic Focus               |                         |
|                        |   | Hepatocellular Adenoma           |                         |
|                        |   | Hepatocellular Carcinoma         | Multiple                |
|                        |   | Hypertrophy                      | Minimal                 |
|                        |   | Infiltration Cellular            | Mononuclear CI, Minimal |
|                        |   | Mixed Cell Focus                 |                         |
|                        | [ Hepatocellular Adenoma TGLs = 3-12 ]        |                                  |                         |
|                        | [ Hepatocellular Carcinoma TGLs = 1,2-10+11 ] |                                  |                         |
| * Lung                 |   | Alveolar/Bronchiolar Adenoma     | Metastatic (Liver)      |
|                        |   | Hepatocellular Carcinoma         |                         |
| * Prostate             |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Salivary Glands      |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen               |   | Hematopoietic Cell Proliferation | Mild                    |
| * Stomach, Forestomach | Epithelium                                    | Hyperplasia                      | Moderate                |
|                        |   | Inflammation                     | Chronic, Mild           |
|                        |   | Necrosis                         | Mild                    |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	71	<b>TMT:</b>	3	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	732
		<b>DOSE:</b>	0.25 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0601971

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* Thymus [ Necrosis TGLs = 4-13 ] Atrophy Marked

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 72    TMT: 3    SEX: Male    DAY ON TEST: 731  
 DOSE: 0.25 G/KG    DISP: Terminal Sacrifice    HISTO: 0601972

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea
* Urinary Bladder			

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular Zona Reticul	Hyperplasia Hyperplasia	Minimal Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Cardiomyopathy	Minimal
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney	Renal Tubule	Adenoma Nephropathy	Minimal
	[ Adenoma TGLs = 5-13 ]		
* Liver		Clear Cell Focus Eosinophilic Focus Fatty Change Hepatocellular Adenoma Hypertrophy Infiltration Cellular	Mild Multiple Minimal Mononuclear CI, Minimal
	Centrilobular		
	[ Eosinophilic Focus TGLs = 3-12 ]		
	[ Hepatocellular Adenoma TGLs = 1,2-10+11 ]		
* Lung	Bronchus	Hyperplasia	Minimal
* Nose		Inflammation	Chronic, Minimal
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	72	TMT:	3	SEX:	Male	DAY ON TEST:	731
		DOSE:	0.25 G/KG	DISP:	Terminal Sacrifice	HISTO:	0601972

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ORGAN AND ACCOUNTABLE SITE STATUS

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[ Hyperplasia TGLs = 4-13 ]	Inflammation	Chronic, Minimal
* Thymus	Atrophy	Mild
Tooth	Dysplasia	Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 73 TMT: 3 SEX: Male DAY ON TEST: 731  
 DOSE: 0.25 G/KG DISP: Terminal Sacrifice HISTO: 0601973

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thyroid Gland

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Cardiomyopathy	Minimal
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney	Renal Tubule	Hyperplasia	Minimal
	Renal Tubule	Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Fatty Change	Mild
		Hepatocellular Adenoma	
	Centrilobular	Hepatocellular Carcinoma	
		Hypertrophy	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
		[ Clear Cell Focus TGLs = 1-10 ]	
		[ Hepatocellular Adenoma TGLs = 4-13 ]	
		[ Hepatocellular Carcinoma TGLs = 2-11 ]	
		[ Mixed Cell Focus TGLs = 3-12 ]	
* Lung		Alveolar/Bronchiolar Carcinoma	
		Inflammation	Minimal
		[ Alveolar/Bronchiolar Carcinoma TGLs = 6-15 ]	
Mesentery	Fat	Necrosis	Mild

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	73	TMT:	3	SEX:	Male	DAY ON TEST:	731
		DOSE:	0.25 G/KG	DISP:	Terminal Sacrifice	HISTO:	0601973

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ORGAN AND ACCOUNTABLE SITE STATUS

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[ Necrosis TGLs = 5-14 ]

* Nose	Inflammation	Chronic, Minimal
* Prostate	Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands	Infiltration Cellular	Mononuclear CI, Minimal
* Thymus	Atrophy	Mild
* Trachea	Inflammation	Chronic, Mild
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 74    **TMT:** 3    **SEX:** Male    **DAY ON TEST:** 732  
**DOSE:** 0.25 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0601974

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                    | * Epididymis              | * Esophagus                 | * Eye                    |
| * Gallbladder              | * Harderian Gland         | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Lymph Node, Mandibular  | * Lymph Node, Mesenteric    | * Nose                   |
| * Pancreas                 | * Parathyroid Gland       | * Pituitary Gland           | * Preputial Gland        |
| * Seminal Vesicle          | * Skin                    | * Stomach, Forestomach      | * Stomach, Glandular     |
| * Thyroid Gland            | * Trachea                 |                             |                          |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |  |  |   |
|----------------------|--|--|---|
| * Adrenal Cortex     | Subcapsular                                  | Hyperplasia  | Mild  |
| * Islets, Pancreatic |  | Hyperplasia  | Minimal                                       |
| * Kidney             | Renal Tubule<br>Renal Tubule                 | Hyperplasia<br>Mineralization<br>Nephropathy                             | Minimal<br>Minimal<br>Minimal                 |
| * Liver              | Centrilobular                                | Fatty Change<br>Hypertrophy<br>Infiltration Cellular<br>Mixed Cell Focus | Minimal<br>Minimal<br>Mononuclear CI, Minimal |
| * Lung               | [ Alveolar/Bronchiolar Adenoma TGLs = 1-10 ] | Alveolar/Bronchiolar Adenoma   | Multiple                                      |
| * Prostate           |  | Infiltration Cellular  | Mononuclear CI, Minimal                       |
| * Salivary Glands    |  | Infiltration Cellular  | Mononuclear CI, Minimal                       |
| * Spleen             |  | Hematopoietic Cell Proliferation   | Minimal                                       |
| * Testes             | Germinal Epith<br>[ Atrophy TGLs = 2-7 ]     | Atrophy  | Minimal                                       |
| * Thymus             |  | Atrophy  | Minimal                                       |
| Tooth                |  | Dysplasia  | Mild  |
| * Urinary Bladder    |  | Infiltration Cellular  | Mononuclear CI, Minimal                       |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 75    TMT: 3    SEX: Male    DAY ON TEST: 319  
 DOSE: 0.25 G/KG    DISP: Moribund Sacrifice    HISTO: 0601975

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                    | * Epididymis              | * Esophagus                 | * Eye                    |
| * Gallbladder              | * Harderian Gland         | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic      | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric |
| * Nose                     | * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        |
| * Preputial Gland          | * Salivary Glands         | * Seminal Vesicle           | * Skin                   |
| * Stomach, Glandular       | * Testes                  | * Thyroid Gland             | * Trachea                |
| * Urinary Bladder          |                           |                             |                          |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |   |   |                                    |
|------------------------|---|---|------------------------------------|
| * Adrenal Cortex       | Subcapsular   | Hyperplasia   | Mild                               |
| * Kidney               | Renal Tubule  | Mineralization  | Minimal                            |
| * Liver                | Centrilobular   | Hypertrophy<br>Infiltration Cellular                    | Minimal<br>Mononuclear CI, Minimal |
| * Lung                 | Alveolus<br>[ Alveolar/Bronchiolar Carcinoma TGLs = 1,2-10+11 ] | Alveolar/Bronchiolar Carcinoma<br>Infiltration Cellular | Multiple<br>Histiocyte, Moderate   |
| * Prostate             |   | Infiltration Cellular                                   | Mononuclear CI, Minimal            |
| * Spleen               | Lymph Follicle  | Atrophy   | Minimal                            |
| * Stomach, Forestomach | Epithelium  | Hyperplasia<br>Inflammation                             | Minimal<br>Chronic, Mild           |
| * Thymus               | Epithel Cell  | Atrophy<br>Hyperplasia                                  | Marked<br>Mild                     |

PRIMARY CAUSE OF DEATH    - Lung    Alveolar/Bronchiolar Carcinoma



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 76 TMT: 3 SEX: Male DAY ON TEST: 731  
 DOSE: 0.25 G/KG DISP: Terminal Sacrifice HISTO: 0601976

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Epididymis             | * Esophagus                | * Eye                     |
| * Gallbladder               | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lymph Node, Mandibular  |
| * Lymph Node, Mesenteric    | * Nose                   | * Pancreas                 | * Parathyroid Gland       |
| * Pituitary Gland           | * Prostate               | * Seminal Vesicle          | * Skin                    |
| * Spleen                    | * Stomach, Glandular     | * Testes                   | * Thyroid Gland           |
| * Trachea                   |                          |                            |                           |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |   |                                |                         |
|----------------------|---|--------------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                                     | Hyperplasia                    | Minimal                 |
| * Harderian Gland    |   | Infiltration Cellular          | Mononuclear CI, Minimal |
| * Heart              |   | Cardiomyopathy                 | Minimal                 |
| * Islets, Pancreatic |   | Hyperplasia                    | Mild                    |
| * Kidney             | Renal Tubule                                    | Hyperplasia                    | Minimal                 |
|                      | Renal Tubule                                    | Mineralization                 | Minimal                 |
|                      |   | Nephropathy                    | Mild                    |
| * Liver              |   | Eosinophilic Focus             |                         |
|                      |   | Fatty Change                   | Minimal                 |
|                      | Centrilobular                                   | Hepatocellular Adenoma         | Multiple                |
|                      |   | Hypertrophy                    | Minimal                 |
|                      |   | Infiltration Cellular          | Mononuclear CI, Minimal |
|                      |   | Mixed Cell Focus               |                         |
|                      | [ Eosinophilic Focus TGLs = 3-12 ]              |                                |                         |
|                      | [ Hepatocellular Adenoma TGLs = 1,2,4-3+10+11 ] |                                |                         |
| * Lung               | Alveolus  | Alveolar/Bronchiolar Carcinoma |                         |
|                      |   | Infiltration Cellular          | Histiocyte, Moderate    |
|                      |   | Inflammation                   | Mild                    |
|                      | [ Alveolar/Bronchiolar Carcinoma TGLs = 5-13 ]  |                                |                         |
| * Preputial Gland    |   | Inflammation                   | Minimal                 |
| * Salivary Glands    |   | Infiltration Cellular          | Mononuclear CI, Minimal |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	76	TMT:	3	SEX:	Male	DAY ON TEST:	731
		DOSE:	0.25 G/KG	DISP:	Terminal Sacrifice	HISTO:	0601976

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ORGAN AND ACCOUNTABLE SITE STATUS

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* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation Necrosis	Mild Chronic, Mild Mild
[ Necrosis TGLs = 6-14 ]			
* Thymus		Atrophy	Marked
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 77 TMT: 3 SEX: Male DAY ON TEST: 596  
 DOSE: 0.25 G/KG DISP: Moribund Sacrifice HISTO: 0601977

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Mammary Gland \* Thymus

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Epididymis		Infiltration Cellular	Mononuclear CI, Mild
* Heart	Myocardium	Mineralization	Minimal
* Kidney	Renal Tubule	Hyperplasia	Minimal
	Renal Tubule	Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Fatty Change	Minimal
	Centrilobular	Hypertrophy	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
		Necrosis	Mild
	[ Necrosis TGLs = 3-3+4+5 ]		
Mesentery	Fat	Necrosis	Moderate
	[ Necrosis TGLs = 2-11 ]		
* Skin	Subcut Tiss	Hemangiosarcoma	
	[ Hemangiosarcoma TGLs = 1-10 ]		
* Spleen		Hematopoietic Cell Proliferation	Moderate
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
		Inflammation	Chronic, Mild
Tooth		Dysplasia	Minimal

PRIMARY CAUSE OF DEATH - Skin Subcut Tiss Hemangiosarcoma

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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ANIMAL NUM: 77    TMT: 3  
DOSE: 0.25 G/KG

SEX: Male  
DISP: Moribund Sacrifice

DAY ON TEST: 596  
HISTO: 0601977

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ORGAN AND ACCOUNTABLE SITE STATUS

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 78    TMT: 3    SEX: Male    DAY ON TEST: 732  
 DOSE: 0.25 G/KG    DISP: Terminal Sacrifice    HISTO: 0601978

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     |
| * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          |
| * Prostate                | * Salivary Glands           | * Skin                   | * Spleen                   |
| * Stomach, Forestomach    | * Stomach, Glandular        | * Testes                 | * Thyroid Gland            |
| * Trachea                 |                             |                          |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |                                    |                       |                         |
|----------------------|------------------------------------|-----------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                        | Hyperplasia           | Minimal                 |
| * Harderian Gland    |                                    | Infiltration Cellular | Mononuclear CI, Minimal |
| * Islets, Pancreatic |                                    | Hyperplasia           | Minimal                 |
| * Kidney             | Renal Tubule                       | Hyperplasia           | Minimal                 |
|                      | Renal Tubule                       | Mineralization        | Minimal                 |
|                      |                                    | Nephropathy           | Minimal                 |
| * Liver              |                                    | Angiectasis           | Minimal                 |
|                      |                                    | Clear Cell Focus      |                         |
|                      |                                    | Fatty Change          | Minimal                 |
|                      | Centrilobular                      | Hypertrophy           | Minimal                 |
|                      |                                    | Infiltration Cellular | Mononuclear CI, Minimal |
|                      |                                    | Mixed Cell Focus      |                         |
|                      | [ Clear Cell Focus    TGLs = 1-4 ] |                       |                         |
| * Seminal Vesicle    |                                    | Infiltration Cellular | Mononuclear CI, Minimal |
| * Thymus             |                                    | Atrophy               | Marked                  |
| Tooth                |                                    | Dysplasia             | Mild                    |
| * Urinary Bladder    |                                    | Infiltration Cellular | Mononuclear CI, Minimal |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 79    TMT: 3    SEX: Male    DAY ON TEST: 731  
 DOSE: 0.25 G/KG    DISP: Terminal Sacrifice    HISTO: 0601979

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Skin
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Lymphoma Malignant	
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Cardiomyopathy	Minimal
		Lymphoma Malignant	
* Intestine Small, Jejunum	Epithelium	Hyperplasia	Moderate
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney	Renal Tubule	Hyperplasia	Minimal
	Renal Tubule	Mineralization	Minimal
		Nephropathy	Mild
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Fatty Change	Mild
		Hepatoblastoma	
		Hepatocellular Adenoma	Multiple
	Centrilobular	Hypertrophy	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
		Necrosis	Mild

[ Eosinophilic Focus    TGLs = 7-4 ]  
 [ Hepatoblastoma    TGLs = 1-10 ]  
 [ Hepatocellular Adenoma    TGLs = 2,3-11+12 ]  
 [ Mixed Cell Focus    TGLs = 4,5-5+13 ]

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

---

ANIMAL NUM:	79	TMT:	3	SEX:	Male	DAY ON TEST:	731
		DOSE:	0.25 G/KG	DISP:	Terminal Sacrifice	HISTO:	0601979

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ORGAN AND ACCOUNTABLE SITE STATUS

---

* Lung	Lymphoma Malignant	
* Preputial Gland	Lymphoma Malignant	
* Prostate	Lymphoma Malignant	
* Salivary Glands	Infiltration Cellular	Mononuclear CI, Minimal
* Seminal Vesicle	Lymphoma Malignant	
* Spleen	Lymphoma Malignant	
* Stomach, Forestomach	Epithelium	Hyperplasia Mild
		Necrosis Mild
	[ Necrosis TGLs = 6-14 ]	
* Thymus	Atrophy	Mild
Tooth	Dysplasia	Moderate
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 80    TMT: 3    SEX: Male    DAY ON TEST: 695  
 DOSE: 0.25 G/KG    DISP: Moribund Sacrifice    HISTO: 0601980

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                          |
|---------------------------|-----------------------------|--------------------------|--------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow            |
| * Brain                   | * Esophagus                 | * Eye                    | * Gallbladder            |
| * Harderian Gland         | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Islets, Pancreatic     |
| * Lymph Node, Mandibular  | * Lymph Node, Mesenteric    | * Nose                   | * Pancreas               |
| * Parathyroid Gland       | * Pituitary Gland           | * Seminal Vesicle        | * Skin                   |
| * Stomach, Forestomach    | * Testes                    | * Thyroid Gland          | * Trachea                |
| * Urinary Bladder         |                             |                          |                          |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                            |  |                                |                         |
|----------------------------|--|--------------------------------|-------------------------|
| * Adrenal Cortex           | Subcapsular                              | Hyperplasia                    | Minimal                 |
| * Epididymis               |  | Infiltration Cellular          | Mononuclear CI, Minimal |
| * Intestine Small, Jejunum |  | Adenoma                        |                         |
|                            | [ Adenoma TGLs = 5-12 ]                  |                                |                         |
| * Kidney                   | Renal Tubule                             | Hyperplasia                    | Mild                    |
|                            |  | Mineralization                 | Minimal                 |
|                            |  | Nephropathy                    | Minimal                 |
| * Liver                    |  | Basophilic Focus               |                         |
|                            |  | Eosinophilic Focus             |                         |
|                            |  | Fatty Change                   | Minimal                 |
|                            |  | Hepatoblastoma                 |                         |
|                            |  | Hepatocellular Adenoma         |                         |
|                            |  | Hepatocellular Carcinoma       |                         |
|                            |  | Infiltration Cellular          | Mononuclear CI, Mild    |
|                            |  | Necrosis                       | Moderate                |
|                            |  | Vacuolization Cytoplasmic      | Mild                    |
|                            | [ Eosinophilic Focus TGLs = 10-17 ]      |                                |                         |
|                            | [ Hepatoblastoma TGLs = 9-16 ]           |                                |                         |
|                            | [ Hepatocellular Adenoma TGLs = 8-15 ]   |                                |                         |
|                            | [ Hepatocellular Carcinoma TGLs = 7-14 ] |                                |                         |
|                            | [ Necrosis TGLs = 3-3+4+14+15+16+17 ]    |                                |                         |
| * Lung                     |  | Alveolar/Bronchiolar Carcinoma |                         |

\* PROTOCOL REQUIRED TISSUE



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

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<b>ANIMAL NUM:</b> 80	<b>TMT:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 695
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Moribund Sacrifice	<b>HISTO:</b> 0601980

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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[ Alveolar/Bronchiolar Carcinoma TGLs = 6-13 ]	Hepatoblastoma	Metastatic (Liver)
Lymph Node Pancreatic Note: TGL 4 was in pancreatic lymph node rather than pancreas [ Hepatoblastoma TGLs = 4-11 ]	Hepatoblastoma	Metastatic (Liver)
Mesentery Fat [ Necrosis TGLs = 2-10 ]	Necrosis	Mild
* Preputial Gland	Cyst	Mild
* Prostate	Inflammation	Mild
* Salivary Glands	Infiltration Cellular	Mononuclear CI, Minimal
* Spleen	Hematopoietic Cell Proliferation	Mild
* Stomach, Glandular Glands	Ectasia	Minimal
* Thymus	Atrophy	Marked

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PRIMARY CAUSE OF DEATH - Liver Hepatoblastoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 81    **TMT:** 3    **SEX:** Male    **DAY ON TEST:** 732  
**DOSE:** 0.25 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0601981

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Esophagus                 | * Eye                    | * Gallbladder              |
| * Harderian Gland         | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lymph Node, Mandibular  | * Lymph Node, Mesenteric    | * Nose                   | * Pancreas                 |
| * Parathyroid Gland       | * Pituitary Gland           | * Preputial Gland        | * Seminal Vesicle          |
| * Skin                    | * Spleen                    | * Stomach, Glandular     | * Thyroid Gland            |
| * Trachea                 |                             |                          |                            |

**MISSING**

- |                 |          |
|-----------------|----------|
| * Mammary Gland | * Thymus |
|-----------------|----------|

**OBSERVATIONS**

- |                        |                              |  |  |
|------------------------|------------------------------|--|--|
| * Adrenal Cortex       | Subcapsular                  | Hyperplasia<br>Vacuolization Cytoplasmic   | Minimal<br>Minimal                                     |
| * Epididymis           |                              | Infiltration Cellular  | Mononuclear CI, Mild                                   |
| * Islets, Pancreatic   |                              | Hyperplasia  | Minimal  |
| * Kidney               | Renal Tubule<br>Renal Tubule | Hyperplasia<br>Mineralization<br>Nephropathy   | Minimal<br>Minimal<br>Moderate                         |
| * Liver                | Centrilobular                | Eosinophilic Focus<br>Hepatocellular Carcinoma<br>Hypertrophy<br>Infiltration Cellular<br>Mineralization | Multiple<br>Minimal<br>Mononuclear CI, Minimal<br>Mild |
|                        |                              | [ Eosinophilic Focus TGLs = 2-11 ]<br>[ Hepatocellular Carcinoma TGLs = 1,3,4-10+12+13 ]                 |  |
| * Lung                 | Alveolus                     | Infiltration Cellular  | Histiocyte, Mild                                       |
| * Prostate             |                              | Infiltration Cellular  | Mononuclear CI, Minimal                                |
| * Salivary Glands      |                              | Infiltration Cellular  | Mononuclear CI, Minimal                                |
| * Stomach, Forestomach | Epithelium                   | Hyperplasia<br>Inflammation<br>Necrosis  | Mild<br>Chronic, Mild<br>Mild                          |
|                        |                              | [ Necrosis TGLs = 5-14 ]   |  |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	81	<b>TMT:</b>	3	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	732
		<b>DOSE:</b>	0.25 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0601981

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Testes	Germinal Epith	Atrophy	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 82    TMT: 3    SEX: Male    DAY ON TEST: 423  
 DOSE: 0.25 G/KG    DISP: Moribund Sacrifice    HISTO: 0601982

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Epididymis             | * Esophagus                | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lymph Node, Mandibular  |
| * Lymph Node, Mesenteric    | * Pancreas               | * Pituitary Gland          | * Preputial Gland         |
| * Prostate                  | * Seminal Vesicle        | * Skin                     | * Spleen                  |
| * Stomach, Forestomach      | * Stomach, Glandular     | * Testes                   | * Thymus                  |
| * Thyroid Gland             | * Trachea                | * Urinary Bladder          |                           |

**MISSING**

- |                 |                     |
|-----------------|---------------------|
| * Mammary Gland | * Parathyroid Gland |
|-----------------|---------------------|

**OBSERVATIONS**

- |                      |                             |                       |                              |
|----------------------|-----------------------------|-----------------------|------------------------------|
| * Adrenal Cortex     | Subcapsular                 | Hyperplasia           | Minimal                      |
| * Eye                |                             | Degeneration          | Marked                       |
|                      | [ Degeneration TGLs = 2-9 ] |                       |                              |
| * Harderian Gland    |                             | Carcinoma             |                              |
|                      | [ Carcinoma TGLs = 1-9 ]    |                       |                              |
| * Islets, Pancreatic |                             | Hyperplasia           | Mild                         |
| * Kidney             | Renal Tubule                | Mineralization        | Minimal                      |
|                      |                             | Nephropathy           | Minimal                      |
| * Liver              |                             | Clear Cell Focus      |                              |
|                      | Centrilobular               | Fatty Change          | Mild                         |
|                      |                             | Hypertrophy           | Minimal                      |
|                      |                             | Infiltration Cellular | Mononuclear CI, Minimal      |
| * Lung               |                             | Carcinoma             | Metastatic (Harderian Gland) |
|                      | [ Carcinoma TGLs = 3-10 ]   |                       |                              |
| * Nose               | Nasolacrim Dct              | Inflammation          | Suppurative, Mild            |
| * Salivary Glands    |                             | Infiltration Cellular | Mononuclear CI, Minimal      |

PRIMARY CAUSE OF DEATH - Eye Degeneration  
 CONTRIBUTORY CAUSE OF DEATH - Harderian Gland Carcinoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 83    TMT: 3    SEX: Male    DAY ON TEST: 731  
 DOSE: 0.25 G/KG    DISP: Terminal Sacrifice    HISTO: 0601983

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Seminal Vesicle	* Skin	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Epididymis		Infiltration Cellular	Mononuclear CI, Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney	Renal Tubule	Mineralization Nephropathy	Minimal Minimal
* Liver	Centrilobular	Clear Cell Focus Eosinophilic Focus Fatty Change Hepatocellular Adenoma	Minimal Multiple Minimal
		Hypertrophy Infiltration Cellular Mixed Cell Focus	Mononuclear CI, Minimal
		[ Eosinophilic Focus    TGLs = 2-11 ] [ Hepatocellular Adenoma    TGLs = 1,3-10+12 ]	
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation Hyperplasia	Minimal Lymphoid, Mild
* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation Squamous Cell Papilloma	Mild Chronic, Minimal Multiple
		[ Squamous Cell Papilloma    TGLs = 4-13 ]	

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	83	<b>TMT:</b>	3	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	731
		<b>DOSE:</b>	0.25 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0601983

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* Thymus

Atrophy  
Hyperplasia

Mild  
Histiocytic, Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 84	<b>TMT:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 732
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0601984

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Seminal Vesicle	* Skin	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Harderian Gland		Adenoma	
	[ Adenoma TGLs = 1-9 ]		
* Kidney		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
		Hepatocellular Adenoma	Multiple
		Hepatocellular Carcinoma	
	Centrilobular	Hypertrophy	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
		Necrosis	Minimal
	[ Eosinophilic Focus TGLs = 4-12 ]		
	[ Hepatocellular Adenoma TGLs = 2,6-10+14 ]		
	[ Hepatocellular Carcinoma TGLs = 5-13 ]		
	[ Mixed Cell Focus TGLs = 3-11 ]		
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Stomach, Forestomach		Inflammation	Chronic, Mild
	[ Squamous Cell Papilloma TGLs = 7-15 ]	Squamous Cell Papilloma	

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b> 84	<b>TMT:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 732
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0601984

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Thymus	Atrophy	Marked
Tooth	Dysplasia	Mild
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 85    TMT: 3    SEX: Male    DAY ON TEST: 732  
 DOSE: 0.25 G/KG    DISP: Terminal Sacrifice    HISTO: 0601985

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea		

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney	Renal Tubule Renal Tubule	Hyperplasia Mineralization Nephropathy	Minimal Minimal Moderate
	[ Nephropathy TGLs = 1-4 ]		
* Liver	Centrilobular	Hepatocellular Carcinoma Hypertrophy Infiltration Cellular Mixed Cell Focus	Minimal Mononuclear CI, Minimal
	[ Hepatocellular Carcinoma TGLs = 2,3,4-10+11 ] [ Mixed Cell Focus TGLs = 5-12 ]		
* Lung		Alveolar/Bronchiolar Adenoma Hepatocellular Carcinoma	Metastatic (Liver)
	[ Alveolar/Bronchiolar Adenoma TGLs = 6-13 ] [ Hepatocellular Carcinoma TGLs = 7-14 ]		
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation Lymphoma Malignant	Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	85	<b>TMT:</b>	3	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	732
		<b>DOSE:</b>	0.25 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0601985

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Thymus	Atrophy	Marked
Tooth	Dysplasia	Minimal
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 86	<b>TMT:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 732
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0601986

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lymph Node, Mesenteric  | * Nose                      | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Preputial Gland           | * Seminal Vesicle        | * Skin                     |
| * Spleen                  | * Stomach, Glandular        | * Testes                 | * Thyroid Gland            |
| * Trachea                 | * Urinary Bladder           |                          |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                          |              |   |  |
|--------------------------|--------------|---|--|
| * Adrenal Cortex         | Subcapsular  | Hyperplasia   | Minimal  |
| * Harderian Gland        |              | Hyperplasia<br>Infiltration Cellular  | Mild<br>Mononuclear CI, Minimal                |
| * Islets, Pancreatic     |              | Hyperplasia   | Mild   |
| * Kidney                 | Renal Tubule | Inflammation<br>Metaplasia<br>Mineralization<br>Nephropathy                                       | Minimal<br>Osseous, Mild<br>Minimal<br>Minimal |
| * Liver                  |              | Eosinophilic Focus<br>Hepatocellular Adenoma<br>Hepatocellular Carcinoma<br>Infiltration Cellular | Multiple<br>Mononuclear CI, Minimal            |
|                          |              | [ Eosinophilic Focus TGLs = 3-11 ]  |  |
|                          |              | [ Hepatocellular Adenoma TGLs = 1,2,5-3+10+11 ]   |  |
|                          |              | [ Hepatocellular Carcinoma TGLs = 4-12 ]  |  |
| * Lung                   |              | Alveolar/Bronchiolar Adenoma  |  |
|                          |              | [ Alveolar/Bronchiolar Adenoma TGLs = 6-13 ]  |  |
| * Lymph Node, Mandibular |              | Hyperplasia   | Lymphoid, Moderate                             |
| * Prostate               |              | Infiltration Cellular   | Mononuclear CI, Minimal                        |
| * Salivary Glands        |              | Infiltration Cellular   | Mononuclear CI, Minimal                        |
| * Stomach, Forestomach   | Epithelium   | Hyperplasia   | Mild   |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	86	TMT:	3	SEX:	Male	DAY ON TEST:	732
		DOSE:	0.25 G/KG	DISP:	Terminal Sacrifice	HISTO:	0601986

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ORGAN AND ACCOUNTABLE SITE STATUS

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[ Necrosis TGLs = 7-14 ]	Inflammation	Chronic, Mild
* Thymus	Necrosis	Mild
Tooth	Atrophy	Marked
	Dysplasia	Moderate

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 87    **TMT:** 3    **SEX:** Male    **DAY ON TEST:** 664  
**DOSE:** 0.25 G/KG    **DISP:** Moribund Sacrifice    **HISTO:** 0601987

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Seminal Vesicle
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Hyperplasia	Mild
	[ Hyperplasia TGLs = 2-9 ]		
* Kidney	Renal Tubule	Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
		Hematopoietic Cell Proliferation	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
* Lymph Node, Mandibular		Hyperplasia	Lymphoid, Marked
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Skin		Inflammation	Chronic, Moderate
		Ulcer	Marked
	[ Ulcer TGLs = 3,4,5,6-10+11+12+13 ]		
* Spleen		Hematopoietic Cell Proliferation	Marked
	[ Hematopoietic Cell Proliferation TGLs = 1-4 ]		
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Chronic, Mild
	[ Hyperplasia TGLs = 7-14 ]		
* Thymus		Atrophy	Marked

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	87	TMT:	3	SEX:	Male	DAY ON TEST:	664
		DOSE:	0.25 G/KG	DISP:	Moribund Sacrifice	HISTO:	0601987

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ORGAN AND ACCOUNTABLE SITE STATUS

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Tooth	Dysplasia	Minimal
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

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PRIMARY CAUSE OF DEATH - Skin Ulcer

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 88    **TMT:** 3    **SEX:** Male    **DAY ON TEST:** 484  
**DOSE:** 0.25 G/KG    **DISP:** Natural Death    **HISTO:** 0601988

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Pituitary Gland	* Preputial Gland	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

\* Mammary Gland                      \* Parathyroid Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney	Renal Tubule	Hyperplasia	Minimal
		Nephropathy	Minimal
* Liver		Angiectasis	Minimal
		Fatty Change	Mild
		Hepatocellular Adenoma	
	Centrilobular	Hepatocellular Carcinoma	
		Hypertrophy	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	

Note: Judged that there was only one adenoma on the left lobe, sampled on both slide 10 and slide 4.  
 [ Hepatocellular Adenoma TGLs = 1-10 ]  
 [ Hepatocellular Carcinoma TGLs = 2-11 ]

* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Seminal Vesicle		Inflammation	Minimal
* Spleen		Hematopoietic Cell Proliferation	Moderate
* Thymus		Atrophy	Mild

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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<b>ANIMAL NUM:</b>	88	<b>TMT:</b>	3	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	484
		<b>DOSE:</b>	0.25 G/KG	<b>DISP:</b>	Natural Death	<b>HISTO:</b>	0601988

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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PRIMARY CAUSE OF DEATH - Liver Hepatocellular Carcinoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 89    TMT: 3    SEX: Male    DAY ON TEST: 732  
 DOSE: 0.25 G/KG    DISP: Terminal Sacrifice    HISTO: 0601989

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Nose                    |
| * Pancreas                  | * Parathyroid Gland      | * Pituitary Gland          | * Preputial Gland         |
| * Seminal Vesicle           | * Skin                   | * Spleen                   | * Stomach, Forestomach    |
| * Stomach, Glandular        | * Testes                 | * Thyroid Gland            | * Trachea                 |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |   |                             |  |  |
|---|-----------------------------|--|--|
| * Adrenal Cortex                            | Subcapsular<br>Zona Reticul | Hyperplasia<br>Hyperplasia<br>Hypertrophy  | Minimal<br>Minimal<br>Minimal                  |
| Note: One adrenal gland was missing at trim |                             |  |  |
| * Adren Medulla                             |                             |  |  |
| Note: One adrenal gland was missing at trim |                             |  |  |
| * Epididymis                                |                             | Infiltration Cellular  | Mononuclear CI, Minimal                        |
| * Harderian Gland                           |                             | Infiltration Cellular  | Mononuclear CI, Minimal                        |
| * Kidney                                    | Renal Tubule                | Mineralization<br>Nephropathy  | Minimal<br>Minimal                             |
| * Liver                                     | Centrilobular               | Clear Cell Focus<br>Eosinophilic Focus<br>Hepatocellular Adenoma<br>Hypertrophy<br>Infiltration Cellular<br>Mixed Cell Focus | Multiple<br>Minimal<br>Mononuclear CI, Minimal |
| [ Eosinophilic Focus TGLs = 4-13 ]          |                             |  |  |
| [ Hepatocellular Adenoma TGLs = 1,2-10+11 ] |                             |  |  |
| [ Mixed Cell Focus TGLs = 3-12 ]            |                             |  |  |
| * Prostate                                  |                             | Infiltration Cellular  | Mononuclear CI, Minimal                        |
| * Salivary Glands                           |                             | Infiltration Cellular  | Mononuclear CI, Moderate                       |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

---

<b>ANIMAL NUM:</b>	89	<b>TMT:</b>	3	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	732
		<b>DOSE:</b>	0.25 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0601989

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**ORGAN AND ACCOUNTABLE SITE STATUS**

---

* Thymus	Atrophy	Mild
Tooth	Dysplasia	Minimal
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 90 TMT: 3 SEX: Male DAY ON TEST: 731  
 DOSE: 0.25 G/KG DISP: Terminal Sacrifice HISTO: 0601990

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Seminal Vesicle	* Skin	* Stomach, Glandular
* Thyroid Gland	* Trachea		

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Adenoma Hyperplasia Vacuolization Cytoplasmic	Minimal Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Cardiomyopathy	Minimal
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney		Nephropathy	Moderate
* Liver		Basophilic Focus Eosinophilic Focus Hepatocellular Carcinoma Infiltration Cellular Mixed Cell Focus	Mononuclear CI, Minimal
	[ Basophilic Focus TGLs = 3-11 ] [ Hepatocellular Carcinoma TGLs = 1-10 ] [ Mixed Cell Focus TGLs = 2-11 ]		
* Lung	[ Hepatocellular Carcinoma TGLs = 5-13 ]	Hepatocellular Carcinoma	Metastatic (Liver)
* Prostate		Infiltration Cellular	Mononuclear CI, Mild
* Salivary Glands	Parotid GI	Infiltration Cellular Mineralization	Mononuclear CI, Minimal Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	90	TMT:	3	SEX:	Male	DAY ON TEST:	731
		DOSE:	0.25 G/KG	DISP:	Terminal Sacrifice	HISTO:	0601990

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ORGAN AND ACCOUNTABLE SITE STATUS

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* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation Necrosis	Mild Chronic, Mild Mild
[ Necrosis TGLs = 4-12 ]			
* Testes	Germinal Epith	Atrophy	Moderate
* Thymus		Atrophy	Marked
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 91	<b>TMT:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 732
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0601991

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Esophagus	* Eye
* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thyroid Gland
* Trachea			

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Cardiomyopathy	Minimal
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney	Renal Tubule	Hyperplasia	Minimal
	Renal Tubule	Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Fatty Change	Mild
		Hepatocellular Carcinoma	
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
	[ Hepatocellular Carcinoma TGLs = 1-10 ]		
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Mild
* Spleen		Hyperplasia	Lymphoid, Mild
* Thymus		Atrophy	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 92    **TMT:** 3    **SEX:** Male    **DAY ON TEST:** 731  
**DOSE:** 0.25 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0601992

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lymph Node, Mandibular  |
| * Lymph Node, Mesenteric    | * Pancreas               | * Parathyroid Gland        | * Pituitary Gland         |
| * Seminal Vesicle           | * Skin                   | * Stomach, Forestomach     | * Stomach, Glandular      |
| * Testes                    | * Thyroid Gland          | * Trachea                  |                           |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |              |  |                         |
|----------------------|--------------|--|-------------------------|
| * Adrenal Cortex     | Subcapsular  | Hyperplasia                              | Minimal                 |
| * Epididymis         |              | Infiltration Cellular                    | Mononuclear CI, Minimal |
| * Harderian Gland    |              | Infiltration Cellular                    | Mononuclear CI, Minimal |
| * Islets, Pancreatic |              | Hyperplasia                              | Minimal                 |
| * Kidney             | Renal Tubule | Metaplasia                               | Osseous, Mild           |
|                      |              | Mineralization                           | Minimal                 |
|                      |              | Nephropathy                              | Minimal                 |
| * Liver              |              | Clear Cell Focus                         |                         |
|                      |              | Eosinophilic Focus                       |                         |
|                      |              | Fatty Change                             | Minimal                 |
|                      |              | Hepatocellular Adenoma                   |                         |
|                      |              | Hepatocellular Carcinoma                 |                         |
|                      |              | Infiltration Cellular                    | Mononuclear CI, Minimal |
|                      |              | [ Eosinophilic Focus TGLs = 3-11 ]       |                         |
|                      |              | [ Hepatocellular Adenoma TGLs = 3-11 ]   |                         |
|                      |              | [ Hepatocellular Carcinoma TGLs = 2-10 ] |                         |
| * Lung               | Alveolus     | Alveolar/Bronchiolar Adenoma             |                         |
|                      |              | Infiltration Cellular                    | Histiocyte, Minimal     |
| * Nose               |              | Inflammation                             | Suppurative, Minimal    |
| * Preputial Gland    |              | Cyst                                     | Mild                    |
|                      |              | [ Cyst TGLs = 1-8 ]                      |                         |
| * Prostate           |              | Infiltration Cellular                    | Mononuclear CI, Minimal |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	92	<b>TMT:</b>	3	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	731
		<b>DOSE:</b>	0.25 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0601992

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Salivary Glands	Infiltration Cellular	Mononuclear CI, Minimal
* Spleen	Hematopoietic Cell Proliferation	Minimal
* Thymus	Atrophy	Mild
Tooth	Dysplasia	Moderate
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 93    **TMT:** 3    **SEX:** Male    **DAY ON TEST:** 687  
**DOSE:** 0.25 G/KG    **DISP:** Natural Death    **HISTO:** 0601993

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Harderian Gland           | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    |
| * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Pancreas                 | * Parathyroid Gland       |
| * Pituitary Gland           | * Preputial Gland        | * Salivary Glands          | * Skin                    |
| * Stomach, Glandular        | * Testes                 | * Thyroid Gland            | * Trachea                 |
| * Urinary Bladder           |                          |                            |                           |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |   |                        |                         |
|----------------------|---|------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                                 | Hyperplasia            | Mild                    |
| * Epididymis         |   | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Heart              |   | Cardiomyopathy         | Minimal                 |
|                      | Myocardium                                  | Mineralization         | Minimal                 |
| * Islets, Pancreatic |   | Hyperplasia            | Moderate                |
| * Kidney             | Renal Tubule                                | Mineralization         | Minimal                 |
|                      |   | Nephropathy            | Mild                    |
| * Liver              |   | Basophilic Focus       |                         |
|                      | Centrilobular                               | Fatty Change           | Moderate                |
|                      |   | Hepatoblastoma         |                         |
|                      | Centrilobular                               | Hepatocellular Adenoma | Multiple                |
|                      |   | Hypertrophy            | Mild                    |
|                      |   | Infiltration Cellular  | Mononuclear CI, Minimal |
|                      |   | Mineralization         | Minimal                 |
|                      |   | Mixed Cell Focus       |                         |
|                      |   | Necrosis               | Mild                    |
|                      | [ Basophilic Focus TGLs = 3-11 ]            |                        |                         |
|                      | [ Hepatoblastoma TGLs = 1-10 ]              |                        |                         |
|                      | [ Hepatocellular Adenoma TGLs = 2,4-11+12 ] |                        |                         |
| * Nose               |   | Inflammation           | Chronic, Minimal        |
|                      |   | Polyp, Inflammatory    | Mild                    |
| * Prostate           |   | Inflammation           | Mild                    |

\* PROTOCOL REQUIRED TISSUE



TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	93	TMT:	3	SEX:	Male	DAY ON TEST:	687
		DOSE:	0.25 G/KG	DISP:	Natural Death	HISTO:	0601993

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ORGAN AND ACCOUNTABLE SITE STATUS

---

* Seminal Vesicle		Inflammation	Minimal
* Spleen	Lymph Follic	Atrophy Hematopoietic Cell Proliferation	Moderate Mild
* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation Necrosis	Minimal Chronic, Minimal Mild
	[ Necrosis TGLs = 5-13 ]		
* Thymus		Atrophy	Marked
Tooth		Dysplasia	Moderate
Urethra		Inflammation	Mild

---

PRIMARY CAUSE OF DEATH - Liver Hepatoblastoma

---

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 94    **TMT:** 3    **SEX:** Male    **DAY ON TEST:** 731  
**DOSE:** 0.25 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0601994

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla        | Blood Vessel               | * Bone                    | * Bone Marrow               |
| * Brain                  | * Esophagus                | * Eye                     | * Gallbladder               |
| * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    | * Lymph Node, Mandibular    |
| * Lymph Node, Mesenteric | * Nose                     | * Pancreas                | * Parathyroid Gland         |
| * Pituitary Gland        | * Preputial Gland          | * Skin                    | * Spleen                    |
| * Stomach, Glandular     | * Testes                   | * Thyroid Gland           | * Trachea                   |
| * Urinary Bladder        |                            |                           |                             |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |               |  |                         |
|----------------------|---------------|--|-------------------------|
| * Adrenal Cortex     | Subcapsular   | Hyperplasia                            | Mild                    |
| * Epididymis         |               | Infiltration Cellular                  | Mononuclear CI, Minimal |
| * Harderian Gland    |               | Infiltration Cellular                  | Mononuclear CI, Minimal |
| * Heart              |               | Cardiomyopathy                         | Minimal                 |
| * Islets, Pancreatic |               | Hyperplasia                            | Mild                    |
| * Kidney             | Renal Tubule  | Mineralization                         | Minimal                 |
|                      |               | Nephropathy                            | Mild                    |
| * Liver              |               | Clear Cell Focus                       |                         |
|                      |               | Eosinophilic Focus                     |                         |
|                      |               | Fatty Change                           | Minimal                 |
|                      |               | Hepatoblastoma                         |                         |
|                      |               | Hepatocellular Adenoma                 |                         |
|                      | Centrilobular | Hypertrophy                            | Minimal                 |
|                      |               | Infiltration Cellular                  | Mononuclear CI, Minimal |
|                      |               | Mixed Cell Focus                       |                         |
|                      |               | Tension Lipidosis                      |                         |
|                      |               | [ Eosinophilic Focus TGLs = 1,6-10 ]   |                         |
|                      |               | [ Hepatocellular Adenoma TGLs = 4-12 ] |                         |
|                      |               | [ Mixed Cell Focus TGLs = 2,3-11 ]     |                         |
| * Prostate           |               | Infiltration Cellular                  | Mononuclear CI, Minimal |
| * Salivary Glands    |               | Infiltration Cellular                  | Mononuclear CI, Minimal |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b> 94	<b>TMT:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0601994

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ORGAN AND ACCOUNTABLE SITE STATUS

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* Seminal Vesicle		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Chronic, Mild
		Necrosis	Mild
	[ Necrosis TGLs = 5-13 ]		
* Thymus		Atrophy	Moderate
Tooth		Dysplasia	Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 95    **TMT:** 3    **SEX:** Male    **DAY ON TEST:** 553  
**DOSE:** 0.25 G/KG    **DISP:** Natural Death    **HISTO:** 0601995

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Nose                    | * Pancreas                  | * Parathyroid Gland      | * Pituitary Gland          |
| * Preputial Gland         | * Skin                      | * Stomach, Forestomach   | * Stomach, Glandular       |
| * Testes                  | * Thyroid Gland             | * Trachea                | * Urinary Bladder          |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                   |  |                        |                         |
|-------------------|--|------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular  | Hyperplasia            | Mild                    |
| * Harderian Gland |  | Adenoma                |                         |
|                   | [ Adenoma TGLs = 1-9 ]                             |                        |                         |
| * Kidney          | Renal Tubule                                       | Mineralization         | Minimal                 |
| * Liver           |  | Eosinophilic Focus     |                         |
|                   |  | Fatty Change           | Minimal                 |
|                   |  | Hepatocellular Adenoma | Multiple                |
|                   |  | Infiltration Cellular  | Mononuclear CI, Minimal |
|                   |  | Mixed Cell Focus       |                         |
|                   | [ Hepatocellular Adenoma TGLs = 2,3,4,5-10+11+12 ] |                        |                         |
| * Prostate        |  | Inflammation           | Mild                    |
| * Salivary Glands |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Seminal Vesicle |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Spleen          | Lymph Follic                                       | Atrophy                | Mild                    |
| * Thymus          |  | Atrophy                | Marked                  |
| Tooth             |  | Dysplasia              | Mild                    |

PRIMARY CAUSE OF DEATH - UNCERTAIN

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 96    **TMT:** 3    **SEX:** Male    **DAY ON TEST:** 732  
**DOSE:** 0.25 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0601996

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     |
| * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          |
| * Salivary Glands         | * Seminal Vesicle           | * Skin                   | * Spleen                   |
| * Stomach, Glandular      | * Testes                    | * Thyroid Gland          | * Trachea                  |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |               |   |                         |
|------------------------|---------------|---|-------------------------|
| * Adrenal Cortex       | Subcapsular   | Hyperplasia                                 | Minimal                 |
| * Harderian Gland      |               | Infiltration Cellular                       | Mononuclear CI, Minimal |
| * Islets, Pancreatic   |               | Hyperplasia                                 | Minimal                 |
| * Kidney               | Renal Tubule  | Mineralization                              | Minimal                 |
|                        |               | Nephropathy                                 | Minimal                 |
| * Liver                |               | Eosinophilic Focus                          |                         |
|                        |               | Fatty Change                                | Mild                    |
|                        | Centrilobular | Hepatocellular Adenoma                      | Multiple                |
|                        |               | Hypertrophy                                 | Minimal                 |
|                        |               | Infiltration Cellular                       | Mononuclear CI, Mild    |
|                        |               | Mixed Cell Focus                            |                         |
|                        |               | [ Hepatocellular Adenoma TGLs = 1,2-10+11 ] |                         |
|                        |               | [ Mixed Cell Focus TGLs = 3,4-12+13 ]       |                         |
| * Prostate             |               | Infiltration Cellular                       | Mononuclear CI, Minimal |
| * Stomach, Forestomach | Epithelium    | Hyperplasia                                 | Minimal                 |
|                        |               | Inflammation                                | Chronic, Minimal        |
| * Thymus               |               | Atrophy                                     | Minimal                 |
| Tooth                  |               | Dysplasia                                   | Minimal                 |
| * Urinary Bladder      |               | Infiltration Cellular                       | Mononuclear CI, Minimal |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 97    TMT: 3    SEX: Male    DAY ON TEST: 731  
 DOSE: 0.25 G/KG    DISP: Terminal Sacrifice    HISTO: 0601997

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Pituitary Gland
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Cardiomyopathy	Minimal
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney	Renal Tubule Renal Tubule	Hyperplasia Mineralization Nephropathy	Mild Minimal Minimal
* Liver	Centrilobular	Angiectasis Eosinophilic Focus Fatty Change Hepatocellular Adenoma Hypertrophy Infiltration Cellular Mixed Cell Focus	Minimal Multiple Minimal Mononuclear CI, Minimal
		[ Hepatocellular Adenoma TGLs = 1,2,3,4-10+11+12 ] [ Mixed Cell Focus TGLs = 5-13 ]	
* Parathyroid Gland		Cyst	Mild
* Preputial Gland		Inflammation	Minimal
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Glandular		Mineralization	Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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<b>ANIMAL NUM:</b>	97	<b>TMT:</b>	3	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	731
		<b>DOSE:</b>	0.25 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0601997

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ORGAN AND ACCOUNTABLE SITE STATUS

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\* Thymus  
Tooth

Atrophy  
Dysplasia

Mild  
Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 98    TMT: 3    SEX: Male    DAY ON TEST: 730  
 DOSE: 0.25 G/KG    DISP: Terminal Sacrifice    HISTO: 0601998

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea		

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia Hypertrophy	Mild Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Cardiomyopathy	Minimal
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney	Renal Tubule Renal Tubule	Hyperplasia Mineralization Nephropathy	Minimal Minimal Minimal
* Liver	Centrilobular	Clear Cell Focus Eosinophilic Focus Hepatocellular Adenoma Hypertrophy Infiltration Cellular Mixed Cell Focus	Minimal Mononuclear CI, Minimal
		[ Eosinophilic Focus    TGLs = 3,5-12+13 ] [ Hepatocellular Adenoma    TGLs = 1-10 ] [ Mixed Cell Focus    TGLs = 2-11 ]	
* Lung		Alveolar/Bronchiolar Adenoma	
* Nose		Inflammation	Chronic, Minimal
* Preputial Gland		Inflammation	Minimal
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal

\* PROTOCOL REQUIRED TISSUE



TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	98	<b>TMT:</b>	3	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	730
		<b>DOSE:</b>	0.25 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0601998

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Salivary Glands	Infiltration Cellular	Mononuclear CI, Minimal
* Spleen	Hematopoietic Cell Proliferation	Mild
* Thymus	Atrophy	Marked
Tooth	Dysplasia	Marked
[ Dysplasia TGLs = 4-1 ]		
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 99	<b>TMT:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 732
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0601999

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla        | Blood Vessel               | * Bone                    | * Bone Marrow               |
| * Brain                  | * Esophagus                | * Eye                     | * Gallbladder               |
| * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    | * Lymph Node, Mandibular    |
| * Lymph Node, Mesenteric | * Pancreas                 | * Parathyroid Gland       | * Pituitary Gland           |
| * Preputial Gland        | * Seminal Vesicle          | * Skin                    | * Spleen                    |
| * Stomach, Glandular     | * Testes                   | * Thyroid Gland           | * Trachea                   |
| * Urinary Bladder        |                            |                           |                             |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |  |                       |                         |
|------------------------|--|-----------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                                | Hyperplasia           | Minimal                 |
| * Epididymis           |  | Infiltration Cellular | Mononuclear CI, Minimal |
| * Harderian Gland      |  | Adenoma               |                         |
|                        |  | Infiltration Cellular | Mononuclear CI, Minimal |
|                        | [ Adenoma TGLs = 1-9 ]                     |                       |                         |
| * Heart                |  | Cardiomyopathy        | Minimal                 |
| * Islets, Pancreatic   |  | Hyperplasia           | Minimal                 |
| * Kidney               | Renal Tubule                               | Mineralization        | Minimal                 |
|                        |  | Nephropathy           | Minimal                 |
| * Liver                |  | Angiectasis           | Minimal                 |
|                        |  | Clear Cell Focus      |                         |
|                        |  | Fatty Change          | Minimal                 |
|                        | Centrilobular                              | Hypertrophy           | Minimal                 |
|                        |  | Infiltration Cellular | Mononuclear CI, Minimal |
|                        | [ Clear Cell Focus TGLs = 3-11 ]           | Mixed Cell Focus      |                         |
|                        | [ Mixed Cell Focus TGLs = 2,5,6-10+13+14 ] |                       |                         |
| * Nose                 |  | Inflammation          | Chronic, Minimal        |
| * Prostate             |  | Infiltration Cellular | Mononuclear CI, Minimal |
| * Salivary Glands      |  | Infiltration Cellular | Mononuclear CI, Minimal |
| * Stomach, Forestomach | Epithelium                                 | Hyperplasia           | Minimal                 |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	99	TMT:	3	SEX:	Male	DAY ON TEST:	732
		DOSE:	0.25 G/KG	DISP:	Terminal Sacrifice	HISTO:	0601999

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ORGAN AND ACCOUNTABLE SITE STATUS

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		Inflammation	Chronic, Mild
		Necrosis	Mild
[ Necrosis	TGLs = 4-12 ]		
* Thymus		Atrophy	Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 100    **TMT:** 3    **SEX:** Male    **DAY ON TEST:** 732  
**DOSE:** 0.25 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602000

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                           |                             |                          |
|--------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla        | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                  | * Epididymis              | * Esophagus                 | * Eye                    |
| * Gallbladder            | * Harderian Gland         | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Lung                   | * Lymph Node, Mandibular  | * Lymph Node, Mesenteric    | * Nose                   |
| * Pancreas               | * Parathyroid Gland       | * Pituitary Gland           | * Seminal Vesicle        |
| * Skin                   | * Spleen                  | * Stomach, Glandular        | * Thyroid Gland          |
| * Trachea                | * Urinary Bladder         |                             |                          |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                            |  |   |   |
|----------------------------|--|---|---|
| * Adrenal Cortex           | Subcapsular  | Hyperplasia   | Minimal   |
| * Intestine Small, Jejunum | Epithelium   | Hyperplasia   | Moderate  |
| * Islets, Pancreatic       |  | Hyperplasia   | Mild  |
| * Kidney                   | Renal Tubule   | Mineralization<br>Nephropathy   | Minimal<br>Minimal                              |
| * Liver                    |  | Clear Cell Focus<br>Eosinophilic Focus<br>Fatty Change<br>Hepatocellular Adenoma<br>Infiltration Cellular<br>Necrosis | Minimal<br><br><br>Mononuclear CI, Mild<br>Mild |
|                            | [ Eosinophilic Focus TGLs = 2,4,6-11+12+13 ]<br>[ Hepatocellular Adenoma TGLs = 1-10 ] |   |   |
| * Preputial Gland          | [ Cyst TGLs = 3-8 ]  | Cyst  | Mild  |
| * Prostate                 |  | Infiltration Cellular   | Mononuclear CI, Minimal                         |
| * Salivary Glands          |  | Infiltration Cellular   | Mononuclear CI, Minimal                         |
| * Stomach, Forestomach     | Epithelium   | Hyperplasia<br>Inflammation<br>Necrosis   | Moderate<br>Chronic, Mild<br>Mild               |
|                            | [ Necrosis TGLs = 5-14 ]   |   |   |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	100	<b>TMT:</b>	3	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	732
		<b>DOSE:</b>	0.25 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602000

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Testes	Germinal Epith	Atrophy	Mild
* Thymus		Atrophy	Marked
Tooth		Dysplasia	Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 101	<b>TMT:</b> 5	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602001

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
		Fatty Change	Minimal
		Hepatocellular Adenoma	Multiple
	Centrilobular	Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
	[ Hepatocellular Adenoma	TGLs = 1,2,3,4,5-10+11+12+13+14 ]	
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Thymus		Atrophy	Mild
Tooth		Dysplasia	Moderate
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 102    **TMT:** 5    **SEX:** Male    **DAY ON TEST:** 732  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602002

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lymph Node, Mandibular  |
| * Lymph Node, Mesenteric    | * Pancreas               | * Parathyroid Gland        | * Pituitary Gland         |
| * Prostate                  | * Salivary Glands        | * Seminal Vesicle          | * Skin                    |
| * Spleen                    | * Stomach, Glandular     | * Testes                   | * Thyroid Gland           |
| * Trachea                   |                          |                            |                           |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |  |   |                         |
|------------------------|--|---|-------------------------|
| * Adrenal Cortex       | Subcapsular  | Hyperplasia   | Minimal                 |
| * Epididymis           |  | Infiltration Cellular                                   | Mononuclear CI, Minimal |
| * Harderian Gland      |  | Infiltration Cellular                                   | Mononuclear CI, Minimal |
| * Islets, Pancreatic   |  | Hyperplasia   | Mild                    |
| * Kidney               | Renal Tubule<br>Renal Tubule                               | Hyperplasia<br>Mineralization                           | Minimal<br>Minimal      |
| * Liver                | Centrilobular<br>[ Eosinophilic Focus TGLs = 2-5 ]         | Eosinophilic Focus<br>Fatty Change<br>Hypertrophy       | Minimal<br>Mild         |
| * Lung                 | Alveolus<br>[ Alveolar/Bronchiolar Carcinoma TGLs = 3-10 ] | Alveolar/Bronchiolar Carcinoma<br>Infiltration Cellular | Histiocyte, Mild        |
| * Nose                 |  | Inflammation  | Suppurative, Minimal    |
| * Preputial Gland      | [ Cyst TGLs = 1-8 ]  | Cyst  | Moderate                |
| * Stomach, Forestomach | Epithelium<br>[ Hyperplasia TGLs = 4-11 ]                  | Hyperplasia<br>Inflammation                             | Mild<br>Chronic, Mild   |
| * Thymus               |  | Atrophy   | Mild                    |
| Tooth                  |  | Dysplasia   | Minimal                 |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	102	<b>TMT:</b>	5	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	732
		<b>DOSE:</b>	0.5 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602002

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* Urinary Bladder

Infiltration Cellular

Mononuclear CI, Minimal



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 103	<b>TMT:</b> 5	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602003

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Skin	* Spleen
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea

**MISSING**

* Gallbladder	* Mammary Gland
---------------	-----------------

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney	Renal Tubule	Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
		Fatty Change	Minimal
	Centrilobular	Hepatocellular Adenoma	Multiple
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Eosinophilic Focus TGLs = 2-11 ]		
	[ Hepatocellular Adenoma TGLs = 1,3,4-10+11+12 ]		
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Seminal Vesicle		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Chronic, Minimal
	[ Hyperplasia TGLs = 5-13 ]		
* Thymus		Atrophy	Mild
Tooth		Dysplasia	Mild

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	103	<b>TMT:</b>	5	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	731
		<b>DOSE:</b>	0.5 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602003

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* Urinary Bladder

Infiltration Cellular

Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 104 TMT: 5 SEX: Male DAY ON TEST: 732  
 DOSE: 0.5 G/KG DISP: Terminal Sacrifice HISTO: 0602004

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea
* Urinary Bladder			

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney	Renal Tubule	Mineralization	Minimal
* Liver		Eosinophilic Focus	
		Fatty Change	Minimal
		Hepatocellular Adenoma	
	Centrilobular	Hepatocellular Carcinoma	Multiple
		Hypertrophy	Mild
		Infarct	Moderate
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Eosinophilic Focus TGLs = 3-12 ]		
	[ Hepatocellular Adenoma TGLs = 1-10 ]		
	[ Hepatocellular Carcinoma TGLs = 4,5-13+14 ]		
	[ Infarct TGLs = 2-11 ]		
* Nose		Inflammation	Chronic, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Thymus		Atrophy	Moderate
Tooth		Dysplasia	Marked

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 105 TMT: 5 SEX: Male DAY ON TEST: 732  
 DOSE: 0.5 G/KG DISP: Terminal Sacrifice HISTO: 0602005

