

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

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

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

F2_R2

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

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

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

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

FISCHER 344 RATS MALE	DAY ON TEST																									males (cont...)
	0729	0727	0671	0778	0777	0660	0667	0772	0777	0777	0777	0572	0772	0777	0777	0575	0772	0772	0772	0772	0772	0772	0772	0772	0772	
0.0 G/KG	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	0000
	12	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	

ALIMENTARY SYSTEM

Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Epithelium, Hyperplasia																										1
Epithelium, Necrosis																										
Muscularis, Degeneration																										
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Parasite Metazoan					X			X	X	X															X	
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Ectopic Tissue																										
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Necrosis																										
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Basophilic Focus	X			X					X	X	X		X					X					X	X	X	X
Clear Cell Focus		X		X					X				X	X	X				X	X	X					
Eosinophilic Focus				X					X				X	X								X		X		
Fatty Change, Diffuse											1	1					3						2		2	1
Hematopoietic Cell Proliferation																										
Hepatodiaphragmatic Nodule					X																					
Inflammation, Chronic Active	1	1		1	1				1	1	1	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

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

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

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

	DAY ON TEST																										
FISCHER 344 RATS MALE	0 7 2 9	0 7 2 7	0 6 5 1	0 7 2 8	0 7 2 7	0 6 1 0	0 6 2 9	0 7 2 9	0 7 2 7	0 7 2 8	0 7 2 7	0 5 8 2	0 7 2 8	0 7 2 9	0 5 2 4	0 7 2 7	0 7 2 7	0 7 2 7	0 7 2 7	0 7 2 7	0 7 2 7	0 7 2 7	0 5 2 8	0 7 2 7	0 5 2 8	0 7 2 7	
0.0 G/KG	0 0 0 0 1	0 0 0 0 2	0 0 0 0 3	0 0 0 0 4	0 0 0 0 5	0 0 0 0 6	0 0 0 0 7	0 0 0 0 8	0 0 0 0 9	0 0 0 0 0	0 0 0 0 1	0 0 0 0 1	0 0 0 0 2	0 0 0 0 3	0 0 0 0 4	0 0 0 0 5	0 0 0 0 6	0 0 0 0 7	0 0 0 0 8	0 0 0 0 9	0 0 0 0 0	0 0 0 0 1	0 0 0 0 2	0 0 0 0 3	0 0 0 0 4	0 0 0 0 5	males (cont...)

CARDIOVASCULAR SYSTEM

Blood Vessel	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cardiomyopathy	2	3	2	2	2	1	1	2	3	3	2	2	3	2	3		3	1	3	3	3	3	2	3	2
Atrium, Thrombosis								2																	

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Degeneration, Cystic	3																							
Hypertrophy				1				2																
Necrosis								1																
Vacuolization Cytoplasmic											3													
Zona Fasciculata, Hyperplasia	1	1									1		1										1	
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hyperplasia						1	1																3	1
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hyperplasia																								
Parathyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hyperplasia																	2							
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hemorrhage			2																					
Pars Distalis, Hyperplasia				1	2		1			1			1		3					1				
Thyroid 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

FISCHER 344 RATS MALE	DAY ON TEST																									ANIMAL ID	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			0	
0.0 G/KG	7	7	6	7	7	6	6	7	7	7	7	5	7	7	7	5	7	7	7	7	7	7	7	7	7	7	0		
	2	2	5	2	2	1	2	2	2	2	2	8	2	2	2	0	2	2	2	2	2	2	2	2	2	2	2	0	
	9	7	1	8	7	0	9	9	7	8	7	2	8	7	9	4	7	7	7	8	8	7	7	8	8	8	8	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	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	2	2	2	2	2	2	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	5	0		

C-cell, Hyperplasia

1 2 1 1

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

Coagulating Gland
 Fibrosis
 Inflammation

+
 2

Epididymis
 Inflammation

+ +

Preputial Gland

+ +

Prostate
 Inflammation
 Epithelium, Hyperplasia

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

Seminal Vesicle

+ +

Testes
 Arteriole, Necrosis
 Germinal Epithelium, Degeneration
 Interstitial Cell, Hyperplasia

+
 2 1 1
 1 2 3 1 2 3 1 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

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

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

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

| 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 |
|------------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| FISCHER 344 RATS MALE | | 7 | 7 | 6 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 |
| | | 2 | 2 | 5 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 8 | 2 | 2 | 2 | 0 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 4 |
| 0.0 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 | 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 |

males
(cont...)

Bone +
 Skeletal Muscle +

NERVOUS SYSTEM

Brain +
 Hemorrhage
 Necrosis 1
 Peripheral Nerve +
 Spinal Cord +

RESPIRATORY SYSTEM

Lung +
 Inflammation, Chronic Active 2 2 1 1 2
 Necrosis 2
 Thrombosis
 Alveolar Epithelium, Hyperplasia 3 2 1 1 1 1 2 1
 Alveolar Epithelium, Hypertrophy 1 1
 Alveolar Epithelium, Metaplasia, Squamous 1
 Alveolus, Infiltration Cellular, Histiocyte 1 1 1 1
 Nose +
 Foreign Body
 Inflammation 1 1 1 1 2 1 2 2 2 1
 Olfactory Epithelium, Metaplasia
 Respiratory Epithelium, Hyperplasia 2

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically M .. Missing tissue
 X .. Lesion present A .. Autolysis precludes evaluation
 I .. Insufficient tissue BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

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

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

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

| | | 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 | 6 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | |
| | | 2 | 2 | 5 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 8 | 2 | 2 | 2 | 0 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 4 | |
| | | 9 | 7 | 1 | 8 | 7 | 0 | 9 | 9 | 7 | 8 | 7 | 2 | 8 | 7 | 9 | 4 | 7 | 7 | 7 | 8 | 8 | 7 | 8 | 5 | |
| FISCHER 344 RATS MALE | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | |
| 0.0 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 | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 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 | 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 |
| | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Trachea | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| SPECIAL SENSES SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Eye | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Cornea, Fibrosis | | | | | | | | | | | | | 2 | | | | | | | | | | | | | |
| Iris, Synechia | | | | | | | | | | | | 4 | | | | | | | | | | | | | | |
| Lens, Cataract | | | | | | | | | | | | | | | | | | | 1 | | | | 2 | | | |
| Retina, Degeneration | | | | 2 | | | | | | | | | | | | | | | 1 | 1 | | | 1 | 3 | | |
| Retina, Retinal Detachment | | | | | | | | | | | | 4 | | | | | | | | | | | | | | |
| Harderian Gland | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| URINARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Kidney | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Accumulation, Hyaline Droplet | | | | | | | | | 1 | | | | | | | | | | | | | | | | | |
| Infarct | | | | | | | | | | | | | | | | | | | | 2 | | | | | | |
| Mineralization | | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | | | |
| Nephropathy | | 1 | 1 | 1 | 3 | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | | 1 | 3 | 3 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 2 |
| Cortex, Cyst | | | | | | | | | | | | | | | | | | | | | 2 | | | | | |
| Papilla, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | 4 | |
| Pelvis, Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | 3 | |
| Ureter | | | | | | | | | | | | | | | | | | | | | | | | | + | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | 4 | |
| Urethra | | | | | | | | | | | | | | | | | | | | | | | | | + | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | 4 | |
| Urinary Bladder | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |

males
(cont...)

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

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

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

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

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|-------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----------------------------|--|
| FISCHER 344 RATS MALE | DAY ON TEST | 07 | 07 | 06 | 07 | 07 | 06 | 06 | 07 | 07 | 07 | 07 | 05 | 07 | 07 | 07 | 05 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 05 | males
(cont...) | |
| | | 29 | 27 | 51 | 28 | 27 | 10 | 29 | 29 | 27 | 28 | 27 | 22 | 28 | 27 | 29 | 47 | 27 | 27 | 28 | 28 | 27 | 27 | 28 | 45 | | |
| | 0.0 G/KG | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | | |
| | ANIMAL ID | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | | |
| | | 12 | 33 | 44 | 55 | 66 | 77 | 88 | 99 | 00 | 11 | 11 | 12 | 33 | 44 | 55 | 66 | 77 | 88 | 99 | 00 | 11 | 22 | 23 | 44 | 55 | |

Inflammation
 Transitional Epithelium, Hyperplasia

2 1 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS MALE | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|-----------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|-----|
| | 078 | 078 | 079 | 061 | 072 | 072 | 069 | 051 | 072 | 068 | 072 | 072 | 072 | 072 | 072 | 050 | 072 | 072 | 059 | 072 | 066 | 067 | | 077 |
| 0.0 G/KG | 0026 | 0027 | 0028 | 0029 | 0030 | 0031 | 0032 | 0033 | 0034 | 0035 | 0036 | 0037 | 0038 | 0039 | 0040 | 0041 | 0042 | 0043 | 0044 | 0045 | 0046 | 0047 | 0048 | |
| | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|-----|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Epithelium, Necrosis | | | 1 | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Muscularis, Degeneration | | | 2 | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | | |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | | |
| Parasite Metazoan | | | | | | | X | | | | | X | | | | | | | | | | | | | 7 | |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | | |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | | |
| Ectopic Tissue | | | | | | | | | | | | 2 | | | | | | | | | | | | | 1 | 2.0 |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | | |
| Necrosis | | | | 1 | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | | |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | | |
| Basophilic Focus | X | X | | | X | | | | X | | | X | | | X | | | X | | | X | X | | | 21 | |
| Clear Cell Focus | X | X | | | X | X | | | | | | X | X | X | | | X | | | X | | | | | 18 | |
| Eosinophilic Focus | | | X | | X | | | | X | | | X | X | X | | | X | | | | X | | X | | 15 | |
| Fatty Change, Diffuse | | | | 2 | 1 | | | 2 | | | 4 | | | | 1 | | | | | | | | | | 11 | 1.8 |
| Hematopoietic Cell Proliferation | | | | | | | | | 1 | | | | | 1 | | | | | | | 1 | | | | 3 | 1.0 |
| Hepatodiaphragmatic Nodule | | | | | | | | | | | | | | | | | X | | | | | | | | 2 | |
| Inflammation, Chronic Active | 1 | 1 | | | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | 36 | 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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

| FISCHER 344 RATS MALE
0.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | | |
|-----------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|------|-----|--------|
| | 078 | 078 | 079 | 061 | 072 | 072 | 069 | 051 | 072 | 068 | 072 | 072 | 072 | 072 | 072 | 050 | 072 | 074 | 057 | 066 | | 067 | 077 | |
| ANIMAL ID | 0026 | 0007 | 0008 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | | |
| Mixed Cell Focus | | | | | | | | | | | | | | | | | | | | | | | 4 | |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 2.0 |
| Pigmentation, Hemosiderin | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Bile Duct, Hyperplasia | 1 | 2 | 1 | 1 | 1 | 2 | | | | | | 1 | 1 | 1 | | 2 | 1 | 2 | | | 2 | 1 | 1 | 32 1.3 |
| Centrilobular, Fatty Change | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 2.0 |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | 6 |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Fat, Necrosis | 3 | | | | | | | | | | | | | | | 2 | | 4 | | | | | | 4 2.5 |
| Oral Mucosa | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Pancreas | | | | | | | | | | | | | | | | | | | | | | | | 49 |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | 16 1.3 |
| Acinus, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 6 1.5 |
| Salivary Glands | | | | | | | | | | | | | | | | | | | | | | | | 49 |
| Stomach, Forestomach | | | | | | | | | | | | | | | | | | | | | | | | 49 |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | 8 2.3 |
| Ulcer | | | | | | | | | | | | | | | | | | | | | | | | 4 2.5 |
| Epithelium, Dysplasia | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 6 2.2 |
| Stomach, Glandular | | | | | | | | | | | | | | | | | | | | | | | | 49 |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | 2 2.0 |
| Epithelium, Necrosis | | | | | | | | | | | | | | | | | | | | | | | 1 | 2 1.5 |
| Tooth | | | | | | | | | | | | | | | | | | | | | | | | 10 |
| Malformation | | | | | | | | | | | | | | | | | | | | | | | | 10 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| DAY ON TEST | FISCHER 344 RATS MALE | | | | | | | | | | | | | | | | | | | | * TOTALS | | |
|-------------|-----------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|------|------|
| | 078 | 078 | 079 | 063 | 072 | 079 | 064 | 051 | 078 | 069 | 078 | 078 | 077 | 078 | 078 | 078 | 054 | 078 | 074 | 075 | | 066 | 067 |
| ANIMAL ID | 0026 | 0007 | 0008 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Blood Vessel | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Cardiomyopathy | 2 | 2 | 2 | 2 | 2 | 3 | 2 | 2 | 3 | 2 | 3 | 2 | 3 | 3 | 3 | 2 | 2 | 3 | 2 | 2 | 2 | 3 | 48 | 2.4 |
| Atrium, Thrombosis | | | | | | | | | | | 2 | | | | | | | | | | | | 2 | 2.0 |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | |
| Degeneration, Cystic | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | 2 | 1.5 |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Vacuolization Cytoplasmic | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| Zona Fasciculata, Hyperplasia | 1 | | | | | | | | | | 1 | | | 1 | | | | | | | | | 8 | 1.0 |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | |
| Hyperplasia | | | | | | | | | | | | 4 | 2 | | | | 1 | | | | 1 | 1 | 9 | 1.7 |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | |
| Hyperplasia | | | | | | | | 1 | | | | 4 | | | | | | | | | | | 2 | 2.5 |
| Parathyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Pars Distalis, Hyperplasia | | 3 | 1 | | 1 | | | | 1 | 1 | | 1 | | 2 | 1 | | | | | 1 | 3 | | 17 | 1.5 |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | |

* .. 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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

| FISCHER 344 RATS MALE
0.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | |
|--|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|-----|-----|
| | 0728 | 0728 | 0729 | 0673 | 0778 | 0779 | 0664 | 0551 | 0778 | 0669 | 0551 | 0778 | 0669 | 0551 | 0778 | 0669 | 0551 | 0778 | 0669 | 0551 | | | |
| ANIMAL ID | 00026 | 00007 | 00008 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | |
| Hyperplasia | | | 3 | | | 1 | | 3 | 2 | 3 | 1 | 4 | | | | 1 | | | 3 | | 16 | 2.4 | |
| Lymph Node
Mediastinal, Hyperplasia, Lymphoid | | + | 2 | | | | | | | | | | | | | | | | | | 4 | 3 | 2.0 |
| Lymph Node, Mandibular | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | 0 | | |
| Lymph Node, Mesenteric
Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | 2 | 2.0 |
| Spleen
Accessory Spleen | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | 1 | |
| Hematopoietic Cell Proliferation | 1 | | 1 | | | | | 3 | | | 2 | | | 2 | | 1 | | 2 | 2 | 1 | 10 | 1.7 | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 | |
| Inflammation | | | | | | | | | | | | | | | | | | | 2 | | 1 | 2.0 | |
| Necrosis | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 | |
| Pigmentation, Hemosiderin | 1 | | | 1 | | 1 | 2 | 1 | | | | | 1 | 1 | 1 | 1 | 1 | 1 | | | 31 | 1.1 | |
| Lymphoid Follicle, Atrophy | | | | 4 | | | | | | | | | | | 3 | | | | | | 2 | 3.5 | |
| Thymus
Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | 48 | 47 | 3.3 |
| | 4 | 3 | 4 | 4 | 3 | 3 | 3 | 3 | 3 | 4 | 3 | 3 | 4 | 3 | 3 | 4 | 3 | 4 | 4 | 3 | | | |
| INTEGUMENTARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | |
| Mammary Gland
Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | 48 | 1 | 2.0 |
| | | | | | | | | | | | | | | | 2 | | | | | | | | |
| Skin
Subcutaneous Tissue, Fibrosis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | 1 | 4.0 |
| | | | 4 | | | | | | | | | | | | | | | | | | | | |
| 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS MALE
0.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|---|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|--------|
| | 078 | 079 | 070 | 071 | 072 | 073 | 074 | 075 | 076 | 077 | 078 | 079 | 080 | 081 | 082 | 083 | 084 | 085 | 086 | 087 | | 088 |
| ANIMAL ID | 0026 | 0027 | 0028 | 0029 | 0030 | 0031 | 0032 | 0033 | 0034 | 0035 | 0036 | 0037 | 0038 | 0039 | 0040 | 0041 | 0042 | 0043 | 0044 | 0045 | 0046 | |
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Skeletal Muscle | | | | | | | | | | | | | | | | | | | | | | 1 |
| NERVOUS SYSTEM | | | | | | | | | | | | | | | | | | | | | | |
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | 3 2.0 |
| Peripheral Nerve | | | | | | | | | | | | | | | | | | | | | | 2 |
| Spinal Cord | | | | | | | | | | | | | | | | | | | | | | 2 |
| RESPIRATORY SYSTEM | | | | | | | | | | | | | | | | | | | | | | |
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Inflammation, Chronic Active | | | | | | | | | | | | | | | | | | | | | | 6 1.5 |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | 2 1.5 |
| Thrombosis | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Alveolar Epithelium, Hyperplasia | 1 | | | | | | | | | | | | | | | | | | | | | 19 1.4 |
| Alveolar Epithelium, Hypertrophy | | | | | | | | | | | | | | | | | | | | | | 2 1.0 |
| Alveolar Epithelium, Metaplasia, Squamous | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Alveolus, Infiltration Cellular, Histiocyte | | | | | | | | | | | | | | | | | | | | | | 8 1.0 |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Foreign Body | | | | | | | | | | | | | | | | | | | | | | 1 |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | 18 1.7 |
| Olfactory Epithelium, Metaplasia | | | | | | | | | | | | | | | | | | | | | | 2 2.0 |
| Respiratory Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | 1 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS MALE
0.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | |
|-----------------------------------|-------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|----------|-----|--------|
| | 078 | 078 | 079 | 061 | 072 | 079 | 064 | 051 | 078 | 069 | 071 | 077 | 077 | 077 | 077 | 077 | 054 | 072 | 075 | 077 | | 066 | 067 |
| ANIMAL ID | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| SPECIAL SENSES SYSTEM | | | | | | | | | | | | | | | | | | | | | | | |
| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Cornea, Fibrosis | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Iris, Synechia | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 |
| Lens, Cataract | | | | | | | | | | | | | | | | | | | | | | | 2 1.5 |
| Retina, Degeneration | | | | | | | | | | | | | | 1 | | | | | | | | | 6 1.5 |
| Retina, Retinal Detachment | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| URINARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | |
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Accumulation, Hyaline Droplet | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Infarct | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Mineralization | 1 | | | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 38 1.0 |
| Nephropathy | 2 | 2 | 2 | 1 | 1 | 2 | 2 | 3 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | | 2 | 1 | 1 | 1 | 1 | 1 | 46 1.4 |
| Cortex, Cyst | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Papilla, Necrosis | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 |
| Pelvis, Inflammation | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Ureter | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 |
| Urethra | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |

* .. 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| | | | | | | | | | | | | | | | | | | | | | | | | |
|---|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-----------------|------|
| FISCHER 344 RATS MALE

0.0 G/KG | DAY ON TEST | 078 | 078 | 079 | 061 | 072 | 079 | 064 | 051 | 072 | 068 | 072 | 077 | 077 | 077 | 077 | 050 | 072 | 074 | 057 | 066 | 067 | 077 | 077 |
| | ANIMAL ID | 0026 | 0007 | 0008 | 0000 | 0000 | 0000 | 0003 | 0003 | 0003 | 0003 | 0003 | 0003 | 0003 | 0003 | 0004 | 0004 | 0004 | 0004 | 0004 | 0004 | 0004 | 0004 | 0005 |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |

| | |
|--------------------------------------|--------------|
| Inflammation | 2 2.5 |
| Transitional Epithelium, Hyperplasia | 1 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| 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 |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------------------|---|---|
| FISCHER 344 RATS MALE | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 1 | 5 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 6 | 7 | 7 |
| | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 0 | 2 | 7 | 2 | 2 | 6 | 7 | 2 | 2 | 8 | 2 | 2 | 7 | 2 | 6 | 6 | 2 |
| 0.1 G/KG | 8 | 7 | 7 | 7 | 4 | 7 | 9 | 9 | 8 | 9 | 8 | 8 | 8 | 1 | 8 | 8 | 9 | 7 | 8 | 8 | 3 | 9 | 6 | 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 |
| 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 |
| | | 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 |
| | | | | | | | | | | | | | | | | | | | | | | males
(cont...) | | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Cecum
Inflammation | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | | | | | 1 | | | | | | | | | | | | | | | | | | |
| Intestine Large, Colon
Parasite Metazoan | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | | | | | | X | | | X | | | | | | | | | | | | | | |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Angiectasis | | | | | 1 | | | | | | | | | | | | | | | | | | |
| Basophilic Focus | X | X | X | X | | X | X | X | X | | X | | | | X | X | X | X | | | X | | |
| Clear Cell Focus | | X | X | X | | X | X | | X | X | | | | | X | | X | | | | X | | |
| Degeneration, Cystic | | | | | 1 | | | | | | | | | | | | | | | | 1 | | |
| Eosinophilic Focus | | X | X | X | | | X | | | | | | | | | | | X | | X | X | X | |
| Fatty Change, Diffuse | | | | | 2 | | | | | | 1 | | | | | | | | | | | | 1 |
| Hematopoietic Cell Proliferation | | | | | | | | | | 1 | | | | | | | | | | | | | 1 |
| Hepatodiaphragmatic Nodule | | X | | | | X | | | X | | | | | | X | | | | | | | | X |
| Inflammation, Chronic Active | 1 | 1 | 1 | 1 | | 1 | 1 | | 1 | 1 | 1 | 1 | | 1 | 1 | | 1 | 1 | 1 | | 1 | 1 | 1 |
| Mixed Cell Focus | | | | X | X | X | | | | | X | | | | | | | | | | X | | |
| Necrosis | | | | | | | | | | | | | | 2 | | | | | | | | | |

* .. 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS MALE
0.1 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | males
(cont...) |
|-----------------------------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|--------------------|
| | 07
28 | 07
27 | 07
22 | 07
21 | 07
14 | 07
07 | 07
07 | 07
07 | 07
07 | 07
07 | 07
07 | 07
07 | 07
07 | 07
07 | 07
07 | 07
07 | 07
07 | 07
07 | 07
07 | 07
07 | 07
07 | 07
07 | 07
07 | 07
07 | | |
| ANIMAL ID | 00
00
51 | 00
00
52 | 00
00
53 | 00
00
54 | 00
00
55 | 00
00
56 | 00
00
57 | 00
00
58 | 00
00
59 | 00
00
60 | 00
00
61 | 00
00
62 | 00
00
63 | 00
00
64 | 00
00
65 | 00
00
66 | 00
00
67 | 00
00
68 | 00
00
69 | 00
00
70 | 00
00
71 | 00
00
72 | 00
00
73 | 00
00
74 | 00
00
75 | |
| Bile Duct, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Bile Duct, Hyperplasia | 1 | 2 | 1 | 1 | 3 | 1 | 1 | 1 | 1 | 1 | 1 | | | | 1 | 1 | 1 | 2 | 1 | 2 | 1 | 2 | | 2 | 1 | |
| Centrilobular, Fatty Change | 2 | 1 | | | | 2 | | | | | 1 | | | 1 | | | | | 1 | | | | | | | |
| Centrilobular, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hepatocyte, Hypertrophy | | | | | | | | | | | | | 1 | | | | | | | | | | | | | |
| Oval Cell, Hyperplasia | | | | | 2 | | | | | | | | | | | | | | | | | | | | | |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Oral Mucosa | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Squamous | | | | | | | | | | | | | | | | | | | | | | | | | +
3 | |
| Pancreas | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Basophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Acinus, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Salivary Glands | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach, Forestomach | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach, Glandular | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Epithelium, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Tooth | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | |

* .. 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 | FISCHER 344 RATS MALE | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------|-----------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | 0728 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | | 0727 | | | |
| ANIMAL ID | 0051 | 0052 | 0053 | 0054 | 0055 | 0056 | 0057 | 0058 | 0059 | 0060 | 0061 | 0062 | 0063 | 0064 | 0065 | 0066 | 0067 | 0068 | 0069 | 0070 | 0071 | 0072 | 0073 | 0074 | 0075 |
| Malformation | | | | | | | | | | | | | | | | | | | | | | | | | |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Blood Vessel | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cardiomyopathy | 3 | 2 | 3 | 2 | 2 | 3 | 3 | 2 | 3 | 2 | 2 | 3 | 1 | 1 | 2 | 3 | 1 | 4 | 2 | 3 | 3 | 2 | 4 | 3 | |
| Atrium, Thrombosis | | | | | | | | | | | | | | | | | 1 | | | | | | | | |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | |
| Hypertrophy | 2 | | | | | | | | | | | | | | | | | | 1 | 1 | | | | |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Zona Fasciculata, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | |
| Islets, Pancreatic | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Parathyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Pars Distalis, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | |
| Thyroid Gland | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | |

* .. 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

| FISCHER 344 RATS MALE
0.1 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | males
(cont...) | | |
|-----------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|--------------------|-----------------------|-----------------------|
| | 0
7
2
8 | 0
7
2
7 | 0
7
2
7 | 0
7
2
7 | 0
7
1
4 | 0
7
2
7 | 0
7
2
9 | 0
7
0
9 | 0
7
2
8 | 0
7
2
9 | 0
6
7
8 | 0
7
2
8 | 0
7
2
8 | 0
1
6
8 | 0
5
7
8 | 0
7
2
8 | 0
7
2
8 | 0
6
8
9 | 0
7
2
7 | 0
7
2
8 | 0
6
7
3 | 0
7
2
9 | 0
6
6
6 | 0
7
2
7 | 0
6
6
7 | | 0
7
2
4 | 0
7
1
5 |
| | 0
0
0
5
1 | 0
0
0
5
2 | 0
0
0
5
3 | 0
0
0
5
4 | 0
0
0
5
5 | 0
0
0
5
6 | 0
0
0
5
7 | 0
0
0
5
8 | 0
0
0
5
9 | 0
0
0
6
0 | 0
0
0
6
1 | 0
0
0
6
2 | 0
0
0
6
3 | 0
0
0
6
4 | 0
0
0
6
5 | 0
0
0
6
6 | 0
0
0
6
7 | 0
0
0
6
8 | 0
0
0
6
9 | 0
0
0
7
0 | 0
0
0
7
1 | 0
0
0
7
2 | 0
0
0
7
3 | 0
0
0
7
4 | 0
0
0
7
5 | | 0
0
0
7
6 | 0
0
0
7
7 |

Necrosis

Lymph Node
Mediastinal, Infiltration Cellular, Plasma Cell

+

Lymph Node, Mandibular

M M

Lymph Node, Mesenteric
Atrophy

+
1

Spleen
Amyloid Deposition
Hematopoietic Cell Proliferation
Pigmentation, Hemosiderin
Lymphoid Follicle, Atrophy

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

Thymus
Atrophy

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

INTEGUMENTARY SYSTEM

Mammary Gland

+ +

Skin
Cyst Epithelial Inclusion
Inflammation

+
X
1

MUSCULOSKELETAL SYSTEM

Bone

+ +

* .. 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS MALE | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | ANIMAL ID | males
(cont...) |
|-----------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-----------|--------------------|
| | 0728 | 0727 | 0722 | 0721 | 0714 | 0707 | 0707 | 0707 | 0707 | 0706 | 0707 | 0707 | 0701 | 0705 | 0707 | 0707 | 0706 | 0707 | 0706 | 0707 | 0706 | 0706 | 0707 | | |
| 0.1 G/KG | 0051 | 0052 | 0053 | 0054 | 0055 | 0056 | 0057 | 0058 | 0059 | 0060 | 0061 | 0062 | 0063 | 0064 | 0065 | 0066 | 0067 | 0068 | 0069 | 0070 | 0071 | 0072 | 0073 | 0074 | 0075 |

NERVOUS SYSTEM

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

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Congestion | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Chronic Active | | | | | 1 | | | | | | | | | | 1 | | | | | | | | | 1 | |
| Alveolar Epithelium, Hyperplasia | | | | 1 | | 1 | 1 | | | | 3 | 2 | | | 1 | | | | 2 | | | | | | |
| Alveolar Epithelium, Metaplasia, Squamous | | | | | | | | | | | | | | | | 2 | | | | | | | | | |
| Alveolus, Infiltration Cellular, Histiocyte | | | | | | | | | | | 1 | | | | | | | | | | | | 1 | | |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Foreign Body | | X | | | | | | | | | | | | | | | | | X | | | | | | |
| Inflammation | | 3 | | | 2 | | | | | 1 | 1 | | | | 2 | 2 | | 2 | 2 | | | | | | |
| Olfactory Epithelium, Metaplasia | | | | | | | | | | | | | | | | | | | | | | | | | |
| Respiratory Epithelium, Hyperplasia | | | | 1 | | | | | | 2 | 4 | | | | | | | | | | | | | | |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Ear | | | | | | | | | | | | | | | | | | | | | | | | | |
| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Lens, Cataract | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Retina, Degeneration | | | | | | | | | | | | | | | 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 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | males
(cont...) | | |
|--|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|---|---|
| FISCHER 344 RATS MALE | | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 1 | 5 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | | | |
| 0.1 G/KG | | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 0 | 2 | 7 | 2 | 2 | 6 | 7 | 2 | 2 | 8 | 2 | 2 | 2 | 7 | 2 | 6 | | 2 | 1 |
| ANIMAL ID | | 8 | 7 | 7 | 7 | 4 | 7 | 9 | 9 | 8 | 9 | 8 | 8 | 8 | 1 | 8 | 8 | 9 | 7 | 8 | 8 | 3 | 7 | 6 | | 2 | 4 |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | 0 | 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 | 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 | |
| Harderian Gland | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| URINARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Kidney | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Mineralization | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | | 1 | |
| Nephropathy | | 2 | 3 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 2 | 1 | | 1 | 2 | 1 | 1 | 3 | 2 | 1 | 1 | 1 | 1 | 1 | 3 | |
| Pelvis, Dilatation | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pelvis, Transitional Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| <hr/> | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Ureter | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <hr/> | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Urinary Bladder | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |

* .. 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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

| DAY ON TEST | FISCHER 344 RATS MALE | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | |
|-------------|-----------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|------|------|------|------|
| | 0030 | 0072 | 0078 | 0072 | 0072 | 0072 | 0072 | 0072 | 0072 | 0072 | 0072 | 0072 | 0072 | 0072 | 0072 | 0072 | 0072 | 0072 | 0072 | 0072 | | 0072 | | | |
| 0.1 G/KG | 0076 | 0077 | 0078 | 0079 | 0080 | 0081 | 0082 | 0083 | 0084 | 0085 | 0086 | 0087 | 0088 | 0089 | 0090 | 0091 | 0092 | 0093 | 0094 | 0095 | 0096 | 0097 | 0098 | 0099 | 0100 |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|-------|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Intestine Large, Cecum
Inflammation | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 1.0 |
| Intestine Large, Colon
Parasite Metazoan | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 2 |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | | 50 | 1 1.0 |
| Basophilic Focus | | X | X | | | X | X | | X | | X | X | X | X | X | X | | | X | | X | | X | | | 30 | |
| Clear Cell Focus | | | | X | X | | X | | X | | X | X | X | X | | | | X | | X | | X | X | X | | 25 | |
| Degeneration, Cystic | | | | | | | | 1 | | | | 1 | | | | | | | | | | | | | | 4 1.0 | |
| Eosinophilic Focus | | | | X | | | X | X | | | X | | X | X | | | | | X | | X | X | X | | | 18 | |
| Fatty Change, Diffuse | | 1 | | | | | 1 | | | | 1 | | | | | | | | | | | | | 1 | 1 | 8 1.1 | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | 1 | | | 3 1.0 | |
| Hepatodiaphragmatic Nodule | | | | | | | | | | | | | | | X | | | | X | | | | | | | 7 | |
| Inflammation, Chronic Active | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | | 1 | 1 | 1 | | | 39 1.0 | |
| Mixed Cell Focus | | | | | | | | | | | | | | | | | | | | | | | | | | 5 | |
| Necrosis | | | | | | | | | | | | | | | 1 | | | | | | | | | | | 2 1.5 | |

* .. 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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

| FISCHER 344 RATS MALE
0.1 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | | |
|-----------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|-------|--------|--------|
| | 0030 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | | 0077 | | |
| ANIMAL ID | 00076 | 00077 | 00078 | 00079 | 00080 | 00081 | 00082 | 00083 | 00084 | 00085 | 00086 | 00087 | 00088 | 00089 | 00090 | 00091 | 00092 | 00093 | 00094 | 00095 | 00096 | | | |
| Bile Duct, Cyst | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | | |
| Bile Duct, Hyperplasia | | 2 | | 1 | 1 | 1 | 1 | 2 | | | 1 | 1 | 1 | 2 | 2 | | 1 | 1 | 1 | | 3 | 1 | 1 | 39 1.3 |
| Centrilobular, Fatty Change | | | | | | | | | | | | | | | 1 | | | | | | | | 7 1.3 | |
| Centrilobular, Necrosis | | | | | | | | | | | | | | | | | | 1 | 3 | | | | 2 2.0 | |
| Hepatocyte, Hypertrophy | | | | | | | | | | | | | | | 1 | | | | | | | | 2 1.0 | |
| Oval Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | 2 | | 2 2.0 | |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | 8 | |
| Fat, Necrosis | | | | | | | | | | | | | | | | | 1 | | | | | 1 | 2 | 7 1.4 |
| Oral Mucosa | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Hyperplasia, Squamous | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 | |
| Pancreas | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | 13 1.0 | |
| Basophilic Focus | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Acinus, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | 9 1.2 | |
| Salivary Glands | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Stomach, Forestomach | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | 4 1.5 | |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | 2 1.0 | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | 4 1.5 | |
| Stomach, Glandular | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | 3 1.0 | |
| Epithelium, Necrosis | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Tooth | | | | | | | | | | | | | | | | | | | | | | | 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

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

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

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

| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
|-----------------------|-------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| FISCHER 344 RATS MALE | DAY ON TEST | 0
3
0 | 0
7
7 | 0
7
8 | 0
7
9 | 0
7
8 | 0
7
9 | 0
7
8 | 0
7
9 | 0
7
9 | 0
5
5 | 0
7
7 | 0
6
6 | 0
7
7 | 0
7
7 | 0
7
2 | 0
7
0 | 0
7
7 | 0
5
7 | 0
6
1 | 0
7
2 | 0
7
8 | 0
7
2 | 0
7
7 | 0
7
7 | | | |
| | ANIMAL ID | 0
0
0
7
6 | 0
0
0
7
7 | 0
0
0
7
8 | 0
0
0
7
9 | 0
0
0
8
0 | 0
0
0
8
1 | 0
0
0
8
2 | 0
0
0
8
3 | 0
0
0
8
4 | 0
0
0
8
5 | 0
0
0
8
6 | 0
0
0
8
7 | 0
0
0
8
8 | 0
0
0
8
8 | 0
0
0
8
8 | 0
0
0
8
9 | 0
0
0
8
9 | 0
0
0
9
0 | 0
0
0
9
1 | 0
0
0
9
2 | 0
0
0
9
3 | 0
0
0
9
4 | 0
0
0
9
5 | 0
0
0
9
6 | 0
0
0
9
7 | 0
0
0
9
8 | 0
0
0
9
9 |
| 0.1 G/KG | | | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | | |

| | | | | | | | | | | | | | | | | | | | | | | | |
|--------------|---|---|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------------|
| Malformation | 1 | 1 | 1 | 1 | | | | | | | | | | | | | | | | | | | 6 1.0 |
|--------------|---|---|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------------|

