

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

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

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

F2_R2

C Number: C20007
Lock Date: 03/27/2007
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.2.0

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FISCHER 344 RATS MALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
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Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Dosing Accident		1	1	3
Moribund Sacrifice	10	10	13	13
Natural Death	5	4	2	3
Survivors				
Natural Death			1	
Terminal Sacrifice	34	35	33	31
Animals Examined Microscopically	49	50	50	50

ALIMENTARY SYSTEM

Esophagus	(49)	(50)	(50)	(50)
Epithelium, Hyperplasia	1 (2%)			
Epithelium, Necrosis	1 (2%)			
Muscularis, Degeneration	1 (2%)			
Intestine Large, Cecum	(49)	(50)	(50)	(50)
Inflammation		1 (2%)		
Intestine Large, Colon	(49)	(50)	(50)	(50)
Parasite Metazoan	7 (14%)	2 (4%)	5 (10%)	2 (4%)
Intestine Small, Duodenum	(49)	(50)	(50)	(50)
Ectopic Tissue	1 (2%)			
Intestine Small, Ileum	(49)	(50)	(50)	(50)
Necrosis	1 (2%)			
Liver	(49)	(50)	(50)	(50)
Angiectasis		1 (2%)	2 (4%)	1 (2%)
Basophilic Focus	21 (43%)	30 (60%)	18 (36%)	13 (26%)
Clear Cell Focus	18 (37%)	25 (50%)	25 (50%)	11 (22%)
Degeneration, Cystic		4 (8%)	3 (6%)	5 (10%)
Eosinophilic Focus	15 (31%)	18 (36%)	14 (28%)	13 (26%)
Fatty Change, Diffuse	11 (22%)	8 (16%)	12 (24%)	8 (16%)
Fibrosis				1 (2%)
Hematopoietic Cell Proliferation	3 (6%)	3 (6%)	1 (2%)	
Hepatodiaphragmatic Nodule	2 (4%)	7 (14%)	4 (8%)	1 (2%)

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

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FISCHER 344 RATS MALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Inflammation, Chronic Active	36 (73%)	39 (78%)	32 (64%)	34 (68%)
Mixed Cell Focus	4 (8%)	5 (10%)	4 (8%)	
Necrosis	1 (2%)	2 (4%)		1 (2%)
Pigmentation, Hemosiderin	1 (2%)		2 (4%)	2 (4%)
Tension Lipidosis				1 (2%)
Bile Duct, Cyst		1 (2%)		
Bile Duct, Hyperplasia	32 (65%)	39 (78%)	40 (80%)	34 (68%)
Centrilobular, Degeneration			1 (2%)	
Centrilobular, Fatty Change	1 (2%)	7 (14%)	4 (8%)	21 (42%)
Centrilobular, Necrosis		2 (4%)		1 (2%)
Hepatocyte, Hyperplasia			1 (2%)	
Hepatocyte, Hypertrophy		2 (4%)	2 (4%)	22 (44%)
Oval Cell, Hyperplasia		2 (4%)	1 (2%)	1 (2%)
Mesentery	(6)	(8)	(7)	(6)
Hemorrhage	1 (17%)			
Thrombosis			1 (14%)	
Fat, Necrosis	4 (67%)	7 (88%)	6 (86%)	5 (83%)
Oral Mucosa	(1)	(1)	(0)	(1)
Hyperplasia, Squamous		1 (100%)		
Pancreas	(49)	(50)	(50)	(50)
Atrophy	16 (33%)	13 (26%)	18 (36%)	18 (36%)
Basophilic Focus		1 (2%)		
Inflammation			2 (4%)	1 (2%)
Acinus, Hyperplasia	6 (12%)	9 (18%)	9 (18%)	2 (4%)
Acinus, Metaplasia, Hepatocyte				6 (12%)
Salivary Glands	(49)	(50)	(50)	(50)
Atrophy		1 (2%)	1 (2%)	
Stomach, Forestomach	(49)	(50)	(50)	(50)
Erosion			1 (2%)	4 (8%)
Inflammation	8 (16%)	4 (8%)	9 (18%)	22 (44%)
Mineralization		2 (4%)	1 (2%)	3 (6%)
Ulcer	4 (8%)		6 (12%)	13 (26%)
Epithelium, Dysplasia	1 (2%)		2 (4%)	1 (2%)
Epithelium, Hyperplasia	6 (12%)	4 (8%)	11 (22%)	27 (54%)
Stomach, Glandular	(49)	(50)	(50)	(50)
Hyperplasia				1 (2%)