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Skin	* Spleen
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Cardiomyopathy	Mild
* Islets, Pancreatic		Hyperplasia	Moderate
* Kidney	Renal Tubule Renal Tubule	Hyperplasia Mineralization Nephropathy	Minimal Minimal Minimal
* Liver	Centrilobular	Clear Cell Focus Eosinophilic Focus Fatty Change Hepatocellular Adenoma Hypertrophy Infiltration Cellular Mixed Cell Focus	Minimal Multiple Mild Mononuclear CI, Minimal
		[ Eosinophilic Focus TGLs = 3,4-12+13 ] [ Hepatocellular Adenoma TGLs = 1,2-10+11 ]	
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Seminal Vesicle		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation	Minimal Chronic, Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	105	<b>TMT:</b>	5	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	732
		<b>DOSE:</b>	0.5 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602005

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Thymus	Atrophy	Moderate
Tooth	Dysplasia	Moderate
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 106	<b>TMT:</b> 5	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602006

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Blood Vessel             | * Bone                    | * Bone Marrow               | * Brain                  |
| * Esophagus                | * Eye                     | * Gallbladder               | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric |
| * Pancreas                 | * Parathyroid Gland       | * Pituitary Gland           | * Preputial Gland        |
| * Seminal Vesicle          | * Skin                    | * Spleen                    | * Stomach, Forestomach   |
| * Stomach, Glandular       | * Testes                  | * Thyroid Gland             | * Trachea                |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |  |                           |                         |
|----------------------|--|---------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                              | Hyperplasia               | Minimal                 |
|                      |  | Vacuolization Cytoplasmic | Minimal                 |
| * Adrenal Medulla    |  | Hyperplasia               | Mild                    |
| * Epididymis         |  | Infiltration Cellular     | Mononuclear CI, Minimal |
| * Harderian Gland    |  | Infiltration Cellular     | Mononuclear CI, Minimal |
| * Heart              |  | Cardiomyopathy            | Minimal                 |
| * Islets, Pancreatic |  | Hyperplasia               | Minimal                 |
| * Kidney             | Renal Tubule                             | Mineralization            | Minimal                 |
|                      |  | Nephropathy               | Minimal                 |
| * Liver              |  | Clear Cell Focus          |                         |
|                      |  | Eosinophilic Focus        |                         |
|                      |  | Fatty Change              | Minimal                 |
|                      |  | Hepatocellular Adenoma    |                         |
|                      | Centrilobular                            | Hepatocellular Carcinoma  |                         |
|                      |  | Hypertrophy               | Mild                    |
|                      |  | Infiltration Cellular     | Mononuclear CI, Minimal |
|                      | [ Clear Cell Focus TGLs = 2-5 ]          |                           |                         |
|                      | [ Hepatocellular Adenoma TGLs = 3-11 ]   |                           |                         |
|                      | [ Hepatocellular Carcinoma TGLs = 1-10 ] |                           |                         |
| * Nose               |  | Inflammation              | Chronic, Minimal        |
| * Prostate           |  | Infiltration Cellular     | Mononuclear CI, Minimal |
| * Salivary Glands    |  | Infiltration Cellular     | Mononuclear CI, Minimal |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	106	<b>TMT:</b>	5	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	731
		<b>DOSE:</b>	0.5 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602006

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Thymus	Atrophy	Marked
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 107    **TMT:** 5    **SEX:** Male    **DAY ON TEST:** 731  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602007

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Testes	* Thyroid Gland	* Trachea

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Cardiomyopathy	Minimal
* Islets, Pancreatic		Hyperplasia	Moderate
* Kidney	Renal Tubule	Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Angiectasis	Minimal
		Clear Cell Focus	
		Eosinophilic Focus	
		Fatty Change	Minimal
		Hepatoblastoma	Multiple
		Hepatocellular Adenoma	
	Centrilobular	Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
		Necrosis	Mild
	[ Eosinophilic Focus TGLs = 4,5-14+15 ]		
	[ Hepatoblastoma TGLs = 2,3-11+12 ]		
	[ Hepatocellular Adenoma TGLs = 4,6-13 ]		
Mesentery	Fat	Necrosis	Mild
	[ Necrosis TGLs = 1-10 ]		
* Nose		Inflammation	Chronic, Minimal

\* PROTOCOL REQUIRED TISSUE



TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	107	TMT:	5	SEX:	Male	DAY ON TEST:	731
		DOSE:	0.5 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602007

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ORGAN AND ACCOUNTABLE SITE STATUS

---

* Prostate		Fibrosis	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Glandular	Glands	Ectasia	Minimal
* Thymus		Atrophy	Mild
Tooth		Dysplasia	Marked
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 108 TMT: 5 SEX: Male DAY ON TEST: 731  
 DOSE: 0.5 G/KG DISP: Terminal Sacrifice HISTO: 0602008

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    |
| * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     | * Pancreas                |
| * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          | * Prostate                |
| * Seminal Vesicle           | * Skin                   | * Spleen                   | * Stomach, Forestomach    |
| * Stomach, Glandular        | * Testes                 | * Trachea                  | * Urinary Bladder         |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |  |                       |                         |
|----------------------|--|-----------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                                  | Hyperplasia           | Mild                    |
| * Epididymis         |  | Infiltration Cellular | Mononuclear CI, Minimal |
| * Harderian Gland    |  | Infiltration Cellular | Mononuclear CI, Minimal |
| * Islets, Pancreatic |  | Hyperplasia           | Mild                    |
| * Kidney             | Renal Tubule                                 | Cyst                  | Mild                    |
|                      | Renal Tubule                                 | Mineralization        | Minimal                 |
|                      |  | Nephropathy           | Minimal                 |
|                      | [ Cyst TGLs = 1-10 ]                         |                       |                         |
| * Liver              |  | Angiectasis           | Minimal                 |
|                      |  | Clear Cell Focus      |                         |
|                      |  | Eosinophilic Focus    |                         |
|                      |  | Fatty Change          | Mild                    |
|                      | Centrilobular                                | Hypertrophy           | Mild                    |
|                      |  | Infiltration Cellular | Mononuclear CI, Minimal |
|                      |  | Mixed Cell Focus      |                         |
|                      | [ Eosinophilic Focus TGLs = 2,3,5-11+12+14 ] |                       |                         |
|                      | [ Mixed Cell Focus TGLs = 4-13 ]             |                       |                         |
| * Salivary Glands    |  | Infiltration Cellular | Mononuclear CI, Minimal |
| * Thymus             |  | Atrophy               | Mild                    |
| * Thyroid Gland      |  | Cyst                  | Minimal                 |
| Tooth                |  | Dysplasia             | Mild                    |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 109 TMT: 5 SEX: Male DAY ON TEST: 731  
 DOSE: 0.5 G/KG DISP: Terminal Sacrifice HISTO: 0602009

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla        | Blood Vessel               | * Bone                    | * Bone Marrow               |
| * Brain                  | * Esophagus                | * Eye                     | * Gallbladder               |
| * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      | * Lung                      |
| * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Nose                    | * Pancreas                  |
| * Parathyroid Gland      | * Pituitary Gland          | * Seminal Vesicle         | * Skin                      |
| * Stomach, Glandular     | * Testes                   | * Thyroid Gland           | * Trachea                   |
| * Urinary Bladder        |                            |                           |                             |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |   |                                  |                         |
|------------------------|---|----------------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                                 | Hyperplasia                      | Mild                    |
| * Epididymis           |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Harderian Gland      |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Heart                |   | Cardiomyopathy                   | Minimal                 |
| * Kidney               |   | Nephropathy                      | Mild                    |
| * Liver                |   | Angiectasis                      | Mild                    |
|                        |   | Eosinophilic Focus               |                         |
|                        |   | Hepatocellular Adenoma           | Multiple                |
|                        |   | Hepatocellular Carcinoma         |                         |
|                        | Centrilobular                               | Hypertrophy                      | Mild                    |
|                        |   | Infiltration Cellular            | Mononuclear CI, Minimal |
|                        | [ Angiectasis TGLs = 5-14 ]                 |                                  |                         |
|                        | [ Eosinophilic Focus TGLs = 3-12 ]          |                                  |                         |
|                        | [ Hepatocellular Adenoma TGLs = 2,4-11+13 ] |                                  |                         |
|                        | [ Hepatocellular Carcinoma TGLs = 1-10 ]    |                                  |                         |
| * Preputial Gland      |   | Inflammation                     | Mild                    |
| * Prostate             |   | Infiltration Cellular            | Mononuclear CI, Mild    |
| * Salivary Glands      |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen               |   | Hematopoietic Cell Proliferation | Minimal                 |
|                        |   | Hyperplasia                      | Lymphoid, Mild          |
| * Stomach, Forestomach | Epithelium                                  | Hyperplasia                      | Moderate                |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b> 109	<b>TMT:</b> 5	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602009

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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		Necrosis	Minimal
* Thymus	[ Necrosis TGLs = 6-15 ]	Atrophy	Moderate

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 110 TMT: 5 SEX: Male DAY ON TEST: 616  
 DOSE: 0.5 G/KG DISP: Moribund Sacrifice HISTO: 0602010

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Blood Vessel	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Eye	* Gallbladder
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Pituitary Gland
* Preputial Gland	* Seminal Vesicle	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

\* Mammary Gland \* Parathyroid Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Adrenal Medulla		Pheochromocytoma Benign	
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Cardiomyopathy	Minimal
* Kidney	Renal Tubule	Mineralization	Minimal
* Liver	Centrilobular	Eosinophilic Focus	
		Hepatocellular Adenoma	
		Hepatocellular Carcinoma	
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Eosinophilic Focus TGLs = 4-13 ]		
	[ Hepatocellular Adenoma TGLs = 3-12 ]		
	[ Hepatocellular Carcinoma TGLs = 2-11 ]		
* Lung		Hepatocellular Carcinoma	Metastatic (Liver)
* Prostate		Inflammation	Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Skin		Ulcer	Moderate
	[ Ulcer TGLs = 1-10 ]		
* Spleen		Hematopoietic Cell Proliferation	Mild
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
		Inflammation	Chronic, Mild

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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<b>ANIMAL NUM:</b> 110	<b>TMT:</b> 5	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 616
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Moribund Sacrifice	<b>HISTO:</b> 0602010

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**ORGAN AND ACCOUNTABLE SITE STATUS**

---

[ Inflammation TGLs = 5-12 ]		
* Thymus	Atrophy	Moderate

---

PRIMARY CAUSE OF DEATH - Liver Hepatocellular Carcinoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

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<b>ANIMAL NUM:</b> 111	<b>TMT:</b> 5	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 732
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602011

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Nose                    | * Pancreas                  | * Parathyroid Gland      | * Pituitary Gland          |
| * Salivary Glands         | * Seminal Vesicle           | * Skin                   | * Stomach, Glandular       |
| * Testes                  | * Thyroid Gland             | * Trachea                | * Urinary Bladder          |

**MISSING**

- \* Mammary Gland
- 

**OBSERVATIONS**

- |                        |                             |  |  |
|------------------------|-----------------------------|--|--|
| * Adrenal Cortex       | Subcapsular                 | Hyperplasia  | Minimal                                    |
| * Harderian Gland      |                             | Hyperplasia  | Marked                                     |
| * Kidney               | Renal Tubule                | Mineralization<br>Nephropathy                        | Minimal<br>Minimal                         |
| * Liver                | Centrilobular               | Fatty Change<br>Hypertrophy<br>Infiltration Cellular | Minimal<br>Mild<br>Mononuclear CI, Minimal |
| * Preputial Gland      |                             | Inflammation   | Mild                                       |
| * Prostate             |                             | Infiltration Cellular                                | Mononuclear CI, Minimal                    |
| * Spleen               |                             | Hematopoietic Cell Proliferation                     | Mild                                       |
| * Stomach, Forestomach | Epithelium                  | Hyperplasia  | Mild                                       |
|                        | [ Hyperplasia TGLs = 1-10 ] |  |  |
| * Thymus               |                             | Atrophy  | Mild                                       |
| Tooth                  |                             | Dysplasia  | Mild                                       |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 112 TMT: 5 SEX: Male DAY ON TEST: 623  
 DOSE: 0.5 G/KG DISP: Natural Death HISTO: 0602012

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Epididymis             | * Esophagus                | * Eye                     |
| * Gallbladder               | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     | * Pancreas                |
| * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          | * Salivary Glands         |
| * Seminal Vesicle           | * Skin                   | * Stomach, Forestomach     | * Stomach, Glandular      |
| * Thyroid Gland             | * Trachea                | * Urinary Bladder          |                           |

**MISSING**

- \* Mammary Gland

**AUTO PRECLUDES DIAG.**

- \* Spleen

**OBSERVATIONS**

- |                   |   |                          |                         |
|-------------------|---|--------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                                 | Hyperplasia              | Minimal                 |
| * Harderian Gland |   | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Heart           |   | Cardiomyopathy           | Moderate                |
| * Kidney          | Renal Tubule                                | Mineralization           | Mild                    |
| * Liver           |   | Eosinophilic Focus       | Metastatic (Testes)     |
|                   |   | Hemangiosarcoma          | Multiple                |
|                   |   | Hepatocellular Adenoma   |                         |
|                   |   | Hepatocellular Carcinoma |                         |
|                   |   | Infiltration Cellular    | Mononuclear CI, Minimal |
|                   |   | Tension Lipidosis        |                         |
|                   | [ Hemangiosarcoma TGLs = 2-11 ]             |                          |                         |
|                   | [ Hepatocellular Adenoma TGLs = 3,5-11+12 ] |                          |                         |
|                   | [ Hepatocellular Carcinoma TGLs = 4-12 ]    |                          |                         |
| * Lung            |   | Hemangiosarcoma          | Metastatic (Testes)     |
|                   | [ Hemangiosarcoma TGLs = 6,7,8-13+14 ]      |                          |                         |
| * Prostate        |   | Inflammation             | Mild                    |
| * Testes          |   | Hemangiosarcoma          |                         |
|                   | [ Hemangiosarcoma TGLs = 1-10 ]             |                          |                         |

\* PROTOCOL REQUIRED TISSUE



TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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<b>ANIMAL NUM:</b>	112	<b>TMT:</b>	5	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	623
		<b>DOSE:</b>	0.5 G/KG	<b>DISP:</b>	Natural Death	<b>HISTO:</b>	0602012

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**ORGAN AND ACCOUNTABLE SITE STATUS**

---

* Thymus	Atrophy	Marked
Tooth	Dysplasia	Moderate

---

PRIMARY CAUSE OF DEATH - Testes Hemangiosarcoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 113    **TMT:** 5    **SEX:** Male    **DAY ON TEST:** 670  
**DOSE:** 0.5 G/KG    **DISP:** Moribund Sacrifice    **HISTO:** 0602013

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Gallbladder	* Harderian Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Seminal Vesicle	* Skin	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
		Fatty Change	Minimal
	Centrilobular	Hepatocellular Carcinoma	Multiple
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
		Necrosis	Mild
	[ Eosinophilic Focus TGLs = 5-13 ]		
	[ Hepatocellular Carcinoma TGLs = 2,3-11+12 ]		
* Lung		Alveolar/Bronchiolar Adenoma	
		Hepatocellular Carcinoma	Metastatic (Liver)
	[ Alveolar/Bronchiolar Adenoma TGLs = 4-10 ]		
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hemangiosarcoma	
		Hematopoietic Cell Proliferation	Mild
	[ Hemangiosarcoma TGLs = 1-10 ]		
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Chronic, Mild
		Necrosis	Mild
	[ Necrosis TGLs = 6-14 ]		

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b> 113	<b>TMT:</b> 5	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 670
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Moribund Sacrifice	<b>HISTO:</b> 0602013

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**ORGAN AND ACCOUNTABLE SITE STATUS**

---

\* Thymus

Atrophy

Marked

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PRIMARY CAUSE OF DEATH - Liver Hepatocellular Carcinoma  
CONTRIBUTORY CAUSE OF DEATH - Spleen Hemangiosarcoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 114 TMT: 5 SEX: Male DAY ON TEST: 730  
 DOSE: 0.5 G/KG DISP: Terminal Sacrifice HISTO: 0602014

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia Vacuolization Cytoplasmic	Mild Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney	Renal Tubule	Mineralization Nephropathy	Minimal Minimal
* Liver		Angiectasis Clear Cell Focus Degeneration Eosinophilic Focus Fatty Change Hepatoblastoma	Minimal Cystic, Minimal Minimal
	Centrilobular	Hypertrophy Infiltration Cellular Mixed Cell Focus	Mild Mononuclear CI, Minimal
	[ Clear Cell Focus TGLs = 6-15 ] [ Eosinophilic Focus TGLs = 2,5-11+14 ] [ Hepatoblastoma TGLs = 3-12 ] [ Mixed Cell Focus TGLs = 1,4-10+13 ]		
* Lung	[ Alveolar/Bronchiolar Carcinoma TGLs = 7-16 ]	Alveolar/Bronchiolar Carcinoma	
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b> 114	<b>TMT:</b> 5	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602014

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Salivary Glands	Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Inflammation	Chronic, Minimal
* Thymus	Atrophy	Mild
Tooth	Dysplasia	Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 115 TMT: 5 SEX: Male DAY ON TEST: 731  
 DOSE: 0.5 G/KG DISP: Terminal Sacrifice HISTO: 0602015

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Bone Marrow	* Brain
* Esophagus	* Eye	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Seminal Vesicle	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Adrenal Medulla		Pheochromocytoma Benign	
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Adenoma	
	[ Adenoma TGLs = 1-9 ]		
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney	Renal Tubule	Nephropathy	Mild
		Pigmentation	Lipofuscin, Mild
* Liver		Eosinophilic Focus	Multiple
		Hepatoblastoma	Multiple
		Hepatocellular Adenoma	Mononuclear CI, Minimal
		Infiltration Cellular	
	[ Eosinophilic Focus TGLs = 5-13 ]		
	[ Hepatoblastoma TGLs = 3,6-11+14 ]		
	[ Hepatocellular Adenoma TGLs = 4,7-12+15 ]		
* Lung		Hepatoblastoma	Metastatic (Liver)
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Skin		Ulcer	Moderate
	[ Ulcer TGLs = 2-10 ]		
* Spleen		Hematopoietic Cell Proliferation	Mild

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	115	TMT:	5	SEX:	Male	DAY ON TEST:	731
		DOSE:	0.5 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602015

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ORGAN AND ACCOUNTABLE SITE STATUS

---

* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation Necrosis	Mild Chronic, Mild Mild
[ Necrosis TGLs = 8-16 ]			
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 116    **TMT:** 5    **SEX:** Male    **DAY ON TEST:** 732  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602016

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                    | * Esophagus               | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric |
| * Nose                     | * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        |
| * Seminal Vesicle          | * Skin                    | * Stomach, Forestomach      | * Stomach, Glandular     |
| * Testes                   | * Thyroid Gland           | * Urinary Bladder           |                          |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |  |                       |                         |
|----------------------|--|-----------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                                | Hyperplasia           | Mild                    |
| * Epididymis         |  | Infiltration Cellular | Mononuclear CI, Minimal |
| * Eye                | Cornea                                     | Inflammation          | Chronic, Mild           |
| * Gallbladder        |  | Infiltration Cellular | Mononuclear CI, Minimal |
| * Harderian Gland    |  | Adenoma               |                         |
|                      |  | Inflammation          | Granulomatous, Mild     |
|                      | [ Adenoma TGLs = 1-9 ]                     |                       |                         |
| * Islets, Pancreatic |  | Hyperplasia           | Minimal                 |
| * Kidney             | Renal Tubule                               | Mineralization        | Minimal                 |
|                      |  | Nephropathy           | Minimal                 |
| * Liver              |  | Clear Cell Focus      |                         |
|                      |  | Eosinophilic Focus    |                         |
|                      |  | Fatty Change          | Mild                    |
|                      | Centrilobular                              | Hypertrophy           | Mild                    |
|                      |  | Infiltration Cellular | Mononuclear CI, Minimal |
|                      |  | Mixed Cell Focus      |                         |
|                      | [ Clear Cell Focus TGLs = 4-12 ]           |                       |                         |
|                      | [ Eosinophilic Focus TGLs = 5-13 ]         |                       |                         |
|                      | [ Mixed Cell Focus TGLs = 2,3,6-10+11+14 ] |                       |                         |
| * Preputial Gland    |  | Inflammation          | Minimal                 |
| * Prostate           |  | Infiltration Cellular | Mononuclear CI, Minimal |
| * Salivary Glands    |  | Infiltration Cellular | Mononuclear CI, Minimal |

\* PROTOCOL REQUIRED TISSUE



TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	116	TMT:	5	SEX:	Male	DAY ON TEST:	732
		DOSE:	0.5 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602016

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ORGAN AND ACCOUNTABLE SITE STATUS

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* Spleen		Hematopoietic Cell Proliferation Hyperplasia	Minimal Lymphoid, Marked
* Thymus		Atrophy	Moderate
Tooth		Dysplasia	Minimal
* Trachea	Epithelium	Cytoplasmic Alteration Inflammation	Mild Chronic, Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 117 TMT: 5 SEX: Male DAY ON TEST: 679  
 DOSE: 0.5 G/KG DISP: Moribund Sacrifice HISTO: 0602017

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla        | Blood Vessel               | * Bone                    | * Bone Marrow               |
| * Brain                  | Coagulating Gland          | * Epididymis              | * Esophagus                 |
| * Eye                    | * Gallbladder              | * Harderian Gland         | * Heart                     |
| * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    | * Lymph Node, Mandibular    |
| * Lymph Node, Mesenteric | * Pancreas                 | * Parathyroid Gland       | * Pituitary Gland           |
| * Preputial Gland        | * Seminal Vesicle          | * Skin                    | * Stomach, Glandular        |
| * Testes                 | * Trachea                  |                           |                             |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |              |                          |                         |
|----------------------|--------------|--------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular  | Hyperplasia              | Minimal                 |
| * Islets, Pancreatic |              | Hyperplasia              | Minimal                 |
| * Kidney             | Renal Tubule | Cyst                     | Minimal                 |
| * Liver              |              | Fatty Change             | Minimal                 |
|                      |              | Hepatoblastoma           |                         |
|                      |              | Hepatocellular Carcinoma |                         |
|                      |              | Infarct                  | Mild                    |
|                      |              | Infiltration Cellular    | Mononuclear CI, Minimal |
- Note: TGL 3 was examined microscopically and determined to be a hepatic lesion rather than a mesenteric one, as had been diagnosed grossly  
 [ Hepatoblastoma TGLs = 2-11 ]  
 [ Hepatocellular Carcinoma TGLs = 1-10 ]  
 [ Infarct TGLs = 3-12 ]
- |                                       |                |                                  |                         |
|---------------------------------------|----------------|----------------------------------|-------------------------|
| * Nose                                | Nasolacrim Dct | Inflammation                     | Suppurative, Minimal    |
| * Preputial GI                        |                |                                  |                         |
| Note: One preputial gland was missing |                |                                  |                         |
| * Prostate                            |                | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Salivary Glands                     |                | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen                              |                | Hematopoietic Cell Proliferation | Mild                    |
| * Stomach, Forestomach                | Epithelium     | Hyperplasia                      | Mild                    |
|                                       |                | Inflammation                     | Chronic, Mild           |
|                                       |                | Necrosis                         | Mild                    |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

---

ANIMAL NUM:	117	TMT:	5	SEX:	Male	DAY ON TEST:	679
		DOSE:	0.5 G/KG	DISP:	Moribund Sacrifice	HISTO:	0602017

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ORGAN AND ACCOUNTABLE SITE STATUS

---

[ Necrosis TGLs = 4-13 ]

* Thymus		Atrophy	Marked
* Thyroid Gland	Follicle	Hyperplasia	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

---

PRIMARY CAUSE OF DEATH - Liver Hepatocellular Carcinoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 118    **TMT:** 5    **SEX:** Male    **DAY ON TEST:** 534  
**DOSE:** 0.5 G/KG    **DISP:** Moribund Sacrifice    **HISTO:** 0602018

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Cortex         | * Adrenal Medulla          | Blood Vessel              | * Bone                      |
| * Bone Marrow            | * Brain                    | * Epididymis              | * Esophagus                 |
| * Eye                    | * Gallbladder              | * Harderian Gland         | * Heart                     |
| * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lymph Node, Mandibular  | * Lymph Node, Mesenteric    |
| * Pancreas               | * Parathyroid Gland        | * Pituitary Gland         | * Preputial Gland           |
| * Prostate               | * Salivary Glands          | * Seminal Vesicle         | * Skin                      |
| * Stomach, Glandular     | * Testes                   | * Thyroid Gland           | * Trachea                   |
| * Urinary Bladder        |                            |                           |                             |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |   |                                  |                         |
|------------------------|---|----------------------------------|-------------------------|
| * Islets, Pancreatic   |   | Hyperplasia                      | Minimal                 |
| * Kidney               | Renal Tubule                                  | Hyperplasia                      | Mild                    |
|                        | [ Nephropathy TGLs = 3-4 ]                    | Nephropathy                      | Marked                  |
| * Liver                |   | Hepatocellular Carcinoma         | Multiple                |
|                        | [ Hepatocellular Carcinoma TGLs = 1,2-10+11 ] | Infiltration Cellular            | Mononuclear Cl, Minimal |
| * Lung                 |   | Hepatocellular Carcinoma         | Metastatic (Liver)      |
| * Nose                 |   | Inflammation                     | Chronic, Minimal        |
| * Spleen               |   | Hematopoietic Cell Proliferation | Minimal                 |
| * Stomach, Forestomach | Epithelium                                    | Hyperplasia                      | Minimal                 |
|                        |   | Inflammation                     | Chronic, Mild           |
|                        |   | Necrosis                         | Moderate                |
| * Thymus               |   | Atrophy                          | Marked                  |

PRIMARY CAUSE OF DEATH    - Kidney Nephropathy

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 119    **TMT:** 5    **SEX:** Male    **DAY ON TEST:** 730  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602019

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Epididymis             | * Esophagus                | * Eye                     |
| * Gallbladder               | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    |
| * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     | * Pancreas                |
| * Parathyroid Gland         | * Pituitary Gland        | * Seminal Vesicle          | * Skin                    |
| * Stomach, Glandular        | * Testes                 | * Thyroid Gland            | * Trachea                 |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |               |   |                         |
|------------------------|---------------|---|-------------------------|
| * Adrenal Cortex       | Subcapsular   | Hyperplasia   | Mild                    |
| * Harderian Gland      |               | Infiltration Cellular                                   | Mononuclear CI, Minimal |
| * Heart                |               | Cardiomyopathy  | Minimal                 |
| * Islets, Pancreatic   |               | Hyperplasia   | Mild                    |
| * Kidney               | Renal Tubule  | Mineralization  | Minimal                 |
|                        |               | Nephropathy   | Mild                    |
| * Liver                |               | Eosinophilic Focus                                      |                         |
|                        |               | Hepatocellular Adenoma                                  |                         |
|                        | Centrilobular | Hepatocellular Carcinoma                                | Multiple                |
|                        |               | Hypertrophy   | Mild                    |
|                        |               | Infiltration Cellular                                   | Mononuclear CI, Minimal |
|                        |               | Mixed Cell Focus  |                         |
|                        |               | Necrosis  | Mild                    |
|                        |               | [ Eosinophilic Focus TGLs = 3-12 ]                      |                         |
|                        |               | [ Hepatocellular Adenoma TGLs = 5-14 ]                  |                         |
|                        |               | [ Hepatocellular Carcinoma TGLs = 1,2,4,6-10+11+13+15 ] |                         |
| * Preputial Gland      |               | Cyst  | Mild                    |
| * Prostate             |               | Infiltration Cellular                                   | Mononuclear CI, Minimal |
| * Salivary Glands      |               | Infiltration Cellular                                   | Mononuclear CI, Minimal |
| * Spleen               |               | Angiectasis   | Mild                    |
|                        |               | Hematopoietic Cell Proliferation                        | Minimal                 |
| * Stomach, Forestomach | Epithelium    | Hyperplasia   | Mild                    |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	119	TMT:	5	SEX:	Male	DAY ON TEST:	730
		DOSE:	0.5 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602019

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ORGAN AND ACCOUNTABLE SITE STATUS

---

[ Hyperplasia TGLs = 7-16 ]	Inflammation	Chronic, Mild
* Thymus	Necrosis	Mild
* Urinary Bladder	Atrophy	Marked
	Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 120    **TMT:** 5    **SEX:** Male    **DAY ON TEST:** 731  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602020

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Esophagus                 | * Eye                    | * Gallbladder              |
| * Harderian Gland         | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lymph Node, Mandibular  | * Lymph Node, Mesenteric    | * Nose                   | * Pancreas                 |
| * Pituitary Gland         | * Preputial Gland           | * Seminal Vesicle        | * Skin                     |
| * Stomach, Glandular      | * Testes                    | * Thyroid Gland          | * Trachea                  |
| * Urinary Bladder         |                             |                          |                            |

**MISSING**

- |                 |                     |
|-----------------|---------------------|
| * Mammary Gland | * Parathyroid Gland |
|-----------------|---------------------|

**OBSERVATIONS**

- |                        |              |   |                         |
|------------------------|--------------|---|-------------------------|
| * Adrenal Cortex       | Subcapsular  | Hyperplasia                                       | Mild                    |
| * Epididymis           |              | Infiltration Cellular                             | Mononuclear CI, Minimal |
| * Islets, Pancreatic   |              | Hyperplasia                                       | Marked                  |
| * Kidney               | Renal Tubule | Hyperplasia                                       | Mild                    |
|                        | Renal Tubule | Mineralization                                    | Minimal                 |
|                        |              | Nephropathy                                       | Mild                    |
| * Liver                |              | Clear Cell Focus                                  |                         |
|                        |              | Eosinophilic Focus                                |                         |
|                        |              | Fatty Change                                      | Minimal                 |
|                        |              | Hepatoblastoma                                    |                         |
|                        |              | Hepatocellular Carcinoma                          |                         |
|                        |              | Infiltration Cellular                             | Mononuclear CI, Mild    |
|                        |              | Mixed Cell Focus                                  |                         |
|                        |              | [ Eosinophilic Focus TGLs = 3,4,5,7-12+13+14+16 ] |                         |
|                        |              | [ Hepatoblastoma TGLs = 2-11 ]                    |                         |
|                        |              | [ Hepatocellular Carcinoma TGLs = 1-10 ]          |                         |
| * Lung                 | Alveolus     | Infiltration Cellular                             | Histiocyte, Minimal     |
| * Prostate             |              | Infiltration Cellular                             | Mononuclear CI, Minimal |
| * Salivary Glands      |              | Infiltration Cellular                             | Mononuclear CI, Minimal |
| * Spleen               |              | Hematopoietic Cell Proliferation                  | Mild                    |
| * Stomach, Forestomach | Epithelium   | Hyperplasia                                       | Moderate                |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	120	TMT:	5	SEX:	Male	DAY ON TEST:	731
		DOSE:	0.5 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602020

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ORGAN AND ACCOUNTABLE SITE STATUS

---

	Inflammation	Chronic, Mild
	Necrosis	Mild
[ Necrosis TGLs = 6-15 ]		
* Thymus	Atrophy	Marked



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 121    **TMT:** 5    **SEX:** Male    **DAY ON TEST:** 731  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602021

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    |
| * Lymph Node, Mesenteric    | * Nose                   | * Pancreas                 | * Parathyroid Gland       |
| * Pituitary Gland           | * Preputial Gland        | * Salivary Glands          | * Seminal Vesicle         |
| * Spleen                    | * Stomach, Forestomach   | * Stomach, Glandular       | * Testes                  |
| * Thyroid Gland             | * Trachea                |                            |                           |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                          |   |                       |                         |
|--------------------------|---|-----------------------|-------------------------|
| * Adrenal Cortex         | Subcapsular   | Hyperplasia           | Minimal                 |
| * Epididymis             |   | Infiltration Cellular | Mononuclear CI, Minimal |
| * Harderian Gland        |   | Carcinoma             |                         |
|                          |   | Infiltration Cellular | Mononuclear CI, Minimal |
| * Islets, Pancreatic     |   | Hyperplasia           | Mild                    |
| * Kidney                 | Renal Tubule  | Mineralization        | Minimal                 |
|                          |   | Nephropathy           | Minimal                 |
| * Liver                  | Centrilobular   | Eosinophilic Focus    |                         |
|                          |   | Hypertrophy           | Mild                    |
|                          |   | Infiltration Cellular | Mononuclear CI, Minimal |
|                          | [ Eosinophilic Focus TGLs = 3,4,5,6,7,8-12+13+14+15 ] |                       |                         |
| * Lymph Node, Mandibular |   | Hyperplasia           | Lymphoid, Marked        |
|                          | [ Hyperplasia TGLs = 9-6 ]                            |                       |                         |
| * Prostate               |   | Infiltration Cellular | Mononuclear CI, Minimal |
| * Skin                   |   | Ulcer                 | Moderate                |
|                          | [ Ulcer TGLs = 1,2-10+11 ]                            |                       |                         |
| * Thymus                 |   | Atrophy               | Marked                  |
| Tooth                    |   | Dysplasia             | Moderate                |
| * Urinary Bladder        |   | Infiltration Cellular | Mononuclear CI, Minimal |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 122	<b>TMT:</b> 5	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 580
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 0602022

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                    | * Epididymis              | * Esophagus                 | * Eye                    |
| * Gallbladder              | * Harderian Gland         | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Kidney                  | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric |
| * Pancreas                 | * Parathyroid Gland       | * Pituitary Gland           | * Preputial Gland        |
| * Prostate                 | * Seminal Vesicle         | * Skin                      | * Stomach, Glandular     |
| * Testes                   | * Thyroid Gland           | * Trachea                   | * Urinary Bladder        |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |   |                                  |                         |
|------------------------|---|----------------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                                   | Hyperplasia                      | Minimal                 |
| * Islets, Pancreatic   |   | Hyperplasia                      | Moderate                |
| * Liver                |   | Eosinophilic Focus               |                         |
|                        |   | Fatty Change                     | Minimal                 |
|                        |   | Hepatocellular Adenoma           | Multiple                |
|                        |   | Hepatocellular Carcinoma         | Multiple                |
|                        |   | Infiltration Cellular            | Mononuclear Cl, Minimal |
|                        | [ Eosinophilic Focus TGLs = 3-12 ]            |                                  |                         |
|                        | [ Hepatocellular Adenoma TGLs = 4,6-12+13 ]   |                                  |                         |
|                        | [ Hepatocellular Carcinoma TGLs = 5,7-13+14 ] |                                  |                         |
| * Lung                 |   | Hepatocellular Carcinoma         | Metastatic (Liver)      |
|                        | [ Hepatocellular Carcinoma TGLs = 1,2-10+11 ] |                                  |                         |
| * Nose                 | Nasolacrim Dct                                | Inflammation                     | Suppurative, Mild       |
| * Salivary Glands      |   | Infiltration Cellular            | Mononuclear Cl, Minimal |
| * Spleen               |   | Hematopoietic Cell Proliferation | Moderate                |
| * Stomach, Forestomach | Epithelium                                    | Hyperplasia                      | Mild                    |
|                        |   | Inflammation                     | Chronic, Mild           |
|                        |   | Necrosis                         | Marked                  |
|                        | [ Necrosis TGLs = 8-15 ]                      |                                  |                         |
| * Thymus               |   | Atrophy                          | Marked                  |

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

---

<b>ANIMAL NUM:</b>	122	<b>TMT:</b>	5	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	580
		<b>DOSE:</b>	0.5 G/KG	<b>DISP:</b>	Natural Death	<b>HISTO:</b>	0602022

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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PRIMARY CAUSE OF DEATH - Liver Hepatocellular Carcinoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 123    **TMT:** 5    **SEX:** Male    **DAY ON TEST:** 605  
**DOSE:** 0.5 G/KG    **DISP:** Moribund Sacrifice    **HISTO:** 0602023

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Epididymis             | * Esophagus                | * Eye                     |
| * Gallbladder               | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Kidney                  |
| * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     | * Pancreas                |
| * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          | * Seminal Vesicle         |
| * Skin                      | * Stomach, Forestomach   | * Stomach, Glandular       | * Testes                  |
| * Thyroid Gland             | * Trachea                |                            |                           |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |   |                                  |                         |
|----------------------|---|----------------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                                   | Hyperplasia                      | Minimal                 |
| * Harderian Gland    |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Heart              |   | Rhabdomyosarcoma                 |                         |
|                      | [ Rhabdomyosarcoma TGLs = 8-3 ]               |                                  |                         |
| * Islets, Pancreatic |   | Hyperplasia                      | Mild                    |
| * Liver              | Centrilobular                                 | Hepatocellular Carcinoma         | Multiple                |
|                      | [ Hepatocellular Carcinoma TGLs = 1,2-10+11 ] | Hypertrophy                      | Mild                    |
|                      |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Lung               | Alveolus                                      | Hepatocellular Carcinoma         | Metastatic (Liver)      |
|                      |   | Infiltration Cellular            | Histiocyte, Moderate    |
|                      | [ Hepatocellular Carcinoma TGLs = 6,7-14+15 ] | Rhabdomyosarcoma                 | Metastatic (Heart)      |
|                      | [ Rhabdomyosarcoma TGLs = 3,4,5-12+13+14 ]    |                                  |                         |
| * Prostate           |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Salivary Glands    |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| Skeletal Muscle      |   | Rhabdomyosarcoma                 | Metastatic (Heart)      |
|                      | [ Rhabdomyosarcoma TGLs = 9,10-16 ]           |                                  |                         |
| * Spleen             |   | Hematopoietic Cell Proliferation | Moderate                |
| * Thymus             |   | Atrophy                          | Marked                  |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b> 123	<b>TMT:</b> 5	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 605
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Moribund Sacrifice	<b>HISTO:</b> 0602023

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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Tooth	Dysplasia	Minimal
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

---

PRIMARY CAUSE OF DEATH - Heart Rhabdomyosarcoma

---

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 124    **TMT:** 5    **SEX:** Male    **DAY ON TEST:** 731  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602024

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Esophagus                 | * Eye                    | * Gallbladder              |
| * Harderian Gland         | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Pancreas                 |
| * Parathyroid Gland       | * Pituitary Gland           | * Salivary Glands        | * Seminal Vesicle          |
| * Spleen                  | * Stomach, Glandular        | * Testes                 | * Thyroid Gland            |
| * Trachea                 | * Urinary Bladder           |                          |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |  |                          |                         |
|------------------------|--|--------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                                  | Hyperplasia              | Minimal                 |
| * Epididymis           |  | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Islets, Pancreatic   |  | Hyperplasia              | Mild                    |
| * Kidney               | Renal Tubule                                 | Mineralization           | Minimal                 |
|                        |  | Nephropathy              | Minimal                 |
| * Liver                |  | Eosinophilic Focus       |                         |
|                        |  | Hepatocellular Adenoma   | Multiple                |
|                        |  | Hepatocellular Carcinoma |                         |
|                        |  | Infiltration Cellular    | Mononuclear CI, Minimal |
|                        |  | Necrosis                 | Mild                    |
|                        | [ Eosinophilic Focus TGLs = 3,6,7-12+15+16 ] |                          |                         |
|                        | [ Hepatocellular Adenoma TGLs = 2-11 ]       |                          |                         |
|                        | [ Hepatocellular Carcinoma TGLs = 1-10 ]     |                          |                         |
| * Nose                 |  | Inflammation             | Suppurative, Minimal    |
| * Preputial Gland      |  | Inflammation             | Mild                    |
| * Prostate             |  | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Skin                 |  | Ulcer                    | Moderate                |
|                        | [ Ulcer TGLs = 4-13 ]                        |                          |                         |
| * Stomach, Forestomach | Epithelium                                   | Hyperplasia              | Moderate                |
|                        |  | Inflammation             | Chronic, Mild           |
|                        |  | Necrosis                 | Mild                    |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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<b>ANIMAL NUM:</b>	124	<b>TMT:</b>	5	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	731
		<b>DOSE:</b>	0.5 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602024

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**ORGAN AND ACCOUNTABLE SITE STATUS**

---

[ Necrosis TGLs = 5-14 ]

\* Thymus  
Tooth

Atrophy  
Dysplasia

Marked  
Marked

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 125    **TMT:** 5    **SEX:** Male    **DAY ON TEST:** 732  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602025

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Glandular	* Testes	* Thyroid Gland
* Trachea			

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney	Renal Tubule	Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Fatty Change	Mild
		Hepatocellular Adenoma	Multiple
		Hepatocellular Carcinoma	
		Infiltration Cellular	Mononuclear CI, Minimal
		Mineralization	Mild
	[ Eosinophilic Focus TGLs = 4,5,6,7-13+14+15+16 ]		
	[ Hepatocellular Adenoma TGLs = 2,3-11+12 ]		
	[ Hepatocellular Carcinoma TGLs = 1-10 ]		
* Lung		Alveolar/Bronchiolar Adenoma	
	[ Alveolar/Bronchiolar Adenoma TGLs = 8-17 ]		
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands	Parotid GI	Hyperplasia	Mild
		Infiltration Cellular	Mononuclear CI, Minimal

\* PROTOCOL REQUIRED TISSUE



TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	125	TMT:	5	SEX:	Male	DAY ON TEST:	732
		DOSE:	0.5 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602025

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ORGAN AND ACCOUNTABLE SITE STATUS

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* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation Necrosis	Moderate Chronic, Mild Mild
[ Necrosis TGLs = 9-18 ]			
* Thymus		Atrophy	Moderate
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 126    **TMT:** 5    **SEX:** Male    **DAY ON TEST:** 732  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602026

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney	Renal Tubule	Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Hepatoblastoma	
		Hepatocellular Adenoma	Multiple
		Hepatocellular Carcinoma	
	Centrilobular	Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Hepatoblastoma TGLs = 3-12 ]		
	[ Hepatocellular Adenoma TGLs = 2,4,5-11+13+14 ]		
	[ Hepatocellular Carcinoma TGLs = 1-10 ]		
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Seminal Vesicle		Infiltration Cellular	Mononuclear CI, Minimal
* Thymus		Atrophy	Marked
Tooth		Dysplasia	Moderate
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 127    **TMT:** 5    **SEX:** Male    **DAY ON TEST:** 732  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602027

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    |
| * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     | * Pancreas                |
| * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          | * Skin                    |
| * Spleen                    | * Stomach, Forestomach   | * Stomach, Glandular       | * Testes                  |
| * Thyroid Gland             | * Trachea                |                            |                           |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |               |   |                         |
|----------------------|---------------|---|-------------------------|
| * Adrenal Cortex     | Subcapsular   | Hyperplasia                                 | Minimal                 |
| * Epididymis         |               | Infiltration Cellular                       | Mononuclear CI, Minimal |
| * Harderian Gland    |               | Infiltration Cellular                       | Mononuclear CI, Minimal |
| * Islets, Pancreatic |               | Hyperplasia                                 | Mild                    |
| * Kidney             | Renal Tubule  | Hyperplasia                                 | Mild                    |
|                      | Renal Tubule  | Mineralization                              | Minimal                 |
|                      |               | Nephropathy                                 | Minimal                 |
| * Liver              |               | Clear Cell Focus                            |                         |
|                      |               | Eosinophilic Focus                          |                         |
|                      |               | Fatty Change                                | Minimal                 |
|                      | Centrilobular | Hepatocellular Adenoma                      | Multiple                |
|                      |               | Hypertrophy                                 | Mild                    |
|                      |               | Infiltration Cellular                       | Mononuclear CI, Minimal |
|                      |               | Mixed Cell Focus                            |                         |
|                      |               | [ Eosinophilic Focus TGLs = 2,4-11+13 ]     |                         |
|                      |               | [ Hepatocellular Adenoma TGLs = 1,3-10+12 ] |                         |
|                      |               | [ Mixed Cell Focus TGLs = 5-14 ]            |                         |
| * Prostate           |               | Infiltration Cellular                       | Mononuclear CI, Minimal |
| * Salivary Glands    |               | Infiltration Cellular                       | Mononuclear CI, Minimal |
| * Seminal Vesicle    |               | Infiltration Cellular                       | Mononuclear CI, Minimal |
| * Thymus             |               | Atrophy                                     | Mild                    |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	127	<b>TMT:</b>	5	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	732
		<b>DOSE:</b>	0.5 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602027

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* Urinary Bladder

Infiltration Cellular

Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 128    **TMT:** 5    **SEX:** Male    **DAY ON TEST:** 731  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602028

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lung
* Lymph Node, Mandibular	* Nose	* Pancreas	* Pituitary Gland
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Glandular
* Testes	* Trachea		

**MISSING**

* Mammary Gland	* Parathyroid Gland	* Thyroid Gland
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**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
Note: One epididymis was missing			
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney	Renal Tubule	Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Eosinophilic Focus	Multiple
		Hepatocellular Adenoma	Mononuclear CI, Minimal
		Infiltration Cellular	
	[ Eosinophilic Focus TGLs = 2,4,5,7-11+13+14+16 ]		
	[ Hepatocellular Adenoma TGLs = 1,3,6-10+12+15 ]		
* Lymph Node, Mesenteric		Hyperplasia	Lymphoid, Mild
* Preputial Gland		Inflammation	Mild
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Chronic, Mild
	[ Hyperplasia TGLs = 8-17 ]		
* Testes			
Note: One testis was missing			

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	128	<b>TMT:</b>	5	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	731
		<b>DOSE:</b>	0.5 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602028

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Thymus	Atrophy	Moderate
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 129 TMT: 5 SEX: Male DAY ON TEST: 730  
 DOSE: 0.5 G/KG DISP: Terminal Sacrifice HISTO: 0602029

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Nose	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Seminal Vesicle	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea
* Urinary Bladder			

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney	Renal Tubule	Mineralization	Minimal
		Nephropathy	Minimal
* Liver	Centrilobular	Hepatocellular Adenoma	
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Hepatocellular Adenoma TGLs = 4-13 ]		
* Lung		Alveolar/Bronchiolar Adenoma	
	[ Alveolar/Bronchiolar Adenoma TGLs = 6-15 ]		
Lymph Node	Renal	Lymphoma Malignant	
	[ Lymphoma Malignant TGLs = 3-12 ]		
* Lymph Node, Mandibular		Hyperplasia	Lymphoid, Mild
* Lymph Node, Mesenteric		Lymphoma Malignant	
	[ Lymphoma Malignant TGLs = 5-14 ]		
* Pancreas		Inflammation	Chronic, Mild
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Skin		Ulcer	Moderate
	[ Ulcer TGLs = 1,2-10+11 ]		
* Spleen		Hematopoietic Cell Proliferation	Mild

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	129	<b>TMT:</b>	5	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	730
		<b>DOSE:</b>	0.5 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602029

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Thymus	Lymphoma Malignant Atrophy	Marked
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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 130    **TMT:** 5    **SEX:** Male    **DAY ON TEST:** 668  
**DOSE:** 0.5 G/KG    **DISP:** Moribund Sacrifice    **HISTO:** 0602030

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Pancreas                 |
| * Parathyroid Gland       | * Pituitary Gland           | * Preputial Gland        | * Seminal Vesicle          |
| * Stomach, Forestomach    | * Stomach, Glandular        | * Testes                 | * Thyroid Gland            |
| * Trachea                 | * Urinary Bladder           |                          |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |   |  |                                 |
|----------------------|---|--|---------------------------------|
| * Adrenal Cortex     | Subcapsular<br>Zona Reticul             | Hyperplasia<br>Hyperplasia                                 | Mild<br>Minimal                 |
| * Harderian Gland    |   | Infiltration Cellular                                      | Mononuclear CI, Minimal         |
| * Islets, Pancreatic |   | Hyperplasia  | Mild                            |
| * Kidney             | Renal Tubule                            | Mineralization<br>Nephropathy                              | Minimal<br>Mild                 |
|                      | [ Nephropathy TGLs = 4-4 ]              |  |                                 |
| * Liver              | Centrilobular                           | Eosinophilic Focus<br>Hypertrophy<br>Infiltration Cellular | Mild<br>Mononuclear CI, Minimal |
|                      | [ Eosinophilic Focus TGLs = 5,6-12+13 ] |  |                                 |
| * Nose               |   | Inflammation   | Chronic, Minimal                |
| * Prostate           |   | Infiltration Cellular                                      | Mononuclear CI, Minimal         |
| * Salivary Glands    |   | Infiltration Cellular                                      | Mononuclear CI, Minimal         |
| * Skin               |   | Ulcer  | Marked                          |
|                      | [ Ulcer TGLs = 1,2-10+11 ]              |  |                                 |
| * Spleen             |   | Hemangiosarcoma<br>Hematopoietic Cell Proliferation        | Mild                            |
|                      | [ Hemangiosarcoma TGLs = 3-12 ]         |  |                                 |
| * Thymus             |   | Atrophy  | Marked                          |
| Tooth                |   | Dysplasia  | Moderate                        |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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<b>ANIMAL NUM:</b>	130	<b>TMT:</b>	5	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	668
		<b>DOSE:</b>	0.5 G/KG	<b>DISP:</b>	Moribund Sacrifice	<b>HISTO:</b>	0602030

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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PRIMARY CAUSE OF DEATH      - Skin Ulcer

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 131 TMT: 5 SEX: Male DAY ON TEST: 729  
 DOSE: 0.5 G/KG DISP: Moribund Sacrifice HISTO: 0602031

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Salivary Glands	* Seminal Vesicle	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Mammary Gland \* Thymus

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Epididymis		Granuloma Sperm	Mild
* Kidney	Renal Tubule	Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Amyloid Deposition	Moderate
		Eosinophilic Focus	
		Hepatocellular Adenoma	
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Eosinophilic Focus TGLs = 3,4,6,7-12+13+15+16 ]		
	[ Hepatocellular Adenoma TGLs = 5-14 ]		
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Skin		Cyst Epithelial Inclusion	Mild
		Ulcer	Marked
	[ Ulcer TGLs = 1,2-10+11 ]		
* Spleen		Hematopoietic Cell Proliferation	Moderate
Tooth		Dysplasia	Moderate

PRIMARY CAUSE OF DEATH - Liver Amyloid Deposition

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 132	<b>TMT:</b> 5	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602032

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Cardiomyopathy	Minimal
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Hepatoblastoma	
		Hepatocellular Carcinoma	
		Infiltration Cellular	Mononuclear CI, Mild
		[ Eosinophilic Focus TGLs = 3,4-12+13 ]	
		[ Hepatoblastoma TGLs = 1-10 ]	
		[ Hepatocellular Carcinoma TGLs = 2-11 ]	
* Lung	Alveolar Epith	Alveolar/Bronchiolar Carcinoma	
	Alveolus	Hyperplasia	Minimal
		Infiltration Cellular	Histiocyte, Moderate
		Inflammation	Minimal
		Metaplasia	Osseous, Minimal
		Mineralization	Minimal
		[ Alveolar/Bronchiolar Carcinoma TGLs = 6-15 ]	
		[ Infiltration Cellular TGLs = 5-14 ]	

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	132	<b>TMT:</b>	5	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	731
		<b>DOSE:</b>	0.5 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602032

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen	Lymph Follic	Atrophy	Minimal
* Thymus		Atrophy	Marked
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 133	<b>TMT:</b> 5	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 732
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602033

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lymph Node, Mandibular  |
| * Lymph Node, Mesenteric    | * Nose                   | * Pancreas                 | * Parathyroid Gland       |
| * Preputial Gland           | * Seminal Vesicle        | * Skin                     | * Spleen                  |
| * Stomach, Forestomach      | * Testes                 | * Thyroid Gland            | * Trachea                 |
| * Urinary Bladder           |                          |                            |                           |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |  |                              |                         |
|----------------------|--|------------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                                      | Hyperplasia                  | Minimal                 |
| * Epididymis         |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Harderian Gland    |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Islets, Pancreatic |  | Hyperplasia                  | Mild                    |
| * Kidney             |  | Nephropathy                  | Minimal                 |
| * Liver              |  | Clear Cell Focus             |                         |
|                      |  | Eosinophilic Focus           |                         |
|                      |  | Fatty Change                 | Minimal                 |
|                      | Centrilobular                                    | Hepatocellular Adenoma       | Multiple                |
|                      |  | Hypertrophy                  | Mild                    |
|                      |  | Infiltration Cellular        | Mononuclear CI, Minimal |
|                      | [ Hepatocellular Adenoma TGLs = 3,5,6-12+13+14 ] |                              |                         |
| * Lung               |  | Alveolar/Bronchiolar Adenoma |                         |
| Mesentery            | Fat  | Necrosis                     | Mild                    |
|                      | [ Necrosis TGLs = 1-10 ]                         |                              |                         |
| * Pituitary Gland    | Pars Distalis                                    | Hyperplasia                  | Mild                    |
| * Prostate           |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Salivary Glands    |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Stomach, Glandular |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Thymus             |  | Atrophy                      | Mild                    |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 134    **TMT:** 5    **SEX:** Male    **DAY ON TEST:** 653  
**DOSE:** 0.5 G/KG    **DISP:** Moribund Sacrifice    **HISTO:** 0602034

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Harderian Gland           | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    |
| * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     | * Pancreas                |
| * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          | * Seminal Vesicle         |
| * Skin                      | * Spleen                 | * Stomach, Forestomach     | * Stomach, Glandular      |
| * Testes                    | * Thyroid Gland          | * Trachea                  | * Urinary Bladder         |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |  |                        |                         |
|----------------------|--|------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                            | Hyperplasia            | Mild                    |
| * Epididymis         |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Heart              | Artery                                 | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Islets, Pancreatic |  | Hyperplasia            | Minimal                 |
| * Kidney             | Renal Tubule                           | Hyperplasia            | Minimal                 |
|                      | Renal Tubule                           | Mineralization         | Minimal                 |
| * Liver              |  | Clear Cell Focus       |                         |
|                      |  | Eosinophilic Focus     |                         |
|                      |  | Fatty Change           | Minimal                 |
|                      | Centrilobular                          | Hepatocellular Adenoma |                         |
|                      |  | Hypertrophy            | Mild                    |
|                      |  | Infiltration Cellular  | Mononuclear CI, Minimal |
|                      |  | Mixed Cell Focus       |                         |
|                      |  | Tension Lipidosis      |                         |
|                      | [ Clear Cell Focus TGLs = 2-10 ]       |                        |                         |
|                      | [ Eosinophilic Focus TGLs = 5-11 ]     |                        |                         |
|                      | [ Hepatocellular Adenoma TGLs = 4-13 ] |                        |                         |
|                      | [ Mixed Cell Focus TGLs = 1,3-10+12 ]  |                        |                         |
| * Prostate           |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Salivary Glands    |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Thymus             |  | Atrophy                | Moderate                |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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<b>ANIMAL NUM:</b>	134	<b>TMT:</b>	5	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	653
		<b>DOSE:</b>	0.5 G/KG	<b>DISP:</b>	Moribund Sacrifice	<b>HISTO:</b>	0602034

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ORGAN AND ACCOUNTABLE SITE STATUS

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PRIMARY CAUSE OF DEATH      - UNCERTAIN

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 135 TMT: 5 SEX: Male DAY ON TEST: 683  
 DOSE: 0.5 G/KG DISP: Moribund Sacrifice HISTO: 0602035

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Esophagus                 | * Eye                    | * Gallbladder              |
| * Harderian Gland         | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lymph Node, Mandibular  | * Lymph Node, Mesenteric    | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Seminal Vesicle           | * Stomach, Forestomach   | * Stomach, Glandular       |
| * Testes                  | * Thyroid Gland             | * Trachea                |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |              |                          |                         |
|----------------------|--------------|--------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular  | Hyperplasia              | Minimal                 |
| * Epididymis         |              | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Islets, Pancreatic |              | Hyperplasia              | Minimal                 |
| * Kidney             | Renal Tubule | Hyperplasia              | Minimal                 |
|                      | Renal Tubule | Mineralization           | Minimal                 |
|                      |              | Nephropathy              | Minimal                 |
| * Liver              |              | Basophilic Focus         |                         |
|                      |              | Eosinophilic Focus       |                         |
|                      |              | Hepatocellular Carcinoma |                         |
|                      |              | Infiltration Cellular    | Mononuclear CI, Minimal |
|                      |              | Mixed Cell Focus         |                         |

Note: Based on histology TGL 4 is in the liver rather than the pancreas

- [ Basophilic Focus TGLs = 5-13 ]
- [ Hepatocellular Carcinoma TGLs = 4-12 ]
- [ Mixed Cell Focus TGLs = 3-11 ]

- |                   |  |                       |                         |
|-------------------|--|-----------------------|-------------------------|
| * Lung            |  | Mineralization        | Minimal                 |
| * Nose            |  | Inflammation          | Chronic, Minimal        |
| * Preputial Gland |  | Inflammation          | Minimal                 |
| * Prostate        |  | Infiltration Cellular | Mononuclear CI, Minimal |
| * Salivary Glands |  | Infiltration Cellular | Mononuclear CI, Minimal |
| * Skin            |  | Ulcer                 | Moderate                |

[ Ulcer TGLs = 1-10 ]

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	135	TMT:	5	SEX:	Male	DAY ON TEST:	683
		DOSE:	0.5 G/KG	DISP:	Moribund Sacrifice	HISTO:	0602035

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ORGAN AND ACCOUNTABLE SITE STATUS

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* Spleen	Hematopoietic Cell Proliferation	Moderate
[ Hematopoietic Cell Proliferation TGLs = 2-4 ]		
* Thymus	Atrophy	Marked
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

---

PRIMARY CAUSE OF DEATH - Liver Hepatocellular Carcinoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 136	<b>TMT:</b> 5	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602036

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Testes	* Thyroid Gland	* Trachea

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney	Renal Tubule	Mineralization	Minimal
* Liver	Centrilobular	Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
	[ Mixed Cell Focus TGLs = 1-10 ]		
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Glandular	Glands	Ectasia	Minimal
* Thymus		Atrophy	Minimal
Tooth		Dysplasia	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 137    **TMT:** 5    **SEX:** Male    **DAY ON TEST:** 731  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602037

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Parathyroid Gland	* Pituitary Gland
* Prostate	* Seminal Vesicle	* Skin	* Spleen
* Testes	* Thyroid Gland	* Trachea	

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Adenoma	
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney	Renal Tubule	Hyperplasia	Minimal
	Renal Tubule	Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Angiectasis	Minimal
		Clear Cell Focus	
		Eosinophilic Focus	
		Hepatoblastoma	
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
	[ Eosinophilic Focus	TGLs = 1,5-10+13 ]	
	[ Hepatoblastoma	TGLs = 2-11 ]	
	[ Mixed Cell Focus	TGLs = 3-11 ]	
* Lung		Inflammation	Minimal
* Pancreas	Acinus	Atrophy	Moderate
* Preputial Gland		Inflammation	Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Chronic, Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	137	TMT:	5	SEX:	Male	DAY ON TEST:	731
		DOSE:	0.5 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602037

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ORGAN AND ACCOUNTABLE SITE STATUS

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[ Hyperplasia TGLs = 4-12 ]

- \* Stomach, Glandular
- \* Thymus
- \* Urinary Bladder

Infiltration Cellular  
Atrophy  
Infiltration Cellular

Mononuclear CI, Minimal  
Moderate  
Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 138 TMT: 5 SEX: Male DAY ON TEST: 730  
 DOSE: 0.5 G/KG DISP: Terminal Sacrifice HISTO: 0602038

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Cardiomyopathy	Minimal
* Intestine Small, Jejunum	Peyers Patch	Hyperplasia	Lymphoid, Moderate
	[ Hyperplasia TGLs = 4-13 ]		
* Kidney	Renal Tubule	Cyst	Mild
	Renal Tubule	Hyperplasia	Mild
	Renal Tubule	Mineralization	Minimal
	[ Cyst TGLs = 1-10 ]	Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Fatty Change	Mild
		Hepatocellular Adenoma	
		Hepatocellular Carcinoma	
	Centrilobular	Hypertrophy	Mild
		Mixed Cell Focus	
	[ Eosinophilic Focus TGLs = 3-12 ]		
	[ Hepatocellular Adenoma TGLs = 6-14 ]		
	[ Hepatocellular Carcinoma TGLs = 2-11 ]		
	[ Mixed Cell Focus TGLs = 5-12 ]		

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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<b>ANIMAL NUM:</b>	138	<b>TMT:</b>	5	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	730
		<b>DOSE:</b>	0.5 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602038

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Prostate	Infiltration Cellular	Mononuclear CI, Minimal
* Thymus	Atrophy	Mild
Tooth	Dysplasia	Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 139    **TMT:** 5    **SEX:** Male    **DAY ON TEST:** 711  
**DOSE:** 0.5 G/KG    **DISP:** Natural Death    **HISTO:** 0602039

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                            |                          |                           |
|-----------------------------|----------------------------|--------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel               | * Bone                   | * Bone Marrow             |
| * Brain                     | * Esophagus                | * Eye                    | * Gallbladder             |
| * Harderian Gland           | * Intestine Large, Cecum   | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Jejunum | * Lymph Node, Mandibular | * Lymph Node, Mesenteric  |
| * Nose                      | * Pancreas                 | * Parathyroid Gland      | * Pituitary Gland         |
| * Salivary Glands           | * Seminal Vesicle          | * Skin                   | * Stomach, Forestomach    |
| * Stomach, Glandular        | * Testes                   | * Thyroid Gland          | * Trachea                 |
| * Urinary Bladder           |                            |                          |                           |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                          |                             |                            |                         |
|--------------------------|-----------------------------|----------------------------|-------------------------|
| * Adrenal Cortex         | Subcapsular                 | Hyperplasia                | Minimal                 |
| * Epididymis             |                             | Infiltration Cellular      | Mononuclear CI, Minimal |
| * Heart                  |                             | Cardiomyopathy             | Minimal                 |
| * Intestine Small, Ileum |                             | Inflammation               | Chronic, Mild           |
|                          | [ Inflammation TGLs = 5-4 ] |                            |                         |
| * Islets, Pancreatic     |                             | Hyperplasia                | Mild                    |
| * Kidney                 | Renal Tubule                | Mineralization             | Minimal                 |
| * Liver                  |                             | Eosinophilic Focus         | Minimal                 |
|                          |                             | Fatty Change               | Multiple                |
|                          |                             | Hepatocellular Adenoma     |                         |
|                          |                             | Hepatocellular Carcinoma   |                         |
|                          |                             | Hepatodiaphragmatic Nodule |                         |
|                          | Centrilobular               | Hypertrophy                | Mild                    |
|                          |                             | Necrosis                   | Minimal                 |
|                          |                             | Tension Lipidosis          |                         |

Note: The gross ridge noted on the median lobe (TGL4) corresponded with a microscopic ridge, but best micro diagnosis seemed to be HDN.