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|---|---------------|
| Blood Vessel | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Heart | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Cardiomyopathy | 1 | 3 | 2 | 3 | 3 | 3 | 3 | 2 | 3 | 2 | 2 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 2 | 49 2.4 |
| Atrium, Thrombosis | | | | | | | | | | | | | | | | | | | | 2 | | | 2 1.5 | | |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|--|--|--|---|---|---|--|--|--|---|---|--|--|---|---|---|---|--|---|---|---|---|--------------|--------------|---|---|--|---|---------------|--|---------------|--|--|--|--|--------------|
| Adrenal Cortex | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | | | | | | | | | | | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | | | | | | | | | | | | | |
| Hypertrophy | | | | | | | 1 | | | | | | | | | | | 2 | | | | | | | 5 1.4 | | | | | | | | | | | | |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | | | | | | | | | | | | | |
| Zona Fasciculata, Hyperplasia | | | | | 1 | | | | | | | | | | 1 | 1 | 1 | | | 2 | | | | | | | 1 | | | 6 1.2 | | | | | | | |
| Adrenal Medulla | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | | | | | | | | | | | |
| Hyperplasia | | | | | | 2 | | | | | | | | | | | | | | | 2 | | 4 | | | | | | 1 | | | 11 1.9 | | | | | |
| Islets, Pancreatic | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | | | | | | | | | | | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | 1 | | | | | | | | | | | | | | | | | 2 1.0 |
| Parathyroid Gland | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | | | | | | | | | | | |
| Pituitary Gland | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | | | | | | | | | | | |
| Pars Distalis, Hyperplasia | | | | | 2 | | | | | | 3 | 1 | | | | | 1 | 3 | | | 2 | 4 | | 1 | 1 | 2 | | | | 20 1.9 | | | | | | | |
| Thyroid Gland | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically M .. Missing tissue
 X .. Lesion present A .. Autolysis precludes evaluation
 I .. Insufficient tissue BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

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

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

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

| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
|------------------------------|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|---|--|----|-----|
| FISCHER 344 RATS MALE | | 3 | 7 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | | | |
| 0.1 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 | | 0 | 0 | 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 | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | |
| C-cell, Hyperplasia | | | | | | | | 2 | | | | | | | | 2 | | | | | | | | | | | | | 12 | 1.9 |
| Follicular Cell, Hyperplasia | | | | | | 2 | | | | | | | | | | | | | | | | | | | | | | | 2 | 1.5 |

GENERAL BODY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|
| Tissue NOS | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
|------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------------------|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|--|----|-----|
| Coagulating Gland Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | | 2 | 3.0 |
| Epididymis Inflammation | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | 4 | 1.3 |
| Preputial Gland | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | |
| Prostate Inflammation | | | | | | | 3 | 1 | 2 | | 2 | 3 | 2 | | 2 | 1 | | 2 | 1 | 3 | | | | | | | | | 50 | | 24 | 1.8 |
| Prostate Epithelium, Hyperplasia | | | | | | | 2 | | | | | 3 | | | | | | | 1 | 1 | | | 2 | 1 | | | | | 50 | | 8 | 1.8 |
| Seminal Vesicle | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | |
| Testes Interstitial Cell, Hyperplasia | | | | | | | 2 | | 2 | 1 | 1 | 2 | | | | | | 1 | 1 | | | 2 | | | | | | | 50 | | 15 | 2.1 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|--|----|-----|
| Bone Marrow Hemorrhage | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | 1 | 4.0 |
| Bone Marrow Hyperplasia | | | | | | | | | 4 | | 3 | | | | | | | 3 | | | 3 | 2 | 4 | | | | | | 50 | | 17 | 2.9 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically M .. Missing tissue
 X .. Lesion present A .. Autolysis precludes evaluation
 I .. Insufficient tissue BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

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

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

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

| FISCHER 344 RATS MALE

0.1 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | * TOTALS | | |
|---|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|-----|-----|
| | 0030 | 0072 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0057 | 0077 | 0077 | 0067 | 0077 | 0077 | 0077 | 0077 | 0057 | 0077 | 0067 | 0077 | | | |
| | 0076 | 0077 | 0078 | 0079 | 0080 | 0081 | 0082 | 0083 | 0084 | 0085 | 0086 | 0087 | 0088 | 0088 | 0088 | 0089 | 0089 | 0090 | 0091 | 0092 | 0093 | 0094 | | | |
| ANIMAL ID | 0076 | 0077 | 0078 | 0079 | 0080 | 0081 | 0082 | 0083 | 0084 | 0085 | 0086 | 0087 | 0088 | 0088 | 0088 | 0089 | 0089 | 0090 | 0091 | 0092 | 0093 | 0094 | | | |
| Necrosis | | | | 1 | | | | | | | | | | | | | | | | | | | 1 | 1.0 | |
| Lymph Node
Mediastinal, Infiltration Cellular, Plasma Cell | | | | + | | | | | | | | | | | | | | | + | | | | 3 | 1 | 2.0 |
| Lymph Node, Mandibular | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | 0 | | |
| Lymph Node, Mesenteric
Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 2 | 1.0 |
| Spleen
Amyloid Deposition | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 | 2.0 |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | 3 | | | | | 3 | | 2 | 10 | 2.2 | |
| Pigmentation, Hemosiderin | | | | 1 | | 1 | | 1 | | 1 | | | | 1 | 1 | | 1 | 1 | | | | 1 | 32 | 1.0 | |
| Lymphoid Follicle, Atrophy | | | | | | | | | | | | | | | | | | | | | | 1 | 2 | 2.5 | |
| Thymus
Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 49 | 3.2 |
| | | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 50 | | |
| | | | | | | | | | | | | | | | | | | | | | | 1 | 50 | | |
| | | | | | | | | | | | | | | | | | | | | | | | 1 | 2 | 1.0 |
| | | | | | | | | | | | | | | | | | | | | | | | 50 | | |
| | | | | | | | | | | | | | | | | | | | | | | | 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| DAY ON TEST | FISCHER 344 RATS MALE | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | |
|-------------|-----------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|------|------|------|------|
| | 0030 | 0072 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | | 0077 | | | |
| ANIMAL ID | 0076 | 0077 | 0078 | 0079 | 0080 | 0081 | 0082 | 0083 | 0084 | 0085 | 0086 | 0087 | 0088 | 0089 | 0090 | 0091 | 0092 | 0093 | 0094 | 0095 | 0096 | 0097 | 0098 | 0099 | 0100 |

NERVOUS SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 1.0 |
| Hydrocephalus | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 1.0 |

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|--------|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Congestion | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Inflammation, Chronic Active | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 1.0 |
| Alveolar Epithelium, Hyperplasia | | | | | 4 | | 1 | | 3 | | | | 1 | | | | 1 | | | | | | 1 | | | | 13 1.7 |
| Alveolar Epithelium, Metaplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Alveolus, Infiltration Cellular, Histiocyte | | | | | | | | 1 | | | | | | | | | | | | | | | | | | | 3 1.0 |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Foreign Body | | | | | | | | X | | | | | | | | | X | | | | | | | | | | 4 |
| Inflammation | | | 2 | | | | | 2 | | | | | 2 | | | 2 | | | | 1 | | | | | 1 | | 14 1.8 |
| Olfactory Epithelium, Metaplasia | | | | | | | | 2 | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Respiratory Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 2.3 |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|
| Ear | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Lens, Cataract | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Retina, Degeneration | | | | | | | | | | | | | | | | | | | | | | | | | | | 6 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| DAY ON TEST | FISCHER 344 RATS MALE | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|--|-----------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|-----|
| | 0030 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | 0077 | | |
| 0.1 G/KG | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0076 | 0077 | 0078 | 0079 | 0080 | 0081 | 0082 | 0083 | 0084 | 0085 | 0086 | 0087 | 0088 | 0089 | 0090 | 0091 | 0092 | 0093 | 0094 | 0095 | 0096 | 0097 | 0098 | 0099 | | |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| URINARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Mineralization | | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 43 | 1.0 |
| Nephropathy | | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 47 | 1.2 |
| Pelvis, Dilatation | | | | | | | | | | 2 | | | | | | | | | | | | | | | 1 | 2.0 |
| Pelvis, Transitional Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Ureter | | | | | | | | | | | | | | | | | | | | | | | + | | 1 | |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS MALE | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | ANIMAL ID | |
|-----------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-----------------|--|
| | 0729 | 0727 | 0664 | 0663 | 0772 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0668 | 0772 | 0772 | 0772 | 0777 | 0777 | 0777 | 0777 | | |
| 0.3 G/KG | 0010 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | 0011 | males (cont...) | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Colon
Parasite Metazoan | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 | |
| Basophilic Focus | X | | X | | | | X | X | | X | X | | X | X | | | X | X | | X | X | X | X | X | |
| Clear Cell Focus | X | X | | | X | X | | X | X | | X | | | X | | | | | | X | X | X | X | X | |
| Degeneration, Cystic | | | | | | | | | | | | | | | | | | | | | | | | | |
| Eosinophilic Focus | | | X | X | | X | X | X | X | | | | | X | X | | X | | | | | | | | |
| Fatty Change, Diffuse | 1 | | | | 1 | 1 | | | | | | | 3 | | | | 1 | 2 | | | | | | | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hepatodiaphragmatic Nodule | | | | | | | | | | | | | | X | | | X | | | | X | | | | |
| Inflammation, Chronic Active | 1 | 1 | | | 1 | 1 | 1 | | | 1 | 1 | | | | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | |
| Mixed Cell Focus | | | | | | | | | | | | | | | | X | | | | X | | | | | |
| Pigmentation, Hemosiderin | | | 2 | | | | | | | | | | | 1 | | | | | | | | | | | |
| Bile Duct, Hyperplasia | 2 | | | 2 | 1 | 2 | 2 | 1 | 1 | 1 | 2 | | 2 | 1 | 2 | | | 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

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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

| FISCHER 344 RATS MALE

0.3 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | ANIMAL ID | males
(cont...) | |
|---------------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-----------|--------------------|------|
| | 0729 | 0727 | 0664 | 0663 | 0772 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | | | 0777 |
| Centrilobular, Degeneration | | | | | | | | | | | | | | | | | | | | | | | |
| Centrilobular, Fatty Change | | | | | | | | | 1 | | | | | | | | | | | | | 1 | 2 |
| Hepatocyte, Hyperplasia | | | | | | | | | | | | | | | | | 2 | | | | | | |
| Hepatocyte, Hypertrophy | | | | | | | | | | | | | | 1 | | | | | | | | | 1 |
| Oval Cell, Hyperplasia | | | | | | | | | | | | | | | | | | 1 | | | | | |
| Mesentery | | | | | | | | | + | | | | | | | | | | | | | + | |
| Thrombosis | | | | | | | | | | | | | | | | | | | | | | | |
| Fat, Necrosis | | | | | | | | | 2 | | | | | | | | | | | | | 1 | |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Atrophy | | | | 1 | | | 1 | | 1 | | | | | 1 | | 1 | 2 | | 1 | 1 | 1 | 1 | 1 |
| Inflammation | | | | | | | | | | | | | | | | 1 | | | | | | | 1 |
| Acinus, Hyperplasia | | 2 | | 3 | | | 1 | | | | 1 | | 3 | | | | | | | | | | 1 |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Erosion | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | | | | | | | | | | 2 | | | 4 | 4 | | | | | | | | | |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | |
| Ulcer | | | | | | | | | | | | | 4 | 4 | | | | | | | | | |
| Epithelium, Dysplasia | | | | | | | | | | | | | | | | | | | | | | | |
| Epithelium, Hyperplasia | | 1 | | | | | | | | 2 | | | 3 | 3 | | | | | | | | | |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation | | | | | | | | | | | | | | | | 2 | | | | | | | |
| Epithelium, Necrosis | | | | | | | | | | | | | | | | | | | | | | | |
| Tooth | | | | | | | | | + | | + | | + | | | | | | | | | | + |

* .. 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| DAY ON TEST | FISCHER 344 RATS MALE | | | | | | | | | | | | | | | | | | | | | | | | | ANIMAL ID | 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 | | | |
| 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 0 | | |
| 2 | 2 | 6 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 0 | | |
| 9 | 7 | 4 | 0 | 8 | 7 | 8 | 8 | 9 | 8 | 8 | 8 | 8 | 1 | 8 | 7 | 2 | 9 | 8 | 8 | 8 | 9 | 7 | 7 | 8 | 8 | 0 | | |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 0 | 0 | 0 | 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 | 1 | 0 | | |
| 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 | 2 | 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 | 6 | 1 | | |
| Malformation | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 | 1 | 1 |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Blood Vessel | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Pulmonary Artery, Inflammation, Chronic Active | | | | | | | | | | | | | | | | | | | | | | | | | |
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cardiomyopathy | 3 | 2 | 2 | 2 | 3 | 3 | 2 | 3 | 2 | | 2 | 4 | 3 | 2 | 2 | 3 | 2 | 2 | 2 | 3 | 2 | 3 | 1 | 2 | |
| Mineralization | | | | 1 | | | | | | | | | | | | | | | | | | | | | |
| Atrium, Thrombosis | | | | | | | | | | | | 1 | | | | | | | | | | | | | |
| Coronary Artery, Degeneration | | | | | | | | | | | | | | | | | | | | | 1 | | | | |
| Epicardium, Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | 1 |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | 1 | | | | | | | | | | | | | |
| Hypertrophy | | | | | | | | | | | 1 | | 1 | | | | | | | | | | | 1 | |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | |
| Zona Fasciculata, Hyperplasia | 1 | | | | | | | | 1 | | | | | | | | | | | 1 | | | | 1 | |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | | | | | | | | | | | | | | 3 | | | | | | | | 1 | | 1 | |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | |
| Parathyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 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

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

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

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

| FISCHER 344 RATS MALE
0.3 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | ANIMAL ID | males
(cont...) |
|-----------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-----------|--------------------|
| | 0729 | 0727 | 0726 | 0724 | 0723 | 0722 | 0721 | 0720 | 0719 | 0718 | 0717 | 0716 | 0715 | 0714 | 0713 | 0712 | 0711 | 0710 | 0709 | 0708 | 0707 | 0706 | 0705 | 0704 | | |
| | 0 | 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 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| | 2 | 2 | 6 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 0 | 8 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | |
| | 9 | 7 | 4 | 0 | 8 | 7 | 8 | 8 | 9 | 9 | 8 | 8 | 1 | 8 | 7 | 2 | 9 | 8 | 8 | 9 | 7 | 7 | 8 | 8 | 8 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 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 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 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 | |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pars Distalis, Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pars Distalis, Hyperplasia | 1 | | 1 | | 1 | | 1 | | 1 | | 2 | | | | 2 | | | | | | 1 | | 1 | | 1 |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| C-cell, Hyperplasia | | | | | | | | | | | 3 | 1 | | | 1 | | | 1 | 1 | 4 | 3 | | | | |

GENERAL BODY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------|--|--|--|--|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Peritoneum | | | | | | + | | | | | | | | | | | | | | | | | | | |
|------------|--|--|--|--|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Epididymis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation | | | 1 | | 2 | | | | | | | | | | | | | | | | | | | 2 | |
| Preputial Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation | | | | | | | | | | | | | | | | 2 | | | | | | | | | |
| Prostate | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation | | | | | | | 2 | | 2 | | | 1 | 2 | 2 | 2 | | | 1 | 2 | | | 1 | | | 2 |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | 1 | | | | | | | | |
| Seminal Vesicle | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | |
| Testes | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Interstitial Cell, Hyperplasia | | | | 3 | | | | | | | 4 | | | | 2 | | | | | | | 4 | | | 2 |

* .. 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 | ANIMAL ID | males
(cont...) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|--------------------|
| | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | | |
| FISCHER 344 RATS MALE | 2 | 2 | 6 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 0 | 8 | 8 | 8 | 8 | 9 | 8 | 8 | | |
| 0.3 G/KG | 9 | 7 | 4 | 0 | 8 | 7 | 8 | 8 | 9 | 9 | 8 | 8 | 1 | 8 | 7 | 2 | 9 | 8 | 8 | 9 | 7 | 7 | 8 | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 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 | | |
| | 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 | | |
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |
| Skeletal Muscle | | + | | | | | | | | | | | | | | | | | | | | | | | |
| NERVOUS SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | |
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | |
| Choroid Plexus, Infiltration Cellular, Lymphocyte | | | | | | | | | | | | 2 | | | | | | | | | | | | | |
| RESPIRATORY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |
| Congestion | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Chronic Active | | | | | 1 | | | | | | | | 1 | | 1 | | | | | | 1 | 1 | | | |
| Thrombosis | | | | | | | | | | | | | | | | | | | | | | | | | |
| Alveolar Epithelium, Hyperplasia | | | | | 1 | 1 | | 1 | | | 1 | | 1 | 1 | | | 2 | | 1 | | 3 | | 2 | | |
| Alveolar Epithelium, Hypertrophy | | | | | | | | | | | | | | 1 | | | | | | | | | | | |
| Alveolar Epithelium, Metaplasia | | | | | | | | | | | | | | 2 | | | | | | | | | | | |
| Alveolar Epithelium, Metaplasia, Squamous | | | | | | | | | | | | | | | | | | | | | | | | | |
| Alveolus, Infiltration Cellular, Histiocyte | | | | | 1 | | 1 | | | | 1 | | 2 | 1 | | | | | | | 1 | 1 | | | |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |
| Foreign Body | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | | | | | 2 | | 1 | | 2 | | 1 | | | 1 | | | 2 | | | | | | | | |
| Olfactory Epithelium, Metaplasia | | | | | | | | | | | | | | | | | | | | | | | | | |
| Respiratory Epithelium, Hyperplasia | | | | | 1 | | | | | | | | | | | | | | | | | | | | |
| 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