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FISCHER 344 RATS MALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Inflammation	2 (4%)	3 (6%)	3 (6%)	3 (6%)
Epithelium, Necrosis	2 (4%)	1 (2%)	2 (4%)	3 (6%)
Tooth	(10)	(6)	(9)	(11)
Malformation	10 (100%)	6 (100%)	9 (100%)	11 (100%)

CARDIOVASCULAR SYSTEM

Blood Vessel	(49)	(50)	(50)	(50)
Mineralization				1 (2%)
Pulmonary Artery, Inflammation, Chronic Active			1 (2%)	
Heart	(49)	(50)	(50)	(50)
Cardiomyopathy	48 (98%)	49 (98%)	48 (96%)	46 (92%)
Inflammation, Suppurative				1 (2%)
Mineralization			1 (2%)	
Atrium, Thrombosis	2 (4%)	2 (4%)	3 (6%)	1 (2%)
Coronary Artery, Degeneration			1 (2%)	
Epicardium, Inflammation			1 (2%)	

ENDOCRINE SYSTEM

Adrenal Cortex	(49)	(50)	(50)	(50)
Degeneration, Cystic	1 (2%)			
Hematopoietic Cell Proliferation		1 (2%)	1 (2%)	
Hypertrophy	2 (4%)	5 (10%)	3 (6%)	3 (6%)
Necrosis	1 (2%)	1 (2%)	1 (2%)	1 (2%)
Vacuolization Cytoplasmic	1 (2%)			
Zona Fasciculata, Hyperplasia	8 (16%)	6 (12%)	9 (18%)	13 (26%)
Adrenal Medulla	(49)	(50)	(50)	(50)
Hemorrhage				1 (2%)
Hyperplasia	9 (18%)	11 (22%)	10 (20%)	10 (20%)
Thrombosis				1 (2%)
Islets, Pancreatic	(49)	(50)	(50)	(50)
Hyperplasia	2 (4%)	2 (4%)	2 (4%)	3 (6%)
Parathyroid Gland	(49)	(50)	(48)	(50)
Hyperplasia	1 (2%)		1 (2%)	10 (20%)

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FISCHER 344 RATS MALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Pituitary Gland	(49)	(50)	(50)	(50)
Hemorrhage	1 (2%)		1 (2%)	
Pars Distalis, Angiectasis			1 (2%)	
Pars Distalis, Hyperplasia	17 (35%)	20 (40%)	21 (42%)	11 (22%)
Thyroid Gland	(49)	(50)	(50)	(50)
Infiltration Cellular, Lymphocyte		1 (2%)		
C-cell, Hyperplasia	8 (16%)	12 (24%)	12 (24%)	7 (14%)
Follicular Cell, Hyperplasia		2 (4%)		1 (2%)
Follicular Cell, Hypertrophy				1 (2%)
GENERAL BODY SYSTEM				
Peritoneum	(0)	(0)	(1)	(0)
Tissue NOS	(0)	(1)	(0)	(0)
GENITAL SYSTEM				
Coagulating Gland	(2)	(2)	(0)	(0)
Fibrosis	1 (50%)			
Inflammation	1 (50%)	2 (100%)		
Epididymis	(49)	(50)	(50)	(50)
Inflammation	1 (2%)	4 (8%)	3 (6%)	2 (4%)
Preputial Gland	(49)	(50)	(49)	(50)
Inflammation			1 (2%)	2 (4%)
Duct, Hyperplasia, Atypical				1 (2%)
Prostate	(49)	(50)	(50)	(50)
Atrophy				1 (2%)
Inflammation	28 (57%)	24 (48%)	21 (42%)	16 (32%)
Epithelium, Hyperplasia	9 (18%)	8 (16%)	2 (4%)	3 (6%)
Seminal Vesicle	(49)	(50)	(50)	(50)
Atrophy				1 (2%)
Inflammation			1 (2%)	2 (4%)
Testes	(49)	(50)	(50)	(50)
Cyst				1 (2%)
Arteriole, Necrosis	1 (2%)			