- [ Hepatocellular Adenoma TGLs = 2,3-11+12 ]
- [ Hepatocellular Carcinoma TGLs = 1-10 ]
- [ Hepatodiaphragmatic Nodule TGLs = 4-13 ]

- \* Lung    Alveolar/Bronchiolar Adenoma
- [ Alveolar/Bronchiolar Adenoma TGLs = 6-14 ]

\* PROTOCOL REQUIRED TISSUE



TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	139	TMT:	5	SEX:	Male	DAY ON TEST:	711
		DOSE:	0.5 G/KG	DISP:	Natural Death	HISTO:	0602039

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ORGAN AND ACCOUNTABLE SITE STATUS

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* Preputial Gland		Inflammation	Mild
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen	Lymph Follic	Atrophy	Minimal
* Thymus		Atrophy	Marked
Tooth		Dysplasia	Moderate

---

PRIMARY CAUSE OF DEATH - Liver Hepatocellular Carcinoma

---

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 140 TMT: 5 SEX: Male DAY ON TEST: 683  
 DOSE: 0.5 G/KG DISP: Moribund Sacrifice HISTO: 0602040

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Seminal Vesicle	* Skin	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Mammary Gland \* Thymus

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney	Renal Tubule	Mineralization	Minimal
	[ Nephropathy TGLs = 6-4 ]	Nephropathy	Minimal
* Liver		Eosinophilic Focus	
		Fatty Change	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Mixed Cell Focus TGLs = 1,2,3,4,5-10+11+12+13 ]	Mixed Cell Focus	
* Lung		Alveolar/Bronchiolar Adenoma	Multiple
	[ Alveolar/Bronchiolar Adenoma TGLs = 7,8-14 ]		
* Nose		Inflammation	Suppurative, Mild
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
		Inflammation	Mild
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen	Lymph Follic	Atrophy	Mild
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
		Inflammation	Chronic, Minimal
		Necrosis	Mild

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b> 140	<b>TMT:</b> 5	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 683
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Moribund Sacrifice	<b>HISTO:</b> 0602040

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**ORGAN AND ACCOUNTABLE SITE STATUS**

---

[ Necrosis TGLs = 9-15 ]		
Tooth	Dysplasia	Marked

---

PRIMARY CAUSE OF DEATH - UNCERTAIN

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 141	<b>TMT:</b> 5	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602041

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lymph Node, Mandibular  |
| * Lymph Node, Mesenteric    | * Pancreas               | * Parathyroid Gland        | * Pituitary Gland         |
| * Preputial Gland           | * Seminal Vesicle        | * Skin                     | * Stomach, Forestomach    |
| * Stomach, Glandular        | * Testes                 | * Thyroid Gland            | * Trachea                 |
| * Urinary Bladder           |                          |                            |                           |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |   |                                  |                         |
|----------------------|---|----------------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                                 | Hyperplasia                      | Minimal                 |
| * Epididymis         |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Harderian Gland    |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Islets, Pancreatic |   | Hyperplasia                      | Mild                    |
| * Kidney             | Renal Tubule                                | Hyperplasia                      | Minimal                 |
|                      | Renal Tubule                                | Mineralization                   | Minimal                 |
|                      |   | Nephropathy                      | Minimal                 |
| * Liver              |   | Eosinophilic Focus               |                         |
|                      |   | Hepatocellular Adenoma           | Multiple                |
|                      |   | Hepatocellular Carcinoma         |                         |
|                      | Centrilobular                               | Hypertrophy                      | Mild                    |
|                      |   | Infiltration Cellular            | Mononuclear CI, Minimal |
|                      | [ Eosinophilic Focus TGLs = 4,5-3+13 ]      |                                  |                         |
|                      | [ Hepatocellular Adenoma TGLs = 1,2-10+11 ] |                                  |                         |
|                      | [ Hepatocellular Carcinoma TGLs = 3-12 ]    |                                  |                         |
| * Lung               |   | Hepatocellular Carcinoma         | Metastatic (Liver)      |
| * Nose               |   | Inflammation                     | Suppurative, Mild       |
| * Prostate           |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Salivary Glands    |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen             |   | Hematopoietic Cell Proliferation | Mild                    |
| * Thymus             |   | Atrophy                          | Mild                    |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	141	<b>TMT:</b>	5	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	731
		<b>DOSE:</b>	0.5 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602041

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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Tooth	Infiltration Cellular Dysplasia	Histiocyte, Mild Marked
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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 142    **TMT:** 5    **SEX:** Male    **DAY ON TEST:** 455  
**DOSE:** 0.5 G/KG    **DISP:** Natural Death    **HISTO:** 0602042

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                    | * Epididymis              | * Esophagus                 | * Eye                    |
| * Gallbladder              | * Harderian Gland         | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic      | * Kidney                    | * Lymph Node, Mandibular |
| * Lymph Node, Mesenteric   | * Pancreas                | * Pituitary Gland           | * Salivary Glands        |
| * Seminal Vesicle          | * Skin                    | * Spleen                    | * Stomach, Forestomach   |
| * Stomach, Glandular       | * Testes                  | * Thyroid Gland             | * Trachea                |
| * Urinary Bladder          |                           |                             |                          |

**MISSING**

- |                 |                     |
|-----------------|---------------------|
| * Mammary Gland | * Parathyroid Gland |
|-----------------|---------------------|

**OBSERVATIONS**

- |                   |  |                              |                         |
|-------------------|--|------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                                  | Hyperplasia                  | Minimal                 |
| * Liver           |  | Fatty Change                 | Minimal                 |
|                   | Centrilobular                                | Hepatocellular Carcinoma     |                         |
|                   |  | Hypertrophy                  | Mild                    |
|                   |  | Infiltration Cellular        | Mononuclear CI, Minimal |
|                   |  | Necrosis                     | Moderate                |
|                   | [ Hepatocellular Carcinoma TGLs = 1-10 ]     |                              |                         |
| * Lung            |  | Alveolar/Bronchiolar Adenoma |                         |
|                   | [ Alveolar/Bronchiolar Adenoma TGLs = 2-11 ] |                              |                         |
| * Nose            |  | Inflammation                 | Chronic, Minimal        |
| * Preputial Gland |  | Cyst                         | Mild                    |
| * Prostate        |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Thymus          |  | Atrophy                      | Mild                    |

**PRIMARY CAUSE OF DEATH**    - Liver    Hepatocellular Carcinoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 143 TMT: 5 SEX: Male DAY ON TEST: 731  
 DOSE: 0.5 G/KG DISP: Terminal Sacrifice HISTO: 0602043

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Skin
* Spleen	* Stomach, Glandular	* Testes	* Thyroid Gland
* Trachea			

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney	Renal Tubule	Amyloid Deposition	Minimal
	Renal Tubule	Hyperplasia	Minimal
		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Angiectasis	Minimal
		Eosinophilic Focus	
		Hepatocellular Adenoma	Multiple
		Hepatocellular Carcinoma	Multiple
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Hepatocellular Adenoma TGLs = 3,4,5-12+13+14 ]		
	[ Hepatocellular Carcinoma TGLs = 1,2-10+11 ]		
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Seminal Vesicle		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
	[ Hyperplasia TGLs = 6-15 ]	Inflammation	Chronic, Mild

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b> 143	<b>TMT:</b> 5	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602043

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Thymus	Atrophy	Moderate
Tooth	Dysplasia	Mild
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 144    **TMT:** 5    **SEX:** Male    **DAY ON TEST:** 732  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602044

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla        | Blood Vessel               | * Bone                    | * Bone Marrow               |
| * Brain                  | * Esophagus                | * Eye                     | * Gallbladder               |
| * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lymph Node, Mandibular  | * Lymph Node, Mesenteric    |
| * Nose                   | * Pancreas                 | * Parathyroid Gland       | * Pituitary Gland           |
| * Preputial Gland        | * Prostate                 | * Seminal Vesicle         | * Skin                      |
| * Spleen                 | * Stomach, Forestomach     | * Stomach, Glandular      | * Testes                    |
| * Thyroid Gland          | * Trachea                  |                           |                             |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |  |                                |                         |
|----------------------|--|--------------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                                    | Hyperplasia                    | Minimal                 |
| * Epididymis         |  | Infiltration Cellular          | Mononuclear CI, Minimal |
| * Harderian Gland    |  | Infiltration Cellular          | Mononuclear CI, Minimal |
| * Heart              |  | Cardiomyopathy                 | Minimal                 |
| * Islets, Pancreatic |  | Hyperplasia                    | Minimal                 |
| * Kidney             | Renal Tubule                                   | Mineralization                 | Minimal                 |
|                      |  | Nephropathy                    | Minimal                 |
| * Liver              |  | Clear Cell Focus               |                         |
|                      |  | Eosinophilic Focus             |                         |
|                      |  | Fatty Change                   | Minimal                 |
|                      |  | Infiltration Cellular          | Mononuclear CI, Minimal |
|                      |  | Mixed Cell Focus               |                         |
|                      | [ Eosinophilic Focus TGLs = 1,4-10+13 ]        |                                |                         |
|                      | [ Mixed Cell Focus TGLs = 2,3,5-11+12+14 ]     |                                |                         |
| * Lung               |  | Alveolar/Bronchiolar Carcinoma |                         |
|                      | [ Alveolar/Bronchiolar Carcinoma TGLs = 6-15 ] |                                |                         |
| * Salivary Glands    |  | Infiltration Cellular          | Mononuclear CI, Minimal |
| * Thymus             |  | Atrophy                        | Marked                  |
| Tooth                |  | Dysplasia                      | Mild                    |
| * Urinary Bladder    |  | Infiltration Cellular          | Mononuclear CI, Minimal |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 145 TMT: 5 SEX: Male DAY ON TEST: 731  
 DOSE: 0.5 G/KG DISP: Terminal Sacrifice HISTO: 0602045

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Nose	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Seminal Vesicle	* Skin	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea		

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Gallbladder		Inflammation	Granulomatous, Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Histiocytic Sarcoma	
	Renal Tubule	Inflammation	Moderate
	[ Inflammation TGLs = 2,3-4+11+12 ]	Mineralization	Minimal
* Liver		Eosinophilic Focus	
		Hepatocellular Adenoma	Multiple
	Centrilobular	Histiocytic Sarcoma	
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Eosinophilic Focus TGLs = 4,7,8-13+16+17 ]	Mineralization	Minimal
	[ Hepatocellular Adenoma TGLs = 4,5,6-13+14+15 ]		
* Lung		Alveolar/Bronchiolar Adenoma	
		Alveolar/Bronchiolar Carcinoma	
		Histiocytic Sarcoma	
		Inflammation	Mild
Lymph Node	Renal	Hyperplasia	Lymphoid, Marked
	[ Hyperplasia TGLs = 1-10 ]		

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	145	TMT:	5	SEX:	Male	DAY ON TEST:	731
		DOSE:	0.5 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602045

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ORGAN AND ACCOUNTABLE SITE STATUS

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* Lymph Node, Mesenteric [ Hyperplasia TGLs = 9-18 ]	Hyperplasia	Lymphoid, Marked
* Pancreas	Inflammation	Granulomatous, Minimal
* Prostate	Inflammation	Mild
* Salivary Glands	Infiltration Cellular	Mononuclear CI, Minimal
* Spleen	Histiocytic Sarcoma	
* Stomach, Forestomach Epithelium [ Hyperplasia TGLs = 10-19 ]	Hyperplasia Inflammation	Mild Chronic, Minimal
* Thymus	Atrophy Infiltration Cellular	Mild Histiocyte, Mild
Tooth	Dysplasia	Minimal
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 146 TMT: 5 SEX: Male DAY ON TEST: 494  
 DOSE: 0.5 G/KG DISP: Moribund Sacrifice HISTO: 0602046

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Epididymis                | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Pancreas                |
| * Parathyroid Gland         | * Prostate               | * Seminal Vesicle          | * Skin                    |
| * Spleen                    | * Stomach, Glandular     | * Testes                   | * Thyroid Gland           |
| * Trachea                   | * Urinary Bladder        |                            |                           |

MISSING

- \* Mammary Gland

OBSERVATIONS

- |  |                |                       |                         |
|--|----------------|-----------------------|-------------------------|
| * Adrenal Cortex   | Subcapsular    | Hyperplasia           | Mild                    |
| * Brain  | Hypothalamus   | Compression           | Marked                  |
| * Eye  |                |                       |                         |
| Note: No corresponding microscopic finding for eye opacity |                |                       |                         |
| * Harderian Gland  |                | Infiltration Cellular | Mononuclear CI, Minimal |
| * Kidney   | Renal Tubule   | Mineralization        | Minimal                 |
| * Liver  |                | Fatty Change          | Moderate                |
|  |                | Infiltration Cellular | Mononuclear CI, Minimal |
| * Nose   | Respirat Epith | Hyperplasia           | Minimal                 |
| * Pituitary Gland  | Pars Distalis  | Adenoma               |                         |
| [ Adenoma TGLs = 2-10 ]                                    |                |                       |                         |
| * Preputial Gland  |                | Inflammation          | Mild                    |
| [ Inflammation TGLs = 1-8 ]                                |                |                       |                         |
| * Salivary Glands  |                | Infiltration Cellular | Mononuclear CI, Minimal |
| * Stomach, Forestomach                                     | Epithelium     | Hyperplasia           | Mild                    |
|  |                | Inflammation          | Chronic, Mild           |
|  |                | Necrosis              | Moderate                |
| [ Necrosis TGLs = 4-11 ]                                   |                |                       |                         |
| * Thymus   |                | Atrophy               | Moderate                |
| Tooth  |                | Dysplasia             | Mild                    |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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<b>ANIMAL NUM:</b>	146	<b>TMT:</b>	5	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	494
		<b>DOSE:</b>	0.5 G/KG	<b>DISP:</b>	Moribund Sacrifice	<b>HISTO:</b>	0602046

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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PRIMARY CAUSE OF DEATH      - Pituitary Gland Pars Distalis Adenoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 147    **TMT:** 5    **SEX:** Male    **DAY ON TEST:** 730  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602047

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| Lymph Node                | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     |
| * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          |
| * Seminal Vesicle         | * Stomach, Glandular        | * Testes                 | * Thyroid Gland            |
| * Trachea                 |                             |                          |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |   |                                  |                         |
|----------------------|---|----------------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                                       | Hyperplasia                      | Minimal                 |
| * Harderian Gland    |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Islets, Pancreatic |   | Hyperplasia                      | Minimal                 |
| * Kidney             |   | Nephropathy                      | Minimal                 |
| * Liver              |   | Clear Cell Focus                 |                         |
|                      |   | Eosinophilic Focus               |                         |
|                      | Centrilobular                                     | Hepatocellular Adenoma           |                         |
|                      |   | Hepatocellular Carcinoma         |                         |
|                      |   | Hypertrophy                      | Mild                    |
|                      |   | Infiltration Cellular            | Mononuclear CI, Minimal |
|                      | [ Eosinophilic Focus    TGLs = 2-11 ]             |                                  |                         |
|                      | [ Hepatocellular Adenoma    TGLs = 1-10 ]         |                                  |                         |
|                      | [ Hepatocellular Carcinoma    TGLs = 3-12 ]       |                                  |                         |
| * Lung               |   | Alveolar/Bronchiolar Carcinoma   |                         |
|                      | Bronchus  | Infiltration Cellular            | Histiocyte, Minimal     |
|                      | Alveolus  | Infiltration Cellular            | Histiocyte, Mild        |
|                      | [ Alveolar/Bronchiolar Carcinoma    TGLs = 4-13 ] |                                  |                         |
| * Prostate           |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Salivary Glands    |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Skin               |   | Cyst Epithelial Inclusion        | Minimal                 |
| * Spleen             |   | Hematopoietic Cell Proliferation | Mild                    |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	147	TMT:	5	SEX:	Male	DAY ON TEST:	730
		DOSE:	0.5 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602047

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ORGAN AND ACCOUNTABLE SITE STATUS

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* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation	Mild Chronic, Minimal
	[ Hyperplasia TGLs = 5-14 ]		
* Thymus		Atrophy	Marked
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 148    **TMT:** 5    **SEX:** Male    **DAY ON TEST:** 660  
**DOSE:** 0.5 G/KG    **DISP:** Natural Death    **HISTO:** 0602048

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Nose                    |
| * Pancreas                  | * Parathyroid Gland      | * Preputial Gland          | * Skin                    |
| * Stomach, Glandular        | * Thyroid Gland          | * Trachea                  |                           |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |              |   |  |
|------------------------|--------------|---|--|
| * Adrenal Cortex       | Subcapsular  | Hyperplasia   | Minimal  |
| * Epididymis           |              | Granuloma Sperm<br>Infiltration Cellular  | Moderate<br>Mononuclear CI, Minimal                        |
| * Harderian Gland      |              | Infiltration Cellular   | Mononuclear CI, Minimal                                    |
| * Kidney               | Renal Tubule | Mineralization<br>Nephropathy   | Minimal<br>Minimal   |
| * Liver                |              | Eosinophilic Focus<br>Fatty Change<br>Hepatocellular Adenoma<br>Hepatocellular Carcinoma<br>Infiltration Cellular<br>Necrosis | Minimal<br>Multiple<br><br>Mononuclear CI, Minimal<br>Mild |
|                        |              | [ Eosinophilic Focus    TGLs = 4-13 ]   |  |
|                        |              | [ Hepatocellular Adenoma    TGLs = 2,3-11+12 ]  |  |
|                        |              | [ Hepatocellular Carcinoma    TGLs = 1-10 ]   |  |
| * Pituitary Gland      |              | Cyst  | Minimal  |
| * Prostate             |              | Infiltration Cellular   | Mononuclear CI, Minimal                                    |
| * Salivary Glands      |              | Infiltration Cellular   | Mononuclear CI, Minimal                                    |
| * Seminal Vesicle      |              | Infiltration Cellular   | Mononuclear CI, Minimal                                    |
| * Spleen               |              | Hematopoietic Cell Proliferation  | Mild   |
| * Stomach, Forestomach | Epithelium   | Hyperplasia<br>Inflammation   | Mild<br>Chronic, Minimal                                   |

\* PROTOCOL REQUIRED TISSUE



TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b> 148	<b>TMT:</b> 5	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 660
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 0602048

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Testes	Germinal Epith	Mineralization	Minimal
* Thymus		Atrophy	Mild
* Urinary Bladder		Atrophy	Marked
		Infiltration Cellular	Mononuclear CI, Minimal

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PRIMARY CAUSE OF DEATH - Liver Hepatocellular Carcinoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 149	<b>TMT:</b> 5	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602049

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     |
| * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        | * Seminal Vesicle          |
| * Skin                    | * Stomach, Glandular        | * Testes                 | * Thyroid Gland            |
| * Trachea                 |                             |                          |                            |

**MISSING**

- |                 |          |
|-----------------|----------|
| * Mammary Gland | * Thymus |
|-----------------|----------|

**OBSERVATIONS**

- |                      |              |   |                         |
|----------------------|--------------|---|-------------------------|
| * Adrenal Cortex     | Subcapsular  | Hyperplasia                                 | Minimal                 |
| * Harderian Gland    |              | Infiltration Cellular                       | Mononuclear CI, Minimal |
| * Islets, Pancreatic |              | Hyperplasia                                 | Mild                    |
| * Kidney             | Renal Tubule | Hyperplasia                                 | Minimal                 |
|                      | Renal Tubule | Mineralization                              | Minimal                 |
|                      |              | Nephropathy                                 | Mild                    |
| * Liver              |              | Angiectasis                                 | Minimal                 |
|                      |              | Basophilic Focus                            |                         |
|                      |              | Clear Cell Focus                            |                         |
|                      |              | Eosinophilic Focus                          |                         |
|                      |              | Fatty Change                                | Minimal                 |
|                      |              | Hepatocellular Adenoma                      | Multiple                |
|                      |              | Hepatocellular Carcinoma                    |                         |
|                      |              | Infiltration Cellular                       | Mononuclear CI, Minimal |
|                      |              | [ Eosinophilic Focus TGLs = 4-12 ]          |                         |
|                      |              | [ Hepatocellular Adenoma TGLs = 2,5-10+13 ] |                         |
|                      |              | [ Hepatocellular Carcinoma TGLs = 3-11 ]    |                         |
| * Preputial Gland    |              | Cyst  | Mild                    |
|                      |              | [ Cyst TGLs = 1-8 ]                         |                         |
| * Prostate           |              | Infiltration Cellular                       | Mononuclear CI, Minimal |
| * Salivary Glands    |              | Infiltration Cellular                       | Mononuclear CI, Minimal |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	149	TMT:	5	SEX:	Male	DAY ON TEST:	730
		DOSE:	0.5 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602049

---

ORGAN AND ACCOUNTABLE SITE STATUS

---

* Spleen		Hematopoietic Cell Proliferation	Mild
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Chronic, Minimal
	[ Hyperplasia TGLs = 6-14 ]		
Tooth		Dysplasia	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 150 TMT: 5 SEX: Male DAY ON TEST: 732  
 DOSE: 0.5 G/KG DISP: Terminal Sacrifice HISTO: 0602050

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Seminal Vesicle	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea		

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular Zona Reticul	Hyperplasia Hyperplasia	Minimal Mild
* Epididymis		Granuloma Sperm Infiltration Cellular	Mild Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney	Renal Tubule Renal Tubule	Hyperplasia Mineralization Nephropathy	Minimal Minimal Mild
* Liver		Eosinophilic Focus Hepatoblastoma Hepatocellular Carcinoma Infiltration Cellular	Mononuclear CI, Minimal
	[ Eosinophilic Focus TGLs = 4,5,6,7-13+14+15 ] [ Hepatoblastoma TGLs = 3-12 ] [ Hepatocellular Carcinoma TGLs = 3-12 ]		
* Lung		Hepatocellular Carcinoma	Metastatic (Liver)
* Preputial Gland		Cyst	Mild
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Skin	Subcut Tiss	Hemangiosarcoma Ulcer	Moderate

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	150	TMT:	5	SEX:	Male	DAY ON TEST:	732
		DOSE:	0.5 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602050

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ORGAN AND ACCOUNTABLE SITE STATUS

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Note: TGL 2 was a dermal lesion rather than mammary gland  
[ Hemangiosarcoma TGLs = 2-11 ]  
[ Ulcer TGLs = 1-10 ]

* Spleen		Hematopoietic Cell Proliferation	Mild
* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation	Minimal Chronic, Mild
* Thymus		Atrophy	Marked
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 151	<b>TMT:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602051

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lymph Node, Mandibular  |
| * Lymph Node, Mesenteric    | * Nose                   | * Pancreas                 | * Parathyroid Gland       |
| * Pituitary Gland           | * Seminal Vesicle        | * Skin                     | * Spleen                  |
| * Stomach, Forestomach      | * Stomach, Glandular     | * Testes                   | * Thyroid Gland           |
| * Trachea                   |                          |                            |                           |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |   |               |   |  |
|---|---------------|---|--|
| * Adrenal Cortex  | Subcapsular   | Hyperplasia   | Mild   |
| * Epididymis  |               | Infiltration Cellular   | Mononuclear CI, Minimal                                |
| * Harderian Gland   |               | Adenoma<br>Infiltration Cellular                                      | Mononuclear CI, Minimal                                |
| * Islets, Pancreatic  |               | Adenoma<br>Hyperplasia  | Minimal  |
| Note: Based on histology, TGL 6 was in the pancreatic islets, not the pancreatic lymph node.<br>[ Adenoma TGLs = 6-15 ] |               |   |  |
| * Kidney  | Renal Tubule  | Hyperplasia<br>Metaplasia   | Minimal<br>Osseous, Minimal                            |
|   | Renal Tubule  | Mineralization<br>Nephropathy   | Minimal<br>Minimal                                     |
| * Liver   |               | Angiectasis<br>Clear Cell Focus<br>Eosinophilic Focus<br>Fatty Change | Mild   |
|   | Centrilobular | Hepatocellular Adenoma<br>Hypertrophy<br>Infiltration Cellular        | Minimal<br>Multiple<br>Mild<br>Mononuclear CI, Minimal |
| [ Hepatocellular Adenoma TGLs = 1,2,3,4,5-10+11+12+13+14 ]  |               |   |  |
| * Lung  |               | Alveolar/Bronchiolar Adenoma  | Multiple   |
| [ Alveolar/Bronchiolar Adenoma TGLs = 7-16 ]  |               |   |  |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b> 151	<b>TMT:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602051

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Preputial Gland	Inflammation	Minimal
* Prostate	Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands	Infiltration Cellular	Mononuclear CI, Minimal
* Thymus	Atrophy	Minimal
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 152	<b>TMT:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 596
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Moribund Sacrifice	<b>HISTO:</b> 0602052

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    |
| * Pancreas                  | * Parathyroid Gland      | * Pituitary Gland          | * Preputial Gland         |
| * Seminal Vesicle           | * Skin                   | * Stomach, Forestomach     | * Stomach, Glandular      |
| * Testes                    | * Thymus                 | * Thyroid Gland            | * Trachea                 |
| * Urinary Bladder           |                          |                            |                           |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                          |   |                        |                         |
|--------------------------|---|------------------------|-------------------------|
| * Adrenal Cortex         | Subcapsular                                 | Hyperplasia            | Mild                    |
| * Epididymis             |   | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Harderian Gland        |   | Adenoma                |                         |
|                          | [ Adenoma TGLs = 1-9 ]                      |                        |                         |
| * Islets, Pancreatic     |   | Hyperplasia            | Mild                    |
| * Kidney                 | Renal Tubule                                | Lymphoma Malignant     | Minimal                 |
|                          |   | Mineralization         |                         |
| * Liver                  |   | Clear Cell Focus       |                         |
|                          |   | Eosinophilic Focus     |                         |
|                          |   | Fatty Change           | Mild                    |
|                          | Centrilobular                               | Hepatocellular Adenoma | Multiple                |
|                          |   | Hypertrophy            | Mild                    |
|                          |   | Infiltration Cellular  | Mononuclear CI, Minimal |
|                          | [ Eosinophilic Focus TGLs = 4-12 ]          |                        |                         |
|                          | [ Hepatocellular Adenoma TGLs = 3,5-11+13 ] |                        |                         |
| * Lymph Node, Mandibular |   | Lymphoma Malignant     |                         |
|                          | [ Lymphoma Malignant TGLs = 2-10 ]          |                        |                         |
| * Lymph Node, Mesenteric |   | Lymphoma Malignant     |                         |
| * Nose                   | Nasolacrim Dct                              | Inflammation           | Chronic, Mild           |
|                          |   | Inflammation           | Suppurative, Mild       |
| * Prostate               |   | Infiltration Cellular  | Mononuclear CI, Minimal |

\* PROTOCOL REQUIRED TISSUE



TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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<b>ANIMAL NUM:</b>	152	<b>TMT:</b>	7	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	596
		<b>DOSE:</b>	1.0 G/KG	<b>DISP:</b>	Moribund Sacrifice	<b>HISTO:</b>	0602052

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ORGAN AND ACCOUNTABLE SITE STATUS

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* Salivary Glands	Infiltration Cellular	Mononuclear CI, Minimal
* Spleen	Lymphoma Malignant	

---

PRIMARY CAUSE OF DEATH - Lymph Node, Mandibular Lymphoma Malignant  
 CONTRIBUTORY CAUSE OF DEATH - Harderian Gland Adenoma

---

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 153 TMT: 7 SEX: Male DAY ON TEST: 547  
 DOSE: 1.0 G/KG DISP: Moribund Sacrifice HISTO: 0602053

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Pituitary Gland	* Prostate	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Trachea	* Urinary Bladder		

**MISSING**

\* Mammary Gland \* Parathyroid Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia Hypertrophy	Mild Minimal
* Eye	Cornea	Inflammation	Chronic, Mild
* Harderian Gland		Adenoma	
	[ Adenoma TGLs = 1-9 ]		
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney	Renal Tubule	Mineralization	Minimal
* Liver	Centrilobular	Fatty Change Hypertrophy Infiltration Cellular Tension Lipidosis	Minimal Mild Mononuclear CI, Minimal
* Preputial Gland		Inflammation	Mild
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen	Lymph Follic	Atrophy	Minimal
* Thyroid Gland	Follicular Cel	Adenoma	

PRIMARY CAUSE OF DEATH - Harderian Gland Adenoma  
 CONTRIBUTORY CAUSE OF DEATH - Eye Cornea Inflammation

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 154    **TMT:** 7    **SEX:** Male    **DAY ON TEST:** 731  
**DOSE:** 1.0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602054

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Esophagus                 | * Eye                    | * Gallbladder              |
| * Harderian Gland         | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     |
| * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          |
| * Salivary Glands         | * Seminal Vesicle           | * Skin                   | * Stomach, Forestomach     |
| * Stomach, Glandular      | * Testes                    | * Thyroid Gland          | * Trachea                  |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                   |   |                              |                         |
|-------------------|---|------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                                     | Hyperplasia                  | Mild                    |
| * Epididymis      |   | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Kidney          |   | Nephropathy                  | Minimal                 |
| * Liver           |   | Clear Cell Focus             |                         |
|                   |   | Eosinophilic Focus           |                         |
|                   | Centrilobular                                   | Fatty Change                 | Minimal                 |
|                   |   | Hypertrophy                  | Mild                    |
|                   |   | Infiltration Cellular        | Mononuclear CI, Minimal |
|                   |   | Tension Lipidosis            |                         |
|                   | [ Eosinophilic Focus    TGLs = 1,2,3-10+11+12 ] |                              |                         |
| * Lung            |   | Alveolar/Bronchiolar Adenoma |                         |
| Mesentery         | Fat   | Necrosis                     | Mild                    |
|                   | [ Necrosis    TGLs = 4-13 ]                     |                              |                         |
| * Prostate        |   | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Spleen          |   | Hyperplasia                  | Lymphoid, Minimal       |
| * Thymus          |   | Atrophy                      | Mild                    |
| Tooth             |   | Dysplasia                    | Mild                    |
| * Urinary Bladder |   | Infiltration Cellular        | Mononuclear CI, Minimal |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 155 TMT: 7 SEX: Male DAY ON TEST: 465  
 DOSE: 1.0 G/KG DISP: Natural Death HISTO: 0602055

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Kidney                    | * Lung                   | * Lymph Node, Mandibular   | * Lymph Node, Mesenteric  |
| * Nose                      | * Pancreas               | * Pituitary Gland          | * Prostate                |
| * Salivary Glands           | * Seminal Vesicle        | * Skin                     | * Stomach, Forestomach    |
| * Stomach, Glandular        | * Testes                 | * Thyroid Gland            | * Trachea                 |
| * Urinary Bladder           |                          |                            |                           |

**MISSING**

- |                 |                     |
|-----------------|---------------------|
| * Mammary Gland | * Parathyroid Gland |
|-----------------|---------------------|

**OBSERVATIONS**

- |                   |                                  |                                  |                         |
|-------------------|----------------------------------|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                      | Hyperplasia                      | Minimal                 |
| * Epididymis      |                                  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Harderian Gland |                                  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Liver           | Centrilobular                    | Hemangiosarcoma                  |                         |
|                   |                                  | Hypertrophy                      | Mild                    |
|                   |                                  | Infiltration Cellular            | Mononuclear CI, Mild    |
|                   |                                  | Necrosis                         | Moderate                |
|                   | [ Hemangiosarcoma TGLs = 4-11 ]  |                                  |                         |
|                   | [ Necrosis TGLs = 2,3-3+4+5+10 ] |                                  |                         |
| * Preputial Gland |                                  | Inflammation                     | Mild                    |
| * Spleen          |                                  | Hematopoietic Cell Proliferation | Marked                  |
| * Thymus          |                                  | Atrophy                          | Marked                  |

PRIMARY CAUSE OF DEATH - Liver Hemangiosarcoma

Animal Note: TGL 4 was located in the liver, not the mesenteric lymph node as described at necropsy

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 156 TMT: 7 SEX: Male DAY ON TEST: 596  
 DOSE: 1.0 G/KG DISP: Moribund Sacrifice HISTO: 0602056

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Pancreas	* Pituitary Gland
* Preputial Gland	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea			

**MISSING**

\* Mammary Gland \* Parathyroid Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Eye	Antr Chamber	Inflammation	Suppurative, Moderate
	[ Inflammation TGLs = 4-9 ]		
* Harderian Gland		Adenoma	
	[ Adenoma TGLs = 5-9 ]	Infiltration Cellular	Mononuclear CI, Minimal
* Kidney	Renal Tubule	Hyperplasia	Minimal
		Nephropathy	Mild
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Fatty Change	Minimal
		Hepatocellular Adenoma	Multiple
		Hepatocellular Carcinoma	Multiple
	Centrilobular	Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
	[ Hepatocellular Adenoma TGLs = 2,6-10+11 ]		
	[ Hepatocellular Carcinoma TGLs = 1,3-10+11 ]		
* Lung		Hepatocellular Carcinoma	Metastatic (Liver)
* Nose		Inflammation	Chronic, Minimal
	Nasolacrim Dct	Inflammation	Suppurative, Minimal
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	156	<b>TMT:</b>	7	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	596
		<b>DOSE:</b>	1.0 G/KG	<b>DISP:</b>	Moribund Sacrifice	<b>HISTO:</b>	0602056

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Salivary Glands	Infiltration Cellular	Mononuclear CI, Minimal
* Spleen	Hematopoietic Cell Proliferation	Mild
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

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PRIMARY CAUSE OF DEATH - Liver Hepatocellular Carcinoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 157	<b>TMT:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602057

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea		

**MISSING**

* Gallbladder	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia Vacuolization Cytoplasmic	Mild Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney		Hydronephrosis Nephropathy	Moderate Minimal
	[ Hydronephrosis TGLs = 2-11 ]		
* Liver	Centrilobular	Eosinophilic Focus Hypertrophy Infiltration Cellular	Mild Mononuclear CI, Minimal
	[ Eosinophilic Focus TGLs = 1,4,5-10+13+14 ]		
* Lung	Alveolar Epith Alveolus	Alveolar/Bronchiolar Carcinoma Hyperplasia Infiltration Cellular	Mild Histiocyte, Moderate
	[ Alveolar/Bronchiolar Carcinoma TGLs = 3-12 ]		
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation	Mild Chronic, Mild
	[ Hyperplasia TGLs = 6-15 ]		
* Thymus		Atrophy	Marked
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 158 TMT: 7 SEX: Male DAY ON TEST: 732  
 DOSE: 1.0 G/KG DISP: Terminal Sacrifice HISTO: 0602058

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea

**MISSING**

\* Gallbladder \* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Cardiomyopathy	Minimal
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Angiectasis	Mild
		Degeneration	Cystic, Minimal
		Eosinophilic Focus	
		Fatty Change	Minimal
		Hepatoblastoma	
		Hepatocellular Adenoma	Multiple
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Eosinophilic Focus TGLs = 4,5-13+14 ]		
	[ Hepatoblastoma TGLs = 1-10 ]		
	[ Hepatocellular Adenoma TGLs = 2,3-11+12 ]		
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Chronic, Minimal
	[ Hyperplasia TGLs = 6-15 ]		
* Thymus		Atrophy	Mild

\* PROTOCOL REQUIRED TISSUE



TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	158	<b>TMT:</b>	7	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	732
		<b>DOSE:</b>	1.0 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602058

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* Urinary Bladder

Infiltration Cellular

Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 159	<b>TMT:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602059

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla        | Blood Vessel               | * Bone                    | * Bone Marrow               |
| * Brain                  | * Esophagus                | * Eye                     | * Gallbladder               |
| * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    | * Lymph Node, Mandibular    |
| * Lymph Node, Mesenteric | * Nose                     | * Pancreas                | * Parathyroid Gland         |
| * Pituitary Gland        | * Preputial Gland          | * Seminal Vesicle         | * Skin                      |
| * Stomach, Forestomach   | * Testes                   | * Thyroid Gland           | * Trachea                   |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |  |                                  |                         |
|----------------------|--|----------------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                              | Hyperplasia                      | Minimal                 |
| * Epididymis         |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Harderian Gland    |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Heart              |  | Cardiomyopathy                   | Minimal                 |
| * Islets, Pancreatic |  | Hyperplasia                      | Minimal                 |
| * Kidney             |  | Nephropathy                      | Minimal                 |
| * Liver              | Centrilobular                            | Eosinophilic Focus               |                         |
|                      |  | Hepatocellular Carcinoma         |                         |
|                      |  | Hypertrophy                      | Mild                    |
|                      |  | Infiltration Cellular            | Mononuclear CI, Minimal |
|                      | [ Eosinophilic Focus TGLs = 2-11 ]       |                                  |                         |
|                      | [ Hepatocellular Carcinoma TGLs = 1-10 ] |                                  |                         |
| * Prostate           |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Salivary Glands    |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen             |  | Hematopoietic Cell Proliferation | Mild                    |
| * Stomach, Glandular | Glands                                   | Ectasia                          | Minimal                 |
| * Thymus             |  | Atrophy                          | Marked                  |
| * Urinary Bladder    |  | Infiltration Cellular            | Mononuclear CI, Minimal |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 160	<b>TMT:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 732
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602060

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Islets, Pancreatic
* Nose	* Pancreas	* Pituitary Gland	* Preputial Gland
* Prostate	* Seminal Vesicle	* Skin	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Mammary Gland	* Parathyroid Gland
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**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia Lymphoma Malignant	Minimal
* Harderian Gland		Hyperplasia	Mild
* Intestine Small, Jejunum	Peyers Patch	Lymphoma Malignant	
	[ Lymphoma Malignant TGLs = 12-18 ]		
* Kidney	Renal Tubule	Mineralization Nephropathy	Minimal Mild
* Liver	Bile Duct	Amyloid Deposition Cyst Eosinophilic Focus Hematopoietic Cell Proliferation Hepatocellular Adenoma Infiltration Cellular Necrosis	Moderate Mild Mild Mononuclear CI, Minimal Mild
	[ Cyst TGLs = 6-13 ]		
	[ Eosinophilic Focus TGLs = 7,13,14,15-14+19+20+21 ]		
	[ Hepatocellular Adenoma TGLs = 5-12 ]		
* Lung	[ Alveolar/Bronchiolar Adenoma TGLs = 11-17 ]	Alveolar/Bronchiolar Adenoma	
Lymph Node	Lumbar Renal Pancreatic	Lymphoma Malignant Lymphoma Malignant Lymphoma Malignant	
	[ Lymphoma Malignant TGLs = 3-10 ]		

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

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<b>ANIMAL NUM:</b> 160	<b>TMT:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 732
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602060

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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[ Lymphoma Malignant	TGLs = 4-11 ]		
[ Lymphoma Malignant	TGLs = 10-16 ]		
* Lymph Node, Mandibular		Lymphoma Malignant	
* Lymph Node, Mesenteric		Lymphoma Malignant	
[ Lymphoma Malignant	TGLs = 9-15 ]		
Peritoneum		Inflammation	Chronic, Mild
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Lymphoma Malignant	
[ Lymphoma Malignant	TGLs = 2-4 ]		
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Chronic, Mild
		Necrosis	Minimal
[ Necrosis	TGLs = 16-22 ]		
* Thymus		Atrophy	Marked
		Inflammation	Chronic Active, Moderate
Tooth		Dysplasia	Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 161    **TMT:** 7    **SEX:** Male    **DAY ON TEST:** 731  
**DOSE:** 1.0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602061

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Prostate	* Seminal Vesicle	* Spleen	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Adenoma	
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Adenoma TGLs = 1-9 ]		
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
	Centrilobular	Hepatocellular Adenoma	Multiple
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Hepatocellular Adenoma TGLs = 3,4,5,6,7-11+12+13+14 ]		
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Lymph Node, Mandibular		Hyperplasia	Lymphoid, Moderate
* Preputial Gland		Inflammation	Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Skin		Ulcer	Moderate
	[ Ulcer TGLs = 2-10 ]		
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Chronic, Minimal
	[ Hyperplasia TGLs = 8-15 ]		

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	161	<b>TMT:</b>	7	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	731
		<b>DOSE:</b>	1.0 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602061

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Thymus	Atrophy	Marked
Tooth	Dysplasia	Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 162 TMT: 7 SEX: Male DAY ON TEST: 673  
 DOSE: 1.0 G/KG DISP: Natural Death HISTO: 0602062

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Harderian Gland           | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    |
| * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     | * Pancreas                |
| * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          | * Salivary Glands         |
| * Skin                      | * Testes                 | * Thyroid Gland            | * Trachea                 |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |  |                           |                         |
|----------------------|--|---------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                              | Hyperplasia               | Minimal                 |
| * Epididymis         |  | Granuloma Sperm           | Mild                    |
| * Heart              | Valve                                    | Inflammation              | Marked                  |
|                      |  | Inflammation              | Suppurative, Mild       |
| * Islets, Pancreatic |  | Hyperplasia               | Minimal                 |
| * Kidney             | Renal Tubule                             | Mineralization            | Minimal                 |
|                      | Renal Tubule                             | Nephropathy               | Mild                    |
|                      |  | Pigmentation              | Lipofuscin, Moderate    |
| * Liver              |  | Eosinophilic Focus        |                         |
|                      |  | Hepatoblastoma            | Multiple                |
|                      |  | Infiltration Cellular     | Mononuclear CI, Minimal |
|                      |  | Inflammation              | Suppurative, Moderate   |
|                      |  | Mixed Cell Focus          |                         |
|                      |  | Necrosis                  | Minimal                 |
|                      |  | Vacuolization Cytoplasmic | Mild                    |
|                      | [ Eosinophilic Focus TGLs = 3-12 ]       |                           |                         |
|                      | [ Hepatoblastoma TGLs = 1,2,4-10+11+13 ] |                           |                         |
| Peritoneum           |  | Inflammation              | Chronic, Moderate       |
| * Prostate           |  | Hyperplasia               | Mild                    |
|                      |  | Inflammation              | Mild                    |
| * Seminal Vesicle    |  | Hyperplasia               | Mild                    |
|                      |  | Inflammation              | Mild                    |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	162	TMT:	7	SEX:	Male	DAY ON TEST:	673
		DOSE:	1.0 G/KG	DISP:	Natural Death	HISTO:	0602062

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ORGAN AND ACCOUNTABLE SITE STATUS

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* Spleen	Lymph Follic	Atrophy Hematopoietic Cell Proliferation	Marked Moderate
* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation	Mild Chronic, Minimal
	[ Hyperplasia TGLs = 5-14 ]		
* Stomach, Glandular		Hepatoblastoma	Metastatic (Liver)
* Thymus		Atrophy	Marked
* Urinary Bladder		Hepatoblastoma	Metastatic (Liver)

---

PRIMARY CAUSE OF DEATH - Heart Valve Inflammation

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 163 TMT: 7 SEX: Male DAY ON TEST: 732  
 DOSE: 1.0 G/KG DISP: Terminal Sacrifice HISTO: 0602063

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea
* Urinary Bladder			

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular Zona Reticul	Hyperplasia Hyperplasia	Minimal Mild
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Cardiomyopathy	Minimal
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney	Renal Tubule	Mineralization Nephropathy	Minimal Mild
* Liver		Eosinophilic Focus Hepatocellular Adenoma Infiltration Cellular	Multiple Mononuclear CI, Minimal
	[ Hepatocellular Adenoma TGLs = 1,2,3,4,5,6-10+11+12+13+14+15 ]		
* Nose		Inflammation Polyp, Inflammatory	Suppurative, Mild Mild
* Preputial Gland		Inflammation	Minimal
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation	Mild Chronic, Minimal
	[ Hyperplasia TGLs = 7-16 ]		
* Thymus		Atrophy	Marked

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	163	<b>TMT:</b>	7	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	732
		<b>DOSE:</b>	1.0 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602063

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**ORGAN AND ACCOUNTABLE SITE STATUS**

---

Tooth

Dysplasia

Marked

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 164 TMT: 7 SEX: Male DAY ON TEST: 732  
 DOSE: 1.0 G/KG DISP: Terminal Sacrifice HISTO: 0602064

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Gallbladder	* Harderian Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Lymph Node, Mandibular	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Seminal Vesicle	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Lymph Node, Mesenteric \* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
		Vacuolization Cytoplasmic	Minimal
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney	Renal Tubule	Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
		Hepatoblastoma	Multiple
		Hepatocellular Adenoma	Multiple
		Infiltration Cellular	Mononuclear Cl, Minimal
		Necrosis	Minimal
	[ Hepatoblastoma TGLs = 4,5-13+14 ]		
	[ Hepatocellular Adenoma TGLs = 6,7,8-15+16+17 ]		
* Lung		Alveolar/Bronchiolar Adenoma	
	[ Alveolar/Bronchiolar Adenoma TGLs = 3-12 ]		
* Preputial Gland		Inflammation	Minimal
* Prostate		Infiltration Cellular	Mononuclear Cl, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear Cl, Minimal
* Skin		Inflammation	Chronic, Mild
		Ulcer	Moderate
	[ Ulcer TGLs = 1,2-10+11 ]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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<b>ANIMAL NUM:</b>	164	<b>TMT:</b>	7	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	732
		<b>DOSE:</b>	1.0 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602064

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ORGAN AND ACCOUNTABLE SITE STATUS

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* Thymus	Inflammation Atrophy	Chronic, Minimal Marked
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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 165 TMT: 7 SEX: Male DAY ON TEST: 732  
 DOSE: 1.0 G/KG DISP: Terminal Sacrifice HISTO: 0602065

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Eye	Retrobulbar	Inflammation	Chronic, Mild
* Harderian Gland		Carcinoma	
	[ Carcinoma TGLs = 7-9 ]	Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney		Nephropathy	Minimal
* Liver		Hepatocellular Adenoma	Multiple
	Centrilobular	Hepatocholangiocarcinoma	
	[ Hepatocellular Adenoma TGLs = 2,3,4,5-11+12+13+14 ]	Hypertrophy	Mild
	[ Hepatocholangiocarcinoma TGLs = 1-10 ]	Infiltration Cellular	Mononuclear CI, Minimal
* Lung		Carcinoma	Metastatic (Harderian Gland)
	[ Carcinoma TGLs = 6-3 ]		
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Mild
* Stomach, Forestomach	Epithelium	Hyperplasia	Moderate
	[ Hyperplasia TGLs = 8-15 ]	Inflammation	Chronic, Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	165	<b>TMT:</b>	7	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	732
		<b>DOSE:</b>	1.0 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602065

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Thymus	Atrophy	Mild
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 166	<b>TMT:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602066

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Nose                    | * Pancreas                  | * Parathyroid Gland      | * Pituitary Gland          |
| * Seminal Vesicle         | * Skin                      | * Spleen                 | * Stomach, Forestomach     |
| * Stomach, Glandular      | * Testes                    | * Thyroid Gland          | * Trachea                  |
| * Urinary Bladder         |                             |                          |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                   |  |                          |                         |
|-------------------|--|--------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                              | Hyperplasia              | Minimal                 |
| * Harderian Gland |  | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Kidney          |  | Nephropathy              | Minimal                 |
| * Liver           | Centrilobular                            | Hepatocellular Carcinoma |                         |
|                   |  | Hypertrophy              | Mild                    |
|                   |  | Infiltration Cellular    | Mononuclear CI, Minimal |
|                   |  | Necrosis                 | Minimal                 |
|                   | [ Hepatocellular Carcinoma TGLs = 1-10 ] |                          |                         |
| * Preputial Gland |  | Inflammation             | Minimal                 |
| * Prostate        |  | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Salivary Glands |  | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Thymus          |  | Atrophy                  | Mild                    |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 167    **TMT:** 7    **SEX:** Male    **DAY ON TEST:** 731  
**DOSE:** 1.0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602067

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                          |                           |
|-----------------------------|--------------------------|--------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                   | * Bone Marrow             |
| * Brain                     | * Epididymis             | * Esophagus              | * Eye                     |
| * Gallbladder               | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Lymph Node, Mandibular | * Lymph Node, Mesenteric  |
| * Nose                      | * Pancreas               | * Parathyroid Gland      | * Seminal Vesicle         |
| * Skin                      | * Stomach, Glandular     | * Testes                 | * Thyroid Gland           |
| * Trachea                   | * Urinary Bladder        |                          |                           |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                            |   |                          |                         |
|----------------------------|---|--------------------------|-------------------------|
| * Adrenal Cortex           | Subcapsular   | Hyperplasia              | Minimal                 |
| * Harderian Gland          |   | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Heart                    |   | Cardiomyopathy           | Minimal                 |
| * Intestine Small, Jejunum | Peyers Patch  | Hyperplasia              | Lymphoid, Marked        |
|                            | [ Hyperplasia TGLs = 8-11 ]                                   |                          |                         |
| * Islets, Pancreatic       |   | Hyperplasia              | Mild                    |
| * Kidney                   |   | Nephropathy              | Minimal                 |
| * Liver                    |   | Eosinophilic Focus       |                         |
|                            |   | Fatty Change             | Minimal                 |
|                            |   | Hepatoblastoma           |                         |
|                            |   | Hepatocellular Adenoma   | Multiple                |
|                            |   | Hepatocellular Carcinoma |                         |
|                            | Centrilobular   | Hypertrophy              | Mild                    |
|                            |   | Infiltration Cellular    | Mononuclear CI, Minimal |
|                            | [ Hepatoblastoma TGLs = 1-15 ]                                |                          |                         |
|                            | [ Hepatocellular Adenoma TGLs = 3,4,5,6,7,10-13+14+15+16+17 ] |                          |                         |
| * Lung                     |   | Hepatocellular Carcinoma | Metastatic (Liver)      |
| * Pituitary Gland          |   | Cyst                     | Minimal                 |
| * Preputial Gland          |   | Inflammation             | Mild                    |
| * Prostate                 |   | Infiltration Cellular    | Mononuclear CI, Mild    |
| * Salivary Glands          |   | Infiltration Cellular    | Mononuclear CI, Minimal |

\* PROTOCOL REQUIRED TISSUE



TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	167	TMT:	7	SEX:	Male	DAY ON TEST:	731
		DOSE:	1.0 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602067

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ORGAN AND ACCOUNTABLE SITE STATUS

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* Spleen		Lymphoma Malignant	
	[ Lymphoma Malignant TGLs = 2-12 ]		
* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation Necrosis	Mild Chronic, Mild Minimal
	[ Necrosis TGLs = 9-10 ]		
* Thymus		Atrophy	Marked

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 168	<b>TMT:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602068

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     | * Pancreas                |
| * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          | * Salivary Glands         |
| * Skin                      | * Stomach, Glandular     | * Thyroid Gland            | * Trachea                 |
| * Urinary Bladder           |                          |                            |                           |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |   |                                  |                         |
|------------------------|---|----------------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                                   | Hyperplasia                      | Minimal                 |
| * Epididymis           |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Harderian Gland      |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Kidney               |   | Nephropathy                      | Mild                    |
| * Liver                |   | Eosinophilic Focus               |                         |
|                        |   | Hepatoblastoma                   |                         |
|                        |   | Hepatocellular Adenoma           |                         |
|                        |   | Hepatocellular Carcinoma         | Multiple                |
|                        | Centrilobular                                 | Hypertrophy                      | Mild                    |
|                        |   | Infiltration Cellular            | Mononuclear CI, Minimal |
|                        | [ Eosinophilic Focus TGLs = 6-11 ]            |                                  |                         |
|                        | [ Hepatoblastoma TGLs = 5-13 ]                |                                  |                         |
|                        | [ Hepatocellular Adenoma TGLs = 3-4 ]         |                                  |                         |
|                        | [ Hepatocellular Carcinoma TGLs = 1,2-11+12 ] |                                  |                         |
| * Lung                 |   | Hepatocellular Carcinoma         | Metastatic (Liver)      |
| * Prostate             |   | Atrophy                          | Moderate                |
|                        |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Seminal Vesicle      |   | Atrophy                          | Moderate                |
| * Spleen               |   | Hematopoietic Cell Proliferation | Mild                    |
| * Stomach, Forestomach | Epithelium                                    | Hyperplasia                      | Mild                    |
|                        |   | Inflammation                     | Chronic, Mild           |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	168	TMT:	7	SEX:	Male	DAY ON TEST:	730
		DOSE:	1.0 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602068

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ORGAN AND ACCOUNTABLE SITE STATUS

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			Necrosis	Minimal
	[ Necrosis	TGLs = 4-10 ]		
* Testes		Germinal Epith	Atrophy	Mild
* Thymus			Atrophy	Marked
Tooth			Dysplasia	Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 169	<b>TMT:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 574
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 0602069

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla        | Blood Vessel               | * Bone                    | * Bone Marrow               |
| * Brain                  | * Esophagus                | * Eye                     | * Gallbladder               |
| * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Kidney                  | * Lymph Node, Mandibular    |
| * Lymph Node, Mesenteric | * Nose                     | * Pancreas                | * Parathyroid Gland         |
| * Pituitary Gland        | * Preputial Gland          | * Seminal Vesicle         | * Skin                      |
| * Spleen                 | * Stomach, Forestomach     | * Stomach, Glandular      | * Testes                    |
| * Thyroid Gland          | * Trachea                  | * Urinary Bladder         |                             |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |  |                              |                         |
|----------------------|--|------------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                                      | Hyperplasia                  | Minimal                 |
| * Epididymis         |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Harderian Gland    |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Heart              |  | Cardiomyopathy               | Mild                    |
| * Islets, Pancreatic |  | Hyperplasia                  | Mild                    |
| * Liver              |  | Eosinophilic Focus           |                         |
|                      |  | Fatty Change                 | Minimal                 |
|                      |  | Hepatocellular Adenoma       |                         |
|                      | Centrilobular                                    | Hepatocellular Carcinoma     | Multiple                |
|                      |  | Hypertrophy                  | Mild                    |
|                      |  | Infiltration Cellular        | Mononuclear CI, Minimal |
|                      |  | Necrosis                     | Moderate                |
|                      | [ Eosinophilic Focus TGLs = 6-10+14 ]            |                              |                         |
|                      | [ Hepatocellular Adenoma TGLs = 1-10 ]           |                              |                         |
|                      | [ Hepatocellular Carcinoma TGLs = 2,3-11+12 ]    |                              |                         |
|                      | [ Necrosis TGLs = 7-15 ]                         |                              |                         |
| * Lung               |  | Alveolar/Bronchiolar Adenoma | Multiple                |
|                      | [ Alveolar/Bronchiolar Adenoma TGLs = 4,5,8-13 ] | Hepatocellular Carcinoma     | Metastatic (Liver)      |
| * Prostate           |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Salivary Glands    |  | Infiltration Cellular        | Mononuclear CI, Minimal |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b> 169	<b>TMT:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 574
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 0602069

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Thymus	Atrophy	Marked
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PRIMARY CAUSE OF DEATH - Lung Alveolar/Bronchiolar Adenoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 170 TMT: 7 SEX: Male DAY ON TEST: 668  
 DOSE: 1.0 G/KG DISP: Natural Death HISTO: 0602070

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Epididymis             | * Esophagus                | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    |
| * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Pancreas                 | * Parathyroid Gland       |
| * Pituitary Gland           | * Preputial Gland        | * Seminal Vesicle          | * Skin                    |
| * Spleen                    | * Stomach, Forestomach   | * Stomach, Glandular       | * Testes                  |
| * Thyroid Gland             | * Trachea                |                            |                           |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |  |                             |  |   |
|--|-----------------------------|--|---|
| * Adrenal Cortex                         | Subcapsular<br>Zona Reticul | Hyperplasia<br>Hyperplasia   | Mild<br>Mild                            |
| * Eye                                    | Cornea                      | Inflammation   | Chronic, Minimal                        |
| Note: Both optic nerves were missing     |                             |  |   |
| * Harderian Gland                        |                             | Adenoma  |   |
| [ Adenoma TGLs = 1-9 ]                   |                             |  |   |
| * Islets, Pancreatic                     |                             | Hyperplasia  | Minimal                                 |
| * Kidney                                 | Renal Tubule                | Mineralization   | Minimal                                 |
| * Liver                                  | Centrilobular               | Clear Cell Focus<br>Hepatocellular Adenoma<br>Hepatocellular Carcinoma | Mild<br>Mononuclear CI, Mild<br>Minimal |
| [ Hepatocellular Adenoma TGLs = 3-11 ]   |                             |  |   |
| [ Hepatocellular Carcinoma TGLs = 2-10 ] |                             |  |   |
| * Nose                                   |                             | Inflammation   | Chronic, Minimal                        |
| * Prostate                               |                             | Infiltration Cellular  | Mononuclear CI, Minimal                 |
| * Salivary Glands                        |                             | Infiltration Cellular  | Mononuclear CI, Minimal                 |
| * Thymus                                 |                             | Atrophy  | Mild                                    |
| * Urinary Bladder                        |                             | Infiltration Cellular  | Mononuclear CI, Minimal                 |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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ANIMAL NUM: 170    TMT: 7  
DOSE: 1.0 G/KG

