

**Experiment Number:** 20007 - 03  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** RATS/F 344/N

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
Kava kava extract  
**CAS Number:** 9000-38-8

**Date Report Requested:** 09/13/2016  
**Time Report Requested:** 11:41:17  
**First Dose M/F:** 09/15/03 / 09/16/03  
**Lab:** BAT

**NTP Study Number:** C20007  
**Lock Date:** 05/24/2004  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 3.0.2.3\_002  
**PWG Approval Date:** NONE

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DAY ON TEST		0	0	0	0	0	0	0	0	0	
<b>FISCHER 344 RATS MALE</b>		0	0	0	0	0	0	0	0	0	
		9	9	9	9	9	9	9	9	9	
		3	3	3	3	3	3	3	3	3	
	<b>0 G/KG</b>										
ANIMAL ID		0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	1	
		1	2	3	4	5	6	7	8	9	0
<b>* TOTALS</b>											

**ALIMENTARY SYSTEM**

Esophagus	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Liver	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Hematopoietic Cell Proliferation									1		<b>1 1.0</b>
Infiltration Cellular, Mononuclear Cell	1	1	1	1	1	1			1	1	<b>9 1.0</b>
Vacuolization Cytoplasmic				1							<b>1 1.0</b>
Pancreas	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Acinus, Atrophy				1							<b>1 1.0</b>
Salivary Glands	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	<b>10</b>

**CARDIOVASCULAR SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

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Lab: BAT

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	ANIMAL ID	
	9	9	9	9	9	9	9	9	9	9		
FISCHER 344 RATS MALE	3	3	3	3	3	3	3	3	3	3		
0 G/KG	0	0	0	0	0	0	0	0	0	0		
	0	0	0	0	0	0	0	0	0	0		
	0	0	0	0	0	0	0	0	0	0		
	0	0	0	0	0	0	0	0	0	0		
	0	0	0	0	0	0	0	0	0	1		
	1	2	3	4	5	6	7	8	9	0		
											<b>* TOTALS</b>	

Blood Vessel	+	+	+	+	+	+	+	+	+	+		<b>10</b>
Heart	+	+	+	+	+	+	+	+	+	+		<b>10</b>
Cardiomyopathy	1		2	1	2	1	1	2	1	1		<b>9 1.3</b>

**ENDOCRINE SYSTEM**

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+		<b>10</b>
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+		<b>10</b>
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+		<b>10</b>
Parathyroid Gland	+	+	+	+	+	+	+	+	+	+		<b>10</b>
Pituitary Gland	+	+	+	+	+	+	+	+	+	+		<b>10</b>
Pars Distalis, Hypertrophy									1			<b>1 1.0</b>
Thyroid Gland	+	+	+	+	+	+	+	+	+	+		<b>10</b>
Cyst						X	X					<b>2</b>

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

Epididymis	+	+	+	+	+	+	+	+	+	+		<b>10</b>
Inflammation									1			<b>1 1.0</b>
Preputial Gland	+	+	+	+	+	+	+	+	+	+		<b>10</b>

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Lab: BAT

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	ANIMAL ID		
	9	9	9	9	9	9	9	9	9	9			
FISCHER 344 RATS MALE	3	3	3	3	3	3	3	3	3	3			
0 G/KG	0	0	0	0	0	0	0	0	0	0			
	0	0	0	0	0	0	0	0	0	0			
	0	0	0	0	0	0	0	0	0	0			
	0	0	0	0	0	0	0	0	0	1			
	1	2	3	4	5	6	7	8	9	0			* TOTALS
Prostate	+	+	+	+	+	+	+	+	+	+			10
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+			10
Testes	+	+	+	+	+	+	+	+	+	+			10
<b>HEMATOPOIETIC SYSTEM</b>													
Bone Marrow	+	+	+	+	+	+	+	+	+	+			10
Lymph Node, Mandibular	M	M	M	M	M	M	M	M	M	M			0
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+			10
Spleen	+	+	+	+	+	+	+	+	+	+			10
Thymus	+	+	+	+	+	+	+	+	+	+			10
<b>INTEGUMENTARY SYSTEM</b>													
Mammary Gland	+	+	M	+	M	+	+	+	M	+			7
Skin	+	+	+	+	+	+	+	+	+	+			10
<b>MUSCULOSKELETAL SYSTEM</b>													
Bone	+	+	+	+	+	+	+	+	+	+			10
<b>NERVOUS SYSTEM</b>													
Brain	+	+	+	+	+	+	+	+	+	+			10

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DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	<b>FISCHER 344 RATS MALE</b>	0	0	0	0	0	0	0	0	0
<b>0 G/KG</b>	9	9	9	9	9	9	9	9	9	9
<b>ANIMAL ID</b>	3	3	3	3	3	3	3	3	3	3
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	1
	1	2	3	4	5	6	7	8	9	0
<b>* TOTALS</b>										

