

**Experiment Number:** 20007 - 04

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH  
AVERAGE SEVERITY GRADES[b]**

**Date Report Requested:** 09/13/2016

**Test Type:** 90-DAY

Kava kava extract

**Time Report Requested:** 11:24:53

**Route:** GAVAGE

**CAS Number:** 9000-38-8

**First Dose M/F:** 09/18/03 / 09/17/03

**Species/Strain:** MICE/B6C3F1

**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

Test Type: 90-DAY

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CAS Number: 9000-38-8

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
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**Disposition Summary**

Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Natural Death						4
Survivors						
Terminal Sacrifice	10	10	10	10	10	6
Animals Examined Microscopically	10	10	10	10	10	10

## ALIMENTARY SYSTEM

Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Gallbladder	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(0)	(10)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic	6 [1.0]	7 [1.0]	4 [1.0]	7 [1.0]	7 [1.0]	4 [1.0]
Necrosis		1 [1.0]		1 [1.0]	1 [1.0]	4 [1.0]
Centrilobular, Hypertrophy				9 [1.0]	10 [2.0]	7 [2.6]
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Artery, Inflammation	1 [1.0]					
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic						1 [2.0]
Mineralization						1 [1.0]
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation	1 [2.0]					1 [1.0]

## CARDIOVASCULAR SYSTEM

Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
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a - Number of animals examined microscopically at site and number of animals with lesion

b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

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Lab: BAT

B6C3F1 MICE MALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Heart	(10)	(0)	(0)	(0)	(0)	(10)
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Hypertrophy	1 [1.0]					1 [1.0]
Hypertrophy, Focal						1 [1.0]
Subcapsular, Hyperplasia	5 [1.0]					6 [1.0]
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(7)	(0)	(0)	(0)	(0)	(7)
Cyst	1					
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Epididymis	(10)	(0)	(0)	(0)	(0)	(10)
Preputial Gland	(10)	(0)	(0)	(0)	(0)	(10)
Prostate	(10)	(0)	(0)	(0)	(0)	(10)
Seminal Vesicle	(10)	(0)	(0)	(0)	(0)	(10)
Testes	(10)	(0)	(0)	(0)	(0)	(10)
Hypoplasia						1 [3.0]
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Lymph Node, Mandibular	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)

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B6C3F1 MICE MALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Spleen	(10)	(10)	(10)	(10)	(10)	(10)
Thymus	(10)	(10)	(10)	(10)	(10)	(10)
Necrosis						3 [1.7]
<b>INTEGUMENTARY SYSTEM</b>						
Skin	(10)	(0)	(0)	(0)	(0)	(10)
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
<b>NERVOUS SYSTEM</b>						
Brain	(10)	(0)	(0)	(0)	(0)	(10)
<b>RESPIRATORY SYSTEM</b>						
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Congestion						2 [3.0]
Inflammation, Chronic Active	1 [1.0]					
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
<b>SPECIAL SENSES SYSTEM</b>						
Eye	(10)	(0)	(0)	(0)	(0)	(10)
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
<b>URINARY SYSTEM</b>						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)

a - Number of animals examined microscopically at site and number of animals with lesion

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Species/Strain: MICE/B6C3F1

Lab: BAT

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B6C3F1 MICE MALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Mineralization	2 [1.0]					
Nephropathy	2 [1.0]					
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

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

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B6C3F1 MICE FEMALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
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**Disposition Summary**

Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Dosing Accident						1
Natural Death						3
Survivors						
Terminal Sacrifice	10	10	10	10	10	6
Animals Examined Microscopically	10	10	10	10	10	10

## ALIMENTARY SYSTEM

Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Hemorrhage						1 [3.0]
Inflammation, Acute						1 [2.0]
Gallbladder	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(0)	(10)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic	9 [1.0]	10 [1.0]	10 [1.0]	9 [1.0]	8 [1.0]	4 [1.0]
Necrosis		1 [1.0]	1 [1.0]	1 [1.0]		
Centrilobular, Hypertrophy				2 [1.0]	5 [1.0]	4 [1.5]
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Acinus, Vacuolization Cytoplasmic	1 [2.0]					2 [2.0]
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Mineralization						1 [1.0]
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
Cyst	1					1
Inflammation, Chronic						1 [1.0]
Mineralization						1 [2.0]

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B6C3F1 MICE FEMALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>CARDIOVASCULAR SYSTEM</b>						
Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
Heart	(10)	(0)	(0)	(0)	(0)	(10)
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Subcapsular, Hyperplasia	10 [1.3]					8 [1.0]
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(7)	(0)	(0)	(0)	(0)	(10)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
Cyst						1
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Clitoral Gland	(10)	(0)	(0)	(0)	(0)	(10)
Ovary	(10)	(0)	(0)	(0)	(0)	(10)
Uterus	(10)	(0)	(0)	(0)	(0)	(10)
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Lymph Node, Mandibular	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Spleen	(10)	(10)	(10)	(10)	(10)	(10)

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B6C3F1 MICE FEMALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Thymus Necrosis	(10)	(10)	(10)	(10)	(10)	(10) 2 [2.0]
<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(10)	(0)	(0)	(0)	(0)	(9)
Skin Inflammation	(10)	(0)	(0)	(0)	(0)	(10) 1 [1.0]
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
<b>NERVOUS SYSTEM</b>						
Brain	(10)	(0)	(0)	(0)	(0)	(10)
<b>RESPIRATORY SYSTEM</b>						
Lung Congestion	(10)	(0)	(0)	(0)	(0)	(10) 1 [3.0]
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
<b>SPECIAL SENSES SYSTEM</b>						
Eye	(10)	(0)	(0)	(0)	(0)	(9)
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
<b>URINARY SYSTEM</b>						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)

a - Number of animals examined microscopically at site and number of animals with lesion

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B6C3F1 MICE FEMALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Nephropathy						1 [1.0]
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(9)

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

a - Number of animals examined microscopically at site and number of animals with lesion

b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)