

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

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

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/22/2014

Time Report Requested: 23:12:11

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
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)
Centrilobular, Hypertrophy				9 [1.0]	10 [2.0]	7 [2.6]
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]
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]

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
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
Heart	(10)	(0)	(0)	(0)	(0)	(10)
ENDOCRINE SYSTEM						
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)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
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]
HEMATOPOIETIC SYSTEM						
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 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
Spleen	(10)	(10)	(10)	(10)	(10)	(10)
Thymus	(10)	(10)	(10)	(10)	(10)	(10)
Necrosis						3 [1.7]
INTEGUMENTARY SYSTEM						
Skin	(10)	(0)	(0)	(0)	(0)	(10)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(0)	(10)
RESPIRATORY SYSTEM						
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)
SPECIAL SENSES SYSTEM						
Eye	(10)	(0)	(0)	(0)	(0)	(10)
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
Mineralization	2 [1.0]					
Nephropathy	2 [1.0]					
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

END OF MALE DATA

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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
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)
Centrilobular, Hypertrophy				2 [1.0]	5 [1.0]	4 [1.5]
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]		
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]

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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
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
Cyst	1					1
Inflammation, Chronic						1 [1.0]
Mineralization						1 [2.0]
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
Heart	(10)	(0)	(0)	(0)	(0)	(10)
ENDOCRINE SYSTEM						
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
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(10)	(0)	(0)	(0)	(0)	(10)
Ovary	(10)	(0)	(0)	(0)	(0)	(10)
Uterus	(10)	(0)	(0)	(0)	(0)	(10)
HEMATOPOIETIC SYSTEM						
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 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
Thymus Necrosis	(10)	(10)	(10)	(10)	(10)	(10) 2 [2.0]
INTEGUMENTARY SYSTEM						
Mammary Gland	(10)	(0)	(0)	(0)	(0)	(9)
Skin Inflammation	(10)	(0)	(0)	(0)	(0)	(10) 1 [1.0]
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(0)	(10)
RESPIRATORY SYSTEM						
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)
SPECIAL SENSES SYSTEM						
Eye	(10)	(0)	(0)	(0)	(0)	(9)
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
URINARY SYSTEM						
Kidney Nephropathy	(10)	(0)	(0)	(0)	(0)	(10) 1 [1.0]
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(9)

**** END OF REPORT ****

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