**RESPIRATORY SYSTEM**

Lung	+	+	+	+	+	+	+	+	+	+	<b>10</b>	
Metaplasia, Osseous, Focal		1									<b>1</b>	<b>1.0</b>
Metaplasia, Osseous					1						<b>1</b>	<b>1.0</b>
Alveolus, Infiltration Cellular, Histiocyte	1								1		<b>2</b>	<b>1.0</b>
Interstitial, Infiltration Cellular, Mononuclear Cell		1		1			1				<b>3</b>	<b>1.0</b>
Interstitial, Inflammation, Chronic	1										<b>1</b>	<b>1.0</b>
Nose	+	+	+	+	+	+	+	+	+	+	<b>10</b>	
Inflammation, Suppurative			1								<b>1</b>	<b>1.0</b>
Squamous Epithelium, Hyperplasia, Squamous						1					<b>1</b>	<b>1.0</b>
Trachea	+	+	+	+	+	+	+	+	+	+	<b>10</b>	

**SPECIAL SENSES SYSTEM**

Eye	+	+	+	+	+	+	+	+	+	+	<b>10</b>	
Harderian Gland	+	+	+	+	+	+	+	+	+	+	<b>10</b>	
Infiltration Cellular, Mononuclear Cell	1										<b>1</b>	<b>1.0</b>

**URINARY SYSTEM**

Kidney	+	+	+	+	+	+	+	+	+	+	<b>10</b>	
Accumulation, Hyaline Droplet					2	2					<b>2</b>	<b>2.0</b>
Casts Protein							1				<b>1</b>	<b>1.0</b>
Infiltration Cellular, Mononuclear Cell	1										<b>1</b>	<b>1.0</b>
Mineralization	1	1	1					1			<b>4</b>	<b>1.0</b>

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DAY ON TEST	0	0	0	0	0	0	0	0	0	0	
	9	9	9	9	9	9	9	9	9	9	
FISCHER 344 RATS MALE	3	3	3	3	3	3	3	3	3	3	
0 G/KG											
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	1	2	3	4	5	6	7	8	9	0	
											* TOTALS
Nephropathy	1	1	1	1	1		1		1		7 1.0
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	10

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Lab: BAT

FISCHER 344 RATS MALE	DAY ON TEST	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
0.125 G/KG		9	9	9	9	9	9	9	9	9	
		3	3	3	3	3	3	3	3	3	
	ANIMAL ID	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		1	1	1	1	1	1	1	1	2	
		1	2	3	4	5	6	7	8	9	
<b>* TOTALS</b>											

ALIMENTARY SYSTEM

Liver	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Hematopoietic Cell Proliferation							1				<b>1 1.0</b>
Infiltration Cellular, Mononuclear Cell	1	1	1		1	1		1	1		<b>7 1.0</b>

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

NONE

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

NONE

HEMATOPOIETIC SYSTEM

Bone Marrow	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Spleen	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Thymus	+	+	+	+	+	+	+	+	+	+	<b>10</b>

INTEGUMENTARY SYSTEM

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<b>FISCHER 344 RATS MALE</b>	DAY ON TEST	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		9	9	9	9	9	9	9	9	9	
		3	3	3	3	3	3	3	3	3	
<b>0.125 G/KG</b>	ANIMAL ID	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		1	1	1	1	1	1	1	1	2	
		1	2	3	4	5	6	7	8	9	0
<b>* TOTALS</b>											

NONE

**MUSCULOSKELETAL SYSTEM**

NONE

**NERVOUS SYSTEM**

NONE

**RESPIRATORY SYSTEM**

NONE

**SPECIAL SENSES SYSTEM**

NONE

**URINARY SYSTEM**

NONE

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FISCHER 344 RATS MALE	DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0.25 G/KG		9	9	2	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
		3	3	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	3
		1	2	3	4	5	6	7	8	9	0								
<b>* TOTALS</b>																			

ALIMENTARY SYSTEM

Esophagus																				1
Intestine Large, Cecum																				1
Intestine Large, Colon																				1
Intestine Large, Rectum																				1
Intestine Small, Duodenum																				1
Intestine Small, Ileum																				1
Intestine Small, Jejunum																				1
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	10
Infiltration Cellular, Mononuclear Cell				1		1		1		1		1		1		1				5 1.0
Pancreas																				1
Salivary Glands																				1
Stomach, Forestomach																				1
Stomach, Glandular																				1

CARDIOVASCULAR SYSTEM

Blood Vessel																				1
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DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	9	9	2	9	9	9	9	9	9	9
FISCHER 344 RATS MALE	3	3	2	3	3	3	3	3	3	3
0.25 G/KG										
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	2	2	2	2	2	2	2	2	2	3
	1	2	3	4	5	6	7	8	9	0
										* TOTALS

Heart + 1

ENDOCRINE SYSTEM

Adrenal Cortex + 1

Adrenal Medulla + 1

Islets, Pancreatic + 1

Parathyroid Gland + 1

Pituitary Gland + 1

Thyroid Gland + 1

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

Epididymis + 1

Preputial Gland + 1

Prostate + 1

Seminal Vesicle + 1

Testes + 1

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DAY ON TEST		0	0	0	0	0	0	0	0	0	0
<b>FISCHER 344 RATS MALE</b>		0	0	0	0	0	0	0	0	0	0
		9	9	2	9	9	9	9	9	9	9
		3	3	2	3	3	3	3	3	3	3
<b>0.25 G/KG</b>		0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0
		2	2	2	2	2	2	2	2	2	3
		1	2	3	4	5	6	7	8	9	0
<b>* TOTALS</b>											

**HEMATOPOIETIC SYSTEM**

Bone Marrow	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Lymph Node, Mandibular				M							<b>0</b>
Lymph Node, Mesenteric				+							<b>1</b>
Spleen	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Thymus	+	+	+	+	+	+	+	+	+	+	<b>10</b>