SEX: Male  
DISP: Natural Death

DAY ON TEST: 668  
HISTO: 0602070

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ORGAN AND ACCOUNTABLE SITE STATUS

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PRIMARY CAUSE OF DEATH    - Liver    Hepatocellular Carcinoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 171	<b>TMT:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602071

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Nose                    | * Pancreas                  | * Parathyroid Gland      | * Pituitary Gland          |
| * Preputial Gland         | * Prostate                  | * Salivary Glands        | * Seminal Vesicle          |
| * Skin                    | * Spleen                    | * Stomach, Forestomach   | * Stomach, Glandular       |
| * Testes                  | * Thyroid Gland             | * Trachea                | * Urinary Bladder          |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                   |  |  |   |
|-------------------|--|--|---|
| * Adrenal Cortex  | Subcapsular  | Hyperplasia  | Minimal   |
| * Harderian Gland |  | Infiltration Cellular  | Mononuclear CI, Minimal                                       |
| * Kidney          | Renal Tubule<br>Papilla  | Mineralization<br>Necrosis<br>Nephropathy  | Mild<br>Minimal<br>Minimal                                    |
| * Liver           | Centrilobular  | Clear Cell Focus<br>Eosinophilic Focus<br>Fatty Change<br>Hepatocellular Adenoma<br>Hypertrophy<br>Infiltration Cellular | Minimal<br><br><br>Minimal<br>Mild<br>Mononuclear CI, Minimal |
|                   | [ Eosinophilic Focus TGLs = 2,3,4-11+12+13 ]<br>[ Hepatocellular Adenoma TGLs = 1-10 ] |  |   |
| * Thymus          |  | Atrophy  | Mild  |
| Tooth             |  | Dysplasia  | Minimal   |



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 172 TMT: 7 SEX: Male DAY ON TEST: 732  
 DOSE: 1.0 G/KG DISP: Terminal Sacrifice HISTO: 0602072

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular Zona Reticul	Hyperplasia Hyperplasia	Minimal Moderate
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Gallbladder		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney	Renal Tubule Renal Tubule	Hyperplasia Mineralization Nephropathy	Minimal Minimal Minimal
* Liver		Eosinophilic Focus Hepatoblastoma Hepatocellular Adenoma Hepatocellular Carcinoma Infiltration Cellular	Mononuclear CI, Minimal
	[ Eosinophilic Focus TGLs = 2,4,5,6-11+13+14+15 ] [ Hepatoblastoma TGLs = 3-12 ] [ Hepatocellular Adenoma TGLs = 2-11 ] [ Hepatocellular Carcinoma TGLs = 1-10 ]		
* Preputial Gland		Inflammation	Minimal
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	172	TMT:	7	SEX:	Male	DAY ON TEST:	732
		DOSE:	1.0 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602072

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ORGAN AND ACCOUNTABLE SITE STATUS

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[ Necrosis TGLs = 7-16 ]	Inflammation	Chronic, Mild
* Thymus	Necrosis	Minimal
Tooth	Atrophy	Mild
* Urinary Bladder	Dysplasia	Minimal
	Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 173 TMT: 7 SEX: Male DAY ON TEST: 582  
 DOSE: 1.0 G/KG DISP: Moribund Sacrifice HISTO: 0602073

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lymph Node, Mesenteric  |
| * Pancreas                  | * Parathyroid Gland      | * Pituitary Gland          | * Preputial Gland         |
| * Prostate                  | * Salivary Glands        | * Seminal Vesicle          | * Skin                    |
| * Stomach, Glandular        | * Testes                 | * Thyroid Gland            | * Trachea                 |
| * Urinary Bladder           |                          |                            |                           |

**MISSING**

- |                          |                 |          |
|--------------------------|-----------------|----------|
| * Lymph Node, Mandibular | * Mammary Gland | * Thymus |
|--------------------------|-----------------|----------|

**OBSERVATIONS**

- |                      |               |                                    |                         |
|----------------------|---------------|------------------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular   | Hyperplasia                        | Minimal                 |
| * Epididymis         |               | Infiltration Cellular              | Mononuclear CI, Minimal |
| * Harderian Gland    |               | Infiltration Cellular              | Mononuclear CI, Minimal |
| * Islets, Pancreatic |               | Hyperplasia                        | Mild                    |
| * Kidney             | Renal Tubule  | Inflammation                       | Moderate                |
|                      | Renal Tubule  | Mineralization                     | Minimal                 |
|                      | Renal Tubule  | Nephropathy                        | Mild                    |
| * Liver              | Centrilobular | Pigmentation                       | Lipofuscin, Mild        |
|                      |               | Fatty Change                       | Marked                  |
|                      |               | Hepatoblastoma                     |                         |
|                      |               | Hepatocellular Adenoma             |                         |
|                      |               | Infiltration Cellular              | Mononuclear CI, Mild    |
|                      |               | Mineralization                     | Mild                    |
|                      |               | Necrosis                           | Moderate                |
|                      |               | [ Fatty Change TGLs = 2-3+4+5+11 ] |                         |
|                      |               | [ Hepatoblastoma TGLs = 1-10 ]     |                         |
|                      |               | [ Necrosis TGLs = 2-3+4+5+11 ]     |                         |
| * Lung               |               | Hepatoblastoma                     | Metastatic (Liver)      |
| * Nose               |               | Inflammation                       | Chronic, Minimal        |
| * Spleen             | Lymph Follic  | Atrophy                            | Marked                  |
|                      |               | Hematopoietic Cell Proliferation   | Moderate                |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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<b>ANIMAL NUM:</b>	173	<b>TMT:</b>	7	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	582
		<b>DOSE:</b>	1.0 G/KG	<b>DISP:</b>	Moribund Sacrifice	<b>HISTO:</b>	0602073

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**ORGAN AND ACCOUNTABLE SITE STATUS**

---

\* Stomach, Forestomach

Inflammation  
Necrosis

Chronic, Minimal  
Moderate

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PRIMARY CAUSE OF DEATH - Liver Hepatoblastoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 174    **TMT:** 7    **SEX:** Male    **DAY ON TEST:** 392  
**DOSE:** 1.0 G/KG    **DISP:** Moribund Sacrifice    **HISTO:** 0602074

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Nose                    |
| * Pituitary Gland           | * Preputial Gland        | * Seminal Vesicle          | * Skin                    |
| * Stomach, Glandular        | * Testes                 | * Thymus                   | * Thyroid Gland           |
| * Trachea                   | * Urinary Bladder        |                            |                           |

**MISSING**

- |                 |                     |
|-----------------|---------------------|
| * Mammary Gland | * Parathyroid Gland |
|-----------------|---------------------|

**OBSERVATIONS**

- |                        |                               |                                  |                         |
|------------------------|-------------------------------|----------------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                   | Hyperplasia                      | Minimal                 |
| * Epididymis           |                               | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Harderian Gland      |                               | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Kidney               |                               | Nephropathy                      | Minimal                 |
| * Liver                | Centrilobular                 | Eosinophilic Focus               | Minimal                 |
|                        |                               | Fatty Change                     | Mild                    |
|                        |                               | Hypertrophy                      | Mononuclear CI, Minimal |
|                        |                               | Infiltration Cellular            | Moderate                |
|                        |                               | Necrosis                         |                         |
|                        | [ Necrosis TGLs = 2,3-11+12 ] |                                  |                         |
| * Pancreas             | Duct                          | Cyst                             |                         |
|                        | [ Cyst TGLs = 1-10 ]          |                                  |                         |
| * Prostate             |                               | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Salivary Glands      |                               | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen               |                               | Hematopoietic Cell Proliferation | Mild                    |
| * Stomach, Forestomach |                               | Inflammation                     | Chronic, Minimal        |

PRIMARY CAUSE OF DEATH - UNCERTAIN

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 175 TMT: 7 SEX: Male DAY ON TEST: 731  
 DOSE: 1.0 G/KG DISP: Terminal Sacrifice HISTO: 0602075

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thyroid Gland
* Trachea			

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney	Renal Tubule	Hyperplasia	Minimal
	Renal Tubule	Mineralization	Minimal
	Papilla	Necrosis	Minimal
		Nephropathy	Minimal
* Liver		Angiectasis	Mild
		Clear Cell Focus	
		Eosinophilic Focus	
		Fatty Change	Mild
		Hepatocellular Adenoma	Multiple
	Centrilobular	Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
	[ Eosinophilic Focus TGLs = 2,4,5,6-11+13+14+15 ]		
	[ Hepatocellular Adenoma TGLs = 1,3-10+12 ]		
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Thymus		Atrophy	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 176 TMT: 7 SEX: Male DAY ON TEST: 582  
 DOSE: 1.0 G/KG DISP: Natural Death HISTO: 0602076

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Harderian Gland           | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    |
| * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     | * Pancreas                |
| * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          | * Salivary Glands         |
| * Skin                      | * Stomach, Glandular     | * Testes                   | * Thyroid Gland           |
| * Trachea                   |                          |                            |                           |

MISSING

- \* Mammary Gland

OBSERVATIONS

- |                        |                                    |                                  |                         |
|------------------------|------------------------------------|----------------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                        | Hyperplasia                      | Mild                    |
| * Epididymis           |                                    | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Heart                |                                    | Cardiomyopathy                   | Minimal                 |
| * Islets, Pancreatic   |                                    | Hyperplasia                      | Minimal                 |
| * Kidney               | Renal Tubule                       | Hyperplasia                      | Minimal                 |
|                        | Renal Tubule                       | Mineralization                   | Minimal                 |
| * Liver                |                                    | Eosinophilic Focus               |                         |
|                        |                                    | Fatty Change                     | Minimal                 |
|                        | Centrilobular                      | Hepatoblastoma                   |                         |
|                        |                                    | Hypertrophy                      | Mild                    |
|                        |                                    | Infiltration Cellular            | Mononuclear CI, Minimal |
|                        |                                    | Necrosis                         | Mild                    |
|                        | [ Eosinophilic Focus TGLs = 2-10 ] |                                  |                         |
|                        | [ Hepatoblastoma TGLs = 1-10 ]     |                                  |                         |
| * Prostate             |                                    | Inflammation                     | Moderate                |
| * Seminal Vesicle      |                                    | Inflammation                     | Minimal                 |
| * Spleen               | Lymph Follic                       | Atrophy                          | Moderate                |
|                        |                                    | Hematopoietic Cell Proliferation | Moderate                |
| * Stomach, Forestomach | Epithelium                         | Hyperplasia                      | Minimal                 |
|                        |                                    | Inflammation                     | Chronic, Minimal        |
|                        |                                    | Necrosis                         | Moderate                |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	176	TMT:	7	SEX:	Male	DAY ON TEST:	582
		DOSE:	1.0 G/KG	DISP:	Natural Death	HISTO:	0602076

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ORGAN AND ACCOUNTABLE SITE STATUS

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* Thymus		Atrophy	Marked
Urethra		Inflammation	Moderate
		Necrosis	Moderate
* Urinary Bladder	Transit Epithe	Cytoplasmic Alteration	Mild

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PRIMARY CAUSE OF DEATH - Liver Hepatoblastoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 177	<b>TMT:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602077

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Prostate	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea		

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney	Renal Tubule	Hyperplasia	Minimal
	Renal Tubule	Mineralization	Minimal
		Nephropathy	Mild
* Liver		Eosinophilic Focus	
	Centrilobular	Hepatocellular Carcinoma	
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Eosinophilic Focus TGLs = 2,3-11+12 ]		
	[ Hepatocellular Carcinoma TGLs = 1-10 ]		
* Lung		Hepatocellular Carcinoma	Metastatic (Liver)
* Preputial Gland		Inflammation	Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Thymus		Atrophy	Marked
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 178    **TMT:** 7    **SEX:** Male    **DAY ON TEST:** 692  
**DOSE:** 1.0 G/KG    **DISP:** Moribund Sacrifice    **HISTO:** 0602078

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Cortex           | * Adrenal Medulla         | Blood Vessel                | * Bone                   |
| * Bone Marrow              | * Brain                   | * Epididymis                | * Esophagus              |
| * Eye                      | * Gallbladder             | * Harderian Gland           | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Lymph Node, Mandibular  | * Nose                      | * Pancreas               |
| * Parathyroid Gland        | * Pituitary Gland         | * Preputial Gland           | * Prostate               |
| * Salivary Glands          | * Seminal Vesicle         | * Stomach, Glandular        | * Testes                 |
| * Thyroid Gland            | * Trachea                 |                             |                          |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                          |   |                         |
|--------------------------|---|-------------------------|
| * Heart                  | Cardiomyopathy                              | Minimal                 |
| * Islets, Pancreatic     | Hyperplasia                                 | Minimal                 |
| * Kidney                 | Nephropathy                                 | Mild                    |
| * Liver                  | Angiectasis                                 | Minimal                 |
|                          | Basophilic Focus                            |                         |
|                          | Eosinophilic Focus                          |                         |
|                          | Hepatocellular Adenoma                      | Multiple                |
|                          | Hepatocellular Carcinoma                    |                         |
|                          | Centrilobular                               |                         |
|                          | Hypertrophy                                 | Mild                    |
|                          | Infiltration Cellular                       | Mononuclear CI, Minimal |
|                          | Necrosis                                    | Minimal                 |
|                          | [ Eosinophilic Focus TGLs = 7-16 ]          |                         |
|                          | [ Hepatocellular Adenoma TGLs = 4,6-13+15 ] |                         |
|                          | [ Hepatocellular Carcinoma TGLs = 3-12 ]    |                         |
| * Lung                   | Hepatocellular Carcinoma                    | Metastatic (Liver)      |
|                          | Inflammation                                | Minimal                 |
| * Lymph Node, Mesenteric | Lymphoma Malignant                          |                         |
|                          | [ Lymphoma Malignant TGLs = 5-14 ]          |                         |
| * Skin                   | Hemorrhage                                  | Moderate                |
|                          | Ulcer                                       | Moderate                |
|                          | [ Hemorrhage TGLs = 2-11 ]                  |                         |
|                          | [ Ulcer TGLs = 1-10 ]                       |                         |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	178	TMT:	7	SEX:	Male	DAY ON TEST:	692
		DOSE:	1.0 G/KG	DISP:	Moribund Sacrifice	HISTO:	0602078

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ORGAN AND ACCOUNTABLE SITE STATUS

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* Spleen		Hematopoietic Cell Proliferation	Mild
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
		Inflammation	Chronic, Mild
		Necrosis	Mild
	[ Necrosis TGLs = 8-17 ]		
* Thymus		Atrophy	Moderate
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

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PRIMARY CAUSE OF DEATH - Liver Hepatocellular Carcinoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 179 TMT: 7 SEX: Male DAY ON TEST: 732  
 DOSE: 1.0 G/KG DISP: Terminal Sacrifice HISTO: 0602079

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Epididymis             | * Esophagus                | * Eye                     |
| * Gallbladder               | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lymph Node, Mandibular  |
| * Lymph Node, Mesenteric    | * Nose                   | * Pancreas                 | * Parathyroid Gland       |
| * Pituitary Gland           | * Preputial Gland        | * Prostate                 | * Seminal Vesicle         |
| * Stomach, Glandular        | * Testes                 | * Thyroid Gland            | * Trachea                 |
| * Urinary Bladder           |                          |                            |                           |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                                       |               |  |                         |
|---------------------------------------|---------------|--|-------------------------|
| * Adrenal Cortex                      | Subcapsular   | Hyperplasia                                  | Minimal                 |
| * Harderian Gland                     |               | Infiltration Cellular                        | Mononuclear CI, Minimal |
| * Heart                               |               | Cardiomyopathy                               | Minimal                 |
| * Islets, Pancreatic                  |               | Hyperplasia                                  | Minimal                 |
| * Kidney                              | Renal Tubule  | Hyperplasia                                  | Mild                    |
|                                       | Renal Tubule  | Mineralization                               | Minimal                 |
|                                       |               | Nephropathy                                  | Mild                    |
| * Liver                               |               | Eosinophilic Focus                           |                         |
|                                       | Centrilobular | Hepatocellular Carcinoma                     |                         |
|                                       |               | Hypertrophy                                  | Mild                    |
|                                       |               | Infiltration Cellular                        | Mononuclear CI, Minimal |
|                                       |               | [ Eosinophilic Focus TGLs = 5,6,8-14+15+17 ] |                         |
|                                       |               | [ Hepatocellular Carcinoma TGLs = 7-16 ]     |                         |
| * Lung                                |               | Hepatocellular Carcinoma                     | Metastatic (Liver)      |
|                                       | Bronchus      | Hyperplasia                                  | Mild                    |
| * Preputial GI                        |               |  |                         |
| Note: One preputial gland was missing |               |  |                         |
| * Salivary Glands                     |               | Infiltration Cellular                        | Mononuclear CI, Minimal |
| * Skin                                |               | Ulcer  | Moderate                |
|                                       |               | [ Ulcer TGLs = 1,2,3,4-10+11+12+13 ]         |                         |
| * Spleen                              |               | Hematopoietic Cell Proliferation             | Mild                    |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	179	<b>TMT:</b>	7	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	732
		<b>DOSE:</b>	1.0 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602079

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation	Minimal Chronic, Minimal
* Thymus		Atrophy	Marked

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 180	<b>TMT:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602080

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Pituitary Gland	* Preputial Gland	* Prostate
* Seminal Vesicle	* Stomach, Glandular	* Testes	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney	Renal Tubule	Mineralization	Minimal
		Nephropathy	Mild
* Liver		Angiectasis	Minimal
		Clear Cell Focus	
		Eosinophilic Focus	
		Fatty Change	Minimal
		Hepatocellular Adenoma	Multiple
		Hepatocellular Carcinoma	
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
		[ Eosinophilic Focus TGLs = 7-15 ]	
		[ Hepatocellular Adenoma TGLs = 2,3,5-11+12+14 ]	
		[ Hepatocellular Carcinoma TGLs = 4-13 ]	
		[ Mixed Cell Focus TGLs = 6-14 ]	
* Parathyroid Gland		Cyst	Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Skin	Subcut Tiss	Fibrosarcoma	
	[ Fibrosarcoma TGLs = 1-10 ]		

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	180	TMT:	7	SEX:	Male	DAY ON TEST:	730
		DOSE:	1.0 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602080

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ORGAN AND ACCOUNTABLE SITE STATUS

---

* Spleen	Hyperplasia	Lymphoid, Minimal
* Stomach, Forestomach	Inflammation	Chronic, Mild
	Necrosis	Mild
	Squamous Cell Papilloma	
[ Squamous Cell Papilloma TGLs = 8-16 ]		
* Thymus	Atrophy	Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 181 TMT: 7 SEX: Male DAY ON TEST: 718  
 DOSE: 1.0 G/KG DISP: Natural Death HISTO: 0602081

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney		Nephropathy	Mild
* Liver		Eosinophilic Focus	
		Hepatoblastoma	
		Hepatocellular Adenoma	Multiple
		Hepatocellular Carcinoma	Multiple
		Infiltration Cellular	Mononuclear CI, Mild
	[ Hepatoblastoma TGLs = 3-12 ]		
	[ Hepatocellular Adenoma TGLs = 4,5-13+14 ]		
	[ Hepatocellular Carcinoma TGLs = 1,2-10+11 ]		
* Lung		Hepatocellular Carcinoma	Metastatic (Liver)
* Spleen		Hematopoietic Cell Proliferation	Mild
* Thymus		Atrophy	Marked

PRIMARY CAUSE OF DEATH - Liver Hepatocellular Carcinoma  
 CONTRIBUTORY CAUSE OF DEATH - Liver Hepatoblastoma



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 182 TMT: 7 SEX: Male DAY ON TEST: 732  
 DOSE: 1.0 G/KG DISP: Terminal Sacrifice HISTO: 0602082

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Epididymis             | * Esophagus                | * Eye                     |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Nose                    |
| * Pancreas                  | * Parathyroid Gland      | * Pituitary Gland          | * Preputial Gland         |
| * Prostate                  | * Seminal Vesicle        | * Skin                     | * Spleen                  |
| * Stomach, Forestomach      | * Stomach, Glandular     | * Testes                   | * Thymus                  |
| * Trachea                   | * Urinary Bladder        |                            |                           |

**MISSING**

- |               |                 |
|---------------|-----------------|
| * Gallbladder | * Mammary Gland |
|---------------|-----------------|

**OBSERVATIONS**

- |                   |                |  |                         |
|-------------------|----------------|--|-------------------------|
| * Adrenal Cortex  | Subcapsular    | Hyperplasia                                      | Minimal                 |
| * Harderian Gland |                | Infiltration Cellular                            | Mononuclear CI, Minimal |
| * Kidney          | Renal Tubule   | Mineralization                                   | Minimal                 |
| * Liver           |                | Angiectasis                                      | Mild                    |
|                   |                | Clear Cell Focus                                 |                         |
|                   |                | Eosinophilic Focus                               |                         |
|                   |                | Fatty Change                                     | Mild                    |
|                   |                | Hepatocellular Adenoma                           | Multiple                |
|                   | Centrilobular  | Hepatocellular Carcinoma                         |                         |
|                   |                | Hypertrophy                                      | Mild                    |
|                   |                | Infiltration Cellular                            | Mononuclear CI, Minimal |
|                   |                | [ Eosinophilic Focus TGLs = 4,6-13+15 ]          |                         |
|                   |                | [ Hepatocellular Adenoma TGLs = 1,2,5-10+11+14 ] |                         |
|                   |                | [ Hepatocellular Carcinoma TGLs = 3-12 ]         |                         |
| * Salivary Glands |                | Infiltration Cellular                            | Mononuclear CI, Minimal |
| * Thyroid Gland   | Follicular Cel | Adenoma  |                         |
| Tooth             |                | Dysplasia  | Minimal                 |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 183	<b>TMT:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 732
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602083

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     |
| * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          |
| * Prostate                | * Seminal Vesicle           | * Skin                   | * Stomach, Glandular       |
| * Testes                  | * Thyroid Gland             | * Trachea                | * Urinary Bladder          |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |   |   |   |
|------------------------|---|---|---|
| * Adrenal Cortex       | Subcapsular   | Hyperplasia   | Mild  |
| * Harderian Gland      |   | Hyperplasia<br>Infiltration Cellular  | Moderate<br>Mononuclear CI, Minimal                 |
| * Kidney               | Renal Tubule<br>Renal Tubule  | Hyperplasia<br>Mineralization<br>Nephropathy  | Minimal<br>Minimal<br>Minimal                       |
| * Liver                | Centrilobular   | Angiectasis<br>Clear Cell Focus<br>Eosinophilic Focus<br>Hepatocellular Adenoma<br>Hepatocellular Carcinoma<br>Hypertrophy<br>Infiltration Cellular | Mild<br>Multiple<br>Mild<br>Mononuclear CI, Minimal |
|                        | [ Eosinophilic Focus TGLs = 4-13 ]<br>[ Hepatocellular Adenoma TGLs = 2,3-11+12 ]<br>[ Hepatocellular Carcinoma TGLs = 1-10 ] |   |   |
| * Lung                 | [ Hepatocellular Carcinoma TGLs = 5-14 ]  | Hepatocellular Carcinoma  | Metastatic (Liver)                                  |
| * Salivary Glands      |   | Infiltration Cellular   | Mononuclear CI, Minimal                             |
| * Spleen               | Lymph Follic  | Atrophy   | Moderate  |
| * Stomach, Forestomach | Epithelium  | Hyperplasia<br>Inflammation   | Minimal<br>Chronic, Minimal                         |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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ANIMAL NUM:	183	TMT:	7	SEX:	Male	DAY ON TEST:	732
		DOSE:	1.0 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602083

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ORGAN AND ACCOUNTABLE SITE STATUS

---

[ Hyperplasia	TGLs = 6-15 ]		
* Thymus		Atrophy	Minimal
Tooth		Dysplasia	Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 184 TMT: 7 SEX: Male DAY ON TEST: 731  
 DOSE: 1.0 G/KG DISP: Terminal Sacrifice HISTO: 0602084

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla        | Blood Vessel               | * Bone                    | * Bone Marrow               |
| * Brain                  | * Esophagus                | * Eye                     | * Gallbladder               |
| * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      | * Lymph Node, Mandibular    |
| * Lymph Node, Mesenteric | * Nose                     | * Pancreas                | * Parathyroid Gland         |
| * Pituitary Gland        | * Seminal Vesicle          | * Skin                    | * Spleen                    |
| * Stomach, Glandular     | * Testes                   | * Thyroid Gland           | * Trachea                   |
| * Urinary Bladder        |                            |                           |                             |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                   |  |   |                                 |
|-------------------|--|---|---------------------------------|
| * Adrenal Cortex  | Subcapsular<br>Zona Reticul                      | Hyperplasia<br>Hyperplasia  | Mild<br>Mild                    |
| * Epididymis      |  | Infiltration Cellular   | Mononuclear CI, Minimal         |
| * Harderian Gland |  | Hyperplasia<br>Infiltration Cellular  | Mild<br>Mononuclear CI, Minimal |
| * Heart           |  | Cardiomyopathy  | Minimal                         |
| * Kidney          | Renal Tubule                                     | Mineralization<br>Nephropathy   | Minimal<br>Minimal              |
| * Liver           | Centrilobular                                    | Clear Cell Focus<br>Eosinophilic Focus<br>Hepatocellular Adenoma<br>Hypertrophy<br>Mixed Cell Focus | Multiple<br>Mild                |
|                   | [ Eosinophilic Focus TGLs = 2-11 ]               |   |                                 |
|                   | [ Hepatocellular Adenoma TGLs = 3,4,5-12+13+14 ] |   |                                 |
|                   | [ Mixed Cell Focus TGLs = 6-15 ]                 |   |                                 |
| * Lung            | [ Alveolar/Bronchiolar Adenoma TGLs = 7-16 ]     | Alveolar/Bronchiolar Adenoma  |                                 |
| Mesentery         | Fat  | Necrosis  | Moderate                        |
|                   | [ Necrosis TGLs = 1-10 ]                         |   |                                 |
| * Preputial Gland |  | Inflammation  | Minimal                         |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	184	<b>TMT:</b>	7	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	731
		<b>DOSE:</b>	1.0 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602084

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation	Minimal Chronic, Minimal
* Thymus		Atrophy	Marked

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 185    **TMT:** 7    **SEX:** Male    **DAY ON TEST:** 731  
**DOSE:** 1.0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602085

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Prostate
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney	Renal Tubule	Mineralization Nephropathy	Minimal Minimal
* Liver	Centrilobular	Eosinophilic Focus Fatty Change Hepatocellular Adenoma	Minimal
		Hypertrophy Infiltration Cellular Mixed Cell Focus	Mild Mononuclear CI, Minimal
		[ Eosinophilic Focus TGLs = 2,3,4-11+13 ] [ Hepatocellular Adenoma TGLs = 1-10+12 ] [ Mixed Cell Focus TGLs = 5-14 ]	
* Preputial Gland		Inflammation	Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation Necrosis	Mild Chronic, Mild Mild
		[ Necrosis TGLs = 6-15 ]	
* Thymus		Atrophy	Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 186    **TMT:** 7    **SEX:** Male    **DAY ON TEST:** 730  
**DOSE:** 1.0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602086

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Kidney                  |
| * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     | * Pancreas                |
| * Parathyroid Gland         | * Pituitary Gland        | * Prostate                 | * Salivary Glands         |
| * Seminal Vesicle           | * Skin                   | * Spleen                   | * Stomach, Glandular      |
| * Testes                    | * Thyroid Gland          | * Trachea                  | * Urinary Bladder         |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |   |                        |                         |
|------------------------|---|------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular   | Hyperplasia            | Minimal                 |
| * Epididymis           |   | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Harderian Gland      |   | Infiltration Cellular  | Mononuclear CI, Mild    |
| * Islets, Pancreatic   |   | Hyperplasia            | Minimal                 |
| * Liver                |   | Eosinophilic Focus     |                         |
|                        |   | Hepatocellular Adenoma | Multiple                |
|                        |   | Infiltration Cellular  | Mononuclear CI, Minimal |
|                        |   | Mixed Cell Focus       |                         |
|                        | [ Eosinophilic Focus TGLs = 1,6-10+15 ]               |                        |                         |
|                        | [ Hepatocellular Adenoma TGLs = 2,3,4,5-11+12+13+14 ] |                        |                         |
| * Lung                 |   | Inflammation           | Minimal                 |
| * Preputial Gland      |   | Inflammation           | Mild                    |
| * Stomach, Forestomach | Epithelium  | Hyperplasia            | Mild                    |
|                        |   | Inflammation           | Chronic, Mild           |
|                        | [ Hyperplasia TGLs = 7-16 ]                           |                        |                         |
| * Thymus               |   | Atrophy                | Mild                    |
| Tooth                  |   | Dysplasia              | Minimal                 |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 187    **TMT:** 7    **SEX:** Male    **DAY ON TEST:** 731  
**DOSE:** 1.0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602087

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     |
| * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          |
| * Seminal Vesicle         | * Skin                      | * Spleen                 | * Stomach, Forestomach     |
| * Stomach, Glandular      | * Testes                    | * Thyroid Gland          | * Trachea                  |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |               |  |                         |
|----------------------|---------------|--|-------------------------|
| * Adrenal Cortex     | Subcapsular   | Hyperplasia                              | Minimal                 |
| * Harderian Gland    |               | Infiltration Cellular                    | Mononuclear CI, Minimal |
| * Islets, Pancreatic |               | Hyperplasia                              | Mild                    |
| * Kidney             |               | Metaplasia                               | Osseous, Mild           |
|                      |               | Nephropathy                              | Minimal                 |
| * Liver              |               | Clear Cell Focus                         |                         |
|                      |               | Eosinophilic Focus                       |                         |
|                      | Centrilobular | Fatty Change                             | Mild                    |
|                      |               | Hypertrophy                              | Mild                    |
|                      |               | Infiltration Cellular                    | Mononuclear CI, Minimal |
|                      |               | Mixed Cell Focus                         |                         |
|                      |               | [ Clear Cell Focus    TGLs = 2,4-11+12 ] |                         |
|                      |               | [ Fatty Change    TGLs = 3-3+5+11 ]      |                         |
|                      |               | [ Mixed Cell Focus    TGLs = 1-10 ]      |                         |
| * Prostate           |               | Infiltration Cellular                    | Mononuclear CI, Minimal |
| * Salivary Glands    |               | Infiltration Cellular                    | Mononuclear CI, Mild    |
| * Thymus             |               | Atrophy                                  | Mild                    |
| Tooth                |               | Dysplasia                                | Moderate                |
| * Urinary Bladder    |               | Infiltration Cellular                    | Mononuclear CI, Minimal |

\* PROTOCOL REQUIRED TISSUE



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 188    TMT: 7    SEX: Male    DAY ON TEST: 732  
 DOSE: 1.0 G/KG    DISP: Terminal Sacrifice    HISTO: 0602088

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lymph Node, Mandibular  | * Lymph Node, Mesenteric    | * Nose                   | * Pancreas                 |
| * Parathyroid Gland       | * Pituitary Gland           | * Preputial Gland        | * Prostate                 |
| * Seminal Vesicle         | * Skin                      | * Stomach, Forestomach   | * Stomach, Glandular       |
| * Testes                  | * Thyroid Gland             | * Trachea                |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |   |                              |                         |
|----------------------|---|------------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                               | Hyperplasia                  | Minimal                 |
| * Harderian Gland    |   | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Islets, Pancreatic |   | Hyperplasia                  | Minimal                 |
| * Kidney             | Renal Tubule                              | Mineralization               | Minimal                 |
| * Liver              |   | Clear Cell Focus             |                         |
|                      |   | Eosinophilic Focus           |                         |
|                      |   | Fatty Change                 | Mild                    |
|                      | Centrilobular                             | Hepatocellular Adenoma       |                         |
|                      |   | Hypertrophy                  | Mild                    |
|                      |   | Infiltration Cellular        | Mononuclear CI, Minimal |
|                      | [ Eosinophilic Focus    TGLs = 2-11 ]     |                              |                         |
|                      | [ Hepatocellular Adenoma    TGLs = 1-10 ] |                              |                         |
| * Lung               |   | Alveolar/Bronchiolar Adenoma |                         |
| * Salivary Glands    |   | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Spleen             | Lymph Follic                              | Atrophy                      | Moderate                |
| * Thymus             |   | Atrophy                      | Moderate                |
| Tooth                |   | Dysplasia                    | Minimal                 |
| * Urinary Bladder    |   | Infiltration Cellular        | Mononuclear CI, Minimal |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 189 TMT: 7 SEX: Male DAY ON TEST: 730  
 DOSE: 1.0 G/KG DISP: Terminal Sacrifice HISTO: 0602089

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Nose                    | * Pancreas                  | * Parathyroid Gland      | * Pituitary Gland          |
| * Preputial Gland         | * Salivary Glands           | * Seminal Vesicle        | * Skin                     |
| * Spleen                  | * Stomach, Forestomach      | * Stomach, Glandular     | * Testes                   |
| * Thyroid Gland           | * Trachea                   |                          |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |   |               |  |                         |
|---|---------------|--|-------------------------|
| * Adrenal Cortex  | Subcapsular   | Hyperplasia<br>Hypertrophy                             | Minimal<br>Minimal      |
| * Harderian Gland   |               | Infiltration Cellular                                  | Mononuclear CI, Minimal |
| * Kidney  | Renal Tubule  | Mineralization   | Minimal                 |
| * Liver   |               | Clear Cell Focus<br>Eosinophilic Focus<br>Fatty Change | Mild<br>Mild            |
|   | Centrilobular | Hypertrophy<br>Infiltration Cellular                   | Mononuclear CI, Minimal |
| Note: No corresponding microscopic lesion found for left liver lobe nodule (TGL 1).<br>[ Eosinophilic Focus TGLs = 2-11 ] |               |  |                         |
| * Prostate  |               | Infiltration Cellular                                  | Mononuclear CI, Minimal |
| * Thymus  |               | Atrophy  | Minimal                 |
| * Urinary Bladder   |               | Infiltration Cellular                                  | Mononuclear CI, Minimal |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 190	<b>TMT:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602090

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Hyperplasia	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Cardiomyopathy	Minimal
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney	Renal Tubule	Hyperplasia	Minimal
	Renal Tubule	Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Fatty Change	Minimal
		Hepatocellular Adenoma	Multiple
	Centrilobular	Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Eosinophilic Focus TGLs = 5-14 ]		
	[ Hepatocellular Adenoma TGLs = 1,2,3,4-10+11+12+13+14 ]		
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hyperplasia	Lymphoid, Mild
* Thymus		Atrophy	Moderate

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 191 TMT: 7 SEX: Male DAY ON TEST: 731  
 DOSE: 1.0 G/KG DISP: Terminal Sacrifice HISTO: 0602091

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Kidney
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Testes
* Thyroid Gland	* Trachea		

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Hyperplasia	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Mild
* Liver		Angiectasis	Mild
		Clear Cell Focus	
		Eosinophilic Focus	
		Hepatocellular Adenoma	Multiple
	Centrilobular	Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Hepatocellular Adenoma	TGLs = 2,3,4,5,6,7-11+12+13+14+15+16 ]	
Mesentery	Fat	Necrosis	Moderate
	[ Necrosis	TGLs = 1-10 ]	
* Preputial Gland		Cyst	Mild
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Glandular		Infiltration Cellular	Mononuclear CI, Minimal
* Thymus		Atrophy	Mild
Tooth		Dysplasia	Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	191	<b>TMT:</b>	7	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	731
		<b>DOSE:</b>	1.0 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602091

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* Urinary Bladder

Infiltration Cellular

Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 192 TMT: 7 SEX: Male DAY ON TEST: 731  
 DOSE: 1.0 G/KG DISP: Terminal Sacrifice HISTO: 0602092

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea	* Urinary Bladder	

MISSING

\* Mammary Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Hyperplasia	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney	Renal Tubule	Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Angiectasis	Minimal
		Clear Cell Focus	
		Eosinophilic Focus	
		Fatty Change	Mild
	Centrilobular	Hepatocellular Adenoma	Multiple
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
		[ Eosinophilic Focus TGLs = 2-11 ]	
		[ Hepatocellular Adenoma TGLs = 1,3-10+12 ]	
* Preputial Gland		Cyst	Moderate
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Thymus		Atrophy	Mild

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	192	<b>TMT:</b>	7	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	731
		<b>DOSE:</b>	1.0 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602092

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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Tooth	Epithel Cell	Hyperplasia Dysplasia	Mild Minimal
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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 193	<b>TMT:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 595
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 0602093

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

Blood Vessel	* Bone	* Brain	* Epididymis
* Esophagus	* Eye	* Gallbladder	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Lung	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Seminal Vesicle	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Histiocytic Sarcoma Hyperplasia	Minimal
* Adrenal Medulla		Histiocytic Sarcoma	
* Bone Marrow		Histiocytic Sarcoma	
* Eye			
Note: Both optic nerves were missing			
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart	Myocardium	Cardiomyopathy Mineralization	Mild Mild
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney	Renal Tubule	Histiocytic Sarcoma Mineralization	Minimal
	[ Histiocytic Sarcoma TGLs = 4-4 ]		
* Liver		Histiocytic Sarcoma	
	[ Histiocytic Sarcoma TGLs = 5,6-3+4+5+11+12 ]		
Lymph Node	Renal	Histiocytic Sarcoma	
	[ Histiocytic Sarcoma TGLs = 2-11 ]		
* Lymph Node, Mandibular		Histiocytic Sarcoma	
* Lymph Node, Mesenteric		Histiocytic Sarcoma	
* Nose	Nasolacrim Dct	Inflammation	Suppurative, Mild
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal

\* PROTOCOL REQUIRED TISSUE



TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	193	TMT:	7	SEX:	Male	DAY ON TEST:	595
		DOSE:	1.0 G/KG	DISP:	Natural Death	HISTO:	0602093

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ORGAN AND ACCOUNTABLE SITE STATUS

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* Skin	Subcut Tiss	Histiocytic Sarcoma	
	[ Histiocytic Sarcoma TGLs = 1-10 ]		
* Spleen		Histiocytic Sarcoma	
	[ Histiocytic Sarcoma TGLs = 3-4 ]		
* Stomach, Forestomach		Histiocytic Sarcoma	
* Thymus		Atrophy	Marked

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PRIMARY CAUSE OF DEATH - Liver Histiocytic Sarcoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 194    **TMT:** 7    **SEX:** Male    **DAY ON TEST:** 731  
**DOSE:** 1.0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602094

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                          |                           |                             |
|--------------------------|--------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla        | Blood Vessel             | * Bone                    | * Bone Marrow               |
| * Brain                  | * Esophagus              | * Eye                     | * Gallbladder               |
| * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Islets, Pancreatic     | * Lung                    | * Lymph Node, Mandibular    |
| * Lymph Node, Mesenteric | * Nose                   | * Pancreas                | * Pituitary Gland           |
| * Preputial Gland        | * Seminal Vesicle        | * Skin                    | * Stomach, Forestomach      |
| * Testes                 | * Trachea                | * Urinary Bladder         |                             |

**MISSING**

- |                 |                     |
|-----------------|---------------------|
| * Mammary Gland | * Parathyroid Gland |
|-----------------|---------------------|

**OBSERVATIONS**

- |                            |  |                        |                         |
|----------------------------|--|------------------------|-------------------------|
| * Adrenal Cortex           | Subcapsular                            | Hyperplasia            | Mild                    |
| * Epididymis               |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Harderian Gland          |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Heart                    |  | Lymphoma Malignant     |                         |
| * Intestine Small, Jejunum |  | Adenoma                |                         |
|                            | [ Adenoma TGLs = 4-12 ]                |                        |                         |
| * Kidney                   | Papilla                                | Necrosis               | Minimal                 |
|                            |  | Nephropathy            | Minimal                 |
| * Liver                    |  | Clear Cell Focus       |                         |
|                            |  | Eosinophilic Focus     |                         |
|                            |  | Hepatocellular Adenoma |                         |
|                            | Centrilobular                          | Hypertrophy            | Mild                    |
|                            |  | Infiltration Cellular  | Mononuclear CI, Mild    |
|                            |  | Lymphoma Malignant     |                         |
|                            | [ Eosinophilic Focus TGLs = 3-11 ]     |                        |                         |
|                            | [ Hepatocellular Adenoma TGLs = 2-10 ] |                        |                         |
| * Prostate                 |  | Lymphoma Malignant     |                         |
| * Salivary Glands          |  | Lymphoma Malignant     |                         |
| * Spleen                   |  | Lymphoma Malignant     |                         |
|                            | [ Lymphoma Malignant TGLs = 1-4 ]      |                        |                         |
| * Stomach, Glandular       |  | Lymphoma Malignant     |                         |
| * Thymus                   |  | Atrophy                | Mild                    |

\* PROTOCOL REQUIRED TISSUE

**TDMS No.** 20007 - 06  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
**CAS Number:** 9000-38-8

**Date Report Requested:** 04/13/2009  
**Time Report Requested:** 08:27:00  
**First Dose M/F:** 08/24/04 / 08/23/04  
**Lab:** BAT

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<b>ANIMAL NUM:</b>	194	<b>TMT:</b>	7	<b>SEX:</b>	Male	<b>DAY ON TEST:</b>	731
		<b>DOSE:</b>	1.0 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602094

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* Thyroid Gland  
Tooth

Lymphoma Malignant  
Dysplasia

Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 195 TMT: 7 SEX: Male DAY ON TEST: 732  
 DOSE: 1.0 G/KG DISP: Terminal Sacrifice HISTO: 0602095

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Prostate	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thyroid Gland
* Trachea			

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Epididymis		Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Hyperplasia	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Cardiomyopathy	Minimal
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney	Renal Tubule	Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Fatty Change	Minimal
		Hepatoblastoma	Multiple
		Hepatocellular Adenoma	Multiple
		Hepatocellular Carcinoma	Multiple
	Centrilobular	Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
		Necrosis	Mild
		[ Eosinophilic Focus TGLs = 3-11 ]	
		[ Hepatoblastoma TGLs = 5-4+12 ]	
		[ Hepatocellular Adenoma TGLs = 6,7-13 ]	
		[ Hepatocellular Carcinoma TGLs = 2,4-10+12 ]	
* Lung		Alveolar/Bronchiolar Adenoma	

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	195	TMT:	7	SEX:	Male	DAY ON TEST:	732
		DOSE:	1.0 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602095

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ORGAN AND ACCOUNTABLE SITE STATUS

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[ Alveolar/Bronchiolar Adenoma TGLs = 8-3 ]		
* Preputial Gland	Cyst	Mild
[ Cyst TGLs = 1-8 ]		
* Salivary Glands	Infiltration Cellular	Mononuclear CI, Minimal
* Thymus	Atrophy	Mild
Tooth	Dysplasia	Minimal
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 196	<b>TMT:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 732
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602096

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Nose                     |
| * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        | * Preputial Gland          |
| * Seminal Vesicle         | * Skin                      | * Stomach, Glandular     | * Testes                   |
| * Thyroid Gland           | * Trachea                   |                          |                            |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |  |               |                                  |  |
|--|---------------|----------------------------------|--|
| * Adrenal Cortex                                     | Subcapsular   | Hyperplasia                      | Minimal                                      |
| * Harderian Gland                                    |               | Infiltration Cellular            | Mononuclear CI, Minimal                      |
| * Kidney   | Renal Tubule  | Mineralization                   | Minimal                                      |
|  |               | Nephropathy                      | Minimal                                      |
| * Liver  |               | Angiectasis                      | Mild   |
|  |               | Clear Cell Focus                 |  |
|  |               | Eosinophilic Focus               |  |
|  |               | Fatty Change                     | Minimal                                      |
|  |               | Hepatocellular Adenoma           |  |
|  |               | Hepatocellular Carcinoma         |  |
|  | Centrilobular | Hypertrophy                      | Mild   |
|  |               | Infiltration Cellular            | Mononuclear CI, Minimal                      |
|  |               | Mixed Cell Focus                 |  |
| Note: No corresponding microscopic finding for TGL 1 |               |                                  |  |
|  |               |                                  | [ Eosinophilic Focus TGLs = 3-12 ]           |
|  |               |                                  | [ Hepatocellular Adenoma TGLs = 2-11 ]       |
|  |               |                                  | [ Hepatocellular Carcinoma TGLs = 4-13 ]     |
| * Lung   |               | Alveolar/Bronchiolar Adenoma     |  |
|  |               |                                  | [ Alveolar/Bronchiolar Adenoma TGLs = 6-15 ] |
| * Prostate   |               | Infiltration Cellular            | Mononuclear CI, Minimal                      |
| * Salivary Glands                                    |               | Infiltration Cellular            | Mononuclear CI, Minimal                      |
| * Spleen   |               | Hematopoietic Cell Proliferation | Minimal                                      |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	196	TMT:	7	SEX:	Male	DAY ON TEST:	732
		DOSE:	1.0 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602096

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ORGAN AND ACCOUNTABLE SITE STATUS

---

* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation Squamous Cell Papilloma	Moderate Chronic, Mild
	[ Squamous Cell Papilloma TGLs = 5-14 ]		
* Thymus		Atrophy	Moderate
Tooth		Dysplasia	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 197 TMT: 7 SEX: Male DAY ON TEST: 731  
 DOSE: 1.0 G/KG DISP: Terminal Sacrifice HISTO: 0602097

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Epididymis                | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Pancreas                 |
| * Parathyroid Gland       | * Pituitary Gland           | * Preputial Gland        | * Seminal Vesicle          |
| * Skin                    | * Spleen                    | * Stomach, Forestomach   | * Stomach, Glandular       |
| * Testes                  | * Thyroid Gland             | * Trachea                | * Urinary Bladder          |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                      |               |   |                         |
|----------------------|---------------|---|-------------------------|
| * Adrenal Cortex     | Subcapsular   | Hyperplasia                                 | Minimal                 |
| * Harderian Gland    |               | Infiltration Cellular                       | Mononuclear CI, Minimal |
| * Islets, Pancreatic |               | Hyperplasia                                 | Minimal                 |
| * Kidney             | Renal Tubule  | Hyperplasia                                 | Minimal                 |
|                      | Renal Tubule  | Mineralization                              | Minimal                 |
|                      |               | Nephropathy                                 | Minimal                 |
| * Liver              |               | Clear Cell Focus                            |                         |
|                      |               | Eosinophilic Focus                          |                         |
|                      |               | Fatty Change                                | Mild                    |
|                      | Centrilobular | Hepatocellular Adenoma                      | Multiple                |
|                      |               | Hypertrophy                                 | Mild                    |
|                      |               | Infiltration Cellular                       | Mononuclear CI, Minimal |
|                      |               | Mixed Cell Focus                            |                         |
|                      |               | [ Eosinophilic Focus TGLs = 1,2-10+11 ]     |                         |
|                      |               | [ Hepatocellular Adenoma TGLs = 4,5-13+14 ] |                         |
|                      |               | [ Mixed Cell Focus TGLs = 3-12 ]            |                         |
| * Nose               |               | Inflammation                                | Chronic, Minimal        |
| * Prostate           |               | Infiltration Cellular                       | Mononuclear CI, Minimal |
| * Salivary Glands    |               | Infiltration Cellular                       | Mononuclear CI, Minimal |
| * Thymus             |               | Atrophy                                     | Minimal                 |
| Tooth                |               | Dysplasia                                   | Moderate                |

\* PROTOCOL REQUIRED TISSUE



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 198 TMT: 7 SEX: Male DAY ON TEST: 707  
 DOSE: 1.0 G/KG DISP: Moribund Sacrifice HISTO: 0602098

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Eye
* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Preputial Gland	* Seminal Vesicle	* Skin
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart	Artery	Infiltration Cellular	Mononuclear CI, Minimal
* Kidney	Renal Tubule	Mineralization	Minimal
		Nephropathy	Mild
* Liver		Eosinophilic Focus	
		Fatty Change	Minimal
		Hepatocellular Adenoma	
	Centrilobular	Hepatocellular Carcinoma	
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
		Necrosis	Moderate
	[ Hepatocellular Adenoma TGLs = 1-10 ]		
	[ Hepatocellular Carcinoma TGLs = 2-11 ]		
* Lung		Hepatocellular Carcinoma	Metastatic (Liver)
	[ Hepatocellular Carcinoma TGLs = 3,4,5,6,7-12+13+14 ]		
* Pituitary Gland		Cyst	Minimal
* Prostate		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Mild
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Chronic, Mild

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

---

ANIMAL NUM:	198	TMT:	7	SEX:	Male	DAY ON TEST:	707
		DOSE:	1.0 G/KG	DISP:	Moribund Sacrifice	HISTO:	0602098

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ORGAN AND ACCOUNTABLE SITE STATUS

---

[ Necrosis TGLs = 8-15 ]	Necrosis	Mild
* Thymus	Atrophy	Marked
Tooth	Dysplasia	Minimal
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

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PRIMARY CAUSE OF DEATH - Liver Hepatocellular Carcinoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 199    **TMT:** 7    **SEX:** Male    **DAY ON TEST:** 732  
**DOSE:** 1.0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602099

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla        | Blood Vessel               | * Bone                    | * Bone Marrow               |
| * Brain                  | * Esophagus                | * Eye                     | * Gallbladder               |
| * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    | * Lymph Node, Mesenteric    |
| * Nose                   | * Pancreas                 | * Parathyroid Gland       | * Pituitary Gland           |
| * Preputial Gland        | * Seminal Vesicle          | * Stomach, Glandular      | * Testes                    |
| * Thyroid Gland          | * Trachea                  | * Urinary Bladder         |                             |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                          |  |                          |                         |
|--------------------------|--|--------------------------|-------------------------|
| * Adrenal Cortex         | Subcapsular                              | Hyperplasia              | Minimal                 |
| * Epididymis             |  | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Harderian Gland        |  | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Heart                  |  | Cardiomyopathy           | Minimal                 |
| * Islets, Pancreatic     |  | Hyperplasia              | Minimal                 |
| * Kidney                 | Renal Tubule                             | Mineralization           | Minimal                 |
|                          |  | Nephropathy              | Mild                    |
| * Liver                  |  | Eosinophilic Focus       |                         |
|                          |  | Hepatoblastoma           |                         |
|                          | Centrilobular                            | Hepatocellular Carcinoma |                         |
|                          |  | Hypertrophy              | Mild                    |
|                          |  | Infiltration Cellular    | Mononuclear CI, Minimal |
|                          |  | Mixed Cell Focus         |                         |
|                          | [ Eosinophilic Focus TGLs = 2-11 ]       |                          |                         |
|                          | [ Hepatoblastoma TGLs = 5-11 ]           |                          |                         |
|                          | [ Hepatocellular Carcinoma TGLs = 1-10 ] |                          |                         |
| Lymph Node               | Renal Iliac                              | Lymphoma Malignant       |                         |
|                          | [ Lymphoma Malignant TGLs = 3-12 ]       | Lymphoma Malignant       |                         |
|                          | [ Lymphoma Malignant TGLs = 4-13 ]       |                          |                         |
| * Lymph Node, Mandibular |  | Lymphoma Malignant       |                         |
| * Prostate               |  | Lymphoma Malignant       |                         |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	199	TMT:	7	SEX:	Male	DAY ON TEST:	732
		DOSE:	1.0 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602099

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ORGAN AND ACCOUNTABLE SITE STATUS

---

* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Skin	Subcut Tiss	Lymphoma Malignant	
* Spleen		Lymphoma Malignant	
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
	[ Hyperplasia TGLs = 6-14 ]		
* Thymus		Lymphoma Malignant	
Tooth		Dysplasia	Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 200	<b>TMT:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 732
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602100

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla        | Blood Vessel               | * Bone                    | * Bone Marrow               |
| * Brain                  | * Esophagus                | * Eye                     | * Gallbladder               |
| * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    | * Lymph Node, Mandibular    |
| * Lymph Node, Mesenteric | * Nose                     | * Pancreas                | * Parathyroid Gland         |
| * Pituitary Gland        | * Preputial Gland          | * Seminal Vesicle         | * Skin                      |
| * Spleen                 | * Testes                   | * Thyroid Gland           | * Trachea                   |

**MISSING**

- \* Mammary Gland

**OBSERVATIONS**

- |                        |  |  |                                     |
|------------------------|--|--|-------------------------------------|
| * Adrenal Cortex       | Subcapsular                                      | Hyperplasia<br>Vacuolization Cytoplasmic   | Mild<br>Minimal                     |
| * Epididymis           |  | Infiltration Cellular  | Mononuclear CI, Minimal             |
| * Harderian Gland      |  | Hyperplasia<br>Infiltration Cellular   | Moderate<br>Mononuclear CI, Minimal |
| * Heart                |  | Cardiomyopathy   | Minimal                             |
| * Islets, Pancreatic   |  | Hyperplasia  | Minimal                             |
| * Kidney               | Renal Tubule                                     | Mineralization<br>Nephropathy  | Minimal<br>Minimal                  |
| * Liver                | Centrilobular                                    | Eosinophilic Focus<br>Hepatoblastoma<br>Hepatocellular Adenoma<br>Hepatocellular Carcinoma | Multiple                            |
|                        |  | Hypertrophy<br>Infiltration Cellular   | Mild<br>Mononuclear CI, Minimal     |
|                        | [ Eosinophilic Focus TGLs = 7-11 ]               |  |                                     |
|                        | [ Hepatoblastoma TGLs = 5-14 ]                   |  |                                     |
|                        | [ Hepatocellular Adenoma TGLs = 2,3,4-11+12+13 ] |  |                                     |
|                        | [ Hepatocellular Carcinoma TGLs = 1-10 ]         |  |                                     |
| * Prostate             |  | Infiltration Cellular  | Mononuclear CI, Minimal             |
| * Salivary Glands      |  | Infiltration Cellular  | Mononuclear CI, Minimal             |
| * Stomach, Forestomach | Epithelium                                       | Hyperplasia  | Mild                                |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	200	TMT:	7	SEX:	Male	DAY ON TEST:	732
		DOSE:	1.0 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602100

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ORGAN AND ACCOUNTABLE SITE STATUS

---

[ Hyperplasia TGLs = 6-15 ]	Inflammation	Chronic, Minimal
* Stomach, Glandular Glands	Ectasia	Mild
* Thymus	Atrophy	Mild
Tooth	Dysplasia	Minimal
* Urinary Bladder	Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 201	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602101

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Hyperplasia Infiltration Cellular	Minimal Mononuclear CI, Minimal
* Kidney		Nephropathy	Minimal
* Liver		Infiltration Cellular Mixed Cell Focus	Mononuclear CI, Minimal
	[ Mixed Cell Focus TGLs = 1-10 ]		
* Lung		Lymphoma Malignant	
Lymph Node	Mediastinal	Lymphoma Malignant	
	[ Lymphoma Malignant TGLs = 5-12 ]		
* Lymph Node, Mandibular		Lymphoma Malignant	
	[ Lymphoma Malignant TGLs = 2-11 ]		
* Lymph Node, Mesenteric		Lymphoma Malignant	
	[ Lymphoma Malignant TGLs = 4-5 ]		
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Lymphoma Malignant	
	[ Lymphoma Malignant TGLs = 3-4 ]		
* Thymus		Lymphoma Malignant	
* Urinary Bladder		Lymphoma Malignant	
* Uterus	Endometrium	Hyperplasia	Cystic, Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 202    **TMT:** 2    **SEX:** Female    **DAY ON TEST:** 731  
**DOSE:** 0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602102

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Blood Vessel           | * Bone Marrow              | * Brain                   | * Clitoral Gland            |
| * Esophagus              | * Eye                      | * Gallbladder             | * Harderian Gland           |
| * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      | * Kidney                    |
| * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Mammary Gland           | * Nose                      |
| * Ovary                  | * Pancreas                 | * Parathyroid Gland       | * Pituitary Gland           |
| * Salivary Glands        | * Skin                     | * Stomach, Forestomach    | * Stomach, Glandular        |
| * Thymus                 | * Thyroid Gland            | * Trachea                 |                             |

**OBSERVATIONS**

- |                   |  |                                  |                         |
|-------------------|--|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                              | Hyperplasia                      | Mild                    |
| * Adrenal Medulla |  | Hyperplasia                      | Minimal                 |
| * Bone            |  | Fibrosis                         | Mild                    |
| * Heart           |  | Cardiomyopathy                   | Minimal                 |
| * Liver           |  | Fatty Change                     | Minimal                 |
|                   |  | Hepatocellular Adenoma           |                         |
|                   |  | Hepatocellular Carcinoma         |                         |
|                   |  | Infiltration Cellular            | Mononuclear CI, Minimal |
|                   | [ Hepatocellular Adenoma TGLs = 3-11 ]   |                                  |                         |
|                   | [ Hepatocellular Carcinoma TGLs = 4-12 ] |                                  |                         |
| * Lung            |  | Hepatocellular Carcinoma         | Metastatic (Liver)      |
| Mesentery         | Fat                                      | Necrosis                         | Moderate                |
|                   | [ Necrosis TGLs = 2-10 ]                 |                                  |                         |
| * Spleen          |  | Hematopoietic Cell Proliferation | Mild                    |
| * Urinary Bladder |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                              | Hyperplasia                      | Cystic, Mild            |
|                   | [ Hyperplasia TGLs = 1-7 ]               |                                  |                         |



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 203	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602103

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Nose                      | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Salivary Glands           | * Skin                   | * Stomach, Forestomach     |
| * Stomach, Glandular      | * Thyroid Gland             | * Trachea                |                            |

**MISSING**

- \* Ovary

**OBSERVATIONS**

- |                   |  |                                  |                         |
|-------------------|--|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                            | Hyperplasia                      | Mild                    |
| * Harderian Gland |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Kidney          |  | Mineralization                   | Minimal                 |
|                   |  | Nephropathy                      | Mild                    |
| * Liver           |  | Fatty Change                     | Mild                    |
|                   |  | Hepatocellular Adenoma           |                         |
|                   |  | Infiltration Cellular            | Mononuclear CI, Minimal |
|                   | [ Hepatocellular Adenoma TGLs = 1-10 ] |                                  |                         |
| Lymph Node        | Pancreatic                             | Lymphoma Malignant               |                         |
|                   | [ Lymphoma Malignant TGLs = 2-11 ]     |                                  |                         |
| * Spleen          |  | Hematopoietic Cell Proliferation | Mild                    |
| * Thymus          |  | Atrophy                          | Minimal                 |
| * Urinary Bladder |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                            | Hyperplasia                      | Cystic, Mild            |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 204    **TMT:** 2    **SEX:** Female    **DAY ON TEST:** 729  
**DOSE:** 0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602104

