

TDMS No. 20007 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
Time Report Requested: 10:57:30
First Dose M/F: 08/24/04 / 08/23/04
Lab: BAT

F_M3

C Number: C20007
Lock Date: 05/10/2007
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.1.0

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	DAY ON TEST																								
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	7	7	7	5	5	6	6	7	6	7	7	5	7	7	4	6	6	7	7	7	7	3	6	7	7
	3	3	3	7	7	6	5	3	6	3	3	8	3	3	5	4	4	3	0	3	3	6	4	3	3
	1	2	2	9	0	8	2	2	8	1	1	7	1	0	5	4	7	2	3	1	0	9	8	2	1
B6C3F1 MICE MALE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
0 G/KG	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5

males
(cont...)

ALIMENTARY SYSTEM

Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Gallbladder	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Infiltration Cellular, Mononuclear Cell																								
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Amyloid Deposition																								
Serosa, Inflammation, Granulomatous				2																				
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Inflammation, Chronic										2														
Epithelium, Hyperplasia										2														
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Angiectasis																								
Basophilic Focus				X	X																			
Clear Cell Focus			X		X			X	X								X	X						X

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DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	7	7	7	5	5	6	6	7	6	7	7	5	7	7	4	6	6	7	7	7	7	3	6	7	7
ANIMAL ID	3	3	3	7	7	6	5	3	6	3	3	8	3	3	5	4	4	3	0	3	3	6	4	3	3
	1	2	2	9	0	8	2	2	8	1	1	7	1	0	5	4	7	2	3	1	0	9	8	2	1
B6C3F1 MICE MALE 0 G/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
Degeneration, Cystic Eosinophilic Focus																									
Fatty Change	2		1	2	2																				
Fibrosis																									
Hematopoietic Cell Proliferation																									
Infiltration Cellular, Mononuclear Cell	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1
Mineralization																									
Mixed Cell Focus	X	X	X																						
Necrosis																									
Tension Lipidosis																									
Mesentery																									
Inflammation, Chronic																									
Fat, Necrosis	2																								
Pancreas																									
Acinus, Atrophy																									
Acinus, Hypertrophy																									
Salivary Glands																									
Infiltration Cellular, Mononuclear Cell	1	1	2		2	1	1	1	1	1		1	1	1	1	1		1	1	2			1	1	1
Parotid Gland, Atrophy																									
Stomach, Forestomach																									
Inflammation, Chronic																									
Necrosis																									
Epithelium, Hyperplasia																									
Stomach, Glandular																									

males (cont...)

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	DAY ON TEST																									
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	7	7	7	5	5	6	6	7	6	7	7	5	7	7	4	6	6	7	7	7	7	3	6	7	7	
	3	3	3	7	7	6	5	3	6	3	3	8	3	3	5	4	4	3	0	3	3	6	4	3	3	
	1	2	2	9	0	8	2	2	8	1	1	7	1	0	5	4	7	2	3	1	0	9	8	2	1	
B6C3F1 MICE MALE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
0 G/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	males (cont...)

Infiltration Cellular, Mononuclear Cell																											
Ulcer																											
Epithelium, Hyperplasia																											
Glands, Ectasia																											
Tooth																											
Dysplasia	3	2	4	2	2	1	1		4		2	3									4	3	1	3		1	4

CARDIOVASCULAR SYSTEM

Blood Vessel	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cardiomyopathy																											
Artery, Infiltration Cellular, Mononuclear Cell																											
Mycocardium, Mineralization																											

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hypertrophy																											
Infiltration Cellular, Mononuclear Cell																											
Vacuolization Cytoplasmic																											
Subcapsular, Hyperplasia	4	2	2	2	2	1	1	2		1	1	1		1	1	1	1	2	1	2	1	1	1	1	1	1	
Zona Reticularis, Hyperplasia																											

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	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	7	7	7	5	5	6	6	7	6	7	7	5	7	7	4	6	6	7	7	7	7	3	6	7	7
	3	3	3	7	7	6	5	3	6	3	3	8	3	3	5	4	4	3	0	3	3	6	4	3	3
	1	2	2	9	0	8	2	2	8	1	1	7	1	0	5	4	7	2	3	1	0	9	8	2	1
B6C3F1 MICE MALE	ANIMAL ID																								
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0 G/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5
Adrenal Medulla Hyperplasia	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Islets, Pancreatic Hyperplasia	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Parathyroid Gland Cyst Infiltration Cellular, Mononuclear Cell	M	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Pituitary Gland Cyst Pars Distalis, Hyperplasia	+	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	
Thyroid Gland Atrophy Cyst Follicle, Hyperplasia	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	

males
(cont...)

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	7	7	7	5	5	6	6	7	6	7	7	5	7	7	4	6	6	7	7	7	7	3	6	7	7
	3	3	3	7	7	6	5	3	6	3	3	8	3	3	5	4	4	3	0	3	3	6	4	3	3
	1	2	2	9	0	8	2	2	8	1	1	7	1	0	5	4	7	2	3	1	0	9	8	2	1
Epididymis Granuloma Sperm Infiltration Cellular, Mononuclear Cell	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
	1		1			1	1	1		1	1		1			1	1	1	1	1		1		1	

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DAY ON TEST	0 0																								
	7 7 7 5 5 6 6 7 6 7 7 5 7 7 4 6 6 7 7 7 7 3 6 7 7																								
ANIMAL ID	3 3 3 7 7 6 5 3 6 3 3 8 3 3 5 4 4 3 0 3 3 6 4 3 3																								
	1 2 2 9 0 8 2 2 8 1 1 7 1 0 5 4 7 2 3 1 0 9 8 2 1																								
B6C3F1 MICE MALE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0 G/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5

males
(cont...)

Preputial Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cyst															2	2					2			
Inflammation							1		1				1	2			1				2			
Prostate	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hyperplasia																					1			
Infiltration Cellular, Mononuclear Cell		1					1		1		1		1	1			1	1	1		1			1
Inflammation				1	2	3																		
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Fibrosis	2		1																					
Infiltration Cellular, Mononuclear Cell				1																				
Inflammation	1		1			1																		
Testes	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Inflammation																								
Mineralization																								
Germinal Epithelium, Atrophy																								

HEMATOPOIETIC SYSTEM

Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Lymph Node, Mandibular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Atrophy						3																		

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		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		7	7	7	5	5	6	6	7	6	7	7	5	7	7	4	6	6	7	7	7	7	3	6	7	7	0
		3	3	3	7	7	6	5	3	6	3	3	8	3	3	5	4	4	3	0	3	3	6	4	3	3	0
		1	2	2	9	0	8	2	2	8	1	1	7	1	0	5	4	7	2	3	1	0	9	8	2	1	0
B6C3F1 MICE MALE	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0 G/KG		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		1	2	3	4	5	6	7	8	9	0	1	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2

Spleen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hematopoietic Cell Proliferation	2					3				2		3					1		3							
Hyperplasia, Lymphoid																										
Lymphoid Follicle, Atrophy				3	2	4					2															2
Thymus	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	+	+
Atrophy			1	3	4	4	2	1	4	2	4	4	3	4	1		1		2		2			2	4	
Hyperplasia, Histiocytic	3																									

INTEGUMENTARY SYSTEM

Mammary Gland	M	M	M	M	M	+	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Inflammation, Chronic																										
Ulcer																										

MUSCULOSKELETAL SYSTEM

Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cranium, Hyperostosis																										
Skeletal Muscle																										+

NERVOUS SYSTEM

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DAY ON TEST	0 0																								
	7 7 7 5 5 6 6 7 6 7 7 5 7 7 4 6 6 7 7 7 7 3 6 7 7																								
ANIMAL ID	3 3 3 7 7 6 5 3 6 3 3 8 3 3 5 4 4 3 0 3 3 6 4 3 3																								
	1 2 2 9 0 8 2 2 8 1 1 7 1 0 5 4 7 2 3 1 0 9 8 2 1																								
B6C3F1 MICE MALE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0 G/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1	2	3	4	5	6	7	8	9	0	1	1	1	1	1	1	1	1	1	1	2	2	3	4	5

males (cont...)

Brain +

RESPIRATORY SYSTEM

Lung +
 Alveolar Epithelium, Hyperplasia +
 Alveolus, Infiltration Cellular, Histiocyte 1 2 1
 Bronchus, Hyperplasia 2

Nose +
 Inflammation, Suppurative +
 Inflammation, Chronic 1 1 1 1
 Nasolacrimal Duct, Inflammation, Suppurative 2
 Respiratory Epithelium, Hyperplasia 2

Trachea +

SPECIAL SENSES SYSTEM

Eye +

Harderian Gland +
 Fibrosis +
 Hyperplasia 2 1
 Infiltration Cellular, Mononuclear Cell 1

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DAY ON TEST	0 0																								
	7 7 7 5 5 6 6 7 6 7 7 5 7 7 4 6 6 7 7 7 7 3 6 7 7																								
ANIMAL ID	3 3 3 7 7 6 5 3 6 3 3 8 3 3 5 4 4 3 0 3 3 6 4 3 3																								
	1 2 2 9 0 8 2 2 8 1 1 7 1 0 5 4 7 2 3 1 0 9 8 2 1																								
B6C3F1 MICE MALE 0 G/KG	0 0																								
	0 0																								
	0 0																								
	0 0																								
	1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5																								

males (cont...)

URINARY SYSTEM

Kidney	+ +																								
Hydronephrosis																									
Inflammation	2 2 3																								
Mineralization	3																								
Nephropathy	2 1																								
Cortex, Medulla, Necrosis	3 3 3																								
Papilla, Necrosis	3																								
Renal Tubule, Hyperplasia	1																								
Renal Tubule, Mineralization	1 1 2 2 1																								
Renal Tubule, Pigmentation, Lipofuscin																									
Urethra	+																								
Inflammation	3																								
Urinary Bladder	+ +																								
Infiltration Cellular, Mononuclear Cell	1 1																								
Inflammation	1 1 3																								

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 + .. Tissue examined microscopically
 x .. Lesion present
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 BLANK .. Not examined microscopically
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 2) Mild 4) Marked

DAY ON TEST	0 0																								* TOTALS
	7 7 7 7 7 7 6 7 7 7 7 7 7 7 7 5 7 7 7 6 7 7 7 7 6																								
B6C3F1 MICE MALE 0 G/KG	3 3 3 3 3 3 1 3 3 3 3 3 3 3 3 3 3 3 3 2 3 3 3 3 8																								* TOTALS
	2 2 0 1 0 2 7 2 2 1 1 1 2 1 0 3 2 2 2 6 2 1 0 0 3																								
ANIMAL ID	0 0																								* TOTALS
	0 0																								
ANIMAL ID	2 2 2 2 3 3 3 3 3 3 3 3 3 3 3 4 4 4 4 4 4 4 4 5																								* TOTALS
	6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0																								

ALIMENTARY SYSTEM

Esophagus	+ +																								50				
Gallbladder	+ M + + +																								49				
Infiltration Cellular, Mononuclear Cell																									1	1 1.0			
Intestine Large, Cecum	+ +																								50				
Amyloid Deposition																									2	1 2.0			
Serosa, Inflammation, Granulomatous																									1	2.0			
Intestine Large, Colon	+ +																								50				
Intestine Large, Rectum	+ +																								50				
Intestine Small, Duodenum	+ +																								50				
Intestine Small, Ileum	+ +																								50				
Inflammation, Chronic																									1	2.0			
Epithelium, Hyperplasia																									1	2.0			
Intestine Small, Jejunum	+ +																								50				
Liver	+ +																								50				
Angiectasis	1																								1	1	3 1.0		
Basophilic Focus																										2			
Clear Cell Focus	X X X																								X X	X X	X X	X X	18

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	DAY ON TEST																								* TOTALS	
	0732	0733	0730	0731	0732	0737	0737	0737	0737	0737	0737	0737	0737	0737	0737	0737	0737	0737	0737	0737	0737	0737	0737	0737		0737
B6C3F1 MICE MALE	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	
0 G/KG	226	227	228	229	230	231	232	233	234	235	236	237	238	239	240	241	242	243	244	245	246	247	248	249	250	
Degeneration, Cystic Eosinophilic Focus		X		X	X	X	X	X		X		X	X	X			X	X		X	X	X				1 1.0 28
Fatty Change	2	1	1	1	1	1			1	2	1	1	1			1	1	1	2	1						32 1.3
Fibrosis																										1 2.0
Hematopoietic Cell Proliferation							2																			1 2.0
Infiltration Cellular, Mononuclear Cell	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	49 1.0
Mineralization																										1 1.0
Mixed Cell Focus	X				X						X		X				X	X	X							15
Necrosis																1										3 1.7
Tension Lipidosis	X											X					X									5
Mesentery																										
Inflammation, Chronic																										3
Fat, Necrosis																										2 2.0
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Acinus, Atrophy																										1 4.0
Acinus, Hypertrophy		2								1																2 1.5
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Infiltration Cellular, Mononuclear Cell	1	1	1		1		2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	43 1.1
Parotid Gland, Atrophy																										1 2.0
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Inflammation, Chronic		2			1	2		2				1						2	1		1			2	1	19 1.7
Necrosis						2		1										2						2		8 2.0
Epithelium, Hyperplasia		3			1	2		3				2						2	3		3			2	2	18 2.3
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50

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TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

	DAY ON TEST																								* TOTALS
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	7	7	7	7	7	7	6	7	7	7	7	7	7	7	5	7	7	7	6	7	7	7	7	6	
	3	3	3	3	3	3	1	3	3	3	3	3	3	3	1	3	3	3	2	3	3	3	3	8	
	2	2	0	1	0	2	7	2	2	1	1	1	2	1	0	3	2	2	2	6	2	1	0	3	
B6C3F1 MICE MALE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
0 G/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2	2	2	2	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	5	
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	

Infiltration Cellular, Mononuclear Cell																								1	1		2 1.0	
Ulcer																											1 2.0	
Epithelium, Hyperplasia																											2 2.0	
Glands, Ectasia																										1	1	2 1.0
Tooth	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	33			
Dysplasia	1	1	2	1	4		2	1		4	2		3	1		4	1		3		3	1	3	33 2.3				

CARDIOVASCULAR SYSTEM

Blood Vessel	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Cardiomyopathy																											14 1.2
Artery, Infiltration Cellular, Mononuclear Cell																										1	2 1.0
Myocardium, Mineralization																											1 2.0

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Hypertrophy																											1 1.0
Infiltration Cellular, Mononuclear Cell																											1 1.0
Vacuolization Cytoplasmic																										1	2 1.5
Subcapsular, Hyperplasia	1	1	1		2	1	1	1	1	2	1	2	1	1	1	1	1		1	2		2	1	1	44 1.3		
Zona Reticularis, Hyperplasia																										2	5 2.0

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DAY ON TEST	0 0																								* TOTALS
	7 7 7 7 7 6 7 7 7 7 7 7 7 7 5 7 7 7 6 7 7 7 7 6																								
B6C3F1 MICE MALE 0 G/KG	3 3 3 3 3 1 3 3 3 3 3 3 3 3 1 3 3 3 2 3 3 3 3 8																								
	2 2 0 1 0 2 7 2 2 1 1 1 2 1 0 3 2 2 2 6 2 1 0 0 3																								
ANIMAL ID	0 0																								
	0 0																								
	0 0																								
	2 2 2 2 3 3 3 3 3 3 3 3 3 3 4 4 4 4 4 4 4 4 4 5																								
	6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0																								
Adrenal Medulla Hyperplasia	+ +																								50
																									1 2.0
Islets, Pancreatic Hyperplasia	+ +																								50
	2 1 2 2 3 3 3 1 2 2 2 1 1 2 1 2 3 1 1 1																								37 1.9
Parathyroid Gland Cyst	+ + + M + + + + + + + + + + + + + + + + + +																								47
Infiltration Cellular, Mononuclear Cell																									1 1.0
	2																								1 2.0
Pituitary Gland Cyst	+ +																								49
Pars Distalis, Hyperplasia																									1 1.0
	1																								1 2.0
Thyroid Gland Atrophy	+ +																								50
Cyst																									1 3.0
Follicle, Hyperplasia	2																								4 1.8
	1																								1 2.0

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

Epididymis	+ +																								50
Granuloma Sperm																									2 2.5
Infiltration Cellular, Mononuclear Cell	1 1																								29 1.0

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DAY ON TEST	0 0																								* TOTALS
	7 7 7 7 7 6 7 7 7 7 7 7 7 7 5 7 7 7 6 7 7 7 7 6																								
B6C3F1 MICE MALE 0 G/KG	3 3 3 3 3 1 3 3 3 3 3 3 3 3 1 3 3 3 2 3 3 3 3 8																								
	2 2 0 1 0 2 7 2 2 1 1 1 2 1 0 3 2 2 2 6 2 1 0 0 3																								
ANIMAL ID	0 0																								
	0 0																								
0 G/KG	2 2 2 2 3 3 3 3 3 3 3 3 3 3 4 4 4 4 4 4 4 4 4 5																								
	6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0																								

Preputial Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Cyst					2																				4 2.0
Inflammation						3														4			3 3		10 2.1
Prostate	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Hyperplasia																									1 1.0
Infiltration Cellular, Mononuclear Cell	1	1	1	2	1			1	1	1		1		1	1							1	1	1	29 1.0
Inflammation																			2						4 2.0
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Fibrosis																									2 1.5
Infiltration Cellular, Mononuclear Cell											1			1								1			4 1.0
Inflammation				1										1								1			6 1.0
Testes	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Inflammation															2										1 2.0
Mineralization									1																1 1.0
Germinal Epithelium, Atrophy																					2	2			2 2.0

HEMATOPOIETIC SYSTEM

Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Lymph Node, Mandibular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Atrophy																									1 3.0

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	DAY ON TEST																								
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	7	7	7	7	7	7	6	7	7	7	7	7	7	7	7	5	7	7	7	6	7	7	7	6	
	3	3	3	3	3	3	1	3	3	3	3	3	3	3	3	1	3	3	3	2	3	3	3	3	
	2	2	0	1	0	2	7	2	2	1	1	1	2	1	0	3	2	2	2	6	2	1	0	3	
B6C3F1 MICE MALE																									
0 G/KG	ANIMAL ID																								
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2	2	2	2	3	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	5	
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	
																								* TOTALS	

Spleen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50			
Hematopoietic Cell Proliferation		1				4	3				2	3			1	3					2			16	2.4		
Hyperplasia, Lymphoid								2						2										3	2.0		
Lymphoid Follicle, Atrophy														3						2				6	2.7		
Thymus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	48			
Atrophy	1	4		2	1	4	4	2	4	2	2	2	2	4	3	2	3	3		3	2	4	3	2	4	41	2.7
Hyperplasia, Histiocytic																									1	3.0	

INTEGUMENTARY SYSTEM

Mammary Gland	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	1	
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Inflammation, Chronic																									2	1	2.0
Ulcer																									3	1	3.0

MUSCULOSKELETAL SYSTEM

Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Cranium, Hyperostosis													2													1	2.0
Skeletal Muscle																										2	

NERVOUS SYSTEM

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Page 15

DAY ON TEST	0																								* TOTALS	
	7	7	7	7	7	7	6	7	7	7	7	7	7	7	7	5	7	7	7	6	7	7	7	6		
	3	3	3	3	3	3	1	3	3	3	3	3	3	3	3	1	3	3	3	2	3	3	3	8		
	2	2	0	1	0	2	7	2	2	1	1	1	2	1	0	3	2	2	2	6	2	1	0	3		
B6C3F1 MICE MALE 0 G/KG	ANIMAL ID																								* TOTALS	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	2	2	2	2	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	4		5
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	0		

Brain + 50

RESPIRATORY SYSTEM

Lung	+ +																								50	
Alveolar Epithelium, Hyperplasia																									2	2 1.5
Alveolus, Infiltration Cellular, Histiocyte																										2 1.5
Bronchus, Hyperplasia																									2	2 2.0
Nose	+ +																								50	
Inflammation, Suppurative																										1 2.0
Inflammation, Chronic																									1	9 1.0
Nasolacrimal Duct, Inflammation, Suppurative																									1	1 2.0
Respiratory Epithelium, Hyperplasia																									1	1 2.0
Trachea	+ +																								50	

SPECIAL SENSES SYSTEM

Eye	+ +																								50	
Harderian Gland	+ +																								50	
Fibrosis																									2	1 2.0
Hyperplasia																									3	4 2.0
Infiltration Cellular, Mononuclear Cell																									1	36 1.1

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DAY ON TEST	0																								* TOTALS
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	7	7	7	7	7	7	6	7	7	7	7	7	7	7	7	5	7	7	7	6	7	7	7	7	6
	3	3	3	3	3	3	1	3	3	3	3	3	3	3	3	1	3	3	3	2	3	3	3	3	8
	2	2	0	1	0	2	7	2	2	1	1	1	2	1	0	3	2	2	2	6	2	1	0	0	3
B6C3F1 MICE MALE 0 G/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2	2	2	2	3	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	5
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0

URINARY SYSTEM

Kidney	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50					
Hydronephrosis					2			2															2		6	2.2				
Inflammation													3													2	3.0			
Mineralization																					1						3	1.0		
Nephropathy		1	1	1	3	2	2		1	1			1		1	1		1	1	1	1	4	3	2	2		32	1.4		
Cortex, Medulla, Necrosis													3							4							6	3.2		
Papilla, Necrosis					2																		2	2			3	2.0		
Renal Tubule, Hyperplasia							2					1								2							6	1.3		
Renal Tubule, Mineralization	1		1	1						1	1		1	1	1		1		1	1	1		1		1		31	1.1		
Renal Tubule, Pigmentation, Lipofuscin						2																					1	2.0		
Urethra																														
Inflammation																											2		2	2.5
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50			
Infiltration Cellular, Mononuclear Cell						1		1					1	1			1	1										20	1.0	
Inflammation													3															4	2.0	

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
DAY ON TEST		5	4	7	6	7	7	7	7	7	7	4	6	7	7	7	7	5	6	7	7	7	7	3		
		4	3	3	9	3	3	0	2	3	3	3	6	3	3	3	3	5	2	3	3	3	3	1		
		6	7	1	3	2	2	7	0	1	1	2	1	4	1	1	2	2	3	3	2	2	1	1	2	9
																									
B6C3F1 MICE MALE 0.25 G/KG	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		5	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	7	7	7	7	7	
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5

males
(cont...)