**INTEGUMENTARY SYSTEM**

Mammary Gland				+							<b>1</b>
Skin				+							<b>1</b>

**MUSCULOSKELETAL SYSTEM**

Bone				+							<b>1</b>
------	--	--	--	---	--	--	--	--	--	--	----------

**NERVOUS SYSTEM**

Brain				+							<b>1</b>
-------	--	--	--	---	--	--	--	--	--	--	----------

**RESPIRATORY SYSTEM**

Lung				+							<b>1</b>
Nose				+							<b>1</b>

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1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20007 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	<b>FISCHER 344 RATS MALE</b>	0	0	0	0	0	0	0	0	0
<b>0.25 G/KG</b>	9	9	2	9	9	9	9	9	9	9
<b>ANIMAL ID</b>	3	3	2	3	3	3	3	3	3	3
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	2	2	2	2	2	2	2	2	2	3
	1	2	3	4	5	6	7	8	9	0
<b>* TOTALS</b>										

Trachea	+	<b>1</b>
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**SPECIAL SENSES SYSTEM**

Eye	+	<b>1</b>
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Harderian Gland	+	<b>1</b>
-----------------	---	----------

**URINARY SYSTEM**

Kidney	+	<b>1</b>
--------	---	----------

Urinary Bladder	+	<b>1</b>
-----------------	---	----------

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
+ .. Tissue examined microscopically  
X .. Lesion present  
I .. Insufficient tissue  
M .. Missing tissue  
A .. Autolysis precludes evaluation  
BLANK .. Not examined microscopically

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Experiment Number: 20007 - 03

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Species/Strain: RATS/F 344/N

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Kava kava extract

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First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

<b>FISCHER 344 RATS MALE</b>	DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
<b>0.5 G/KG</b>	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
		1	2	3	4	5	6	7	8	9	0								
<b>* TOTALS</b>																			

**ALIMENTARY SYSTEM**

Liver	+	+	+	+	+	+	+	+	+	+	+								<b>10</b>
Hepatodiaphragmatic Nodule	X																		<b>1</b>
Infiltration Cellular, Mononuclear Cell			1	1					1	1	1								<b>5 1.0</b>
Vacuolization Cytoplasmic											1								<b>1 1.0</b>
Bile Duct, Hyperplasia			1																<b>1 1.0</b>

**CARDIOVASCULAR SYSTEM**

NONE

**ENDOCRINE SYSTEM**

NONE

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

NONE

**HEMATOPOIETIC SYSTEM**

Bone Marrow	+	+	+	+	+	+	+	+	+	+	+								<b>10</b>
Spleen	+	+	+	+	+	+	+	+	+	+	+								<b>10</b>
Thymus	+	+	+	+	+	+	+	+	+	+	+								<b>10</b>

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

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Experiment Number: 20007 - 03

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Species/Strain: RATS/F 344/N

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Kava kava extract

CAS Number: 9000-38-8

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First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

<b>FISCHER 344 RATS MALE</b>	DAY ON TEST	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		9	9	9	9	9	9	9	9	9	
		3	3	3	3	3	3	3	3	3	
<b>0.5 G/KG</b>	ANIMAL ID	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		3	3	3	3	3	3	3	3	4	
		1	2	3	4	5	6	7	8	9	0
<b>* TOTALS</b>											

**INTEGUMENTARY SYSTEM**

NONE

**MUSCULOSKELETAL SYSTEM**

NONE

**NERVOUS SYSTEM**

NONE

**RESPIRATORY SYSTEM**

NONE

**SPECIAL SENSES SYSTEM**

NONE

**URINARY SYSTEM**

NONE

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

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P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract

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Date Report Requested: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

FISCHER 344 RATS MALE 1.0 G/KG	DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
		3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		4	4	4	4	4	4	4	4	4	4	4	4	4	4	5	5	5	5
		1	2	3	4	5	6	7	8	9	9	9	9	9	9	0	0	0	0
<b>* TOTALS</b>																			

ALIMENTARY SYSTEM

Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	10
Infiltration Cellular, Mononuclear Cell	1	1					1	1											5 1.0
Hepatocyte, Hypertrophy			1																1 1.0

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

NONE

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

NONE

HEMATOPOIETIC SYSTEM

Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	10
Spleen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	10
Hematopoietic Cell Proliferation					2														1 2.0
Thymus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	10

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+ .. Tissue examined microscopically  
X .. Lesion present  
I .. Insufficient tissue  
M .. Missing tissue  
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1-4 .. Lesion qualified as:  
1) Minimal 3) Moderate  
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Experiment Number: 20007 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

<b>FISCHER 344 RATS MALE</b>	DAY ON TEST	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		9	9	9	9	9	9	9	9	9	
		3	3	3	3	3	3	3	3	3	
<b>1.0 G/KG</b>	ANIMAL ID	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		4	4	4	4	4	4	4	4	5	
		1	2	3	4	5	6	7	8	9	0

**\* TOTALS**

**INTEGUMENTARY SYSTEM**

NONE

**MUSCULOSKELETAL SYSTEM**

NONE

**NERVOUS SYSTEM**

NONE

**RESPIRATORY SYSTEM**

NONE

**SPECIAL SENSES SYSTEM**

NONE

**URINARY SYSTEM**

NONE

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

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Experiment Number: 20007 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Kava kava extract