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone Marrow              | * Brain                   |
| * Clitoral Gland            | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Mammary Gland           |
| * Nose                      | * Pancreas               | * Parathyroid Gland        | * Pituitary Gland         |
| * Skin                      | * Spleen                 | * Stomach, Forestomach     | * Thymus                  |
| * Thyroid Gland             | * Trachea                |                            |                           |

**OBSERVATIONS**

- |                      |                            |                       |                         |
|----------------------|----------------------------|-----------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                | Hyperplasia           | Mild                    |
| * Bone               |                            | Fibrosis              | Moderate                |
| * Harderian Gland    |                            | Infiltration Cellular | Mononuclear CI, Minimal |
| * Kidney             |                            | Mineralization        | Minimal                 |
|                      |                            | Nephropathy           | Minimal                 |
| * Liver              |                            | Fatty Change          | Minimal                 |
|                      |                            | Infiltration Cellular | Mononuclear CI, Minimal |
|                      |                            | Necrosis              | Minimal                 |
|                      |                            | Tension Lipidosis     |                         |
| * Ovary              |                            | Hemorrhage            | Moderate                |
|                      |                            | Lymphoma Malignant    |                         |
|                      | [ Hemorrhage TGLs = 2-7 ]  |                       |                         |
| * Salivary Glands    |                            | Infiltration Cellular | Mononuclear CI, Minimal |
| * Stomach, Glandular |                            | Infiltration Cellular | Mononuclear CI, Minimal |
| * Urinary Bladder    |                            | Infiltration Cellular | Mononuclear CI, Minimal |
| * Uterus             | Endometrium                | Hyperplasia           | Cystic, Moderate        |
|                      | [ Hyperplasia TGLs = 1-7 ] |                       |                         |

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

ANIMAL NUM: 205 TMT: 2 SEX: Female DAY ON TEST: 544  
DOSE: 0 G/KG DISP: Natural Death HISTO: 0602105

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

MISSING

\* Clitoral Gland \* Pancreas \* Spleen

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Histiocytic Sarcoma Hyperplasia	Minimal
* Eye	Note: Both optic nerves were missing		
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Liver		Fatty Change	Moderate
* Lymph Node, Mandibular		Histiocytic Sarcoma	
* Thymus		Histiocytic Sarcoma	

PRIMARY CAUSE OF DEATH - Thymus Histiocytic Sarcoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 206	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602106

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Parathyroid Gland
* Pituitary Gland	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea		

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Fatty Change	Mild
		Infiltration Cellular	Mononuclear CI, Mild
* Pancreas		Inflammation	Chronic, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hyperplasia	Lymphoid, Minimal
* Thymus		Atrophy	Mild
		Infiltration Cellular	Histiocyte, Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Moderate

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 207    **TMT:** 2    **SEX:** Female    **DAY ON TEST:** 729  
**DOSE:** 0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602107

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Nose                      | * Ovary                  | * Pancreas                 |
| * Parathyroid Gland       | * Pituitary Gland           | * Skin                   | * Stomach, Forestomach     |
| * Stomach, Glandular      | * Thyroid Gland             | * Trachea                |                            |

**OBSERVATIONS**

- |                   |   |                                  |                         |
|-------------------|---|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                                   | Hyperplasia                      | Mild                    |
| * Harderian Gland |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Kidney          |   | Mineralization                   | Minimal                 |
|                   |   | Nephropathy                      | Mild                    |
| * Liver           |   | Fatty Change                     | Mild                    |
|                   |   | Hepatocellular Carcinoma         | Multiple                |
|                   |   | Infiltration Cellular            | Mononuclear CI, Minimal |
|                   | [ Hepatocellular Carcinoma TGLs = 1,2-10+11 ] |                                  |                         |
| * Salivary Glands |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen          |   | Hematopoietic Cell Proliferation | Mild                    |
| * Thymus          |   | Atrophy                          | Mild                    |
|                   |   | Infiltration Cellular            | Histiocyte, Mild        |
| * Urinary Bladder |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                                   | Hyperplasia                      | Cystic, Mild            |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 208    **TMT:** 2    **SEX:** Female    **DAY ON TEST:** 731  
**DOSE:** 0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602108

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone Marrow              | * Brain                   |
| * Clitoral Gland            | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Mammary Gland           |
| * Nose                      | * Ovary                  | * Pancreas                 | * Parathyroid Gland       |
| * Pituitary Gland           | * Skin                   | * Stomach, Forestomach     | * Stomach, Glandular      |
| * Thyroid Gland             | * Trachea                | * Urinary Bladder          |                           |

**OBSERVATIONS**

- |                   |                                    |                                  |                         |
|-------------------|------------------------------------|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                        | Hyperplasia                      | Mild                    |
| * Bone            |                                    | Fibrosis                         | Mild                    |
| * Harderian Gland |                                    | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Kidney          | Renal Tubule                       | Hyperplasia                      | Minimal                 |
|                   |                                    | Mineralization                   | Minimal                 |
|                   |                                    | Nephropathy                      | Minimal                 |
| * Liver           |                                    | Angiectasis                      | Minimal                 |
|                   |                                    | Eosinophilic Focus               |                         |
|                   |                                    | Fatty Change                     | Mild                    |
|                   |                                    | Infiltration Cellular            | Mononuclear CI, Minimal |
|                   |                                    | Mixed Cell Focus                 |                         |
|                   | [ Eosinophilic Focus TGLs = 2-10 ] |                                  |                         |
|                   | [ Mixed Cell Focus TGLs = 1-4 ]    |                                  |                         |
| * Salivary Glands |                                    | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen          |                                    | Hematopoietic Cell Proliferation | Minimal                 |
| * Thymus          |                                    | Atrophy                          | Mild                    |
| * Uterus          | Endometrium                        | Hyperplasia                      | Cystic, Minimal         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 209    **TMT:** 2    **SEX:** Female    **DAY ON TEST:** 684  
**DOSE:** 0 G/KG    **DISP:** Moribund Sacrifice    **HISTO:** 0602109

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Clitoral Gland            | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Kidney                    | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Mammary Gland           |
| * Nose                      | * Pancreas               | * Parathyroid Gland        | * Skin                    |
| * Spleen                    | * Stomach, Glandular     | * Thyroid Gland            | * Trachea                 |
| * Uterus                    |                          |                            |                           |

**OBSERVATIONS**

- |                        |  |                              |                         |
|------------------------|--|------------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                                  | Hyperplasia                  | Mild                    |
| * Brain                | Hypothalamus                                 | Compression                  | Marked                  |
| * Eye                  | Note: Both optic nerves were missing         |                              |                         |
| * Harderian Gland      |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Liver                |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Lung                 | [ Alveolar/Bronchiolar Adenoma TGLs = 2-11 ] | Alveolar/Bronchiolar Adenoma |                         |
| * Ovary                |  | Cystadenoma                  |                         |
| * Pituitary Gland      | Pars Intermed<br>[ Adenoma TGLs = 1-10 ]     | Adenoma                      |                         |
| * Salivary Glands      |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Stomach, Forestomach | Epithelium<br>[ Hyperplasia TGLs = 3-12 ]    | Hyperplasia<br>Inflammation  | Mild<br>Chronic, Mild   |
| * Thymus               |  | Atrophy                      | Moderate                |
| * Urinary Bladder      |  | Infiltration Cellular        | Mononuclear CI, Minimal |

**PRIMARY CAUSE OF DEATH** - Pituitary Gland Pars Intermed Adenoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 210    **TMT:** 2    **SEX:** Female    **DAY ON TEST:** 730  
**DOSE:** 0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602110

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	Ear	* Esophagus
* Eye	* Gallbladder	* Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Intestine Small, Duodenum		Adenoma	
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Infiltration Cellular	Mononuclear CI, Minimal
* Ovary			
Note: One ovary was missing			
* Spleen		Hematopoietic Cell Proliferation	Moderate
* Thymus		Atrophy	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Moderate
	[ Hyperplasia TGLs = 1-7 ]		



TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	211	TMT:	2	SEX:	Female	DAY ON TEST:	729
		DOSE:	0 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602111

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ORGAN AND ACCOUNTABLE SITE STATUS

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NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

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OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Fatty Change	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
* Thymus		Atrophy	Mild
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 212 TMT: 2 SEX: Female DAY ON TEST: 731  
 DOSE: 0 G/KG DISP: Terminal Sacrifice HISTO: 0602112

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Fatty Change	Mild
		Hepatocellular Adenoma	
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
	[ Eosinophilic Focus TGLs = 5-12 ]		
	[ Hepatocellular Adenoma TGLs = 1-10 ]		
	[ Mixed Cell Focus TGLs = 4-11 ]		
* Ovary		Cystadenoma	
	[ Cystadenoma TGLs = 2-7 ]		
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Mild
		Hyperplasia	Lymphoid, Mild
* Thymus		Atrophy	Mild
		Infiltration Cellular	Histiocyte, Mild
* Uterus	Endometrium	Hyperplasia	Cystic, Moderate
	[ Hyperplasia TGLs = 3-7 ]		

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 213	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602113

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Nose                      | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Skin                      | * Stomach, Forestomach   | * Stomach, Glandular       |
| * Thymus                  | * Thyroid Gland             | * Trachea                |                            |

**OBSERVATIONS**

- |                   |                            |                                  |                         |
|-------------------|----------------------------|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                | Hyperplasia                      | Mild                    |
| * Harderian Gland |                            | Atrophy                          | Minimal                 |
|                   |                            | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Liver           |                            | Fatty Change                     | Minimal                 |
|                   |                            | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Lung            | Alveolar Epith             | Hyperplasia                      | Minimal                 |
| * Ovary           |                            | Cystadenoma                      |                         |
|                   | [ Cystadenoma TGLs = 1-7 ] |                                  |                         |
| * Salivary Glands |                            | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen          |                            | Hematopoietic Cell Proliferation | Mild                    |
| * Urinary Bladder |                            | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                | Hyperplasia                      | Cystic, Minimal         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 214	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602114

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Clitoral Gland           | * Esophagus               | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic      | * Mammary Gland             | * Parathyroid Gland      |
| * Pituitary Gland          | * Skin                    | * Stomach, Forestomach      | * Stomach, Glandular     |
| * Thyroid Gland            | * Trachea                 |                             |                          |

**OBSERVATIONS**

- |                          |                                      |                       |                         |
|--------------------------|--------------------------------------|-----------------------|-------------------------|
| * Adrenal Cortex         | Subcapsular                          | Hyperplasia           | Mild                    |
| * Brain                  |                                      | Lymphoma Malignant    |                         |
| * Eye                    |                                      | Lymphoma Malignant    |                         |
| * Gallbladder            |                                      | Lymphoma Malignant    |                         |
| * Harderian Gland        |                                      | Lymphoma Malignant    |                         |
| * Kidney                 |                                      | Lymphoma Malignant    | Minimal                 |
|                          |                                      | Mineralization        | Minimal                 |
|                          |                                      | Nephropathy           |                         |
| * Liver                  |                                      | Fatty Change          | Minimal                 |
|                          |                                      | Infiltration Cellular | Mononuclear CI, Minimal |
|                          |                                      | Lymphoma Malignant    |                         |
|                          | [ Lymphoma Malignant TGLs = 2-10 ]   |                       |                         |
| * Lung                   |                                      | Lymphoma Malignant    |                         |
| * Lymph Node, Mandibular |                                      | Lymphoma Malignant    |                         |
|                          | [ Lymphoma Malignant TGLs = 4-6+10 ] |                       |                         |
| * Lymph Node, Mesenteric |                                      | Lymphoma Malignant    |                         |
|                          | [ Lymphoma Malignant TGLs = 3-5 ]    |                       |                         |
| * Nose                   |                                      | Lymphoma Malignant    |                         |
| * Ovary                  |                                      | Lymphoma Malignant    |                         |
| * Pancreas               |                                      | Lymphoma Malignant    |                         |
| * Salivary Glands        |                                      | Lymphoma Malignant    |                         |
| * Spleen                 |                                      | Lymphoma Malignant    |                         |
|                          | [ Lymphoma Malignant TGLs = 1-4 ]    |                       |                         |
| * Thymus                 |                                      | Atrophy               | Mild                    |
|                          |                                      | Lymphoma Malignant    |                         |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	214	<b>TMT:</b>	2	<b>SEX:</b>	Female	<b>DAY ON TEST:</b>	731
		<b>DOSE:</b>	0 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602114

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* Urinary Bladder  
\* Uterus

Endometrium

Lymphoma Malignant  
Hyperplasia

Cystic, Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 215	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602115

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Ovary	* Pancreas	* Parathyroid Gland	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Nephropathy	Minimal
* Liver		Fatty Change	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
* Lung		Inflammation	Minimal
* Nose		Inflammation	Chronic, Minimal
* Pituitary Gland	Pars Distalis	Adenoma	
[ Adenoma TGLs = 1-6 ]			
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Thymus		Atrophy	Moderate
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

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<b>ANIMAL NUM:</b> 216	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602116

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Mammary Gland            |
| * Nose                    | * Pancreas                  | * Parathyroid Gland      | * Pituitary Gland          |
| * Skin                    | * Spleen                    | * Stomach, Forestomach   | * Stomach, Glandular       |
| * Thymus                  | * Thyroid Gland             | * Trachea                |                            |
- 

**OBSERVATIONS**

- |                      |             |                       |                         |
|----------------------|-------------|-----------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular | Hyperplasia           | Mild                    |
| * Harderian Gland    |             | Infiltration Cellular | Mononuclear CI, Minimal |
| * Islets, Pancreatic |             | Adenoma               |                         |
| * Kidney             |             | Metaplasia            | Osseous, Minimal        |
| * Liver              |             | Fatty Change          | Minimal                 |
|                      |             | Infiltration Cellular | Mononuclear CI, Minimal |
| * Ovary              |             | Cystadenoma           |                         |
| * Salivary Glands    |             | Infiltration Cellular | Mononuclear CI, Minimal |
| * Urinary Bladder    |             | Infiltration Cellular | Mononuclear CI, Minimal |
| * Uterus             | Endometrium | Hyperplasia           | Cystic, Minimal         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 217    **TMT:** 2    **SEX:** Female    **DAY ON TEST:** 729  
**DOSE:** 0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602117

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone Marrow            | * Brain                    |
| * Clitoral Gland          | * Esophagus                 | * Eye                    | * Gallbladder              |
| * Harderian Gland         | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Mammary Gland            |
| * Nose                    | * Ovary                     | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Salivary Glands           | * Skin                   | * Spleen                   |
| * Stomach, Forestomach    | * Thyroid Gland             | * Trachea                |                            |

**OBSERVATIONS**

- |                      |                            |                       |                         |
|----------------------|----------------------------|-----------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                | Hyperplasia           | Mild                    |
| * Bone               |                            | Fibrosis              | Minimal                 |
| * Kidney             |                            | Nephropathy           | Mild                    |
| * Liver              |                            | Fatty Change          | Minimal                 |
|                      |                            | Infiltration Cellular | Mononuclear CI, Minimal |
|                      |                            | Necrosis              | Minimal                 |
| * Lung               | Alveolar Epith             | Hyperplasia           | Minimal                 |
| * Stomach, Glandular | Glands                     | Ectasia               | Minimal                 |
| * Thymus             |                            | Atrophy               | Mild                    |
| * Urinary Bladder    |                            | Infiltration Cellular | Mononuclear CI, Minimal |
| * Uterus             | Endometrium                | Hyperplasia           | Cystic, Moderate        |
|                      | [ Hyperplasia TGLs = 1-7 ] |                       |                         |



TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b> 218	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 560
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 0602118

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ORGAN AND ACCOUNTABLE SITE STATUS

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**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Harderian Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea			

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**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Liver		Fatty Change	Mild
		Hepatocellular Adenoma	
	[ Hepatocellular Adenoma TGLs = 1-10 ]	Infiltration Cellular	Mononuclear CI, Minimal
* Nose		Inflammation	Chronic, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Thymus		Atrophy	Moderate
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild

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PRIMARY CAUSE OF DEATH - UNCERTAIN

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 219    **TMT:** 2    **SEX:** Female    **DAY ON TEST:** 701  
**DOSE:** 0 G/KG    **DISP:** Moribund Sacrifice    **HISTO:** 0602119

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone Marrow              | * Brain                   |
| * Clitoral Gland            | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Mammary Gland           |
| * Nose                      | * Ovary                  | * Pancreas                 | * Parathyroid Gland       |
| * Pituitary Gland           | * Salivary Glands        | * Skin                     | * Stomach, Glandular      |
| * Thyroid Gland             | * Trachea                |                            |                           |

**OBSERVATIONS**

- |                        |                                  |                       |                         |
|------------------------|----------------------------------|-----------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                      | Hyperplasia           | Mild                    |
| * Bone                 |                                  | Fibrosis              | Minimal                 |
| * Harderian Gland      |                                  | Infiltration Cellular | Mononuclear CI, Minimal |
| * Kidney               |                                  | Mineralization        | Minimal                 |
|                        |                                  | Nephropathy           | Mild                    |
| * Liver                |                                  | Fatty Change          | Minimal                 |
|                        |                                  | Infiltration Cellular | Mononuclear CI, Minimal |
|                        |                                  | Mixed Cell Focus      |                         |
|                        |                                  | Necrosis              | Mild                    |
|                        |                                  | Sarcoma               |                         |
|                        |                                  | Tension Lipidosis     |                         |
|                        | [ Mixed Cell Focus TGLs = 3-10 ] |                       |                         |
|                        | [ Sarcoma TGLs = 1-10 ]          |                       |                         |
| Mesentery              | Fat                              | Necrosis              | Mild                    |
|                        | [ Necrosis TGLs = 2-11 ]         |                       |                         |
| Peripheral Nerve       | Axon                             | Degeneration          | Moderate                |
|                        |                                  | Infiltration Cellular | Mononuclear CI, Mild    |
| Spinal Cord            | Axon                             | Degeneration          | Moderate                |
|                        |                                  | Sarcoma               | Metastatic (Liver)      |
| * Spleen               |                                  | Hyperplasia           | Lymphoid, Mild          |
| * Stomach, Forestomach | Epithelium                       | Hyperplasia           | Minimal                 |
| * Thymus               |                                  | Atrophy               | Moderate                |
| * Urinary Bladder      |                                  | Infiltration Cellular | Mononuclear CI, Minimal |
| * Uterus               | Endometrium                      | Hyperplasia           | Cystic, Minimal         |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

---

ANIMAL NUM: 219    TMT: 2  
                  DOSE: 0 G/KG

SEX: Female  
DISP: Moribund Sacrifice

DAY ON TEST: 701  
              HISTO: 0602119

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ORGAN AND ACCOUNTABLE SITE STATUS

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PRIMARY CAUSE OF DEATH        - Liver Sarcoma

---

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 220	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602120

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                          |                           |
|-----------------------------|--------------------------|--------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone Marrow            | * Brain                   |
| * Clitoral Gland            | * Esophagus              | * Eye                    | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Islets, Pancreatic     | * Lung                    |
| * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Mammary Gland          | * Nose                    |
| * Ovary                     | * Pancreas               | * Parathyroid Gland      | * Pituitary Gland         |
| * Salivary Glands           | * Skin                   | * Stomach, Forestomach   | * Stomach, Glandular      |
| * Thyroid Gland             | * Trachea                |                          |                           |

**OBSERVATIONS**

- |  |                                    |                                  |                         |
|--|------------------------------------|----------------------------------|-------------------------|
| * Adrenal Cortex   | Subcapsular                        | Hyperplasia                      | Mild                    |
| * Bone   |                                    | Fibrosis                         | Minimal                 |
| * Clitoral Gl  |                                    |                                  |                         |
| Note: One clitoral gland was missing (some ductal tissue from this gland was on slide 8) |                                    |                                  |                         |
| * Harderian Gland  |                                    | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Intestine Small, Jejunum   |                                    | Adenoma                          |                         |
| * Kidney   |                                    | Mineralization                   | Minimal                 |
|  |                                    | Nephropathy                      | Minimal                 |
| * Liver  |                                    | Eosinophilic Focus               |                         |
|  |                                    | Fatty Change                     | Minimal                 |
|  |                                    | Infiltration Cellular            | Mononuclear CI, Minimal |
|  |                                    | Mixed Cell Focus                 |                         |
|  | [ Eosinophilic Focus TGLs = 2-11 ] |                                  |                         |
|  | [ Mixed Cell Focus TGLs = 1-10 ]   |                                  |                         |
| * Spleen   |                                    | Hematopoietic Cell Proliferation | Minimal                 |
| * Thymus   |                                    | Atrophy                          | Minimal                 |
| * Urinary Bladder  |                                    | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus   | Endometrium                        | Hyperplasia                      | Cystic, Mild            |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 221	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602121

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Nose                      | * Ovary                  | * Pancreas                 |
| * Parathyroid Gland       | * Pituitary Gland           | * Skin                   | * Stomach, Forestomach     |
| * Stomach, Glandular      | * Thyroid Gland             | * Trachea                | * Urinary Bladder          |
| * Uterus                  |                             |                          |                            |

**OBSERVATIONS**

- |                   |  |                                  |                         |
|-------------------|--|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular  | Hyperplasia                      | Mild                    |
| * Harderian Gland |  | Hyperplasia                      | Mild                    |
| * Kidney          |  | Metaplasia                       | Osseous, Mild           |
|                   |  | Nephropathy                      | Minimal                 |
| * Liver           |  | Fatty Change                     | Mild                    |
|                   |  | Hepatocellular Adenoma           |                         |
|                   |  | Infiltration Cellular            | Mononuclear CI, Minimal |
|                   | [ Hepatocellular Adenoma TGLs = 2-11 ]   |                                  |                         |
| * Ovary           |  |                                  |                         |
|                   | Note: One ovary was missing  |                                  |                         |
| * Salivary Glands |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| Skeletal Muscle   |  | Rhabdomyosarcoma                 |                         |
|                   | Note: TGL 1 was described grossly as mammary mass, but microscopic suggests skeletal muscle neoplasm |                                  |                         |
|                   | [ Rhabdomyosarcoma TGLs = 1-10 ]   |                                  |                         |
| * Spleen          |  | Hematopoietic Cell Proliferation | Mild                    |
| * Thymus          |  | Atrophy                          | Mild                    |

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

ANIMAL NUM: 222 TMT: 2 DOSE: 0 G/KG

SEX: Female DISP: Natural Death

DAY ON TEST: 581 HISTO: 0602122

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- \* Adrenal Medulla, \* Brain, \* Gallbladder, \* Intestine Small, Duodenum, \* Lymph Node, Mesenteric, \* Parathyroid Gland, \* Stomach, Glandular, \* Uterus, Blood Vessel, \* Clitoral Gland, \* Intestine Large, Cecum, \* Intestine Small, Ileum, \* Mammary Gland, \* Pituitary Gland, \* Thyroid Gland, \* Bone, \* Esophagus, \* Intestine Large, Colon, \* Intestine Small, Jejunum, \* Ovary, \* Skin, \* Trachea, \* Bone Marrow, \* Eye, \* Intestine Large, Rectum, \* Islets, Pancreatic, \* Pancreas, \* Stomach, Forestomach, \* Urinary Bladder

MISSING

- \* Lymph Node, Mandibular

OBSERVATIONS

- \* Adrenal Cortex Subcapsular Hyperplasia Minimal
\* Harderian Gland Infiltration Cellular Mononuclear CI, Minimal
\* Heart [ Alveolar/Bronchiolar Carcinoma TGLs = 1-3 ] Alveolar/Bronchiolar Carcinoma Metastatic (Lung)
\* Kidney [ Alveolar/Bronchiolar Carcinoma TGLs = 3,4-11+12 ] Alveolar/Bronchiolar Carcinoma Metastatic (Lung)
\* Liver Fatty Change Minimal
\* Lung [ Alveolar/Bronchiolar Carcinoma TGLs = 2,5-10+13 ] Alveolar/Bronchiolar Carcinoma Multiple
\* Nose Olfactory Epi Degeneration Mild
\* Salivary Glands Infiltration Cellular Mononuclear CI, Minimal
\* Spleen Lymph Follic Atrophy Mild
Hematopoietic Cell Proliferation Moderate
\* Thymus Atrophy Marked
Epithel Cell Hyperplasia Minimal

PRIMARY CAUSE OF DEATH - Lung Alveolar/Bronchiolar Carcinoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 223	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602123

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Brain	Chor Plexus	Infiltration Cellular	Mononuclear CI, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Nephropathy	Mild
* Liver		Infiltration Cellular	Mononuclear CI, Marked
	[ Infiltration Cellular TGLs = 2-10 ]		
* Lymph Node, Mandibular		Hyperplasia	Lymphoid, Moderate
* Ovary		Luteoma	
* Pituitary Gland	Pars Distalis	Hyperplasia	Marked
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Moderate
* Thymus		Hyperplasia	Histiocytic, Moderate
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Mild
* Uterus	Endometrium	Hyperplasia	Cystic, Moderate
	[ Hyperplasia TGLs = 1-7 ]		

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 224    **TMT:** 2    **SEX:** Female    **DAY ON TEST:** 730  
**DOSE:** 0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602124

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Nose                      | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Skin                      | * Stomach, Forestomach   | * Stomach, Glandular       |
| * Thyroid Gland           | * Trachea                   | * Urinary Bladder        |                            |

**OBSERVATIONS**

- |                   |             |                                  |                         |
|-------------------|-------------|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular | Hyperplasia                      | Mild                    |
| * Harderian Gland |             | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Kidney          |             | Nephropathy                      | Minimal                 |
| * Liver           |             | Fatty Change                     | Minimal                 |
|                   |             | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Ovary           |             | Angiectasis                      | Mild                    |
| * Salivary Glands |             | Infiltration Cellular            | Mononuclear CI, Mild    |
| * Spleen          |             | Hematopoietic Cell Proliferation | Minimal                 |
| * Thymus          |             | Atrophy                          | Minimal                 |
| * Uterus          | Endometrium | Hyperplasia                      | Cystic, Moderate        |
|                   |             | Metaplasia                       | Squamous, Mild          |
|                   |             | Polyp Stromal                    |                         |
- [ Hyperplasia TGLs = 1-7 ]



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 225 TMT: 2 SEX: Female DAY ON TEST: 610  
 DOSE: 0 G/KG DISP: Natural Death HISTO: 0602125

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia Mineralization Vacuolization Cytoplasmic	Mild Minimal Minimal
* Bone		Fibrosis	Minimal
* Clitoral GI			
Note: One clitoral gland was missing			
* Liver		Fatty Change Infiltration Cellular	Moderate Mononuclear CI, Minimal
* Lung		Histiocytic Sarcoma	
Mesentery	Fat	Necrosis	Moderate
[ Necrosis TGLs = 2-11 ]			
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Skin	Subcut Tiss	Histiocytic Sarcoma	
Note: Based on histology, TGL 1 was in the skin rather than skeletal muscle			
[ Histiocytic Sarcoma TGLs = 1-10 ]			
* Spleen	Lymph Follic	Atrophy Hematopoietic Cell Proliferation	Mild Moderate
* Thymus		Atrophy	Marked
* Uterus	Endometrium	Hyperplasia	Cystic, Mild
[ Hyperplasia TGLs = 3-7 ]			

PRIMARY CAUSE OF DEATH - Skin Subcut Tiss Histiocytic Sarcoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 226    **TMT:** 2    **SEX:** Female    **DAY ON TEST:** 729  
**DOSE:** 0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602126

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone Marrow              | * Brain                   |
| * Clitoral Gland            | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Kidney                    | * Lung                   | * Lymph Node, Mandibular   | * Lymph Node, Mesenteric  |
| * Mammary Gland             | * Nose                   | * Ovary                    | * Pancreas                |
| * Parathyroid Gland         | * Skin                   | * Spleen                   | * Stomach, Forestomach    |
| * Stomach, Glandular        | * Thyroid Gland          | * Trachea                  |                           |

**OBSERVATIONS**

- |                            |               |                       |                         |
|----------------------------|---------------|-----------------------|-------------------------|
| * Adrenal Cortex           | Subcapsular   | Hyperplasia           | Mild                    |
| * Bone                     |               | Fibrosis              | Minimal                 |
| * Harderian Gland          |               | Adenoma               |                         |
|                            |               | Infiltration Cellular | Mononuclear CI, Minimal |
| * Liver                    |               | Clear Cell Focus      |                         |
|                            |               | Eosinophilic Focus    |                         |
|                            |               | Fatty Change          | Mild                    |
|                            |               | Infiltration Cellular | Mononuclear CI, Minimal |
| Mesentery                  | Fat           | Necrosis              | Moderate                |
| [ Necrosis TGLs = 2-10 ]   |               |                       |                         |
| * Pituitary Gland          | Pars Distalis | Hyperplasia           | Mild                    |
| * Salivary Glands          |               | Infiltration Cellular | Mononuclear CI, Minimal |
| * Thymus                   |               | Atrophy               | Minimal                 |
| * Urinary Bladder          |               | Infiltration Cellular | Mononuclear CI, Minimal |
| * Uterus                   | Endometrium   | Hyperplasia           | Cystic, Moderate        |
|                            |               | Inflammation          | Suppurative, Mild       |
| [ Hyperplasia TGLs = 1-7 ] |               |                       |                         |

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

ANIMAL NUM: 227 TMT: 2 SEX: Female DAY ON TEST: 421  
DOSE: 0 G/KG DISP: Moribund Sacrifice HISTO: 0602127

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Eye	Antr Chamber	Inflammation	Suppurative, Moderate
	[ Inflammation TGLs = 1-9 ]		
* Harderian Gland		Adenoma	
	[ Adenoma TGLs = 2-9 ]		
* Liver		Fatty Change	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Mild
* Uterus	Endometrium	Hyperplasia	Cystic, Mild

PRIMARY CAUSE OF DEATH - Harderian Gland Adenoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 228	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602128

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone Marrow              | * Brain                   |
| * Clitoral Gland            | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Kidney                    | * Lung                   | * Lymph Node, Mandibular   | * Lymph Node, Mesenteric  |
| * Mammary Gland             | * Nose                   | * Ovary                    | * Pancreas                |
| * Parathyroid Gland         | * Pituitary Gland        | * Skin                     | * Stomach, Forestomach    |
| * Stomach, Glandular        | * Thyroid Gland          | * Trachea                  |                           |

**OBSERVATIONS**

- |                                     |               |                                  |                         |
|-------------------------------------|---------------|----------------------------------|-------------------------|
| * Adrenal Cortex                    | Subcapsular   | Hyperplasia                      | Mild                    |
| * Bone                              |               | Fibrosis                         | Minimal                 |
| * Eye                               |               |                                  |                         |
| Note: Both optic nerves are missing |               |                                  |                         |
| * Harderian Gland                   |               | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Liver                             |               | Fatty Change                     | Minimal                 |
|                                     |               | Infiltration Cellular            | Mononuclear CI, Minimal |
|                                     |               | Mixed Cell Focus                 |                         |
|                                     |               | Tension Lipidosis                |                         |
| Mesentery                           | Fat           | Necrosis                         | Mild                    |
| [ Necrosis                          | TGLs = 1-10 ] |                                  |                         |
| * Salivary Glands                   |               | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen                            |               | Hematopoietic Cell Proliferation | Minimal                 |
| * Thymus                            |               | Atrophy                          | Mild                    |
| * Urinary Bladder                   |               | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus                            | Endometrium   | Hyperplasia                      | Cystic, Mild            |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 229	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 639
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 0602129

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Nose                      | * Ovary                  | * Pancreas                 |
| * Parathyroid Gland       | * Pituitary Gland           | * Salivary Glands        | * Skin                     |
| * Stomach, Glandular      | * Thyroid Gland             | * Trachea                | * Urinary Bladder          |

**OBSERVATIONS**

- |                        |               |   |                              |
|------------------------|---------------|---|------------------------------|
| * Adrenal Cortex       | Subcapsular   | Hyperplasia                                 | Mild                         |
| * Harderian Gland      |               | Infiltration Cellular                       | Mononuclear CI, Minimal      |
| * Liver                |               | Fatty Change<br>Necrosis                    | Mild<br>Minimal              |
| * Lung                 |               | Rhabdomyosarcoma                            | Metastatic (Skeletal Muscle) |
| Skeletal Muscle        |               | Rhabdomyosarcoma                            |                              |
| [ Rhabdomyosarcoma     | TGLs = 1-10 ] |   |                              |
| * Spleen               | Lymph Follic  | Atrophy<br>Hematopoietic Cell Proliferation | Marked<br>Mild               |
| * Stomach, Forestomach | Epithelium    | Hyperplasia<br>Inflammation                 | Minimal<br>Chronic, Minimal  |
| * Thymus               |               | Rhabdomyosarcoma                            | Metastatic (Skeletal Muscle) |
| [ Rhabdomyosarcoma     | TGLs = 3-11 ] |   |                              |
| * Uterus               | Endometrium   | Hyperplasia                                 | Cystic, Moderate             |

PRIMARY CAUSE OF DEATH - Skeletal Muscle Rhabdomyosarcoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 230	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602130

ORGAN AND ACCOUNTABLE SITE STATUS

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Clitoral Gland	* Esophagus	* Eye	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Skin	* Stomach, Glandular	* Trachea	

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Brain	Hypothalamus	Compression	Marked
* Gallbladder		Cyst	Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart	Artery	Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Minimal
* Kidney		Nephropathy	Mild
* Liver		Infiltration Cellular	Mononuclear CI, Minimal
* Mammary Gland		Hyperplasia	Mild
		Inflammation	Chronic Active, Mild
		Metaplasia	Squamous, Mild
Mesentery	Fat	Necrosis	Moderate
[ Necrosis TGLs = 1-10 ]			
* Pituitary Gland	Pars Distalis	Adenoma	
[ Adenoma TGLs = 2-11 ]			
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Mild
* Stomach, Forestomach		Squamous Cell Papilloma	
[ Squamous Cell Papilloma TGLs = 3-12 ]			
* Thymus		Atrophy	Mild
* Thyroid Gland	Follicle	Hyperplasia	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 231 TMT: 2 SEX: Female DAY ON TEST: 730  
 DOSE: 0 G/KG DISP: Terminal Sacrifice HISTO: 0602131

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Skin
* Stomach, Forestomach	* Thyroid Gland	* Trachea	* Urinary Bladder

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone		Fibrosis	Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Inflammation	Minimal
* Liver		Eosinophilic Focus	
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
	[ Eosinophilic Focus TGLs = 2-10 ]		
	[ Mixed Cell Focus TGLs = 3-11 ]		
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Ovary		Cystadenoma	
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Mild
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Stomach, Glandular		Adenoma	
		Mineralization	Minimal
* Thymus		Atrophy	Mild
* Uterus	Endometrium	Hyperplasia	Cystic, Moderate
	[ Hyperplasia TGLs = 1-7 ]		

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 232	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602132

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea		

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone		Fibrosis	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Liver		Fatty Change	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
* Ovary		Cyst	
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hyperplasia	Lymphoid, Mild
* Thymus		Atrophy	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild
		Polyp Stromal	



TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

ANIMAL NUM: 233 TMT: 2 SEX: Female DAY ON TEST: 523  
DOSE: 0 G/KG DISP: Moribund Sacrifice HISTO: 0602133

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Uterus

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone		Fibrosis	Moderate
* Kidney	Renal Tubule	Hyperplasia	Minimal
	[ Nephropathy TGLs = 1-4 ]	Nephropathy	Marked
* Liver		Eosinophilic Focus	
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen	Lymph Follic	Atrophy	Moderate
* Thymus		Atrophy	Marked
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

PRIMARY CAUSE OF DEATH - Kidney Nephropathy

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 234    **TMT:** 2    **SEX:** Female    **DAY ON TEST:** 688  
**DOSE:** 0 G/KG    **DISP:** Natural Death    **HISTO:** 0602134

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Brain                  |
| * Esophagus                | * Eye                     | * Gallbladder               | * Heart                  |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic      | * Kidney                    | * Mammary Gland          |
| * Nose                     | * Ovary                   | * Pancreas                  | * Parathyroid Gland      |
| * Pituitary Gland          | * Skin                    | * Stomach, Forestomach      | * Stomach, Glandular     |
| * Thyroid Gland            | * Trachea                 | * Urinary Bladder           | * Uterus                 |

**OBSERVATIONS**

- |  |                       |                         |
|--|-----------------------|-------------------------|
| * Adrenal Cortex                       | Histiocytic Sarcoma   |                         |
| * Bone Marrow                          | Histiocytic Sarcoma   |                         |
| * Clitoral Gland                       | Inflammation          | Minimal                 |
| * Harderian Gland                      | Infiltration Cellular | Mononuclear CI, Minimal |
| * Intestine Large, Cecum               | Inflammation          | Chronic, Minimal        |
| * Liver                                | Fatty Change          | Mild                    |
|  | Histiocytic Sarcoma   |                         |
| [ Histiocytic Sarcoma TGLs = 2-3+4+5 ] |                       |                         |
| * Lung                                 | Histiocytic Sarcoma   |                         |
| * Lymph Node, Mandibular               | Histiocytic Sarcoma   |                         |
| * Lymph Node, Mesenteric               | Histiocytic Sarcoma   |                         |
| * Salivary Glands                      | Infiltration Cellular | Mononuclear CI, Minimal |
| * Spleen                               | Histiocytic Sarcoma   |                         |
| [ Histiocytic Sarcoma TGLs = 1-4 ]     |                       |                         |
| * Thymus                               | Atrophy               | Marked                  |

PRIMARY CAUSE OF DEATH - Liver Histiocytic Sarcoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 235	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602135

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lung                   | * Lymph Node, Mandibular   |
| * Lymph Node, Mesenteric  | * Mammary Gland             | * Nose                   | * Ovary                    |
| * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        | * Skin                     |
| * Stomach, Glandular      | * Thyroid Gland             | * Trachea                |                            |

**OBSERVATIONS**

- |                        |   |                                  |                         |
|------------------------|---|----------------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                             | Hyperplasia                      | Mild                    |
| * Harderian Gland      |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Liver                |   | Angiectasis                      | Minimal                 |
|                        |   | Fatty Change                     | Mild                    |
|                        |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Salivary Glands      |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen               |   | Hematopoietic Cell Proliferation | Minimal                 |
|                        |   | Hyperplasia                      | Lymphoid, Minimal       |
| * Stomach, Forestomach |   | Squamous Cell Papilloma          |                         |
|                        | [ Squamous Cell Papilloma TGLs = 1-10 ] |                                  |                         |
| * Thymus               |   | Atrophy                          | Mild                    |
| * Urinary Bladder      |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus               | Endometrium                             | Hyperplasia                      | Cystic, Moderate        |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 236    **TMT:** 2    **SEX:** Female    **DAY ON TEST:** 731  
**DOSE:** 0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602136

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea		

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Atrophy Hyperplasia	Minimal Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Liver		Hemangiosarcoma Hematopoietic Cell Proliferation Infiltration Cellular Necrosis	Mild Mononuclear CI, Minimal Moderate
	[ Hemangiosarcoma TGLs = 5-13 ] [ Necrosis TGLs = 4,6-12+14 ]		
* Lymph Node, Mandibular		Hyperplasia	Lymphoid, Mild
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Skin	[ Ulcer TGLs = 1,2-10+11 ]	Ulcer	Marked
* Spleen	[ Hematopoietic Cell Proliferation TGLs = 3-4 ]	Hematopoietic Cell Proliferation	Marked
* Thymus		Atrophy	Marked
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

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<b>ANIMAL NUM:</b> 237	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602137

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mesenteric | * Mammary Gland            |
| * Nose                    | * Ovary                     | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Salivary Glands           | * Skin                   | * Stomach, Glandular       |
| * Thyroid Gland           | * Trachea                   |                          |                            |
- 

**OBSERVATIONS**

- |                          |   |                                  |                         |
|--------------------------|---|----------------------------------|-------------------------|
| * Adrenal Cortex         | Subcapsular                             | Hyperplasia                      | Mild                    |
| * Harderian Gland        |   | Adenoma                          |                         |
|                          | [ Adenoma TGLs = 1-9 ]                  |                                  |                         |
| * Kidney                 | Renal Tubule                            | Hyperplasia                      | Minimal                 |
| * Liver                  |   | Fatty Change                     | Minimal                 |
|                          |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Lymph Node, Mandibular |   | Hyperplasia                      | Lymphoid, Marked        |
|                          | [ Hyperplasia TGLs = 3-6 ]              |                                  |                         |
| * Spleen                 |   | Hematopoietic Cell Proliferation | Mild                    |
|                          |   | Hyperplasia                      | Lymphoid, Minimal       |
| * Stomach, Forestomach   |   | Squamous Cell Papilloma          |                         |
|                          | [ Squamous Cell Papilloma TGLs = 4-10 ] |                                  |                         |
| * Thymus                 |   | Atrophy                          | Marked                  |
| * Urinary Bladder        |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus                 | Endometrium                             | Hyperplasia                      | Cystic, Moderate        |
|                          | [ Hyperplasia TGLs = 2-7 ]              |                                  |                         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 238    **TMT:** 2    **SEX:** Female    **DAY ON TEST:** 729  
**DOSE:** 0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602138

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lung                   | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Nose                      | * Ovary                  | * Pancreas                 |
| * Parathyroid Gland       | * Pituitary Gland           | * Skin                   | * Stomach, Forestomach     |
| * Stomach, Glandular      | * Thyroid Gland             | * Trachea                |                            |

**OBSERVATIONS**

- |                          |                                  |                                  |                         |
|--------------------------|----------------------------------|----------------------------------|-------------------------|
| * Adrenal Cortex         | Subcapsular                      | Hyperplasia                      | Mild                    |
| * Harderian Gland        |                                  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Liver                  |                                  | Eosinophilic Focus               |                         |
|                          |                                  | Fatty Change                     | Minimal                 |
|                          |                                  | Infiltration Cellular            | Mononuclear CI, Minimal |
|                          |                                  | Mixed Cell Focus                 |                         |
|                          | [ Mixed Cell Focus TGLs = 2-10 ] |                                  |                         |
| * Lymph Node, Mandibular |                                  | Hyperplasia                      | Lymphoid, Marked        |
| Mesentery                | Fat                              | Necrosis                         | Moderate                |
|                          | [ Necrosis TGLs = 3-11 ]         |                                  |                         |
| * Salivary Glands        |                                  | Infiltration Cellular            | Mononuclear CI, Mild    |
| * Spleen                 |                                  | Hematopoietic Cell Proliferation | Mild                    |
|                          |                                  | Lymphoma Malignant               |                         |
| * Thymus                 |                                  | Atrophy                          | Mild                    |
|                          |                                  | Infiltration Cellular            | Histiocyte, Moderate    |
| * Urinary Bladder        |                                  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus                 | Endometrium                      | Hyperplasia                      | Cystic, Moderate        |
|                          | [ Hyperplasia TGLs = 1-7 ]       |                                  |                         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 239	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602139

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Ovary                     | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Salivary Glands           | * Skin                   | * Stomach, Glandular       |
| * Thyroid Gland           | * Trachea                   |                          |                            |

**OBSERVATIONS**

- |                        |   |                                  |                         |
|------------------------|---|----------------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular   | Hyperplasia                      | Mild                    |
| * Harderian Gland      |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Kidney               |   | Nephropathy                      | Minimal                 |
| * Liver                |   | Hepatocellular Adenoma           | Mononuclear CI, Minimal |
|                        | [ Hepatocellular Adenoma TGLs = 2-11 ]  | Infiltration Cellular            |                         |
| * Nose                 |   | Inflammation                     | Chronic, Mild           |
| Skeletal Muscle        |   | Rhabdomyosarcoma                 |                         |
|                        | Note: TGL 1 was a skeletal muscle tumor, although it was described grossly as being in the skin |                                  |                         |
|                        | [ Rhabdomyosarcoma TGLs = 1-10 ]  |                                  |                         |
| * Spleen               |   | Hematopoietic Cell Proliferation | Mild                    |
| * Stomach, Forestomach |   | Inflammation                     | Chronic, Mild           |
| * Thymus               |   | Atrophy                          | Mild                    |
| * Urinary Bladder      |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus               | Endometrium   | Hyperplasia                      | Cystic, Minimal         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 240	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602140

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lung                   | * Lymph Node, Mandibular   |
| * Lymph Node, Mesenteric  | * Mammary Gland             | * Nose                   | * Ovary                    |
| * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        | * Skin                     |
| * Stomach, Forestomach    | * Stomach, Glandular        | * Thyroid Gland          | * Trachea                  |

**OBSERVATIONS**

- |                   |  |                           |                         |
|-------------------|--|---------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                            | Hyperplasia               | Mild                    |
| * Harderian Gland |  | Infiltration Cellular     | Mononuclear CI, Minimal |
| * Liver           |  | Fatty Change              | Mild                    |
|                   |  | Hepatocellular Adenoma    |                         |
|                   | [ Hepatocellular Adenoma TGLs = 1-10 ] | Infiltration Cellular     | Mononuclear CI, Minimal |
| * Salivary Glands |  | Infiltration Cellular     | Mononuclear CI, Minimal |
| * Spleen          |  | Mast Cell Tumor Malignant |                         |
| * Thymus          |  | Atrophy                   | Marked                  |
| * Urinary Bladder |  | Infiltration Cellular     | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                            | Hyperplasia               | Cystic, Mild            |



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 241	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602141

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Nose                      | * Ovary                  | * Pancreas                 |
| * Parathyroid Gland       | * Pituitary Gland           | * Skin                   | * Spleen                   |
| * Stomach, Forestomach    | * Stomach, Glandular        | * Thymus                 | * Thyroid Gland            |
| * Trachea                 |                             |                          |                            |

**OBSERVATIONS**

- |                   |  |                                |                         |
|-------------------|--|--------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                                    | Hyperplasia                    | Mild                    |
| * Harderian Gland |  | Infiltration Cellular          | Mononuclear CI, Minimal |
| * Liver           |  | Angiectasis                    | Minimal                 |
|                   |  | Clear Cell Focus               |                         |
|                   |  | Eosinophilic Focus             |                         |
|                   |  | Fatty Change                   | Mild                    |
|                   |  | Hepatocellular Adenoma         |                         |
|                   |  | Infiltration Cellular          | Mononuclear CI, Minimal |
|                   |  | Mixed Cell Focus               |                         |
|                   | [ Clear Cell Focus TGLs = 2-10 ]               |                                |                         |
|                   | [ Hepatocellular Adenoma TGLs = 4-12 ]         |                                |                         |
|                   | [ Mixed Cell Focus TGLs = 3,6-11+14 ]          |                                |                         |
| * Lung            |  | Alveolar/Bronchiolar Carcinoma |                         |
|                   | [ Alveolar/Bronchiolar Carcinoma TGLs = 5-13 ] |                                |                         |
| * Salivary Glands |  | Infiltration Cellular          | Mononuclear CI, Minimal |
| * Urinary Bladder |  | Infiltration Cellular          | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                                    | Hyperplasia                    | Cystic, Moderate        |
|                   | [ Hyperplasia TGLs = 1-7 ]                     |                                |                         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 242    **TMT:** 2    **SEX:** Female    **DAY ON TEST:** 731  
**DOSE:** 0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602142

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lung                   | * Lymph Node, Mandibular   |
| * Lymph Node, Mesenteric  | * Mammary Gland             | * Nose                   | * Pancreas                 |
| * Parathyroid Gland       | * Pituitary Gland           | * Skin                   | * Spleen                   |
| * Stomach, Forestomach    | * Stomach, Glandular        | * Thyroid Gland          | * Trachea                  |

**OBSERVATIONS**

- |                   |                     |                       |                         |
|-------------------|---------------------|-----------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular         | Hyperplasia           | Mild                    |
| * Harderian Gland |                     | Infiltration Cellular | Mononuclear CI, Minimal |
| * Liver           |                     | Fatty Change          | Mild                    |
|                   |                     | Infiltration Cellular | Mononuclear CI, Minimal |
| * Ovary           |                     | Cyst                  | Mild                    |
|                   | [ Cyst TGLs = 1-7 ] |                       |                         |
| * Salivary Glands |                     | Infiltration Cellular | Mononuclear CI, Minimal |
| * Thymus          |                     | Atrophy               | Marked                  |
| Tooth             |                     | Dysplasia             | Minimal                 |
| * Urinary Bladder |                     | Infiltration Cellular | Mononuclear CI, Minimal |
| * Uterus          | Endometrium         | Hyperplasia           | Cystic, Mild            |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 243    **TMT:** 2    **SEX:** Female    **DAY ON TEST:** 729  
**DOSE:** 0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602143

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Liver		Fatty Change	Minimal
		Infiltration Cellular	Mononuclear CI, Mild
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hyperplasia	Lymphoid, Mild
* Thymus		Atrophy	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Marked
	[ Hyperplasia TGLs = 1-7 ]		

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	244	TMT:	2	SEX:	Female	DAY ON TEST:	394
		DOSE:	0 G/KG	DISP:	Accidently Killed	HISTO:	0602144

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ORGAN AND ACCOUNTABLE SITE STATUS

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NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Harderian Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Pituitary Gland	* Salivary Glands	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

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MISSING

\* Parathyroid Gland

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OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Liver		Fatty Change Infiltration Cellular	Minimal Mononuclear CI, Minimal
* Lung		Hemorrhage	Moderate
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal

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PRIMARY CAUSE OF DEATH - Lung Hemorrhage

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 245	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602145

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lung                   | * Lymph Node, Mandibular   |
| * Lymph Node, Mesenteric  | * Mammary Gland             | * Nose                   | * Pancreas                 |
| * Parathyroid Gland       | * Spleen                    | * Stomach, Forestomach   | * Stomach, Glandular       |
| * Thyroid Gland           | * Trachea                   | * Urinary Bladder        |                            |

**OBSERVATIONS**

- |                   |                                  |                       |                         |
|-------------------|----------------------------------|-----------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                      | Hyperplasia           | Mild                    |
| * Harderian Gland |                                  | Infiltration Cellular | Mononuclear CI, Minimal |
| * Liver           |                                  | Fatty Change          | Mild                    |
|                   |                                  | Infiltration Cellular | Mononuclear CI, Minimal |
|                   | [ Mixed Cell Focus TGLs = 2-11 ] | Mixed Cell Focus      |                         |
| * Ovary           |                                  | Cyst                  | Minimal                 |
| * Pituitary Gland |                                  | Cyst                  | Minimal                 |
|                   | Pars Distalis                    | Hyperplasia           | Mild                    |
| * Salivary Glands |                                  | Infiltration Cellular | Mononuclear CI, Minimal |
| * Skin            |                                  | Inflammation          | Chronic, Moderate       |
|                   | [ Inflammation TGLs = 1-10 ]     |                       |                         |
| * Thymus          |                                  | Atrophy               | Marked                  |
| * Uterus          | Endometrium                      | Hyperplasia           | Cystic, Mild            |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 246	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602146

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Ovary	* Parathyroid Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Trachea	* Uterus

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone		Fibrosis	Minimal
* Harderian Gland		Adenoma	
		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Mineralization	Minimal
* Liver		Fatty Change	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
Lymph Node	Mediastinal	Hyperplasia	Lymphoid, Marked
* Nose		Inflammation	Chronic, Minimal
* Pancreas		Inflammation	Chronic, Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Moderate
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Thymus		Atrophy	Moderate
* Thyroid Gland		Ectopic Thymus	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	247	TMT:	2	SEX:	Female	DAY ON TEST:	700
		DOSE:	0 G/KG	DISP:	Natural Death	HISTO:	0602147

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ORGAN AND ACCOUNTABLE SITE STATUS

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NORMAL

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea		

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MISSING

* Lymph Node, Mandibular	* Salivary Glands
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OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone		Fibrosis	Mild
* Harderian Gland		Adenoma	
	[ Adenoma TGLs = 1-9 ]		
* Liver		Fatty Change	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Mild
* Thymus		Atrophy	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus		Inflammation	Suppurative, Minimal

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PRIMARY CAUSE OF DEATH - UNCERTAIN

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

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<b>ANIMAL NUM:</b> 248	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602148

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Clitoral Gland         | * Esophagus                | * Eye                     |
| * Gallbladder               | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Kidney                  |
| * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Mammary Gland            | * Nose                    |
| * Ovary                     | * Pancreas               | * Parathyroid Gland        | * Pituitary Gland         |
| * Skin                      | * Spleen                 | * Stomach, Forestomach     | * Stomach, Glandular      |
| * Thyroid Gland             | * Trachea                |                            |                           |
- 

**OBSERVATIONS**

- |                      |  |   |                                 |
|----------------------|--|---|---------------------------------|
| * Adrenal Cortex     | Subcapsular                                  | Hyperplasia   | Mild                            |
| * Harderian Gland    |  | Hyperplasia<br>Infiltration Cellular                      | Mild<br>Mononuclear CI, Minimal |
| * Heart              |  | Cardiomyopathy  | Minimal                         |
| * Islets, Pancreatic |  | Hyperplasia   | Minimal                         |
| * Liver              |  | Fatty Change<br>Infiltration Cellular<br>Mixed Cell Focus | Mild<br>Mononuclear CI, Minimal |
|                      | [ Mixed Cell Focus TGLs = 1-10 ]             |   |                                 |
| * Lung               | [ Alveolar/Bronchiolar Adenoma TGLs = 2-11 ] | Alveolar/Bronchiolar Adenoma                              | Multiple                        |
| * Salivary Glands    |  | Infiltration Cellular                                     | Mononuclear CI, Minimal         |
| * Thymus             |  | Atrophy   | Marked                          |
| * Urinary Bladder    |  | Infiltration Cellular                                     | Mononuclear CI, Minimal         |
| * Uterus             | Endometrium                                  | Hyperplasia   | Cystic, Minimal                 |



TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b> 249	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602149

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ORGAN AND ACCOUNTABLE SITE STATUS

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**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Pituitary Gland	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea

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**MISSING**

\* Parathyroid Gland

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**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone		Fibrosis	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Hyperplasia	Mild
* Kidney		Metaplasia	Osseous, Minimal
		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
		Infiltration Cellular	Mononuclear CI, Mild
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Thymus		Atrophy	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild
		Inflammation	Suppurative, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 250	<b>TMT:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602150

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Nose                      | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Salivary Glands           | * Skin                   | * Stomach, Forestomach     |
| * Thyroid Gland           | * Trachea                   |                          |                            |

**OBSERVATIONS**

- |                      |  |                          |                         |
|----------------------|--|--------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                              | Hyperplasia              | Mild                    |
| * Harderian Gland    |  | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Kidney             | Papilla                                  | Amyloid Deposition       | Minimal                 |
|                      |  | Necrosis                 | Mild                    |
| * Liver              |  | Hepatocellular Carcinoma |                         |
|                      |  | Infiltration Cellular    | Mononuclear CI, Minimal |
|                      |  | Mixed Cell Focus         |                         |
|                      | [ Hepatocellular Carcinoma TGLs = 2-11 ] |                          |                         |
| Mesentery            | Fat                                      | Necrosis                 | Mild                    |
|                      | [ Necrosis TGLs = 1-10 ]                 |                          |                         |
| * Ovary              |  | Cyst                     | Mild                    |
| * Spleen             |  | Lymphoma Malignant       |                         |
| * Stomach, Glandular |  | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Thymus             |  | Atrophy                  | Marked                  |
|                      |  | Infiltration Cellular    | Histiocyte, Moderate    |
| * Urinary Bladder    |  | Infiltration Cellular    | Mononuclear CI, Mild    |
|                      |  | Lymphoma Malignant       |                         |
| * Uterus             | Endometrium                              | Hyperplasia              | Cystic, Minimal         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 251    **TMT:** 4    **SEX:** Female    **DAY ON TEST:** 681  
**DOSE:** 0.25 G/KG    **DISP:** Moribund Sacrifice    **HISTO:** 0602151

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Nose                      | * Ovary                  | * Pancreas                 |
| * Parathyroid Gland       | * Pituitary Gland           | * Salivary Glands        | * Skin                     |
| * Stomach, Glandular      | * Thyroid Gland             | * Trachea                |                            |

**OBSERVATIONS**

- |                        |                                       |                       |                         |
|------------------------|---------------------------------------|-----------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                           | Hyperplasia           | Mild                    |
| * Harderian Gland      |                                       | Infiltration Cellular | Mononuclear CI, Minimal |
| * Kidney               |                                       | Nephropathy           | Minimal                 |
| * Liver                |                                       | Fatty Change          | Mild                    |
|                        |                                       | Infiltration Cellular | Mononuclear CI, Minimal |
|                        |                                       | Mixed Cell Focus      |                         |
|                        |                                       | Tension Lipidosis     |                         |
|                        | [ Mixed Cell Focus TGLs = 1,2-10+11 ] |                       |                         |
| * Spleen               | Lymph Follic                          | Atrophy               | Mild                    |
| * Stomach, Forestomach | Epithelium                            | Hyperplasia           | Mild                    |
|                        |                                       | Inflammation          | Chronic, Moderate       |
|                        |                                       | Ulcer                 | Moderate                |
| * Thymus               |                                       | Atrophy               | Marked                  |
| * Urinary Bladder      |                                       | Infiltration Cellular | Mononuclear CI, Minimal |
| * Uterus               | Endometrium                           | Hyperplasia           | Cystic, Minimal         |

PRIMARY CAUSE OF DEATH - UNCERTAIN

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 252    **TMT:** 4    **SEX:** Female    **DAY ON TEST:** 731  
**DOSE:** 0.25 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602152

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lung                   | * Lymph Node, Mandibular   |
| * Lymph Node, Mesenteric  | * Mammary Gland             | * Nose                   | * Pancreas                 |
| * Parathyroid Gland       | * Pituitary Gland           | * Salivary Glands        | * Skin                     |
| * Spleen                  | * Stomach, Forestomach      | * Stomach, Glandular     | * Thyroid Gland            |
| * Trachea                 |                             |                          |                            |

**OBSERVATIONS**

- |                   |                                    |                       |                         |
|-------------------|------------------------------------|-----------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                        | Hyperplasia           | Mild                    |
| * Harderian Gland |                                    | Adenoma               |                         |
|                   | [ Adenoma TGLs = 1-9 ]             |                       |                         |
| * Liver           |                                    | Eosinophilic Focus    |                         |
|                   |                                    | Fatty Change          | Minimal                 |
|                   |                                    | Infiltration Cellular | Mononuclear CI, Minimal |
|                   | [ Eosinophilic Focus TGLs = 4-10 ] |                       |                         |
| * Ovary           |                                    | Cystadenoma           |                         |
|                   | [ Cystadenoma TGLs = 2-7 ]         |                       |                         |
| * Thymus          |                                    | Atrophy               | Mild                    |
| * Urinary Bladder |                                    | Infiltration Cellular | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                        | Hyperplasia           | Cystic, Moderate        |
|                   | [ Hyperplasia TGLs = 3-7 ]         |                       |                         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 253	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602153

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone		Fibrosis	Mild
* Harderian Gland		Hyperplasia	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
* Liver	Centrilobular	Fatty Change	Minimal
		Hypertrophy	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Thymus		Atrophy	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Moderate
	[ Hyperplasia TGLs = 1-7 ]		

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 254	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602154