ALIMENTARY SYSTEM

Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Gallbladder	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Jejunum Epithelium, Hyperplasia	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Angiectasis					1	1																		
Basophilic Focus																								
Clear Cell Focus			X			X					X			X	X						X	X		
Eosinophilic Focus	X		X			X		X	X	X		X	X	X	X		X		X	X	X	X		
Fatty Change	1	2		1	1	1	2		1	1		1	1	1	1	2	1	2				2	2	1
Hematopoietic Cell Proliferation							4																	
Infarct																								

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l .. Insufficient tissue
M .. Missing tissue
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BLANK .. Not examined microscopically
1-4 .. Lesion qualified as:
1) Minimal 3) Moderate
2) Mild 4) Marked

	DAY ON TEST																									males (cont...)		
	0 5 4 6	0 4 3 7	0 7 3 1	0 6 9 3	0 7 3 2	0 7 3 2	0 7 0 7	0 7 2 0	0 7 3 1	0 7 3 1	0 7 3 2	0 4 3 1	0 6 3 1	0 7 3 1	0 7 3 2	0 5 3 2	0 6 2 3	0 7 3 2	0 7 3 2	0 7 3 1	0 7 3 1	0 7 3 1	0 7 3 2	0 7 3 1	0 7 3 2			
B6C3F1 MICE MALE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
0.25 G/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	6	6	7	7	7	7	7	7	
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5			
Infiltration Cellular, Mononuclear Cell	1	2	1	1	1	1		1	1	1	1	1		1	1	1		1	1	1	1	1	1	1	1	1		
Mineralization																												
Mixed Cell Focus				X	X	X		X		X		X	X	X							X		X	X				
Necrosis				1											3					2	2							
Tension Lipidosis																X												
Vacuolization Cytoplasmic																												
Centrilobular, Fatty Change																												
Centrilobular, Hypertrophy		1	1		1	1				1		1	1	1		1	1	1	1		1	1	1	1	1	1		
Mesentery				+						+						+										+		
Fat, Necrosis				2						2						2										2		
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Infiltration Cellular, Mononuclear Cell				1						1	1	1	1	1	1	1	1				1	1	1	1	1	1		
Parotid Gland, Mineralization																												
Submandibular Gland, Atrophy								2																				
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Inflammation, Chronic	2						1							1			1			1		1	2	1		2		
Necrosis	1																						2					
Epithelium, Hyperplasia	1						2					1			1		1		1		1	3	2			1		
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Mineralization																												
Glands, Ectasia																												
Tooth				+	+	+	+	+		+	+			+	+	+	+	+		+	+			+		+		

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1) Minimal 3) Moderate
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DAY ON TEST	0 0																								
	5 4 7 6 7 7 7 7 7 7 7 4 6 7 7 7 7 5 6 7 7 7 7 7 3																								
ANIMAL ID	4 3 3 9 3 3 0 2 3 3 3 3 6 3 3 3 3 5 2 3 3 3 3 3 1																								
	6 7 1 3 2 2 7 0 1 1 2 1 4 1 1 2 2 3 3 2 2 1 1 2 9																								
B6C3F1 MICE MALE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0.25 G/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	7	7	7	7	7	
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5

males (cont...)

Dysplasia	2	2	4	3	3	1	2	4	2	3	1	1	3	2	1	2
Inflammation, Suppurative														3		

CARDIOVASCULAR SYSTEM

Blood Vessel	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cardiomyopathy			1			1	3								1	1			1	1				
Inflammation, Suppurative			2																					
Inflammation, Chronic							3																	
Artery, Infiltration Cellular, Mononuclear Cell								1																
Myocardium, Mineralization								1				1												

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hypertrophy																								
Vacuolization Cytoplasmic Subcapsular, Hyperplasia	1	2	2	1	2	1		1	1	1	1	2	1	1	1	2		1		1	2	2	2	
Zona Reticularis, Hyperplasia						2															2			
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hyperplasia	3		2	2	1	2	1		3	2	2		2	2		3	1		2		1	2	1	1

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 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

	DAY ON TEST	Animals																									males (cont...)
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	5	4	7	6	7	7	7	7	7	7	7	4	6	7	7	7	7	5	6	7	7	7	7	7	3		
	4	3	3	9	3	3	0	2	3	3	3	3	6	3	3	3	3	5	2	3	3	3	3	3	1		
	6	7	1	3	2	2	7	0	1	1	2	1	4	1	1	2	2	3	3	2	2	1	1	2	9		
B6C3F1 MICE MALE 0.25 G/KG	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
		5	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	7	7	7	7	7		
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	

Parathyroid Gland
Cyst

+ + + M + + + + + + + M M + + + + + + + M + + + +

Pituitary Gland

+ +

Thyroid Gland

+ +

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

Coagulating Gland
Hyperplasia

+
2

Epididymis
Infiltration Cellular, Mononuclear Cell
Inflammation, Chronic

+
 1 2 1 1 1 1 1 1

Penis
Infiltration Cellular, Polymorphonuclear

+
1

Preputial Gland
Cyst
Inflammation

+
 2 2
 1

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

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1) Minimal 3) Moderate

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TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
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Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | males
(cont...) |
|---|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| B6C3F1 MICE MALE | 5 | 4 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 4 | 6 | 7 | 7 | 7 | 7 | 5 | 6 | 7 | 7 | 7 | 7 | 3 | | |
| 0.25 G/KG | 4 | 3 | 3 | 9 | 3 | 3 | 0 | 2 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 5 | 2 | 3 | 3 | 3 | 3 | 1 | | |
| | 6 | 7 | 1 | 3 | 2 | 2 | 7 | 0 | 1 | 1 | 2 | 1 | 4 | 1 | 1 | 2 | 2 | 3 | 3 | 2 | 2 | 1 | 1 | 2 | 9 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | |
| Prostate | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Infiltration Cellular, Mononuclear Cell | | | | 1 | | | 1 | | | 1 | 1 | 1 | | | 1 | 1 | | 1 | | 1 | 1 | 1 | 1 | 1 | | |
| Inflammation | 3 | | 1 | 3 | | | 2 | | | | | | | | | | | 2 | 2 | | | | | | | |
| Mineralization | | | | | | | | | | | | | | 1 | | | | | | | | | | | | |
| Seminal Vesicle | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Infiltration Cellular, Mononuclear Cell | | | | | | | | | | | | | | 1 | | | | | | | | | | | | |
| Inflammation | 2 | | | | | | | | | | | | | | | | | | 1 | 2 | | | | | | |
| Testes | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Germinal Epithelium, Atrophy | | | | | | | | | | | | | | | | | | | | | | | | 1 | | |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Lymph Node | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mandibular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | 3 | | | |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Hyperplasia, Lymphoid | | | | 3 | | | | | | | | | | | | | | | | | | | | | |
| Spleen | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Hematopoietic Cell Proliferation | | | | | | | 3 | 3 | | | | | 2 | | 1 | | 2 | | 2 | 2 | | | 1 | | |
| Hyperplasia, Lymphoid | | | | | | | | | 2 | | | | | | | | | | | | | | | | |
| Lymphoid Follicle, Atrophy | | | | 2 | | | | | | | | | | | | | | | 4 | | | | | 1 | |

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 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
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 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 5 4 7 6 7 7 7 7 7 7 7 4 6 7 7 7 7 5 6 7 7 7 7 7 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 4 3 3 9 3 3 0 2 3 3 3 3 6 3 3 3 3 5 2 3 3 3 3 3 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 7 1 3 2 2 7 0 1 1 2 1 4 1 1 2 2 3 3 2 2 1 1 2 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0.25 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

males (cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Thymus | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Atrophy | | | 3 | 3 | | 3 | | 4 | 2 | 2 | 2 | | 4 | 2 | 4 | 2 | 1 | | 3 | 2 | 4 | 2 | 2 | 1 | 4 |
| Ectopic Thyroid | | | | | | | | | | | | | | 1 | | | | | | | | | | | |
| Hyperplasia, Histiocytic | | | | | | | | | | | | | | | | | | | | | | | | | |
| Epithelial Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 2 |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mammary Gland | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | |
| Ulcer | | | | | | | | | | | | | | | | | | | | | | | | | |

MUSCULOSKELETAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

NERVOUS SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | |

RESPIRATORY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
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 M .. Missing tissue
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 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 23

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 5 4 7 6 7 7 7 7 7 7 7 4 6 7 7 7 7 5 6 7 7 7 7 7 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 4 3 3 9 3 3 0 2 3 3 3 3 6 3 3 3 3 5 2 3 3 3 3 3 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 7 1 3 2 2 7 0 1 1 2 1 4 1 1 2 2 3 3 2 2 1 1 2 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0.25 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

males (cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Alveolar Epithelium, Hyperplasia | | | | | | | | | 1 | | | | | | | | | | | | | 1 | | |
| Alveolus, Infiltration Cellular, Histiocyte | | | | | | | | | | | 1 | 1 | | | | | | | | | | | | 3 |
| Bronchus, Hyperplasia | | | | | | | | | | | 1 | | | | | | | | | | | 1 | | |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation, Suppurative | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Chronic | | | | 1 | | | | | | | | | | 1 | | | | | 1 | | 1 | 1 | | |
| Polyp, Inflammatory | | | | | 2 | | | | | | | | | | | | | | | | | | | |
| Nasolacrimal Duct, Inflammation, Suppurative | | | | | | | 2 | | | | | | | | | | | | | | | | | |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | 2 | |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Degeneration | | | | | | | | | | | | | | | | | | | | | | | | |
| Cornea, Inflammation, Chronic | | | | 3 | | | | | | | | | | | | | | | | | | | | |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | 3 | | |
| Infiltration Cellular, Mononuclear Cell | | | | | | 1 | 1 | 1 | 1 | | | 1 | | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 5 4 7 6 7 7 7 7 7 7 7 4 6 7 7 7 7 5 6 7 7 7 7 7 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 4 3 3 9 3 3 0 2 3 3 3 3 6 3 3 3 3 5 2 3 3 3 3 3 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 7 1 3 2 2 7 0 1 1 2 1 4 1 1 2 2 3 3 2 2 1 1 2 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
0.25 G/KG | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 6 6 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 | | | | | | | | | | | | | | | | | | | | | | | | |

males (cont...)

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Kidney | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Hydronephrosis | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Metaplasia, Osseous | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | | | |
| Nephropathy | 2 1 1 1 1 1 1 1 1 2 1 1 1 1 1 1 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Thrombosis | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Renal Tubule, Dilatation | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Renal Tubule, Hyperplasia | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Renal Tubule, Mineralization | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Urethra | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Cyst | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Urinary Bladder | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | 1 3 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | 1 4 4 | | | | | | | | | | | | | | | | | | | | | | | | |
| Transitional Epithelium, Hyperplasia | 4 | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 25

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 5 7 7 6 7 4 7 7 7 7 6 4 7 7 7 7 6 7 5 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 9 3 3 9 3 2 3 3 3 3 6 8 3 3 3 3 8 3 5 3 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 6 2 1 5 2 3 1 2 2 2 4 4 2 1 2 1 7 1 3 2 1 0 2 2 | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
0.25 G/KG | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 9 | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | * TOTALS | | | | | | | | | | | | | | | | | | | | | | | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|-----------|--------------|---------------|
| Esophagus | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | |
| Gallbladder | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | |
| Intestine Large, Cecum | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | |
| Intestine Large, Colon | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | |
| Intestine Large, Rectum | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | |
| Intestine Small, Duodenum | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | |
| Intestine Small, Ileum | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | |
| Intestine Small, Jejunum Epithelium, Hyperplasia | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | |
| | 3 | | | | | | | | | | | | | | | | | | | | | | | | 3 | 2 3.0 | |
| Liver | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | |
| Angiectasis | 1 | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 | 6 1.0 |
| Basophilic Focus | X | | | | | | | | | | | | | | | | | | | | | | | | 3 | 3 | 18 |
| Clear Cell Focus | X X | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2 | 32 |
| Eosinophilic Focus | X | | | | | | | | | | | | | | | | | | | | | | | | 32 | 32 | 34 1.3 |
| Fatty Change | 1 1 1 2 1 2 1 | | | | | | | | | | | | | | | | | | | | | | | | 11 | 11 | 2 2.5 |
| Hematopoietic Cell Proliferation | 1 | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 | 1 3.0 |
| Infarct | | | | | | | | | | | | | | | | | | | | | | | | | 0 | 0 | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|---|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-----------|
| | 0731 | 0756 | 0772 | 0776 | 0675 | 0742 | 0774 | 0777 | 0777 | 0777 | 0676 | 0474 | 0477 | 0777 | 0777 | 0676 | 0775 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | | |
| B6C3F1 MICE MALE | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | | |
| 0.25 G/KG | 7766 | 7777 | 7778 | 7779 | 8800 | 8801 | 8802 | 8803 | 8804 | 8805 | 8806 | 8807 | 8808 | 8809 | 9900 | 9901 | 9902 | 9903 | 9904 | 9905 | 9906 | 9907 | 9908 | 9909 | |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 2 | 47 |
| Mineralization | | | | | | 2 | | | | | | | | | | | 1 | | | | | | | | 2 |
| Mixed Cell Focus | X | | X | X | | | | X | X | X | | | X | X | X | X | X | X | X | X | X | X | X | | 28 |
| Necrosis | | | 2 | | 2 | 3 | | | | 1 | | | | | | | 2 | | | | | | 2 | | 10 |
| Tension Lipidosis | | | | | | | | | | | | | | | | | | X | | | | | | | 2 |
| Vacuolization Cytoplasmic | | | | | | 2 | | | | | | | | | | | | | | | | | | | 1 |
| Centrilobular, Fatty Change | | | | | | | | | | | | | | | | | | | 3 | | | | | | 1 |
| Centrilobular, Hypertrophy | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | | | 1 | 1 | | | 2 | 1 | | 1 | 1 | 1 | 1 | | 34 |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | 6 |
| Fat, Necrosis | | | + | | | + | | | | | | | | | | | | | | | | | | | 6 |
| Pancreas | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Salivary Glands | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Infiltration Cellular, Mononuclear Cell | 1 | | | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 3 | 1 | 2 | 1 | | 1 | 1 | | 1 | 1 | 36 |
| Parotid Gland, Mineralization | | | | | | | | | | | | | | | 1 | | | | | | | | | | 1 |
| Submandibular Gland, Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Stomach, Forestomach | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Inflammation, Chronic | 2 | 2 | | | | 2 | | 1 | 2 | | | 2 | 2 | | | 2 | | | 1 | 2 | | 1 | | 2 | 22 |
| Necrosis | 2 | | | | 2 | | 2 | | | | | 2 | | | | 2 | | | 2 | 2 | | | | 2 | 11 |
| Epithelium, Hyperplasia | 2 | 1 | | | 2 | | 2 | | 2 | | | 2 | 2 | | | 2 | | | 1 | 2 | | 1 | | 1 | 22 |
| Stomach, Glandular | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 |
| Glands, Ectasia | | | | | | | 1 | | | | | | | | | | | | | | | | | | 1 |
| Tooth | | | | | | | | | | | | | | | | | | | | | | | | | 32 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ .. Tissue examined microscopically
x .. Lesion present
I .. Insufficient tissue
M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically
1-4 .. Lesion qualified as:
1) Minimal 3) Moderate
2) Mild 4) Marked

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|-------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|-----------------|
| | 7 5 7 7 6 7 4 7 7 7 7 6 4 7 7 7 7 6 7 5 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
0.25 G/KG | 3 9 3 3 9 3 2 3 3 3 3 6 8 3 3 3 3 8 3 5 3 3 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
| | 1 6 2 1 5 2 3 1 2 2 2 4 4 2 1 2 1 7 1 3 2 1 0 2 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
| 0.25 G/KG | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 9 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
| | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| Dysplasia | 1 2 3 | | | | | | | | | | | | | | | | | | | | | | | | 32 2.1
1 3.0 |
| Inflammation, Suppurative | 2 1 3 1 1 3 3 1 2 1 1 4 2 | | | | | | | | | | | | | | | | | | | | | | | | |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------|
| Blood Vessel | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Heart | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Cardiomyopathy | 1 | | | | | | | | | | | | | | | | | | | | | | | | 16 1.1 |
| Inflammation, Suppurative | 1 | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Inflammation, Chronic | 1 | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Artery, Infiltration Cellular, Mononuclear Cell | 1 | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Myocardium, Mineralization | 1 | | | | | | | | | | | | | | | | | | | | | | | | 4 1.0 |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------|
| Adrenal Cortex | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Hypertrophy | 1 | | | | | | | | | | | | | | | | | | | | | | | | 2 1.0 |
| Vacuolization Cytoplasmic | 1 | | | | | | | | | | | | | | | | | | | | | | | | 2 1.0 |
| Subcapsular, Hyperplasia | 1 2 1 1 1 1 2 1 1 1 1 1 1 1 1 2 2 2 1 2 2 1 1 | | | | | | | | | | | | | | | | | | | | | | | | 45 1.3 |
| Zona Reticularis, Hyperplasia | 1 | | | | | | | | | | | | | | | | | | | | | | | | 3 1.7 |
| Adrenal Medulla | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Islets, Pancreatic | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Hyperplasia | 2 1 2 1 2 2 2 2 2 2 2 1 1 3 2 1 1 2 1 2 | | | | | | | | | | | | | | | | | | | | | | | | 35 1.7 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | | |
|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|---|--|
| | 7 5 7 7 6 7 4 7 7 7 7 6 4 7 7 7 7 6 7 5 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 9 3 3 9 3 2 3 3 3 3 6 8 3 3 3 3 8 3 5 3 3 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 6 2 1 5 2 3 1 2 2 2 4 4 2 1 2 1 7 1 3 2 1 0 2 2 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 0.25 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|
| Parathyroid Gland Cyst | + | + | + | + | + | + | M | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | 44 | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 2.0 |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |

GENERAL BODY SYSTEM
 NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|--------|
| Coagulating Gland Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 2.0 |
| Epididymis Infiltration Cellular, Mononuclear Cell Inflammation, Chronic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 22 1.2 |
| | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 2.0 |
| Penis Infiltration Cellular, Polymorphonuclear | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 1.0 |
| Preputial Gland Cyst Inflammation | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 5 2.0 |
| | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 4 1.0 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
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 1) Minimal 3) Moderate
 2) Mild 4) Marked

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|-------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| | 7 5 7 7 6 7 4 7 7 7 7 6 4 7 7 7 7 6 7 5 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 9 3 3 9 3 2 3 3 3 3 6 8 3 3 3 3 8 3 5 3 3 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
| | 1 6 2 1 5 2 3 1 2 2 2 4 4 2 1 2 1 7 1 3 2 1 0 2 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| 0.25 G/KG | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 9 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------|
| Prostate | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Infiltration Cellular, Mononuclear Cell | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | 1 1 1 1 1 1 1 1 1 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | | | | | | | | | | | | | | | | | | | | | | | | 31 1.0 |
| Mineralization | 2 2 2 | | | | | | | | | | | | | | | | | | | | | | | | 9 2.1 |
| Seminal Vesicle | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Infiltration Cellular, Mononuclear Cell | 1 1 1 | | | | | | | | | | | | | | | | | | | | | | | | 4 1.0 |
| Inflammation | 1 1 1 | | | | | | | | | | | | | | | | | | | | | | | | 5 1.4 |
| Testes | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Germinal Epithelium, Atrophy | 2 3 2 | | | | | | | | | | | | | | | | | | | | | | | | 4 2.0 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------|
| Bone Marrow | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Lymph Node | + | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Lymph Node, Mandibular | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Hyperplasia, Lymphoid | 3 4 | | | | | | | | | | | | | | | | | | | | | | | | 3 3.3 |
| Lymph Node, Mesenteric | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Spleen | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Hematopoietic Cell Proliferation | 3 2 1 1 1 4 3 1 1 2 | | | | | | | | | | | | | | | | | | | | | | | | 19 1.9 |
| Hyperplasia, Lymphoid | 2 2 | | | | | | | | | | | | | | | | | | | | | | | | 3 2.0 |
| Lymphoid Follicle, Atrophy | 3 2 | | | | | | | | | | | | | | | | | | | | | | | | 5 2.4 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|---|
| | 7 5 7 7 6 7 4 7 7 7 7 6 4 7 7 7 7 6 7 5 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 9 3 3 9 3 2 3 3 3 3 6 8 3 3 3 3 8 3 5 3 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 6 2 1 5 2 3 1 2 2 2 4 4 2 1 2 1 7 1 3 2 1 0 2 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 0.25 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | |
| | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
| | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|--------|
| Thymus | + | M | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 47 | |
| Atrophy | 4 | | 4 | 2 | 4 | | | 2 | 4 | 4 | 4 | 4 | 2 | 2 | 4 | 1 | 2 | 4 | 3 | 4 | 1 | 2 | 4 | 1 | 4 | 41 2.8 |
| Ectopic Thyroid | | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Hyperplasia, Histiocytic | | | | | | | | 2 | | | | | | | | | | | | | | | | | | 1 2.0 |
| Epithelial Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Mammary Gland | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | 0 |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Ulcer | | | | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 |

MUSCULOSKELETAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
|------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|

NERVOUS SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |

RESPIRATORY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | | |
|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|---|--|
| | 7 5 7 7 6 7 4 7 7 7 7 6 4 7 7 7 7 6 7 5 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 9 3 3 9 3 2 3 3 3 3 6 8 3 3 3 3 8 3 5 3 3 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 6 2 1 5 2 3 1 2 2 2 4 4 2 1 2 1 7 1 3 2 1 0 2 2 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 0.25 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Inflammation | 2 | | | | | | | | | | | | | | | | | | | | | | | | | 2 1.5 |
| Alveolar Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 3 1.0 |
| Alveolus, Infiltration Cellular, Histiocyte | 3 | | | | | 2 | | | | | | | | | | | | | | | | | | | | 6 1.8 |
| Bronchus, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 2 1.0 |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Inflammation, Suppurative | | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | 8 1.0 |
| Polyp, Inflammatory | | | | | | | | | | | | | | | | | | | | | | | | | | 2 2.0 |
| Nasolacrimal Duct, Inflammation, Suppurative | | | | | | | | | | | | | | | | | | | | | | | | | | 2 2.0 |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|
| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Degeneration | | | | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 |
| Cornea, Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 3 2.3 |
| Infiltration Cellular, Mononuclear Cell | 1 | | 1 | 1 | | | | | | | | | | | | | | | | | | | | | | 30 1.0 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ .. Tissue examined microscopically
x .. Lesion present
I .. Insufficient tissue
M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically
1-4 .. Lesion qualified as:
1) Minimal 3) Moderate
2) Mild 4) Marked

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 10:57:30

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 6 | 6 | 7 | 7 | 7 | 6 | 5 | 7 | 7 | 7 | 5 | 6 | 7 |
| 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 2 | 7 | 3 | 3 | 3 | 7 | 3 | 3 | 3 | 3 | 8 | 0 | 3 | 3 |
| 1 | 2 | 1 | 2 | 2 | 1 | 1 | 1 | 1 | 1 | 6 | 2 | 3 | 0 | 0 | 1 | 2 | 9 | 4 | 0 | 1 | 1 | 0 | 5 | 1 | 2 |
| B6C3F1 MICE MALE
0.5 G/KG | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

males (cont...)

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Gallbladder
Infiltration Cellular, Mononuclear Cell
Inflammation, Granulomatous | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Ileum
Inflammation, Chronic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Jejunum
Peyer's Patch, Hyperplasia, Lymphoid | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Liver
Amyloid Deposition | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Angiectasis | | | | | | | | 1 | 1 | 2 | | | | | 1 | | | | | | | | | | |
| Basophilic Focus | X | | | | | | | | | | | | | | | | | | | | | | | | |
| Clear Cell Focus | X | | | X | X | X | X | | | | | | X | X | | | | | X | | | | | X | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | males
(cont...) | |
|---|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|--------------------|--|
| | 0
7
3
1 | 0
7
3
2 | 0
7
3
1 | 0
7
3
2 | 0
7
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2 | 0
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1 | 0
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1 | 0
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1 | 0
7
3
1 | 0
7
3
1 | | |
| B6C3F1 MICE MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 0.5 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | |
| Degeneration, Cystic Eosinophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fatty Change | X | X | X | X | X | X | X | X | X | X | | | | | | | | | | | | | | | | |
| Hepatodiaphragmatic Nodule | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | | | 1 | | 1 | 1 | | | | | | | | | | | | |
| Infarct | | | | 3 | | | | | | | | | | | | | | | 2 | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | | |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | | | 2 | |
| Mixed Cell Focus | X | | | | X | | | X | | | | | | X | X | | | | X | X | | | | | | |
| Necrosis | | | | | | | 2 | | | | | | | | | 2 | | | | 2 | | | | 2 | | |
| Tension Lipidosis | | | | | | | | | | | | | X | | | | | | | | | | | | | |
| Centrilobular, Hypertrophy | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | | | | 2 | | 2 | | 2 | | | |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fat, Necrosis | | | | | | | + | | | | | | | | | | | | | | | | | | | |
| Pancreas | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Granulomatous | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Acinus, Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Salivary Glands | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | | 1 | 1 | | | |
| Parotid Gland, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 2 | |
| Stomach, Forestomach | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ .. Tissue examined microscopically
x .. Lesion present
I .. Insufficient tissue
M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically
1-4 .. Lesion qualified as:
1) Minimal 3) Moderate
2) Mild 4) Marked

TDMS No. 20007 - 06
 Test Type: CHRONIC
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P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 7 7 7 7 7 7 7 7 7 6 7 6 6 7 7 7 6 5 7 7 7 5 6 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 3 3 3 3 3 1 3 2 7 3 3 3 7 3 3 3 3 8 0 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 2 1 2 2 1 1 1 1 6 2 3 0 0 1 2 9 4 0 1 1 0 5 1 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0.5 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |
| | males (cont...) | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Stomach, Glandular Infiltration Cellular, Mononuclear Cell Glands, Ectasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Tooth Dysplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | 3 | 1 | 2 | 4 | 3 | | 4 | 2 | | | | 2 | 3 | | 2 | 1 | | | | | 3 | | 1 | 4 | |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Blood Vessel | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Heart Cardiomyopathy Artery, Infiltration Cellular, Mononuclear Cell | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | | | | | 2 | 1 | 1 | | 1 | 1 | | 3 | | | | | | | | | 1 | | | | |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adrenal Cortex Vacuolization Cytoplasmic Subcapsular, Hyperplasia Zona Reticularis, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | | | | | | 1 | | | | | | | 2 | | | | | | | | | | | | |
| | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 1 | 1 | 1 | 1 | 2 | 1 | 2 | 1 | | 2 | 2 | 1 | 1 | 1 | 1 | 1 |
| Adrenal Medulla Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | | | | | | 2 | | | | | | | | | | | | | | | | | | | |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 36

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 7 7 7 7 7 7 7 7 7 7 6 7 6 6 7 7 7 6 5 7 7 7 5 6 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 3 3 3 3 3 3 1 3 2 7 3 3 3 7 3 3 3 3 8 0 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 2 1 2 2 1 1 1 1 1 6 2 3 0 0 1 2 9 4 0 1 1 0 5 1 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0.5 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

males (cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Prostate | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Fibrosis | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | 1 1 1 1 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | 1 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Seminal Vesicle | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | 1 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Testes | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Germinal Epithelium, Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Bone Marrow | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node | | | | | | | | | | | | | | | | | | | | | | | | | |
| Renal, Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mandibular | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Lymphoid | 4 | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mesenteric | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | |
| Spleen | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Angiectasis | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Hematopoietic Cell Proliferation | 1 2 2 2 2 1 2 1 1 2 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Lymphoid | 2 4 | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
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 Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 7 7 7 7 7 7 7 7 7 6 7 6 6 7 7 7 6 5 7 7 7 5 6 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 3 3 3 3 3 1 3 2 7 3 3 3 7 3 3 3 3 8 0 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 2 1 2 2 1 1 1 1 6 2 3 0 0 1 2 9 4 0 1 1 0 5 1 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 0.5 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

males (cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lymphoid Follicle, Atrophy | | | | | | | | | | | | | | | | | | | | | | | | |
| Thymus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Atrophy | 2 | 2 | 2 | 3 | 3 | 4 | 2 | 2 | 3 | 3 | 2 | 4 | 4 | 2 | | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 |
| Infiltration Cellular, Histiocyte | | | | | | | | | | | | | | | | | | | | | | | | |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|--|--|---|
| Mammary Gland | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | | | | |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | | |
| Cyst Epithelial Inclusion | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Ulcer | | | | | | | | | | 3 | | | | | | | 3 | | | | | | | 3 | | | | 3 |

MUSCULOSKELETAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Skeletal Muscle | | | | | | | | | | | | | | | | | | | | | | | | + |

NERVOUS SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hypothalamus, Compression | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 39

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 7 7 7 7 7 7 7 7 6 7 6 6 7 7 7 6 5 7 7 7 5 6 7 7 | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 3 3 3 3 3 1 3 2 7 3 3 3 7 3 3 3 3 8 0 3 3 | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 2 1 2 2 1 1 1 1 6 2 3 0 0 1 2 9 4 0 1 1 0 5 1 2 | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
0.5 G/KG | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 | | | | | | | | | | | | | | | | | | | | | | | |

males (cont...)

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|---|--|--|--|--|--|--|--|--|--|--|--|---|--|
| Lung | + | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Metaplasia, Osseous | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Alveolar Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Alveolus, Infiltration Cellular, Histiocyte | 2 | | | | | | | | | | | | 1 | | | | | | | | | | | | 3 | |
| Bronchus, Infiltration Cellular, Histiocyte | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Nose | + | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Suppurative | 1 | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Inflammation, Chronic | | | | | | | | | | | | | 1 | | | | | | | | | | | | | |
| Nasolacrimal Duct, Inflammation, Suppurative | | | | | | | | | | | | | 1 | | | | | | | | | | | | 2 | |
| Respiratory Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Trachea | + | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Chronic | | | | | | | | | | | | | 2 | | | | | | | | | | | | | |
| Epithelium, Cytoplasmic Alteration | | | | | | | | | | | | | 2 | | | | | | | | | | | | | |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Eye | + | | | | | | | | | | | | | | | | | | | | | | | | | |
| Cornea, Inflammation, Chronic | | | | | | | | | | | | | 2 | | | | | | | | | | | | | |
| Harderian Gland | + | | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract

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Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 7 7 7 7 7 7 7 7 7 6 7 6 6 7 7 7 6 5 7 7 7 5 6 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 3 3 3 3 3 1 3 2 7 3 3 3 7 3 3 3 3 8 0 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 2 1 2 2 1 1 1 1 6 2 3 0 0 1 2 9 4 0 1 1 0 5 1 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 0.5 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |
| | males (cont...) | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Hyperplasia | 4 | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Inflammation, Granulomatous | 2 | | | | | | | | | | | | | | | | | | | | | | | |

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|--|---|---|---|---|--|---|---|---|---|---|---|---|
| Kidney | + | | | | | | | | | | | | | | | | | | | | | | | |
| Amyloid Deposition | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | |
| Nephropathy | 1 | | 1 | | 1 | 1 | 1 | 1 | 2 | | 1 | | 1 | 1 | 2 | 1 | | 4 | 2 | 2 | 1 | | 1 | 1 |
| Renal Tubule, Cyst | 2 | | | | | | | | | | | | | | | | | | | | | | | |
| Renal Tubule, Hyperplasia | 1 | | | | | | | | | | | | | | | | | | | | | | | |
| Renal Tubule, Mineralization | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | 2 | | 1 | 1 | | 1 | | 2 | 2 | | | | | |
| Renal Tubule, Pigmentation, Lipofuscin | 2 | | | | | | | | | | | | | | | | | | | | | | | |
| Urinary Bladder | + | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | 1 | | 1 | 1 | 1 | | | | | | | | | | | 1 | 1 | | 1 | 1 | | 1 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ .. Tissue examined microscopically
x .. Lesion present
I .. Insufficient tissue
M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically
1-4 .. Lesion qualified as:
1) Minimal 3) Moderate
2) Mild 4) Marked
Page 41

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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 Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|--|
| | 7 7 7 7 6 7 7 7 6 6 7 7 7 7 6 7 4 7 7 7 4 7 6 7 7 | | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 6 2 3 3 5 8 3 3 3 1 8 3 5 3 3 3 9 3 6 3 3 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 2 1 0 8 9 1 2 3 3 1 1 0 1 3 1 5 1 2 1 4 0 0 0 2 | | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 0.5 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | |
| | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Gallbladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Infiltration Cellular, Mononuclear Cell | | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Inflammation, Granulomatous | | | | | | | | | | | | | | | | | | | | | | 2 | | | | 1 2.0 |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Peyer's Patch, Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Amyloid Deposition | | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | | 7 1.1 |
| Basophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Clear Cell Focus | X | X | | | | | | | | | | | | | | | | | | | | | | | | 19 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|---|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------------|----------|
| | 0732 | 0733 | 0731 | 0730 | 0728 | 0727 | 0727 | 0727 | 0726 | 0726 | 0727 | 0727 | 0727 | 0727 | 0726 | 0727 | 0724 | 0727 | 0727 | 0727 | 0724 | 0726 | 0727 | 0727 | |
| B6C3F1 MICE MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 0.5 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| ANIMAL ID | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | |
| | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | |
| Degeneration, Cystic Eosinophilic Focus | X | X | X | | X | X | X | X | X | | X | X | X | X | | X | X | X | | X | X | X | X | 1 1.0
42 | |
| Fatty Change | | 1 | | | | | | 1 | 1 | | | | 2 | 1 | 1 | | 1 | | | 3 | | 1 | 1 | 27 1.2
1 | |
| Hepatodiaphragmatic Nodule Infarct | | | | | | | | | | | | | | X | | | | | | | | | | 2 2.5 | |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 47 1.0 | |
| Mineralization | | | | | | | | | | | | | | | | | | | | 1 | | | | 2 1.5 | |
| Mixed Cell Focus | | X | | | | | | | X | X | X | X | X | | X | | | | X | | | | | 15 | |
| Necrosis | | | | | | | | | | | | | | 1 | | | 3 | | | | | 2 | | 7 2.0 | |
| Tension Lipidosis | | | | | | | | X | | | | | | X | | | | | | | | | | 3 | |
| Centrilobular, Hypertrophy | 2 | 2 | | 2 | 2 | | | 2 | 2 | | 2 | | 2 | 2 | | 2 | 2 | | | 2 | | 2 | | 30 2.0 | |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | 2 | |
| Fat, Necrosis | | | | | | | | | 2 | | | | | | | | | | | | | | | 2 2.0 | |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Inflammation, Granulomatous | | | | | | | | | | | | | | | | | | | | 1 | | | | 1 1.0 | |
| Inflammation, Chronic Acinus, Atrophy | | | | 2 | | | | | | | | | | 3 | | | | | | | | | | 1 2.0
1 3.0 | |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | | | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 40 1.0 | |
| Parotid Gland, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Inflammation, Chronic | | | 2 | | | | | | | | | | 1 | | 1 | | 2 | | 1 | 2 | 1 | 1 | 1 | 24 1.6 | |
| Mineralization | | | | | | | | | | | | | | | | | | | | | 1 | | | 1 1.0 | |
| Necrosis | | | | | | | | | | | | | | | 2 | | | | | 3 | | | | 12 2.3 | |
| Epithelium, Hyperplasia | | | 2 | | | | | | | | | 2 | | 1 | | 2 | | 2 | 2 | 2 | 2 | 2 | 1 | 25 2.0 | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ .. Tissue examined microscopically
x .. Lesion present
I .. Insufficient tissue
M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically
1-4 .. Lesion qualified as:
1) Minimal 3) Moderate
2) Mild 4) Marked