CAS Number: 9000-38-8

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Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

DAY ON TEST		0	0	0	0	0	0	0	0	0	
<b>FISCHER 344 RATS MALE</b>		0	0	0	0	0	0	0	0	0	
		9	9	8	9	8	9	9	9	0	
		3	3	0	3	0	3	3	3	5	
<b>2.0 G/KG</b>		0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		5	5	5	5	5	5	5	5	6	
		1	2	3	4	5	6	7	8	9	0
<b>* TOTALS</b>											

**ALIMENTARY SYSTEM**

Esophagus	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Liver	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Infiltration Cellular, Mixed Cell	1										<b>1 1.0</b>
Infiltration Cellular, Mononuclear Cell		1		1			1	1	1		<b>5 1.0</b>
Pancreas	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Salivary Glands	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Inflammation					1						<b>1 1.0</b>
Mineralization			2								<b>1 2.0</b>
Ulcer									2		<b>1 2.0</b>
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	<b>10</b>

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+ .. Tissue examined microscopically

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M .. Missing tissue

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BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

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Experiment Number: 20007 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

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Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

FISCHER 344 RATS MALE	DAY ON TEST	0	0	0	0	0	0	0	0	0	
		9	9	8	9	8	9	9	9	9	0
2.0 G/KG		3	3	0	3	0	3	3	3	3	5
	ANIMAL ID	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		5	5	5	5	5	5	5	5	6	
		1	2	3	4	5	6	7	8	9	0
<b>* TOTALS</b>											

CARDIOVASCULAR SYSTEM

Blood Vessel	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Heart	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Cardiomyopathy	1	1	1		1	1	1	1	1		<b>8 1.0</b>

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Parathyroid Gland	+	+	+	+	+	+	+	M	+	+	<b>9</b>
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Cyst		X									<b>1</b>

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

Epididymis	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Preputial Gland	+	+	+	+	+	+	+	+	+	+	<b>10</b>

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Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

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Kava kava extract

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Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	ANIMAL ID		
	9	9	8	9	8	9	9	9	9	0			
<b>FISCHER 344 RATS MALE</b>	3	3	0	3	0	3	3	3	3	5			
<b>2.0 G/KG</b>	0	0	0	0	0	0	0	0	0	0			
	0	0	0	0	0	0	0	0	0	0			
	0	0	0	0	0	0	0	0	0	0			
	5	5	5	5	5	5	5	5	5	6			
	1	2	3	4	5	6	7	8	9	0			
												<b>* TOTALS</b>	
Inflammation												1	1 1.0
Prostate	+	+	+	+	+	+	+	+	+	+			10
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+			10
Atrophy												3	1 3.0
Testes	+	+	+	+	+	+	+	+	+	+			10
<b>HEMATOPOIETIC SYSTEM</b>													
Bone Marrow	+	+	+	+	+	+	+	+	+	+			10
Lymph Node, Mandibular	M	M	M	M	M	M	M	M	M	M			0
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+			10
Spleen	+	+	+	+	+	+	+	+	+	+			10
Atrophy												2	3 1.7
Thymus	+	+	+	+	+	+	+	+	+	+			10
Necrosis												2	1 2.0
<b>INTEGUMENTARY SYSTEM</b>													
Mammary Gland	+	+	+	+	+	+	+	+	+	M			9
Skin	+	+	+	+	+	+	+	+	+	+			10
<b>MUSCULOSKELETAL SYSTEM</b>													

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 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
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Route: GAVAGE

Species/Strain: RATS/F 344/N

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Kava kava extract

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Date Report Requested: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

FISCHER 344 RATS MALE 2.0 G/KG	DAY ON TEST										ANIMAL ID				
	0 9 3	0 9 3	0 8 0	0 9 3	0 8 0	0 9 3	0 9 3	0 9 3	0 9 3	0 9 3					0 0 5
	0	0	0	0	0	0	0	0	0	0	0 0 0 5 1				
	+	+	+	+	+	+	+	+	+	+					<b>* TOTALS</b>
Bone	+	+	+	+	+	+	+	+	+	+					<b>10</b>
<b>NERVOUS SYSTEM</b>															
Brain	+	+	+	+	+	+	+	+	+	+					<b>10</b>
<b>RESPIRATORY SYSTEM</b>															
Lung	+	+	+	+	+	+	+	+	+	+					<b>10</b>
Inflammation	1				1		1								<b>3 1.0</b>
Inflammation, Granulomatous			1	1											<b>2 1.0</b>
Metaplasia, Osseous				1											<b>1 1.0</b>
Interstitial, Infiltration Cellular, Mononuclear Cell	1			1		1			1						<b>4 1.0</b>
Interstitial, Inflammation, Chronic		1													<b>1 1.0</b>
Nose	+	+	+	+	+	+	+	+	+	+					<b>10</b>
Inflammation									1						<b>1 1.0</b>
Inflammation, Acute							1								<b>1 1.0</b>
Trachea	+	+	+	+	+	+	+	+	+	+					<b>10</b>
<b>SPECIAL SENSES SYSTEM</b>															
Eye	+	+	+	+	+	+	+	+	+	+					<b>10</b>
Harderian Gland	+	+	+	+	+	+	+	+	+	+					<b>10</b>
<b>URINARY SYSTEM</b>															
Kidney	+	+	+	+	+	+	+	+	+	+					<b>10</b>