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Germinal Epithelium, Degeneration	3 (6%)			
Interstitial Cell, Hyperplasia	17 (35%)	15 (30%)	10 (20%)	4 (8%)

HEMATOPOIETIC SYSTEM

Bone Marrow	(49)	(50)	(50)	(50)
Hemorrhage		1 (2%)		
Hyperplasia	16 (33%)	17 (34%)	24 (48%)	29 (58%)
Necrosis		1 (2%)		1 (2%)
Lymph Node	(4)	(3)	(2)	(5)
Mediastinal, Ectasia			1 (50%)	
Mediastinal, Hyperplasia, Lymphoid	3 (75%)			1 (20%)
Mediastinal, Infiltration Cellular, Plasma Cell		1 (33%)	1 (50%)	
Lymph Node, Mesenteric	(49)	(50)	(50)	(50)
Atrophy	2 (4%)	2 (4%)		5 (10%)
Spleen	(49)	(50)	(50)	(50)
Accessory Spleen	1 (2%)			1 (2%)
Amyloid Deposition		1 (2%)		
Fibrosis				2 (4%)
Hematopoietic Cell Proliferation	10 (20%)	10 (20%)	7 (14%)	5 (10%)
Hemorrhage	1 (2%)			
Hyperplasia, Histiocytic				1 (2%)
Inflammation	1 (2%)			
Necrosis	1 (2%)			
Pigmentation, Hemosiderin	31 (63%)	32 (64%)	35 (70%)	32 (64%)
Thrombosis				2 (4%)
Lymphoid Follicle, Atrophy	2 (4%)	2 (4%)	2 (4%)	1 (2%)
Lymphoid Follicle, Hyperplasia			1 (2%)	
Thymus	(48)	(50)	(50)	(50)
Atrophy	47 (98%)	49 (98%)	49 (98%)	46 (92%)

INTEGUMENTARY SYSTEM

Mammary Gland	(48)	(50)	(50)	(50)
Hyperplasia	1 (2%)			

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FISCHER 344 RATS MALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Skin	(49)	(50)	(50)	(50)
Cyst Epithelial Inclusion		1 (2%)		1 (2%)
Inflammation		2 (4%)		1 (2%)
Epidermis, Hyperplasia, Basal Cell			1 (2%)	
Subcutaneous Tissue, Fibrosis	1 (2%)			
MUSCULOSKELETAL SYSTEM				
Bone	(49)	(50)	(50)	(50)
Osteopetrosis				1 (2%)
Ligament, Mineralization				1 (2%)
Skeletal Muscle	(1)	(0)	(1)	(1)
NERVOUS SYSTEM				
Brain	(49)	(50)	(50)	(50)
Hemorrhage	1 (2%)	1 (2%)		2 (4%)
Hydrocephalus		1 (2%)		1 (2%)
Necrosis	2 (4%)		2 (4%)	2 (4%)
Choroid Plexus, Infiltration Cellular, Lymphocyte			1 (2%)	
Spinal Cord	(2)	(0)	(0)	(0)
RESPIRATORY SYSTEM				
Lung	(49)	(50)	(50)	(50)
Congestion		1 (2%)	1 (2%)	1 (2%)
Foreign Body				1 (2%)
Hemorrhage				1 (2%)
Inflammation, Granulomatous				3 (6%)
Inflammation, Chronic Active	6 (12%)	3 (6%)	9 (18%)	9 (18%)
Necrosis	2 (4%)			
Thrombosis	1 (2%)		1 (2%)	
Alveolar Epithelium, Hyperplasia	19 (39%)	13 (26%)	20 (40%)	15 (30%)