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 10:57:30

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
| | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 7 | 4 | 7 | 7 | 7 | 4 | 7 | 6 | 7 | 7 | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
| | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | |
| B6C3F1 MICE MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 0.5 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | |
| | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|-----|-----|
| Stomach, Glandular Infiltration Cellular, Mononuclear Cell Glands, Ectasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 2 | 1.0 | |
| | | | | | | | | | 1 | | | | | | | | | | | | | | | | | | | | 1.0 |
| Tooth Dysplasia | + | | | | + | + | | | | | | + | + | + | + | + | | | + | + | + | + | | | + | 27 | 27 | 2.4 | |
| | 3 | | | | 3 | 3 | | | | | | 1 | 2 | 3 | 4 | 4 | | | 2 | 2 | 1 | 2 | | | 1 | | | | |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|-----|
| Blood Vessel | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 11 | 1.3 |
| Cardiomyopathy | | | | | | | | | 1 | | | | | | | | | | | | | | | | | | | 1.0 |
| Artery, Infiltration Cellular, Mononuclear Cell | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|-----|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 2 | 1.5 |
| Vacuolization Cytoplasmic Subcapsular, Hyperplasia | 2 | 1 | 1 | 1 | 2 | 2 | 1 | 1 | 2 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | | 48 | 1.3 |
| Zona Reticularis, Hyperplasia | | | | | 1 | | | | | | | | | | | | | | | | | | | | 2 | | | 1.5 |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 | 2.0 |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ .. Tissue examined microscopically
x .. Lesion present
I .. Insufficient tissue
M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically
1-4 .. Lesion qualified as:
1) Minimal 3) Moderate
2) Mild 4) Marked

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------------|
| | 7 7 7 7 6 7 7 7 6 6 7 7 7 7 6 7 4 7 7 7 4 7 6 7 7
3 3 3 3 6 2 3 3 5 8 3 3 3 1 8 3 5 3 3 3 9 3 6 3 3
2 2 1 0 8 9 1 2 3 3 1 1 0 1 3 1 5 1 2 1 4 0 0 0 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
0.5 G/KG | ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | | 1 | | | | | | | | | | | | | | | | | | | | | | | |
| | | 2 2 2 2 3 3 3 3 3 3 3 3 3 3 4 4 4 4 4 4 4 4 4 5 | | | | | | | | | | | | | | | | | | | | | | | |
| | | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia | 2 | 1 | | 2 | 2 | 2 | 1 | 1 | | 2 | 2 | 2 | 2 | | 2 | 1 | | 1 | 2 | 1 | | | | | 36 1.8 |
| Parathyroid Gland | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | 46 |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | 1 | | 1 1.0 |
| Pars Distalis, Hyperplasia | | | | | | | | | 2 | | | | | | | | | | | | | | | | 1 2.0 |
| Thyroid Gland | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Follicle, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------------|--------------|
| Coagulating Gland | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Epididymis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Granuloma Sperm | | | | | | 2 | | | | | | | | | | | | | | | | | 3 | 2 | 3 2.3 | |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | 1 | 1 | | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | | | 1 | 1 | 33 1.0 | |
| Preputial Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Cyst | | | | | | | | | | | | | | | | | 2 | | | | | | | 2 | 2 | 5 2.2 |
| Inflammation | | | | 2 | | | | | | | 1 | 1 | 2 | | | | | | | | 2 | | | | 9 1.7 | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|-------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| | 7 7 7 7 6 7 7 7 6 6 7 7 7 7 6 7 4 7 7 7 4 7 6 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 6 2 3 3 5 8 3 3 3 1 8 3 5 3 3 3 9 3 6 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 2 1 0 8 9 1 2 3 3 1 1 0 1 3 1 5 1 2 1 4 0 0 0 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| 0.5 G/KG | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 2 2 2 3 3 3 3 3 3 3 3 3 3 4 4 4 4 4 4 4 4 4 5 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------|
| Prostate | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Infiltration Cellular, Mononuclear Cell | 1 | | | | | | | | | | | | | | | | | | | | | | | | 38 1.0 |
| Inflammation | 2 2 | | | | | | | | | | | | | | | | | | | | | | | | 4 1.8 |
| Seminal Vesicle | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Infiltration Cellular, Mononuclear Cell | 1 1 | | | | | | | | | | | | | | | | | | | | | | | | 6 1.0 |
| Testes | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Germinal Epithelium, Atrophy | 2 | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------|-------|
| Bone Marrow | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Lymph Node | | | | | | | | | | | | | | | | | | | | | | | | | 3 | |
| Renal, Hyperplasia, Lymphoid | + | | | | | | | | | | | | | | | | | | | | | | | | 4 | 1 4.0 |
| Lymph Node, Mandibular | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Hyperplasia, Lymphoid | 2 | | | | | | | | | | | | | | | | | | | | | | | | 2 3.0 | |
| Lymph Node, Mesenteric | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Hyperplasia, Lymphoid | 2 | | | | | | | | | | | | | | | | | | | | | | | | 2 3.0 | |
| Spleen | + | | | | | | | | | | | | | | | | | | | | | | | | 49 | |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Hematopoietic Cell Proliferation | 2 2 3 3 2 | | | | | | | | | | | | | | | | | | | | | | | | 21 2.0 | |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | 2 3.0 | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|
| | 7 7 7 7 6 7 7 7 6 6 7 7 7 7 6 7 4 7 7 7 4 7 6 7 7 | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 6 2 3 3 5 8 3 3 3 1 8 3 5 3 3 3 9 3 6 3 3 | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 2 1 0 8 9 1 2 3 3 1 1 0 1 3 1 5 1 2 1 4 0 0 0 2 | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0.5 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Inflammation | | | | | | | 1 | | | | | 1 | | | | | | | | | 2 | | | 3 1.3 |
| Metaplasia, Osseous | | | | | | | 1 | | | | | | | | | | | | | | | | | 1 1.0 |
| Mineralization | | | | | | | 1 | | 1 | | | | | | | | | | | | | | | 2 1.0 |
| Alveolar Epithelium, Hyperplasia | | | | | | | 1 | | | | | | | | | | | | | | | | | 1 1.0 |
| Alveolus, Infiltration Cellular, Histiocyte | | | | | | | 3 | | | | | | | | | | | | | | | 2 | | 5 2.2 |
| Bronchus, Infiltration Cellular, Histiocyte | | | | | | | | | | | | | | | | | | | | | | 1 | | 1 1.0 |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Inflammation, Suppurative | | | | | | | | | | | | | | | 2 | 2 | | | | | | | | 4 1.5 |
| Inflammation, Chronic | | | | | | 1 | | | | 1 | | | | | | | 1 | | | | | | | 7 1.0 |
| Nasolacrimal Duct, Inflammation, Suppurative | | | | | | | | | | | | | | | | | | | | | | | | 2 1.5 |
| Respiratory Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | 1 | | 1 1.0 |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Epithelium, Cytoplasmic Alteration | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Cornea, Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 10:57:30

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 0 |
| | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 7 | 4 | 7 | 7 | 7 | 4 | 7 | 6 | 7 | 7 | |
| | 3 | 3 | 3 | 3 | 6 | 2 | 3 | 3 | 5 | 8 | 3 | 3 | 3 | 1 | 8 | 3 | 5 | 3 | 3 | 3 | 9 | 3 | 6 | 3 | 3 | |
| | 2 | 2 | 1 | 0 | 8 | 9 | 1 | 2 | 3 | 3 | 1 | 1 | 0 | 1 | 3 | 1 | 5 | 1 | 2 | 1 | 4 | 0 | 0 | 0 | 2 | |
| B6C3F1 MICE MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 0.5 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| ANIMAL ID | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | |
| | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|--|---|--|---|---|--|--|---|--|---|--|---|---|--|---|---|---|---|---|---|---|---|----|-----|
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 4.0 |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | 1 | | 1 | | 1 | 1 | | | 1 | | 1 | | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 34 | 1.0 |
| Inflammation, Granulomatous | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|-----|
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Amyloid Deposition | | | | | | | | | | | | | | | | | | 1 | | | | | | | | 1 | 1.0 |
| Inflammation | | | | | | | | | | | | | | | | | | | | 3 | | | | | | 1 | 3.0 |
| Nephropathy | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | | 1 | | 1 | 1 | | 1 | 1 | | 1 | 1 | | 1 | 1 | 2 | 2 | 37 | 1.3 | |
| Renal Tubule, Cyst | | | | | | | | | | | | | | | 2 | | | | | | | | | | 3 | 1.7 | |
| Renal Tubule, Hyperplasia | | 2 | | | | | | | | 1 | 1 | | 1 | 2 | | | 1 | 1 | | | | | 1 | 1 | 13 | 1.3 | |
| Renal Tubule, Mineralization | 1 | 1 | 1 | 1 | 1 | 1 | | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | 38 | 1.0 | |
| Renal Tubule, Pigmentation, Lipofuscin | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 | |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | 1 | | | | | 1 | | | 1 | 1 | 1 | | | | | 1 | 1 | 1 | | 1 | 1 | 1 | 26 | 1.0 | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 49

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 5 5 7 4 5 7 7 7 7 7 6 7 7 7 7 7 5 6 7 7 5 3 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
1.0 G/KG | 3 9 4 3 6 9 3 3 3 3 3 7 3 3 3 3 3 7 6 3 3 8 9 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 6 7 1 5 6 1 2 0 2 1 3 2 2 2 1 1 0 4 8 1 2 2 2 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| 1.0 G/KG | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 | | | | | | | | | | | | | | | | | | | | | | | | |
| 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 | | | | | | | | | | | | | | | | | | | | | | | | | |

males
(cont...)

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Esophagus | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Gallbladder
Infiltration Cellular, Mononuclear Cell | + + + + + M M + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Large, Cecum | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Large, Colon | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Large, Rectum | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Small, Duodenum | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Small, Ileum | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Small, Jejunum
Peyer's Patch, Hyperplasia, Lymphoid | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Liver
Amyloid Deposition | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Angiectasis | 2 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Basophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | |
| Clear Cell Focus | X X X X | | | | | | | | | | | | | | | | | | | | | | | | |
| Degeneration, Cystic | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Eosinophilic Focus | X | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | | males
(cont...) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|
| | 7 | 5 | 5 | 7 | 4 | 5 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 5 | 6 | 7 | 7 | 5 | 3 | 7 | | |
| ANIMAL ID | 3 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 9 | 4 | 3 | 6 | 9 | 3 | 3 | 3 | 3 | 3 | 7 | 3 | 3 | 3 | 3 | 3 | 3 | 7 | 6 | 3 | 3 | 8 | 9 | 3 | | |
| B6C3F1 MICE MALE
1.0 G/KG | 1 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 | 7 | 1 | 5 | 6 | 1 | 2 | 0 | 2 | 1 | 3 | 2 | 2 | 2 | 1 | 1 | 0 | 4 | 8 | 1 | 2 | 2 | 2 | 1 | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 1.0 G/KG | 1 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | |
| ANIMAL ID | 5 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | | |
| 1.0 G/KG | 1 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | |
| Fatty Change | 1 | 2 | 1 | 1 | | 1 | | 1 | | | | | | | | | 1 | | 1 | | 1 | | | 1 | 2 | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | 2 | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 2 | 1 | 1 | |
| Inflammation, Suppurative | | | | | | | | | | | | 3 | | | | | | | | | | | | | | |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | 2 | | | |
| Mixed Cell Focus | | | | | | | X | | | | | | X | | | | | | | | | | | | X | |
| Necrosis | | | | | 3 | | | | | | 2 | | 1 | | 1 | | 1 | | | 3 | 1 | | 3 | 3 | | |
| Tension Lipidosis | | | | X | X | | | | | | | | | | | | | | | | | | | | | |
| Vacuolization Cytoplasmic | | | | | | | | | | | | | | 2 | | | | | | | | | | | | |
| Bile Duct, Cyst | | | | | | | | | | 2 | | | | | | | | | | | | | | | | |
| Centrilobular, Fatty Change | | | | | | | | | | | | | | | | | | | | | | | 4 | | | |
| Centrilobular, Hypertrophy | 2 | 2 | 2 | 2 | 2 | 2 | 2 | | 2 | | 2 | | | | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fat, Necrosis | | | | | | | + | | | | | | | | | | | | | | | | | | | |
| Pancreas | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Duct, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Salivary Glands | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | 1 | | | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | | 1 | 1 | | 1 | | 1 | | |
| Stomach, Forestomach | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach, Glandular | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | | | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

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TDMS No. 20007 - 06

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Kava kava extract

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Lab: BAT

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|-------------|----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | 7 | 5 | 5 | 7 | 4 | 5 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 5 | 6 | 7 | 7 | 5 | 3 | 7 | | |
| | | 3 | 9 | 4 | 3 | 6 | 9 | 3 | 3 | 3 | 3 | 7 | 3 | 3 | 3 | 3 | 3 | 7 | 6 | 3 | 3 | 8 | 9 | 3 | | |
| | | 1 | 6 | 7 | 1 | 5 | 6 | 1 | 2 | 0 | 2 | 1 | 3 | 2 | 2 | 2 | 1 | 1 | 0 | 4 | 8 | 1 | 2 | 2 | 1 | |
| B6C3F1 MICE MALE | ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | |
| | | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | |
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |
| | | 1.0 G/KG | | | | | | | | | | | | | | | | | | | | | | | | |

Glands, Ectasia

1

Tooth
Dysplasia

+

+

+

+

+

+

2

1

1

4

1

1

1

CARDIOVASCULAR SYSTEM

Blood Vessel

+ +

Heart

+ +

Cardiomyopathy
Inflammation, Suppurative
Artery, Infiltration Cellular, Mononuclear
Cell
Myocardium, Mineralization
Valve, Inflammation

1

1

2

1

2

4

ENDOCRINE SYSTEM

Adrenal Cortex

+ +

Hypertrophy
Vacuolization Cytoplasmic
Subcapsular, Hyperplasia
Zona Reticularis, Hyperplasia

1

1

1

2

2

2

2

1

1

1

1

1

1

1

1

1

1

1

1

1

2

1

1

1

2

2

1

3

1

1

1

Adrenal Medulla

+ +

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

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| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 5 5 7 4 5 7 7 7 7 7 6 7 7 7 7 7 5 6 7 7 5 3 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 9 4 3 6 9 3 3 3 3 3 7 3 3 3 3 3 7 6 3 3 8 9 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 6 7 1 5 6 1 2 0 2 1 3 2 2 2 1 1 0 4 8 1 2 2 2 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
1.0 G/KG | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 | | | | | | | | | | | | | | | | | | | | | | | | |

males (cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|--|---|--|---|---|---|---|--|--|--|--|---|---|---|---|---|---|---|---|--|---|---|---|
| Atrophy | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | | 1 | | 1 | 1 | 1 | 1 | | | | | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | | 1 | 1 | 1 |
| Inflammation | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Seminal Vesicle | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Atrophy | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Testes | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Germinal Epithelium, Atrophy | 2 | | | | | | | | | | | | | | | | | | | | | | | | |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Bone Marrow | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mandibular | + M + + | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Lymphoid | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mesenteric | + + + + + + + + + + + + + M + + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | | | | | |
| Spleen | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Hematopoietic Cell Proliferation | 4 2 2 3 1 2 3 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Lymphoid | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymphoid Follicle, Atrophy | 1 4 4 | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
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 1) Minimal 3) Moderate
 2) Mild 4) Marked
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TDMS No. 20007 - 06
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 Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------------------|
| | 7 5 5 7 4 5 7 7 7 7 7 6 7 7 7 7 7 5 6 7 7 5 3 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
1.0 G/KG | 3 9 4 3 6 9 3 3 3 3 3 7 3 3 3 3 3 7 6 3 3 8 9 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 6 7 1 5 6 1 2 0 2 1 3 2 2 2 1 1 0 4 8 1 2 2 2 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| 1.0 G/KG | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | males
(cont...) |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Thymus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + |
| Atrophy | 1 | | | 2 | 4 | | 4 | 2 | 4 | 4 | 4 | 4 | 4 | 4 | 2 | 2 | 4 | 4 | 4 | 2 | 2 | 2 | | | | | 2 |
| Inflammation, Chronic Active Epithelial Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mammary Gland | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Chronic Ulcer | | | | | | | | | | | | | | | | | | | | | | | | | | | |

MUSCULOSKELETAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

NERVOUS SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

RESPIRATORY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------------------|
| | 7 5 5 7 4 5 7 7 7 7 7 6 7 7 7 7 7 5 6 7 7 5 3 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 9 4 3 6 9 3 3 3 3 3 7 3 3 3 3 3 7 6 3 3 8 9 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 6 7 1 5 6 1 2 0 2 1 3 2 2 2 1 1 0 4 8 1 2 2 2 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
1.0 G/KG | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | males
(cont...) |

Lung +
 Inflammation
 Alveolar Epithelium, Hyperplasia 2 1
 Alveolus, Infiltration Cellular, Histiocyte 3
 Bronchus, Hyperplasia

Nose +
 Inflammation, Suppurative 2
 Inflammation, Chronic 2 1 1 1
 Polyp, Inflammatory 2
 Nasolacrimal Duct, Inflammation, Suppurative 2 1

Trachea +

SPECIAL SENSES SYSTEM

Eye +
 Anterior Chamber, Inflammation, Suppurative 3
 Cornea, Inflammation, Chronic 2 1
 Retrobulbar, Inflammation, Chronic 2

