

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

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

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

**Date Report Requested:** 10/17/2014  
**Time Report Requested:** 21:45:42  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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

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Species/Strain: Rat/F 344/N

Lab: BAT

F 344/N Rat 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						
Moribund Sacrifice			1			
Natural Death						3
Survivors						
Terminal Sacrifice	10	10	9	10	10	7
Animals Examined Microscopically	10	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>						
Esophagus	(10)	(0)	(1)	(0)	(0)	(10)
Intestine Large, Cecum	(10)	(0)	(1)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(1)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(0)	(1)	(0)	(0)	(10)
Intestine Small, Duodenum	(10)	(0)	(1)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(1)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(1)	(0)	(0)	(10)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Bile Duct, Hyperplasia				1 (10%)		
Hematopoietic Cell Proliferation	1 (10%)	1 (10%)				
Hepatocyte, Hypertrophy					1 (10%)	
Hepatodiaphragmatic Nodule				1 (10%)		
Infiltration Cellular, Mixed Cell						1 (10%)
Infiltration Cellular, Mononuclear CI	9 (90%)	7 (70%)	5 (50%)	5 (50%)	5 (50%)	5 (50%)
Vacuolization Cytoplasmic	1 (10%)			1 (10%)		
Pancreas	(10)	(0)	(1)	(0)	(0)	(10)
Acinus, Atrophy	1 (10%)					
Salivary Glands	(10)	(0)	(1)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(1)	(0)	(0)	(10)
Inflammation						1 (10%)

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F 344/N Rat 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						1 (10%)
Ulcer						1 (10%)
Stomach, Glandular	(10)	(0)	(1)	(0)	(0)	(10)
<b>CARDIOVASCULAR SYSTEM</b>						
Blood Vessel	(10)	(0)	(1)	(0)	(0)	(10)
Heart	(10)	(0)	(1)	(0)	(0)	(10)
Cardiomyopathy	9 (90%)					8 (80%)
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(0)	(1)	(0)	(0)	(10)
Adrenal Medulla	(10)	(0)	(1)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(1)	(0)	(0)	(10)
Parathyroid Gland	(10)	(0)	(1)	(0)	(0)	(9)
Pituitary Gland	(10)	(0)	(1)	(0)	(0)	(10)
Pars Distalis, Hypertrophy	1 (10%)					
Thyroid Gland	(10)	(0)	(1)	(0)	(0)	(10)
Cyst	2 (20%)					1 (10%)
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Epididymis	(10)	(0)	(1)	(0)	(0)	(10)
Inflammation	1 (10%)					
Preputial Gland	(10)	(0)	(1)	(0)	(0)	(10)
Inflammation						1 (10%)
Prostate	(10)	(0)	(1)	(0)	(0)	(10)
Seminal Vesicle	(10)	(0)	(1)	(0)	(0)	(10)
Atrophy						1 (10%)
Testes	(10)	(0)	(1)	(0)	(0)	(10)
<b>HEMATOPOIETIC SYSTEM</b>						

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F 344/N Rat MALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Lymph Node, Mesenteric	(10)	(0)	(1)	(0)	(0)	(10)
Spleen	(10)	(10)	(10)	(10)	(10)	(10)
Atrophy						3 (30%)
Hematopoietic Cell Proliferation					1 (10%)	
Thymus	(10)	(10)	(10)	(10)	(10)	(10)
Necrosis						1 (10%)
INTEGUMENTARY SYSTEM						
Mammary Gland	(7)	(0)	(1)	(0)	(0)	(9)
Skin	(10)	(0)	(1)	(0)	(0)	(10)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(1)	(0)	(0)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(1)	(0)	(0)	(10)
RESPIRATORY SYSTEM						
Lung	(10)	(0)	(1)	(0)	(0)	(10)
Alveolus, Infiltration Cellular, Histiocyte Inflammation	2 (20%)					3 (30%)
Inflammation, Granulomatous						2 (20%)
Interstitial, Infiltration Cellular, Mononuclear Cl	3 (30%)					4 (40%)
Interstitial, Inflammation, Chronic	1 (10%)					1 (10%)
Metaplasia, Osseous	1 (10%)					1 (10%)
Metaplasia, Osseous, Focal	1 (10%)					
Nose	(10)	(0)	(1)	(0)	(0)	(10)
Inflammation						1 (10%)
Inflammation, Acute						1 (10%)
Inflammation, Suppurative	1 (10%)					
Squam Epithel, Hyperplasia, Squamous	1 (10%)					

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F 344/N Rat MALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Trachea	(10)	(0)	(1)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
Eye	(10)	(0)	(1)	(0)	(0)	(10)
Harderian Gland	(10)	(0)	(1)	(0)	(0)	(10)
Infiltration Cellular, Mononuclear CI	1 (10%)					
URINARY SYSTEM						
Kidney	(10)	(0)	(1)	(0)	(0)	(10)
Accumulation, Hyaline Droplet	2 (20%)					1 (10%)
Casts Protein	1 (10%)					
Infiltration Cellular, Mononuclear CI	1 (10%)					
Mineralization	4 (40%)					3 (30%)
Nephropathy	7 (70%)					7 (70%)
Urinary Bladder	(10)	(0)	(1)	(0)	(0)	(10)