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

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

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

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|--------------------|
| FISCHER 344 RATS MALE | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | males
(cont...) |
| | 0
7
2
9 | 0
7
2
7 | 0
6
6
4 | 0
6
3
0 | 0
7
2
8 | 0
7
2
7 | 0
7
2
8 | 0
7
2
8 | 0
7
2
9 | 0
7
2
9 | 0
7
2
8 | 0
7
2
8 | 0
7
2
8 | 0
7
2
1 | 0
7
2
8 | 0
7
2
7 | 0
6
8
9 | 0
7
2
8 | 0
7
2
8 | 0
7
2
9 | 0
7
2
7 | 0
7
2
7 | 0
7
2
8 | 0
7
2
8 | | |
| 0.3 G/KG | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0
0
1
0
1 | 0
0
1
0
2 | 0
0
1
0
3 | 0
0
1
0
4 | 0
0
1
0
5 | 0
0
1
0
6 | 0
0
1
0
7 | 0
0
1
0
8 | 0
0
1
0
9 | 0
0
1
0
0 | 0
0
1
0
1 | 0
0
1
0
2 | 0
0
1
0
3 | 0
0
1
0
4 | 0
0
1
0
5 | 0
0
1
0
6 | 0
0
1
0
7 | 0
0
1
0
8 | 0
0
1
0
9 | 0
0
1
0
0 | 0
0
1
0
1 | 0
0
1
0
2 | 0
0
1
0
3 | 0
0
1
0
4 | 0
0
1
0
5 | |
| | 0 | 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 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------|---|--|--|---|--|--|--|---|--|--|--|--|---|---|--|--|--|---|---|---|--|--|--|---|--|---|
| Ear | | | | | | | | | | | | | | | | | | | | | | | | | | + |
| Eye | + | | | | | | | | | | | | | | | | | | | | | | | | | |
| Cornea, Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lens, Cataract | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Retina, Degeneration | 1 | | | 1 | | | | 3 | | | | | 2 | 1 | | | | 1 | 1 | 1 | | | | 3 | | |
| Harderian Gland | + | | | | | | | | | | | | | | | | | | | | | | | | | |
| Zymbal's Gland | | | | | | | | | | | | | | | | | | | | | | | | | | |

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kidney | + | | | | | | | | | | | | | | | | | | | | | | | | | |
| Accumulation, Hyaline Droplet | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Infarct | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Inflammation, Acute | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Mineralization | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | |
| Nephropathy | 2 | 1 | 1 | 1 | 2 | 2 | 2 | 3 | 1 | 2 | 2 | 3 | 3 | 2 | 2 | 1 | 2 | 2 | 1 | 2 | 1 | 2 | 1 | 1 | 3 | |
| Pelvis, Transitional Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Urinary Bladder | + | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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

| FISCHER 344 RATS MALE | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|-----------------------|-------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----------|----|
| | 07 | 07 | 07 | 07 | 05 | 06 | 07 | 06 | 07 | 07 | 07 | 07 | 06 | 06 | 07 | 06 | 06 | 07 | 07 | 05 | 07 | 04 | | 06 |
| 0.3 G/KG | 27 | 27 | 27 | 28 | 29 | 26 | 29 | 22 | 22 | 22 | 22 | 28 | 08 | 07 | 06 | 03 | 07 | 09 | 00 | 08 | 02 | 04 | 04 | 02 |
| | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 |
| | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | |
| | 22 | 22 | 22 | 22 | 33 | 33 | 33 | 33 | 33 | 33 | 33 | 33 | 33 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | |
| | 66 | 77 | 88 | 99 | 00 | 11 | 22 | 33 | 44 | 55 | 66 | 77 | 88 | 99 | 00 | 11 | 22 | 33 | 44 | 55 | 66 | 77 | 88 | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----|--------|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Parasite Metazoan | | X | | | | X | | | | | | | X | | | | | | | | | | | 5 |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | 2 1.0 |
| Basophilic Focus | X | | X | X | | | | | | | X | X | | | | | X | | | | | | X | 18 |
| Clear Cell Focus | X | X | | X | | | | X | X | X | X | X | | | X | | X | X | | X | X | | X | 25 |
| Degeneration, Cystic | | | | | | | 1 | | | | | | | 1 | | 2 | | | | | | | | 3 1.3 |
| Eosinophilic Focus | X | | | | | | X | | | | | | | | X | | X | | | X | | | | 14 |
| Fatty Change, Diffuse | | | | | 2 | | 1 | | | | 1 | | | | | | 4 | 1 | | | | | 1 | 12 1.6 |
| Hematopoietic Cell Proliferation | | | 2 | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Hepatodiaphragmatic Nodule | | | | | | | | | | | | | | | X | | | | | | | | | 4 |
| Inflammation, Chronic Active | 1 | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 | | | | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | 32 1.0 |
| Mixed Cell Focus | | | | | X | | | | | | | | | X | | | | | | | | | | 4 |
| Pigmentation, Hemosiderin | | | | | | | | | | | | | | | | | | | | | | | | 2 1.5 |
| Bile Duct, Hyperplasia | 1 | 1 | | 1 | 2 | 1 | 1 | 2 | 2 | 3 | 2 | 2 | | 1 | 1 | | 1 | 1 | 1 | 2 | 2 | | 1 1 | 40 1.4 |

* .. 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS MALE
0.3 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|-----------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|----|
| | 0727 | 0727 | 0727 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | | |
| ANIMAL ID | 00126 | 00127 | 00128 | 00129 | 00130 | 00131 | 00132 | 00133 | 00134 | 00135 | 00136 | 00137 | 00138 | 00139 | 00140 | 00141 | 00142 | 00143 | 00144 | 00145 | 00146 | 00147 | 00148 | 00149 | 00150 | |
| Centrilobular, Degeneration | | | | 2 | | | | | | | | | | | | | | | | | | | | | 1 | |
| Centrilobular, Fatty Change | | | | | | | | | | | | | | | | | | | | | | | | | | 4 |
| Hepatocyte, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Hepatocyte, Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Oval Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | | 7 |
| Thrombosis | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | 6 |
| Pancreas | | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | 18 |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Acinus, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 9 |
| Salivary Glands | | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Stomach, Forestomach | | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Erosion | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | 9 |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Ulcer | | | | | | | | | | | | | | | | | | | | | | | | | | 6 |
| Epithelium, Dysplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 11 |
| Stomach, Glandular | | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Epithelium, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Tooth | | | | | | | | | | | | | | | | | | | | | | | | | | 9 |

* .. 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| DAY ON TEST | FISCHER 344 RATS MALE | | | | | | | | | | | | | | | | | | | | * TOTALS | | | |
|-------------|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|---|---|--|
| | 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 | 6 | 7 | 6 | 7 | 7 | 7 | 7 | 6 | 6 | 7 | 6 | 6 | 7 | 5 | 7 | 4 | 6 | 7 | | |
| 2 | 2 | 2 | 2 | 9 | 6 | 0 | 9 | 2 | 2 | 2 | 2 | 8 | 0 | 2 | 1 | 7 | 2 | 9 | 2 | 2 | 5 | 6 | 2 | |
| 7 | 7 | 7 | 8 | 8 | 4 | 9 | 4 | 8 | 9 | 7 | 7 | 9 | 8 | 7 | 6 | 3 | 7 | 9 | 0 | 8 | 4 | 4 | 8 | |
| 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 | |
| 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 | 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 | |

Malformation 1 1 1 1 1 9 1.0

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|-----|-----|
| Blood Vessel | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | |
| Pulmonary Artery, Inflammation, Chronic Active | | | | | | | | | | | | | | | | | | | | | | 2 | | 1 | 2.0 | | |
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | |
| Cardiomyopathy | 2 | 2 | 1 | 2 | 3 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 2 | 2 | 2 | 2 | 3 | 2 | 1 | 2 | 3 | 3 | 3 | 2 | 48 | 2.3 | |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Atrium, Thrombosis | | | | 2 | | | | | | | | | | | | | | | 2 | | | | | | | 3 | 1.7 |
| Coronary Artery, Degeneration | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Epicardium, Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|-----|-----|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 1.0 |
| Necrosis | | | | | | | | | | | | | | | | 1 | | | | | | | | | | 1 | 1.0 |
| Zona Fasciculata, Hyperplasia | 1 | | | | | | | | | | 1 | 1 | | | | | | | 1 | | | 1 | | | | 9 | 1.0 |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | |
| Hyperplasia | | | | | 1 | 1 | | | | | 1 | | | | | | 4 | | 2 | 3 | | | | | 10 | 1.8 | |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | |
| Hyperplasia | | | | | | 1 | | | | | | | | | | 1 | | | | | | | | | 2 | 1.0 | |
| Parathyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | 48 | | | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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

| FISCHER 344 RATS MALE
0.3 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | |
|---|-------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----------|----|----|--------|--------|
| | 07 | 07 | 07 | 07 | 05 | 06 | 07 | 06 | 07 | 07 | 07 | 07 | 06 | 06 | 07 | 06 | 06 | 07 | 07 | 05 | | 07 | 04 | 06 | 07 |
| ANIMAL ID | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | |
| | 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 | 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 | |
| Pituitary Gland Hemorrhage | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Pars Distalis, Angiectasis | | | | | | | | | | | | | | | | | | | | 2 | | | | 1 2.0 | |
| Pars Distalis, Hyperplasia | | 2 | 3 | | | 2 | | | | | 1 | 1 | 1 | 1 | 1 | | | 1 | | 2 | | | 2 | 21 1.4 | |
| Thyroid Gland C-cell, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| | | 1 | | 4 | | | | | | 1 | | | | 1 | 1 | | | | | | | | | 12 1.8 | |
| GENERAL BODY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | |
| Peritoneum | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| GENITAL SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | |
| Epididymis Inflammation | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| | | | | | | | | | | | | | | | | | | | | | | | | 3 1.7 | |
| Preputial Gland Inflammation | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | 49 | |
| | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Prostate Inflammation Epithelium, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| | | | | 2 | | | 2 | 2 | 2 | 2 | 1 | | | | 2 | | | 1 | | | 1 | | 4 | 1 | 21 1.8 |
| | | | | | | | | | | | | | | | | | | | | | | | 1 | 2 1.0 | |
| Seminal Vesicle Inflammation | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 2.0 | |
| Testes Interstitial Cell, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| | | | | | | 2 | | 1 | | | | | | | 2 | 2 | | | | | | | 2 | 10 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| DAY ON TEST | FISCHER 344 RATS MALE | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | |
|-------------|-----------------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----------|----|----|----|----|
| | 07 | 07 | 07 | 07 | 05 | 06 | 07 | 06 | 07 | 07 | 07 | 07 | 06 | 06 | 07 | 06 | 06 | 07 | 07 | 05 | | 07 | 04 | 06 | 07 |
| 0.3 G/KG | 27 | 27 | 27 | 28 | 29 | 26 | 09 | 04 | 09 | 02 | 02 | 02 | 08 | 00 | 02 | 01 | 07 | 02 | 09 | 00 | 08 | 02 | 05 | 06 | 08 |
| ANIMAL ID | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 |
| | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 |
| | 22 | 22 | 22 | 22 | 33 | 33 | 33 | 33 | 33 | 33 | 33 | 33 | 33 | 33 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 55 |
| | 66 | 67 | 68 | 69 | 00 | 01 | 02 | 03 | 04 | 05 | 06 | 07 | 08 | 09 | 00 | 01 | 02 | 03 | 04 | 05 | 06 | 07 | 08 | 09 | 00 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|--------|
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Hyperplasia | | | 3 | | 2 | 3 | | | | 1 | | 1 | 3 | 2 | 2 | 2 | 3 | | | 3 | | 1 | | 1 | 24 2.1 | |
| Lymph Node | | | | | | | | | | | | | | | + | | | | | | | + | | | 2 | |
| Mediastinal, Ectasia | | | | | | | | | | | | | | | 2 | | | | | | | | | | 1 2.0 | |
| Mediastinal, Infiltration Cellular, Plasma Cell | | | | | | | | | | | | | | | | | | | | | | 3 | | | 1 3.0 | |
| Lymph Node, Mandibular | 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 | |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Spleen | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Hematopoietic Cell Proliferation | | | 2 | | | 2 | | | | | | | | 1 | | 2 | | | | | | | | | 7 1.7 | |
| Pigmentation, Hemosiderin | 1 | | | 1 | 1 | | 1 | 2 | | 1 | 1 | 1 | 1 | 1 | | | | 1 | | 1 | 1 | 1 | 1 | 1 | 35 1.1 | |
| Lymphoid Follicle, Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | 2 3.0 | |
| Lymphoid Follicle, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 | |
| Thymus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Atrophy | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 3 | 4 | 3 | 3 | 3 | 3 | 4 | 3 | 4 | | 3 | 3 | 4 | 3 | 3 | 3 | 4 | 3 | 49 3.3 |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Epidermis, Hyperplasia, Basal Cell | | | | | | | | | | | | | | | | | | | | | | | | 3 | 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
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

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

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

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

| FISCHER 344 RATS MALE
0.3 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | |
|-----------------------------------|-------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----------|----|----|----|----|
| | 07 | 07 | 07 | 07 | 05 | 06 | 07 | 06 | 07 | 07 | 07 | 07 | 06 | 06 | 07 | 06 | 06 | 07 | 07 | 05 | | 07 | 07 | 04 | 06 |
| ANIMAL ID | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 |
| | 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 |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Skeletal Muscle | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |

NERVOUS SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Necrosis | | | | | 3 | | | | | | | | | | | | | | | | | | | | | 2 | 3.0 |
| Choroid Plexus, Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Congestion | | | | | 3 | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| Inflammation, Chronic Active | | | | | | | | | 1 | | 1 | 1 | | | | | | | | | | | | 2 | | 9 | 1.1 |
| Thrombosis | | | | | | | | | | | | | | | | | | | | 1 | | | | | | 1 | 1.0 |
| Alveolar Epithelium, Hyperplasia | 1 | 1 | | | | | | | 1 | | 2 | | 1 | 2 | 1 | | 2 | | | | | 1 | 1 | | | 20 | 1.4 |
| Alveolar Epithelium, Hypertrophy | | | | | | 2 | | | | | | | | | | | | | | | | | | | | 2 | 1.5 |
| Alveolar Epithelium, Metaplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Alveolar Epithelium, Metaplasia, Squamous | | | | | | | | | | | | | | 2 | | | | | | | | | | | | 1 | 2.0 |
| Alveolus, Infiltration Cellular, Histiocyte | | | | | 1 | | | | | | | | | | | | | | | | | 1 | 1 | | | 11 | 1.1 |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Foreign Body | | | | | | | | | | | | | | | | | | | | | | | X | | | 1 | |
| Inflammation | | | | | | | | | | | | | 1 | 2 | | | | | | | | | 2 | | | 10 | 1.6 |
| Olfactory Epithelium, Metaplasia | | | | | | | | | | | | | | | | | | | | | | | 1 | | | 3 | 1.3 |
| Respiratory Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| 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

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

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

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

| FISCHER 344 RATS MALE
0.3 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | |
|-----------------------------------|-------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----------|----|----|----|----|
| | 07 | 07 | 07 | 07 | 05 | 06 | 07 | 06 | 07 | 07 | 07 | 07 | 06 | 06 | 07 | 06 | 06 | 07 | 07 | 05 | | 07 | 07 | 04 | 06 |
| ANIMAL ID | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 |
| | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 |
| | 22 | 22 | 22 | 22 | 33 | 33 | 33 | 33 | 33 | 33 | 33 | 33 | 33 | 33 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 55 |
| | 67 | 67 | 68 | 69 | 00 | 01 | 02 | 03 | 04 | 05 | 06 | 07 | 08 | 09 | 00 | 01 | 02 | 03 | 04 | 05 | 06 | 07 | 08 | 09 | 00 |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|--|
| Ear | | | | | | | | | | | | | | | | | | | | | | | | 1 | | |
| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Cornea, Inflammation | | | | | | | | | | | | | | | | | | | | | | | | 3 | 1 3.0 | |
| Lens, Cataract | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2 2.0 | |
| Retina, Degeneration | | | | | | | | | | | | | | | | | | | | | | | | 1 | 10 1.5 | |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Zymbal's Gland | | | | | | | | | | | | | | | | | | | | | | | | + | 1 | |

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------|-----|-----|
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Accumulation, Hyaline Droplet | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | | |
| Infarct | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | | |
| Inflammation, Acute | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | | |
| Mineralization | 1 | 1 | 1 | 1 | | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 41 | 1.0 | |
| Nephropathy | 2 | 1 | 1 | 2 | 1 | 1 | 2 | 2 | 1 | 1 | 2 | 3 | 1 | 1 | 2 | 1 | 1 | 3 | 2 | 2 | 3 | 2 | 2 | 3 | 2 | 48 | 1.8 |
| Pelvis, Transitional Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 2.0 | | |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | 2 1 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| | | DAY ON TEST | | | | | | | | | | | | | | | | | | | | males
(cont...) | | |
|------------------------------|-----------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|---|---|
| FISCHER 344 RATS MALE | | 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 | 7 | 7 | 5 | 5 | 7 | 7 | 6 | 7 | 7 | 4 | 6 | 7 | 6 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | | 6 | 7 |
| | ANIMAL ID | 2 | 2 | 5 | 8 | 2 | 2 | 2 | 2 | 0 | 4 | 7 | 2 | 4 | 2 | 2 | 2 | 9 | 6 | 2 | 2 | 7 | 7 | |
| | | 7 | 7 | 6 | 9 | 8 | 9 | 9 | 7 | 9 | 7 | 3 | 8 | 0 | 9 | 9 | 7 | 4 | 5 | 7 | 7 | 9 | 7 | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 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 | |
| | | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 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 | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Parasite Metazoan | X | | | | | | | | | X | | | | | | | | | | | | | |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | |
| Basophilic Focus | | | | | | | | | | X | | | X | | X | | | | X | | X | | X |
| Clear Cell Focus | | | X | X | | | X | | | | | X | | X | X | | | | | X | | X | X |
| Degeneration, Cystic | | | | | | | | | | 2 | | 1 | | | | | 1 | | | | | | |
| Eosinophilic Focus | X | | X | | X | | | | | | X | X | X | | X | X | | | | X | | | |
| Fatty Change, Diffuse | 1 | | | | | | | 2 | | 1 | | | | | | 1 | | | | | | | |
| Fibrosis | | | | | | | | | | | | | | | | | | | | | | | |
| Hepatodiaphragmatic Nodule | | | | | | | | X | | | | | | | | | | | | | | | |
| Inflammation, Chronic Active | 1 | 1 | 1 | | 1 | 1 | 1 | | | 1 | 1 | | 1 | 1 | 1 | 1 | | | 1 | | 1 | | 1 |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | |
| Pigmentation, Hemosiderin | | | | | | | | | | | | | | | | 1 | | | | | | | |
| Tension Lipidosis | | | | | | | 2 | | | | | | | | | | | | | | | | |