Harderian Gland +
 Hyperplasia 2
 Infiltration Cellular, Mononuclear Cell 1

URINARY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------------------|
| | 7 5 5 7 4 5 7 7 7 7 7 6 7 7 7 7 7 5 6 7 7 5 3 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
1.0 G/KG | 3 9 4 3 6 9 3 3 3 3 3 7 3 3 3 3 3 7 6 3 3 8 9 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 6 7 1 5 6 1 2 0 2 1 3 2 2 2 1 1 0 4 8 1 2 2 2 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| 1.0 G/KG | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | males
(cont...) |
| | | | | | | | | | | | | | | | | | | | | | | | | | 1 |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|-----------|
| Kidney | + | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hydronephrosis | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Metaplasia, Osseous | 1 | | | | | | | | | | | | | | | | | | | | | | | | | |
| Nephropathy | 1 | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Papilla, Necrosis | 1 | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Renal Tubule, Hyperplasia | 1 | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Renal Tubule, Mineralization | 1 1 1 | | | | | | | | | | | | | | | | | | | | | | | | | 1 1 1 1 1 |
| Renal Tubule, Pigmentation, Lipofuscin | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Urethra | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Urinary Bladder | + | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | 1 | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Transitional Epithelium, Cytoplasmic Alteration | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 5 7 6 7 7 7 7 7 7 7 7 7 7 7 7 7 5 7 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
1.0 G/KG | 8 3 9 3 3 1 3 3 3 3 3 3 3 3 3 3 9 3 3 3 3 0 3 3 | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 1 2 2 0 8 2 2 1 1 0 1 2 0 1 1 1 5 1 2 2 1 7 2 2 | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | |
| | 7 7 7 7 8 8 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 | | | | | | | | | | | | | | | | | | | | | | | |
| * TOTALS | | | | | | | | | | | | | | | | | | | | | | | | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------|
| Esophagus | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Gallbladder | + + + + + + M + | | | | | | | | | | | | | | | | | | | | | | | | 47 |
| Infiltration Cellular, Mononuclear Cell | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Intestine Large, Cecum | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Intestine Large, Colon | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Intestine Large, Rectum | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Intestine Small, Duodenum | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Intestine Small, Ileum | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Intestine Small, Jejunum | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Peyer's Patch, Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 |
| Liver | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Amyloid Deposition | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Angiectasis | 1 1 2 2 2 1 2 | | | | | | | | | | | | | | | | | | | | | | | | 10 1.7 |
| Basophilic Focus | X | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Clear Cell Focus | X | | | | | | | | | | | | | | | | | | | | | | | | 21 |
| Degeneration, Cystic | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Eosinophilic Focus | X | | | | | | | | | | | | | | | | | | | | | | | | 43 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|---|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|
| | 0582 | 0576 | 0567 | 0577 | 0577 | 0577 | 0577 | 0577 | 0577 | 0577 | 0577 | 0577 | 0577 | 0577 | 0577 | 0577 | 0577 | 0577 | 0577 | 0577 | 0577 | 0577 | 0577 | 0577 | |
| B6C3F1 MICE MALE | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | |
| 1.0 G/KG | 76 | 77 | 78 | 79 | 80 | 81 | 82 | 83 | 84 | 85 | 86 | 87 | 88 | 88 | 88 | 88 | 88 | 88 | 88 | 88 | 88 | 88 | 88 | 88 | |
| Fatty Change | 1 | | | | 1 | 2 | | | 1 | 2 | 2 | 2 | 1 | 2 | | | | 1 | 1 | 2 | 1 | | | | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | |
| Inflammation, Suppurative | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mixed Cell Focus | | | | | X | | | | X | X | X | X | | | | | X | | | X | X | | X | | |
| Necrosis | 2 | | 1 | | | | | | | | | | | | | | | 2 | | | | 3 | | | |
| Tension Lipidosis | | | | | | | | | | | | | | | | | | | | | | | | | |
| Vacuolization Cytoplasmic | | | | | | | | | | | | | | | | | | | | | | | | | |
| Bile Duct, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | |
| Centrilobular, Fatty Change | | | | | | | | | | | | | | | | | | | | | | | | | |
| Centrilobular, Hypertrophy | 2 | 2 | 2 | 2 | | 2 | 2 | 2 | 2 | | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | | |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pancreas | | | | | | | | | | | | | | | | | | | | | | | | | |
| Duct, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | |
| Salivary Glands | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | | | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach, Forestomach | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Chronic | 1 | | 2 | 1 | 2 | | | 1 | 1 | 2 | 2 | | | | | | | | 2 | | 2 | | 1 | | |
| Necrosis | 3 | | 2 | | 2 | | | | | 2 | | | | | | | | | | | 2 | | | | |
| Epithelium, Hyperplasia | 1 | | 1 | 1 | | | | 1 | 1 | 2 | 2 | | | | | | | | | 3 | 2 | 2 | 2 | | |
| Stomach, Glandular | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
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TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| DAY ON TEST | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|-------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 5 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 50 |
| 8 | 3 | 9 | 3 | 3 | 1 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 33 |
| 2 | 1 | 2 | 2 | 0 | 8 | 2 | 2 | 1 | 1 | 0 | 1 | 2 | 0 | 1 | 1 | 1 | 1 | 5 | 1 | 2 | 2 | 1 | 7 | 2 | 1.3 |

B6C3F1 MICE MALE
1.0 G/KG

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|-----|
| Islets, Pancreatic
Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 33 | 1.3 |
| Parathyroid Gland
Cyst | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | 44 | 1 | 1.0 |
| Pituitary Gland
Cyst | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 2 | 1.0 |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |

GENERAL BODY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|---|-----|
| Peritoneum
Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2 | 2.5 |
|-------------------------------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|---|-----|

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|-----|
| Epididymis
Granuloma Sperm
Infiltration Cellular, Mononuclear Cell | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 | 2.0 |
| | 1 | | | | 1 | 1 | | | | 1 | 1 | 1 | | | 1 | 1 | 1 | | | 1 | 1 | | | 1 | 28 | | 1.0 |
| Preputial Gland
Cyst
Inflammation | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 3 | 2.3 |
| | | 1 | | | | | | | 1 | 1 | 2 | | | | 2 | 3 | | | 2 | | | | | | 13 | | 1.3 |
| Prostate | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
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 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 0 |
| | 5 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | |
| | 8 | 3 | 9 | 3 | 3 | 1 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 9 | 3 | 3 | 3 | 3 | 0 | 3 | 3 |
| | 2 | 1 | 2 | 2 | 0 | 8 | 2 | 2 | 1 | 1 | 0 | 1 | 2 | 0 | 1 | 1 | 1 | 1 | 5 | 1 | 2 | 2 | 1 | 7 | 2 | 2 |
| B6C3F1 MICE MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.0 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 |
| | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Inflammation | | | | 1 | | | | | | | | | 1 | | | | | | | | | | | | | 2 1.0 |
| Alveolar Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 2 1.5 |
| Alveolus, Infiltration Cellular, Histiocyte | | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Bronchus, Hyperplasia | | | | 2 | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Inflammation, Suppurative | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | 1 | | | 5 1.2 |
| Polyp, Inflammatory | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Nasolacrimal Duct, Inflammation, Suppurative | | | | | | | | | | | | | | | | 2 | | | | | | | | | | 3 1.7 |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|
| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Anterior Chamber, Inflammation, Suppurative | | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Cornea, Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | 2 1.5 |
| Retrolbulbar, Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Hyperplasia | | | | | | | | 3 | 2 | | | | | | 2 | 1 | 1 | | | | | | | | | 8 1.9 |
| Infiltration Cellular, Mononuclear Cell | | | 1 | | 1 | | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 39 1.0 |

URINARY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| | 5 7 6 7 7 7 7 7 7 7 7 7 7 7 7 7 5 7 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
1.0 G/KG | 8 3 9 3 3 1 3 3 3 3 3 3 3 3 3 3 9 3 3 3 3 0 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 1 2 2 0 8 2 2 1 1 0 1 2 0 1 1 1 5 1 2 2 1 7 2 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------|
| Kidney | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Hydronephrosis | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Metaplasia, Osseous | | | | | | | | | | | | | | | | | | | | | | | | | 2 1.5 |
| Nephropathy | 2 2 2 2 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 2 2 1 | | | | | | | | | | | | | | | | | | | | | | | | 38 1.3 |
| Papilla, Necrosis | 1 | | | | | | | | | | | | | | | | | | | | | | | | 3 1.0 |
| Renal Tubule, Hyperplasia | 1 1 2 1 | | | | | | | | | | | | | | | | | | | | | | | | 10 1.1 |
| Renal Tubule, Mineralization | 1 | | | | | | | | | | | | | | | | | | | | | | | | 31 1.0 |
| Renal Tubule, Pigmentation, Lipofuscin | | | | | | | | | | | | | | | | | | | | | | | | | 2 2.5 |
| Urethra | + | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Inflammation | 3 | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Necrosis | 3 | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Urinary Bladder | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Infiltration Cellular, Mononuclear Cell | 1 | | | | | | | | | | | | | | | | | | | | | | | | 20 1.0 |
| Transitional Epithelium, Cytoplasmic Alteration | 2 | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |

*** END OF MALE DATA ***

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 65

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 7 7 7 5 7 7 7 6 7 7 7 7 7 7 7 5 7 7 7 5 7 7 6 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
0 G/KG | 3 3 3 2 4 2 2 3 8 3 2 3 2 3 3 3 2 6 0 3 2 8 2 3 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 1 0 9 4 9 9 1 4 0 9 1 9 1 1 0 9 0 1 0 9 1 9 0 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 1 1 1 1 1 2 2 2 2 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 | | | | | | | | | | | | | | | | | | | | | | | | |

females (cont...)

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Esophagus | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Gallbladder Cyst | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Large, Cecum Inflammation, Chronic | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Large, Colon | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Large, Rectum | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Small, Duodenum | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Small, Ileum | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Small, Jejunum | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Liver | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | |
| Clear Cell Focus | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Eosinophilic Focus | X | | | | | | | | | | | | | | | | | | | | | | | | |
| Fatty Change | 1 2 1 3 2 2 2 2 2 1 1 2 1 1 2 1 1 2 1 1 2 1 1 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | 1 1 1 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 4 1 1 | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 10:57:30

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 5 | 7 | 7 | 6 | 6 |
| | 3 | 3 | 3 | 2 | 4 | 2 | 2 | 3 | 8 | 3 | 2 | 3 | 2 | 3 | 3 | 3 | 2 | 6 | 0 | 3 | 2 | 8 | 2 | 3 | 1 |
| | 0 | 1 | 0 | 9 | 4 | 9 | 9 | 1 | 4 | 0 | 9 | 1 | 9 | 1 | 1 | 0 | 9 | 0 | 1 | 0 | 9 | 1 | 9 | 0 | 0 |
| B6C3F1 MICE FEMALE
0 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

females (cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mixed Cell Focus | X | | | | | | | | X | | | X | | | | | | | X | X | | | | | |
| Necrosis | | | | 1 | | | | | | | | | | | | 1 | | | 2 | | | | | | |
| Tension Lipidosis | | | | X | | | | | | | | | | | | | | | X | | | | | | |
| Mesentery | | | | + | | | | | | | | | | | | | | | + | | | | | | + |
| Fat, Necrosis | | | | 3 | | | | | | | | | | | | | | | 2 | | | | | | 3 |
| Pancreas | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Inflammation, Chronic | | | | | 1 | | | | | | | | | | | | | | | | | | | | |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Infiltration Cellular, Mononuclear Cell | 1 | | | 1 | | 1 | 1 | 1 | 1 | | | 1 | 1 | | 1 | 1 | | 1 | | 1 | 1 | 3 | 2 | 1 | |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Inflammation, Chronic | | | | | | | | | | | | | | | | 2 | | | | | | | | | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | 2 | | | | | | | | | |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Infiltration Cellular, Mononuclear Cell | | | | 1 | | | | | | | | | | | | | | | | | | | | | |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | | | |
| Glands, Ectasia | | | | | | | | | | | | | | | | | | | | | | | | | |
| Tooth | | | | | | | | | | | | | | | | | | | | | | | | | |
| Dysplasia | | | | | | | | | | | | | | | | | | | | | | | | | |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Blood Vessel | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|--------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ .. Tissue examined microscopically
x .. Lesion present
I .. Insufficient tissue
M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically
1-4 .. Lesion qualified as:
1) Minimal 3) Moderate
2) Mild 4) Marked

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 5 | 7 | 7 | 6 | |
| | 3 | 3 | 3 | 2 | 4 | 2 | 2 | 3 | 8 | 3 | 2 | 3 | 2 | 3 | 3 | 3 | 2 | 6 | 0 | 3 | 2 | 8 | 2 | 3 | 1 | |
| | 0 | 1 | 0 | 9 | 4 | 9 | 9 | 1 | 4 | 0 | 9 | 1 | 9 | 1 | 1 | 0 | 9 | 0 | 1 | 0 | 9 | 1 | 9 | 0 | 0 | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 0 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | females (cont...) |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cardiomyopathy | | 1 | | | | | | | | | | | | | | | | | | | | | | | |
| Artery, Infiltration Cellular, Mononuclear Cell | | | | | | | | | | | | | | | | | | | | | | | | | |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Vacuolization Cytoplasmic Subcapsular, Hyperplasia | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 2 | 1 |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | | 1 | | | | | | | | | | | | | | | | | | | | | | | |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | | | | | | | | | 1 | | | | | | | | | | | | | | | | |
| Parathyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pars Distalis, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 4 |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Ectopic Thymus | | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
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 Page 68

TDMS No. 20007 - 06
 Test Type: CHRONIC
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P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
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| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 7 7 7 5 7 7 7 6 7 7 7 7 7 7 7 5 7 7 7 5 7 7 6 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
0 G/KG | 3 3 3 2 4 2 2 3 8 3 2 3 2 3 3 3 2 6 0 3 2 8 2 3 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 1 0 9 4 9 9 1 4 0 9 1 9 1 1 0 9 0 1 0 9 1 9 0 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 1 1 1 1 1 2 2 2 2 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 | | | | | | | | | | | | | | | | | | | | | | | | |

females
(cont...)

Infiltration Cellular, Mononuclear Cell
 Follicle, Hyperplasia

GENERAL BODY SYSTEM
 NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Clitoral Gland Inflammation | + + + + M + | | | | | | | | | | | | | | | | | | | | | | | | |
| Ovary Angiectasis Cyst Hemorrhage | + + M + 2 + | | | | | | | | | | | | | | | | | | | | | | | | |
| Uterus Inflammation, Suppurative Metaplasia, Squamous Endometrium, Hyperplasia, Cystic | + | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 2 2 3 3 2 1 3 1 3 1 2 1 1 3 2 1 2 3 3 2 | | | | | | | | | | | | | | | | | | | | | | | | |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Bone Marrow | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node | + + | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 7 7 7 5 7 7 7 6 7 7 7 7 7 7 7 5 7 7 7 5 7 7 6 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 2 4 2 2 3 8 3 2 3 2 3 3 3 2 6 0 3 2 8 2 3 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 1 0 9 4 9 9 1 4 0 9 1 9 1 1 0 9 0 1 0 9 1 9 0 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
0 G/KG | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 1 1 1 1 1 2 2 2 2 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 females (cont...) | | | | | | | | | | | | | | | | | | | | | | | | |

Mediastinal, Hyperplasia, Lymphoid

Lymph Node, Mandibular
Hyperplasia, Lymphoid

+ M + + +
3

Lymph Node, Mesenteric

+ +

Spleen
Hematopoietic Cell Proliferation
Hyperplasia, Lymphoid
Lymphoid Follicle, Atrophy

+ + + + M +
2 2 1 3 2 2 1 2 3 1 2 3 2 2 2 3 1 2 3 1 3
1 2

Thymus
Atrophy
Hyperplasia, Histiocytic
Infiltration Cellular, Histiocyte
Epithelial Cell, Hyperplasia

+
1 2 2 2 3 1 2 2 2 3 2 3 2 3 3 1 2 4 1 4
2
3 1

INTEGUMENTARY SYSTEM

Mammary Gland
Hyperplasia
Inflammation, Chronic Active
Metaplasia, Squamous

+ +

Skin
Inflammation, Chronic
Ulcer

+ +

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 7 7 7 5 7 7 7 6 7 7 7 7 7 7 7 5 7 7 7 5 7 7 6 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
0 G/KG | 3 3 3 2 4 2 2 3 8 3 2 3 2 3 3 3 2 6 0 3 2 8 2 3 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 1 0 9 4 9 9 1 4 0 9 1 9 1 1 0 9 0 1 0 9 1 9 0 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 1 1 1 1 1 2 2 2 2 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 | | | | | | | | | | | | | | | | | | | | | | | | |

females
(cont...)

MUSCULOSKELETAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Bone | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Fibrosis | 2 3 2 1 1 1 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Skeletal Muscle | + | | | | | | | | | | | | | | | | | | | | | | | | |

NERVOUS SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Brain | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Choroid Plexus, Infiltration Cellular,
Mononuclear Cell | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Hypothalamus, Compression | 4 | | | | | | | | | | | | | | | | | | | | | | | | |
| Peripheral Nerve | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Axon, Degeneration | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Spinal Cord | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Axon, Degeneration | 3 | | | | | | | | | | | | | | | | | | | | | | | | |

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Lung | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 7 7 7 7 5 7 7 7 6 7 7 7 7 7 7 7 5 7 7 7 5 7 7 6 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 2 4 2 2 3 8 3 2 3 2 3 3 3 2 6 0 3 2 8 2 3 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 1 0 9 4 9 9 1 4 0 9 1 9 1 1 0 9 0 1 0 9 1 9 0 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

females (cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------------|---|--|--|--|--|--|--|--|--|--|---|---|--|--|--|--|--|--|--|--|---|--|--|--|--|--|
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Alveolar Epithelium, Hyperplasia | | | | | | | | | | | 1 | 1 | | | | | | | | | | | | | | |
| Nose | + | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Chronic | | | | | | | | | | | 1 | 1 | | | | | | | | | | | | | | |
| Olfactory Epithelium, Degeneration | | | | | | | | | | | | | | | | | | | | | 2 | | | | | |
| Trachea | + | | | | | | | | | | | | | | | | | | | | | | | | | |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Ear | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | + | | | | | | | | | | | | | | |
| Eye | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Anterior Chamber, Inflammation, Suppurative | | | | | | | | | | | | | | | | | | | | | | | | | |
| Harderian Gland | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Atrophy | | | | | | | | | | | 1 | | | | | | | | | | | | | | |
| Hyperplasia | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Kidney | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Amyloid Deposition | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 72

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 10:57:30

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

| DAY ON TEST | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
|---|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DAY ON TEST | | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 5 | 7 | 7 | 6 | |
| DAY ON TEST | | 3 | 3 | 3 | 2 | 4 | 2 | 2 | 3 | 8 | 3 | 2 | 3 | 2 | 3 | 3 | 3 | 2 | 6 | 0 | 3 | 2 | 8 | 2 | 3 | 1 |
| DAY ON TEST | | 0 | 1 | 0 | 9 | 4 | 9 | 9 | 1 | 4 | 0 | 9 | 1 | 9 | 1 | 1 | 0 | 9 | 0 | 1 | 0 | 9 | 1 | 9 | 0 | 0 |
| B6C3F1 MICE FEMALE
0 G/KG | ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | ANIMAL ID | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | |
| | ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | |
| | ANIMAL ID | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |
| Metaplasia, Osseous Mineralization | | | | 1 | 1 | | 1 | 1 | 1 | | 1 | 1 | 1 | | 1 | | | | 1 | 1 | | | | | | |
| Nephropathy | 1 | | | 2 | 1 | | 1 | 2 | 1 | | 1 | 1 | 1 | | 1 | 1 | | 2 | | 2 | 1 | 1 | | 2 | 1 | |
| Papilla, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Renal Tubule, Hyperplasia | | | | | | | | | 1 | | | | | | | | | | | | | | | | | |
| Urinary Bladder Infiltration Cellular, Mononuclear Cell | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Urinary Bladder Infiltration Cellular, Mononuclear Cell | | 1 | 1 | 1 | | 1 | 1 | | 1 | 1 | | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | 2 | | | | |

females (cont...)