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

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Lab: BAT

F 344/N Rat 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						
Moribund Sacrifice	1					
Natural Death					1	4
Survivors						
Terminal Sacrifice	9	10	10	10	9	6
Animals Examined Microscopically	10	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>						
Esophagus	(10)	(0)	(0)	(0)	(1)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(1)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(1)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(1)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(1)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(1)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(1)	(10)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Congestion					1 (10%)	
Hepatocyte, Hypertrophy				3 (30%)	3 (30%)	10 (100%)
Hepatodiaphragmatic Nodule	2 (20%)	1 (10%)		1 (10%)		
Infiltration Cellular, Mononuclear CI	8 (80%)	8 (80%)	4 (40%)	7 (70%)	8 (80%)	2 (20%)
Inflammation	1 (10%)				1 (10%)	
Mesentery	(1)	(0)	(0)	(1)	(0)	(0)
Necrosis, Fatty				1 (100%)		
Necrosis, Focal	1 (100%)					
Pancreas	(10)	(0)	(0)	(0)	(1)	(10)
Acinus, Atrophy						1 (10%)
Salivary Glands	(10)	(0)	(0)	(0)	(1)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(1)	(10)

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Lab: BAT

F 344/N Rat FEMALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Inflammation						1 (10%)
Mineralization						1 (10%)
Ulcer						1 (10%)
Stomach, Glandular	(10)	(0)	(0)	(0)	(1)	(10)
<b>CARDIOVASCULAR SYSTEM</b>						
Blood Vessel	(10)	(0)	(0)	(0)	(1)	(10)
Heart	(10)	(0)	(0)	(0)	(1)	(10)
Cardiomyopathy	5 (50%)					2 (20%)
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(0)	(0)	(0)	(1)	(10)
Adrenal Medulla	(10)	(0)	(0)	(0)	(1)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(1)	(10)
Parathyroid Gland	(10)	(0)	(0)	(0)	(1)	(10)
Pituitary Gland	(10)	(0)	(0)	(0)	(1)	(10)
Thyroid Gland	(10)	(0)	(0)	(0)	(1)	(9)
Cyst	2 (20%)					1 (11%)
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Clitoral Gland	(10)	(0)	(0)	(0)	(1)	(10)
Ovary	(10)	(0)	(0)	(0)	(1)	(10)
Uterus	(10)	(0)	(0)	(0)	(1)	(10)
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(1)	(10)
Spleen	(10)	(10)	(10)	(10)	(10)	(10)
Atrophy	1 (10%)					3 (30%)
Thymus	(10)	(10)	(10)	(10)	(10)	(10)

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Species/Strain: Rat/F 344/N

Lab: BAT

F 344/N Rat FEMALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Necrosis	1 (10%)					3 (30%)
<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(10)	(0)	(0)	(0)	(1)	(10)
Skin	(10)	(0)	(0)	(0)	(1)	(10)
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(0)	(0)	(0)	(1)	(10)
<b>NERVOUS SYSTEM</b>						
Brain	(10)	(0)	(0)	(0)	(1)	(9)
Brain, Cerebrum	(0)	(0)	(0)	(0)	(0)	(1)
Hemorrhage						1 (100%)
<b>RESPIRATORY SYSTEM</b>						
Lung	(10)	(0)	(0)	(0)	(1)	(10)
Alveolus, Infiltration Cellular, Histiocyte Congestion, Acute, Diffuse Inflammation	1 (10%)					4 (40%) 1 (10%) 1 (10%)
Inflammation, Chronic	1 (10%)					
Interstitial, Infiltration Cellular, Mononuclear CI	3 (30%)				1 (100%)	3 (30%)
Metaplasia, Osseous	1 (10%)					
Nose	(10)	(0)	(0)	(0)	(1)	(10)
Trachea	(10)	(0)	(0)	(0)	(1)	(10)
<b>SPECIAL SENSES SYSTEM</b>						
Eye	(10)	(0)	(0)	(0)	(1)	(10)
Cornea, Neovascularization						2 (20%)
Harderian Gland	(10)	(0)	(0)	(0)	(1)	(10)
Infiltration Cellular, Mononuclear CI						1 (10%)
<b>URINARY SYSTEM</b>						
Kidney	(10)	(0)	(0)	(0)	(1)	(10)

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**First Dose M/F:** NA / NA

**Lab:** BAT

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<b>F 344/N Rat 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>
Mineralization	8 (80%)				1 (100%)	3 (30%)
Urinary Bladder	(10)	(0)	(0)	(0)	(1)	(10)

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

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