* .. 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS MALE
1.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | males
(cont...) |
|-----------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|--------------------|
| | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | 0727 | |
| ANIMAL ID | 0015 | 0015 | 0015 | 0015 | 0015 | 0015 | 0015 | 0015 | 0015 | 0015 | 0015 | 0015 | 0015 | 0015 | 0015 | 0015 | 0015 | 0015 | 0015 | 0015 | 0015 |
| Bile Duct, Hyperplasia | | | | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 3 | 2 | 2 | 2 | | | 1 |
| Centrilobular, Fatty Change | | 1 | | | 2 | 2 | | | | | 2 | | 1 | | 1 | | | 2 | | | 2 |
| Centrilobular, Necrosis | | | | | | | | | | | | | | | | | | | | | |
| Hepatocyte, Hypertrophy | 2 | | | 1 | | | 2 | | | | 1 | 2 | | 1 | 2 | | | 2 | | | 1 |
| Oval Cell, Hyperplasia | | | | | | | | | | | | | | | | | 1 | | | | |
| Mesentery | | | | | | | + | | | | | | | | | | | | | | + |
| Fat, Necrosis | | | | | | | | | | | | | | | | 2 | | | | | 2 |
| Oral Mucosa | | | | + | | | | | | | | | | | | | | | | | |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Atrophy | | | | | | 1 | | 1 | 1 | | | | 1 | | 1 | | 1 | 4 | 1 | 1 | 1 |
| Inflammation | | | | | | 2 | | | | | | | | | | | | | | | |
| Acinus, Hyperplasia | | | | | | | | 2 | | | | | | | | | | | | | |
| Acinus, Metaplasia, Hepatocyte | | | | | | | | | | | | | | | | | | 2 | | 1 | 1 |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Erosion | | | | | | | | | | | 1 | | | | | | | | | | |
| Inflammation | | | | 2 | | | 3 | | 2 | | 3 | 2 | 3 | | 2 | | 2 | | 3 | | 2 |
| Mineralization | | | | | | | | | | | | 2 | | | | | 1 | | | | |
| Ulcer | | | | 2 | | | 3 | | 2 | | | 2 | 1 | | 1 | | 1 | | 1 | | 1 |
| Epithelium, Dysplasia | | | | | | | | | | | | | | | | | | 4 | | | |
| Epithelium, Hyperplasia | | | | 2 | | 2 | 3 | | 3 | 2 | 3 | 3 | 4 | | 3 | 1 | 2 | 1 | 4 | | 2 |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | | | | | | | | | | | | | | | | | 2 | | | | |

* .. 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS MALE
1.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | ANIMAL ID | males
(cont...) | |
|-----------------------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|-----------|--------------------|------------------|
| | 0
7
2
7 | 0
7
2
7 | 0
5
5
6 | 0
5
8
9 | 0
7
2
8 | 0
7
2
9 | 0
6
2
9 | 0
7
2
7 | 0
7
0
9 | 0
4
4
7 | 0
6
2
3 | 0
7
6
8 | 0
7
2
0 | 0
6
4
9 | 0
7
2
7 | 0
6
9
4 | 0
6
6
5 | 0
7
2
7 | 0
7
2
9 | 0
6
7
7 | 0
0
3
0 | 0
7
2
7 | | | 0
7
2
8 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 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 | 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 | |

Epithelium, Necrosis

3

Tooth

Malformation

+

+

+

+

+

1

1

1

1

1

CARDIOVASCULAR SYSTEM

Blood Vessel

Mineralization

+ +

Heart

Cardiomyopathy

Inflammation, Suppurative

Atrium, Thrombosis

+ +

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

ENDOCRINE SYSTEM

Adrenal Cortex

Hypertrophy

Necrosis

Zona Fasciculata, Hyperplasia

+ +

1

1 1

Adrenal Medulla

Hemorrhage

Hyperplasia

Thrombosis

+ +

2 2 2 3 2 1

Islets, Pancreatic

Hyperplasia

+ +

Parathyroid 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS MALE
1.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | ANIMAL ID | males
(cont...) | | | | |
|-----------------------------------|-------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|-----------|--------------------|----|----|----|----|
| | 07 | 07 | 05 | 05 | 07 | 07 | 06 | 07 | 07 | 04 | 06 | 07 | 06 | 07 | 07 | 07 | 06 | 06 | 07 | 07 | | | 06 | 07 | 00 | 07 |
| | 27 | 27 | 25 | 28 | 22 | 22 | 22 | 22 | 20 | 24 | 27 | 22 | 24 | 22 | 22 | 22 | 29 | 26 | 26 | 27 | 27 | 26 | 27 | 20 | 27 | 27 |
| | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 |
| | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 |
| | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 66 | 66 | 66 | 66 | 66 | 66 | 66 | 66 | 66 | 66 | 66 | 66 | 66 | 66 | 66 | 66 | 66 |
| | 12 | | 34 | | 56 | | 78 | | 90 | 11 | 22 | 33 | 44 | 55 | 66 | 77 | 88 | 99 | 00 | 11 | 22 | 33 | 44 | 55 | 66 | |

Hyperplasia 1 3 1 2 2

Pituitary Gland Pars Distalis, Hyperplasia +
 2 3 1 2

Thyroid Gland C-cell, Hyperplasia +
 Follicular Cell, Hyperplasia 1 1
 Follicular Cell, Hypertrophy 1

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

Epididymis Inflammation +

Preputial Gland Inflammation +
 Duct, Hyperplasia, Atypical 1 4

Prostate Atrophy +
 Inflammation 1 1 2 3 1 3 2 3
 Epithelium, Hyperplasia 1

Seminal Vesicle Atrophy +
 Inflammation 2

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

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| FISCHER 344 RATS MALE | 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 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | | 7 | 7 | 5 | 5 | 7 | 7 | 6 | 7 | 7 | 4 | 6 | 7 | 6 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 6 | 7 | 7 | 0 | 7 | 7 | 0 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| | | 2 | 2 | 5 | 8 | 2 | 2 | 2 | 2 | 0 | 4 | 7 | 2 | 4 | 2 | 2 | 2 | 9 | 6 | 6 | 2 | 2 | 7 | 2 | 3 | 2 | 2 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| 1.0 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 | |
| | | 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 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | |
| | | 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 | 7 | 7 | 7 | 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 | | | | | | | | | | |

**males
(cont...)**

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|--|
| Testes | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Cyst | 4 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Interstitial Cell, Hyperplasia | | | | | | | | | | 1 | | | 3 | | | | | | | | | | | | | | | | | | | | | | | | |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |
| Hyperplasia | 2 | | | 3 | | 1 | | 3 | 3 | | 3 | | | | | | | 4 | 4 | 3 | | | 4 | 2 | | | | | | | | | | | | | | |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | 2 | | | | | | | | | | | | | | | |
| Lymph Node | | | | | | | | | | + | | | | | | | | | | | | | + | | | | | | | | | | | | | | | |
| Mediastinal, Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mandibular | 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 | M | M | M | M | M | M | M | M | M | | |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Atrophy | | | | | 2 | 2 | 1 | | 3 | | 1 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Spleen | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Accessory Spleen | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fibrosis | | | | | | | | | | | | | 1 | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | 1 | 1 | | | | | | | | | | | 2 | | | | | | | | | | | | | | | |
| Hyperplasia, Histiocytic | | | | | | | | | | | | | | | | | | | | | | | 2 | | | | | | | | | | | | | | | |
| Pigmentation, Hemosiderin | | | 1 | 1 | | 1 | 1 | 1 | | | 1 | 1 | 1 | 2 | 1 | 1 | 1 | | | | | | | | 1 | | | | | | | | | | | | 1 | 1 |
| Thrombosis | | | | | | | | | 2 | | | | | | | | | | | | | | 3 | | | | | | | | | | | | | | | |
| Lymphoid Follicle, Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Thymus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Atrophy | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 2 | 4 | 3 | | 3 | 4 | 3 | 3 | 3 | 4 | 3 | 4 | 3 | 4 | 3 | 4 | 3 | 4 | 3 | 4 | 3 | | | | | | | 3 | 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS MALE | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | ANIMAL ID | males
(cont...) |
|-----------------------|-------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|-----------|--------------------|
| | 0
7 | 0
7 | 0
5 | 0
5 | 0
7 | 0
7 | 0
6 | 0
7 | 0
7 | 0
4 | 0
6 | 0
7 | 0
6 | 0
7 | 0
7 | 0
6 | 0
6 | 0
7 | 0
7 | 0
6 | 0
7 | 0
0 | 0
7 | 0
7 | | |
| 1.0 G/KG | 2 | 2 | 5 | 8 | 2 | 2 | 2 | 2 | 0 | 4 | 7 | 2 | 4 | 2 | 2 | 2 | 9 | 6 | 6 | 2 | 2 | 7 | 2 | 3 | 2 | 2 |
| | 7 | 7 | 6 | 9 | 8 | 9 | 9 | 7 | 9 | 7 | 3 | 8 | 0 | 9 | 9 | 7 | 4 | 5 | 7 | 7 | 9 | 7 | 0 | 7 | 8 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 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 | |
| | 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 | |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst Epithelial Inclusion | | | | 3 | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | |

MUSCULOSKELETAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Osteopetrosis | | | | | | | | | | | | | | | | | | | | | | | | | |
| Ligament, Mineralization | | | | | | | | | | | | | | | | | | | | | | | | | |
| Skeletal Muscle | | | | | | | | | | | | | | | | | | | | | | | | | + |

NERVOUS SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hemorrhage | | | | | | | | | | 2 | | | | | | | | | | | | | | | |
| Hydrocephalus | | | | | | | | | | | 1 | | | | | | | | | | | | | | |
| Necrosis | | | | | | | | | | | 2 | | | | | | | | | | | | | | |

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Congestion | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Foreign Body | | | | | | | X | | | | | | | | | | | | | | | | | | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Inflammation, Granulomatous | | | | | | 3 | | 1 | | | | | | | | | | | | | | | | | 1 |
| Inflammation, Chronic Active | | | | | | | | | | | | | | 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

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

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

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

| | | | |
|---|---|--|----------------------------------|
| FISCHER 344 RATS MALE

1.0 G/KG | DAY ON TEST
0 0
7 7 5 5 7 7 6 7 7 4 6 7 6 7 7 6 6 7 7 6 7 0 7 7
2 2 5 8 2 2 2 2 0 4 7 2 4 2 2 2 9 6 2 2 7 2 3 2 2
7 7 6 9 8 8 9 9 7 9 7 3 8 9 9 7 4 5 7 7 9 7 0 7 7 8 | ANIMAL ID
0 0
0 0
1 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
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...) |
| | Pelvis, Inflammation
Pelvis, Transitional Epithelium, Hyperplasia

Urinary Bladder
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

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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

| FISCHER 344 RATS MALE
1.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|-----------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|---------------|
| | 0729 | 0729 | 0727 | 0728 | 0727 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | |
| ANIMAL ID | 00176 | 00077 | 00078 | 00079 | 00080 | 00081 | 00082 | 00083 | 00084 | 00085 | 00086 | 00087 | 00088 | 00089 | 00090 | 00091 | 00092 | 00093 | 00094 | 00095 | 00096 | 00097 | 00098 | 00099 | 00100 |
| Bile Duct, Hyperplasia | 1 | 1 | 1 | 1 | 1 | | 2 | | 1 | 1 | | 2 | 1 | 1 | | | 3 | | 1 | 1 | 1 | 1 | | 2 | 34 1.4 |
| Centrilobular, Fatty Change | | 1 | 2 | 2 | 2 | 2 | | 1 | | | | | | 2 | | 1 | | | 1 | 2 | | 2 | 2 | | 21 1.7 |
| Centrilobular, Necrosis | | | | | | | | | | | 3 | | | | | | | | | | | | | | 1 3.0 |
| Hepatocyte, Hypertrophy | | 1 | 1 | 1 | 1 | 1 | | 1 | 2 | 1 | | | 1 | 2 | | | | | 2 | | 1 | | | 2 | 22 1.4 |
| Oval Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | 6 |
| Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | 5 1.6 |
| Oral Mucosa | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Atrophy | | | 1 | 3 | | | 1 | | 1 | | | | | | 1 | | | | 2 | | 1 | | | 1 | 18 1.3 |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Acinus, Hyperplasia | | | | 2 | | | | | | | | | | | | | | | | | | | | | 2 2.0 |
| Acinus, Metaplasia, Hepatocyte | | | | | | | | | | | | 2 | | | | | | | | 1 | 2 | | | | 6 1.5 |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Erosion | | | | | | | | | | | | 1 | | | | | 1 | | | | | | 1 | | 4 1.0 |
| Inflammation | 1 | 2 | | | | | 1 | | 3 | 2 | | 2 | | | | 1 | 1 | | 2 | | 1 | | 2 | | 22 2.0 |
| Mineralization | | | | | | | 2 | | | | | | | | | | | | | | | | | | 3 1.7 |
| Ulcer | 1 | 1 | | | | | 2 | | 3 | | | | | | | | | | | | | | | | 13 1.6 |
| Epithelium, Dysplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 |
| Epithelium, Hyperplasia | 1 | 3 | | | | | 1 | 3 | 4 | | 3 | | | | 1 | 1 | | 4 | | | | 1 | 1 | | 27 2.3 |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | 2 | | 1 2.0 |
| Inflammation | | | 2 | | | | | | | 1 | | | | | | | | | | | | | | | 3 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS MALE
1.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|-----------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|------|
| | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | | 0729 |
| ANIMAL ID | 00176 | 00177 | 00178 | 00179 | 00180 | 00181 | 00182 | 00183 | 00184 | 00185 | 00186 | 00187 | 00188 | 00189 | 00190 | 00191 | 00192 | 00193 | 00194 | 00195 | 00196 | 00197 | 00198 | 00199 | 00200 | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------|---|--|--|---|--|--|---|--|--|---|--|--|---|--|--|---|--|--|---|--|--|---|--|--|---|-----|--|----|----|-----|
| Epithelium, Necrosis | 2 | | | | | | | | | | | | 2 | | | | | | | | | | | | 3 | 2.3 | | | | |
| Tooth Malformation | + | | | + | | | + | | | + | | | + | | | + | | | + | | | + | | | + | | | 11 | 11 | 1.1 |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|--|--|--|--|--|--|--|----|---|-----|-----|
| Blood Vessel Mineralization | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | 1 | 1.0 | |
| Heart | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | | |
| Cardiomyopathy | 2 | 1 | 2 | 3 | 2 | 2 | 3 | 2 | 2 | 3 | 2 | 2 | 1 | 2 | 2 | 2 | | | | | | | | | | | 46 | 2.3 |
| Inflammation, Suppurative | | | | | | | | | | | | | 2 | | | | | | | | | | | | | 1 | 2.0 | |
| Atrium, Thrombosis | | | | | | | | | | | | | 2 | | | | | | | | | | | | | 1 | 2.0 | |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|---|---|--|---|--|--|--|--|--|--|--|--|--|---|---|---|---|--|--|--|--|--|--|--|----|---|---|-----|----|-----|-----|-----|
| Adrenal Cortex | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | | | | | | |
| Hypertrophy | | | | 1 | | | | | | | | | | | | | 1 | | | | | | | | | | | | | 3 | 1.0 | |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 | 2.0 | | | | |
| Zona Fasciculata, Hyperplasia | 1 | 1 | | | | | | | | | | | | | 2 | 1 | | | | | | | | | | | | | 1 | 13 | 1.1 | |
| Adrenal Medulla | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | | | | | | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 1 | 3.0 | | | | |
| Hyperplasia | | | | | | | | | | | | | | 1 | 4 | | | | | | | | | | | | | 1 | 10 | 1.9 | | |
| Thrombosis | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 | 2.0 | | | | |
| Islets, Pancreatic | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | | | | | | |
| Hyperplasia | | | | 4 | | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 1 | 2.7 |
| Parathyroid 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS MALE
1.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | | | |
|---|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|-------|-------|-------|------|----|-----|
| | 0729 | 0729 | 0729 | 0728 | 0727 | 0727 | 0727 | 0726 | 0725 | 0726 | 0726 | 0724 | 0727 | 0724 | 0727 | 0727 | 0727 | 0727 | 0720 | 0727 | | 0727 | 0727 | 0725 | 0727 | | |
| ANIMAL ID | 00176 | 00077 | 00078 | 00089 | 00080 | 00081 | 00082 | 00083 | 00084 | 00085 | 00086 | 00087 | 00088 | 00089 | 00090 | 00091 | 00092 | 00093 | 00094 | 00095 | 00096 | 00097 | 00098 | 00099 | | | |
| Hyperplasia | | | 3 | | | 1 | | | | | | | | | | | | | | | | | 1 | 2 | 2 | 10 | 1.8 |
| Pituitary Gland
Pars Distalis, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| | | | 1 | | | | | 1 | | | 1 | | | | 1 | | | | | | | | 1 | 1 | 2 | 11 | 1.5 |
| Thyroid Gland
C-cell, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| | | | | | | 4 | | | | 1 | 1 | | | | 1 | | | | | | | 1 | | | | 7 | 1.4 |
| Follicular Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | 2 | | | 1 | 2.0 |
| Follicular Cell, Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Epididymis
Inflammation | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| | | | | | | | | | | | 2 | | | | | | | | | | | 1 | | | | 2 | 1.5 |
| Preputial Gland
Inflammation | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Duct, Hyperplasia, Atypical | | | | | | | | | | | | | | | | | | | | | | | | 4 | | 2 | 4.0 |
| | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Prostate
Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| | | | | | | | 2 | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Inflammation | | | 2 | | | | | | 3 | 3 | | | | 2 | | 1 | | 1 | | | | | | 1 | 2 | 16 | 1.9 |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | 1 | | | | 1 | | | | 1 | | | | 3 | 1.0 |
| Seminal Vesicle
Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| | | | | | | | 2 | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Inflammation | | | | | | | | | | | 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