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

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First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

		0	0	0	0	0	0	0	0	0	
<b>FISCHER 344 RATS MALE</b>	DAY ON TEST	0	0	0	0	0	0	0	0	0	
		9	9	8	9	8	9	9	9	9	0
		3	3	0	3	0	3	3	3	3	5
	<b>2.0 G/KG</b>										
	ANIMAL ID	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		5	5	5	5	5	5	5	5	5	6
		1	2	3	4	5	6	7	8	9	0
<b>* TOTALS</b>											
Accumulation, Hyaline Droplet						2					<b>1 2.0</b>
Mineralization		1				1		1			<b>3 1.0</b>
Nephropathy		1	1		1	1	1	1	1		<b>7 1.0</b>
Urinary Bladder		+	+	+	+	+	+	+	+	+	<b>10</b>

\*\*\* END OF MALE DATA \*\*\*

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

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2) Mild 4) Marked

Experiment Number: 20007 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	<b>FISCHER 344 RATS FEMALE</b>	0	0	0	0	0	0	0	0	0
	9	9	9	9	1	9	9	9	9	9
<b>0 G/KG</b>	3	3	3	3	8	3	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	6	6	6	6	6	6	6	6	6	7
	1	2	3	4	5	6	7	8	9	0
<b>* TOTALS</b>										

**ALIMENTARY SYSTEM**

Esophagus	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Liver	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Hepatodiaphragmatic Nodule	X							X			<b>2</b>
Infiltration Cellular, Mononuclear Cell	1	1	1	1		1	1	1	1		<b>8 1.0</b>
Inflammation		1									<b>1 1.0</b>
Mesentery								+			<b>1</b>
Necrosis, Focal								2			<b>1 2.0</b>
Pancreas	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Salivary Glands	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	<b>10</b>

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

Experiment Number: 20007 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	
	9	9	9	9	1	9	9	9	9	9	
FISCHER 344 RATS FEMALE	3	3	3	3	8	3	3	3	3	3	
0 G/KG											
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	6	6	6	6	6	6	6	6	6	7	
	1	2	3	4	5	6	7	8	9	0	
<b>* TOTALS</b>											
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	<b>10</b>
<b>CARDIOVASCULAR SYSTEM</b>											
Blood Vessel	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Heart	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Cardiomyopathy		1	1			1			1	1	<b>5 1.0</b>
<b>ENDOCRINE SYSTEM</b>											
Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Parathyroid Gland	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Cyst			X		X						<b>2</b>
<b>GENERAL BODY SYSTEM</b>											
NONE											
<b>GENITAL SYSTEM</b>											
Clitoral Gland	+	+	+	+	+	+	+	+	+	+	<b>10</b>

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked

Experiment Number: 20007 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	ANIMAL ID	
	9	9	9	9	1	9	9	9	9	9		
<b>FISCHER 344 RATS FEMALE</b>	3	3	3	3	8	3	3	3	3	3		
<b>0 G/KG</b>	0	0	0	0	0	0	0	0	0	0		
	0	0	0	0	0	0	0	0	0	0		
	0	0	0	0	0	0	0	0	0	0		
	6	6	6	6	6	6	6	6	6	7		
	1	2	3	4	5	6	7	8	9	0		
<b>* TOTALS</b>												

Ovary	+	+	+	+	+	+	+	+	+	+		<b>10</b>
Uterus	+	+	+	+	+	+	+	+	+	+		<b>10</b>

**HEMATOPOIETIC SYSTEM**

Bone Marrow	+	+	+	+	+	+	+	+	+	+		<b>10</b>
Lymph Node, Mandibular	M	M	M	M	M	M	M	M	M	M		<b>0</b>
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+		<b>10</b>
Spleen Atrophy	+	+	+	+	+	+	+	+	+	+		<b>10</b>
					2							<b>1 2.0</b>
Thymus Necrosis	+	+	+	+	+	+	+	+	+	+		<b>10</b>
					2							<b>1 2.0</b>

**INTEGUMENTARY SYSTEM**

Mammary Gland	+	+	+	+	+	+	+	+	+	+		<b>10</b>
Skin	+	+	+	+	+	+	+	+	+	+		<b>10</b>

**MUSCULOSKELETAL SYSTEM**

Bone	+	+	+	+	+	+	+	+	+	+		<b>10</b>
------	---	---	---	---	---	---	---	---	---	---	--	-----------

**NERVOUS SYSTEM**

Brain	+	+	+	+	+	+	+	+	+	+		<b>10</b>
-------	---	---	---	---	---	---	---	---	---	---	--	-----------

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+ .. Tissue examined microscopically  
X .. Lesion present  
I .. Insufficient tissue  
M .. Missing tissue  
A .. Autolysis precludes evaluation  
BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:  
1) Minimal 3) Moderate  
2) Mild 4) Marked



Experiment Number: 20007 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

DAY ON TEST		0	0	0	0	0	0	0	0	0	
FISCHER 344 RATS FEMALE		0	0	0	0	0	0	0	0	0	
0 G/KG		9	9	9	9	1	9	9	9	9	
ANIMAL ID		3	3	3	3	8	3	3	3	3	
		0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		6	6	6	6	6	6	6	6	7	
		1	2	3	4	5	6	7	8	9	0
<b>* TOTALS</b>											