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ .. Tissue examined microscopically
x .. Lesion present
I .. Insufficient tissue
M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically
1-4 .. Lesion qualified as:
1) Minimal 3) Moderate
2) Mild 4) Marked

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 10:57:30

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
| | 7 | 4 | 7 | 6 | 7 | 7 | 7 | 5 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 3 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| B6C3F1 MICE FEMALE
0 G/KG | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
| | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | |
| ANIMAL ID | 9 | 1 | 9 | 9 | 9 | 0 | 0 | 3 | 8 | 0 | 1 | 9 | 9 | 0 | 0 | 9 | 1 | 9 | 4 | 0 | 1 | 0 | 0 | 0 | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Gallbladder Cyst | + | + | + | + | + | 1 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Cecum Inflammation, Chronic | + | + | + | + | + | + | + | + | 1 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Angiectasis | | | | | | | | | | 1 | | | | | | | | | | | | | | | 3 |
| Clear Cell Focus | X | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Eosinophilic Focus | X | | | | | X | | X | | | | | | X | | | | | | | | | | X | 9 |
| Fatty Change | 2 | 2 | 1 | 2 | | | 2 | | 2 | 2 | | 1 | 1 | | 2 | 2 | 2 | 1 | 1 | 2 | 1 | 2 | 2 | | 39 |
| Hematopoietic Cell Proliferation | | | | | | | | | | | 2 | | | | | | | | | | | | | | 1 |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | 1 | | 1 | 1 | 1 | | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 45 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ .. Tissue examined microscopically
x .. Lesion present
I .. Insufficient tissue
M .. Missing tissue
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TDMS No. 20007 - 06
 Test Type: CHRONIC
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 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
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 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|----------|-----------------|-----------|----------|----------|----------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | | |
| B6C3F1 MICE FEMALE | 7 | 4 | 7 | 6 | 7 | 7 | 7 | 5 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 3 | 7 | 7 | 7 | 7 | 7 | 7 | | | | | |
| 0 G/KG | 2 | 2 | 2 | 3 | 2 | 3 | 3 | 2 | 8 | 3 | 3 | 2 | 2 | 3 | 3 | 2 | 3 | 2 | 9 | 3 | 3 | 0 | 3 | 3 | | | | | |
| | 9 | 1 | 9 | 9 | 9 | 0 | 0 | 3 | 8 | 0 | 1 | 9 | 9 | 0 | 0 | 9 | 1 | 9 | 4 | 0 | 1 | 0 | 0 | 1 | | | | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | | |
| | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | | | | | |
| | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 | | | | | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | |
| Mixed Cell Focus | | | X | | | X | | | | | | | X | | | X | | | X | | | X | | | X | 12 | | | |
| Necrosis | | | | 1 | | | | | | | 3 | | | | | | | | | | | | | | | | 5 | | |
| Tension Lipidosis | | | X | | | | | | | | | | | | | | | | | | | | | | | | | 3 | |
| Mesentery | + | + | + | | | | | | | | | | | + | | | | | | | | | | | + | 8 | | | |
| Fat, Necrosis | 3 | 2 | 3 | | | | | | | | | | | 3 | | | | | | | | | | | 2 | 8 | | | |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | | | |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | 1 | | | 2 | | | | | | |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | | | |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | M | 1 | 1 | 1 | 1 | 1 | 34 | | | |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | |
| Inflammation, Chronic | | | | 1 | | | | | | | | | | | 2 | | | | | | | | | | | 3 | | | |
| Epithelium, Hyperplasia | | | | 1 | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | |
| Infiltration Cellular, Mononuclear Cell | | | | | | | | | | | | | | | | | | | | | | | 1 | | | 2 | | | |
| Mineralization | | | | | 1 | | | | | | | | | | | | | | | | | | | 1 | | | | | |
| Glands, Ectasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 | | | | |
| Tooth | | | | | | | | | | | | | | | | | + | | | | | | | 1 | | | | | |
| Dysplasia | | | | | | | | | | | | | | | | | 1 | | | | | | | 1 | | | | | |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|
| Blood Vessel | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
|--------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 75

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|---------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|--|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 7 | 4 | 7 | 6 | 7 | 7 | 7 | 5 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 3 | 7 | 7 | 7 | 7 | 7 | 7 | | |
| | 2 | 2 | 2 | 3 | 2 | 3 | 3 | 2 | 8 | 3 | 3 | 2 | 2 | 3 | 3 | 2 | 3 | 2 | 9 | 3 | 3 | 0 | 3 | 3 | 3 | |
| | 9 | 1 | 9 | 9 | 9 | 0 | 0 | 3 | 8 | 0 | 1 | 9 | 9 | 0 | 0 | 9 | 1 | 9 | 4 | 0 | 1 | 0 | 0 | 1 | 0 | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 0 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | |
| | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Cardiomyopathy | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2 1.0 |
| Artery, Infiltration Cellular, Mononuclear Cell | | | | | | | | 1 | | | | | | | | | | | | | | | | | | 1 1.0 |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|-------|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Atrophy | | | | | | | | | | | | 1 | | | | | | | | | | | | | | 1 1.0 |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Vacuolization Cytoplasmic Subcapsular, Hyperplasia | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 49 1.9 | |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 4 1.3 |
| Parathyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | M | + | 48 |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 1.0 |
| Pars Distalis, Hyperplasia | 2 | | | | | | | | | | | | | | | | | | | | | | | | 2 | 4 2.8 |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Ectopic Thymus | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 1.0 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

TDMS No. 20007 - 06

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 04/13/2009

Time Report Requested: 10:57:30

First Dose M/F: 08/24/04 / 08/23/04

Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 4 7 6 7 7 7 5 6 7 7 7 7 7 7 7 3 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
0 G/KG | 2 2 2 3 2 3 3 2 8 3 3 2 2 3 3 2 3 2 9 3 3 0 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | |
| | 9 1 9 9 9 0 0 3 8 0 1 9 9 0 0 9 1 9 4 0 1 0 0 1 0 | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| * TOTALS | 2 | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 | | | | | | | | | | | | | | | | | | | | | | | |

| | | |
|---|---|-------|
| Infiltration Cellular, Mononuclear Cell | 1 | 1 1.0 |
| Follicle, Hyperplasia | 2 | 1 2.0 |

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

| | | | | |
|---|---|-----------------------|-----|--------|
| Clitoral Gland Inflammation | + | 1 | 49 | 1 1.0 |
| Ovary Angiectasis | + | | 49 | 1 2.0 |
| Ovary Cyst | | X | | 4 1.7 |
| Ovary Hemorrhage | | | 2 | 1 3.0 |
| Uterus Inflammation, Suppurative | + | | 50 | 3 1.3 |
| Uterus Metaplasia, Squamous | | | 2 | 1 2.0 |
| Uterus Endometrium, Hyperplasia, Cystic | 3 2 2 3 1 3 2 | 3 2 3 3 1 2 3 2 4 1 2 | 1 1 | 42 2.1 |

HEMATOPOIETIC SYSTEM

| | | | | |
|-------------|---|--|----|---|
| Bone Marrow | + | | 50 | |
| Lymph Node | | | | 3 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ .. Tissue examined microscopically
x .. Lesion present
I .. Insufficient tissue
M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically
1-4 .. Lesion qualified as:
1) Minimal 3) Moderate
2) Mild 4) Marked

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| | 7 4 7 6 7 7 7 5 6 7 7 7 7 7 7 7 7 3 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
0 G/KG | 2 2 2 3 2 3 3 2 8 3 3 2 2 3 3 2 3 2 9 3 3 0 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 9 1 9 9 9 0 0 3 8 0 1 9 9 0 0 9 1 9 4 0 1 0 0 1 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 2 2 3 3 3 3 3 3 3 3 3 3 3 3 3 3 4 4 4 4 4 4 5 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|-----------------------------------|
| Mediastinal, Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | 4 | 1 4.0 |
| Lymph Node, Mandibular
Hyperplasia, Lymphoid | + M + + + | | | | | | | | | | | | | | | | | | | | | | | | 48 | 4 3.3 |
| Lymph Node, Mesenteric | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Spleen
Hematopoietic Cell Proliferation
Hyperplasia, Lymphoid
Lymphoid Follicle, Atrophy | + | | | | | | | | | | | | | | | | | | | | | | | | 49 | 26 1.8
7 1.6
4 2.8 |
| Thymus
Atrophy
Hyperplasia, Histiocytic
Infiltration Cellular, Histiocyte
Epithelial Cell, Hyperplasia | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | 39 2.6
1 3.0
5 2.4
1 1.0 |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|-------------------------|
| Mammary Gland
Hyperplasia
Inflammation, Chronic Active
Metaplasia, Squamous | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | 1 2.0
1 2.0
1 2.0 |
| Skin
Inflammation, Chronic
Ulcer | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | 1 3.0
1 4.0 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
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TDMS No. 20007 - 06
 Test Type: CHRONIC
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P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| DAY ON TEST | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|---|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 7 | 4 | 7 | 6 | 7 | 7 | 7 | 5 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 3 | 7 | 7 | 7 | 7 | 7 | 0 | 0 |
| 2 | 2 | 2 | 3 | 2 | 3 | 3 | 2 | 8 | 3 | 3 | 2 | 2 | 3 | 3 | 2 | 3 | 2 | 9 | 3 | 3 | 0 | 3 | 3 | 3 | 0 |
| 9 | 1 | 9 | 9 | 9 | 0 | 0 | 3 | 8 | 0 | 1 | 9 | 9 | 0 | 0 | 9 | 1 | 9 | 4 | 0 | 1 | 0 | 0 | 1 | 0 | 0 |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 | 5 |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
| Metaplasia, Osseous | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Nephropathy | | | | | | 2 | | | 4 | | | | | | | 1 | | | | | | | | | 1 |
| Papilla, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Renal Tubule, Hyperplasia | | | | | | | | | 1 | | | | | 1 | | | | | | | | | | | 3 |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Infiltration Cellular, Mononuclear Cell | 1 | | 1 | | 1 | | 1 | | 1 | | 1 | | 1 | | 1 | | 1 | | 1 | | 1 | | 1 | 2 | 34 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 81

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 6 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 5 5 7 6 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 8 3 2 2 3 2 3 1 3 3 3 3 3 2 2 3 2 6 2 3 6 2 0 3 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 1 9 9 0 9 1 1 1 1 1 1 0 0 4 9 0 3 5 1 0 6 9 1 0 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
0.25 G/KG | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 | | | | | | | | | | | | | | | | | | | | | | | | |

females (cont...)

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Esophagus
Inflammation, Chronic | + + + + + + + + + + + + 2 + + + + + + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | | | | | |
| Gallbladder
Cyst | + + + + + + + M + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Large, Cecum | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Large, Colon | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Large, Rectum | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Small, Duodenum | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Small, Ileum | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Small, Jejunum | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Liver | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Basophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | |
| Eosinophilic Focus | X | | | | | | | | | | | | | | | | | | | | | | | | |
| Fatty Change | 2 1 1 2 2 2 2 2 2 2 2 2 2 1 2 1 4 1 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Hematopoietic Cell Proliferation | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | 1 1 1 1 1 1 1 1 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Mixed Cell Focus | X X | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
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Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|------------------------------|
| | 6 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 5 5 7 6 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 8 3 2 2 3 2 3 1 3 3 3 3 3 2 2 3 2 6 2 3 6 2 0 3 2 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 1 9 9 0 9 1 1 1 1 1 1 0 0 4 9 0 3 5 1 0 6 9 1 0 9 | | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | females
(cont...) |
| 0.25 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | |
| | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Blood Vessel Mineralization | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | | | | | | | | | | | | | | | | | | | | | | | 2 | | |
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cardiomyopathy | | | | | 2 | | | | | | | | | | | | | | | | | | | | |
| Thrombosis | | | | | | | | | | | | | | | | | | | | 4 | | | | | |
| Artery, Infiltration Cellular, Mononuclear Cell | | | | | | 1 | | | | | | | | | | 1 | | | | | | | | | |
| Myocardium, Mineralization | | | | | | | | | | | | | | | | 1 | | | | | | | 3 | | |
| Valve, Inflammation | | | | | | | | | | | | | | | | | | | | | | | 4 | | |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Subcapsular, Hyperplasia | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | | | | | 1 | | | | | | | | | | | | | | | | | 1 | 1 | | |
| Parathyroid Gland | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | 1 | | M |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pars Distalis, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
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TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 6 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 5 5 7 6 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 8 3 2 2 3 2 3 1 3 3 3 3 3 2 2 3 2 6 2 3 6 2 0 3 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 1 9 9 0 9 1 1 1 1 1 1 0 0 4 9 0 3 5 1 0 6 9 1 0 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0.25 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

females
(cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Thyroid Gland Cyst | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|--------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

GENERAL BODY SYSTEM
 NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Ovary | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | |
| Cyst | | | | | | | | 1 | | | | 1 | 1 | 1 | | | | | | | | | | 1 | |
| Thrombosis | | | | | | | | | | | | | | | | | | | | | | | | | |
| Uterus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation, Suppurative | | | | | | | | | | | | | | | | | | | | | | | | | |
| Metaplasia, Squamous | | | | | | | | | | | | | | | | | | | | | | | | | |
| Endometrium, Hyperplasia, Cystic | 1 | 3 | 3 | 1 | 1 | 2 | 3 | 1 | 1 | 2 | 2 | 1 | 2 | 1 | 2 | 2 | | 1 | | 3 | 1 | 1 | 2 | 1 | 1 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone Marrow Fibrosis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

| DAY ON TEST | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | | | | | females
(cont...) |
|-------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 5 | 7 | 6 | 7 | 7 | 7 | |
| 8 | 3 | 2 | 2 | 3 | 2 | 3 | 1 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 3 | 2 | 6 | 2 | 3 | 6 | 2 | 0 | 3 | 2 | |
| 1 | 1 | 9 | 9 | 0 | 9 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 4 | 9 | 0 | 3 | 5 | 1 | 0 | 6 | 9 | 1 | 0 | 9 | |

B6C3F1 MICE FEMALE

0.25 G/KG

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lymph Node
Mediastinal, Hyperplasia, Plasma Cell | | | | | | | | | | | | | | | | | | | | | | | | | | + | 3 |
| Lymph Node, Mandibular
Hyperplasia, Lymphoid | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Lymph Node, Mesenteric
Hyperplasia, Plasma Cell | | | | | | | | | | | | | | | | | | | | | | | | | | + | 3 |
| Spleen
Hematopoietic Cell Proliferation
Hyperplasia, Lymphoid
Lymphoid Follicle, Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Thymus
Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Skin
Ulcer
Subcutaneous Tissue, Fibrosis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

MUSCULOSKELETAL SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
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 Page 86

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| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 6 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 5 5 7 6 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 8 3 2 2 3 2 3 1 3 3 3 3 3 2 2 3 2 6 2 3 6 2 0 3 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 1 9 9 0 9 1 1 1 1 1 1 0 0 4 9 0 3 5 1 0 6 9 1 0 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0.25 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |
| | females (cont...) | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Fibrosis | | | | 2 | | | | | | | | | | | | | | | | | | | | | |
| Joint, Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | |
| Skeletal Muscle | | | | | | | | | | | | | | | | | | | | | | | | | |

NERVOUS SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation, Acute | | | | | | | | | | | | | | | | | | | | | | | | | |
| Metaplasia, Osseous | | | | | | | | | | | | | | | | | | | | | | | 1 | | |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | | | |
| Alveolar Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Alveolus, Infiltration Cellular, Histiocyte | | | | | | | | | | | | | | | | | | | | | | | | | |
| Serosa, Fibrosis | | | | | | | | | | | | | | | | | | | | | | | 1 | | |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | 1 | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
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|---|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|------------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 7 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 6 | 3 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | | |
| | 3 | 0 | 3 | 1 | 9 | 6 | 3 | 3 | 3 | 2 | 7 | 2 | 3 | 6 | 7 | 3 | 3 | 2 | 2 | 2 | 2 | 3 | 3 | 1 | 3 | |
| | 0 | 8 | 0 | 5 | 7 | 9 | 1 | 1 | 0 | 9 | 5 | 9 | 1 | 9 | 2 | 0 | 0 | 9 | 9 | 9 | 9 | 0 | 0 | 8 | 1 | |
| B6C3F1 MICE FEMALE | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 0.25 G/KG | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | |
| | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 | 0 | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | |
| | | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
| Necrosis | 2 | | 1 | | | | X | | X | | | | 1 | | | | | | | | | | | | 4 | 1.3 |
| Tension Lipidosis | | | | | | | | | | | | | X | | | | | | | | | | | | 8 | |
| Centrilobular, Hypertrophy | | | 1 | | | | | | | | | | 1 | | 1 | | 1 | | 1 | | | | 1 | | 20 | 1.0 |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | 10 | |
| Fat, Necrosis | | | | | | | | | | | 2 | | 3 | | 2 | | | | | | | | 3 | | 4 | 2.9 |
| Pancreas | | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Duct, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 4.0 |
| Salivary Glands | | | | | | | | | | | | | | | | | | | | | | | | | 49 | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Infiltration Cellular, Mononuclear Cell | 1 | | 1 | | 1 | | 1 | | 1 | | 1 | | 1 | | 1 | | 1 | | 2 | | | | 1 | | 33 | 1.1 |
| Stomach, Forestomach | | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Erosion | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Inflammation, Chronic | | | 2 | | | | | | | | | | 1 | | 1 | | | | | | | | | | 6 | 1.5 |
| Ulcer | | | 2 | | | | | | | | | | | | | | | | | | | | | | 2 | 2.5 |
| Epithelium, Hyperplasia | | | 1 | | | | | | | | | | 1 | | 1 | | 2 | | | | | | | | 6 | 1.3 |
| Stomach, Glandular | | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Infiltration Cellular, Mononuclear Cell | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Glands, Ectasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Tooth | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Dysplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |

CARDIOVASCULAR SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ .. Tissue examined microscopically
x .. Lesion present
I .. Insufficient tissue
M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically
1-4 .. Lesion qualified as:
1) Minimal 3) Moderate
2) Mild 4) Marked

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 0 |
| | 7 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 6 | 3 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| | 3 | 0 | 3 | 1 | 9 | 6 | 3 | 3 | 3 | 2 | 7 | 2 | 3 | 6 | 7 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 1 | 3 |
| | 0 | 8 | 0 | 5 | 7 | 9 | 1 | 1 | 0 | 9 | 5 | 9 | 1 | 9 | 2 | 0 | 0 | 9 | 9 | 9 | 9 | 9 | 0 | 0 | 8 | 1 |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0.25 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ANIMAL ID | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 |
| | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 0 |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|-------|
| Blood Vessel Mineralization | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 2.0 | |
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 2.0 |
| Cardiomyopathy | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 |
| Thrombosis | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 |
| Artery, Infiltration Cellular, Mononuclear Cell | | | | | | | | | | | | | | | | | | | | | | | | | | | | 4 1.0 |
| Myocardium, Mineralization | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 2.0 |
| Valve, Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 4.0 |

| ENDOCRINE SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Subcapsular, Hyperplasia | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 50 | 2.0 |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 4 1.0 |
| Parathyroid Gland | M | + | + | + | M | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 44 | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Pars Distalis, Hyperplasia | 1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | 4 1.3 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
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|---------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 7 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 6 | 3 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| | 3 | 0 | 3 | 1 | 9 | 6 | 3 | 3 | 3 | 2 | 7 | 2 | 3 | 6 | 7 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | |
| | 0 | 8 | 0 | 5 | 7 | 9 | 1 | 1 | 0 | 9 | 5 | 9 | 1 | 9 | 2 | 0 | 0 | 9 | 9 | 9 | 9 | 0 | 0 | 8 | 1 |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 0.25 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 |
| | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
| | | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Thyroid Gland Cyst | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| | | | | | | | | | | | | | | 1 | | | | | | | | | | | 1 1.0 |