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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

| FISCHER 344 RATS MALE
1.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | | |
|------------------------------------|-------------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|--------|
| | 07
29 | 07
29 | 07
27 | 07
28 | 07
27 | 07
28 | 06
09 | 05
08 | 06
08 | 06
07 | 06
04 | 07
05 | 04
02 | 07
05 | 07
02 | 07
02 | 07
09 | 07
09 | 07
03 | 07
08 | | 07
08 | 07
09 | 05
09 | 07
09 | |
| ANIMAL ID | 00176 | 00077 | 00078 | 00079 | 00080 | 00081 | 00082 | 00083 | 00084 | 00085 | 00086 | 00087 | 00088 | 00089 | 00090 | 00091 | 00092 | 00093 | 00094 | 00095 | 00096 | 00097 | 00098 | 00099 | 00100 | |
| Testes | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 | |
| Interstitial Cell, Hyperplasia | | | | | | | | | | 2 | | 4 | | | | | | | | | | | | | 4 2.5 | |
| HEMATOPOIETIC SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Hyperplasia | | 1 | | 1 | 1 | 2 | 3 | | | | 2 | 3 | 3 | 2 | | 2 | 1 | 3 | | 3 | 2 | 2 | 1 | 2 | 3 | 29 2.4 |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Lymph Node | | | | | | | | | | | | | + | | | | | + | | | | + | | | 5 | |
| Mediastinal, Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | 2 | | | 1 2.0 | |
| Lymph Node, Mandibular | 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 | |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | 5 1.8 | |
| Spleen | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Accessory Spleen | | | | | | | | | | | | | | | | | | | | | | | X | 1 | | |
| Fibrosis | | | | | | | 2 | | | | | | | | | | | | | | | | | 2 1.5 | | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | 2 | | 2 | | | | | | | | | | | 5 1.6 | | |
| Hyperplasia, Histiocytic | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | | |
| Pigmentation, Hemosiderin | 1 | 1 | 1 | 1 | | 1 | 1 | 2 | 2 | 1 | | | 1 | 2 | 1 | 1 | | | 1 | | 1 | | 1 | 32 1.1 | | |
| Thrombosis | | | | | | | | | | | | | | | | | | | | | | | | | 2 2.5 | |
| Lymphoid Follicle, Atrophy | | | | | | | | 2 | | | | | | | | | | | | | | | | 1 2.0 | | |
| Thymus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Atrophy | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 3 | 4 | 4 | 3 | 3 | 3 | 3 | 3 | 3 | | | 4 | 2 | 3 | 3 | 3 | 4 | 46 3.2 | |

* .. 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS MALE
1.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | | |
|-----------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|-------|-------|-------|
| | 079 | 079 | 077 | 072 | 072 | 072 | 078 | 069 | 058 | 066 | 066 | 044 | 074 | 045 | 022 | 022 | 029 | 029 | 003 | 008 | | 007 | 007 | 005 |
| ANIMAL ID | 00176 | 00077 | 00077 | 00072 | 00072 | 00072 | 00078 | 00069 | 00058 | 00066 | 00066 | 00044 | 00074 | 00045 | 00022 | 00022 | 00029 | 00029 | 00003 | 00008 | 00007 | 00007 | 00005 | 00007 |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Cyst Epithelial Inclusion | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | 2 | | | 1 | 2.0 |

MUSCULOSKELETAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Osteopetrosis | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 | 2.0 |
| Ligament, Mineralization | | | | | | | | | | | | 2 | | | | | | | | | | | | 1 | 2.0 |
| Skeletal Muscle | | | | | | | | | | | | | | | | | | | | | | | | 1 | |

NERVOUS SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | 2 | | 2 | 2.0 |
| Hydrocephalus | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | 1 | | 2 | 1.5 |

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Congestion | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Foreign Body | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Inflammation, Granulomatous | | | | | | | | | | | | | | | | | | | | | | | | 3 | 1.7 |
| Inflammation, Chronic Active | | | | 1 | 1 | | | | | 1 | 1 | | | | 1 | | | | | | | | | 9 | 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS MALE
1.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | |
|---|-------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|----------|-----|-----|
| | 079 | 079 | 077 | 072 | 072 | 072 | 078 | 069 | 058 | 066 | 066 | 044 | 074 | 045 | 022 | 022 | 022 | 003 | 008 | 007 | | 007 | 005 |
| ANIMAL ID | 001 | 001 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 |
| Alveolar Epithelium, Hyperplasia | 1 | 1 | | 2 | | | | | | | 2 | | 1 | 1 | | | | 1 | | 1 | 1 | | 15 |
| Alveolar Epithelium, Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Alveolus, Infiltration Cellular, Histiocyte | | | | | | | 3 | | | 1 | | | | | | | | 1 | | 1 | 1 | | 9 |
| Arteriole, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Serosa, Inflammation, Acute | | | | | | | | 2 | | | | | | | | | | | | | | | 1 |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Foreign Body | | | | | | | | | | | | | | | | | | | | X | | | 2 |
| Inflammation | | | 2 | | | | | | 1 | 1 | 2 | 1 | | | | 1 | | 2 | 1 | | 2 | 1 | 18 |
| Olfactory Epithelium, Metaplasia | | | | | | | | | 2 | 2 | | | | | | | | | | 2 | | | 5 |
| Respiratory Epithelium, Hyperplasia | | | | | | 1 | | | | | | | | | | | | | 1 | | | | 4 |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| SPECIAL SENSES SYSTEM | | | | | | | | | | | | | | | | | | | | | | | |
| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Anterior Chamber, Inflammation | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Iris, Inflammation | | | | | | | | 1 | | | | | | | | | | | | | | | 2 |
| Retina, Degeneration | | 1 | 2 | | 2 | | | | | 2 | | 1 | | | | 1 | | 1 | | | | | 16 |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| URINARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | |
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Accumulation, Hyaline Droplet | | | | | | | | | | | | | | | | | | | | | | 1 | 2 |
| Hyperplasia, Oncocytic | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Mineralization | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | | 1 | 1 | 1 | 1 | | 34 |
| Nephropathy | 2 | 4 | 3 | 2 | 4 | 4 | 2 | 2 | 4 | 4 | 1 | 4 | 2 | 3 | 1 | 3 | 2 | | 4 | 2 | 3 | 3 | 48 |
| Cortex, Cyst | | | | | | | | | | | | | | | | | | | | | | | 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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

| FISCHER 344 RATS MALE
1.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|--|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|
| | 079 | 079 | 077 | 078 | 077 | 078 | 069 | 058 | 066 | 066 | 044 | 074 | 044 | 077 | 077 | 077 | 077 | 000 | 072 | 077 | 077 | 022 | 022 | 055 | 077 | |
| ANIMAL ID | 00176 | 00077 | 00078 | 00079 | 00080 | 00081 | 00082 | 00083 | 00084 | 00085 | 00086 | 00087 | 00088 | 00089 | 00090 | 00091 | 00092 | 00093 | 00094 | 00095 | 00096 | 00097 | 00098 | 00099 | 00100 | |
| Pelvis, Inflammation | | | | | | | | | | 1 | | | | | | | | | | | | | | | | 1 |
| Pelvis, Transitional Epithelium, Hyperplasia | | 1 | | | | 1 | | | | 2 | | 1 | | | | | | 1 | | | | | | | | 15 |
| Urinary Bladder Inflammation | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| | | | | | | | | | | | | | | | | | | | | | | | | 3 | | 2 |

*** 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

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

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

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

| FISCHER 344 RATS FEMALE | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | females
(cont...) |
|-------------------------|-------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----------------------|
| | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | |
| 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 | |
| ANIMAL ID | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | |
| | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | |
| | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | |
| | 12 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Colon
Parasite Metazoan | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Angiectasis | | | | | | | | | | | 2 | | | | | | | | | | | | | |
| Basophilic Focus | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Clear Cell Focus | | | | | | | | X | | | | X | | | | | | | | | | X | X | |
| Eosinophilic Focus | | | | X | X | X | X | | | | X | X | X | | | X | X | | | | X | | X | X |
| Fatty Change, Focal | | | | | | | | | | | | | | | | | | | | | | | | |
| Fatty Change, Diffuse | | | | | | | | | 2 | | | | | 2 | | | | | | | | 1 | | 1 |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | |
| Hepatodiaphragmatic Nodule | | | | | | | | | | | | | | | | | | | | | | X | | |
| Inflammation, Chronic Active | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 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 | | | | | | | | | | | | 2 | | | | | | | | | | | | |
| Pigmentation, Hemosiderin | | | | | | | | | | | | 2 | | | | | | | | | | | | |

* .. 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 | | | | | | | | | | | | | | | | | | | | | | | | | females
(cont...) |
|-------------------------|--|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|
| FISCHER 344 RATS 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 G/KG | | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 0 | 7 | 7 | |
| 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 | |
| | | 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 | 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 | |
| Artery, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Bile Duct, Hyperplasia | | | | | | 1 | 1 | | | | 1 | 1 | | | 1 | | | 1 | | | | | | | | | |
| Hepatocyte, Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Serosa, Fibrosis | | | | | | | | | | | | | | | | | | | | | | | 2 | | | | |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pancreas | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Basophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Acinus, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Salivary Glands | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach, Forestomach | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Atypical | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Ulcer | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach, Glandular | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Epithelium, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Tooth | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Malformation | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------------|
| | 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 | | |
| FISCHER 344 RATS FEMALE | | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | | |
| | | 0 | 2 | 3 | 2 | 2 | 2 | 3 | 2 | 0 | 3 | 3 | 3 | 2 | 3 | 2 | 0 | 2 | 2 | 1 | 2 | 0 | 2 | 2 | 2 | | |
| 0.0 G/KG | ANIMAL ID | 5 | 8 | 0 | 9 | 9 | 9 | 0 | 6 | 0 | 0 | 0 | 0 | 1 | 0 | 9 | 5 | 9 | 8 | 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 | | |
| | | 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 | 1 | 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 | females (cont...) |

Inflammation

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Cardiomyopathy | 1 | 2 | 2 | 1 | 2 | 2 | 1 | 3 | | 1 | 2 | 2 | 2 | 2 | 2 | 2 | | 3 | 1 | 2 | | 2 | | 3 | 2 |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Degeneration, Cystic | | | | | | 2 | | | | | | | 1 | | | | | | | | | | | |
| Hypertrophy | | | | | | | | | | | | | | 1 | | | | | | | | | | |
| Necrosis | | | | | 2 | | | | | | | | | | | | | | | | | | | |
| Zona Fasciculata, Hyperplasia | | | | 1 | 1 | | | | | | | 1 | | | | | | | | | 1 | | 1 | |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | |
| Parathyroid Gland | M | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Pars Distalis, Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Pars Distalis, Hyperplasia | | | | | | | | | 2 | 1 | | 2 | | | | | | | | | | 1 | | |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| C-cell, Hyperplasia | | | | | | 3 | | 1 | | | | | | | | 1 | | 3 | | 1 | | | | 3 |
| Follicular Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | 3 | | | |

GENERAL BODY 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| | | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------------|--|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------------------|------|------|------|
| | | 0705 | 0708 | 0730 | 0729 | 0779 | 0779 | 0777 | 0777 | 0757 | 0777 | 0777 | 0777 | 0766 | 0777 | 0777 | 0770 | 0777 | 0777 | 0777 | 0757 | | 0777 | 0770 | 0777 |
| FISCHER 344 RATS FEMALE | | ANIMAL ID | | | | | | | | | | | | | | | | | | | | females
(cont...) | | | |
| | | 0001 | 0002 | 0003 | 0004 | 0005 | 0006 | 0007 | 0008 | 0009 | 0010 | 0011 | 0012 | 0013 | 0014 | 0015 | 0016 | 0017 | 0018 | 0019 | 0020 | | 0021 | 0022 | 0023 |
| Hematopoietic Cell Proliferation | | 1 | 1 | | | | | 1 | | | | | | | | 1 | 1 | | | 1 | | 1 | | 1 | 1 |
| Hyperplasia, Histiocytic | | 3 | | | | | | | | | | | | | | | | | | | | | | | |
| Pigmentation, Hemosiderin | | 1 | 1 | 1 | | | 1 | 2 | 2 | 1 | | 1 | 2 | 1 | | 2 | 1 | 1 | 1 | 2 | 1 | 1 | | 1 | 1 |
| Lymphoid Follicle, Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymphoid Follicle, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | |
| Thymus | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Atrophy | | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | | 3 | 3 |
| Infiltration Cellular, Plasma Cell | | | | | | | | | | | | | | | | | | | | | | | | | |
| INTEGUMENTARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mammary Gland | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Skin | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| MUSCULOSKELETAL SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | |
| Bone | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Osteopetrosis | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Skeletal Muscle | | | | | | | | | | | | | | | | | | | | | | | | | + |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| NERVOUS SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | |
| Brain | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| RESPIRATORY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lung | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

* .. 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------|-----------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| FISCHER 344 RATS FEMALE | 0.0 G/KG | 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 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 0 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| | | 0 | 2 | 3 | 2 | 2 | 2 | 3 | 2 | 0 | 3 | 3 | 3 | 2 | 2 | 3 | 2 | 0 | 2 | 2 | 2 | 2 | 1 | 2 | 0 | 2 | 0 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | | 5 | 8 | 0 | 9 | 9 | 9 | 0 | 9 | 6 | 0 | 0 | 0 | 0 | 8 | 1 | 0 | 9 | 5 | 9 | 8 | 9 | 0 | 8 | 9 | 0 | 9 | 8 | 9 | 8 | 9 | 8 | 9 | 8 | 8 |
| 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 | |
| | 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 | 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 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | |

females
(cont...)

Harderian Gland +

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Infarct | | | | | | | | | | | | | | | | 1 | | | | | | | | | | | | | | | | | | |
| Mineralization | 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 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Nephropathy | 1 | | 1 | | 1 | | 1 | 1 | | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | | 1 | 1 | | 1 | 1 | | 1 | 1 | | 1 | 1 | | 1 | 1 | |
| Cortex, Cyst | | | | | | | 2 | | | | | | | | 1 | | | | | | | | | | | | | | | | | | | |
| Medulla, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pelvis, Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

* .. 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS FEMALE
0.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | |
|-------------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|------|------|-----|-----|
| | 0692 | 0450 | 0701 | 0703 | 0709 | 0709 | 0709 | 0709 | 0709 | 0709 | 0709 | 0709 | 0709 | 0709 | 0709 | 0709 | 0709 | 0709 | 0709 | 0709 | | 0709 | 0709 | | |
| ANIMAL ID | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | | | |
| Artery, Necrosis | | | | | | | | | | | | | | | | | | | | | | 2 | 1 | 2.0 | |
| Bile Duct, Hyperplasia | | | | | | | | | | 1 | | | 1 | | | | | 1 | 1 | 1 | | | 1 | 12 | 1.0 |
| Hepatocyte, Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | 2 | 5 | 1.6 |
| Serosa, Fibrosis | | | | | | | | | | | | | | | | | | | | | | | 3 | 1 | 3.0 |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | 10 |
| Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | | 1 | 10 | 1.5 |
| Pancreas | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | 1 | 13 | 1.0 |
| Basophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Acinus, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 | 1.0 |
| Salivary Glands | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Stomach, Forestomach | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Hyperplasia, Atypical | | | | | | | | | | | | | | | | | | | | | | | 4 | 1 | 4.0 |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | 5 | 2.0 |
| Ulcer | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 5 | 2.2 |
| Stomach, Glandular | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Epithelium, Necrosis | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 | 1.0 |
| Tooth | | | | | | | | | | | | | | | | | | | | | | | | | 5 |
| Malformation | | | | | | | | | | | | | | | | | | | | | | | 1 | 5 | 1.0 |

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

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

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

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

| FISCHER 344 RATS FEMALE
0.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | | |
|-------------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|--------|----------|------|--------|
| | 0692 | 0450 | 0701 | 0703 | 0702 | 0703 | 0702 | 0709 | 0509 | 0609 | 0605 | 0709 | 0702 | 0709 | 0703 | 0603 | 0703 | 0608 | 0603 | 0604 | 0709 | 0607 | 0702 | 0708 | | 0702 | 0709 |
| ANIMAL ID | 0022 | 0022 | 0022 | 0022 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0044 | 0044 | 0044 | 0044 | 0044 | 0044 | 0044 | 0044 | 0044 | 0044 | 0044 | 0044 | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | 3 | 1 3.0 | | |
| Heart | | | | | | | | | | | | | | | | | | | | | | | | 50 | | | |
| Cardiomyopathy | 2 | | 1 | 2 | 2 | 2 | 2 | 1 | | 1 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 42 1.9 |
| ENDOCRINE SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Adrenal Cortex | | | | | | | | | | | | | | | | | | | | | | | | 50 | | | |
| Degeneration, Cystic | | | | | | | | | | | | | | | | | | | | | | | | 3 1.3 | | | |
| Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | | 2 2.5 | | | |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | 2 3.0 | | | |
| Zona Fasciculata, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 6 1.0 | | | |
| Adrenal Medulla | | | | | | | | | | | | | | | | | | | | | | | | 50 | | | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 3 1.3 | | | |
| Islets, Pancreatic | | | | | | | | | | | | | | | | | | | | | | | | 50 | | | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | | | |
| Parathyroid Gland | | | | | | | | | | | | | | | | | | | | | | | | 44 | | | |
| Pituitary Gland | | | | | | | | | | | | | | | | | | | | | | | | 50 | | | |
| Pars Distalis, Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | | | |
| Pars Distalis, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 11 1.7 | | | |
| Thyroid Gland | | | | | | | | | | | | | | | | | | | | | | | | 50 | | | |
| C-cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 15 2.1 | | | |
| Follicular Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 | | | |

GENERAL BODY 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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

| DAY ON TEST | FISCHER 344 RATS FEMALE | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|-------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|
| | 0692 | 0450 | 0701 | 0703 | 0702 | 0703 | 0702 | 0709 | 0709 | 0519 | 0669 | 0671 | 0777 | 0777 | 0777 | 0777 | 0666 | 0777 | 0666 | 0777 | 0666 | 0777 | 0777 | 0777 | |
| 0.0 G/KG | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0022 | 0022 | 0022 | 0022 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | |
| | 67 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 50 |

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|----------------|
| Clitoral Gland Inflammation | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | 1 3.0 |
| Ovary Cyst, Multiple | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | 7 2.6
1 4.0 |
| Uterus Endometrium, Hyperplasia, Cystic | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | 5 1.6 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|----------------|
| Bone Marrow Hemorrhage | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | 1 3.0 |
| Bone Marrow Hyperplasia | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | 26 2.1 |
| Bone Marrow Myelofibrosis | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | 2 1.5 |
| Bone Marrow Necrosis | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | 1 3.0 |
| Lymph Node | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Lymph Node, Mandibular | M | | | | | | | | | | | | | | | | | | | | | | | | 0 | |
| Lymph Node, Mesenteric Atrophy Inflammation | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | 1 3.0
2 2.5 |
| Spleen | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |

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

+ .. Tissue examined microscopically

M .. Missing tissue

X .. Lesion present

A .. Autolysis precludes evaluation

I .. Insufficient tissue

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

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

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

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

| FISCHER 344 RATS FEMALE
0.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|--|-------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|---------------|
| | 0692 | 0450 | 0701 | 0730 | 0770 | 0773 | 0777 | 0779 | 0519 | 0669 | 0665 | 0777 | 0777 | 0777 | 0777 | 0666 | 0777 | 0666 | 0666 | 0777 | 0666 | 0777 | 0777 | 0777 | |
| ANIMAL ID | 002226 | 002227 | 002228 | 002229 | 002230 | 002231 | 002232 | 002233 | 002234 | 002235 | 002236 | 002237 | 002238 | 002239 | 002240 | 002241 | 002242 | 002243 | 002244 | 002245 | 002246 | 002247 | 002248 | 002249 | |
| Hematopoietic Cell Proliferation
Hyperplasia, Histiocytic
Pigmentation, Hemosiderin
Lymphoid Follicle, Atrophy
Lymphoid Follicle, Necrosis | | 2 | 2 | | 1 | | 1 | 1 | | | 4 | 1 | | | | | 1 | 1 | | | | | 1 | | 19 1.3 |
| Thymus Atrophy
Infiltration Cellular, Plasma Cell | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| | 3 | 4 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 48 3.0 |
| | | | 2 | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| INTEGUMENTARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| MUSCULOSKELETAL SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | |
| Bone Osteopetrosis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Skeletal Muscle Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| NERVOUS SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | |
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| RESPIRATORY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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

| DAY ON TEST | FISCHER 344 RATS FEMALE | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|-------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|------|
| | 0692 | 0450 | 0701 | 0703 | 0702 | 0703 | 0702 | 0709 | 0509 | 0606 | 0601 | 0702 | 0703 | 0703 | 0700 | 0603 | 0703 | 0606 | 0602 | 0703 | | 0702 |
| 0.0 G/KG | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | |
| | 0022 | 0022 | 0022 | 0022 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0044 | 0044 | 0044 | 0044 | 0044 | 0044 | 0044 | 0044 |
| | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Atelectasis | | | | | | | | | | | | | | | | | | | | | | | 1 | 4.0 |
| Congestion | 2 | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Inflammation, Chronic Active | | | | | | | 1 | | | | | | | | | 4 | | | | | 1 | | 4 | 2.0 |
| Alveolar Epithelium, Hyperplasia | | | | | | | | | | | | | | | 2 | | 1 | | | 1 | 1 | | 11 | 1.1 |
| Alveolar Epithelium, Hypertrophy | | | | | | | | | | | | | | | | | | | | 1 | | | 1 | 1.0 |
| Alveolar Epithelium, Metaplasia | | | | | | | | | | | | | | | | | | 2 | | | | | 1 | 2.0 |
| Alveolar Epithelium, Metaplasia, Squamous | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Alveolus, Infiltration Cellular, Histiocyte | | | | | | | 1 | | | 1 | | | 1 | | | 1 | | | | | | | 12 | 1.0 |
| Mediastinum, Foreign Body | | X | | | | | | | | | | | | | | | | | | | | | 1 | |
| Mediastinum, Inflammation, Chronic Active | 4 | | | | | | | | | | | | | | | | | | | | | | 1 | 4.0 |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Foreign Body | | | | | | | | | | | | | | | | | | | | | X | | 2 | |
| Inflammation | | | 2 | | | | | | | | | | | | | | | | | | 1 | | 8 | 1.1 |
| Olfactory Epithelium, Metaplasia | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Ear | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Cornea, Fibrosis | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Cornea, Inflammation | | | | | | | 2 | | | | | | | | | | | | | | | | 1 | 2.0 |
| Lens, Cataract | | | | | | | | | | | | | | | | | | 3 | | | | | 2 | 3.5 |
| Retina, Degeneration | | | | | | 1 | 1 | | | | | | | | | | | 4 | | | | | 5 | 2.6 |
| Retina, Gliosis | | | | | | | | | | | | 2 | | | | | | | | | | | 1 | 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS FEMALE | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | | |
|-------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|------|--------|
| | 0692 | 0450 | 0701 | 0730 | 0770 | 0777 | 0777 | 0777 | 0777 | 0559 | 0669 | 0666 | 0777 | 0777 | 0777 | 0777 | 0666 | 0777 | 0777 | 0666 | 0666 | 0777 | 0666 | 0777 | | 0777 | 0777 |
| 0.0 G/KG | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0022 | 0022 | 0022 | 0022 | 0033 | 0033 | 0033 | 0033 | 0033 | 0044 | 0045 | 0066 | 0067 | 0077 | 0077 | 0077 | 0077 | 0066 | 0077 | 0077 | 0066 | 0066 | 0077 | 0066 | 0077 | 0077 | 0077 |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| URINARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Infarct | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 1.0 |
| Mineralization | | 1 | 1 | | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 43 1.0 |
| Nephropathy | | | | | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | | | | 1 | 1 | | 34 1.0 |
| Cortex, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 1.5 |
| Medulla, Cyst | | 1 | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Pelvis, Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS FEMALE
0.1 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | ANIMAL ID | females
(cont...) | | | |
|-------------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-----------|----------------------|------|------|------|
| | 0727 | 0639 | 0678 | 0729 | 0779 | 0770 | 0773 | 0773 | 0773 | 0773 | 0773 | 0773 | 0675 | 0729 | 0778 | 0778 | 0779 | 0770 | 0773 | 0531 | | | 0671 | 0722 | 0773 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 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 | 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 |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Parasite Metazoan | | | | | | | X | | | | | | | | | | | | | | | | | |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Angiectasis | | | | | | | | | 2 | | | | | | | | | | 1 | | | | | |
| Basophilic Focus | | X | X | X | X | X | X | X | X | X | X | | X | | X | X | X | X | | X | | X | X | X |
| Clear Cell Focus | | X | | | | | X | | | X | | | | | | | | X | | | X | | | |
| Eosinophilic Focus | | X | X | X | | X | X | | X | X | X | | X | | X | X | X | | | X | | X | X | X |
| Fatty Change, Diffuse | 2 | 1 | | | | | | | | 1 | | | | 2 | | | | | 1 | | | | | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | 1 | 1 | 1 | | | | | | | |
| Hepatodiaphragmatic Nodule | | X | | | | | | | | | | | | | | | | | | | | | X | |
| Inflammation, Chronic Active | | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 |
| Mixed Cell Focus | | X | | | | | | | | X | | | | | X | | | X | | | | | | |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | |

* .. 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS FEMALE
0.1 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | ANIMAL ID | females
(cont...) | | | | | | | |
|-------------------------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|-----------|----------------------|------------------|------------------|------------------|------------------|------------------|---|--|
| | 0
7
2
7 | 0
6
3
9 | 0
6
7
8 | 0
7
2
9 | 0
7
2
9 | 0
7
3
0 | 0
7
3
0 | 0
7
3
0 | 0
7
2
8 | 0
7
3
0 | 0
7
3
0 | 0
7
0
5 | 0
6
7
2 | 0
7
7
8 | 0
7
2
8 | 0
7
2
8 | 0
7
2
9 | 0
7
3
0 | 0
7
3
0 | 0
5
3
8 | 0
6
3
1 | | | 0
7
2
9 | 0
0
5
1 | 0
7
2
3 | 0
7
2
4 | 0
7
7
5 | | |
| Bile Duct, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Bile Duct, Hyperplasia | 3 | | | 1 | | | 1 | 1 | 2 | 1 | 2 | | | | | | | 1 | | | 1 | | | | | | | | | |
| Centrilobular, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hepatocyte, Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Oval Cell, Hyperplasia | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Serosa, Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Oral Mucosa | | | | | | | | | | | | | | | | | | | | | | | + | | | | | | | |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Atrophy | | 1 | | | | | | | 1 | | | | | 1 | | | | | 1 | | | 2 | | | | | | | | |
| Acinus, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Acinus, Metaplasia, Hepatocyte | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Erosion | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | 2 | 1 | | | | | | | | | 1 | 3 | | | | | | | | | 3 | | | | | | | | | |
| Ulcer | 4 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Epithelium, Hyperplasia | 2 | 2 | | | | | | | | | 1 | 1 | 4 | | | | | | | | | 4 | | | | | | | | |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Inflammation | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Epithelium, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Tooth | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

* .. 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS FEMALE
0.1 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | ANIMAL ID | females
(cont...) | | | | | |
|-------------------------------------|-------------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|-----------|----------------------|----------|----------|----------|----------|--|
| | 07
27 | 06
38 | 06
78 | 07
29 | 07
79 | 07
70 | 07
73 | 07
73 | 07
80 | 07
30 | 07
30 | 07
30 | 07
50 | 07
60 | 07
70 | 07
73 | 07
73 | 07
80 | 07
81 | 07
91 | | | 07
01 | 07
03 | 07
04 | 07
05 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00251 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00252 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00253 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00254 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00255 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00256 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00257 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00258 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00259 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00260 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00261 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00262 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00263 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00264 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00265 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00266 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00267 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00268 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00269 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00270 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00271 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00272 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00273 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00274 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00275 | |

Malformation

1

1

CARDIOVASCULAR SYSTEM

Blood Vessel

+ +

Heart

+ +

Cardiomyopathy

1 1 2 2 2 2 3 2 2 1 2 2 2 1 1 2 2 2 2 2 2 2 2

Atrium, Thrombosis

Valve, Thrombosis

2

ENDOCRINE SYSTEM

Adrenal Cortex

+ +

Amyloid Deposition

2

Degeneration, Cystic

1 1 2 1

Hypertrophy

1

Zona Fasciculata, Hyperplasia

1 1 1 1

Adrenal Medulla

+ +

Necrosis

Islets, Pancreatic

+ +

Parathyroid Gland

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

Pituitary Gland

+ +

Pars Distalis, Angiectasis

1

Pars Distalis, Hyperplasia

1 4 2 1 2 2 3 3

Thyroid Gland

+ +

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

+ .. Tissue examined microscopically

M .. Missing tissue

1-4 .. Lesion qualified as:

X .. Lesion present

A .. Autolysis precludes evaluation

1) Minimal 3) Moderate

I .. Insufficient tissue

BLANK .. Not examined microscopically

2) Mild 4) Marked

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

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

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

| FISCHER 344 RATS FEMALE
0.1 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | ANIMAL ID | females
(cont...) | | | |
|-------------------------------------|-------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|-----------|----------------------|----|----|----|
| | 07 | 06 | 06 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 06 | 07 | 07 | 07 | 07 | 07 | 05 | 06 | | | 07 | 00 | 07 |
| | 2 | 3 | 7 | 2 | 2 | 3 | 3 | 3 | 2 | 3 | 3 | 0 | 7 | 2 | 2 | 2 | 3 | 3 | 5 | 3 | 2 | 5 | 2 | 3 | |
| | 7 | 9 | 8 | 9 | 9 | 0 | 0 | 0 | 8 | 0 | 0 | 5 | 0 | 9 | 8 | 8 | 9 | 0 | 8 | 1 | 9 | 1 | 8 | 0 | |
| | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | |
| | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | 22 | |
| | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | |
| | 12 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 10 | 11 | 12 | 13 | 14 | 15 |
| C-cell, Hyperplasia | 2 | | | 2 | 1 | 2 | | | | | 4 | 3 | 3 | | 1 | | 1 | 1 | | 1 | | | | 1 | |
| Follicular Cell, Hyperplasia | | | 1 | | | | | | | | | | | | | | | | | | | | | | |

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | | | | 3 | | | | | | | | | | | | | | | 3 | | | | | |
| Inflammation | | | | | | | | | 2 | | | | | | | | | | | | | | | |
| Ovary | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst | | | | | | | | | | | | | | | | 1 | 4 | | | | | | | 1 |
| Uterus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Congestion | | | | | | | | | | | | | | | 4 | | | | | | | | | |
| Hemorrhage | | | | | | | | | 3 | | | | | | | | | | | | 2 | | | |
| Necrosis | | | | | | | | | | | | | | | | 3 | | | | | | | | |
| Endometrium, Hyperplasia, Cystic | | | | | | | | | | | | | | | 2 | 1 | | | | | | | | |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | 4 | 2 | | | 3 | 2 | | 1 | 1 | 1 | | | 4 | 3 | 2 | | 1 | 1 | | 4 | | | | |
| Myelofibrosis | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mandibular | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS FEMALE
0.1 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | ANIMAL ID | females
(cont...) | |
|---|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|-----------|----------------------|------------------|
| | 0
7
2
7 | 0
6
3
9 | 0
6
7
8 | 0
7
2
9 | 0
7
2
9 | 0
7
3
0 | 0
7
3
0 | 0
7
3
0 | 0
7
2
8 | 0
7
3
0 | 0
7
3
0 | 0
7
0
5 | 0
7
0
9 | 0
7
2
8 | 0
7
2
8 | 0
7
2
9 | 0
7
3
0 | 0
7
3
0 | 0
5
3
8 | 0
6
3
1 | 0
7
2
9 | 0
0
5
1 | 0
7
2
3 | 0
7
2
4 | | | 0
7
7
5 |
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Atelectasis | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Chronic Active | 2 | | | | | 1 | | | | | | | | | | | | | | | | | | | | | |
| Alveolar Epithelium, Hyperplasia | | 1 | | | | | | | | | 1 | 2 | 3 | | 1 | 1 | | | | | | | | 4 | | | |
| Alveolar Epithelium, Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | | 2 | | | |
| Alveolar Epithelium, Metaplasia, Squamous | | | | | | | | | | | | | 1 | | | | | | | | | | | | | | |
| Alveolus, Infiltration Cellular, Histiocyte | | | | 1 | | | 1 | | 1 | | | | | | 1 | 1 | | | 1 | 1 | | | 1 | | | | |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| SPECIAL SENSES SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Lens, Cataract | | | | | | | | | | | | | | 4 | | | | | | | | | | | | | |
| Retina, Degeneration | | | | | | | | | | | | | 4 | | | | 2 | | | | | | | | | | |
| Retina, Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| URINARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Accumulation, Hyaline Droplet | | | | | | | | | | | | | | | | | | | | | | | | | | 3 | |
| Glomerulosclerosis | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infarct | | | | | | | | 2 | | | | | | | 1 | | | | | | | | | | | | |
| Mineralization | 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 |
| Nephropathy | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | | | 2 | | 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

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------|-----------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------------------------------|
| FISCHER 344 RATS FEMALE | DAY ON TEST | 077 | 066 | 067 | 077 | 077 | 077 | 077 | 077 | 077 | 077 | 077 | 066 | 077 | 077 | 077 | 077 | 077 | 055 | 066 | 077 | 000 | 077 | 077 | females
(cont...) |
| | 0.1 G/KG | 277 | 398 | 788 | 299 | 299 | 330 | 330 | 288 | 330 | 330 | 050 | 700 | 299 | 288 | 288 | 299 | 330 | 330 | 588 | 111 | 299 | 518 | 230 | |
| | ANIMAL ID | 0051 | 0052 | 0053 | 0054 | 0055 | 0056 | 0057 | 0058 | 0059 | 0060 | 0061 | 0062 | 0063 | 0064 | 0065 | 0066 | 0067 | 0068 | 0069 | 0070 | 0071 | 0072 | 0073 | |

Pelvis, Inflammation

Urinary Bladder

+ +

* .. 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 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------|-----------------|-------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|-----------------|
| | | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 06 | 06 | 07 | 06 | 00 | 07 | 06 | 07 | 07 | 07 | 06 | | 07 | 07 | 06 | 07 | 07 | 07 | | |
| FISCHER 344 RATS FEMALE | | 29 | 29 | 28 | 29 | 28 | 29 | 22 | 20 | 11 | 88 | 51 | 29 | 55 | 03 | 33 | 33 | 29 | 55 | 99 | 33 | 08 | 22 | 32 | 29 | 32 | 29 | | | |
| | 0.1 G/KG | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | | 00 | * TOTALS |
| | | 27 | 27 | 27 | 27 | 28 | 28 | 28 | 28 | 28 | 28 | 28 | 28 | 28 | 28 | 28 | 28 | 28 | 28 | 28 | 28 | 28 | 28 | 28 | 28 | 28 | 28 | | 28 | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|-----|-----|-----|-----|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 | 1.0 | | | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | | |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | 1 | | |
| Parasite Metazoan | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | | |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | | |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | | |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | | |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | | |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1.5 |
| Basophilic Focus | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | | 42 | | |
| Clear Cell Focus | | X | | X | X | X | | | | | X | | | | | X | | | | | | X | | | | | X | X | | | | 14 | | |
| Eosinophilic Focus | | X | X | X | X | X | X | | | X | X | | | | X | X | X | | | X | X | | X | X | | X | X | X | | | | 31 | | |
| Fatty Change, Diffuse | | | | | | | | 2 | | | | | 2 | | 1 | 1 | | | | | | | | | | | | | | | | 10 | 1.4 | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 1.0 | |
| Hepatodiaphragmatic Nodule | | | X | | | | X | | | | | | | | | | X | | | | | X | | | | | | | | | | 6 | | |
| Inflammation, Chronic Active | 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 | 1 | | 40 | 1.0 | | |
| Mixed Cell Focus | | | X | X | | | X | | | | | | | | | | X | | | | | X | | | | | | X | | | | 10 | | |
| Necrosis | | | | | | | | | | | | | | | 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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

| FISCHER 344 RATS FEMALE
0.1 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | | |
|-------------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|-----|-----|
| | 0729 | 0729 | 0728 | 0729 | 0728 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | | | |
| ANIMAL ID | 0076 | 0077 | 0078 | 0079 | 0080 | 0081 | 0082 | 0083 | 0084 | 0085 | 0086 | 0087 | 0088 | 0089 | 0090 | 0091 | 0092 | 0093 | 0094 | 0095 | 0096 | 0097 | 0098 | 0099 | 0100 | | |
| Bile Duct, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 | |
| Bile Duct, Hyperplasia | | | | 1 | | 1 | | 2 | 1 | | | 2 | | | | | | | 2 | | 1 | | | | | 15 | 1.5 |
| Centrilobular, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| Hepatocyte, Hypertrophy | | | | | | | | | | | | | | 1 | | | | | | | | | | | | 2 | 1.0 |
| Oval Cell, Hyperplasia | | | | | | | | | | | | 2 | | | | | | | | | | | | | | 2 | 2.0 |
| Serosa, Fibrosis | | | | | | | | | | | | | | | | | | 2 | | | | | | | | 1 | 2.0 |
| Mesentery | | | | + | | | + | | | | | | | | | | | + | + | + | | | | | | 9 | |
| Fat, Necrosis | | | | 2 | | | 2 | | | | | | | | | | | 3 | 2 | 2 | | | | | | 9 | 1.9 |
| Oral Mucosa | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Atrophy | | | | 1 | 1 | | 2 | | | | | | | | | | 1 | | | | | | 3 | | | 10 | 1.4 |
| Acinus, Hyperplasia | | | | | | | | | | | | | | | | | | | | 1 | | | | | | 3 | 1.3 |
| Acinus, Metaplasia, Hepatocyte | | | | | | | | | | | | 1 | | | | | | | | | | | | | | 1 | 1.0 |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Erosion | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Inflammation | | | | | | | | | | | | 1 | | | | | | | | 1 | | | | | | 7 | 1.7 |
| Ulcer | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 4.0 |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 6 | 2.3 |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2.0 |
| Epithelium, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Tooth | | | | | | | | | | | | | | | | | | | | | | | | | | 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