RESPIRATORY SYSTEM

Lung	+	+	+	+	+	+	+	+	+	+	<b>10</b>	
Inflammation, Chronic												<b>1 1.0</b>
Metaplasia, Osseous												<b>1 1.0</b>
Alveolus, Infiltration Cellular, Histiocyte												<b>1 1.0</b>
Interstitialium, Infiltration Cellular, Mononuclear Cell												<b>3 1.0</b>
Nose	+	+	+	+	+	+	+	+	+	+	<b>10</b>	
Trachea	+	+	+	+	+	+	+	+	+	+	<b>10</b>	

SPECIAL SENSES SYSTEM

Eye	+	+	+	+	+	+	+	+	+	+	<b>10</b>	
Harderian Gland	+	+	+	+	+	+	+	+	+	+	<b>10</b>	

URINARY SYSTEM

Kidney	+	+	+	+	+	+	+	+	+	+	<b>10</b>	
Mineralization												<b>8 1.0</b>
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	<b>10</b>	

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
+ .. Tissue examined microscopically  
X .. Lesion present  
I .. Insufficient tissue  
M .. Missing tissue  
A .. Autolysis precludes evaluation  
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1-4 .. Lesion qualified as:  
1) Minimal 3) Moderate  
2) Mild 4) Marked

Experiment Number: 20007 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

<b>FISCHER 344 RATS FEMALE</b>	DAY ON TEST	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		9	9	9	9	9	9	9	9	9	
		3	3	3	3	3	3	3	3	3	
<b>0.125 G/KG</b>	ANIMAL ID	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		7	7	7	7	7	7	7	7	8	
	1	2	3	4	5	6	7	8	9	0	
<b>* TOTALS</b>											

**ALIMENTARY SYSTEM**

Liver	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Hepatodiaphragmatic Nodule							X				<b>1</b>
Infiltration Cellular, Mononuclear Cell	1	1		1	1		1	1	1		<b>8 1.0</b>

**CARDIOVASCULAR SYSTEM**

NONE

**ENDOCRINE SYSTEM**

NONE

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

NONE

**HEMATOPOIETIC SYSTEM**

Bone Marrow	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Spleen	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Thymus	+	+	+	+	+	+	+	+	+	+	<b>10</b>

**INTEGUMENTARY SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

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1-4 .. Lesion qualified as:

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Experiment Number: 20007 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

<b>FISCHER 344 RATS FEMALE</b>	DAY ON TEST	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		9	9	9	9	9	9	9	9	9	
		3	3	3	3	3	3	3	3	3	
<b>0.125 G/KG</b>	ANIMAL ID	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		7	7	7	7	7	7	7	7	8	
		1	2	3	4	5	6	7	8	9	0

\* TOTALS

NONE

**MUSCULOSKELETAL SYSTEM**

NONE

**NERVOUS SYSTEM**

NONE

**RESPIRATORY SYSTEM**

NONE

**SPECIAL SENSES SYSTEM**

NONE

**URINARY SYSTEM**

NONE

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20007 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

<b>FISCHER 344 RATS FEMALE</b>	DAY ON TEST	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
<b>0.25 G/KG</b>		9	9	9	9	9	9	9	9	9	
		3	3	3	3	3	3	3	3	3	
	ANIMAL ID	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		8	8	8	8	8	8	8	8	9	
		1	2	3	4	5	6	7	8	9	
<b>* TOTALS</b>											

**ALIMENTARY SYSTEM**

Liver	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Infiltration Cellular, Mononuclear Cell			1				1	1		1	<b>4 1.0</b>

**CARDIOVASCULAR SYSTEM**

NONE

**ENDOCRINE SYSTEM**

NONE

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

NONE

**HEMATOPOIETIC SYSTEM**

Bone Marrow	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Spleen	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Thymus	+	+	+	+	+	+	+	+	+	+	<b>10</b>

**INTEGUMENTARY SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
+ .. Tissue examined microscopically M .. Missing tissue  
X .. Lesion present A .. Autolysis precludes evaluation  
I .. Insufficient tissue BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:  
1) Minimal 3) Moderate  
2) Mild 4) Marked

Experiment Number: 20007 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

<b>FISCHER 344 RATS FEMALE</b>	DAY ON TEST	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		9	9	9	9	9	9	9	9	9	
		3	3	3	3	3	3	3	3	3	
<b>0.25 G/KG</b>	ANIMAL ID	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		8	8	8	8	8	8	8	8	9	
		1	2	3	4	5	6	7	8	9	
<b>* TOTALS</b>											

NONE

**MUSCULOSKELETAL SYSTEM**

NONE

**NERVOUS SYSTEM**

NONE

**RESPIRATORY SYSTEM**

NONE

**SPECIAL SENSES SYSTEM**

NONE

**URINARY SYSTEM**

NONE

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

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Experiment Number: 20007 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

FISCHER 344 RATS FEMALE	DAY ON TEST	0	0	0	0	0	0	0	0	0	
		9	9	9	9	9	9	9	9	9	
0.5 G/KG	ANIMAL ID	3	3	3	3	3	3	3	3	3	
		0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	1	
		9	9	9	9	9	9	9	9	0	
		1	2	3	4	5	6	7	8	9	0
<b>* TOTALS</b>											