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FISCHER 344 RATS MALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Alveolar Epithelium, Hypertrophy	2 (4%)		2 (4%)	1 (2%)
Alveolar Epithelium, Metaplasia			1 (2%)	
Alveolar Epithelium, Metaplasia, Squamous	1 (2%)	1 (2%)	1 (2%)	
Alveolus, Infiltration Cellular, Histiocyte	8 (16%)	3 (6%)	11 (22%)	9 (18%)
Arteriole, Hyperplasia				1 (2%)
Serosa, Inflammation, Acute				1 (2%)
Nose	(49)	(50)	(50)	(50)
Foreign Body	1 (2%)	4 (8%)	1 (2%)	2 (4%)
Inflammation	18 (37%)	14 (28%)	10 (20%)	18 (36%)
Olfactory Epithelium, Metaplasia	2 (4%)	1 (2%)	3 (6%)	5 (10%)
Respiratory Epithelium, Hyperplasia	1 (2%)	3 (6%)	1 (2%)	4 (8%)

SPECIAL SENSES SYSTEM

Ear	(0)	(2)	(1)	(0)
Eye	(49)	(50)	(50)	(50)
Anterior Chamber, Inflammation				1 (2%)
Cornea, Fibrosis	1 (2%)			
Cornea, Inflammation			1 (2%)	
Iris, Inflammation				2 (4%)
Iris, Synechia	1 (2%)			
Lens, Cataract	2 (4%)	1 (2%)	2 (4%)	
Retina, Degeneration	6 (12%)	6 (12%)	10 (20%)	16 (32%)
Retina, Retinal Detachment	1 (2%)			
Harderian Gland	(49)	(50)	(50)	(50)
Zymbal's Gland	(0)	(0)	(1)	(0)

URINARY SYSTEM

Kidney	(49)	(50)	(50)	(50)
Accumulation, Hyaline Droplet	1 (2%)		1 (2%)	2 (4%)
Hyperplasia, Oncocytic				1 (2%)
Infarct	1 (2%)		1 (2%)	
Inflammation, Acute			1 (2%)	
Mineralization	38 (78%)	43 (86%)	41 (82%)	34 (68%)

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FISCHER 344 RATS MALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Nephropathy	46 (94%)	47 (94%)	48 (96%)	48 (96%)
Cortex, Cyst	1 (2%)			1 (2%)
Papilla, Necrosis	1 (2%)			
Pelvis, Dilatation		1 (2%)		
Pelvis, Inflammation	1 (2%)			1 (2%)
Pelvis, Transitional Epithelium, Hyperplasia		1 (2%)	1 (2%)	15 (30%)
Ureter	(1)	(1)	(0)	(0)
Inflammation	1 (100%)			
Urethra	(1)	(0)	(0)	(0)
Inflammation	1 (100%)			
Urinary Bladder	(49)	(50)	(50)	(50)
Inflammation	2 (4%)		1 (2%)	2 (4%)
Transitional Epithelium, Hyperplasia	1 (2%)			