ORGAN AND ACCOUNTABLE SITE STATUS

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Clitoral Gland         | * Esophagus                | * Eye                     |
| * Gallbladder               | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Lung                    |
| * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Mammary Gland            | * Nose                    |
| * Pancreas                  | * Parathyroid Gland      | * Pituitary Gland          | * Skin                    |
| * Thyroid Gland             | * Trachea                |                            |                           |

**OBSERVATIONS**

- |                        |   |                                  |                         |
|------------------------|---|----------------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                                     | Hyperplasia                      | Mild                    |
| * Harderian Gland      |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Heart                | Artery  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Islets, Pancreatic   |   | Hyperplasia                      | Minimal                 |
| * Kidney               |   | Mineralization                   | Minimal                 |
|                        |   | Nephropathy                      | Minimal                 |
| * Liver                |   | Fatty Change                     | Mild                    |
|                        |   | Hematopoietic Cell Proliferation | Minimal                 |
|                        |   | Hepatocellular Adenoma           | Multiple                |
|                        | Centrilobular                                   | Hepatocellular Carcinoma         | Multiple                |
|                        |   | Hypertrophy                      | Minimal                 |
|                        |   | Infiltration Cellular            | Mononuclear CI, Minimal |
|                        | [ Hepatocellular Adenoma TGLs = 5-12+13 ]       |                                  |                         |
|                        | [ Hepatocellular Carcinoma TGLs = 3,4-10+11 ]   |                                  |                         |
| * Ovary                |   | Cystadenoma                      |                         |
|                        | [ Cystadenoma TGLs = 1-7 ]                      |                                  |                         |
| * Salivary Glands      |   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen               |   | Hematopoietic Cell Proliferation | Marked                  |
|                        | [ Hematopoietic Cell Proliferation TGLs = 2-4 ] |                                  |                         |
| * Stomach, Forestomach | Epithelium                                      | Hyperplasia                      | Minimal                 |
|                        |   | Inflammation                     | Chronic, Minimal        |
|                        |   | Squamous Cell Papilloma          |                         |
|                        | [ Squamous Cell Papilloma TGLs = 6-14 ]         |                                  |                         |
| * Stomach, Glandular   | Glands  | Ectasia                          | Minimal                 |
|                        |   | Infiltration Cellular            | Mononuclear CI, Minimal |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	254	<b>TMT:</b>	4	<b>SEX:</b>	Female	<b>DAY ON TEST:</b>	729
		<b>DOSE:</b>	0.25 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602154

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Thymus		Atrophy	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 255	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602155

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla        | Blood Vessel               | * Bone                    | * Brain                     |
| * Clitoral Gland         | * Esophagus                | * Eye                     | * Gallbladder               |
| * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      | * Lung                      |
| * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Mammary Gland           | * Nose                      |
| * Ovary                  | * Pancreas                 | * Parathyroid Gland       | * Pituitary Gland           |
| * Skin                   | * Stomach, Forestomach     | * Stomach, Glandular      | * Thyroid Gland             |
| * Trachea                | * Urinary Bladder          |                           |                             |

**OBSERVATIONS**

- |                   |  |                                  |                         |
|-------------------|--|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                              | Hyperplasia                      | Mild                    |
| * Bone Marrow     |  | Hemangiosarcoma                  |                         |
| * Harderian Gland |  | Adenoma                          |                         |
|                   |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Heart           |  | Cardiomyopathy                   | Mild                    |
| * Kidney          |  | Metaplasia                       | Osseous, Minimal        |
|                   |  | Mineralization                   | Minimal                 |
| * Liver           |  | Hemangiosarcoma                  |                         |
|                   |  | Hepatocellular Adenoma           |                         |
|                   |  | Hepatocellular Carcinoma         |                         |
|                   |  | Infiltration Cellular            | Mononuclear CI, Minimal |
|                   | [ Hepatocellular Adenoma TGLs = 2-11 ]   |                                  |                         |
|                   | [ Hepatocellular Carcinoma TGLs = 1-10 ] |                                  |                         |
| * Salivary Glands |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen          |  | Hematopoietic Cell Proliferation | Minimal                 |
|                   |  | Hyperplasia                      | Lymphoid, Minimal       |
| * Thymus          |  | Atrophy                          | Minimal                 |
| * Uterus          | Endometrium                              | Hyperplasia                      | Cystic, Minimal         |



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 256	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602156

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mesenteric | * Mammary Gland            |
| * Nose                    | * Ovary                     | * Parathyroid Gland      | * Pituitary Gland          |
| * Salivary Glands         | * Skin                      | * Spleen                 | * Stomach, Forestomach     |
| * Stomach, Glandular      | * Thyroid Gland             | * Trachea                |                            |

**OBSERVATIONS**

- |                          |  |                        |                         |
|--------------------------|--|------------------------|-------------------------|
| * Adrenal Cortex         | Subcapsular                            | Hyperplasia            | Mild                    |
| * Harderian Gland        |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Kidney                 | Renal Tubule                           | Hyperplasia            | Minimal                 |
| * Liver                  |  | Hepatocellular Adenoma | Multiple                |
|                          |  | Infiltration Cellular  | Mononuclear CI, Minimal |
|                          |  | Tension Lipidosis      |                         |
|                          | [ Hepatocellular Adenoma TGLs = 2-11 ] |                        |                         |
| * Lymph Node, Mandibular |  | Hyperplasia            | Lymphoid, Mild          |
| * Pancreas               | Duct                                   | Cyst                   | Marked                  |
|                          | [ Cyst TGLs = 1-10 ]                   |                        |                         |
| * Thymus                 |  | Atrophy                | Mild                    |
| * Urinary Bladder        |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Uterus                 | Endometrium                            | Hyperplasia            | Cystic, Mild            |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 257    **TMT:** 4    **SEX:** Female    **DAY ON TEST:** 731  
**DOSE:** 0.25 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602157

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                    | * Clitoral Gland          | * Esophagus                 | * Eye                    |
| * Gallbladder              | * Harderian Gland         | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular |
| * Lymph Node, Mesenteric   | * Mammary Gland           | * Nose                      | * Pancreas               |
| * Parathyroid Gland        | * Pituitary Gland         | * Salivary Glands           | * Skin                   |
| * Spleen                   | * Stomach, Forestomach    | * Stomach, Glandular        | * Thyroid Gland          |
| * Trachea                  | * Urinary Bladder         |                             |                          |

**OBSERVATIONS**

- |                  |               |  |  |
|------------------|---------------|--|--|
| * Adrenal Cortex | Subcapsular   | Hyperplasia  | Mild                                       |
| * Kidney         |               | Mineralization<br>Nephropathy                        | Minimal<br>Mild                            |
| * Liver          | Centrilobular | Fatty Change<br>Hypertrophy<br>Infiltration Cellular | Mild<br>Minimal<br>Mononuclear CI, Minimal |
| * Ovary          |               | Cyst   | Minimal                                    |
| * Thymus         |               | Atrophy  | Minimal                                    |
| * Uterus         | Endometrium   | Hyperplasia  | Cystic, Moderate                           |
| [ Hyperplasia    | TGLs = 1-7 ]  |  |  |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 258    **TMT:** 4    **SEX:** Female    **DAY ON TEST:** 711  
**DOSE:** 0.25 G/KG    **DISP:** Natural Death    **HISTO:** 0602158

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Harderian Gland         | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Mammary Gland            |
| * Nose                    | * Ovary                     | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Skin                      | * Stomach, Forestomach   | * Stomach, Glandular       |
| * Thyroid Gland           | * Trachea                   |                          |                            |

**MISSING**

- \* Gallbladder

**OBSERVATIONS**

- |                   |  |                                  |                         |
|-------------------|--|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                              | Hyperplasia                      | Mild                    |
| * Kidney          |  | Nephropathy                      | Minimal                 |
| * Liver           |  | Hepatocellular Adenoma           |                         |
|                   |  | Hepatocellular Carcinoma         |                         |
|                   |  | Infiltration Cellular            | Mononuclear CI, Minimal |
|                   | [ Hepatocellular Adenoma TGLs = 2-11 ]   |                                  |                         |
|                   | [ Hepatocellular Carcinoma TGLs = 1-10 ] |                                  |                         |
| * Lung            |  | Hepatocellular Carcinoma         | Metastatic (Liver)      |
|                   | [ Hepatocellular Carcinoma TGLs = 3-12 ] |                                  |                         |
| * Salivary Glands |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen          |  | Hematopoietic Cell Proliferation | Moderate                |
| * Thymus          |  | Atrophy                          | Moderate                |
| Tooth             |  | Dysplasia                        | Minimal                 |
| * Urinary Bladder |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                              | Hyperplasia                      | Cystic, Minimal         |

PRIMARY CAUSE OF DEATH    - Liver    Hepatocellular Carcinoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 259	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602159

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Pituitary Gland	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea		

**MISSING**

\* Parathyroid Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone Marrow		Fibrosis	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Liver		Fatty Change	Mild
	Centrilobular	Hepatocellular Carcinoma	
		Hypertrophy	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
		Tension Lipidosis	
	[ Hepatocellular Carcinoma TGLs = 1-10 ]		
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hyperplasia	Lymphoid, Mild
* Thymus		Atrophy	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 260 TMT: 4 SEX: Female DAY ON TEST: 731  
 DOSE: 0.25 G/KG DISP: Terminal Sacrifice HISTO: 0602160

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Skin	* Thyroid Gland	* Trachea	

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Lymphoma Malignant	
* Kidney		Lymphoma Malignant	
* Liver		Fatty Change	Mild
		Hepatocellular Adenoma	Mononuclear CI, Mild
	[ Hepatocellular Adenoma TGLs = 3-11 ]	Infiltration Cellular	
* Lung		Lymphoma Malignant	
* Ovary			
	Note: One ovary was missing		
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Lymphoma Malignant	
	[ Lymphoma Malignant TGLs = 2-10 ]		
* Stomach, Forestomach		Lymphoma Malignant	
* Stomach, Glandular		Lymphoma Malignant	
* Thymus		Atrophy	Mild
		Lymphoma Malignant	
* Urinary Bladder		Lymphoma Malignant	
* Uterus	Endometrium	Hyperplasia	Cystic, Mild
	[ Hyperplasia TGLs = 1-7 ]		

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 261    **TMT:** 4    **SEX:** Female    **DAY ON TEST:** 731  
**DOSE:** 0.25 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602161

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
Note: One adrenal gland was missing			
* Adren Medulla			
Note: One adrenal gland was missing			
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Liver		Fatty Change	Mild
	Centrilobular	Hepatocellular Adenoma	Multiple
		Hypertrophy	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
	[ Hepatocellular Adenoma	TGLs = 1,2,3-10+11+12 ]	
	[ Mixed Cell Focus	TGLs = 4,5-13+14 ]	
* Ovary		Cyst	Minimal
		Cystadenoma	
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Thymus		Atrophy	Marked
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 262    **TMT:** 4    **SEX:** Female    **DAY ON TEST:** 730  
**DOSE:** 0.25 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602162

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Clitoral Gland         | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Mammary Gland           |
| * Nose                      | * Pancreas               | * Parathyroid Gland        | * Pituitary Gland         |
| * Skin                      | * Spleen                 | * Stomach, Glandular       | * Thyroid Gland           |
| * Trachea                   |                          |                            |                           |

**OBSERVATIONS**

- |                        |   |                         |                         |
|------------------------|---|-------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                             | Hyperplasia             | Mild                    |
| * Esophagus            |   | Inflammation            | Chronic, Mild           |
| * Harderian Gland      |   | Infiltration Cellular   | Mononuclear CI, Minimal |
| * Kidney               |   | Mineralization          | Minimal                 |
| * Liver                | Centrilobular                           | Fatty Change            | Mild                    |
|                        |   | Hypertrophy             | Minimal                 |
|                        |   | Infiltration Cellular   | Mononuclear CI, Minimal |
|                        |   | Tension Lipidosis       |                         |
| * Ovary                |   | Cyst                    | Minimal                 |
|                        |   | Cystadenoma             |                         |
|                        |   | Teratoma Benign         |                         |
| * Salivary Glands      |   | Infiltration Cellular   | Mononuclear CI, Minimal |
| * Stomach, Forestomach |   | Squamous Cell Papilloma |                         |
|                        | [ Squamous Cell Papilloma TGLs = 1-10 ] |                         |                         |
| * Thymus               |   | Atrophy                 | Minimal                 |
| * Urinary Bladder      |   | Infiltration Cellular   | Mononuclear CI, Minimal |
| * Uterus               | Endometrium                             | Hyperplasia             | Cystic, Minimal         |

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	263	TMT:	4	SEX:	Female	DAY ON TEST:	730
		DOSE:	0.25 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602163

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ORGAN AND ACCOUNTABLE SITE STATUS

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NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder			

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OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Liver		Eosinophilic Focus	
	Centrilobular	Fatty Change	Mild
		Hypertrophy	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
* Ovary		Cyst	Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Thymus		Atrophy	Mild
* Uterus	Endometrium	Hyperplasia	Cystic, Mild



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 264    **TMT:** 4    **SEX:** Female    **DAY ON TEST:** 724  
**DOSE:** 0.25 G/KG    **DISP:** Natural Death    **HISTO:** 0602164

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla        | Blood Vessel               | * Bone                    | * Brain                     |
| * Clitoral Gland         | * Esophagus                | * Eye                     | * Gallbladder               |
| * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      | * Kidney                    |
| * Lung                   | * Lymph Node, Mandibular   | * Lymph Node, Mesenteric  | * Mammary Gland             |
| * Nose                   | * Ovary                    | * Pancreas                | * Parathyroid Gland         |
| * Pituitary Gland        | * Skin                     | * Stomach, Forestomach    | * Stomach, Glandular        |
| * Thyroid Gland          | * Urinary Bladder          |                           |                             |

**OBSERVATIONS**

- |   |                      |   |                                    |
|---|----------------------|---|------------------------------------|
| * Adrenal Cortex                                | Subcapsular          | Hyperplasia                             | Mild                               |
| * Bone Marrow                                   |                      | Hemangiosarcoma                         |                                    |
| * Harderian Gland                               |                      | Infiltration Cellular                   | Mononuclear CI, Minimal            |
| * Heart   | Artery<br>Myocardium | Infiltration Cellular<br>Mineralization | Mononuclear CI, Minimal<br>Minimal |
| * Liver   |                      | Infiltration Cellular<br>Necrosis       | Mononuclear CI, Minimal<br>Minimal |
| Mesentery                                       | Fat                  | Necrosis                                | Moderate                           |
| [ Necrosis TGLs = 2-10 ]                        |                      |   |                                    |
| * Salivary Glands                               |                      | Infiltration Cellular                   | Mononuclear CI, Minimal            |
| * Spleen  |                      | Hematopoietic Cell Proliferation        | Moderate                           |
| [ Hematopoietic Cell Proliferation TGLs = 1-4 ] |                      |   |                                    |
| * Thymus  |                      | Atrophy                                 | Moderate                           |
| * Trachea                                       |                      | Inflammation                            | Chronic, Minimal                   |
| * Uterus  | Endometrium          | Hyperplasia                             | Cystic, Minimal                    |

**PRIMARY CAUSE OF DEATH** - Bone Marrow Hemangiosarcoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 265	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602165

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mesenteric | * Mammary Gland            |
| * Nose                    | * Ovary                     | * Pancreas               | * Parathyroid Gland        |
| * Skin                    | * Stomach, Forestomach      | * Stomach, Glandular     | * Thyroid Gland            |
| * Trachea                 |                             |                          |                            |

**OBSERVATIONS**

- |                                      |                                |                                  |                          |
|--------------------------------------|--------------------------------|----------------------------------|--------------------------|
| * Adrenal Cortex                     | Subcapsular                    | Hyperplasia                      | Mild                     |
| * Clitoral Gl                        |                                |                                  |                          |
| Note: One clitoral gland was missing |                                |                                  |                          |
| * Harderian Gland                    |                                | Infiltration Cellular            | Mononuclear CI, Minimal  |
| * Kidney                             |                                | Hydronephrosis                   | Marked                   |
|                                      |                                | Mineralization                   | Minimal                  |
|                                      |                                | Nephropathy                      | Minimal                  |
|                                      | [ Hydronephrosis TGLs = 1-10 ] |                                  |                          |
| * Liver                              |                                | Infiltration Cellular            | Mononuclear CI, Minimal  |
| * Lymph Node, Mandibular             |                                | Hyperplasia                      | Lymphoid, Minimal        |
| * Pituitary Gland                    |                                | Cyst                             | Minimal                  |
| * Salivary Glands                    |                                | Infiltration Cellular            | Mononuclear CI, Mild     |
| * Spleen                             |                                | Hematopoietic Cell Proliferation | Mild                     |
|                                      |                                | Lymphoma Malignant               |                          |
| * Thymus                             |                                | Atrophy                          | Minimal                  |
| * Urinary Bladder                    |                                | Infiltration Cellular            | Mononuclear CI, Moderate |
|                                      |                                | Inflammation                     | Marked                   |
| * Uterus                             | Endometrium                    | Hyperplasia                      | Cystic, Mild             |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 266	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602166

ORGAN AND ACCOUNTABLE SITE STATUS

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Mammary Gland            |
| * Nose                    | * Pancreas                  | * Parathyroid Gland      | * Pituitary Gland          |
| * Salivary Glands         | * Skin                      | * Stomach, Forestomach   | * Stomach, Glandular       |
| * Thyroid Gland           | * Trachea                   |                          |                            |

**OBSERVATIONS**

- |                          |                           |                                  |                         |
|--------------------------|---------------------------|----------------------------------|-------------------------|
| * Adrenal Cortex         | Subcapsular               | Hyperplasia                      | Mild                    |
| * Harderian Gland        |                           | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Kidney                 |                           | Nephropathy                      | Minimal                 |
| * Liver                  | Centrilobular             | Fatty Change                     | Minimal                 |
|                          |                           | Hypertrophy                      | Minimal                 |
|                          |                           | Infiltration Cellular            | Mononuclear CI, Minimal |
| Lymph Node               | Mediastinal               | Hyperplasia                      | Plasma Cell, Moderate   |
| * Lymph Node, Mesenteric |                           | Hyperplasia                      | Plasma Cell, Moderate   |
| * Ovary                  |                           | Cystadenoma                      |                         |
|                          |                           | Hemangioma                       |                         |
|                          | [ Hemangioma TGLs = 1-7 ] |                                  |                         |
| * Spleen                 |                           | Hematopoietic Cell Proliferation | Mild                    |
| * Thymus                 |                           | Atrophy                          | Minimal                 |
| * Urinary Bladder        |                           | Infiltration Cellular            | Mononuclear CI, Mild    |
| * Uterus                 | Endometrium               | Hyperplasia                      | Cystic, Mild            |

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

ANIMAL NUM: 267 TMT: 4 SEX: Female DAY ON TEST: 723  
DOSE: 0.25 G/KG DISP: Natural Death HISTO: 0602167

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder
* Uterus			

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Adenoma	
Note: One Harderian gland was missing [ Adenoma TGLs = 2-9 ]			
* Heart	Valve	Inflammation Thrombosis	Marked Marked
* Kidney	Papilla	Mineralization Necrosis	Minimal Mild
* Liver		Infiltration Cellular	Mononuclear CI, Minimal
* Lung		Alveolar/Bronchiolar Adenoma	
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLs = 1-10 ]			
* Thymus		Atrophy	Mild

PRIMARY CAUSE OF DEATH - Heart Valve Inflammation

Animal Note: One eye was missing (cannibalized)

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 268    **TMT:** 4    **SEX:** Female    **DAY ON TEST:** 565  
**DOSE:** 0.25 G/KG    **DISP:** Natural Death    **HISTO:** 0602168

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                    | * Clitoral Gland          | * Esophagus                 | * Eye                    |
| * Gallbladder              | * Harderian Gland         | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Kidney                  | * Lung                      | * Lymph Node, Mandibular |
| * Lymph Node, Mesenteric   | * Mammary Gland           | * Nose                      | * Ovary                  |
| * Pancreas                 | * Parathyroid Gland       | * Pituitary Gland           | * Skin                   |
| * Spleen                   | * Stomach, Glandular      | * Thyroid Gland             | * Trachea                |
| * Urinary Bladder          |                           |                             |                          |

**OBSERVATIONS**

- |                                      |             |                       |                         |
|--------------------------------------|-------------|-----------------------|-------------------------|
| * Adrenal Cortex                     | Subcapsular | Hyperplasia           | Mild                    |
| * Clitoral Gland                     |             |                       |                         |
| Note: One clitoral gland was missing |             |                       |                         |
| * Islets, Pancreatic                 |             | Hyperplasia           | Minimal                 |
| * Liver                              |             | Fatty Change          | Mild                    |
|                                      |             | Infiltration Cellular | Mononuclear CI, Minimal |
| Mesentery                            | Fat         | Necrosis              | Moderate                |
| [ Necrosis TGLs = 1,2-10+11 ]        |             |                       |                         |
| * Salivary Glands                    |             | Atrophy               | Minimal                 |
|                                      |             | Infiltration Cellular | Mononuclear CI, Minimal |
| * Stomach, Forestomach               |             | Inflammation          | Chronic, Minimal        |
| * Thymus                             |             | Atrophy               | Marked                  |
| * Uterus                             | Endometrium | Hyperplasia           | Cystic, Minimal         |

PRIMARY CAUSE OF DEATH - UNCERTAIN

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 269    **TMT:** 4    **SEX:** Female    **DAY ON TEST:** 521  
**DOSE:** 0.25 G/KG    **DISP:** Natural Death    **HISTO:** 0602169

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Kidney                  | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Mammary Gland            |
| * Ovary                   | * Pancreas                  | * Parathyroid Gland      | * Pituitary Gland          |
| * Spleen                  | * Stomach, Forestomach      | * Stomach, Glandular     | * Thyroid Gland            |
| * Trachea                 | * Urinary Bladder           | * Uterus                 |                            |

**OBSERVATIONS**

- |   |             |                       |                         |
|---|-------------|-----------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular | Hyperplasia           | Mild                    |
| * Eye   |             |                       |                         |
| Note: One eye was missing   |             |                       |                         |
| * Harderian Gland   |             | Infiltration Cellular | Mononuclear CI, Minimal |
| * Islets, Pancreatic  |             | Hyperplasia           | Minimal                 |
| * Liver   |             | Tension Lipidosis     |                         |
| * Lung  | Serosa      | Fibrosis              | Minimal                 |
| * Nose  |             | Inflammation          | Chronic, Minimal        |
| * Salivary Glands   |             | Infiltration Cellular | Mononuclear CI, Minimal |
| * Skin  | Subcut Tiss | Schwannoma Malignant  |                         |
| Note: Based on histology TGL 1 was a dermal tumor rather than a pulmonary tumor as described grossly<br>[ Schwannoma Malignant TGLs = 1-10+11 ] |             |                       |                         |
| * Thymus  |             | Atrophy               | Marked                  |

**PRIMARY CAUSE OF DEATH**    - Skin Subcut Tiss Schwannoma Malignant

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 270    **TMT:** 4    **SEX:** Female    **DAY ON TEST:** 730  
**DOSE:** 0.25 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602170

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Mammary Gland            |
| * Nose                    | * Pancreas                  | * Parathyroid Gland      | * Pituitary Gland          |
| * Skin                    | * Stomach, Forestomach      | * Stomach, Glandular     | * Thyroid Gland            |
| * Trachea                 |                             |                          |                            |

**OBSERVATIONS**

- |                   |  |                                  |                         |
|-------------------|--|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                                    | Hyperplasia                      | Mild                    |
| * Harderian Gland |  | Adenoma                          |                         |
|                   | [ Adenoma TGLs = 1-9 ]                         | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Kidney          |  | Nephropathy                      | Minimal                 |
| * Liver           |  | Fatty Change                     | Minimal                 |
|                   |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Lung            |  | Alveolar/Bronchiolar Carcinoma   |                         |
|                   | [ Alveolar/Bronchiolar Carcinoma TGLs = 2-10 ] |                                  |                         |
| * Ovary           |  | Cystadenoma                      |                         |
| * Salivary Glands |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen          |  | Hematopoietic Cell Proliferation | Mild                    |
|                   |  | Hyperplasia                      | Lymphoid, Mild          |
| * Thymus          |  | Atrophy                          | Mild                    |
| * Urinary Bladder |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                                    | Hyperplasia                      | Cystic, Moderate        |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 271    **TMT:** 4    **SEX:** Female    **DAY ON TEST:** 666  
**DOSE:** 0.25 G/KG    **DISP:** Natural Death    **HISTO:** 0602171

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | * Bone Marrow             | * Brain                     | * Clitoral Gland         |
| * Esophagus                | * Eye                     | * Gallbladder               | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular |
| * Lymph Node, Mesenteric   | * Mammary Gland           | * Nose                      | * Ovary                  |
| * Pancreas                 | * Pituitary Gland         | * Salivary Glands           | * Skin                   |
| * Stomach, Forestomach     | * Stomach, Glandular      | * Thyroid Gland             | * Trachea                |
| * Urinary Bladder          |                           |                             |                          |

**OBSERVATIONS**

- |                     |                                 |                                  |                         |
|---------------------|---------------------------------|----------------------------------|-------------------------|
| * Adrenal Cortex    | Subcapsular                     | Hyperplasia                      | Mild                    |
| Blood Vessel        |                                 | Mineralization                   | Mild                    |
| * Bone              |                                 | Osteosarcoma                     |                         |
|                     | [ Osteosarcoma TGLs = 2-10 ]    |                                  |                         |
| * Harderian Gland   |                                 | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Heart             | Myocardium                      | Mineralization                   | Moderate                |
| * Kidney            |                                 | Mineralization                   | Mild                    |
| * Liver             |                                 | Fatty Change                     | Marked                  |
|                     |                                 | Infiltration Cellular            | Mononuclear CI, Minimal |
|                     | [ Fatty Change TGLs = 1-3+4+5 ] | Mixed Cell Focus                 |                         |
| * Parathyroid Gland |                                 | Cyst                             | Minimal                 |
| * Spleen            | Lymph Follic                    | Atrophy                          | Mild                    |
|                     |                                 | Hematopoietic Cell Proliferation | Mild                    |
| * Thymus            |                                 | Atrophy                          | Marked                  |
| * Uterus            | Endometrium                     | Hyperplasia                      | Cystic, Minimal         |

**PRIMARY CAUSE OF DEATH** - Bone Osteosarcoma



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 272    **TMT:** 4    **SEX:** Female    **DAY ON TEST:** 729  
**DOSE:** 0.25 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602172

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Amyloid Deposition	Minimal
		Mineralization	Minimal
		Nephropathy	Mild
* Liver		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
* Mammary Gland		Adenoma	
	[ Adenoma TGLs = 1-10 ]		
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Thymus		Atrophy	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

ANIMAL NUM: 273 TMT: 4 SEX: Female DAY ON TEST: 701  
DOSE: 0.25 G/KG DISP: Natural Death HISTO: 0602173

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Pituitary Gland
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea			

MISSING

\* Parathyroid Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Mineralization	Mild
* Liver		Basophilic Focus	
		Hepatocellular Carcinoma	
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Basophilic Focus TGLs = 4-12 ]		
	[ Hepatocellular Carcinoma TGLs = 1-10 ]		
* Lung		Metaplasia	Osseous, Minimal
Mesentery	Fat	Necrosis	Marked
	[ Necrosis TGLs = 2,3-11 ]		
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Thymus		Atrophy	Moderate
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild

PRIMARY CAUSE OF DEATH - Liver Hepatocellular Carcinoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 274 TMT: 4 SEX: Female DAY ON TEST: 730  
 DOSE: 0.25 G/KG DISP: Terminal Sacrifice HISTO: 0602174

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Gallbladder		Cyst	Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Nephropathy	Minimal
* Liver		Fatty Change	Minimal
	Centrilobular	Hepatocellular Carcinoma	Minimal
	[ Hepatocellular Carcinoma TGLs = 1-10 ]	Hypertrophy	Mononuclear CI, Minimal
		Infiltration Cellular	
* Lung		Hepatocellular Carcinoma	Metastatic (Liver)
	Alveolar Epith	Hyperplasia	Minimal
Mesentery	Fat	Necrosis	Moderate
	[ Necrosis TGLs = 2-11 ]		
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Thymus		Atrophy	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 275	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602175

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lung                   | * Lymph Node, Mandibular   |
| * Lymph Node, Mesenteric  | * Mammary Gland             | * Nose                   | * Pancreas                 |
| * Parathyroid Gland       | * Pituitary Gland           | * Skin                   | * Spleen                   |
| * Stomach, Forestomach    | * Stomach, Glandular        | * Thymus                 | * Thyroid Gland            |
| * Trachea                 | * Urinary Bladder           |                          |                            |

**OBSERVATIONS**

- |                   |  |                        |                         |
|-------------------|--|------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                            | Hyperplasia            | Mild                    |
| * Harderian Gland |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Liver           |  | Fatty Change           | Minimal                 |
|                   | Centrilobular                          | Hepatocellular Adenoma | Minimal                 |
|                   | [ Hepatocellular Adenoma TGLs = 1-10 ] | Hypertrophy            | Mononuclear CI, Minimal |
|                   |  | Infiltration Cellular  |                         |
| * Ovary           |  | Cyst                   | Minimal                 |
| * Salivary Glands |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                            | Hyperplasia            | Cystic, Minimal         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 276    **TMT:** 4    **SEX:** Female    **DAY ON TEST:** 730  
**DOSE:** 0.25 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602176

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Brain                   |
| * Clitoral Gland            | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lung                      | * Lymph Node, Mesenteric | * Mammary Gland            | * Nose                    |
| * Pancreas                  | * Skin                   | * Stomach, Forestomach     | * Stomach, Glandular      |
| * Thyroid Gland             | * Trachea                |                            |                           |

**MISSING**

- \* Parathyroid Gland

**OBSERVATIONS**

- |                          |                            |                                  |                         |
|--------------------------|----------------------------|----------------------------------|-------------------------|
| * Adrenal Cortex         | Subcapsular                | Hyperplasia                      | Mild                    |
| * Bone Marrow            |                            | Fibrosis                         | Mild                    |
| * Harderian Gland        |                            | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Kidney                 |                            | Amyloid Deposition               | Minimal                 |
|                          |                            | Mineralization                   | Mild                    |
|                          |                            | Nephropathy                      | Mild                    |
| * Liver                  |                            | Infiltration Cellular            | Mononuclear CI, Mild    |
| * Lymph Node, Mandibular |                            | Hyperplasia                      | Lymphoid, Mild          |
| * Ovary                  |                            | Cyst                             | Minimal                 |
|                          |                            | Cystadenoma                      |                         |
| * Pituitary Gland        | Pars Distalis              | Hyperplasia                      | Minimal                 |
| * Salivary Glands        |                            | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen                 |                            | Hematopoietic Cell Proliferation | Mild                    |
| * Thymus                 |                            | Atrophy                          | Minimal                 |
| * Urinary Bladder        |                            | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus                 | Endometrium                | Hyperplasia                      | Cystic, Mild            |
|                          | [ Hyperplasia TGLs = 1-7 ] |                                  |                         |

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

ANIMAL NUM: 277 TMT: 4 SEX: Female DAY ON TEST: 708  
DOSE: 0.25 G/KG DISP: Natural Death HISTO: 0602177

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Esophagus	* Eye	* Gallbladder	* Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Liver	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Uterus

MISSING

\* Clitoral Gland \* Mammary Gland

AUTO PRECLUDES DIAG.

\* Spleen \* Urinary Bladder

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
Note: One adrenal gland was missing			
* Adren Medulla			
Note: One adrenal gland was missing			
* Bone		Osteosarcoma	
Note: Femur was missing (cannibalized) but bone and marrow evaluated at other sites			
[ Osteosarcoma TGLs = 1-10 ]			
* Kidney		Inflammation	Mild
* Lung		Alveolar/Bronchiolar Adenoma	Acute, Mild
		Inflammation	Minimal
		Mineralization	

PRIMARY CAUSE OF DEATH - Bone Osteosarcoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 278    **TMT:** 4    **SEX:** Female    **DAY ON TEST:** 730  
**DOSE:** 0.25 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602178

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Mammary Gland            |
| * Nose                    | * Ovary                     | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Skin                      | * Stomach, Forestomach   | * Stomach, Glandular       |
| * Thyroid Gland           | * Trachea                   |                          |                            |

**OBSERVATIONS**

- |                   |  |                              |                         |
|-------------------|--|------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                                  | Hyperplasia                  | Mild                    |
| * Harderian Gland |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Kidney          |  | Nephropathy                  | Mild                    |
| * Liver           |  | Fatty Change                 | Minimal                 |
|                   |  | Hepatocellular Carcinoma     |                         |
|                   |  | Infiltration Cellular        | Mononuclear CI, Minimal |
|                   |  | Necrosis                     | Mild                    |
|                   | [ Hepatocellular Carcinoma TGLs = 1-10 ]     |                              |                         |
| * Lung            | Alveolus                                     | Alveolar/Bronchiolar Adenoma |                         |
|                   | [ Alveolar/Bronchiolar Adenoma TGLs = 3-11 ] | Infiltration Cellular        | Histiocyte, Mild        |
| * Salivary Glands |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Spleen          |  | Lymphoma Malignant           |                         |
| * Thymus          |  | Atrophy                      | Marked                  |
| * Urinary Bladder |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                                  | Hyperplasia                  | Cystic, Minimal         |
|                   | [ Hyperplasia TGLs = 2-7 ]                   |                              |                         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 279    **TMT:** 4    **SEX:** Female    **DAY ON TEST:** 715  
**DOSE:** 0.25 G/KG    **DISP:** Natural Death    **HISTO:** 0602179

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Mammary Gland            |
| * Nose                    | * Ovary                     | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Skin                      | * Stomach, Glandular     | * Thyroid Gland            |
| * Trachea                 |                             |                          |                            |

**OBSERVATIONS**

- |                        |  |                                  |                         |
|------------------------|--|----------------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                                  | Hyperplasia                      | Mild                    |
| * Harderian Gland      |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Kidney               |  | Nephropathy                      | Minimal                 |
| * Liver                |  | Eosinophilic Focus               |                         |
|                        |  | Fatty Change                     | Minimal                 |
|                        | Centrilobular                                | Hepatocellular Carcinoma         |                         |
|                        |  | Hypertrophy                      | Minimal                 |
|                        |  | Infiltration Cellular            | Mononuclear CI, Minimal |
|                        | [ Hepatocellular Carcinoma TGLs = 1-10 ]     |                                  |                         |
| * Lung                 |  | Alveolar/Bronchiolar Adenoma     |                         |
|                        |  | Hepatocellular Carcinoma         | Metastatic (Liver)      |
|                        | [ Alveolar/Bronchiolar Adenoma TGLs = 2-11 ] |                                  |                         |
| * Salivary Glands      |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen               |  | Hematopoietic Cell Proliferation | Moderate                |
| * Stomach, Forestomach | Epithelium                                   | Hyperplasia                      | Minimal                 |
|                        |  | Inflammation                     | Chronic, Mild           |
|                        |  | Ulcer                            | Mild                    |
|                        | [ Hyperplasia TGLs = 3-12 ]                  |                                  |                         |
| * Thymus               |  | Atrophy                          | Minimal                 |
| * Urinary Bladder      |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus               | Endometrium                                  | Hyperplasia                      | Cystic, Moderate        |

**PRIMARY CAUSE OF DEATH** - Liver Hepatocellular Carcinoma



TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

ANIMAL NUM: 280 TMT: 4 SEX: Female DAY ON TEST: 697  
DOSE: 0.25 G/KG DISP: Moribund Sacrifice HISTO: 0602180

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea		

MISSING

\* Parathyroid Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Mild
* Liver		Hematopoietic Cell Proliferation	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
		Necrosis	Minimal
* Ovary		Cyst	Minimal
		Cystadenoma	
* Spleen		Hematopoietic Cell Proliferation	Mild
* Thymus		Atrophy	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Moderate
	[ Hyperplasia TGLs = 1-7 ]		

PRIMARY CAUSE OF DEATH - UNCERTAIN

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 281    **TMT:** 4    **SEX:** Female    **DAY ON TEST:** 669  
**DOSE:** 0.25 G/KG    **DISP:** Moribund Sacrifice    **HISTO:** 0602181

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Mammary Gland	* Nose	* Pancreas
* Pituitary Gland	* Salivary Glands	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea		

**MISSING**

\* Parathyroid Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia Lymphoma Malignant	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Lymphoma Malignant	
* Kidney		Lymphoma Malignant Nephropathy	Minimal
* Liver		Hematopoietic Cell Proliferation Hepatocellular Adenoma Infiltration Cellular	Mild Mononuclear CI, Minimal
	[ Hepatocellular Adenoma TGLs = 9-18 ]		
Lymph Node	Deep Cervical Lumbar Mediastinal	Lymphoma Malignant Lymphoma Malignant Lymphoma Malignant	
	[ Lymphoma Malignant TGLs = 4-13 ]		
	[ Lymphoma Malignant TGLs = 7-16 ]		
	[ Lymphoma Malignant TGLs = 8-17 ]		
* Lymph Node, Mandibular		Lymphoma Malignant	
	[ Lymphoma Malignant TGLs = 6-15 ]		
* Lymph Node, Mesenteric		Lymphoma Malignant	
	[ Lymphoma Malignant TGLs = 5-14 ]		
* Ovary		Cyst Lymphoma Malignant	Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b> 281	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 669
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Moribund Sacrifice	<b>HISTO:</b> 0602181

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**ORGAN AND ACCOUNTABLE SITE STATUS**

---

* Skin		Ulcer	Marked
	[ Ulcer TGLs = 1,2,3-10+11+12 ]		
* Spleen		Lymphoma Malignant	
	[ Lymphoma Malignant TGLs = 10-4 ]		
* Thymus		Lymphoma Malignant	
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild

---

PRIMARY CAUSE OF DEATH - Spleen Lymphoma Malignant

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 282	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602182

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Mammary Gland          | * Nose                     |
| * Ovary                   | * Pancreas                  | * Parathyroid Gland      | * Pituitary Gland          |
| * Skin                    | * Stomach, Forestomach      | * Stomach, Glandular     | * Thyroid Gland            |
| * Trachea                 |                             |                          |                            |

**OBSERVATIONS**

- |                          |                                  |  |                                 |
|--------------------------|----------------------------------|--|---------------------------------|
| * Adrenal Cortex         | Subcapsular                      | Hyperplasia  | Mild                            |
| * Harderian Gland        |                                  | Hyperplasia<br>Infiltration Cellular   | Mild<br>Mononuclear CI, Minimal |
| * Kidney                 |                                  | Mineralization<br>Nephropathy  | Minimal<br>Minimal              |
| * Liver                  |                                  | Fatty Change<br>Infiltration Cellular<br>Mixed Cell Focus<br>Tension Lipidosis | Mild<br>Mononuclear CI, Minimal |
|                          | [ Mixed Cell Focus TGLs = 2-10 ] |  |                                 |
| * Lymph Node, Mandibular |                                  | Lymphoma Malignant   |                                 |
| * Lymph Node, Mesenteric |                                  | Lymphoma Malignant   |                                 |
| * Salivary Glands        |                                  | Infiltration Cellular  | Mononuclear CI, Minimal         |
| * Spleen                 |                                  | Lymphoma Malignant   |                                 |
| * Thymus                 |                                  | Lymphoma Malignant   |                                 |
| * Urinary Bladder        |                                  | Infiltration Cellular  | Mononuclear CI, Minimal         |
| * Uterus                 | Endometrium                      | Hyperplasia  | Cystic, Moderate                |
|                          | [ Hyperplasia TGLs = 1-7 ]       |  |                                 |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 283    **TMT:** 4    **SEX:** Female    **DAY ON TEST:** 731  
**DOSE:** 0.25 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602183

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea			

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Hyperplasia	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Hepatocellular Carcinoma Infiltration Cellular	Mononuclear CI, Minimal
	[ Hepatocellular Carcinoma TGLs = 2-10 ]		
* Lymph Node, Mandibular		Hyperplasia	Lymphoid, Moderate
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Skin	Subcut Tiss	Fibrosarcoma Fibrosis	Mild
	Note: TGL 3 was in the skin (pinna of ear) rather than Zymbals Gland [ Fibrosarcoma TGLs = 3-11 ]		
* Spleen		Hematopoietic Cell Proliferation	Mild
* Thymus		Atrophy	Marked
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Moderate
	[ Hyperplasia TGLs = 1-7 ]		

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 284	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602184

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Blood Vessel	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Adrenal Medulla		Pheochromocytoma Benign	
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Liver		Fatty Change	Mild
		Hepatocellular Adenoma	Multiple
		Infiltration Cellular	Mononuclear CI, Minimal
		Tension Lipidosis	
	[ Hepatocellular Adenoma TGLs = 4,5-11+12 ]		
Mesentery	Fat	Necrosis	Mild
	[ Necrosis TGLs = 1-10 ]		
* Ovary		Hemangioma	
	[ Hemangioma TGLs = 3-7 ]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Thymus		Atrophy	Moderate
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Moderate
	[ Hyperplasia TGLs = 2-7 ]	Metaplasia	Squamous, Moderate

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 285	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602185

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Nose                      | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Skin                      | * Stomach, Forestomach   | * Stomach, Glandular       |
| * Thyroid Gland           | * Trachea                   |                          |                            |

**OBSERVATIONS**

- |                   |                                    |   |                         |
|-------------------|------------------------------------|---|-------------------------|
| * Adrenal Cortex  | Subcapsular                        | Hyperplasia                                 | Mild                    |
| * Harderian Gland |                                    | Infiltration Cellular                       | Mononuclear CI, Minimal |
| * Kidney          |                                    | Nephropathy                                 | Minimal                 |
| * Liver           |                                    | Eosinophilic Focus<br>Infiltration Cellular | Mononuclear CI, Minimal |
|                   | [ Eosinophilic Focus TGLs = 1-10 ] |   |                         |
| * Ovary           |                                    | Cyst  | Minimal                 |
| * Salivary Glands |                                    | Infiltration Cellular                       | Mononuclear CI, Minimal |
| * Spleen          |                                    | Hematopoietic Cell Proliferation            | Minimal                 |
| * Thymus          |                                    | Atrophy                                     | Minimal                 |
| * Urinary Bladder |                                    | Infiltration Cellular                       | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                        | Hyperplasia                                 | Cystic, Moderate        |

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b> 286	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 575
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 0602186

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ORGAN AND ACCOUNTABLE SITE STATUS

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**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

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**AUTO PRECLUDES DIAG.**

\* Spleen

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**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Bone	Joint	Inflammation	Chronic, Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Liver		Fatty Change	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
* Nose		Inflammation	Chronic, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Thymus		Atrophy	Mild

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PRIMARY CAUSE OF DEATH - UNCERTAIN

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 287	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602187

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Nose                      | * Ovary                  | * Pancreas                 |
| * Parathyroid Gland       | * Pituitary Gland           | * Skin                   | * Stomach, Forestomach     |
| * Stomach, Glandular      | * Thyroid Gland             | * Trachea                | * Urinary Bladder          |

**OBSERVATIONS**

- |                   |               |                                  |                         |
|-------------------|---------------|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular   | Hyperplasia                      | Mild                    |
| * Harderian Gland |               | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Kidney          |               | Mineralization                   | Minimal                 |
|                   |               | Nephropathy                      | Minimal                 |
| * Liver           |               | Eosinophilic Focus               |                         |
|                   | Centrilobular | Fatty Change                     | Minimal                 |
|                   |               | Hypertrophy                      | Minimal                 |
|                   |               | Infiltration Cellular            | Mononuclear CI, Minimal |
|                   |               | Mixed Cell Focus                 |                         |
| * Salivary Glands |               | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen          |               | Hematopoietic Cell Proliferation | Mild                    |
|                   |               | Hyperplasia                      | Lymphoid, Mild          |
| * Thymus          |               | Atrophy                          | Minimal                 |
| * Uterus          | Endometrium   | Hyperplasia                      | Cystic, Moderate        |
|                   |               | Inflammation                     | Suppurative, Mild       |
- [ Hyperplasia TGLs = 1-7 ]

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 288    **TMT:** 4    **SEX:** Female    **DAY ON TEST:** 731  
**DOSE:** 0.25 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602188

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Skin	* Stomach, Glandular	* Thyroid Gland	* Trachea

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone		Fibrosis	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney	Papilla	Mineralization	Minimal
		Necrosis	Mild
		Nephropathy	Mild
* Liver		Fatty Change	Minimal
		Hepatocellular Adenoma	
	Centrilobular	Hypertrophy	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
		Tension Lipidosis	
	[ Hepatocellular Adenoma TGLs = 3-11 ]		
Mesentery	Fat	Necrosis	Moderate
	[ Necrosis TGLs = 2-10 ]		
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hyperplasia	Lymphoid, Mild
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
* Thymus		Atrophy	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Moderate
	[ Hyperplasia TGLs = 1-7 ]		

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 289	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 669
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Moribund Sacrifice	<b>HISTO:</b> 0602189

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Parathyroid Gland	* Pituitary Gland	* Stomach, Glandular
* Trachea			

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Gallbladder		Liposarcoma	Metastatic (Skin)
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Intestine Small, Duodenum		Liposarcoma	Metastatic (Skin)
* Kidney	Papilla	Mineralization	Mild
		Necrosis	Mild
* Liver		Fatty Change	Minimal
		Liposarcoma	Metastatic (Skin)
		Necrosis	Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLs = 4-12 ]			
* Pancreas		Liposarcoma	Metastatic (Skin)
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
Skeletal Muscle		Liposarcoma	Metastatic (Skin)
[ Liposarcoma TGLs = 3-11 ]			
* Skin	Subcut Tiss	Liposarcoma	
Note: TGL 1 was in skin based on microscopic examination			
[ Liposarcoma TGLs = 1-10 ]			
* Spleen		Liposarcoma	Metastatic (Skin)
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
		Inflammation	Chronic, Minimal
* Thymus		Atrophy	Marked
* Thyroid Gland		Cyst	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 08:27:00

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

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<b>ANIMAL NUM:</b> 289	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 669
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Moribund Sacrifice	<b>HISTO:</b> 0602189

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ORGAN AND ACCOUNTABLE SITE STATUS

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* Uterus	Endometrium	Hyperplasia	Cystic, Moderate
[ Hyperplasia	TGLs = 2-7 ]		

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PRIMARY CAUSE OF DEATH - Skin Subcut Tiss Liposarcoma

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b> 290	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 372
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 0602190

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ORGAN AND ACCOUNTABLE SITE STATUS

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**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Esophagus	* Eye	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Uterus		

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**MISSING**

* Clitoral Gland	* Gallbladder	* Harderian Gland	* Intestine Large, Rectum
* Lymph Node, Mandibular	* Salivary Glands	* Urinary Bladder	

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**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Eye			
Note: One eye was cannibalized			
* Heart	Valve	Inflammation	Marked
* Liver		Infiltration Cellular	Mononuclear CI, Minimal
* Nose			
Note: First and second nasal sections were missing			

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PRIMARY CAUSE OF DEATH - Heart Valve Inflammation

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 291 TMT: 4 SEX: Female DAY ON TEST: 730  
 DOSE: 0.25 G/KG DISP: Terminal Sacrifice HISTO: 0602191

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Pancreas	* Parathyroid Gland	* Skin
* Stomach, Glandular	* Thyroid Gland	* Trachea	

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone		Fibrosis	Mild
* Harderian Gland		Hyperplasia	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Fatty Change	Minimal
	Centrilobular	Hepatocellular Carcinoma	
		Hypertrophy	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
	[ Hepatocellular Carcinoma TGLs = 2-4 ]		
* Ovary		Cyst	Minimal
		Hemangioma	
		Thrombosis	Marked
	[ Hemangioma TGLs = 1-7 ]		
* Pituitary Gland	Pars Distalis	Adenoma	
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Stomach, Forestomach		Erosion	Mild
	Epithelium	Hyperplasia	Mild
		Inflammation	Chronic, Minimal
	[ Hyperplasia TGLs = 3-10 ]		
* Thymus		Atrophy	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	291	<b>TMT:</b>	4	<b>SEX:</b>	Female	<b>DAY ON TEST:</b>	730
		<b>DOSE:</b>	0.25 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602191

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Uterus	Endometrium	Hyperplasia	Cystic, Mild
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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 292	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602192

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Mammary Gland            |
| * Nose                    | * Ovary                     | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Salivary Glands           | * Skin                   | * Spleen                   |
| * Stomach, Forestomach    | * Stomach, Glandular        | * Thyroid Gland          | * Trachea                  |

**OBSERVATIONS**

- |                      |               |                       |                         |
|----------------------|---------------|-----------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular   | Hyperplasia           | Mild                    |
| * Harderian Gland    |               | Infiltration Cellular | Mononuclear CI, Minimal |
| * Islets, Pancreatic |               | Adenoma               |                         |
| * Kidney             |               | Mineralization        | Minimal                 |
| * Liver              | Centrilobular | Fatty Change          | Minimal                 |
|                      |               | Hypertrophy           | Minimal                 |
|                      |               | Infiltration Cellular | Mononuclear CI, Minimal |
|                      |               | Lymphoma Malignant    |                         |
|                      |               | Mixed Cell Focus      |                         |
| [ Mixed Cell Focus   | TGLs = 1-4 ]  |                       |                         |
| * Thymus             |               | Atrophy               | Marked                  |
| * Urinary Bladder    |               | Infiltration Cellular | Mononuclear CI, Minimal |
| * Uterus             | Endometrium   | Hyperplasia           | Cystic, Mild            |



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 293	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602193

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone Marrow              | * Brain                   |
| * Clitoral Gland            | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Mammary Gland           |
| * Nose                      | * Pancreas               | * Parathyroid Gland        | * Pituitary Gland         |
| * Skin                      | * Spleen                 | * Stomach, Forestomach     | * Stomach, Glandular      |
| * Thyroid Gland             | * Trachea                |                            |                           |

**OBSERVATIONS**

- |                   |                                       |                        |                         |
|-------------------|---------------------------------------|------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                           | Hyperplasia            | Mild                    |
| * Bone            |                                       | Fibrosis               | Minimal                 |
| * Harderian Gland |                                       | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Kidney          |                                       | Nephropathy            | Minimal                 |
| * Liver           |                                       | Fatty Change           | Mild                    |
|                   |                                       | Hepatocellular Adenoma |                         |
|                   |                                       | Infiltration Cellular  | Mononuclear CI, Minimal |
|                   | [ Hepatocellular Adenoma TGLs = 1-5 ] |                        |                         |
| * Ovary           |                                       | Angiectasis            | Moderate                |
| * Salivary Glands |                                       | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Thymus          |                                       | Atrophy                | Minimal                 |
| * Urinary Bladder |                                       | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                           | Hyperplasia            | Cystic, Minimal         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 294    **TMT:** 4    **SEX:** Female    **DAY ON TEST:** 729  
**DOSE:** 0.25 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602194

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart	Artery	Infiltration Cellular	Mononuclear CI, Minimal
* Liver		Fatty Change	Minimal
	Centrilobular	Hematopoietic Cell Proliferation	Minimal
		Hypertrophy	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Mild
* Spleen		Hematopoietic Cell Proliferation	Mild
* Thymus		Atrophy	Mild
* Uterus	Endometrium	Hyperplasia	Cystic, Moderate
		Metaplasia	Squamous, Mild

[ Hyperplasia TGLs = 1-7 ]

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 295 TMT: 4 SEX: Female DAY ON TEST: 729  
 DOSE: 0.25 G/KG DISP: Terminal Sacrifice HISTO: 0602195

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla        | Blood Vessel               | * Bone Marrow             | * Brain                     |
| * Clitoral Gland         | * Esophagus                | * Eye                     | * Gallbladder               |
| * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      | * Lung                      |
| * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Mammary Gland           | * Nose                      |
| * Pancreas               | * Parathyroid Gland        | * Pituitary Gland         | * Salivary Glands           |
| * Skin                   | * Stomach, Glandular       | * Thyroid Gland           | * Trachea                   |
| * Uterus                 |                            |                           |                             |

OBSERVATIONS

- |                        |  |                                  |                         |
|------------------------|--|----------------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                              | Hyperplasia                      | Mild                    |
| * Bone                 |  | Fibrosis                         | Mild                    |
| * Harderian Gland      |  | Adenoma                          |                         |
|                        |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Heart                | Artery                                   | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Kidney               |  | Nephropathy                      | Minimal                 |
| * Liver                |  | Fatty Change                     | Mild                    |
|                        | Centrilobular                            | Hepatocellular Carcinoma         |                         |
|                        |  | Hypertrophy                      | Minimal                 |
|                        |  | Infiltration Cellular            | Mononuclear CI, Minimal |
|                        | [ Hepatocellular Carcinoma TGLs = 1-10 ] |                                  |                         |
| * Ovary                |  | Cystadenoma                      |                         |
| * Spleen               |  | Hematopoietic Cell Proliferation | Minimal                 |
| * Stomach, Forestomach |  | Squamous Cell Papilloma          |                         |
|                        | [ Squamous Cell Papilloma TGLs = 2-11 ]  |                                  |                         |
| * Thymus               |  | Atrophy                          | Mild                    |
| * Urinary Bladder      |  | Infiltration Cellular            | Mononuclear CI, Minimal |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 296	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602196

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Mammary Gland            |
| * Nose                    | * Ovary                     | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Salivary Glands           | * Skin                   | * Stomach, Forestomach     |
| * Stomach, Glandular      | * Thyroid Gland             | * Trachea                |                            |

**OBSERVATIONS**

- |                   |  |                                  |                         |
|-------------------|--|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                              | Hyperplasia                      | Mild                    |
| * Harderian Gland |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Kidney          |  | Nephropathy                      | Minimal                 |
| * Liver           |  | Eosinophilic Focus               |                         |
|                   |  | Hepatocellular Carcinoma         |                         |
|                   |  | Infiltration Cellular            | Mononuclear CI, Minimal |
|                   |  | Mixed Cell Focus                 |                         |
|                   | [ Hepatocellular Carcinoma TGLs = 2-11 ] |                                  |                         |
|                   | [ Mixed Cell Focus TGLs = 3-12 ]         |                                  |                         |
| * Lung            |  | Hepatocellular Carcinoma         | Metastatic (Liver)      |
| Mesentery         | Fat                                      | Necrosis                         | Moderate                |
|                   | [ Necrosis TGLs = 1-10 ]                 |                                  |                         |
| * Spleen          |  | Hematopoietic Cell Proliferation | Minimal                 |
| * Thymus          |  | Atrophy                          | Mild                    |
| * Urinary Bladder |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                              | Hyperplasia                      | Cystic, Mild            |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 297	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602197

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Lung                    | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Mammary Gland            |
| * Nose                    | * Ovary                     | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Salivary Glands           | * Skin                   | * Stomach, Forestomach     |
| * Stomach, Glandular      | * Thyroid Gland             | * Trachea                |                            |

**OBSERVATIONS**

- |                      |                                  |                       |                         |
|----------------------|----------------------------------|-----------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                      | Hyperplasia           | Mild                    |
| * Harderian Gland    |                                  | Infiltration Cellular | Mononuclear CI, Minimal |
| * Islets, Pancreatic |                                  | Hyperplasia           | Minimal                 |
| * Kidney             |                                  | Mineralization        | Minimal                 |
|                      |                                  | Nephropathy           | Minimal                 |
| * Liver              |                                  | Fatty Change          | Minimal                 |
|                      |                                  | Infiltration Cellular | Mononuclear CI, Minimal |
|                      |                                  | Mixed Cell Focus      |                         |
|                      | [ Mixed Cell Focus TGLs = 2-10 ] |                       |                         |
| * Spleen             |                                  | Hyperplasia           | Lymphoid, Mild          |
| * Thymus             |                                  | Atrophy               | Minimal                 |
| * Urinary Bladder    |                                  | Infiltration Cellular | Mononuclear CI, Minimal |
| * Uterus             | Endometrium                      | Hyperplasia           | Cystic, Moderate        |
|                      | [ Hyperplasia TGLs = 1-7 ]       |                       |                         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 298	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602198

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Adenoma Hyperplasia	Mild
* Bone		Fibrosis	Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Mineralization	Minimal
* Liver	Centrilobular	Fatty Change Hypertrophy Infiltration Cellular Mixed Cell Focus	Minimal Minimal Mononuclear CI, Mild
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Thymus		Atrophy	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 299    **TMT:** 4    **SEX:** Female    **DAY ON TEST:** 718  
**DOSE:** 0.25 G/KG    **DISP:** Natural Death    **HISTO:** 0602199

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Mammary Gland	* Nose	* Pancreas
* Pituitary Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Parathyroid Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone		Fibrosis	Moderate
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Lymphoma Malignant	
* Liver		Eosinophilic Focus	
		Fatty Change	Minimal
	Centrilobular	Hepatocellular Carcinoma	
		Hypertrophy	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
	[ Eosinophilic Focus TGLs = 4-13 ]		
	[ Hepatocellular Carcinoma TGLs = 2-11 ]		
	[ Mixed Cell Focus TGLs = 3-12 ]		
* Lung		Lymphoma Malignant	
	[ Lymphoma Malignant TGLs = 10-18 ]		
Lymph Node	Renal	Lymphoma Malignant	
	Lumbar	Lymphoma Malignant	
	Mediastinal	Lymphoma Malignant	
	Bronchial	Lymphoma Malignant	
	[ Lymphoma Malignant TGLs = 5-14 ]		
	[ Lymphoma Malignant TGLs = 6-15 ]		
	[ Lymphoma Malignant TGLs = 7-16 ]		
	[ Lymphoma Malignant TGLs = 8-17 ]		

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b> 299	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 718
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 0602199

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Lymph Node, Mesenteric [ Lymphoma Malignant TGLs = 9-5 ]	Lymphoma Malignant
* Ovary	Lymphoma Malignant
* Spleen [ Lymphoma Malignant TGLs = 1-10 ]	Lymphoma Malignant
* Thymus	Lymphoma Malignant
* Uterus Endometrium	Hyperplasia Cystic, Mild

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PRIMARY CAUSE OF DEATH - Spleen Lymphoma Malignant  
CONTRIBUTORY CAUSE OF DEATH - Liver Hepatocellular Carcinoma

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 300	<b>TMT:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0.25 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602200

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea		

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone		Fibrosis	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver	Centrilobular	Fatty Change	Mild
		Hypertrophy	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
	[ Mixed Cell Focus TGLs = 3-12 ]		
Mesentery	Fat	Necrosis	Marked
	[ Necrosis TGLs = 1,2-10+11 ]		
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Thymus		Atrophy	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 301    **TMT:** 6    **SEX:** Female    **DAY ON TEST:** 730  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602201

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone		Fibrosis	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Liver		Basophilic Focus	
	Centrilobular	Fatty Change	Mild
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
	[ Mixed Cell Focus TGLs = 1-10 ]		
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hyperplasia	Lymphoid, Mild
* Thymus		Atrophy	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 302    **TMT:** 6    **SEX:** Female    **DAY ON TEST:** 534  
**DOSE:** 0.5 G/KG    **DISP:** Natural Death    **HISTO:** 0602202

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Nose                      | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Skin                      | * Stomach, Forestomach   | * Stomach, Glandular       |
| * Thymus                  | * Thyroid Gland             | * Trachea                | * Urinary Bladder          |
| * Uterus                  |                             |                          |                            |