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------------|---------------|
| Clitoral Gland | + | M | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | 48 | |
| Ovary | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | 3 | | | 1 3.0 | |
| Cyst | 1 | | | | 1 | 1 | | | | 1 | | | | | 1 | | | | | | | | | | 10 1.0 | |
| Thrombosis | | | | | | | | | | | | | | | | | 4 | | | | | | | | 1 4.0 | |
| Uterus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Inflammation, Suppurative | | | | | | | | | | | | | | 2 | | | | | | | | | | | 1 2.0 | |
| Metaplasia, Squamous | | | | | | | | | | 3 | | | | | | | | | | 2 | | | | | 2 2.5 | |
| Endometrium, Hyperplasia, Cystic | 2 | | 1 | 3 | 3 | 2 | 3 | 3 | 3 | 3 | | 3 | 3 | 3 | | 2 | 2 | 1 | 3 | | 2 | 3 | 1 | 2 | 2 | 44 2.0 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Fibrosis | 2 | | | | | | | | | | | | | | | | | | | | | | | | 2 2.0 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|---|
| | 7 7 7 7 6 6 7 7 7 7 5 7 7 6 3 7 7 7 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 0 3 1 9 6 3 3 3 2 7 2 3 6 7 3 3 2 2 2 2 3 3 1 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 8 0 5 7 9 1 1 0 9 5 9 1 9 2 0 0 9 9 9 9 0 0 8 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 0.25 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | |
| | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
| | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|-----|-----|
| Lymph Node
Mediastinal, Hyperplasia, Plasma Cell | | | | | | | | | | | | | | | | | | | | | | | | + | 3 | 1 | 3.0 |
| Lymph Node, Mandibular
Hyperplasia, Lymphoid | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | 3 | M | 4 | 2.0 |
| Lymph Node, Mesenteric
Hyperplasia, Plasma Cell | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | 50 | 1 | 3.0 | |
| Spleen
Hematopoietic Cell Proliferation | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |
| | 2 | | | 3 | 2 | | | | | | | | | | | | | | | | | | | | | | |
| Spleen
Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2 | 24 | 1.8 |
| Spleen
Lymphoid Follicle, Atrophy | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2 | 6 | 1.8 |
| | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2 | 2 | 2.0 |
| Thymus
Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |
| | 1 | | 4 | 1 | 2 | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | 50 | 44 | 2.1 | |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|-----|
| Mammary Gland | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| | | | | | | | | | | | | | | | | | | | | | | | | 49 | | |
| Skin
Ulcer | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| | | | | | | | | | | | | | | | | | | | | | | | | 4 | 1 | 4.0 |
| Skin
Subcutaneous Tissue, Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 | 2.0 |

MUSCULOSKELETAL SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|-----------------|--------------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 7 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 6 | 3 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | | |
| | 3 | 0 | 3 | 1 | 9 | 6 | 3 | 3 | 3 | 2 | 7 | 2 | 3 | 6 | 7 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | | |
| | 0 | 8 | 0 | 5 | 7 | 9 | 1 | 1 | 0 | 9 | 5 | 9 | 1 | 9 | 2 | 0 | 0 | 9 | 9 | 9 | 9 | 9 | 0 | 0 | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | | |
| | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 | | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | * TOTALS | |
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Fibrosis | | | | | | | | | | | | | 2 | | | 2 | | 1 | | 2 | | | 1 | 3 | 2 | 8 1.9 |
| Joint, Inflammation, Chronic | | | | | | | | | 1 | | | | | | | | | | | | | | | | 1 1.0 | |
| Skeletal Muscle | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| NERVOUS SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| RESPIRATORY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Inflammation, Acute | | 2 | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Metaplasia, Osseous | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | |
| Mineralization | | 1 | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | |
| Alveolar Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | |
| Alveolus, Infiltration Cellular, Histiocyte | | | 2 | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Serosa, Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Inflammation, Chronic | | | | | | | | | | | | | 1 | | | | | | | | | | | | 2 1.0 | |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 94

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL
 Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 7 7 7 6 6 7 7 7 7 5 7 7 6 3 7 7 7 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
0.25 G/KG | 3 0 3 1 9 6 3 3 3 2 7 2 3 6 7 3 3 2 2 2 2 3 3 1 3 | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 8 0 5 7 9 1 1 0 9 5 9 1 9 2 0 0 9 9 9 9 0 0 8 1 | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| * TOTALS | 2 3 | | | | | | | | | | | | | | | | | | | | | | | |
| | 7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 0 | | | | | | | | | | | | | | | | | | | | | | | |
| 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 | | | | | | | | | | | | | | | | | | | | | | | | |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|-----------------|
| Eye | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Harderian Gland | + + + + + + + + + + + + + + + M + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | | | | | 49 |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 2 1 |
| Infiltration Cellular, Mononuclear Cell | 1 | | | | | | | | | | | | | | | | | | | | | | | | 4 1.5
42 1.0 |

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------|
| Kidney | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Amyloid Deposition | 1 | | | | | | | | | | | | | | | | | | | | | | | | 2 1.0 |
| Hydronephrosis | | | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 |
| Inflammation | 2 | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Metaplasia, Osseous | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Mineralization | 2 1 1 1 1 1 1 1 1 1 2 1 1 1 1 1 1 1 1 1 1 1 1 | | | | | | | | | | | | | | | | | | | | | | | | 20 1.2 |
| Nephropathy | 2 2 1 2 1 1 1 1 1 1 2 1 1 1 1 1 1 1 1 1 1 1 1 | | | | | | | | | | | | | | | | | | | | | | | | 25 1.2 |
| Papilla, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | 3 2.0 |
| Renal Tubule, Hyperplasia | 2 2 | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Urinary Bladder | + A + + + + + + + + + + + + + M + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | | | | | 48 |
| Infiltration Cellular, Mononuclear Cell | 1 | | | | | | | | | | | | | | | | | | | | | | | | 34 1.1 |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 95

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | | females
(cont...) | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|----------------------|
| | 7 5 7 7 7 7 7 7 6 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 2 3 3 2 3 3 3 3 2 2 3 2 3 3 2 3 3 3 3 3 2 2 3 2 | | | | | | | | | | | | | | | | | | | | | | | | | females
(cont...) | |
| | 0 4 9 0 0 9 0 1 8 0 9 9 1 9 0 0 9 1 1 0 0 9 9 0 9 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | females
(cont...) |
| 0.5 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | | |
| Eosinophilic Focus | | | | X | X | | | | | | | X | X | X | X | | | X | | | | X | X | X | | | |
| Fatty Change | 2 | 1 | 2 | | 2 | 2 | 1 | 2 | 1 | 1 | 2 | | 2 | 1 | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | |
| Mixed Cell Focus | X | | | | | | | X | X | | | | | X | | | X | X | | | X | | X | X | | | |
| Necrosis | | | | 1 | | | | | | | | | | | | | | | | | | | | 1 | 1 | | |
| Tension Lipidosis | | | X | | | | | | | | | | X | | | | | X | X | | X | | | | | | |
| Centrilobular, Hypertrophy | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | |
| Mesentery | | | | + | | | + | | | | | | | | | | | | | | | | | + | | | |
| Fat, Necrosis | | | | 2 | | | 3 | | | | | | | | | | | | | | | | | 3 | | | |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Acinus, Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Acinus, Vacuolization Cytoplasmic | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Duct, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | | 1 | 1 | 1 | 1 | | 1 | | | | 1 | | 1 | 1 | 1 | 1 | |
| Duct, Submandibular Gland, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | 2 | | | | |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Erosion | | | | | | | | | | | | | | | | | | | | | | | | | 3 | | |
| Inflammation, Chronic | | | | 1 | | | | | | | | | | | 1 | | | | | | | 3 | | 3 | | | |
| Ulcer | | | | | | | | | | | | | | | | | | | | | | | 3 | | | | |
| Epithelium, Hyperplasia | | | | 1 | | | | | | | | | | | 1 | | | 2 | | | | 3 | | 3 | 2 | | |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ .. Tissue examined microscopically
x .. Lesion present
I .. Insufficient tissue
M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically
1-4 .. Lesion qualified as:
1) Minimal 3) Moderate
2) Mild 4) Marked
Page 97

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 5 7 7 7 7 7 7 6 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 2 3 3 2 3 3 3 3 2 2 3 2 3 3 2 3 3 3 3 2 2 3 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 4 9 0 0 9 0 1 8 0 9 9 1 9 0 0 9 1 1 0 0 9 9 0 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
0.5 G/KG | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 1 1 1 1 1 2 2 2 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 | | | | | | | | | | | | | | | | | | | | | | | | |

females
(cont...)

| | | | | | | | | | | | | | | | | | | | | | | |
|-----------------|--|--|--|--|--|--|--|--|--|--|---|--|--|--|--|--|--|--|--|--|--|---|
| Glands, Ectasia | | | | | | | | | | | 1 | | | | | | | | | | | 1 |
| Tooth Dysplasia | | | | | | | | | | | | | | | | | | | | | | + |
| | | | | | | | | | | | | | | | | | | | | | | 1 |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Blood Vessel | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Heart | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Cardiomyopathy | | | | | | | | | | | | | | | | | | | | | | | | | |
| Artery, Infiltration Cellular, Mononuclear Cell | 1 | | | | | | | | | | | | | | | | | | | | | | | | |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Adrenal Cortex | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Vacuolization Cytoplasmic Subcapsular, Hyperplasia | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Adrenal Medulla | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia | 2 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Islets, Pancreatic | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Parathyroid Gland | + + + + + + + M + + + + + + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| | 3 | 3 | 2 | 3 | 3 | 2 | 3 | 3 | 3 | 3 | 2 | 2 | 3 | 2 | 3 | 3 | 2 | 3 | 3 | 3 | 3 | 2 | 2 | 3 | 2 |
| | 0 | 4 | 9 | 0 | 0 | 9 | 0 | 1 | 8 | 0 | 9 | 9 | 1 | 9 | 0 | 0 | 9 | 1 | 1 | 0 | 0 | 9 | 9 | 0 | 9 |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 0.5 G/KG | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

females
(cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Angiectasis | | | | | | | | | 2 | | | | | | | | | | | | | | | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Pars Distalis, Hyperplasia | | | | | | | | 1 | 3 | | | | 1 | 1 | | | | | | | | | | |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

GENERAL BODY SYSTEM
 NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Ovary | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Cyst | | | | | 1 | | | | 1 | | 2 | | 1 | | | | | | | 1 | | | | | | |
| Thrombosis | | | | | | | | | | | | | | | | | | | 3 | | | | | | | |
| Uterus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Endometrium, Hyperplasia, Cystic | 2 | | 2 | 1 | 2 | 1 | 3 | 2 | | | | 3 | 1 | | 2 | 3 | 2 | 3 | 2 | 1 | 3 | | 1 | 2 | 2 | 2 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 5 7 7 7 7 7 7 6 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 2 3 3 2 3 3 3 3 2 2 3 2 3 3 2 3 3 3 3 2 2 3 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 4 9 0 0 9 0 1 8 0 9 9 1 9 0 0 9 1 1 0 0 9 9 0 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
0.5 G/KG | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 | | | | | | | | | | | | | | | | | | | | | | | | |

females (cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Fibrosis | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mandibular
Hyperplasia, Lymphoid | +
2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mesenteric | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Spleen
Hematopoietic Cell Proliferation
Hyperplasia, Lymphoid
Lymphoid Follicle, Atrophy | +
2 1 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 2 2
2 2 2 2 1 1 3 1 2 1 1 2 2 1 2 2 2 1 2 2 2 2 1 2 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Thymus
Atrophy
Hyperplasia, Histiocytic | +
2 2 2 2 2 1 1 3 1 2 1 1 2 2 1 2 2 2 1 2 2 2 2 2 1 | | | | | | | | | | | | | | | | | | | | | | | | |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Mammary Gland | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Skin
Fibrosis
Inflammation, Chronic
Subcutaneous Tissue, Necrosis | +
3
3
3 | | | | | | | | | | | | | | | | | | | | | | | | |

MUSCULOSKELETAL SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|---|
| | 0730 | 0733 | 0732 | 0733 | 0733 | 0732 | 0733 | 0733 | 0733 | 0733 | 0733 | 0733 | 0733 | 0733 | 0733 | 0733 | 0733 | 0733 | 0733 | 0733 | 0733 | 0733 | 0733 | 0733 | 0733 | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 0.5 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| ANIMAL ID | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

females (cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone Fibrosis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | 2 | | 1 | | | | | | | | | | | | | | | | | | | | | | |

NERVOUS SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lung Inflammation | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nose Glands, Dilatation, Nasolacrimal Duct, Inflammation, Suppurative | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|---------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|-----|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Harderian Gland Atrophy Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
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TDMS No. 20007 - 06
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 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 5 7 7 7 7 7 7 6 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 2 3 3 2 3 3 3 3 2 2 3 2 3 3 2 3 3 3 2 2 3 2 | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 4 9 0 0 9 0 1 8 0 9 9 1 9 0 0 9 1 1 0 0 9 9 0 9 | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
0.5 G/KG | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 1 1 1 1 1 2 2 2 2 | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 | | | | | | | | | | | | | | | | | | | | | | | |

females (cont...)

Infiltration Cellular, Mononuclear Cell 1

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Kidney | + | | | | | | | | | | | | | | | | | | | | | | | |
| Amyloid Deposition | | | | | | | | | | | | | | | | | | | | | | | | |
| Metaplasia, Osseous | | | | | | | | | | | | | | | | | | | | | | | | |
| Mineralization | 1 | | | | | | | | | | | | | | | | | | | | | | | |
| Nephropathy | 1 1 2 1 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | | | | | | | | | | | | | | | | | | | | | | | |
| Papilla, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | |
| Pelvis, Cyst | 2 | | | | | | | | | | | | | | | | | | | | | | | |
| Renal Tubule, Hyperplasia | 1 | | | | | | | | | | | | | | | | | | | | | | | |
| Urinary Bladder | + | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | 1 | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 102

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|--|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 |
| | 2 | 2 | 2 | 2 | 3 | 2 | 5 | 2 | 3 | 3 | 2 | 2 | 2 | 3 | 2 | 3 | 2 | 2 | 3 | 2 | 5 | 1 | 2 | 3 | 2 |
| | 9 | 9 | 9 | 9 | 0 | 9 | 4 | 9 | 0 | 1 | 9 | 9 | 9 | 1 | 9 | 1 | 9 | 9 | 0 | 9 | 6 | 2 | 9 | 1 | 9 |
| B6C3F1 MICE FEMALE
0.5 G/KG | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 |
| 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Gallbladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Duodenum
Epithelium, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Intestine Small, Ileum
Inflammation, Chronic Active
Ulcer | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Intestine Small, Jejunum
Peyer's Patch, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 |
| Liver
Angiectasis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Basophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Clear Cell Focus | | | | | | | | | | | | | | | | | | | | | | | | | 4 4.0 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |

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x .. Lesion present
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A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically
1-4 .. Lesion qualified as:
1) Minimal 3) Moderate
2) Mild 4) Marked
Page 103

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|---|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 0.5 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | |
| Eosinophilic Focus | | | | X | | | X | X | X | | X | | | | | | | | | X | | | | | |
| Fatty Change | 1 | | 1 | | | 1 | | 1 | 1 | 1 | 1 | 2 | 2 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | |
| Hematopoietic Cell Proliferation | 1 | 2 | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | 1 | 2 | 1 | 1 | 1 | 2 | | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | |
| Mixed Cell Focus | X | | | | | | | | | | | X | | X | | | | | | | | X | | | |
| Necrosis | | 1 | | | | | | | | | | | | | | | | | | | | 2 | | | |
| Tension Lipidosis | | | | | X | | | | | | | | | X | | | | | | | | | | | |
| Centrilobular, Hypertrophy | 2 | 2 | | 1 | 2 | 1 | 2 | 1 | 2 | 1 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 1 | 2 | 2 | | 2 | 2 | | |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Acinus, Atrophy | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Acinus, Vacuolization Cytoplasmic | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Duct, Cyst | 4 | | | | | | | | | | | | | | | | | | | | | | | | |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Infiltration Cellular, Mononuclear Cell | 1 | | | | 1 | 1 | | 1 | | | 1 | 1 | 2 | | | 2 | | | 1 | 1 | | 1 | 1 | | |
| Duct, Submandibular Gland, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Erosion | | 3 | | | | | 2 | 3 | 4 | 3 | | | | | 4 | | 3 | 3 | 4 | 3 | 2 | | 4 | | |
| Inflammation, Chronic | | 3 | | | 3 | 3 | 2 | 3 | 3 | 3 | | | | | 3 | 1 | 3 | 4 | 3 | 3 | 2 | 1 | 4 | | |
| Ulcer | | | | | 3 | 3 | | | | | | | | | | | | | | | | | | | |
| Epithelium, Hyperplasia | | 3 | | | 4 | 3 | 3 | 3 | 3 | 4 | | | | | 4 | 1 | 3 | 4 | 4 | 3 | 1 | 2 | 4 | | |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|--|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | | |
| | 2 | 2 | 2 | 2 | 3 | 2 | 5 | 2 | 3 | 3 | 2 | 2 | 2 | 3 | 2 | 3 | 2 | 2 | 3 | 2 | 5 | 1 | 2 | 3 | 2 | |
| | 9 | 9 | 9 | 9 | 0 | 9 | 4 | 9 | 0 | 1 | 9 | 9 | 9 | 1 | 9 | 1 | 9 | 9 | 0 | 9 | 6 | 2 | 9 | 1 | 9 | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 0.5 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | | |
| | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 | | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | * TOTALS | |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------------|
| Glands, Ectasia | | | | | | | | | | | | | | | | | | | | | | | | | 2 1.0 |
| Tooth Dysplasia | | | | | | | | | | | | | | | | | | | | | | | | | 2 1.0 |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Blood Vessel | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Cardiomyopathy | | | 1 | | | | 1 | | | | | | | | | | | | 1 | | | | | | 4 1.0 |
| Artery, Infiltration Cellular, Mononuclear Cell | | | | | | | | | | | | | | 1 | | | | | | 1 | 1 | | | | 3 1.0 |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|-----------|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Vacuolization Cytoplasmic Subcapsular, Hyperplasia | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 50 2.0 | |
| Adrenal Medulla Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 2.0 | |
| Islets, Pancreatic Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 1 2.0 | |
| Parathyroid Gland | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
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TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
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P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
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Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|--------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| | 7 7 7 7 7 7 5 7 7 7 7 7 7 7 7 7 7 7 7 7 5 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
0.5 G/KG | 2 2 2 2 3 2 5 2 3 3 2 2 2 3 2 3 2 2 3 2 5 1 2 3 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 9 9 9 9 0 9 4 9 0 1 9 9 9 1 9 1 9 9 0 9 6 2 9 1 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 2 2 2 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | 49 | |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 1.0 |
| Pars Distalis, Hyperplasia | | | 1 | 1 | | | | | | | | | | | | | | | | | | | | | | | 7 1.3 |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |

GENERAL BODY SYSTEM
 NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|-------|
| Clitoral Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Ovary | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 2.0 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | 6 1.3 |
| Thrombosis | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 3.5 |
| Uterus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Endometrium, Hyperplasia, Cystic | 1 | 2 | 3 | 2 | 3 | 2 | 2 | 1 | 2 | | 2 | 1 | 3 | 4 | 3 | 2 | 3 | 3 | 3 | 1 | 2 | | | 1 | 4 | 42 2.1 | |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
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 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 |
| | 2 | 2 | 2 | 2 | 3 | 2 | 5 | 2 | 3 | 3 | 2 | 2 | 2 | 3 | 2 | 3 | 2 | 2 | 3 | 2 | 5 | 1 | 2 | 3 | 2 |
| | 9 | 9 | 9 | 9 | 0 | 9 | 4 | 9 | 0 | 1 | 9 | 9 | 9 | 1 | 9 | 1 | 9 | 9 | 0 | 9 | 6 | 2 | 9 | 1 | 9 |
| B6C3F1 MICE FEMALE
0.5 G/KG | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Lymph Node, Mandibular
Hyperplasia, Lymphoid | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | 2 | |
| | | | | | | | | | | | | | | | | | | | | | | | | | 4 | 2.0 |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| | | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Spleen
Hematopoietic Cell Proliferation
Hyperplasia, Lymphoid
Lymphoid Follicle, Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| | 2 | 4 | | 1 | 1 | | | | | | | | | 1 | | 1 | | 1 | | | | 4 | | 1 | 1 | |
| | | | | | 4 | | | | | 2 | | | | | 2 | | | | | 2 | | | | | 20 | 1.5 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 6 | 2.0 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 4 | 2.5 |
| Thymus
Atrophy
Hyperplasia, Histiocytic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| | 4 | 2 | 2 | 1 | 1 | 1 | 4 | 1 | | 2 | 1 | 1 | 1 | 1 | M | + | + | + | + | + | + | + | + | + | | |
| | | | | | 2 | | | | | | | | | | | | | | | | | | | | 49 | |
| | | | | | | | | | | | | | | | | | | | | | | | | | 46 | 1.7 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2.0 |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| | | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Skin
Fibrosis
Inflammation, Chronic
Subcutaneous Tissue, Necrosis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| | | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |

MUSCULOSKELETAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | | | | | | | | | | | | | | | | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ .. Tissue examined microscopically
x .. Lesion present
I .. Insufficient tissue
M .. Missing tissue
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TDMS No. 20007 - 06
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 Lab: BAT

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|--|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | | |
| | 2 | 2 | 2 | 2 | 3 | 2 | 5 | 2 | 3 | 3 | 2 | 2 | 2 | 3 | 2 | 3 | 2 | 2 | 3 | 2 | 5 | 1 | 2 | 3 | 2 | |
| | 9 | 9 | 9 | 9 | 0 | 9 | 4 | 9 | 0 | 1 | 9 | 9 | 9 | 1 | 9 | 1 | 9 | 9 | 0 | 9 | 6 | 2 | 9 | 1 | 9 | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 0.5 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | | |
| | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 | | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | * TOTALS | |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Fibrosis | | | 1 | | | | | | | 3 | | | | 1 | | | | | | | | | | | 7 1.6 |

NERVOUS SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Inflammation | | | | | | | | | | | | | | | | | | | | | 1 | | | | 2 1.0 |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Glands, Dilatation | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Nasolacrimal Duct, Inflammation, Suppurative | | | | | | | 2 | | | | | | | | | | | | | | | | | | 1 2.0 |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
|---------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|
| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
|-----|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Atrophy | | | | | | | | | | | | | 1 | | | | | | | | | | | | 1 1.0 |
| Hyperplasia | | | 1 | 2 | | | | | | | | | | | | | | | | 1 | | | | | 5 1.6 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 108

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| DAY ON TEST | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|---------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 0 |
| 2 | 2 | 2 | 2 | 3 | 2 | 5 | 2 | 3 | 3 | 2 | 2 | 2 | 3 | 2 | 3 | 2 | 2 | 3 | 2 | 5 | 1 | 2 | 3 | 2 | 0 |
| 9 | 9 | 9 | 9 | 0 | 9 | 4 | 9 | 0 | 1 | 9 | 9 | 9 | 1 | 9 | 1 | 9 | 9 | 0 | 9 | 6 | 2 | 9 | 1 | 9 | 0 |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0.5 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 | 3 |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|--|--|--|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------------|
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | 1 | 1 | | | | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 42 1.0 |
|---|---|---|---|---|--|--|--|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------------|

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------------|---------------|
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Amyloid Deposition | | | | | | 1 | | | | | | | | | | | | | | | | | | | 2 1.0 |
| Metaplasia, Osseous | | | | 1 | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Mineralization | | | | | | | | | 1 | 1 | | | | | | | | | | | | | | | 7 1.0 |
| Nephropathy | 2 | 1 | 1 | 1 | 1 | 1 | 4 | | 1 | | 1 | 1 | 1 | | | | 1 | | 1 | 1 | | | 1 | 26 1.3 | |
| Papilla, Necrosis | | | | | | | | | 2 | | | | | | | | | | | | | | | | 1 2.0 |
| Pelvis, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Renal Tubule, Hyperplasia | | | | | | | | | 1 | | | | | | | | | | | | | | | | 2 1.0 |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Infiltration Cellular, Mononuclear Cell | | 1 | | 1 | 1 | 1 | 1 | | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | | 1 | 1 | 1 | 40 1.0 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 109

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 6 7 6 7 7 6 5 7 7 7 5 7 7 7 7 7 5 7 7 6 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 2 5 3 7 2 3 8 2 3 3 3 7 3 3 3 3 3 4 2 2 0 2 2 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 4 0 8 9 0 4 3 1 0 1 6 1 0 0 1 1 1 8 9 9 4 3 9 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
1.0 G/KG | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 | | | | | | | | | | | | | | | | | | | | | | | | |

females (cont...)

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Esophagus | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Gallbladder
Cyst
Epithelium, Cytoplasmic Alteration | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Large, Cecum | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Large, Colon | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Large, Rectum | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Small, Duodenum
Metaplasia, Squamous | +
1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Small, Ileum | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Small, Jejunum
Epithelium, Hyperplasia | +
3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Liver
Basophilic Focus
Clear Cell Focus
Eosinophilic Focus
Fatty Change | +
X
X
X X
2 4 2 2 1 1 X X X X X X X X X X
1 1 1 2 1 2 1 1 | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
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| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 7 6 7 6 7 7 6 5 7 7 7 5 7 7 7 7 7 5 7 7 6 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 2 5 3 7 2 3 8 2 3 3 3 7 3 3 3 3 3 4 2 2 0 2 2 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 4 0 8 9 0 4 3 1 0 1 6 1 0 0 1 1 1 8 9 9 4 3 9 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.0 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

females (cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | | | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | | | | 1 | 1 | |
| Mixed Cell Focus | X | | | | | | | | | | X | | | | | | X | X | | | | | | | |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | |
| Tension Lipidosis | | | | | | | | | | | X | | | | | | | X | | | | | | | X |
| Vacuolization Cytoplasmic | | | | | | | | | | | | | | | | | | | | | | 2 | | | |
| Centrilobular, Hypertrophy | | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Mesentery | | | + | | | | | | | | | | | | | | | | | | | | | | |
| Fat, Necrosis | | | 2 | | | | | | | | | | | | | | | | | | | | | | |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Infiltration Cellular, Mononuclear Cell | | | | | | | | | | | | | | | | | | | | | | | | | |
| Acinus, Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Duct, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Infiltration Cellular, Mononuclear Cell | 1 | | 1 | 1 | | | | | | | | | | 1 | | 1 | | 1 | | 1 | | | 1 | 1 | 1 |
| Parotid Gland, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Erosion | | | | | | 4 | | 3 | 3 | 2 | | 3 | 2 | | 3 | | 3 | 2 | | | | | | 2 | |
| Inflammation, Chronic | | 2 | | | 2 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 1 | 3 | | 3 | 3 | 3 | | | | | 3 | |
| Ulcer | | 2 | | | 2 | | 3 | | | | 3 | | | | | | | | 2 | | | | | | |
| Epithelium, Hyperplasia | | 1 | | | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 3 | 1 | 3 | | 3 | 3 | 3 | | | | | 3 | |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Infiltration Cellular, Mononuclear Cell | | | | | | | | | | | | | | 2 | | | | | | | | | | | |
| Ulcer | | 2 | | | | | | | 2 | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
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 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
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TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 7 6 7 6 7 7 6 5 7 7 7 5 7 7 7 7 7 5 7 7 6 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 2 5 3 7 2 3 8 2 3 3 3 7 3 3 3 3 3 4 2 2 0 2 2 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 4 0 8 9 0 4 3 1 0 1 6 1 0 0 1 1 1 8 9 9 4 3 9 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.0 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

females (cont...)

| | | |
|-------------------------|---|---|
| Epithelium, Hyperplasia | 2 | 2 |
| Tooth Dysplasia | + | 1 |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Blood Vessel | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cardiomyopathy | | | | | | | | | | | | | | | | | | | | | | | | |
| Myocardium, Mineralization | 2 | | | | | | | | | | | | | | | | | | | | | | | |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Subcapsular, Hyperplasia | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 2 |
| Zona Reticularis, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | | | | | | | | | | | 2 | | | | | | | | | | 1 | | | |
| Vacuolization Cytoplasmic | 1 | | | | | | | | | | | | | | | | | | | | | | | |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Parathyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
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 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
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 2) Mild 4) Marked

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 7 | 6 | 7 | 6 | 7 | 7 | 6 | 5 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 6 | 7 | 7 | 7 |
| | 2 | 5 | 3 | 7 | 2 | 3 | 8 | 2 | 3 | 3 | 3 | 7 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 2 | 2 | 0 | 2 | 2 | 3 |
| | 5 | 4 | 0 | 8 | 9 | 0 | 4 | 3 | 1 | 0 | 1 | 6 | 1 | 0 | 0 | 1 | 1 | 1 | 8 | 9 | 9 | 4 | 3 | 9 | 1 |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.0 G/KG | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

females (cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pars Distalis, Hyperplasia | | | | | | | | | | | 2 | | | | | | | | | | 2 | 1 | | | |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

GENERAL BODY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Tissue NOS | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | |

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Ovary | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | |
| Uterus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Endometrium, Hyperplasia, Cystic | 2 | | 2 | 1 | 1 | 2 | 1 | | 3 | | 2 | 3 | | 1 | 3 | 1 | 2 | 1 | 1 | | 1 | 2 | 2 | 3 | |
| Vagina | | | | | | | | | | | | | | | | | | | | | | | | | |
| Vacuolization Cytoplasmic | | | | | | | | | | | | | | | | | | | | | | | | | |

HEMATOPOIETIC SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
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| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|
| | 7 6 7 6 7 7 6 5 7 7 7 5 7 7 7 7 7 5 7 7 6 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
1.0 G/KG | 2 5 3 7 2 3 8 2 3 3 3 7 3 3 3 3 3 4 2 2 0 2 2 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 4 0 8 9 0 4 3 1 0 1 6 1 0 0 1 1 1 8 9 9 4 3 9 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| 1.0 G/KG | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 |

females (cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Bone Marrow
Fibrosis
Necrosis | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mandibular
Hyperplasia, Lymphoid | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mesenteric
Hyperplasia, Lymphoid
Inflammation, Granulomatous | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Spleen
Hematopoietic Cell Proliferation
Hyperplasia, Lymphoid
Lymphoid Follicle, Atrophy | A +
1 2 2 1 2 2
4 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Thymus
Atrophy
Hyperplasia, Histiocytic
Infiltration Cellular, Histiocyte | + M + + + + M + + + + + M + + + + + + + + + + + + +
4 4 4 4 1 2 2 1 2 1 2 2 2 3 1 4 4 1 1 | | | | | | | | | | | | | | | | | | | | | | | | |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Mammary Gland | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Skin | + | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 7 | 6 | 7 | 6 | 7 | 7 | 6 | 5 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 6 | 7 | 7 | 7 | |
| | 2 | 5 | 3 | 7 | 2 | 3 | 8 | 2 | 3 | 3 | 3 | 7 | 3 | 3 | 3 | 3 | 3 | 4 | 2 | 2 | 0 | 2 | 2 | 3 | |
| | 5 | 4 | 0 | 8 | 9 | 0 | 4 | 3 | 1 | 0 | 1 | 6 | 1 | 0 | 0 | 1 | 1 | 1 | 8 | 9 | 9 | 4 | 3 | 9 | 1 |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 1.0 G/KG | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

females (cont...)

MUSCULOSKELETAL SYSTEM

Bone +
 Fibrosis 1 2

NERVOUS SYSTEM

Brain +

Peripheral Nerve
 Axon, Degeneration

Spinal Cord

RESPIRATORY SYSTEM

Lung +
 Alveolar Epithelium, Hyperplasia 2
 Alveolus, Infiltration Cellular, Histiocyte 1

Nose +
 Inflammation, Suppurative 2

Trachea +

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 6 7 6 7 7 6 5 7 7 7 5 7 7 7 7 7 5 7 7 6 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
1.0 G/KG | 2 5 3 7 2 3 8 2 3 3 3 7 3 3 3 3 3 4 2 2 0 2 2 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 4 0 8 9 0 4 3 1 0 1 6 1 0 0 1 1 1 8 9 9 4 3 9 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 | | | | | | | | | | | | | | | | | | | | | | | | |

females (cont...)

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Eye | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Harderian Gland | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | 1 | | | | | | | | | | | | | | | | | | | | | | | | |

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Kidney | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Amyloid Deposition | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | |
| Metaplasia, Osseous | 1 1 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Mineralization | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Nephropathy | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Papilla, Necrosis | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Urinary Bladder | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mononuclear Cell | 1 | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
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TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 5 7 1 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 6 7 7 | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 4 1 4 3 3 3 3 3 3 3 3 3 2 2 3 3 3 3 3 3 2 3 2 6 3 3 | | | | | | | | | | | | | | | | | | | | | | | |
| | 8 9 8 0 0 1 0 0 1 0 0 9 9 1 0 0 1 1 1 9 0 9 9 0 0 | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
1.0 G/KG | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 4 | | | | | | | | | | | | | | | | | | | | | | | |
| | 7 7 7 7 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 | | | | | | | | | | | | | | | | | | | | | | | |
| * TOTALS | | | | | | | | | | | | | | | | | | | | | | | | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|-----|
| Esophagus | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Gallbladder | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Epithelium, Cytoplasmic Alteration | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2.0 |
| Intestine Large, Cecum | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Intestine Large, Colon | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Intestine Large, Rectum | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Intestine Small, Duodenum | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Metaplasia, Squamous | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Intestine Small, Ileum | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Intestine Small, Jejunum | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| Liver | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Basophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Clear Cell Focus | | | | | | | | | | | | | | | | | | | | | | | | | X | 5 |
| Eosinophilic Focus | X | | | | | | | | | | | | | | | | | | | | | | | | X | 26 |
| Fatty Change | 1 1 | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.3 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
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| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|-----|
| | 5 7 1 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 6 7 7
4 1 4 3 3 3 3 3 3 3 3 2 2 3 3 3 3 3 3 2 3 2 6 3 3
8 9 8 0 0 1 0 0 1 0 0 9 9 1 0 0 1 1 1 9 0 9 9 0 0 | | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
1.0 G/KG | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 4
7 7 7 7 8 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 0
6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 2.0 | |
| Infiltration Cellular, Mononuclear Cell | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 44 | 1.1 |
| Mixed Cell Focus | | | | | | | | | | | | | | | | | | | | | | | | X | 7 | |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 1.0 | |
| Tension Lipidosis | | | | | | | | | | | | | | | | | | | | | | | | X | 4 | |
| Vacuolization Cytoplasmic | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Centrilobular, Hypertrophy | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 49 | 2.0 |
| Mesentery | + | + | | | + | | | | | | | | | | | + | | | | | | | | + | 6 | |
| Fat, Necrosis | 2 | 2 | | | 4 | | | | | | | | | | 2 | | | | | | | | | 2 | 6 | 2.3 |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Infiltration Cellular, Mononuclear Cell | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 1.0 | |
| Acinus, Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | |
| Duct, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 | |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Infiltration Cellular, Mononuclear Cell | 1 | | | 1 | 1 | 1 | | | | 1 | 1 | 1 | | | 1 | 1 | | | 1 | 1 | 1 | | 1 | 1 | 26 | 1.0 |
| Parotid Gland, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 2.0 | |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Erosion | | | | | | | | | | | | | | | | | | | | | | | | | 3 | |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | 2 4 2 | |
| Ulcer | | | | | | | | | | | | | | | | | | | | | | | | | 2 | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 2 3 3 | |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Infiltration Cellular, Mononuclear Cell | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Ulcer | | | | | | | | | | | | | | | | | | | | | | | | | 2 2.0 | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
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| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 5 7 1 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 6 7 7 | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 4 1 4 3 3 3 3 3 3 3 3 3 2 2 3 3 3 3 3 2 3 2 6 3 3 | | | | | | | | | | | | | | | | | | | | | | | |
| | 8 9 8 0 0 1 0 0 1 0 0 9 9 1 0 0 1 1 1 9 0 9 9 0 0 | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
1.0 G/KG | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 4 | | | | | | | | | | | | | | | | | | | | | | | |
| | 7 7 7 7 8 8 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 | | | | | | | | | | | | | | | | | | | | | | | |
| * TOTALS | | | | | | | | | | | | | | | | | | | | | | | | |

| | |
|-------------------------|--------------|
| Epithelium, Hyperplasia | 2 2.0 |
| Tooth Dysplasia | 2 1.0 |

CARDIOVASCULAR SYSTEM

| | |
|----------------------------|--------------|
| Blood Vessel | 50 |
| Heart | 50 |
| Cardiomyopathy | 1 1.0 |
| Myocardium, Mineralization | 1 2.0 |

ENDOCRINE SYSTEM

| | |
|-------------------------------|---------------|
| Adrenal Cortex | 50 |
| Subcapsular, Hyperplasia | 50 1.9 |
| Zona Reticularis, Hyperplasia | 1 1.0 |
| Adrenal Medulla | 50 |
| Hyperplasia | 2 1.5 |
| Vacuolization Cytoplasmic | 1 1.0 |
| Islets, Pancreatic | 50 |
| Parathyroid Gland | 48 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
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 Page 119

TDMS No. 20007 - 06
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| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|---------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 0 |
| | 5 | 7 | 1 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | | |
| | 4 | 1 | 4 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 2 | 6 | 3 | 3 | |
| | 8 | 9 | 8 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 9 | 9 | 1 | 0 | 0 | 1 | 1 | 1 | 9 | 0 | 9 | 9 | 0 | 0 | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 1.0 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | |
| | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|-----|
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Pars Distalis, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1.8 |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |

GENERAL BODY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|---|-----|
| Tissue NOS | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | | |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|---|-----|-----|-----|
| Clitoral Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | | | |
| Ovary | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | | |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 | | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 | | |
| Uterus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | | |
| Endometrium, Hyperplasia, Cystic | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.8 | |
| Vagina | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | | |
| Vacuolization Cytoplasmic | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |

HEMATOPOIETIC SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 120

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|--------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| | 5 7 1 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 6 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
1.0 G/KG | 4 1 4 3 3 3 3 3 3 3 3 3 2 2 3 3 3 3 3 3 2 3 2 6 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 8 9 8 0 0 1 0 0 1 0 0 0 9 9 1 0 0 1 1 1 9 0 9 9 0 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 7 7 7 7 8 8 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|-----|
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 | |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2.0 |
| Lymph Node, Mandibular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 2.5 |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2.0 |
| Inflammation, Granulomatous | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 3.0 |
| Spleen | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.8 |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2.0 |
| Lymphoid Follicle, Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 3.5 |
| Thymus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 47 | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2.1 |
| Hyperplasia, Histiocytic | | | | | | | | | | | | | | | | | | | | | | | | | | | 4 | 2.0 |
| Infiltration Cellular, Histiocyte | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2.5 |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|---|
| | 5 7 1 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 6 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 4 1 4 3 3 3 3 3 3 3 3 3 2 2 3 3 3 3 3 3 2 3 2 6 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 8 9 8 0 0 1 0 0 1 0 0 0 9 9 1 0 0 1 1 1 9 0 9 9 0 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.0 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 |
| | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |
| | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |

MUSCULOSKELETAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Fibrosis | 1 | | | 1 | | | | | | 2 | | | | 2 | | | | | | | 2 | 3 | 2 | | | 9 1.8 |

NERVOUS SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|----|
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Peripheral Nerve | + | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Axon, Degeneration | 4 | | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 | |
| Spinal Cord | + | | | | | | | | | | | | | | | | | | | | | | | | 1 | |

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|---|----|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Alveolar Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | | |
| Alveolus, Infiltration Cellular, Histiocyte | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | | |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Inflammation, Suppurative | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | | |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