*** END OF MALE ***

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Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Dosing Accident	1	1	2	2
Moribund Sacrifice	12	12	13	6
Natural Death	3	2	11	8
Survivors				
Natural Death		1		
Terminal Sacrifice	34	34	24	34
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Hyperplasia		1 (2%)		
Inflammation		1 (2%)	1 (2%)	
Perforation			1 (2%)	
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Inflammation			1 (2%)	
Necrosis			1 (2%)	
Intestine Large, Colon	(50)	(50)	(50)	(50)
Parasite Metazoan	3 (6%)	1 (2%)	8 (16%)	6 (12%)
Liver	(50)	(50)	(50)	(50)
Angiectasis	1 (2%)	2 (4%)		3 (6%)
Basophilic Focus	44 (88%)	42 (84%)	41 (82%)	11 (22%)
Clear Cell Focus	12 (24%)	14 (28%)	11 (22%)	8 (16%)
Degeneration, Cystic				1 (2%)
Eosinophilic Focus	23 (46%)	31 (62%)	24 (48%)	23 (46%)
Fatty Change, Focal	1 (2%)			
Fatty Change, Diffuse	9 (18%)	10 (20%)	10 (20%)	11 (22%)
Hematopoietic Cell Proliferation	1 (2%)	3 (6%)		
Hepatodiaphragmatic Nodule	5 (10%)	6 (12%)	1 (2%)	2 (4%)
Inflammation, Chronic Active	43 (86%)	40 (80%)	38 (76%)	35 (70%)
Mixed Cell Focus	15 (30%)	10 (20%)	9 (18%)	3 (6%)
Necrosis	2 (4%)	1 (2%)		

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Pigmentation, Hemosiderin	1 (2%)		1 (2%)	1 (2%)
Artery, Necrosis	1 (2%)			
Bile Duct, Cyst		1 (2%)		
Bile Duct, Hyperplasia	12 (24%)	15 (30%)	10 (20%)	10 (20%)
Centrilobular, Fatty Change				2 (4%)
Centrilobular, Necrosis		1 (2%)		1 (2%)
Hepatocyte, Hypertrophy	5 (10%)	2 (4%)	3 (6%)	33 (66%)
Oval Cell, Hyperplasia		2 (4%)	2 (4%)	
Serosa, Fibrosis	1 (2%)	1 (2%)		
Mesentery	(10)	(9)	(7)	(9)
Fat, Necrosis	10 (100%)	9 (100%)	7 (100%)	9 (100%)
Oral Mucosa	(0)	(1)	(2)	(0)
Hyperplasia, Squamous			1 (50%)	
Pancreas	(50)	(50)	(50)	(50)
Atrophy	13 (26%)	10 (20%)	16 (32%)	17 (34%)
Basophilic Focus	1 (2%)			
Inflammation				1 (2%)
Acinus, Hyperplasia	1 (2%)	3 (6%)		
Acinus, Metaplasia, Hepatocyte		1 (2%)		4 (8%)
Salivary Glands	(50)	(50)	(50)	(50)
Atrophy				1 (2%)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Erosion		1 (2%)	2 (4%)	
Hyperplasia, Atypical	1 (2%)			
Inflammation	5 (10%)	7 (14%)	7 (14%)	13 (26%)
Ulcer	1 (2%)	1 (2%)	3 (6%)	7 (14%)
Epithelium, Hyperplasia	5 (10%)	6 (12%)	8 (16%)	19 (38%)
Stomach, Glandular	(50)	(50)	(50)	(50)
Amyloid Deposition			1 (2%)	
Inflammation		2 (4%)		
Epithelium, Hyperplasia			1 (2%)	
Epithelium, Necrosis	1 (2%)	1 (2%)		
Tooth	(5)	(3)	(4)	(2)
Malformation	5 (100%)	3 (100%)	4 (100%)	2 (100%)
Peridontal Tissue, Inflammation				1 (50%)