**OBSERVATIONS**

- |                   |  |                                  |                         |
|-------------------|--|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                              | Hyperplasia                      | Mild                    |
| * Harderian Gland |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Liver           |  | Fatty Change                     | Minimal                 |
|                   | Centrilobular                            | Hepatocellular Carcinoma         |                         |
|                   | [ Hepatocellular Carcinoma TGLs = 1-10 ] | Hypertrophy                      | Mild                    |
|                   |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Lung            |  | Hepatocellular Carcinoma         | Metastatic (Liver)      |
| * Ovary           |  | Cystadenoma                      |                         |
| * Salivary Glands |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen          |  | Hematopoietic Cell Proliferation | Minimal                 |

PRIMARY CAUSE OF DEATH    - Liver    Hepatocellular Carcinoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 303	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602203

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea		

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone		Fibrosis	Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Nephropathy	Minimal
* Liver	Centrilobular	Fatty Change	Mild
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
		Tension Lipidosis	
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Thymus		Atrophy	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 304    **TMT:** 6    **SEX:** Female    **DAY ON TEST:** 730  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602204

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lymph Node, Mesenteric | * Mammary Gland            |
| * Nose                    | * Ovary                     | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Skin                      | * Stomach, Glandular     | * Thyroid Gland            |
| * Trachea                 |                             |                          |                            |

**OBSERVATIONS**

- |   |  |                                  |                         |
|---|--|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular  | Hyperplasia                      | Mild                    |
| * Brain   |  |                                  |                         |
| Note: Brain has hematopoietic cell proliferation, but this diagnosis is not on screen |  |                                  |                         |
| * Harderian Gland   |  | Adenoma                          |                         |
|   |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Liver   |  | Eosinophilic Focus               |                         |
|   | Centrilobular                                      | Hepatocellular Carcinoma         | Multiple                |
|   |  | Hypertrophy                      | Mild                    |
|   |  | Infiltration Cellular            | Mononuclear CI, Mild    |
|   |  | Necrosis                         | Minimal                 |
|   | [ Hepatocellular Carcinoma TGLs = 1,2,3-10+11+12 ] |                                  |                         |
| * Lung  |  | Hepatocellular Carcinoma         | Metastatic (Liver)      |
| * Lymph Node, Mandibular  |  | Hyperplasia                      | Lymphoid, Mild          |
| Mesentery   | Fat  | Necrosis                         | Mild                    |
|   | [ Necrosis TGLs = 4-13 ]                           |                                  |                         |
| * Salivary Glands   |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen  |  | Hematopoietic Cell Proliferation | Mild                    |
| * Stomach, Forestomach  | Epithelium   | Hyperplasia                      | Minimal                 |
|   |  | Inflammation                     | Chronic, Minimal        |
| * Thymus  |  | Atrophy                          | Mild                    |
| * Urinary Bladder   |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus  | Endometrium  | Hyperplasia                      | Cystic, Minimal         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 305	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602205

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia Vacuolization Cytoplasmic	Mild Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Liver		Basophilic Focus Eosinophilic Focus Fatty Change Hepatocellular Adenoma Hypertrophy Infiltration Cellular	Mild Multiple Mild Mononuclear CI, Minimal
	Centrilobular		
	[ Hepatocellular Adenoma TGLs = 1,2-10+11 ]		
* Ovary		Cyst	Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Thymus		Atrophy	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 306	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602206

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Clitoral Gland         | * Esophagus                | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Mammary Gland           |
| * Nose                      | * Ovary                  | * Pancreas                 | * Parathyroid Gland       |
| * Pituitary Gland           | * Skin                   | * Spleen                   | * Stomach, Forestomach    |
| * Stomach, Glandular        | * Thyroid Gland          | * Trachea                  |                           |

**OBSERVATIONS**

- |                             |               |                       |                         |
|-----------------------------|---------------|-----------------------|-------------------------|
| * Adrenal Cortex            | Subcapsular   | Hyperplasia           | Mild                    |
| * Eye                       | Iris          | Melanoma Benign       |                         |
| * Harderian Gland           |               | Infiltration Cellular | Mononuclear CI, Minimal |
| * Kidney                    |               | Mineralization        | Minimal                 |
|                             |               | Nephropathy           | Minimal                 |
| * Liver                     |               | Angiectasis           | Minimal                 |
|                             |               | Fatty Change          | Mild                    |
|                             | Centrilobular | Hypertrophy           | Mild                    |
|                             |               | Infiltration Cellular | Mononuclear CI, Minimal |
| * Ovary                     |               |                       |                         |
| Note: One ovary was missing |               |                       |                         |
| * Salivary Glands           |               | Infiltration Cellular | Mononuclear CI, Minimal |
| * Thymus                    |               | Atrophy               | Mild                    |
| * Urinary Bladder           |               | Infiltration Cellular | Mononuclear CI, Minimal |
| * Uterus                    | Endometrium   | Hyperplasia           | Cystic, Minimal         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 307    **TMT:** 6    **SEX:** Female    **DAY ON TEST:** 730  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602207

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Liver		Fatty Change	Minimal
	Centrilobular	Hepatocellular Adenoma	
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Hepatocellular Adenoma TGLs = 3-11 ]		
Mesentery	Fat	Necrosis	Moderate
	[ Necrosis TGLs = 2-10 ]		
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Thymus		Atrophy	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Moderate
	[ Hyperplasia TGLs = 1-7 ]		



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 308	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602208

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                    | * Clitoral Gland          | * Esophagus                 | * Eye                    |
| * Gallbladder              | * Harderian Gland         | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic      | * Kidney                    | * Lung                   |
| * Lymph Node, Mandibular   | * Lymph Node, Mesenteric  | * Mammary Gland             | * Nose                   |
| * Pancreas                 | * Skin                    | * Stomach, Forestomach      | * Stomach, Glandular     |
| * Thyroid Gland            | * Trachea                 | * Urinary Bladder           |                          |

**MISSING**

- \* Parathyroid Gland

**OBSERVATIONS**

- |                   |               |  |                         |
|-------------------|---------------|--|-------------------------|
| * Adrenal Cortex  | Subcapsular   | Hyperplasia                              | Mild                    |
| * Liver           |               | Fatty Change                             | Mild                    |
|                   |               | Hepatocellular Adenoma                   |                         |
|                   | Centrilobular | Hepatocellular Carcinoma                 |                         |
|                   |               | Hypertrophy                              | Mild                    |
|                   |               | Infiltration Cellular                    | Mononuclear CI, Minimal |
|                   |               | Mixed Cell Focus                         |                         |
|                   |               | [ Hepatocellular Adenoma TGLs = 2-11 ]   |                         |
|                   |               | [ Hepatocellular Carcinoma TGLs = 4-13 ] |                         |
|                   |               | [ Mixed Cell Focus TGLs = 1,3-10+12 ]    |                         |
| * Ovary           |               | Cystadenoma                              |                         |
| * Pituitary Gland |               | Angiectasis                              | Mild                    |
|                   | Pars Distalis | Hyperplasia                              | Moderate                |
| * Salivary Glands |               | Infiltration Cellular                    | Mononuclear CI, Minimal |
| * Spleen          |               | Hematopoietic Cell Proliferation         | Minimal                 |
| * Thymus          |               | Atrophy                                  | Minimal                 |
| * Uterus          | Endometrium   | Hyperplasia                              | Cystic, Mild            |

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	309	TMT:	6	SEX:	Female	DAY ON TEST:	638
		DOSE:	0.5 G/KG	DISP:	Natural Death	HISTO:	0602209

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ORGAN AND ACCOUNTABLE SITE STATUS

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NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Kidney
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

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OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Cardiomyopathy	Minimal
* Islets, Pancreatic		Hyperplasia	Mild
* Liver	Centrilobular	Fatty Change	Minimal
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
* Ovary		Cyst	Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Mild
* Spleen		Hyperplasia	Lymphoid, Mild
* Thymus		Atrophy	Moderate

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PRIMARY CAUSE OF DEATH - UNCERTAIN

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 310	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602210

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

Blood Vessel	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Uterus

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Adrenal Medulla		Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Liver	Centrilobular	Fatty Change	Minimal
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Thymus		Atrophy	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 311	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602211

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Harderian Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Kidney		Nephropathy	Mild
* Liver		Fatty Change	Mild
	Centrilobular	Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
* Lung		Alveolar/Bronchiolar Adenoma	
* Ovary		Cyst	Mild
		Cystadenoma	
* Thymus		Atrophy	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Moderate

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 312    **TMT:** 6    **SEX:** Female    **DAY ON TEST:** 729  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602212

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Clitoral Gland         | * Esophagus                | * Eye                     |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Mammary Gland           |
| * Nose                      | * Ovary                  | * Pancreas                 | * Parathyroid Gland       |
| * Pituitary Gland           | * Skin                   | * Stomach, Forestomach     | * Stomach, Glandular      |
| * Thyroid Gland             | * Trachea                |                            |                           |

**MISSING**

- \* Gallbladder

**OBSERVATIONS**

- |                   |  |                                  |                         |
|-------------------|--|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                                | Hyperplasia                      | Mild                    |
| * Harderian Gland |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Kidney          |  | Mineralization                   | Minimal                 |
| * Liver           |  | Cyst                             | Minimal                 |
|                   | Centrilobular                              | Eosinophilic Focus               |                         |
|                   |  | Hemangiosarcoma                  |                         |
|                   |  | Hypertrophy                      | Mild                    |
|                   |  | Infiltration Cellular            | Mononuclear CI, Mild    |
|                   | [ Eosinophilic Focus TGLs = 3-12 ]         |                                  |                         |
|                   | [ Hemangiosarcoma TGLs = 1,2-3+4+5+10+11 ] |                                  |                         |
| * Salivary Glands |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen          |  | Hemangiosarcoma                  |                         |
|                   |  | Hematopoietic Cell Proliferation | Minimal                 |
| * Thymus          |  | Atrophy                          | Minimal                 |
| * Urinary Bladder |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                                | Hyperplasia                      | Cystic, Minimal         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 313	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602213

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lung                   | * Lymph Node, Mandibular   |
| * Lymph Node, Mesenteric  | * Mammary Gland             | * Nose                   | * Ovary                    |
| * Pancreas                | * Parathyroid Gland         | * Skin                   | * Spleen                   |
| * Stomach, Forestomach    | * Stomach, Glandular        | * Thyroid Gland          | * Trachea                  |
| * Uterus                  |                             |                          |                            |

**OBSERVATIONS**

- |                      |                              |                       |                         |
|----------------------|------------------------------|-----------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular                  | Hyperplasia           | Mild                    |
| * Harderian Gland    |                              | Infiltration Cellular | Mononuclear CI, Minimal |
| * Liver              |                              | Eosinophilic Focus    |                         |
|                      | Centrilobular                | Fatty Change          | Mild                    |
|                      |                              | Hypertrophy           | Mild                    |
|                      |                              | Infiltration Cellular | Mononuclear CI, Minimal |
|                      |                              | Tension Lipidosis     |                         |
| [ Eosinophilic Focus | TGLs = 1,2,3,4-10+11+12+13 ] |                       |                         |
| * Pituitary Gland    | Pars Distalis                | Hyperplasia           | Minimal                 |
| * Salivary Glands    |                              | Infiltration Cellular | Mononuclear CI, Minimal |
| * Thymus             |                              | Atrophy               | Minimal                 |
| * Urinary Bladder    |                              | Infiltration Cellular | Mononuclear CI, Minimal |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 314    **TMT:** 6    **SEX:** Female    **DAY ON TEST:** 729  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602214

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Brain                   |
| * Clitoral Gland            | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Mammary Gland           |
| * Nose                      | * Pancreas               | * Parathyroid Gland        | * Pituitary Gland         |
| * Skin                      | * Spleen                 | * Stomach, Forestomach     | * Stomach, Glandular      |
| * Thyroid Gland             | * Trachea                | * Urinary Bladder          |                           |

**OBSERVATIONS**

- |                   |  |                        |                         |
|-------------------|--|------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                            | Hyperplasia            | Mild                    |
| * Bone Marrow     |  | Fibrosis               | Mild                    |
| * Harderian Gland |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Kidney          |  | Nephropathy            | Minimal                 |
| * Liver           |  | Eosinophilic Focus     |                         |
|                   |  | Fatty Change           | Minimal                 |
|                   | Centrilobular                          | Hepatocellular Adenoma |                         |
|                   |  | Hypertrophy            | Mild                    |
|                   |  | Infiltration Cellular  | Mononuclear CI, Minimal |
|                   |  | Mixed Cell Focus       |                         |
|                   | [ Eosinophilic Focus TGLs = 3-11 ]     |                        |                         |
|                   | [ Hepatocellular Adenoma TGLs = 2-10 ] |                        |                         |
| * Ovary           |  | Cyst                   | Minimal                 |
|                   | [ Cyst TGLs = 1-7 ]                    |                        |                         |
| * Salivary Glands |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Thymus          |  | Atrophy                | Mild                    |
| * Uterus          | Endometrium                            | Hyperplasia            | Cystic, Mild            |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 315	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602215

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                            |                          |
|---------------------------|-----------------------------|----------------------------|--------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                     | * Bone Marrow            |
| * Brain                   | * Clitoral Gland            | * Esophagus                | * Eye                    |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum   | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Jejunum | * Islets, Pancreatic     |
| * Lymph Node, Mandibular  | * Lymph Node, Mesenteric    | * Mammary Gland            | * Nose                   |
| * Ovary                   | * Pancreas                  | * Parathyroid Gland        | * Skin                   |
| * Stomach, Glandular      | * Thyroid Gland             | * Trachea                  |                          |

**OBSERVATIONS**

- |                          |                                    |                                  |                         |
|--------------------------|------------------------------------|----------------------------------|-------------------------|
| * Adrenal Cortex         | Subcapsular                        | Hyperplasia                      | Mild                    |
| * Harderian Gland        |                                    | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Intestine Small, Ileum |                                    | Inflammation                     | Chronic Active, Mild    |
|                          |                                    | Ulcer                            | Minimal                 |
| * Kidney                 |                                    | Nephropathy                      | Minimal                 |
| * Liver                  |                                    | Eosinophilic Focus               |                         |
|                          | Centrilobular                      | Fatty Change                     | Minimal                 |
|                          |                                    | Hypertrophy                      | Mild                    |
|                          |                                    | Infiltration Cellular            | Mononuclear CI, Minimal |
|                          | [ Eosinophilic Focus TGLs = 2-10 ] |                                  |                         |
| * Lung                   |                                    | Inflammation                     | Minimal                 |
| * Pituitary Gland        | Pars Distalis                      | Hyperplasia                      | Minimal                 |
| * Salivary Glands        |                                    | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen                 |                                    | Hematopoietic Cell Proliferation | Minimal                 |
| * Stomach, Forestomach   | Epithelium                         | Hyperplasia                      | Minimal                 |
|                          |                                    | Inflammation                     | Chronic, Minimal        |
| * Thymus                 |                                    | Atrophy                          | Mild                    |
| * Urinary Bladder        |                                    | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus                 | Endometrium                        | Hyperplasia                      | Cystic, Moderate        |
|                          | [ Hyperplasia TGLs = 1-7 ]         |                                  |                         |



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 316	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602216

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lung                   | * Lymph Node, Mandibular   |
| * Lymph Node, Mesenteric  | * Mammary Gland             | * Nose                   | * Ovary                    |
| * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        | * Salivary Glands          |
| * Skin                    | * Spleen                    | * Stomach, Forestomach   | * Thyroid Gland            |
| * Trachea                 |                             |                          |                            |

**OBSERVATIONS**

- |                      |               |                                  |                         |
|----------------------|---------------|----------------------------------|-------------------------|
| * Adrenal Cortex     | Subcapsular   | Hyperplasia                      | Mild                    |
| * Harderian Gland    |               | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Liver              |               | Fatty Change                     | Minimal                 |
|                      | Centrilobular | Hematopoietic Cell Proliferation | Minimal                 |
|                      |               | Hypertrophy                      | Mild                    |
|                      |               | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Stomach, Glandular | Glands        | Ectasia                          | Minimal                 |
|                      | Epithelium    | Hyperplasia                      | Minimal                 |
| * Thymus             |               | Atrophy                          | Minimal                 |
| * Urinary Bladder    |               | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus             | Endometrium   | Hyperplasia                      | Cystic, Mild            |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 317    **TMT:** 6    **SEX:** Female    **DAY ON TEST:** 729  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602217

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Nose                      | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Skin                      | * Spleen                 | * Stomach, Forestomach     |
| * Stomach, Glandular      | * Thyroid Gland             | * Trachea                |                            |

**OBSERVATIONS**

- |                   |  |                                  |                         |
|-------------------|--|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                              | Hyperplasia                      | Mild                    |
| * Harderian Gland |  | Hyperplasia                      | Moderate                |
|                   |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Liver           |  | Fatty Change                     | Minimal                 |
|                   | Centrilobular                            | Hematopoietic Cell Proliferation | Minimal                 |
|                   |  | Hypertrophy                      | Mild                    |
|                   |  | Infiltration Cellular            | Mononuclear CI, Minimal |
|                   | [ Mixed Cell Focus    TGLs = 3,4-10+11 ] | Mixed Cell Focus                 |                         |
| * Lung            |  | Alveolar/Bronchiolar Adenoma     |                         |
| * Ovary           |  | Cystadenoma                      |                         |
|                   | [ Cystadenoma    TGLs = 2-7 ]            |                                  |                         |
| * Salivary Glands |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Thymus          |  | Atrophy                          | Mild                    |
| * Urinary Bladder |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                              | Hyperplasia                      | Cystic, Moderate        |
|                   | [ Hyperplasia    TGLs = 1-7 ]            |                                  |                         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 318 TMT: 6 SEX: Female DAY ON TEST: 731  
 DOSE: 0.5 G/KG DISP: Terminal Sacrifice HISTO: 0602218

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Harderian Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Spleen
* Stomach, Glandular	* Thyroid Gland	* Trachea	

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia Vacuolization Cytoplasmic	Mild Mild
* Kidney		Amyloid Deposition Nephropathy	Minimal Mild
* Liver	Centrilobular	Hypertrophy Infiltration Cellular Tension Lipidosis	Minimal Mononuclear CI, Minimal
* Lung	[ Alveolar/Bronchiolar Carcinoma TGLs = 2-10 ]	Alveolar/Bronchiolar Carcinoma	
* Skin	Subcut Tiss	Fibrosis Fibrous Histiocytoma	Moderate
	Subcut Tiss	Inflammation Necrosis	Chronic, Moderate Moderate
	[ Necrosis TGLs = 1-10 ]		
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
* Thymus		Atrophy	Mild
Tooth		Dysplasia	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 319	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602219

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

Blood Vessel	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Adrenal Medulla		Hyperplasia	Mild
* Kidney		Mineralization	Minimal
* Liver		Eosinophilic Focus	
		Fatty Change	Minimal
	Centrilobular	Hepatocellular Adenoma	Multiple
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
		Tension Lipidosis	
	[ Eosinophilic Focus TGLs = 5-13 ]		
	[ Hepatocellular Adenoma TGLs = 1,3-10+11 ]		
	[ Mixed Cell Focus TGLs = 4-12 ]		
* Ovary		Hemangioma	
		Thrombosis	Moderate
	[ Thrombosis TGLs = 2-7 ]		
* Thymus		Atrophy	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 320	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602220

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Hyperplasia Infiltration Cellular	Minimal Mononuclear CI, Minimal
* Liver	Centrilobular	Fatty Change Hepatocellular Adenoma Hypertrophy Infiltration Cellular Mixed Cell Focus	Minimal Mild Mononuclear CI, Minimal
	[ Hepatocellular Adenoma TGLs = 1-10 ]		
	[ Mixed Cell Focus TGLs = 2-10 ]		
* Nose	Glands	Dilatation	Mild
* Salivary Glands	Duct, Submandibul GI	Hyperplasia Infiltration Cellular	Mild Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Thymus		Atrophy	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Moderate

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 321	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602221

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Nose                      | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Salivary Glands           | * Skin                   | * Spleen                   |
| * Stomach, Glandular      | * Thyroid Gland             | * Trachea                | * Uterus                   |

**OBSERVATIONS**

- |                             |                             |   |   |
|-----------------------------|-----------------------------|---|---|
| * Adrenal Cortex            | Subcapsular                 | Hyperplasia   | Mild                                      |
| * Harderian Gland           |                             | Infiltration Cellular                                     | Mononuclear CI, Minimal                   |
| * Kidney                    |                             | Nephropathy   | Minimal                                   |
| * Liver                     | Centrilobular               | Hypertrophy<br>Infiltration Cellular<br>Tension Lipidosis | Mild<br>Mononuclear CI, Minimal           |
| * Ovary                     |                             | Cyst  | Minimal                                   |
| Note: One ovary was missing |                             |   |   |
| * Stomach, Forestomach      | Epithelium                  | Hyperplasia<br>Inflammation<br>Ulcer                      | Moderate<br>Chronic, Moderate<br>Moderate |
|                             | [ Hyperplasia TGLs = 1-10 ] |   |   |
| * Thymus                    |                             | Atrophy   | Mild                                      |
| * Urinary Bladder           |                             | Infiltration Cellular                                     | Mononuclear CI, Minimal                   |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 322    **TMT:** 6    **SEX:** Female    **DAY ON TEST:** 729  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602222

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia Vacuolization Cytoplasmic	Mild Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Hemangioma Mineralization Nephropathy	Minimal Minimal
	[ Hemangioma TGLs = 1,2,3-10+11+12 ]		
* Liver		Fatty Change Hepatocellular Adenoma Hepatocellular Carcinoma	Minimal Multiple
	Centrilobular	Hypertrophy Infiltration Cellular Mixed Cell Focus	Mild Mononuclear CI, Minimal
	[ Hepatocellular Adenoma TGLs = 4,6-13+15 ] [ Hepatocellular Carcinoma TGLs = 4-13 ] [ Mixed Cell Focus TGLs = 5-14 ]		
Mesentery	Fat	Necrosis	Moderate
	[ Necrosis TGLs = 7-16 ]		
* Ovary			
Note: One ovary was missing			
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hyperplasia	Lymphoid, Minimal
* Thymus		Atrophy	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	322	<b>TMT:</b>	6	<b>SEX:</b>	Female	<b>DAY ON TEST:</b>	729
		<b>DOSE:</b>	0.5 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602222

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Uterus	Endometrium	Hyperplasia	Cystic, Minimal
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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 323	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602223

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Skin	* Thyroid Gland	* Trachea

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney	Pelvis	Cyst	Mild
		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
		Fatty Change	Minimal
	Centrilobular	Hepatocellular Adenoma	
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
		Necrosis	Minimal
	[ Hepatocellular Adenoma TGLs = 1-10 ]		
* Ovary		Granulosa Cell Tumor Benign	
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Hyperplasia	Lymphoid, Mild
* Stomach, Forestomach		Erosion	Moderate
	Epithelium	Hyperplasia	Moderate
		Inflammation	Chronic, Moderate
* Stomach, Glandular	Glands	Ectasia	Minimal
* Thymus		Atrophy	Mild
		Hyperplasia	Histiocytic, Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 324 TMT: 6 SEX: Female DAY ON TEST: 730  
 DOSE: 0.5 G/KG DISP: Terminal Sacrifice HISTO: 0602224

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Stomach, Glandular	* Thyroid Gland	* Trachea

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone		Fibrosis	Minimal
* Harderian Gland		Adenoma	
		Infiltration Cellular	Mononuclear CI, Minimal
* Islets, Pancreatic		Carcinoma	
	[ Carcinoma TGLs = 1-10 ]		
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Carcinoma	Metastatic (Uncertain Primary Site)
		Eosinophilic Focus	
		Fatty Change	Minimal
	Centrilobular	Hepatocellular Adenoma	
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
		Necrosis	Minimal
	[ Eosinophilic Focus TGLs = 4-13 ]		
	[ Hepatocellular Adenoma TGLs = 2-11 ]		
	[ Mixed Cell Focus TGLs = 3-12 ]		
* Lung		Alveolar/Bronchiolar Adenoma	
	[ Alveolar/Bronchiolar Adenoma TGLs = 5-14 ]		
* Ovary			
	Note: One ovary was missing		
* Spleen		Hyperplasia	Lymphoid, Mild
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	324	<b>TMT:</b>	6	<b>SEX:</b>	Female	<b>DAY ON TEST:</b>	730
		<b>DOSE:</b>	0.5 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602224

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Thymus		Atrophy	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 325    **TMT:** 6    **SEX:** Female    **DAY ON TEST:** 729  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602225

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone		Fibrosis	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney	Renal Tubule	Hyperplasia	Minimal
		Nephropathy	Mild
* Liver		Eosinophilic Focus	
		Fatty Change	Minimal
	Centrilobular	Hepatocellular Carcinoma	
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
		Mixed Cell Focus	
	[ Hepatocellular Carcinoma TGLs = 1-10 ]		
	[ Mixed Cell Focus TGLs = 2-11 ]		
* Lymph Node, Mandibular		Hyperplasia	Lymphoid, Mild
* Pituitary Gland		Cyst	Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Mild
* Thymus		Atrophy	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 326    **TMT:** 6    **SEX:** Female    **DAY ON TEST:** 729  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602226

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                    | * Clitoral Gland          | * Esophagus                 | * Eye                    |
| * Gallbladder              | * Harderian Gland         | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic      | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric |
| * Nose                     | * Ovary                   | * Pituitary Gland           | * Skin                   |
| * Stomach, Forestomach     | * Stomach, Glandular      | * Thyroid Gland             | * Trachea                |
| * Urinary Bladder          |                           |                             |                          |

**MISSING**

- \* Parathyroid Gland

**OBSERVATIONS**

- |                   |  |                                  |                         |
|-------------------|--|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                                    | Hyperplasia                      | Mild                    |
| * Kidney          |  | Nephropathy                      | Mild                    |
| * Liver           |  | Fatty Change                     | Minimal                 |
|                   |  | Hematopoietic Cell Proliferation | Minimal                 |
|                   |  | Hepatocellular Adenoma           | Multiple                |
|                   | Centrilobular                                  | Hypertrophy                      | Mild                    |
|                   |  | Infiltration Cellular            | Mononuclear Cl, Minimal |
|                   | [ Hepatocellular Adenoma TGLs = 2,3-11 ]       |                                  |                         |
| * Lung            |  | Alveolar/Bronchiolar Carcinoma   |                         |
|                   | [ Alveolar/Bronchiolar Carcinoma TGLs = 5-12 ] |                                  |                         |
| * Mammary Gland   |  | Adenoma                          |                         |
| * Pancreas        | Acinus   | Atrophy                          | Mild                    |
|                   | Duct   | Cyst                             | Marked                  |
|                   | Acinus   | Vacuolization Cytoplasmic        | Mild                    |
|                   | [ Cyst TGLs = 1,4-10 ]                         |                                  |                         |
| * Salivary Glands |  | Infiltration Cellular            | Mononuclear Cl, Minimal |
| * Spleen          |  | Hematopoietic Cell Proliferation | Mild                    |
| * Thymus          |  | Atrophy                          | Marked                  |
| * Uterus          | Endometrium                                    | Hyperplasia                      | Cystic, Minimal         |

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 327	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602227

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Salivary Glands
* Skin	* Stomach, Glandular	* Thyroid Gland	* Trachea

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Cardiomyopathy	Minimal
* Kidney		Nephropathy	Minimal
* Liver	Centrilobular	Hematopoietic Cell Proliferation	Mild
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Mild
		Necrosis	Minimal
* Lymph Node, Mandibular		Hyperplasia	Lymphoid, Mild
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Hematopoietic Cell Proliferation	Marked
	[ Hematopoietic Cell Proliferation TGLs = 1-10 ]		
* Stomach, Forestomach	Epithelium	Erosion	Moderate
		Hyperplasia	Moderate
		Inflammation	Chronic, Moderate
	[ Hyperplasia TGLs = 3-5+11 ]		
* Thymus		Atrophy	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild
	[ Hyperplasia TGLs = 2-7 ]		

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	328	TMT:	6	SEX:	Female	DAY ON TEST:	729
		DOSE:	0.5 G/KG	DISP:	Terminal Sacrifice	HISTO:	0602228

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ORGAN AND ACCOUNTABLE SITE STATUS

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NORMAL

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

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OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone		Fibrosis	Minimal
* Harderian Gland		Hyperplasia	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Fatty Change	Minimal
		Hepatocellular Carcinoma	
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Hepatocellular Carcinoma TGLs = 2-10 ]		
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Thymus		Atrophy	Mild
* Uterus	Endometrium	Hyperplasia	Cystic, Moderate
	[ Hyperplasia TGLs = 1-7 ]		

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 329	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602229

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Metaplasia	Osseous, Minimal
		Nephropathy	Minimal
* Liver	Centrilobular	Eosinophilic Focus	Minimal
		Hypertrophy	Mononuclear CI, Minimal
	[ Eosinophilic Focus TGLs = 2-10 ]	Infiltration Cellular	
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Thymus		Atrophy	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild
	[ Hyperplasia TGLs = 1-7 ]		



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 330	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602230

ORGAN AND ACCOUNTABLE SITE STATUS

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Nose                      | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Skin                      | * Stomach, Glandular     | * Thyroid Gland            |
| * Trachea                 |                             |                          |                            |

**OBSERVATIONS**

- |                        |                               |   |   |
|------------------------|-------------------------------|---|---|
| * Adrenal Cortex       | Subcapsular                   | Hyperplasia   | Mild                                    |
| * Harderian Gland      |                               | Hyperplasia<br>Infiltration Cellular                            | Mild<br>Mononuclear CI, Minimal         |
| * Kidney               |                               | Nephropathy   | Minimal                                 |
| * Liver                | Centrilobular                 | Hypertrophy<br>Infiltration Cellular<br>Tension Lipidosis       | Mild<br>Mononuclear CI, Minimal         |
| * Ovary                |                               | Cystadenoma   |   |
| * Salivary Glands      |                               | Infiltration Cellular   | Mononuclear CI, Minimal                 |
| * Spleen               |                               | Hematopoietic Cell Proliferation                                | Minimal                                 |
| * Stomach, Forestomach | Epithelium                    | Hyperplasia<br>Inflammation<br>Squamous Cell Papilloma<br>Ulcer | Marked<br>Chronic, Moderate<br>Moderate |
|                        | [ Hyperplasia TGLs = 2-5+10 ] |   |   |
| * Thymus               |                               | Atrophy   | Minimal                                 |
| * Urinary Bladder      |                               | Infiltration Cellular   | Mononuclear CI, Minimal                 |
| * Uterus               | Endometrium                   | Hyperplasia   | Cystic, Moderate                        |
|                        | [ Hyperplasia TGLs = 1-7 ]    |   |   |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 331    **TMT:** 6    **SEX:** Female    **DAY ON TEST:** 729  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602231

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Mammary Gland            |
| * Nose                    | * Pancreas                  | * Parathyroid Gland      | * Pituitary Gland          |
| * Skin                    | * Spleen                    | * Stomach, Glandular     | * Thyroid Gland            |
| * Trachea                 |                             |                          |                            |

**OBSERVATIONS**

- |                        |  |                              |                         |
|------------------------|--|------------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                                  | Hyperplasia                  | Mild                    |
| * Harderian Gland      |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Kidney               |  | Amyloid Deposition           | Minimal                 |
|                        |  | Nephropathy                  | Minimal                 |
| * Liver                | Centrilobular                                | Fatty Change                 | Minimal                 |
|                        |  | Hypertrophy                  | Minimal                 |
|                        |  | Infiltration Cellular        | Mononuclear CI, Mild    |
| * Lung                 |  | Alveolar/Bronchiolar Adenoma |                         |
|                        | [ Alveolar/Bronchiolar Adenoma TGLs = 2-10 ] |                              |                         |
| * Ovary                |  | Cystadenoma                  |                         |
| * Salivary Glands      |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Stomach, Forestomach | Epithelium                                   | Hyperplasia                  | Moderate                |
|                        |  | Inflammation                 | Chronic, Moderate       |
|                        |  | Ulcer                        | Moderate                |
|                        | [ Hyperplasia TGLs = 3-5+10 ]                |                              |                         |
| * Thymus               |  | Atrophy                      | Minimal                 |
|                        |  | Hyperplasia                  | Histiocytic, Mild       |
| * Urinary Bladder      |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Uterus               | Endometrium                                  | Hyperplasia                  | Cystic, Mild            |
|                        | [ Hyperplasia TGLs = 1-7 ]                   |                              |                         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 332    **TMT:** 6    **SEX:** Female    **DAY ON TEST:** 554  
**DOSE:** 0.5 G/KG    **DISP:** Moribund Sacrifice    **HISTO:** 0602232

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Harderian Gland           | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Mammary Gland            |
| * Ovary                   | * Pancreas                  | * Parathyroid Gland      | * Pituitary Gland          |
| * Salivary Glands         | * Skin                      | * Stomach, Glandular     | * Thyroid Gland            |
| * Trachea                 |                             |                          |                            |

**OBSERVATIONS**

- |  |  |  |                                   |
|--|--|--|-----------------------------------|
| * Adrenal Cortex   | Subcapsular                                  | Hyperplasia                            | Mild                              |
| * Heart  |  | Cardiomyopathy                         | Minimal                           |
| * Kidney   |  | Nephropathy                            | Marked                            |
| * Liver  | Centrilobular                                | Hypertrophy                            | Mild                              |
| * Lung   | [ Alveolar/Bronchiolar Adenoma TGLs = 1-10 ] | Alveolar/Bronchiolar Adenoma           |                                   |
| * Nose   | Nasolacrim Dct                               | Inflammation                           | Suppurative, Mild                 |
| * Spleen   | Lymph Follic                                 | Atrophy                                | Marked                            |
| * Stomach, Forestomach   | Epithelium                                   | Erosion<br>Hyperplasia<br>Inflammation | Mild<br>Moderate<br>Chronic, Mild |
| Note: TGL 2 was in the nonglandular (forestomach) rather than glandular stomach, based on microscopic examination<br>[ Hyperplasia TGLs = 2-11 ] |  |  |                                   |
| * Thymus   |  | Atrophy                                | Marked                            |
| * Urinary Bladder  |  | Infiltration Cellular                  | Mononuclear CI, Minimal           |
| * Uterus   | Endometrium                                  | Hyperplasia                            | Cystic, Mild                      |

**PRIMARY CAUSE OF DEATH** - Kidney Nephropathy

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 333	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602233

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                    | * Clitoral Gland          | * Esophagus                 | * Eye                    |
| * Gallbladder              | * Harderian Gland         | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular |
| * Lymph Node, Mesenteric   | * Mammary Gland           | * Nose                      | * Ovary                  |
| * Pancreas                 | * Parathyroid Gland       | * Pituitary Gland           | * Skin                   |
| * Spleen                   | * Stomach, Glandular      | * Thyroid Gland             | * Trachea                |
| * Urinary Bladder          |                           |                             |                          |

**OBSERVATIONS**

- |                        |                                    |                         |                         |
|------------------------|------------------------------------|-------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                        | Hyperplasia             | Mild                    |
| * Kidney               | Renal Tubule                       | Hyperplasia             | Minimal                 |
|                        | Papilla                            | Mineralization          | Minimal                 |
|                        |                                    | Necrosis                | Mild                    |
| * Liver                |                                    | Basophilic Focus        |                         |
|                        |                                    | Eosinophilic Focus      |                         |
|                        |                                    | Fatty Change            | Minimal                 |
|                        | Centrilobular                      | Hypertrophy             | Minimal                 |
|                        |                                    | Infiltration Cellular   | Mononuclear Cl, Minimal |
|                        | [ Eosinophilic Focus TGLs = 1-10 ] |                         |                         |
| * Salivary Glands      |                                    | Infiltration Cellular   | Mononuclear Cl, Minimal |
| * Stomach, Forestomach |                                    | Erosion                 | Moderate                |
|                        | Epithelium                         | Hyperplasia             | Moderate                |
|                        |                                    | Inflammation            | Chronic, Moderate       |
|                        |                                    | Squamous Cell Carcinoma |                         |
|                        | [ Hyperplasia TGLs = 2-5+10 ]      |                         |                         |
| * Thymus               |                                    | Atrophy                 | Minimal                 |
| * Uterus               | Endometrium                        | Hyperplasia             | Cystic, Minimal         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 334 TMT: 6 SEX: Female DAY ON TEST: 730  
 DOSE: 0.5 G/KG DISP: Terminal Sacrifice HISTO: 0602234

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Clitoral Gl			
Note: One clitoral gland was missing			
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
		Fatty Change	Minimal
	Centrilobular	Hepatocellular Adenoma	Multiple
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Mild
	[ Eosinophilic Focus TGLs = 3-3 ]		
	[ Hepatocellular Adenoma TGLs = 1,2-10+11 ]		
* Spleen		Lymphoma Malignant	
* Stomach, Forestomach		Erosion	Marked
	Epithelium	Hyperplasia	Moderate
		Inflammation	Chronic, Moderate
	[ Hyperplasia TGLs = 4-12 ]		
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 335    **TMT:** 6    **SEX:** Female    **DAY ON TEST:** 731  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602235

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lung                   | * Lymph Node, Mandibular   |
| * Lymph Node, Mesenteric  | * Mammary Gland             | * Nose                   | * Ovary                    |
| * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        | * Salivary Glands          |
| * Skin                    | * Spleen                    | * Stomach, Glandular     | * Thyroid Gland            |
| * Trachea                 | * Uterus                    |                          |                            |

**OBSERVATIONS**

- |                        |  |                        |                         |
|------------------------|--|------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                            | Hyperplasia            | Mild                    |
| * Harderian Gland      |  | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Liver                |  | Eosinophilic Focus     |                         |
|                        |  | Fatty Change           | Minimal                 |
|                        | Centrilobular                          | Hepatocellular Adenoma | Minimal                 |
|                        |  | Hypertrophy            | Mononuclear CI, Minimal |
|                        | [ Hepatocellular Adenoma TGLs = 1-10 ] | Infiltration Cellular  |                         |
| Mesentery              | Fat                                    | Necrosis               | Moderate                |
|                        | [ Necrosis TGLs = 2-11 ]               |                        |                         |
| * Stomach, Forestomach | Epithelium                             | Erosion                | Moderate                |
|                        |  | Hyperplasia            | Marked                  |
|                        |  | Inflammation           | Chronic, Moderate       |
|                        | [ Hyperplasia TGLs = 3-5+12 ]          |                        |                         |
| * Thymus               |  | Atrophy                | Mild                    |
| * Urinary Bladder      |  | Infiltration Cellular  | Mononuclear CI, Minimal |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 336	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602236

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone Marrow              | * Brain                   |
| * Clitoral Gland            | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Mammary Gland           |
| * Nose                      | * Pancreas               | * Parathyroid Gland        | * Pituitary Gland         |
| * Skin                      | * Spleen                 | * Stomach, Forestomach     | * Stomach, Glandular      |
| * Thyroid Gland             | * Trachea                |                            |                           |

**OBSERVATIONS**

- |                   |               |                            |                         |
|-------------------|---------------|----------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular   | Hyperplasia                | Mild                    |
| * Bone            |               | Fibrosis                   | Moderate                |
| * Harderian Gland |               | Infiltration Cellular      | Mononuclear CI, Minimal |
| * Kidney          |               | Nephropathy                | Minimal                 |
| * Liver           | Centrilobular | Fatty Change               | Minimal                 |
|                   |               | Hypertrophy                | Mild                    |
|                   |               | Infiltration Cellular      | Mononuclear CI, Minimal |
| * Ovary           |               | Cyst                       | Mild                    |
|                   |               | Cystadenoma                |                         |
|                   |               | [ Cyst TGLs = 1-7 ]        |                         |
|                   |               | [ Cystadenoma TGLs = 1-7 ] |                         |
| * Salivary Glands |               | Infiltration Cellular      | Mononuclear CI, Minimal |
| * Thymus          |               | Atrophy                    | Minimal                 |
| * Urinary Bladder |               | Infiltration Cellular      | Mononuclear CI, Minimal |
| * Uterus          | Endometrium   | Hyperplasia                | Cystic, Mild            |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 337	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602237

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Nose                      | * Pancreas               | * Parathyroid Gland        |
| * Skin                    | * Stomach, Forestomach      | * Stomach, Glandular     | * Thyroid Gland            |
| * Trachea                 |                             |                          |                            |

**OBSERVATIONS**

- |                   |                                    |                       |                         |
|-------------------|------------------------------------|-----------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                        | Hyperplasia           | Minimal                 |
| * Harderian Gland |                                    | Infiltration Cellular | Mononuclear CI, Minimal |
| * Kidney          |                                    | Nephropathy           | Minimal                 |
| * Liver           | Centrilobular                      | Eosinophilic Focus    | Mild                    |
|                   |                                    | Fatty Change          | Minimal                 |
|                   |                                    | Hypertrophy           | Mononuclear CI, Minimal |
|                   |                                    | Infiltration Cellular |                         |
|                   |                                    | Mixed Cell Focus      |                         |
|                   | [ Eosinophilic Focus TGLs = 1-10 ] |                       |                         |
|                   | [ Mixed Cell Focus TGLs = 2-11 ]   |                       |                         |
| * Ovary           |                                    | Angiectasis           | Moderate                |
| * Pituitary Gland | Pars Distalis                      | Adenoma               |                         |
| * Salivary Glands |                                    | Infiltration Cellular | Mononuclear CI, Minimal |
| * Spleen          | Lymph Follicle                     | Atrophy               | Mild                    |
| * Thymus          |                                    | Atrophy               | Minimal                 |
| * Urinary Bladder |                                    | Infiltration Cellular | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                        | Hyperplasia           | Cystic, Minimal         |



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 338	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602238

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Atrophy	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Nephropathy	Minimal
* Liver		Fatty Change	Mild
	Centrilobular	Hepatocellular Adenoma	
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Hepatocellular Adenoma TGLs = 2-10 ]		
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Mild
* Thymus		Atrophy	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Moderate
	[ Hyperplasia TGLs = 1-7 ]		

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 339	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602239

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Clitoral Gland         | * Esophagus                | * Eye                     |
| * Gallbladder               | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Kidney                    | * Lung                   | * Lymph Node, Mandibular   | * Lymph Node, Mesenteric  |
| * Mammary Gland             | * Nose                   | * Pancreas                 | * Parathyroid Gland       |
| * Pituitary Gland           | * Salivary Glands        | * Skin                     | * Stomach, Forestomach    |
| * Stomach, Glandular        | * Thyroid Gland          | * Trachea                  |                           |

**OBSERVATIONS**

- |                   |                                  |                                  |                         |
|-------------------|----------------------------------|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                      | Hyperplasia                      | Mild                    |
| * Harderian Gland |                                  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Heart           | Artery                           | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Liver           | Centrilobular                    | Fatty Change                     | Minimal                 |
|                   |                                  | Hypertrophy                      | Mild                    |
|                   |                                  | Infiltration Cellular            | Mononuclear CI, Minimal |
|                   |                                  | Mixed Cell Focus                 |                         |
|                   |                                  | Tension Lipidosis                |                         |
|                   | [ Mixed Cell Focus TGLs = 2-10 ] |                                  |                         |
| * Ovary           |                                  | Cystadenoma                      |                         |
| * Spleen          |                                  | Hematopoietic Cell Proliferation | Minimal                 |
| * Thymus          |                                  | Atrophy                          | Minimal                 |
| * Urinary Bladder |                                  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                      | Hyperplasia                      | Cystic, Marked          |
|                   | [ Hyperplasia TGLs = 1-7 ]       |                                  |                         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

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<b>ANIMAL NUM:</b> 340	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602240

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea

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**MISSING**

\* Thymus

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**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone		Fibrosis	Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Liver		Fatty Change	Minimal
	Centrilobular	Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen	Lymph Follic	Atrophy	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Moderate

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 341    **TMT:** 6    **SEX:** Female    **DAY ON TEST:** 731  
**DOSE:** 0.5 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602241

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Skin
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Liver	Centrilobular	Fatty Change	Minimal
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Mild
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Stomach, Forestomach	Epithelium	Erosion	Marked
		Hyperplasia	Marked
		Inflammation	Chronic, Moderate
[ Hyperplasia	TGLs = 2-5+10 ]		
* Thymus		Atrophy	Mild
Tooth		Dysplasia	Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild
[ Hyperplasia	TGLs = 1-7 ]		

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 342	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602242

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Mammary Gland            |
| * Nose                    | * Ovary                     | * Pancreas               | * Parathyroid Gland        |
| * Salivary Glands         | * Skin                      | * Spleen                 | * Stomach, Glandular       |
| * Thyroid Gland           | * Trachea                   |                          |                            |

**OBSERVATIONS**

- |                        |  |                                |                         |
|------------------------|--|--------------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                                    | Hyperplasia                    | Mild                    |
| * Harderian Gland      |  | Infiltration Cellular          | Mononuclear CI, Minimal |
| * Kidney               |  | Nephropathy                    | Minimal                 |
| * Liver                | Centrilobular                                  | Fatty Change                   | Mild                    |
|                        |  | Hypertrophy                    | Mild                    |
|                        |  | Infiltration Cellular          | Mononuclear CI, Minimal |
| * Lung                 |  | Alveolar/Bronchiolar Carcinoma |                         |
|                        | [ Alveolar/Bronchiolar Carcinoma TGLs = 2-10 ] |                                |                         |
| * Pituitary Gland      |  | Cyst                           | Minimal                 |
| * Stomach, Forestomach | Epithelium                                     | Hyperplasia                    | Minimal                 |
|                        |  | Inflammation                   | Chronic, Minimal        |
| * Thymus               |  | Atrophy                        | Minimal                 |
| * Urinary Bladder      |  | Infiltration Cellular          | Mononuclear CI, Minimal |
| * Uterus               | Endometrium                                    | Hyperplasia                    | Cystic, Moderate        |
|                        | [ Hyperplasia TGLs = 1-7 ]                     |                                |                         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 343	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602243

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Clitoral Gland         | * Esophagus                | * Eye                     |
| * Gallbladder               | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Kidney                    | * Lung                   | * Lymph Node, Mandibular   | * Lymph Node, Mesenteric  |
| * Mammary Gland             | * Nose                   | * Ovary                    | * Pancreas                |
| * Parathyroid Gland         | * Pituitary Gland        | * Salivary Glands          | * Skin                    |
| * Stomach, Glandular        | * Thyroid Gland          | * Trachea                  |                           |

**OBSERVATIONS**

- |                        |                               |   |  |
|------------------------|-------------------------------|---|--|
| * Adrenal Cortex       | Subcapsular                   | Hyperplasia   | Minimal                                    |
| * Harderian Gland      |                               | Hyperplasia<br>Infiltration Cellular                              | Minimal<br>Mononuclear CI, Minimal         |
| * Heart                |                               | Cardiomyopathy  | Minimal                                    |
| * Liver                | Centrilobular                 | Fatty Change<br>Hypertrophy<br>Infiltration Cellular              | Minimal<br>Mild<br>Mononuclear CI, Minimal |
| * Spleen               |                               | Hematopoietic Cell Proliferation                                  | Minimal                                    |
| * Stomach, Forestomach | Epithelium                    | Erosion<br>Hyperplasia<br>Inflammation<br>Squamous Cell Papilloma | Moderate<br>Moderate<br>Chronic, Moderate  |
|                        | [ Hyperplasia TGLs = 2-5+10 ] |   |  |
| * Thymus               |                               | Atrophy   | Minimal                                    |
| * Urinary Bladder      |                               | Infiltration Cellular   | Mononuclear CI, Minimal                    |
| * Uterus               | Endometrium                   | Hyperplasia   | Cystic, Moderate                           |
|                        | [ Hyperplasia TGLs = 1-7 ]    |   |  |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 344	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602244

ORGAN AND ACCOUNTABLE SITE STATUS

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Ileum	* Islets, Pancreatic	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Skin	* Spleen
* Stomach, Glandular	* Thyroid Gland	* Trachea	

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart	Artery	Infiltration Cellular	Mononuclear CI, Minimal
* Intestine Small, Duodenum	Epithelium	Hyperplasia	Mild
* Intestine Small, Jejunum	Peyers Patch	Hyperplasia	Marked
	[ Hyperplasia TGLs = 3-11 ]		
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Fatty Change	Minimal
	Centrilobular	Hepatocellular Carcinoma	
	[ Hepatocellular Carcinoma TGLs = 2-10 ]	Hypertrophy	Minimal
		Infiltration Cellular	Mononuclear CI, Minimal
* Lung		Inflammation	Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach		Erosion	Moderate
	Epithelium	Hyperplasia	Marked
	[ Hyperplasia TGLs = 4-5+11 ]	Inflammation	Chronic, Marked
* Thymus		Atrophy	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Moderate
	[ Hyperplasia TGLs = 1-7 ]		

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 345	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602245

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Skin	* Spleen	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart	Artery	Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Nephropathy	Minimal
* Liver	Centrilobular	Fatty Change	Minimal
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Epithelium	Erosion	Marked
		Hyperplasia	Marked
		Inflammation	Chronic, Moderate
	[ Hyperplasia TGLs = 1-5+10 ]		
* Thymus		Atrophy	Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 346	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 556
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 0602246

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Liver		Eosinophilic Focus	
	Centrilobular	Fatty Change	Minimal
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
* Ovary		Thrombosis	Marked
	[ Thrombosis TGLs = 2-10 ]		
* Spleen		Hematopoietic Cell Proliferation	Marked
		Hyperplasia	Lymphoid, Moderate
* Stomach, Forestomach		Erosion	Moderate
	Epithelium	Hyperplasia	Moderate
	[ Hyperplasia TGLs = 3-11 ]	Inflammation	Chronic, Moderate
* Thymus		Atrophy	Moderate
* Uterus	Endometrium	Hyperplasia	Cystic, Mild
	[ Hyperplasia TGLs = 1-7 ]		

PRIMARY CAUSE OF DEATH - Ovary Thrombosis

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 347    **TMT:** 6    **SEX:** Female    **DAY ON TEST:** 712  
**DOSE:** 0.5 G/KG    **DISP:** Natural Death    **HISTO:** 0602247

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lung                   | * Lymph Node, Mandibular   |
| * Lymph Node, Mesenteric  | * Mammary Gland             | * Nose                   | * Ovary                    |
| * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        | * Salivary Glands          |
| * Skin                    | * Stomach, Glandular        | * Thyroid Gland          | * Trachea                  |
| * Uterus                  |                             |                          |                            |

**OBSERVATIONS**

- |                        |  |                          |                         |
|------------------------|--|--------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                              | Hyperplasia              | Mild                    |
| * Harderian Gland      |  | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Liver                |  | Fatty Change             | Minimal                 |
|                        |  | Hepatocellular Carcinoma |                         |
|                        | [ Hepatocellular Carcinoma TGLs = 1-10 ] | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Spleen               | Lymph Follic                             | Atrophy                  | Mild                    |
| * Stomach, Forestomach |  | Erosion                  | Mild                    |
|                        | Epithelium                               | Hyperplasia              | Minimal                 |
|                        |  | Inflammation             | Chronic, Mild           |
| * Thymus               |  | Atrophy                  | Marked                  |
| * Urinary Bladder      |  | Infiltration Cellular    | Mononuclear CI, Minimal |

**PRIMARY CAUSE OF DEATH**    - Liver    Hepatocellular Carcinoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 348 TMT: 6 SEX: Female DAY ON TEST: 729  
 DOSE: 0.5 G/KG DISP: Terminal Sacrifice HISTO: 0602248

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Skin	* Spleen
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Uterus

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia Vacuolization Cytoplasmic	Mild Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Liver		Basophilic Focus Fatty Change Hepatoblastoma Hepatocellular Adenoma Hypertrophy Infiltration Cellular Mixed Cell Focus Necrosis	Mild  Multiple Mild Mononuclear CI, Minimal  Mild
	[ Hepatocellular Adenoma TGLs = 1,2,3-10+11+12 ] [ Mixed Cell Focus TGLs = 4-13 ] [ Necrosis TGLs = 5-14 ]		
Mesentery	Fat [ Necrosis TGLs = 6-10 ]	Necrosis	Mild
* Ovary		Angiectasis	Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation	Mild Chronic, Minimal
* Thymus		Atrophy	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 349 TMT: 6 SEX: Female DAY ON TEST: 731  
 DOSE: 0.5 G/KG DISP: Terminal Sacrifice HISTO: 0602249

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lung                   | * Lymph Node, Mandibular   |
| * Lymph Node, Mesenteric  | * Mammary Gland             | * Nose                   | * Ovary                    |
| * Pancreas                | * Parathyroid Gland         | * Skin                   | * Stomach, Glandular       |
| * Thyroid Gland           | * Trachea                   |                          |                            |

**MISSING**

- \* Pituitary Gland

**OBSERVATIONS**

- |                        |                             |                                  |                         |
|------------------------|-----------------------------|----------------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                 | Hyperplasia                      | Mild                    |
| * Harderian Gland      |                             | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Liver                |                             | Angiectasis                      | Minimal                 |
|                        | Centrilobular               | Fatty Change                     | Minimal                 |
|                        |                             | Hypertrophy                      | Mild                    |
|                        |                             | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Salivary Glands      |                             | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen               |                             | Hematopoietic Cell Proliferation | Minimal                 |
| * Stomach, Forestomach |                             | Erosion                          | Marked                  |
|                        | Epithelium                  | Hyperplasia                      | Marked                  |
|                        |                             | Inflammation                     | Chronic, Marked         |
|                        | [ Hyperplasia TGLs = 1-10 ] |                                  |                         |
| * Thymus               |                             | Atrophy                          | Minimal                 |
| * Urinary Bladder      |                             | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus               | Endometrium                 | Hyperplasia                      | Cystic, Minimal         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 350	<b>TMT:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0.5 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602250

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mesenteric | * Mammary Gland            |
| * Nose                    | * Pancreas                  | * Parathyroid Gland      | * Pituitary Gland          |
| * Salivary Glands         | * Stomach, Glandular        | * Thymus                 | * Thyroid Gland            |
| * Trachea                 |                             |                          |                            |

**OBSERVATIONS**

- |                          |                             |                                  |                         |
|--------------------------|-----------------------------|----------------------------------|-------------------------|
| * Adrenal Cortex         | Subcapsular                 | Hyperplasia                      | Mild                    |
| * Harderian Gland        |                             | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Kidney                 |                             | Nephropathy                      | Minimal                 |
| * Liver                  | Centrilobular               | Fatty Change                     | Minimal                 |
|                          |                             | Hypertrophy                      | Mild                    |
|                          |                             | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Lymph Node, Mandibular |                             | Hyperplasia                      | Lymphoid, Mild          |
| * Ovary                  |                             | Cystadenoma                      |                         |
| * Skin                   | Subcut Tiss                 | Hemangioma                       |                         |
| * Spleen                 |                             | Hematopoietic Cell Proliferation | Minimal                 |
| * Stomach, Forestomach   | Epithelium                  | Erosion                          | Moderate                |
|                          |                             | Hyperplasia                      | Moderate                |
|                          |                             | Inflammation                     | Chronic, Moderate       |
|                          |                             | Squamous Cell Carcinoma          |                         |
|                          | [ Hyperplasia TGLs = 2-10 ] |                                  |                         |
| * Urinary Bladder        |                             | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus                 | Endometrium                 | Hyperplasia                      | Cystic, Marked          |
|                          | [ Hyperplasia TGLs = 1-7 ]  |                                  |                         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 351    **TMT:** 8    **SEX:** Female    **DAY ON TEST:** 725  
**DOSE:** 1.0 G/KG    **DISP:** Natural Death    **HISTO:** 0602251

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone                     | * Bone Marrow             |
| * Brain                     | * Clitoral Gland         | * Esophagus                | * Eye                     |
| * Gallbladder               | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Mammary Gland           |
| * Nose                      | * Pancreas               | * Parathyroid Gland        | * Pituitary Gland         |
| * Skin                      | * Stomach, Forestomach   | * Stomach, Glandular       | * Thyroid Gland           |
| * Trachea                   | * Urinary Bladder        |                            |                           |

**AUTO PRECLUDES DIAG.**

- \* Spleen

**OBSERVATIONS**

- |                   |  |                       |                         |
|-------------------|--|-----------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular  | Hyperplasia           | Minimal                 |
| * Harderian Gland |  | Infiltration Cellular | Mononuclear CI, Minimal |
| * Heart           | Myocardium   | Mineralization        | Mild                    |
| * Kidney          |  | Mineralization        | Minimal                 |
| * Liver           |  | Eosinophilic Focus    |                         |
|                   |  | Fatty Change          | Mild                    |
|                   |  | Histiocytic Sarcoma   |                         |
|                   | [ Histiocytic Sarcoma TGLs = 2,3,4,5-10+11+12+13 ] |                       |                         |
| * Ovary           |  | Histiocytic Sarcoma   |                         |
| * Salivary Glands |  | Infiltration Cellular | Mononuclear CI, Minimal |
| * Thymus          |  | Atrophy               | Marked                  |
| * Uterus          |  | Histiocytic Sarcoma   |                         |
|                   | Endometrium  | Hyperplasia           | Cystic, Mild            |
|                   | [ Histiocytic Sarcoma TGLs = 6-14 ]                |                       |                         |
|                   | [ Hyperplasia TGLs = 1-7 ]                         |                       |                         |

**PRIMARY CAUSE OF DEATH** - Liver Histiocytic Sarcoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 352    **TMT:** 8    **SEX:** Female    **DAY ON TEST:** 654  
**DOSE:** 1.0 G/KG    **DISP:** Moribund Sacrifice    **HISTO:** 0602252

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| Blood Vessel              | * Bone                      | * Bone Marrow            | * Brain                    |
| * Clitoral Gland          | * Esophagus                 | * Eye                    | * Gallbladder              |
| * Harderian Gland         | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Ovary                     | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Salivary Glands           | * Skin                   | * Thyroid Gland            |
| * Trachea                 | * Uterus                    |                          |                            |

**MISSING**

- \* Thymus

**OBSERVATIONS**

- |                        |                                 |                           |                         |
|------------------------|---------------------------------|---------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                     | Hyperplasia               | Mild                    |
| * Adrenal Medulla      |                                 | Vacuolization Cytoplasmic | Minimal                 |
| * Kidney               | Papilla                         | Necrosis                  | Mild                    |
| * Liver                | Centrilobular                   | Fatty Change              | Marked                  |
|                        |                                 | Hypertrophy               | Mild                    |
|                        |                                 | Mixed Cell Focus          |                         |
|                        | [ Fatty Change TGLs = 1-3+4+5 ] |                           |                         |
| * Nose                 |                                 | Inflammation              | Suppurative, Mild       |
| * Spleen               | Lymph Follic                    | Atrophy                   | Marked                  |
|                        | [ Atrophy TGLs = 2-4 ]          |                           |                         |
| * Stomach, Forestomach | Epithelium                      | Hyperplasia               | Minimal                 |
|                        |                                 | Inflammation              | Chronic, Mild           |
|                        |                                 | Ulcer                     | Mild                    |
| * Stomach, Glandular   |                                 | Ulcer                     | Mild                    |
| * Urinary Bladder      |                                 | Infiltration Cellular     | Mononuclear CI, Minimal |