ALIMENTARY SYSTEM

Liver	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Hepatodiaphragmatic Nodule			X								<b>1</b>
Infiltration Cellular, Mononuclear Cell	1	1	1	1	1			1			<b>7 1.0</b>
Hepatocyte, Hypertrophy								1	1	1	<b>3 1.0</b>
Mesentery								+			<b>1</b>
Necrosis, Fatty								2			<b>1 2.0</b>

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

NONE

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

NONE

HEMATOPOIETIC SYSTEM

Bone Marrow	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Spleen	+	+	+	+	+	+	+	+	+	+	<b>10</b>

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

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Experiment Number: 20007 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

<b>FISCHER 344 RATS FEMALE</b>  <b>0.5 G/KG</b>	DAY ON TEST	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		9	9	9	9	9	9	9	9	9	
		3	3	3	3	3	3	3	3	3	
	ANIMAL ID	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	1	
		9	9	9	9	9	9	9	9	0	
		1	2	3	4	5	6	7	8	9	

**\* TOTALS**

Thymus	+	+	+	+	+	+	+	+	+	+
--------	---	---	---	---	---	---	---	---	---	---

**10**

**INTEGUMENTARY SYSTEM**

NONE

**MUSCULOSKELETAL SYSTEM**

NONE

**NERVOUS SYSTEM**

NONE

**RESPIRATORY SYSTEM**

NONE

**SPECIAL SENSES SYSTEM**

NONE

**URINARY SYSTEM**

NONE

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

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Experiment Number: 20007 - 03

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Date Report Requested: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

DAY ON TEST		0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>FISCHER 344 RATS FEMALE</b>		0	0	0	0	0	0	0	0	0	0	0	0	0	0
		9	9	9	3	9	9	9	9	9	9	9	9	9	9
		3	3	3	2	3	3	3	3	3	3	3	3	3	3
<b>1.0 G/KG</b>	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0
		1	1	1	1	1	1	1	1	1	1	1	1	1	1
		0	0	0	0	0	0	0	0	0	0	0	0	1	0
		1	2	3	4	5	6	7	8	9	0				
														<b>* TOTALS</b>	

**ALIMENTARY SYSTEM**

Esophagus																+	1
Intestine Large, Cecum																+	1
Intestine Large, Colon																+	1
Intestine Large, Rectum																+	1
Intestine Small, Duodenum																+	1
Intestine Small, Ileum																+	1
Intestine Small, Jejunum																+	1
Liver																+ + + + + + + + +	10
Congestion																2	1 2.0
Infiltration Cellular, Mononuclear Cell																1 1 1 1 1 1 1 1	8 1.0
Inflammation																1	1 1.0
Hepatocyte, Hypertrophy																2 1 1	3 1.3
Pancreas																+	1
Salivary Glands																+	1
Stomach, Forestomach																+	1
Stomach, Glandular																+	1

**CARDIOVASCULAR SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 X .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked



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Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	9	9	9	3	9	9	9	9	9	9
FISCHER 344 RATS FEMALE	3	3	3	2	3	3	3	3	3	3
1.0 G/KG										
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1
	0	0	0	0	0	0	0	0	0	1
	1	2	3	4	5	6	7	8	9	0
<b>* TOTALS</b>										

Blood Vessel + 1

Heart + 1

ENDOCRINE SYSTEM

Adrenal Cortex + 1

Adrenal Medulla + 1

Islets, Pancreatic + 1

Parathyroid Gland + 1

Pituitary Gland + 1

Thyroid Gland + 1

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

Clitoral Gland + 1

Ovary + 1

Uterus + 1

HEMATOPOIETIC SYSTEM

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20007 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	
	9	9	9	3	9	9	9	9	9	9	
FISCHER 344 RATS FEMALE	3	3	3	2	3	3	3	3	3	3	
1.0 G/KG											
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	1	1	1	1	1	1	1	1	1	1	
	0	0	0	0	0	0	0	0	0	0	1
	1	2	3	4	5	6	7	8	9	0	* TOTALS
Bone Marrow	+	+	+	+	+	+	+	+	+	+	10
Lymph Node, Mandibular				M							0
Lymph Node, Mesenteric				+							1
Spleen	+	+	+	+	+	+	+	+	+	+	10
Thymus	+	+	+	+	+	+	+	+	+	+	10
<b>INTEGUMENTARY SYSTEM</b>											
Mammary Gland				+							1
Skin				+							1
<b>MUSCULOSKELETAL SYSTEM</b>											
Bone				+							1
<b>NERVOUS SYSTEM</b>											
Brain				+							1
<b>RESPIRATORY SYSTEM</b>											
Lung				+							1
Interstitial, Infiltration Cellular, Mononuclear Cell				1							1 1.0
Nose				+							1

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20007 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	<b>FISCHER 344 RATS FEMALE</b>	0	0	0	0	0	0	0	0	0
<b>1.0 G/KG</b>	9	9	9	3	9	9	9	9	9	9
<b>ANIMAL ID</b>	3	3	3	2	3	3	3	3	3	3
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1
	0	0	0	0	0	0	0	0	0	1
	1	2	3	4	5	6	7	8	9	0
<b>* TOTALS</b>										

Trachea	+	1
---------	---	---

**SPECIAL SENSES SYSTEM**

Eye	+	1
-----	---	---

Harderian Gland	+	1
-----------------	---	---

**URINARY SYSTEM**

Kidney	+	1
Mineralization	1	1 1.0

Urinary Bladder	+	1
-----------------	---	---

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

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X .. Lesion present

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BLANK .. Not examined microscopically