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CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)
Inflammation	1 (2%)			
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	42 (84%)	45 (90%)	45 (90%)	47 (94%)
Atrium, Thrombosis		1 (2%)		1 (2%)
Valve, Thrombosis		1 (2%)		
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Amyloid Deposition		1 (2%)		
Degeneration, Cystic	3 (6%)	6 (12%)	7 (14%)	6 (12%)
Hemorrhage				1 (2%)
Hypertrophy	2 (4%)	3 (6%)	1 (2%)	3 (6%)
Metaplasia, Osseous			1 (2%)	
Necrosis	2 (4%)		1 (2%)	2 (4%)
Zona Fasciculata, Hyperplasia	6 (12%)	6 (12%)	4 (8%)	9 (18%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Hyperplasia	3 (6%)		1 (2%)	1 (2%)
Necrosis		1 (2%)		
Islets, Pancreatic	(50)	(50)	(50)	(50)
Hyperplasia	1 (2%)		3 (6%)	1 (2%)
Parathyroid Gland	(44)	(47)	(44)	(47)
Pituitary Gland	(50)	(50)	(50)	(50)
Cyst			1 (2%)	
Pars Distalis, Angiectasis	1 (2%)	1 (2%)	1 (2%)	2 (4%)
Pars Distalis, Hyperplasia	11 (22%)	20 (40%)	16 (32%)	23 (46%)
Thyroid Gland	(50)	(50)	(50)	(50)
C-cell, Hyperplasia	15 (30%)	15 (30%)	6 (12%)	4 (8%)
Follicle, Cyst				2 (4%)
Follicular Cell, Hyperplasia	1 (2%)	1 (2%)	4 (8%)	4 (8%)

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TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

FISCHER 344 RATS FEMALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
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GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(50)	(49)	(50)	(49)
Hyperplasia		3 (6%)	5 (10%)	1 (2%)
Inflammation	1 (2%)	2 (4%)		
Ovary	(50)	(50)	(50)	(50)
Cyst	7 (14%)	9 (18%)	6 (12%)	5 (10%)
Cyst, Multiple	1 (2%)			
Uterus	(50)	(50)	(50)	(50)
Congestion		1 (2%)		
Hemorrhage		2 (4%)		1 (2%)
Necrosis		1 (2%)		
Endometrium, Hyperplasia, Adenomatous			1 (2%)	
Endometrium, Hyperplasia, Cystic	5 (10%)	5 (10%)	6 (12%)	10 (20%)
Stroma, Hyperplasia			1 (2%)	

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Hemorrhage	1 (2%)			
Hyperplasia	26 (52%)	27 (54%)	19 (38%)	23 (46%)
Inflammation, Histiocytic			1 (2%)	
Myelofibrosis	2 (4%)	1 (2%)	1 (2%)	1 (2%)
Necrosis	1 (2%)			
Lymph Node	(1)	(3)	(3)	(2)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Atrophy	1 (2%)	1 (2%)	1 (2%)	
Inflammation	2 (4%)			
Spleen	(50)	(50)	(50)	(50)

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TDMS No. 20007 - 05
 Test Type: CHRONIC
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P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Kava kava extract
 CAS Number: 9000-38-8

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 Lab: BAT

FISCHER 344 RATS FEMALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Accessory Spleen			1 (2%)	
Fibrosis		3 (6%)		2 (4%)
Hematopoietic Cell Proliferation	19 (38%)	18 (36%)	17 (34%)	7 (14%)
Hyperplasia, Histiocytic	1 (2%)		1 (2%)	
Pigmentation, Hemosiderin	37 (74%)	37 (74%)	41 (82%)	42 (84%)
Lymphoid Follicle, Atrophy	1 (2%)	1 (2%)	4 (8%)	2 (4%)
Lymphoid Follicle, Necrosis	1 (2%)			
Thymus	(50)	(50)	(49)	(48)
Atrophy	48 (96%)	43 (86%)	47 (96%)	45 (94%)
Infiltration Cellular, Plasma Cell	1 (2%)			
Inflammation			1 (2%)	
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Galactoceles			1 (2%)	
Hyperplasia			2 (4%)	
Skin	(50)	(50)	(50)	(50)
Epidermis, Hyperkeratosis			1 (2%)	
Epidermis, Hyperplasia, Basal Cell		1 (2%)		
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Osteopetrosis	1 (2%)			
Skeletal Muscle	(1)	(0)	(1)	(0)
Inflammation	1 (100%)			
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Hemorrhage		2 (4%)	2 (4%)	
Infiltration Cellular, Mixed Cell			1 (2%)	
Necrosis		3 (6%)	2 (4%)	

