

**Experiment Number:** 20007-04  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)**

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

**Date Report Requested:** 10/22/2014  
**Time Report Requested:** 23:12:44  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**C Number:** C20007  
**Lock Date:** 05/24/2004  
**Cage Range:** All  
**Date Range:** All  
**Reasons For Removal:** All  
**Removal Date Range:** All  
**Treatment Groups:** All  
**Study Gender:** Both  
**PWG Approval Date:** NONE

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B6C3F1 Mouse MALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Disposition Summary</b>						
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
<b>ALIMENTARY SYSTEM</b>						
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)
Centrilobular, Hypertrophy				9 (90%)	10 (100%)	7 (70%)
Inflammation, Chronic	6 (60%)	7 (70%)	4 (40%)	7 (70%)	7 (70%)	4 (40%)
Necrosis		1 (10%)		1 (10%)	1 (10%)	4 (40%)
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Artery, Inflammation	1 (10%)					
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic						1 (10%)
Mineralization						1 (10%)
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation	1 (10%)					1 (10%)
<b>CARDIOVASCULAR SYSTEM</b>						

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

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B6C3F1 Mouse MALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
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)
Hypertrophy	1 (10%)					1 (10%)
Hypertrophy, Focal						1 (10%)
Subcapsular, Hyperplasia	5 (50%)					6 (60%)
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 (14%)					
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 (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)
Thymus	(10)	(10)	(10)	(10)	(10)	(10)

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

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B6C3F1 Mouse MALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Necrosis						3 (30%)
<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 (20%)
Inflammation, Chronic Active	1 (10%)					
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)
Mineralization	2 (20%)					
Nephropathy	2 (20%)					
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

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

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 Lab: BAT

B6C3F1 Mouse 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>Disposition Summary</b>						
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
<b>ALIMENTARY SYSTEM</b>						
Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Hemorrhage						1 (10%)
Inflammation, Acute						1 (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)
Centrilobular, Hypertrophy				2 (20%)	5 (50%)	4 (40%)
Inflammation, Chronic	9 (90%)	10 (100%)	10 (100%)	9 (90%)	8 (80%)	4 (40%)
Necrosis		1 (10%)	1 (10%)	1 (10%)		
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Acinus, Vacuolization Cytoplasmic	1 (10%)					2 (20%)
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Mineralization						1 (10%)
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)

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

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<b>B6C3F1 Mouse FEMALE</b>	<b>0 G/KG</b>	<b>0.125 G/KG</b>	<b>0.25 G/KG</b>	<b>0.5 G/KG</b>	<b>1.0 G/KG</b>	<b>2.0 G/KG</b>
Cyst	1 (10%)					1 (10%)
Inflammation, Chronic						1 (10%)
Mineralization						1 (10%)
<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 (100%)					8 (80%)
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 (10%)
<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)
Thymus	(10)	(10)	(10)	(10)	(10)	(10)
Necrosis						2 (20%)

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<b>B6C3F1 Mouse FEMALE</b>	<b>0 G/KG</b>	<b>0.125 G/KG</b>	<b>0.25 G/KG</b>	<b>0.5 G/KG</b>	<b>1.0 G/KG</b>	<b>2.0 G/KG</b>
<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(10)	(0)	(0)	(0)	(0)	(9)
Skin Inflammation	(10)	(0)	(0)	(0)	(0)	(10)
						1 (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 Congestion	(10)	(0)	(0)	(0)	(0)	(10)
						1 (10%)
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 Nephropathy	(10)	(0)	(0)	(0)	(0)	(10)
						1 (10%)
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(9)

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

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