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Lab: BAT

DAY ON TEST		0	0	0	0	0	0	0	0	0	
<b>FISCHER 344 RATS FEMALE</b>		0	0	0	0	0	0	0	0	0	
		9	9	0	9	9	4	0	0	9	9
		3	3	4	3	3	4	2	4	3	3
	<b>2.0 G/KG</b>	0	0	0	0	0	0	0	0	0	
ANIMAL ID		0	0	0	0	0	0	0	0	0	
		1	1	1	1	1	1	1	1	1	
		1	1	1	1	1	1	1	1	2	
		1	2	3	4	5	6	7	8	9	0
<b>* TOTALS</b>											

**ALIMENTARY SYSTEM**

Esophagus	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Liver	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Infiltration Cellular, Mononuclear Cell	1			1							<b>2 1.0</b>
Hepatocyte, Hypertrophy	2	1	2	1	2	2	3	2	1	1	<b>10 1.7</b>
Pancreas	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Acinus, Atrophy						1					<b>1 1.0</b>
Salivary Glands	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	<b>10</b>
Inflammation									1		<b>1 1.0</b>
Mineralization								1			<b>1 1.0</b>
Ulcer								2			<b>1 2.0</b>

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20007 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	9	9	0	9	9	4	0	0	9	9
FISCHER 344 RATS FEMALE	3	3	4	3	3	4	2	4	3	3
2.0 G/KG	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1
	1	1	1	1	1	1	1	1	1	2
	1	2	3	4	5	6	7	8	9	0

\* TOTALS

Stomach, Glandular

+ + + + + + + + + +

10

CARDIOVASCULAR SYSTEM

Blood Vessel

+ + + + + + + + + +

10

Heart

+ + + + + + + + + +

10

Cardiomyopathy

1 1

2 1.0

ENDOCRINE SYSTEM

Adrenal Cortex

+ + + + + + + + + +

10

Adrenal Medulla

+ + + + + + + + + +

10

Islets, Pancreatic

+ + + + + + + + + +

10

Parathyroid Gland

+ + + + + + + + + +

10

Pituitary Gland

+ + + + + + + + + +

10

Thyroid Gland

+ + + + + + + + + +

9

Cyst

X

1

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

Clitoral Gland

+ + + + + + + + + +

10

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

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Kava kava extract

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First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	
	9	9	0	9	9	4	0	0	9	9	
FISCHER 344 RATS FEMALE	3	3	4	3	3	4	2	4	3	3	
2.0 G/KG	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	
	1	1	1	1	1	1	1	1	1	1	
	1	1	1	1	1	1	1	1	1	2	
	1	2	3	4	5	6	7	8	9	0	
<b>* TOTALS</b>											
Ovary	+	+	+	+	+	+	+	+	+	+	10
Uterus	+	+	+	+	+	+	+	+	+	+	10
<b>HEMATOPOIETIC SYSTEM</b>											
Bone Marrow	+	+	+	+	+	+	+	+	+	+	10
Lymph Node, Mandibular	M	M	M	M	M	M	M	M	M	M	0
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	10
Spleen	+	+	+	+	+	+	+	+	+	+	10
Atrophy			2				2	2			3 2.0
Thymus	+	+	+	+	+	+	+	+	+	+	10
Necrosis			2				2	2			3 2.0
<b>INTEGUMENTARY SYSTEM</b>											
Mammary Gland	+	+	+	+	+	+	+	+	+	+	10
Skin	+	+	+	+	+	+	+	+	+	+	10
<b>MUSCULOSKELETAL SYSTEM</b>											
Bone	+	+	+	+	+	+	+	+	+	+	10
<b>NERVOUS SYSTEM</b>											
Brain	+	+	+	+	+	+	+	+	+	+	10

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

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Kava kava extract

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Date Report Requested: 09/13/2016

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First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	<b>FISCHER 344 RATS FEMALE</b>	0	0	0	0	0	0	0	0	0
	9	9	0	9	9	4	0	0	9	9
	3	3	4	3	3	4	2	4	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1
	1	1	1	1	1	1	1	1	1	2
	1	2	3	4	5	6	7	8	9	0

**\* TOTALS**

Cerebrum, Hemorrhage

2

1 2.0

**RESPIRATORY SYSTEM**

Lung	+	+	+	+	+	+	+	+	+	+	10	
Congestion, Diffuse, Acute			2									1 2.0
Inflammation									1			1 1.0
Alveolus, Infiltration Cellular, Histiocyte	1			1		1			1			4 1.0
Interstitialium, Infiltration Cellular, Mononuclear Cell	1				1		1					3 1.0
Nose	+	+	+	+	+	+	+	+	+	+	10	
Trachea	+	+	+	+	+	+	+	+	+	+	10	

**SPECIAL SENSES SYSTEM**

Eye	+	+	+	+	+	+	+	+	+	+	10	
Cornea, Neovascularization			2							2		2 2.0
Harderian Gland	+	+	+	+	+	+	+	+	+	+	10	
Infiltration Cellular, Mononuclear Cell			2									1 2.0

**URINARY SYSTEM**

Kidney	+	+	+	+	+	+	+	+	+	+	10	
Mineralization	1	1								1		3 1.0
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	10	

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

X .. Lesion present

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\*\*\* END OF REPORT \*\*\*

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+ .. Tissue examined microscopically  
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