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TDMS No. 20007 - 05
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P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
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 Lab: BAT

FISCHER 344 RATS FEMALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Peripheral Nerve	(0)	(0)	(1)	(0)
Spinal Cord	(0)	(0)	(1)	(0)
Hemorrhage			1 (100%)	
Necrosis			1 (100%)	

RESPIRATORY SYSTEM

Lung	(50)	(50)	(50)	(50)
Atelectasis	1 (2%)	1 (2%)		
Congestion	1 (2%)			1 (2%)
Hemorrhage				1 (2%)
Inflammation, Chronic Active	4 (8%)	5 (10%)	2 (4%)	7 (14%)
Alveolar Epithelium, Hyperplasia	11 (22%)	14 (28%)	6 (12%)	7 (14%)
Alveolar Epithelium, Hypertrophy	1 (2%)	1 (2%)		
Alveolar Epithelium, Metaplasia	1 (2%)			
Alveolar Epithelium, Metaplasia, Squamous	1 (2%)	3 (6%)		
Alveolus, Infiltration Cellular, Histiocyte	12 (24%)	17 (34%)	12 (24%)	16 (32%)
Mediastinum, Foreign Body	1 (2%)			
Mediastinum, Inflammation, Chronic Active	1 (2%)			
Nose	(50)	(50)	(50)	(50)
Cyst	1 (2%)			
Foreign Body	2 (4%)			
Inflammation	8 (16%)	2 (4%)	9 (18%)	8 (16%)
Glands, Dilatation			1 (2%)	
Olfactory Epithelium, Metaplasia	1 (2%)		1 (2%)	
Respiratory Epithelium, Hyperplasia			1 (2%)	
Pleura	(0)	(0)	(0)	(1)
Mesothelium, Hyperplasia				1 (100%)
Trachea	(50)	(50)	(50)	(50)
Peritracheal Tissue, Inflammation			1 (2%)	

SPECIAL SENSES SYSTEM

Ear	(1)	(0)	(0)	(1)
Eye	(50)	(50)	(50)	(50)

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Kava kava extract
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FISCHER 344 RATS FEMALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Synechia			1 (2%)	
Cornea, Fibrosis	1 (2%)			1 (2%)
Cornea, Inflammation	1 (2%)		2 (4%)	2 (4%)
Lens, Cataract	2 (4%)	3 (6%)	1 (2%)	3 (6%)
Posterior Chamber, Inflammation				1 (2%)
Retina, Degeneration	5 (10%)	5 (10%)	5 (10%)	12 (24%)
Retina, Dysplasia			1 (2%)	
Retina, Gliosis	1 (2%)		3 (6%)	1 (2%)
Retina, Inflammation		1 (2%)		
Zymbal's Gland	(0)	(0)	(0)	(1)

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Accumulation, Hyaline Droplet		2 (4%)	1 (2%)	1 (2%)
Glomerulosclerosis		1 (2%)		
Infarct	2 (4%)	3 (6%)	4 (8%)	3 (6%)
Mineralization	43 (86%)	43 (86%)	45 (90%)	46 (92%)
Nephropathy	34 (68%)	35 (70%)	37 (74%)	43 (86%)
Cortex, Cyst	2 (4%)			
Medulla, Cyst	1 (2%)			
Papilla, Necrosis			1 (2%)	1 (2%)
Pelvis, Inflammation	1 (2%)	1 (2%)	5 (10%)	4 (8%)
Pelvis, Transitional Epithelium, Hyperplasia			4 (8%)	6 (12%)
Pelvis, Transitional Epithelium, Metaplasia			1 (2%)	
Renal Tubule, Dilatation			1 (2%)	
Renal Tubule, Necrosis			1 (2%)	2 (4%)
Urinary Bladder	(50)	(50)	(50)	(50)

*** END OF REPORT ***

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