PRIMARY CAUSE OF DEATH    - Liver Fatty Change

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 353    **TMT:** 8    **SEX:** Female    **DAY ON TEST:** 730  
**DOSE:** 1.0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602253

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Mammary Gland            |
| * Nose                    | * Ovary                     | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Skin                      | * Spleen                 | * Stomach, Forestomach     |
| * Stomach, Glandular      | * Thyroid Gland             | * Trachea                |                            |

**OBSERVATIONS**

- |                   |  |                                |                         |
|-------------------|--|--------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                                    | Hyperplasia                    | Mild                    |
| * Harderian Gland |  | Infiltration Cellular          | Mononuclear CI, Minimal |
| * Kidney          |  | Nephropathy                    | Minimal                 |
| * Liver           |  | Eosinophilic Focus             |                         |
|                   |  | Fatty Change                   | Mild                    |
|                   | Centrilobular                                  | Hepatocellular Adenoma         |                         |
|                   |  | Hypertrophy                    | Mild                    |
|                   |  | Infiltration Cellular          | Mononuclear CI, Minimal |
|                   | [ Eosinophilic Focus TGLs = 3-11 ]             |                                |                         |
|                   | [ Hepatocellular Adenoma TGLs = 1-10 ]         |                                |                         |
| * Lung            |  | Alveolar/Bronchiolar Carcinoma |                         |
|                   | [ Alveolar/Bronchiolar Carcinoma TGLs = 2-10 ] |                                |                         |
| Mesentery         | Fat  | Necrosis                       | Mild                    |
|                   | [ Necrosis TGLs = 4-12 ]                       |                                |                         |
| * Salivary Glands |  | Infiltration Cellular          | Mononuclear CI, Minimal |
| * Thymus          |  | Atrophy                        | Marked                  |
| * Urinary Bladder |  | Infiltration Cellular          | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                                    | Hyperplasia                    | Cystic, Mild            |



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 354	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 678
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 0602254

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                          |
|---------------------------|-----------------------------|--------------------------|--------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow            |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                    |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Islets, Pancreatic     |
| * Kidney                  | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Mammary Gland          |
| * Nose                    | * Ovary                     | * Pancreas               | * Parathyroid Gland      |
| * Pituitary Gland         | * Skin                      | * Stomach, Forestomach   | * Stomach, Glandular     |
| * Thyroid Gland           | * Trachea                   |                          |                          |

**OBSERVATIONS**

- |                            |  |                                  |                         |
|----------------------------|--|----------------------------------|-------------------------|
| * Adrenal Cortex           | Subcapsular                                    | Hyperplasia                      | Mild                    |
| * Harderian Gland          |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Intestine Small, Jejunum | Epithelium                                     | Hyperplasia                      | Moderate                |
| * Liver                    |  | Basophilic Focus                 |                         |
|                            |  | Fatty Change                     | Mild                    |
|                            | Centrilobular                                  | Hepatocellular Carcinoma         |                         |
|                            |  | Hypertrophy                      | Mild                    |
|                            |  | Infiltration Cellular            | Mononuclear CI, Minimal |
|                            | [ Basophilic Focus TGLs = 3-12 ]               |                                  |                         |
|                            | [ Hepatocellular Carcinoma TGLs = 1-10 ]       |                                  |                         |
| * Lung                     |  | Alveolar/Bronchiolar Carcinoma   |                         |
|                            | [ Alveolar/Bronchiolar Carcinoma TGLs = 2-11 ] |                                  |                         |
| * Salivary Glands          |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen                   |  | Hematopoietic Cell Proliferation | Minimal                 |
|                            |  | Lymphoma Malignant               |                         |
| * Thymus                   |  | Atrophy                          | Marked                  |
| * Urinary Bladder          |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus                   | Endometrium                                    | Hyperplasia                      | Cystic, Minimal         |

PRIMARY CAUSE OF DEATH - Liver Hepatocellular Carcinoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 355	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602255

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone Marrow              | * Brain                   |
| * Clitoral Gland            | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Mammary Gland           |
| * Nose                      | * Pancreas               | * Parathyroid Gland        | * Pituitary Gland         |
| * Salivary Glands           | * Skin                   | * Spleen                   | * Stomach, Glandular      |
| * Thyroid Gland             | * Trachea                | * Urinary Bladder          |                           |

**OBSERVATIONS**

- |                        |                                    |                       |                         |
|------------------------|------------------------------------|-----------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                        | Hyperplasia           | Mild                    |
| * Bone                 |                                    | Fibrosis              | Minimal                 |
| * Harderian Gland      |                                    | Hyperplasia           | Mild                    |
|                        |                                    | Infiltration Cellular | Mononuclear CI, Minimal |
| * Kidney               |                                    | Metaplasia            | Osseous, Minimal        |
| * Liver                | Centrilobular                      | Eosinophilic Focus    |                         |
|                        |                                    | Fatty Change          | Minimal                 |
|                        |                                    | Hypertrophy           | Mild                    |
|                        |                                    | Infiltration Cellular | Mononuclear CI, Minimal |
|                        | [ Eosinophilic Focus TGLs = 2-10 ] |                       |                         |
| * Ovary                |                                    | Cystadenoma           |                         |
|                        | [ Cystadenoma TGLs = 1-7 ]         |                       |                         |
| * Stomach, Forestomach | Epithelium                         | Hyperplasia           | Moderate                |
|                        |                                    | Inflammation          | Chronic, Mild           |
|                        |                                    | Ulcer                 | Mild                    |
|                        | [ Hyperplasia TGLs = 3-10 ]        |                       |                         |
| * Thymus               |                                    | Atrophy               | Marked                  |
| * Uterus               | Endometrium                        | Hyperplasia           | Cystic, Minimal         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 356	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
<b>DOSE:</b> 1.0 G/KG		<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602256

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Nose                      | * Ovary                  | * Pancreas                 |
| * Parathyroid Gland       | * Pituitary Gland           | * Salivary Glands        | * Skin                     |
| * Spleen                  | * Stomach, Glandular        | * Thyroid Gland          | * Trachea                  |

**OBSERVATIONS**

- |                        |                                    |                       |                         |
|------------------------|------------------------------------|-----------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                        | Hyperplasia           | Mild                    |
| * Harderian Gland      |                                    | Infiltration Cellular | Mononuclear CI, Minimal |
| * Kidney               |                                    | Nephropathy           | Minimal                 |
| * Liver                | Centrilobular                      | Clear Cell Focus      |                         |
|                        |                                    | Eosinophilic Focus    |                         |
|                        |                                    | Hypertrophy           | Mild                    |
|                        |                                    | Infiltration Cellular | Mononuclear CI, Minimal |
|                        | [ Clear Cell Focus TGLs = 2-11 ]   |                       |                         |
|                        | [ Eosinophilic Focus TGLs = 1-10 ] |                       |                         |
| * Stomach, Forestomach | Epithelium                         | Erosion               | Marked                  |
|                        |                                    | Hyperplasia           | Moderate                |
|                        |                                    | Inflammation          | Chronic, Moderate       |
|                        | [ Hyperplasia TGLs = 3-5+12 ]      |                       |                         |
| * Thymus               |                                    | Atrophy               | Minimal                 |
| * Urinary Bladder      |                                    | Infiltration Cellular | Mononuclear CI, Minimal |
| * Uterus               | Endometrium                        | Hyperplasia           | Cystic, Mild            |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 357    **TMT:** 8    **SEX:** Female    **DAY ON TEST:** 684  
**DOSE:** 1.0 G/KG    **DISP:** Moribund Sacrifice    **HISTO:** 0602257

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                    | * Clitoral Gland          | * Esophagus                 | * Eye                    |
| * Gallbladder              | * Harderian Gland         | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular |
| * Lymph Node, Mesenteric   | * Mammary Gland           | * Nose                      | * Ovary                  |
| * Pancreas                 | * Parathyroid Gland       | * Pituitary Gland           | * Salivary Glands        |
| * Skin                     | * Stomach, Glandular      | * Thyroid Gland             | * Trachea                |
| * Urinary Bladder          |                           |                             |                          |

**MISSING**

- \* Thymus

**OBSERVATIONS**

- |                        |  |                                  |                   |
|------------------------|--|----------------------------------|-------------------|
| * Adrenal Cortex       | Subcapsular                              | Hyperplasia                      | Mild              |
| * Kidney               |  | Nephropathy                      | Marked            |
| * Liver                | Centrilobular                            | Hepatocellular Carcinoma         |                   |
|                        | [ Hepatocellular Carcinoma TGLs = 1-10 ] | Hypertrophy                      | Mild              |
| * Spleen               | Lymph Follic                             | Atrophy                          | Moderate          |
|                        |  | Hematopoietic Cell Proliferation | Mild              |
| * Stomach, Forestomach | Epithelium                               | Hyperplasia                      | Moderate          |
|                        | [ Hyperplasia TGLs = 2-5 ]               | Inflammation                     | Chronic, Moderate |
|                        |  | Ulcer                            | Moderate          |
| Tissue NOS             |  | Inflammation                     | Chronic, Moderate |
| * Uterus               | Endometrium                              | Hyperplasia                      | Cystic, Minimal   |

**PRIMARY CAUSE OF DEATH**    - Kidney Nephropathy

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 358    **TMT:** 8    **SEX:** Female    **DAY ON TEST:** 523  
**DOSE:** 1.0 G/KG    **DISP:** Moribund Sacrifice    **HISTO:** 0602258

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                    | * Clitoral Gland          | * Esophagus                 | * Eye                    |
| * Gallbladder              | * Harderian Gland         | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular |
| * Lymph Node, Mesenteric   | * Mammary Gland           | * Nose                      | * Ovary                  |
| * Pancreas                 | * Parathyroid Gland       | * Pituitary Gland           | * Salivary Glands        |
| * Skin                     | * Spleen                  | * Thyroid Gland             | * Trachea                |
| * Urinary Bladder          | * Uterus                  |                             |                          |

**OBSERVATIONS**

- |                        |                              |                       |                         |
|------------------------|------------------------------|-----------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                  | Hyperplasia           | Mild                    |
| * Kidney               |                              | Mineralization        | Minimal                 |
|                        | [ Nephropathy TGLs = 1-4 ]   | Nephropathy           | Marked                  |
| * Liver                | Centrilobular                | Hypertrophy           | Mild                    |
|                        |                              | Infiltration Cellular | Mononuclear CI, Minimal |
| * Stomach, Forestomach | Epithelium                   | Erosion               | Moderate                |
|                        | [ Hyperplasia TGLs = 3-11 ]  | Hyperplasia           | Moderate                |
|                        | [ Inflammation TGLs = 2-10 ] | Inflammation          | Chronic, Moderate       |
| * Stomach, Glandular   |                              | Ulcer                 | Mild                    |
|                        | [ Ulcer TGLs = 4-12 ]        |                       |                         |
| * Thymus               |                              | Atrophy               | Mild                    |

PRIMARY CAUSE OF DEATH    - Kidney Nephropathy

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 359    **TMT:** 8    **SEX:** Female    **DAY ON TEST:** 731  
**DOSE:** 1.0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602259

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Nose                      | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Salivary Glands           | * Skin                   | * Spleen                   |
| * Thyroid Gland           | * Trachea                   | * Urinary Bladder        |                            |

**OBSERVATIONS**

- |                        |                               |                       |                         |
|------------------------|-------------------------------|-----------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                   | Hyperplasia           | Mild                    |
| * Harderian Gland      |                               | Infiltration Cellular | Mononuclear CI, Minimal |
| * Kidney               |                               | Mineralization        | Minimal                 |
|                        |                               | Nephropathy           | Minimal                 |
| * Liver                | Centrilobular                 | Fatty Change          | Minimal                 |
|                        |                               | Hypertrophy           | Mild                    |
|                        |                               | Infiltration Cellular | Mononuclear CI, Minimal |
| * Ovary                |                               | Cystadenoma           |                         |
| * Stomach, Forestomach | Epithelium                    | Erosion               | Moderate                |
|                        |                               | Hyperplasia           | Moderate                |
|                        |                               | Inflammation          | Chronic, Moderate       |
|                        | [ Hyperplasia TGLs = 2-5+10 ] |                       |                         |
| * Stomach, Glandular   | Epithelium                    | Hyperplasia           | Mild                    |
| * Thymus               |                               | Atrophy               | Mild                    |
| * Uterus               | Endometrium                   | Hyperplasia           | Cystic, Moderate        |
|                        | [ Polyp Stromal TGLs = 1-7 ]  | Polyp Stromal         |                         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 360	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602260

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Nose                      | * Ovary                  | * Pancreas                 |
| * Parathyroid Gland       | * Pituitary Gland           | * Salivary Glands        | * Skin                     |
| * Spleen                  | * Stomach, Glandular        | * Thyroid Gland          | * Trachea                  |
| * Urinary Bladder         | * Uterus                    |                          |                            |

**OBSERVATIONS**

- |                        |                                    |                       |                         |
|------------------------|------------------------------------|-----------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                        | Hyperplasia           | Mild                    |
| * Harderian Gland      |                                    | Infiltration Cellular | Mononuclear CI, Minimal |
| * Kidney               |                                    | Metaplasia            | Osseous, Minimal        |
|                        |                                    | Mineralization        | Minimal                 |
|                        |                                    | Nephropathy           | Moderate                |
| * Liver                | Centrilobular                      | Eosinophilic Focus    |                         |
|                        |                                    | Hypertrophy           | Mild                    |
|                        |                                    | Infiltration Cellular | Mononuclear CI, Minimal |
|                        | [ Eosinophilic Focus TGLs = 1-10 ] |                       |                         |
| * Stomach, Forestomach | Epithelium                         | Erosion               | Mild                    |
|                        |                                    | Hyperplasia           | Minimal                 |
|                        |                                    | Inflammation          | Chronic, Mild           |
| * Thymus               |                                    | Atrophy               | Minimal                 |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 361	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602261

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Blood Vessel	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Spleen
* Thyroid Gland	* Trachea		

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Adrenal Medulla		Hyperplasia	Mild
* Kidney		Nephropathy	Minimal
* Liver	Centrilobular	Hypertrophy Infiltration Cellular Mixed Cell Focus Tension Lipidosis	Mild Mononuclear CI, Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation Ulcer	Moderate Chronic, Moderate Moderate
	[ Hyperplasia TGLs = 1-5+10 ]		
* Stomach, Glandular	Epithelium	Hyperplasia	Mild
* Thymus		Atrophy	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 362 TMT: 8 SEX: Female DAY ON TEST: 576  
 DOSE: 1.0 G/KG DISP: Natural Death HISTO: 0602262

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lung                   | * Lymph Node, Mandibular   |
| * Lymph Node, Mesenteric  | * Mammary Gland             | * Nose                   | * Ovary                    |
| * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        | * Salivary Glands          |
| * Skin                    | * Spleen                    | * Thymus                 | * Thyroid Gland            |
| * Trachea                 |                             |                          |                            |

**OBSERVATIONS**

- |                        |                                       |  |   |
|------------------------|---------------------------------------|--|---|
| * Adrenal Cortex       | Subcapsular                           | Hyperplasia                            | Mild                                      |
| * Harderian Gland      |                                       | Infiltration Cellular                  | Mononuclear CI, Minimal                   |
| * Liver                | Centrilobular                         | Hypertrophy<br>Infiltration Cellular   | Mild<br>Mononuclear CI, Minimal           |
| * Stomach, Forestomach | Epithelium                            | Erosion<br>Hyperplasia<br>Inflammation | Moderate<br>Moderate<br>Chronic, Moderate |
| * Stomach, Glandular   |                                       | Infiltration Cellular                  | Mononuclear CI, Mild                      |
|                        | [ Infiltration Cellular TGLs = 2-10 ] |  |   |
| * Urinary Bladder      |                                       | Infiltration Cellular                  | Mononuclear CI, Minimal                   |
| * Uterus               | Endometrium                           | Hyperplasia                            | Cystic, Moderate                          |
|                        | [ Hyperplasia TGLs = 1-7 ]            |  |   |

PRIMARY CAUSE OF DEATH - Stomach, Forestomach Erosion

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

ANIMAL NUM: 363 TMT: 8 SEX: Female DAY ON TEST: 731  
DOSE: 1.0 G/KG DISP: Terminal Sacrifice HISTO: 0602263

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Spleen	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Uterus			

MISSING

\* Thymus

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Adenoma	
		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Mineralization	Minimal
	[ Nephropathy TGLs = 1-4 ]	Nephropathy	Marked
* Liver	Centrilobular	Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach		Erosion	Mild
	Epithelium	Hyperplasia	Moderate
	[ Hyperplasia TGLs = 2-5+10 ]	Inflammation	Chronic, Moderate
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 364	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602264

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone Marrow              | * Brain                   |
| * Clitoral Gland            | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Mammary Gland            | * Nose                    |
| * Ovary                     | * Pancreas               | * Parathyroid Gland        | * Pituitary Gland         |
| * Skin                      | * Spleen                 | * Stomach, Glandular       | * Thymus                  |
| * Thyroid Gland             | * Trachea                |                            |                           |

**OBSERVATIONS**

- |                        |  |                              |                         |
|------------------------|--|------------------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                                  | Hyperplasia                  | Mild                    |
| * Bone                 |  | Fibrosis                     | Mild                    |
| * Harderian Gland      |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Kidney               |  | Mineralization               | Minimal                 |
| * Liver                | Centrilobular                                | Fatty Change                 | Minimal                 |
|                        |  | Hypertrophy                  | Mild                    |
|                        |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Lung                 |  | Alveolar/Bronchiolar Adenoma |                         |
|                        | [ Alveolar/Bronchiolar Adenoma TGLs = 1-10 ] |                              |                         |
| * Salivary Glands      |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Stomach, Forestomach | Epithelium                                   | Hyperplasia                  | Minimal                 |
|                        |  | Inflammation                 | Chronic, Minimal        |
| Tooth                  |  | Dysplasia                    | Minimal                 |
| * Urinary Bladder      |  | Infiltration Cellular        | Mononuclear CI, Minimal |
| * Uterus               | Endometrium                                  | Hyperplasia                  | Cystic, Minimal         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 365	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602265

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Adenoma	
	[ Adenoma TGLs = 2-9 ]	Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Lymphoma Malignant	
		Mineralization	Minimal
		Nephropathy	Minimal
* Liver	Centrilobular	Eosinophilic Focus	
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Mild
		Lymphoma Malignant	
* Spleen		Lymphoma Malignant	
* Stomach, Forestomach	Epithelium	Erosion	Moderate
		Hyperplasia	Moderate
		Inflammation	Chronic, Moderate
	[ Lymphoma Malignant TGLs = 3-5+10 ]	Lymphoma Malignant	
* Thymus		Atrophy	Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Moderate
	[ Hyperplasia TGLs = 1-7 ]		

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 366	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602266

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lung                   | * Lymph Node, Mandibular   |
| * Lymph Node, Mesenteric  | * Mammary Gland             | * Nose                   | * Pancreas                 |
| * Parathyroid Gland       | * Pituitary Gland           | * Skin                   | * Spleen                   |
| * Stomach, Forestomach    | * Stomach, Glandular        | * Thyroid Gland          | * Trachea                  |
| * Urinary Bladder         |                             |                          |                            |

**OBSERVATIONS**

- |                   |   |                       |                         |
|-------------------|---|-----------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                             | Hyperplasia           | Mild                    |
| * Harderian Gland |   | Infiltration Cellular | Mononuclear CI, Minimal |
| * Liver           |   | Clear Cell Focus      |                         |
|                   | Centrilobular                           | Eosinophilic Focus    | Mild                    |
|                   |   | Hypertrophy           | Mononuclear CI, Minimal |
|                   | [ Clear Cell Focus TGLs = 1-10 ]        |                       |                         |
|                   | [ Eosinophilic Focus TGLs = 2,3-11+12 ] |                       |                         |
| * Ovary           |   | Cystadenoma           |                         |
| * Salivary Glands |   | Infiltration Cellular | Mononuclear CI, Minimal |
| * Thymus          |   | Atrophy               | Mild                    |
| * Uterus          | Endometrium                             | Hyperplasia           | Cystic, Minimal         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 367	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602267

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                           |                          |                            |
|--------------------------|---------------------------|--------------------------|----------------------------|
| * Adrenal Medulla        | Blood Vessel              | * Bone                   | * Bone Marrow              |
| * Brain                  | * Clitoral Gland          | * Esophagus              | * Eye                      |
| * Gallbladder            | * Harderian Gland         | * Heart                  | * Intestine Large, Cecum   |
| * Intestine Large, Colon | * Intestine Large, Rectum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic     | * Lung                    | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland          | * Nose                    | * Ovary                  | * Pancreas                 |
| * Parathyroid Gland      | * Pituitary Gland         | * Salivary Glands        | * Skin                     |
| * Stomach, Glandular     | * Thyroid Gland           | * Trachea                |                            |

**OBSERVATIONS**

- |                             |  |                                  |                         |
|-----------------------------|--|----------------------------------|-------------------------|
| * Adrenal Cortex            | Subcapsular                                  | Hyperplasia                      | Mild                    |
| * Intestine Small, Duodenum |  | Metaplasia                       | Squamous, Minimal       |
| * Kidney                    | Papilla                                      | Mineralization                   | Mild                    |
|                             |  | Necrosis                         | Mild                    |
| * Liver                     | Centrilobular                                | Eosinophilic Focus               | Mild                    |
|                             |  | Hypertrophy                      | Mononuclear CI, Minimal |
|                             | [ Eosinophilic Focus TGLs = 1,2,4-10+11+13 ] | Infiltration Cellular            |                         |
| * Ovary                     |  |                                  |                         |
| Note: One ovary was missing |  |                                  |                         |
| * Spleen                    |  | Hematopoietic Cell Proliferation | Mild                    |
| * Stomach, Forestomach      | Epithelium                                   | Erosion                          | Moderate                |
|                             |  | Hyperplasia                      | Moderate                |
|                             | [ Hyperplasia TGLs = 3-5+12 ]                | Inflammation                     | Chronic, Moderate       |
| * Thymus                    |  | Atrophy                          | Mild                    |
| * Urinary Bladder           |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus                    | Endometrium                                  | Hyperplasia                      | Cystic, Mild            |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 368 TMT: 8 SEX: Female DAY ON TEST: 731  
 DOSE: 1.0 G/KG DISP: Terminal Sacrifice HISTO: 0602268

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

Blood Vessel	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Skin	* Spleen
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Adrenal Medulla		Hyperplasia	Minimal
* Harderian Gland		Hyperplasia Infiltration Cellular	Mild Mononuclear CI, Minimal
* Liver	Centrilobular	Eosinophilic Focus Fatty Change Hypertrophy Infiltration Cellular Mixed Cell Focus Tension Lipidosis	Mild Mild Mononuclear CI, Minimal
[ Eosinophilic Focus	TGLs = 1,2-10+11 ]		
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Epithelium	Erosion Hyperplasia Inflammation	Mild Moderate Chronic, Moderate
* Thymus		Atrophy	Mild
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 369	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 548
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Moribund Sacrifice	<b>HISTO:</b> 0602269

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Adenoma	
		Hyperplasia	Minimal
	[ Adenoma TGLs = 1-9 ]	Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Nephropathy	Minimal
* Liver	Centrilobular	Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Moderate
		Inflammation	Chronic, Moderate
		Ulcer	Mild
* Thymus		Atrophy	Moderate
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal

PRIMARY CAUSE OF DEATH - Harderian Gland Adenoma



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 370 TMT: 8 SEX: Female DAY ON TEST: 729  
 DOSE: 1.0 G/KG DISP: Terminal Sacrifice HISTO: 0602270

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Clitoral Gl			
Note: One clitoral gland was missing			
* Harderian Gland	Bilateral	Adenoma	
[ Adenoma TGLs = 2-9 ]			
* Kidney		Metaplasia	Osseous, Minimal
* Liver	Centrilobular	Eosinophilic Focus Fatty Change Hypertrophy Infiltration Cellular Mixed Cell Focus	Minimal Mild Mononuclear CI, Minimal
[ Eosinophilic Focus TGLs = 3-11 ]			
[ Mixed Cell Focus TGLs = 1-10 ]			
* Lung	Alveolar Epith Alveolus	Hyperplasia Infiltration Cellular	Mild Histiocyte, Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hyperplasia	Lymphoid, Mild
* Thymus		Atrophy	Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 371	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602271

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                    | * Clitoral Gland          | * Esophagus                 | * Eye                    |
| * Gallbladder              | * Harderian Gland         | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic      | * Kidney                    | * Lung                   |
| * Lymph Node, Mandibular   | * Lymph Node, Mesenteric  | * Mammary Gland             | * Nose                   |
| * Ovary                    | * Pancreas                | * Parathyroid Gland         | * Salivary Glands        |
| * Skin                     | * Spleen                  | * Stomach, Forestomach      | * Stomach, Glandular     |
| * Thymus                   | * Thyroid Gland           | * Trachea                   |                          |

**OBSERVATIONS**

- |                   |   |                        |                         |
|-------------------|---|------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                             | Hyperplasia            | Mild                    |
| * Liver           |   | Eosinophilic Focus     |                         |
|                   |   | Fatty Change           | Mild                    |
|                   | Centrilobular                           | Hepatocellular Adenoma |                         |
|                   |   | Hypertrophy            | Mild                    |
|                   |   | Infiltration Cellular  | Mononuclear CI, Minimal |
|                   | [ Eosinophilic Focus TGLs = 2,3-11+12 ] |                        |                         |
|                   | [ Hepatocellular Adenoma TGLs = 1-10 ]  |                        |                         |
| * Pituitary Gland | Pars Distalis                           | Hyperplasia            | Minimal                 |
| * Urinary Bladder |   | Infiltration Cellular  | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                             | Hyperplasia            | Cystic, Minimal         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 372	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 604
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Moribund Sacrifice	<b>HISTO:</b> 0602272

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Harderian Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea			

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Kidney		Mineralization	Minimal
		Nephropathy	Moderate
* Liver		Eosinophilic Focus	
	Centrilobular	Hepatocellular Carcinoma	
		Hypertrophy	Mild
	[ Hepatocellular Carcinoma TGLs = 1-10 ]	Vacuolization Cytoplasmic	Mild
* Spleen		Hematopoietic Cell Proliferation	Mild
* Thymus		Atrophy	Marked
* Urinary Bladder		Infiltration Cellular	Mononuclear Cl, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild
Vagina		Vacuolization Cytoplasmic	Mild

PRIMARY CAUSE OF DEATH - Liver Hepatocellular Carcinoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 373 TMT: 8 SEX: Female DAY ON TEST: 723  
 DOSE: 1.0 G/KG DISP: Natural Death HISTO: 0602273

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Skin	* Spleen
* Stomach, Glandular	* Thyroid Gland	* Trachea	

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Eye			
Note: Both optic nerves were missing			
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Mineralization Nephropathy	Minimal Mild
* Liver	Centrilobular	Fatty Change Hypertrophy	Minimal Mild
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Epithelium	Erosion Hyperplasia Inflammation	Mild Moderate Chronic, Moderate
	[ Hyperplasia TGLs = 1-10 ]		
* Thymus		Atrophy	Marked
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild

PRIMARY CAUSE OF DEATH - Stomach, Forestomach Erosion

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 374	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602274

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Parathyroid Gland
* Pituitary Gland	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea		

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
		Fatty Change	Minimal
	Centrilobular	Hepatocellular Carcinoma	
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Eosinophilic Focus TGLs = 3,4-11+12 ]		
	[ Hepatocellular Carcinoma TGLs = 2-10 ]		
* Pancreas	Acinus	Hypertrophy	Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hyperplasia	Lymphoid, Mild
* Thymus		Atrophy	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Moderate
	[ Hyperplasia TGLs = 1-7 ]		

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 375	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602275

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lung                   | * Lymph Node, Mandibular   |
| * Lymph Node, Mesenteric  | * Mammary Gland             | * Nose                   | * Ovary                    |
| * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        | * Skin                     |
| * Spleen                  | * Stomach, Forestomach      | * Stomach, Glandular     | * Thyroid Gland            |
| * Trachea                 | * Uterus                    |                          |                            |

**OBSERVATIONS**

- |                   |               |                       |                         |
|-------------------|---------------|-----------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular   | Hyperplasia           | Mild                    |
| * Harderian Gland |               | Infiltration Cellular | Mononuclear CI, Minimal |
| * Liver           | Centrilobular | Hypertrophy           | Mild                    |
|                   |               | Infiltration Cellular | Mononuclear CI, Minimal |
|                   |               | Tension Lipidosis     |                         |
| * Salivary Glands |               | Infiltration Cellular | Mononuclear CI, Minimal |
| * Thymus          |               | Atrophy               | Minimal                 |
| * Urinary Bladder |               | Infiltration Cellular | Mononuclear CI, Minimal |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 376    **TMT:** 8    **SEX:** Female    **DAY ON TEST:** 548  
**DOSE:** 1.0 G/KG    **DISP:** Moribund Sacrifice    **HISTO:** 0602276

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone Marrow              | * Brain                   |
| * Clitoral Gland            | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Kidney                    | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Mammary Gland           |
| * Nose                      | * Ovary                  | * Pancreas                 | * Parathyroid Gland       |
| * Pituitary Gland           | * Skin                   | Spinal Cord                | * Spleen                  |
| * Stomach, Forestomach      | * Stomach, Glandular     | * Thyroid Gland            | * Trachea                 |
| * Urinary Bladder           |                          |                            |                           |

**OBSERVATIONS**

- |  |               |  |                                 |
|--|---------------|--|---------------------------------|
| * Adrenal Cortex   | Subcapsular   | Hyperplasia  | Mild                            |
| * Bone   |               | Fibrosis<br>Osteosarcoma                                   | Minimal                         |
| Note: Based on histology, the spinal cord mass (TGL 1) was in the bone<br>[ Osteosarcoma TGLs = 1-10 ] |               |  |                                 |
| * Harderian Gland  |               | Infiltration Cellular                                      | Mononuclear CI, Minimal         |
| * Liver  | Centrilobular | Eosinophilic Focus<br>Hypertrophy<br>Infiltration Cellular | Mild<br>Mononuclear CI, Minimal |
| * Lung   |               | Osteosarcoma   | Metastatic (Bone)               |
| [ Osteosarcoma TGLs = 2-15 ]   |               |  |                                 |
| Mesentery  | Fat           | Necrosis   | Mild                            |
| [ Necrosis TGLs = 3-16 ]   |               |  |                                 |
| Peripheral Nerve   | Axon          | Degeneration   | Marked                          |
| * Salivary Glands  |               | Infiltration Cellular                                      | Mononuclear CI, Minimal         |
| * Thymus   |               | Atrophy  | Mild                            |
| * Uterus   | Endometrium   | Hyperplasia  | Cystic, Minimal                 |

PRIMARY CAUSE OF DEATH - Bone Osteosarcoma

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 377    **TMT:** 8    **SEX:** Female    **DAY ON TEST:** 719  
**DOSE:** 1.0 G/KG    **DISP:** Moribund Sacrifice    **HISTO:** 0602277

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Uterus	

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
Note: One Harderian gland was missing			
* Heart		Fibrous Histiocytoma	Metastatic (Skin)
* Liver	Centrilobular	Hepatocellular Carcinoma	
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Hepatocellular Carcinoma TGLs = 2-11 ]		
* Lung		Fibrous Histiocytoma	Metastatic (Skin)
	[ Fibrous Histiocytoma TGLs = 4,5-13+14 ]		
Mesentery	Fat	Necrosis	Mild
	[ Necrosis TGLs = 3-12 ]		
* Skin		Fibrous Histiocytoma	
	[ Fibrous Histiocytoma TGLs = 1-10 ]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Thymus		Atrophy	Marked
		Fibrous Histiocytoma	Metastatic (Skin)
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

PRIMARY CAUSE OF DEATH - Skin Fibrous Histiocytoma



TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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ANIMAL NUM:	378	TMT:	8	SEX:	Female	DAY ON TEST:	148
		DOSE:	1.0 G/KG	DISP:	Accidently Killed	HISTO:	0602278

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ORGAN AND ACCOUNTABLE SITE STATUS

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NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Harderian Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

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OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Minimal
* Eye	Note: Both optic nerves were missing		
* Liver	Centrilobular	Hypertrophy Infiltration Cellular	Mild Mononuclear CI, Minimal

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PRIMARY CAUSE OF DEATH - UNCERTAIN

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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 379	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602279

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Skin	* Stomach, Glandular	* Thyroid Gland	* Trachea

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone		Fibrosis	Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Cardiomyopathy	Minimal
* Kidney		Nephropathy	Mild
* Liver		Eosinophilic Focus	
	Centrilobular	Fatty Change	Minimal
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hyperplasia	Lymphoid, Mild
* Stomach, Forestomach	Epithelium	Hyperplasia	Mild
		Inflammation	Chronic, Minimal
	[ Hyperplasia TGLs = 1-10 ]		
* Thymus		Atrophy	Mild
		Infiltration Cellular	Histiocyte, Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 380	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602280

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Skin
* Spleen	* Stomach, Glandular	* Thyroid Gland	* Trachea

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Hyperplasia Infiltration Cellular	Mild Mononuclear CI, Minimal
	[ Hyperplasia TGLs = 5-9 ]		
* Liver	Centrilobular	Eosinophilic Focus Fatty Change Hypertrophy Infiltration Cellular	Minimal Mild Mononuclear CI, Minimal
	[ Eosinophilic Focus TGLs = 4,6-10+12 ]		
Mesentery	Fat	Necrosis	Marked
	[ Necrosis TGLs = 2,3-11+12 ]		
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation	Minimal Chronic, Minimal
* Thymus		Atrophy Infiltration Cellular	Moderate Histiocyte, Moderate
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia Leiomyosarcoma	Cystic, Marked
	[ Leiomyosarcoma TGLs = 1-10 ]		

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 381	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602281

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Liver		Clear Cell Focus	
	Centrilobular	Eosinophilic Focus	
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Eosinophilic Focus TGLs = 3-10 ]		
* Ovary		Hemangiosarcoma	
	[ Hemangiosarcoma TGLs = 2-7 ]		
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Thymus		Atrophy	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Moderate
	[ Hyperplasia TGLs = 1-7 ]		

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 382	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602282

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Uterus

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Metaplasia	Osseous, Mild
		Mineralization	Minimal
* Liver		Eosinophilic Focus	
	Centrilobular	Fatty Change	Minimal
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
		Tension Lipidosis	
	[ Eosinophilic Focus TGLs = 1,2,3,4-3+10+11+12 ]		
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Stomach, Forestomach	Epithelium	Hyperplasia	Minimal
* Thymus		Atrophy	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 383	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602283

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lung                   | * Mammary Gland            |
| * Nose                    | * Ovary                     | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Salivary Glands           | * Skin                   | * Stomach, Forestomach     |
| * Stomach, Glandular      | * Thyroid Gland             | * Trachea                |                            |

**OBSERVATIONS**

- |                          |  |  |                                 |
|--------------------------|--|--|---------------------------------|
| * Adrenal Cortex         | Subcapsular<br>Zona Reticul            | Hyperplasia<br>Hyperplasia                                     | Mild<br>Minimal                 |
| * Harderian Gland        |  | Infiltration Cellular  | Mononuclear CI, Minimal         |
| * Liver                  | Centrilobular                          | Hepatocellular Adenoma<br>Hypertrophy<br>Infiltration Cellular | Mild<br>Mononuclear CI, Minimal |
|                          | [ Hepatocellular Adenoma TGLs = 1-10 ] |  |                                 |
| * Lymph Node, Mandibular |  | Hyperplasia  | Lymphoid, Moderate              |
| * Lymph Node, Mesenteric |  | Hyperplasia  | Lymphoid, Mild                  |
| * Ovary                  | Note: One ovary was missing            |  |                                 |
| * Spleen                 |  | Lymphoma Malignant   |                                 |
| * Thymus                 |  | Atrophy  | Minimal                         |
| * Urinary Bladder        |  | Infiltration Cellular  | Mononuclear CI, Minimal         |
| * Uterus                 | Endometrium                            | Hyperplasia  | Cystic, Minimal                 |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 384	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602284

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone		Fibrosis	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Liver	Centrilobular	Hypertrophy Infiltration Cellular	Mild Mononuclear CI, Minimal
* Ovary		Cystadenoma	
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Lymphoma Malignant	
* Thymus		Atrophy	Minimal
Tooth		Dysplasia	Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 385	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602285

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Kidney                    | * Lung                   | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Nose                      | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Skin                      | * Stomach, Forestomach   | * Stomach, Glandular       |
| * Thyroid Gland           | * Trachea                   |                          |                            |

**OBSERVATIONS**

- |                          |                                   |                       |                         |
|--------------------------|-----------------------------------|-----------------------|-------------------------|
| * Adrenal Cortex         | Subcapsular                       | Hyperplasia           | Mild                    |
| * Harderian Gland        |                                   | Infiltration Cellular | Mononuclear CI, Minimal |
| * Liver                  |                                   | Eosinophilic Focus    |                         |
|                          | Centrilobular                     | Fatty Change          | Minimal                 |
|                          |                                   | Hypertrophy           | Mild                    |
|                          |                                   | Infiltration Cellular | Mononuclear CI, Minimal |
| [ Eosinophilic Focus     | TGLs = 1,2,3,4,5-10+11+12+13+14 ] |                       |                         |
| * Lymph Node, Mandibular |                                   | Hyperplasia           | Lymphoid, Mild          |
| * Ovary                  |                                   | Cyst                  | Minimal                 |
| * Salivary Glands        |                                   | Infiltration Cellular | Mononuclear CI, Minimal |
| * Spleen                 |                                   | Hyperplasia           | Lymphoid, Mild          |
| * Thymus                 |                                   | Atrophy               | Mild                    |
| * Urinary Bladder        |                                   | Infiltration Cellular | Mononuclear CI, Minimal |
| * Uterus                 | Endometrium                       | Hyperplasia           | Cystic, Mild            |



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 386	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602286

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                    | * Clitoral Gland          | * Esophagus                 | * Eye                    |
| * Gallbladder              | * Harderian Gland         | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic      | * Kidney                    | * Lung                   |
| * Lymph Node, Mandibular   | * Lymph Node, Mesenteric  | * Mammary Gland             | * Nose                   |
| * Parathyroid Gland        | * Pituitary Gland         | * Skin                      | * Spleen                 |
| * Stomach, Glandular       | * Thyroid Gland           | * Trachea                   |                          |

**OBSERVATIONS**

- |                               |               |                                      |                                 |
|-------------------------------|---------------|--------------------------------------|---------------------------------|
| * Adrenal Cortex              | Subcapsular   | Hyperplasia                          | Mild                            |
| * Liver                       | Centrilobular | Hypertrophy<br>Infiltration Cellular | Mild<br>Mononuclear CI, Minimal |
| Mesentery                     | Fat           | Necrosis                             | Mild                            |
| [ Necrosis TGLs = 2-11 ]      |               |                                      |                                 |
| * Ovary                       |               | Cyst                                 | Minimal                         |
| * Pancreas                    |               | Infiltration Cellular                | Mononuclear CI, Minimal         |
| * Salivary Glands             |               | Infiltration Cellular                | Mononuclear CI, Minimal         |
| * Stomach, Forestomach        | Epithelium    | Hyperplasia                          | Minimal                         |
| * Thymus                      |               | Atrophy                              | Mild                            |
| * Urinary Bladder             |               | Infiltration Cellular                | Mononuclear CI, Minimal         |
| * Uterus                      | Endometrium   | Hyperplasia<br>Polyp Stromal         | Cystic, Mild                    |
| [ Polyp Stromal TGLs = 1-10 ] |               |                                      |                                 |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 387	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602287

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   |
| * Mammary Gland           | * Nose                      | * Ovary                  | * Pancreas                 |
| * Parathyroid Gland       | * Salivary Glands           | * Skin                   | * Spleen                   |
| * Stomach, Forestomach    | * Stomach, Glandular        | * Thymus                 | * Thyroid Gland            |
| * Trachea                 | * Uterus                    |                          |                            |

**OBSERVATIONS**

- |                   |                                    |                       |                         |
|-------------------|------------------------------------|-----------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                        | Hyperplasia           | Mild                    |
| * Harderian Gland |                                    | Infiltration Cellular | Mononuclear CI, Minimal |
| * Kidney          |                                    | Metaplasia            | Osseous, Minimal        |
|                   |                                    | Nephropathy           | Minimal                 |
| * Liver           |                                    | Eosinophilic Focus    |                         |
|                   | Centrilobular                      | Fatty Change          | Minimal                 |
|                   |                                    | Hypertrophy           | Mild                    |
|                   |                                    | Infiltration Cellular | Mononuclear CI, Minimal |
|                   | [ Eosinophilic Focus TGLs = 1-10 ] |                       |                         |
| * Pituitary Gland | Pars Distalis                      | Hyperplasia           | Mild                    |
| * Urinary Bladder |                                    | Infiltration Cellular | Mononuclear CI, Minimal |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 388	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602288

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                          |                            |                           |                             |
|--------------------------|----------------------------|---------------------------|-----------------------------|
| * Adrenal Medulla        | Blood Vessel               | * Bone Marrow             | * Brain                     |
| * Clitoral Gland         | * Esophagus                | * Eye                     | * Heart                     |
| * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum |
| * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      | * Lung                      |
| * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Mammary Gland           | * Nose                      |
| * Ovary                  | * Pancreas                 | * Parathyroid Gland       | * Pituitary Gland           |
| * Skin                   | * Spleen                   | * Stomach, Forestomach    | * Stomach, Glandular        |
| * Thyroid Gland          | * Trachea                  |                           |                             |

**OBSERVATIONS**

- |                   |               |                       |                         |
|-------------------|---------------|-----------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular   | Hyperplasia           | Mild                    |
| * Bone            |               | Fibrosis              | Mild                    |
| * Gallbladder     |               | Cyst                  | Minimal                 |
| * Harderian Gland |               | Infiltration Cellular | Mononuclear CI, Minimal |
| * Kidney          |               | Mineralization        | Minimal                 |
| * Liver           | Centrilobular | Hypertrophy           | Mild                    |
|                   |               | Infiltration Cellular | Mononuclear CI, Mild    |
| * Salivary Glands |               | Infiltration Cellular | Mononuclear CI, Minimal |
| * Thymus          |               | Atrophy               | Moderate                |
| * Urinary Bladder |               | Infiltration Cellular | Mononuclear CI, Minimal |
| * Uterus          | Endometrium   | Hyperplasia           | Cystic, Mild            |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 389    **TMT:** 8    **SEX:** Female    **DAY ON TEST:** 731  
**DOSE:** 1.0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602289

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea			

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Histiocytic Sarcoma Hyperplasia	Mild
* Bone Marrow		Histiocytic Sarcoma	
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Liver		Hematopoietic Cell Proliferation	Mild
	Centrilobular	Histiocytic Sarcoma	Mild
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Histiocytic Sarcoma TGLs = 1-3+4+5+10 ]		
* Lymph Node, Mandibular		Histiocytic Sarcoma	
* Ovary		Cyst	Minimal
		Histiocytic Sarcoma	
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation	Mild
		Histiocytic Sarcoma	
	[ Histiocytic Sarcoma TGLs = 2,3-4+11 ]		
* Thymus		Histiocytic Sarcoma	
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Marked
	[ Hyperplasia TGLs = 4-7 ]		

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

ANIMAL NUM: 390 TMT: 8 SEX: Female DAY ON TEST: 730  
 DOSE: 1.0 G/KG DISP: Terminal Sacrifice HISTO: 0602290

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Blood Vessel              | * Bone                   | * Bone Marrow              | * Brain                   |
| * Clitoral Gland            | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Kidney                    | * Lung                   | * Lymph Node, Mandibular   | * Lymph Node, Mesenteric  |
| * Mammary Gland             | * Nose                   | * Ovary                    | * Pancreas                |
| * Parathyroid Gland         | * Pituitary Gland        | * Salivary Glands          | * Skin                    |
| * Spleen                    | * Stomach, Forestomach   | * Stomach, Glandular       | * Thyroid Gland           |
| * Trachea                   |                          |                            |                           |

OBSERVATIONS

- |                   |  |                          |                         |
|-------------------|--|--------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                                | Hyperplasia              | Mild                    |
| * Adrenal Medulla |  | Pheochromocytoma Benign  |                         |
| * Harderian Gland |  | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Liver           |  | Eosinophilic Focus       |                         |
|                   |  | Fatty Change             | Minimal                 |
|                   | Centrilobular                              | Hepatocellular Carcinoma |                         |
|                   |  | Hypertrophy              | Mild                    |
|                   |  | Infiltration Cellular    | Mononuclear CI, Minimal |
|                   |  | Mixed Cell Focus         |                         |
|                   |  | Necrosis                 | Minimal                 |
|                   | [ Eosinophilic Focus TGLs = 1,3-10+12 ]    |                          |                         |
|                   | [ Hepatocellular Carcinoma TGLs = 2-11 ]   |                          |                         |
|                   | [ Mixed Cell Focus TGLs = 4,5,7-12+13+14 ] |                          |                         |
| * Thymus          |  | Atrophy                  | Mild                    |
| * Urinary Bladder |  | Infiltration Cellular    | Mononuclear CI, Minimal |
| * Uterus          |  | Hemangioma               |                         |
|                   | [ Hemangioma TGLs = 6-7 ]                  |                          |                         |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 391	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602291

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Skin	* Stomach, Glandular
* Thyroid Gland	* Trachea		

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone Marrow		Fibrosis	Minimal
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Liver	Centrilobular	Hypertrophy Infiltration Cellular	Mild Mononuclear CI, Mild
* Ovary			
Note: One ovary was missing			
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hyperplasia	Lymphoid, Mild
* Stomach, Forestomach	Epithelium	Hyperplasia Inflammation Ulcer	Mild Chronic, Mild Mild
	[ Hyperplasia TGLs = 1-10 ]		
* Thymus		Atrophy	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Mild

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 392    **TMT:** 8    **SEX:** Female    **DAY ON TEST:** 731  
**DOSE:** 1.0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602292

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Pituitary Gland	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Uterus

**MISSING**

\* Parathyroid Gland

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Bone Marrow		Necrosis	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Liver	Centrilobular	Eosinophilic Focus	
		Hepatocellular Adenoma	
		Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
	[ Eosinophilic Focus TGLs = 2-11 ]		
	[ Hepatocellular Adenoma TGLs = 1-10 ]		
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Thymus		Atrophy	Mild
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 393	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602293

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Glandular
* Thyroid Gland	* Trachea		

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney	Papilla	Amyloid Deposition	Mild
		Necrosis	Mild
		Nephropathy	Moderate
* Liver	Centrilobular	Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
* Ovary		Angiectasis	Minimal
* Pituitary Gland		Cyst	Minimal
* Stomach, Forestomach	Epithelium	Erosion	Moderate
		Hyperplasia	Moderate
		Inflammation	Chronic, Marked
	[ Hyperplasia TGLs = 1-10 ]		
* Thymus		Atrophy	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal
* Uterus	Endometrium	Hyperplasia	Cystic, Minimal



TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
 Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 394    **TMT:** 8    **SEX:** Female    **DAY ON TEST:** 731  
**DOSE:** 1.0 G/KG    **DISP:** Terminal Sacrifice    **HISTO:** 0602294

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Skin	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Uterus		

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Kidney		Nephropathy	Minimal
* Liver	Centrilobular	Hypertrophy	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
		Lymphoma Malignant	
* Lung		Alveolar/Bronchiolar Adenoma	
	[ Alveolar/Bronchiolar Adenoma TGLs = 2-11 ]		
* Salivary Glands	Parotid GI	Hyperplasia	Mild
		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Lymphoma Malignant	
	[ Lymphoma Malignant TGLs = 1-10 ]		
* Stomach, Forestomach	Epithelium	Hyperplasia	Moderate
		Inflammation	Chronic, Mild
* Thymus		Atrophy	Minimal
* Urinary Bladder		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 395	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
<b>DOSE:</b> 1.0 G/KG		<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602295

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone Marrow              | * Brain                   |
| * Clitoral Gland            | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Mammary Gland           |
| * Nose                      | * Ovary                  | * Pancreas                 | * Parathyroid Gland       |
| * Pituitary Gland           | * Skin                   | * Spleen                   | * Stomach, Forestomach    |
| * Stomach, Glandular        | * Thyroid Gland          | * Trachea                  |                           |

**OBSERVATIONS**

- |                   |   |                       |                         |
|-------------------|---|-----------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                             | Hyperplasia           | Mild                    |
| * Bone            |   | Fibrosis              | Mild                    |
| * Harderian Gland |   | Adenoma               |                         |
|                   | [ Adenoma TGLs = 1-9 ]                  |                       |                         |
| * Kidney          |   | Nephropathy           | Minimal                 |
| * Liver           |   | Eosinophilic Focus    |                         |
|                   | Centrilobular                           | Fatty Change          | Minimal                 |
|                   |   | Hypertrophy           | Mild                    |
|                   |   | Infiltration Cellular | Mononuclear CI, Minimal |
|                   |   | Mixed Cell Focus      |                         |
|                   | [ Eosinophilic Focus TGLs = 2,3-10+11 ] |                       |                         |
|                   | [ Mixed Cell Focus TGLs = 4,5-12+13 ]   |                       |                         |
| * Ovary           |   |                       |                         |
|                   | Note: One ovary was missing             |                       |                         |
| * Salivary Glands |   | Infiltration Cellular | Mononuclear CI, Minimal |
| * Thymus          |   | Atrophy               | Mild                    |
| * Urinary Bladder |   | Infiltration Cellular | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                             | Hyperplasia           | Cystic, Mild            |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 396	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602296

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	Blood Vessel	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Eye	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular	* Mammary Gland
* Nose	* Parathyroid Gland	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Hyperplasia Lymphoma Malignant	Mild
* Bone		Fibrosis	Moderate
* Gallbladder	Epithelium	Cytoplasmic Alteration	Mild
* Harderian Gland		Infiltration Cellular	Mononuclear CI, Minimal
* Heart		Lymphoma Malignant	
* Kidney		Inflammation	Moderate
* Liver	Centrilobular	Fatty Change Hepatocellular Carcinoma Hypertrophy Lymphoma Malignant	Minimal Mild
	[ Hepatocellular Carcinoma TGLs = 3-11 ]		
	[ Lymphoma Malignant TGLs = 2-3+4+5+10 ]		
* Lung		Lymphoma Malignant	
* Lymph Node, Mesenteric		Lymphoma Malignant	
* Ovary		Lymphoma Malignant	
* Pancreas	Duct	Cyst Lymphoma Malignant	Moderate
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal
* Spleen		Hematopoietic Cell Proliferation Lymphoma Malignant	Moderate
	[ Lymphoma Malignant TGLs = 1-4 ]		
* Thymus		Atrophy Hyperplasia	Mild Histiocytic, Mild

\* PROTOCOL REQUIRED TISSUE

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

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<b>ANIMAL NUM:</b>	396	<b>TMT:</b>	8	<b>SEX:</b>	Female	<b>DAY ON TEST:</b>	730
		<b>DOSE:</b>	1.0 G/KG	<b>DISP:</b>	Terminal Sacrifice	<b>HISTO:</b>	0602296

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Uterus	Endometrium	Hyperplasia	Cystic, Minimal
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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 397	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602297

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                             |                          |                            |                           |
|-----------------------------|--------------------------|----------------------------|---------------------------|
| * Adrenal Medulla           | Blood Vessel             | * Bone Marrow              | * Brain                   |
| * Clitoral Gland            | * Esophagus              | * Eye                      | * Gallbladder             |
| * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   | * Intestine Large, Rectum |
| * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum | * Islets, Pancreatic      |
| * Lung                      | * Lymph Node, Mandibular | * Lymph Node, Mesenteric   | * Mammary Gland           |
| * Nose                      | * Pancreas               | * Parathyroid Gland        | * Pituitary Gland         |
| * Salivary Glands           | * Skin                   | * Spleen                   | * Stomach, Forestomach    |
| * Stomach, Glandular        | * Thyroid Gland          | * Trachea                  |                           |

**OBSERVATIONS**

- |                   |                                    |                       |                         |
|-------------------|------------------------------------|-----------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                        | Hyperplasia           | Mild                    |
| * Bone            |                                    | Fibrosis              | Mild                    |
| * Harderian Gland |                                    | Infiltration Cellular | Mononuclear CI, Minimal |
| * Kidney          |                                    | Nephropathy           | Minimal                 |
| * Liver           |                                    | Clear Cell Focus      |                         |
|                   |                                    | Eosinophilic Focus    |                         |
|                   | Centrilobular                      | Fatty Change          | Minimal                 |
|                   |                                    | Hypertrophy           | Mild                    |
|                   |                                    | Infiltration Cellular | Mononuclear CI, Minimal |
|                   | [ Clear Cell Focus TGLs = 2-11 ]   |                       |                         |
|                   | [ Eosinophilic Focus TGLs = 1-10 ] |                       |                         |
| * Ovary           |                                    | Cyst                  | Minimal                 |
| * Thymus          |                                    | Atrophy               | Minimal                 |
| * Urinary Bladder |                                    | Infiltration Cellular | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                        | Hyperplasia           | Cystic, Mild            |

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

**ANIMAL NUM:** 398    **TMT:** 8    **SEX:** Female    **DAY ON TEST:** 669  
**DOSE:** 1.0 G/KG    **DISP:** Natural Death    **HISTO:** 0602298

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                           |                             |                          |                            |
|---------------------------|-----------------------------|--------------------------|----------------------------|
| * Adrenal Medulla         | Blood Vessel                | * Bone                   | * Bone Marrow              |
| * Brain                   | * Clitoral Gland            | * Esophagus              | * Eye                      |
| * Gallbladder             | * Heart                     | * Intestine Large, Cecum | * Intestine Large, Colon   |
| * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum | * Intestine Small, Jejunum |
| * Islets, Pancreatic      | * Lymph Node, Mandibular    | * Lymph Node, Mesenteric | * Mammary Gland            |
| * Nose                    | * Ovary                     | * Pancreas               | * Parathyroid Gland        |
| * Pituitary Gland         | * Skin                      | * Stomach, Forestomach   | * Stomach, Glandular       |
| * Thyroid Gland           | * Trachea                   |                          |                            |

**OBSERVATIONS**

- |                   |  |                                  |                         |
|-------------------|--|----------------------------------|-------------------------|
| * Adrenal Cortex  | Subcapsular                              | Hyperplasia                      | Mild                    |
| * Harderian Gland |  | Hyperplasia                      | Moderate                |
|                   |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Kidney          |  | Mineralization                   | Minimal                 |
|                   |  | Nephropathy                      | Minimal                 |
| * Liver           |  | Eosinophilic Focus               |                         |
|                   |  | Hemangioma                       |                         |
|                   | Centrilobular                            | Hepatocellular Carcinoma         |                         |
|                   |  | Hypertrophy                      | Mild                    |
|                   |  | Infiltration Cellular            | Mononuclear CI, Minimal |
|                   | [ Hepatocellular Carcinoma TGLs = 1-10 ] |                                  |                         |
| * Lung            |  | Hepatocellular Carcinoma         | Metastatic (Liver)      |
| * Salivary Glands |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Spleen          |  | Hematopoietic Cell Proliferation | Moderate                |
| * Thymus          |  | Atrophy                          | Mild                    |
| * Urinary Bladder |  | Infiltration Cellular            | Mononuclear CI, Minimal |
| * Uterus          | Endometrium                              | Hyperplasia                      | Cystic, Minimal         |

PRIMARY CAUSE OF DEATH - Liver Hepatocellular Carcinoma

TDMS No. 20007 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Kava kava extract  
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
Time Report Requested: 08:27:00  
First Dose M/F: 08/24/04 / 08/23/04  
Lab: BAT

ANIMAL NUM: 399 TMT: 8 SEX: Female DAY ON TEST: 730  
DOSE: 1.0 G/KG DISP: Terminal Sacrifice HISTO: 0602299

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	Blood Vessel	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Eye
* Gallbladder	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Pituitary Gland	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

MISSING

\* Parathyroid Gland

OBSERVATIONS

* Adrenal Cortex	Subcapsular	Hyperplasia	Mild
* Harderian Gland		Adenoma	
	[ Adenoma TGLs = 4-9 ]	Infiltration Cellular	Mononuclear CI, Minimal
* Liver		Fatty Change	Minimal
	Centrilobular	Hepatocellular Adenoma	Multiple
	[ Hepatocellular Adenoma TGLs = 1,2-10 ]	Hypertrophy	Mild
	[ Mixed Cell Focus TGLs = 3-11+12 ]	Infiltration Cellular	Mononuclear CI, Minimal
* Lymph Node, Mesenteric		Mixed Cell Focus	
	[ Inflammation TGLs = 5-5 ]	Inflammation	Granulomatous, Moderate
* Salivary Glands		Infiltration Cellular	Mononuclear CI, Minimal

TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009  
 Time Report Requested: 08:27:00  
 First Dose M/F: 08/24/04 / 08/23/04  
 Lab: BAT

<b>ANIMAL NUM:</b> 400	<b>TMT:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 1.0 G/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 0602300

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

- |                            |                           |                             |                          |
|----------------------------|---------------------------|-----------------------------|--------------------------|
| * Adrenal Medulla          | Blood Vessel              | * Bone                      | * Bone Marrow            |
| * Brain                    | * Clitoral Gland          | * Esophagus                 | * Eye                    |
| * Gallbladder              | * Harderian Gland         | * Heart                     | * Intestine Large, Cecum |
| * Intestine Large, Colon   | * Intestine Large, Rectum | * Intestine Small, Duodenum | * Intestine Small, Ileum |
| * Intestine Small, Jejunum | * Islets, Pancreatic      | * Kidney                    | * Lung                   |
| * Lymph Node, Mandibular   | * Lymph Node, Mesenteric  | * Mammary Gland             | * Nose                   |
| * Ovary                    | * Pancreas                | * Parathyroid Gland         | * Pituitary Gland        |
| * Salivary Glands          | * Skin                    | * Spleen                    | * Stomach, Glandular     |
| * Thyroid Gland            | * Trachea                 |                             |                          |

**OBSERVATIONS**

- |                        |   |                       |                         |
|------------------------|---|-----------------------|-------------------------|
| * Adrenal Cortex       | Subcapsular                                       | Hyperplasia           | Mild                    |
| * Liver                |   | Clear Cell Focus      |                         |
|                        |   | Eosinophilic Focus    |                         |
|                        | Centrilobular                                     | Fatty Change          | Minimal                 |
|                        |   | Hypertrophy           | Mild                    |
|                        | [ Eosinophilic Focus TGLs = 1,3,4,5-10+11+12+13 ] | Infiltration Cellular | Mononuclear CI, Minimal |
| Mesentery              | Fat   | Necrosis              | Mild                    |
|                        | [ Necrosis TGLs = 2-10 ]                          |                       |                         |
| * Stomach, Forestomach | Epithelium  | Hyperplasia           | Minimal                 |
|                        |   | Inflammation          | Chronic, Minimal        |
| * Thymus               |   | Atrophy               | Minimal                 |
| * Urinary Bladder      |   | Infiltration Cellular | Mononuclear CI, Minimal |
| * Uterus               | Endometrium                                       | Hyperplasia           | Cystic, Minimal         |

\*\*\* END OF REPORT \*\*\*