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

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

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

| DAY ON TEST | FISCHER 344 RATS FEMALE | | | | | | | | | | | | | | | | | | | | * TOTALS | | | |
|-------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|------|------|------|
| | 079 | 072 | 078 | 077 | 078 | 079 | 071 | 078 | 075 | 076 | 075 | 070 | 073 | 073 | 070 | 075 | 079 | 073 | 078 | 072 | | 079 | 077 | |
| ANIMAL ID | 0076 | 0077 | 0078 | 0079 | 0080 | 0081 | 0082 | 0083 | 0084 | 0085 | 0086 | 0087 | 0088 | 0089 | 0090 | 0091 | 0092 | 0093 | 0094 | 0095 | 0096 | 0097 | 0098 | 0099 |
| 0 | 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 | 7 | 7 | 7 | 6 | 6 | 7 | 6 | 0 | 7 | 6 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 |
| 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 0 | 8 | 1 | 2 | 0 | 0 | 3 | 3 | 3 | 2 | 0 | 2 | 3 | 2 | 3 | 2 | 2 |
| 9 | 9 | 8 | 9 | 8 | 9 | 9 | 1 | 8 | 5 | 9 | 5 | 5 | 0 | 2 | 0 | 0 | 9 | 5 | 9 | 0 | 8 | 2 | 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 | 3 |
| 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 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 |

Malformation

2

3 1.3

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|
| Blood Vessel | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Cardiomyopathy | 1 | 2 | 1 | 3 | 1 | 2 | 2 | 1 | 2 | 2 | 2 | | | 2 | 2 | 1 | 3 | 1 | 4 | 2 | 2 | 2 | 2 | 45 1.9 |
| Atrium, Thrombosis | | | | | | | | 2 | | | | | | | | | | | | | | | | 1 2.0 |
| Valve, Thrombosis | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Amyloid Deposition | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Degeneration, Cystic | | | | | | | | | | | | | | | | | | | | | 1 | | | 6 1.2 |
| Hypertrophy | | | | | | | | | | 1 | | | | | | | | | | | 1 | | | 3 1.0 |
| Zona Fasciculata, Hyperplasia | | | | | | 1 | | 1 | | | 2 | | | | | | | | | | | | | 6 1.2 |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | 4 | | 1 4.0 |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Parathyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 47 |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Pars Distalis, Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Pars Distalis, Hyperplasia | | | 4 | | 3 | | 2 | | 2 | | | | 1 | | 2 | | | | 2 | | 2 | 2 | 2 | 20 2.2 |
| Thyroid 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS FEMALE
0.1 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | |
|-------------------------------------|-------------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|------|--------|
| | 07
29 | 07
29 | 07
28 | 07
29 | 07
28 | 07
29 | 07
29 | 07
29 | 07
29 | 07
29 | 07
29 | 07
29 | 07
29 | 07
29 | 07
29 | 07
29 | 07
29 | 07
29 | 07
29 | 07
29 | | 07
29 | 07
29 | | |
| ANIMAL ID | 0076 | 0077 | 0078 | 0079 | 0080 | 0081 | 0082 | 0083 | 0084 | 0085 | 0086 | 0087 | 0088 | 0089 | 0090 | 0091 | 0092 | 0093 | 0094 | 0095 | 0096 | 0097 | 0098 | 0099 | |
| C-cell, Hyperplasia | | | | | | | | | | 3 | | | | | | | | 1 | | | 3 | | | | 15 1.9 |
| Follicular Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|-------|-------|-------|
| Clitoral Gland
Hyperplasia
Inflammation | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | 3 2.7 | 2 2.0 | | |
| Ovary
Cyst | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 9 2.0 | | | |
| Uterus
Congestion
Hemorrhage
Necrosis
Endometrium, Hyperplasia, Cystic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 4.0 | 2 2.5 | 1 3.0 | 5 1.2 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|--------|-------|
| Bone Marrow
Hyperplasia
Myelofibrosis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 27 2.3 | 1 2.0 |
| Lymph Node | | | | | | | | | | | | | | | | | | | | | | | | | 3 | | |
| Lymph Node, Mandibular | 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 | | |

* .. 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| DAY ON TEST | | | | | | | | | | | | | | | | | | | | | * TOTALS | | |
|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----------|----|--------------|
| | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 06 | 06 | 07 | 06 | 00 | 07 | 06 | 07 | 07 | 07 | 06 | | 07 | 07 |
| FISCHER 344 RATS FEMALE | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 0 | 8 | 1 | 2 | 0 | 0 | 3 | 3 | 3 | 2 | 0 | 2 | 3 | 2 | 3 | |
| 0.1 G/KG | 9 | 9 | 8 | 9 | 8 | 9 | 9 | 1 | 8 | 5 | 9 | 5 | 5 | 0 | 2 | 0 | 9 | 5 | 9 | 0 | 8 | 2 | |
| ANIMAL ID | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | |
| | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | |
| | 7 | 7 | 7 | 7 | 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 | |
| Lymph Node, Mesenteric Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50
1 3.0 |
| Spleen Fibrosis | + | + | + | + | + | + | + | + | + | + | + | 2 | + | + | + | + | + | + | + | + | + | + | 50
3 1.7 |
| Hematopoietic Cell Proliferation | | | | | 1 | 1 | 1 | | | | | 2 | 1 | | | 3 | | 2 | 1 | | | 1 | 18 1.3 |
| Pigmentation, Hemosiderin | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | | | 2 | 1 | 1 | | 1 | | 2 | 1 | 1 | 1 | 1 | 1 | 37 1.1 |
| Lymphoid Follicle, Atrophy | | | | | | | | | | | 2 | | | | | | | | | | | 1 | 1 2.0 |
| Thymus Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50
43 3.0 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | | | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 3 | |
| INTEGUMENTARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | |
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Skin Epidermis, Hyperplasia, Basal Cell | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50
1 2.0 |
| MUSCULOSKELETAL SYSTEM | | | | | | | | | | | | | | | | | | | | | | | |
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| NERVOUS SYSTEM | | | | | | | | | | | | | | | | | | | | | | | |
| Brain Hemorrhage | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50
2 3.0 |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | 3 1.7 |
| 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

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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

| FISCHER 344 RATS FEMALE
0.1 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | | | |
|---|-------------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|------|------|--------|--|--|
| | 07
29 | 07
29 | 07
28 | 07
29 | 07
28 | 07
29 | 07
29 | 07
29 | 07
29 | 07
29 | 07
29 | 07
29 | 07
29 | 07
29 | 07
29 | 07
29 | 07
29 | 07
29 | 07
29 | 07
29 | | 07
29 | | | | | |
| ANIMAL ID | 0076 | 0077 | 0078 | 0079 | 0080 | 0081 | 0082 | 0083 | 0084 | 0085 | 0086 | 0087 | 0088 | 0089 | 0090 | 0091 | 0092 | 0093 | 0094 | 0095 | 0096 | 0097 | 0098 | 0099 | 0100 | | |
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Atelectasis | | | | | | | | | | | | 4 | | | | | | | | | | | | | 1 4.0 | | |
| Inflammation, Chronic Active | | | 1 | 1 | | | | | | | 1 | | | | | | | | | | | | | | 5 1.2 | | |
| Alveolar Epithelium, Hyperplasia | 1 | 1 | | | | | | | | | | | | 1 | 1 | | | 1 | 3 | | | | 1 | | 14 1.6 | | |
| Alveolar Epithelium, Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | | |
| Alveolar Epithelium, Metaplasia, Squamous | | | 3 | | | | 1 | | | | | | | | | | | | | | | | | | 3 1.7 | | |
| Alveolus, Infiltration Cellular, Histiocyte | | | 1 | | | | | 1 | | 1 | | | | 1 | | | | 1 | 1 | | | | 1 | 1 | 1 1.0 | | |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Inflammation | | | | | | | 1 | | | | | | | | 1 | | | | | | | | | | 2 1.0 | | |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| SPECIAL SENSES SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Lens, Cataract | | | | | | | | | | | | 2 | | | | | | | | | | | | 3 | 3 3.0 | | |
| Retina, Degeneration | | | | | | | | | | | | 3 | 2 | | | | | | | | | | | 4 | 5 3.0 | | |
| Retina, Inflammation | | | | | | | | | | | | 1 | | | | | | | | | | | | | 1 1.0 | | |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| URINARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Accumulation, Hyaline Droplet | | | | | | | | | | | | | | | | | | | | | | | | 3 | 2 3.0 | | |
| Glomerulosclerosis | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 1.0 | | |
| Infarct | | | | | | | | | | | | | | | | | | | | | | | | 2 | 3 1.7 | | |
| Mineralization | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 43 1.0 | | |
| Nephropathy | | | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | | | 1 | 1 | 1 | | 1 | 35 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| DAY ON TEST | FISCHER 344 RATS FEMALE | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|----------------------|-------------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|
| | 0729 | 0729 | 0728 | 0722 | 0728 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | |
| 0.1 G/KG | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | | | | |
| | 00729 | 00729 | 00728 | 00722 | 00728 | 00729 | 00729 | 00729 | 00729 | 00729 | 00729 | 00729 | 00729 | 00729 | 00729 | 00729 | 00729 | 00729 | 00729 | 00729 | 00729 | 00729 | 00729 | 00729 | |
| Pelvis, Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS FEMALE
0.3 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | ANIMAL ID | females
(cont...) |
|-------------------------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|-----------|----------------------|
| | 0
7
0
5 | 0
7
3
0 | 0
0
9
8 | 0
6
2
8 | 0
5
3
2 | 0
5
1
9 | 0
6
1
5 | 0
6
1
8 | 0
7
2
9 | 0
6
1
1 | 0
7
2
9 | 0
7
2
9 | 0
7
2
9 | 0
5
3
9 | 0
4
3
9 | 0
6
5
2 | 0
6
8
8 | 0
7
2
9 | 0
7
2
9 | 0
7
2
9 | 0
5
3
0 | 0
7
1
8 | 0
7
3
0 | 0
7
3
0 | | |
| Bile Duct, Hyperplasia | 3 | | | | | | | | | | 1 | | | | | | | | | | 1 | | | 1 | | |
| Hepatocyte, Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Oval Cell, Hyperplasia | 1 | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Oral Mucosa | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Squamous | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pancreas | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Salivary Glands | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach, Forestomach | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Erosion | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Ulcer | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach, Glandular | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Amyloid Deposition | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Tooth | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Malformation | | | | | | | | | | | | | | | | | | | | | | | | | | |

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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS FEMALE
0.3 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | ANIMAL ID | females
(cont...) | | | |
|-------------------------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|-----------|----------------------|------------------|------------------|------------------|
| | 0
7
0
5 | 0
7
3
0 | 0
0
9
8 | 0
6
2
8 | 0
5
3
2 | 0
5
1
9 | 0
6
1
5 | 0
6
1
8 | 0
7
2
9 | 0
6
8
1 | 0
7
2
9 | 0
7
2
9 | 0
7
2
9 | 0
5
3
9 | 0
4
3
9 | 0
6
5
8 | 0
6
8
8 | 0
7
2
9 | 0
7
2
9 | 0
7
2
9 | | | 0
5
3
0 | 0
7
1
8 | 0
7
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
3
0 | 1
1
1
1 |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 2 | | |
| Cardiomyopathy | 2 | 2 | | 1 | 2 | 2 | 2 | 3 | 2 | 2 | 2 | 2 | 2 | 1 | | 3 | 2 | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 1 | |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Degeneration, Cystic Hypertrophy | | | | | | | | | | | | | | | | | | 2 | | | | 1 | | 1 | |
| Metaplasia, Osseous Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | |
| Zona Fasciculata, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Hyperplasia | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Parathyroid Gland | M | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | M | + | + | |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Cyst | | | | | | | | | | | | | | 1 | | | | | | | | | | | |
| Pars Distalis, Angiectasis | | | | | | | | | | | | | | | | | | | | | | 2 | | | |
| Pars Distalis, Hyperplasia | | | | | | | | | | 1 | 2 | | | 1 | 3 | 2 | | 1 | | | | 2 | | | |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| C-cell, Hyperplasia | | 2 | | | | | | | | | | | | | | | | | | | | | | | |
| Follicular Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | 2 | | | |

GENERAL BODY 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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

| FISCHER 344 RATS FEMALE
0.3 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | females
(cont...) |
|-------------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------------------|
| | 0705 | 0708 | 0709 | 0711 | 0712 | 0713 | 0714 | 0715 | 0716 | 0717 | 0718 | 0719 | 0720 | 0721 | 0722 | 0723 | 0724 | 0725 | 0726 | 0727 | 0728 | 0729 | 0730 | | |
| ANIMAL ID | 0001 | 0002 | 0003 | 0004 | 0005 | 0006 | 0007 | 0008 | 0009 | 0010 | 0011 | 0012 | 0013 | 0014 | 0015 | 0016 | 0017 | 0018 | 0019 | 0020 | 0021 | 0022 | 0023 | 0024 | |

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland
Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | | | | | | | | | 2 | | | | | | | | | | | 1 | | | | 2 |
| Ovary
Cyst | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | | | | | | | | | 4 | | | 1 | | 4 | | | | | | 3 | | | | |
| Uterus
Endometrium, Hyperplasia, Adenomatous
Endometrium, Hyperplasia, Cystic
Stroma, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | | | | | | | | | | | | | | | | | | | | | | 2 | | |
| | | | | | | | | | | | | | | 4 | | | | | | 1 | | | | 3 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone Marrow
Hyperplasia
Inflammation, Histiocytic
Myelofibrosis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | 4 | | | | | | 2 | | | | | | 1 | 1 | | | | | 3 | | 1 | 3 | | 3 |
| Lymph Node | + | | | | | | | | | | | | | | | | | | | | | | | + |
| Lymph Node, Mandibular | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M |
| Lymph Node, Mesenteric
Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Spleen
Accessory Spleen | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

* .. 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS FEMALE | 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 | | | | |
| 0.3 G/KG | 7 | 7 | 0 | 6 | 5 | 5 | 6 | 6 | 7 | 6 | 7 | 7 | 7 | 5 | 4 | 6 | 6 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 0 | | |
| | 0 | 3 | 9 | 2 | 3 | 1 | 1 | 1 | 2 | 8 | 2 | 2 | 2 | 3 | 3 | 5 | 8 | 2 | 2 | 2 | 2 | 3 | 1 | 3 | 3 | 0 | |
| | 5 | 0 | 8 | 8 | 2 | 9 | 5 | 8 | 9 | 1 | 9 | 9 | 9 | 9 | 9 | 2 | 8 | 8 | 9 | 9 | 9 | 0 | 8 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 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 | 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 | 2 | 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 | 0 | |

Peripheral Nerve

Spinal Cord
 Hemorrhage
 Necrosis

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation, Chronic Active | | | | | | | | | | | | | | | | | 1 | | | | | | | |
| Alveolar Epithelium, Hyperplasia | | | | | | | | | 2 | | | | 2 | | | | | | | | | | 1 | 4 |
| Alveolus, Infiltration Cellular, Histiocyte | 1 | | | 1 | | | | | | 1 | 1 | | 1 | | | | | | | 1 | | | | 1 |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation | | | | 1 | | | | | | | | | | 3 | | | | | | 3 | | | 1 | |
| Glands, Dilatation | | | | | | | | | | | | | | | | | | | | | | | 3 | |
| Olfactory Epithelium, Metaplasia | | | | | | | | | | | | | | | | | | | | | | | 3 | |
| Respiratory Epithelium, Hyperplasia | | | | | | | | | 2 | | | | | | | | | | | | | | | |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Peritracheal Tissue, Inflammation | | | | | | | | | | | | | | | | | | | | | | | | 3 |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Synechia | 4 | | | | | | | | | | | | | | | | | | | | | | | |
| Cornea, Inflammation | 2 | | | | 4 | | | | | | | | | | | | | | | | | | | |
| Lens, Cataract | | | | | | | | | | | | | | | | | 4 | | | | | | | |
| Retina, Degeneration | 3 | | | | | | | | | | | | | | | 4 | | | | | | 2 | | |
| Retina, Dysplasia | | | | | | | | | | | | | | | | | | | | | | | | |

* .. 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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

| FISCHER 344 RATS FEMALE
0.3 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | |
|-------------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|-------|------|
| | 0730 | 0629 | 0729 | 0705 | 0672 | 0772 | 0772 | 0772 | 0572 | 0757 | 0667 | 0767 | 0667 | 0557 | 0667 | 0737 | 0637 | 0727 | 0627 | 0777 | | 0677 | 0777 |
| ANIMAL ID | 00326 | 00332 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 50 |
| | 7 | 6 | 7 | 7 | 6 | 7 | 7 | 7 | 5 | 7 | 6 | 7 | 6 | 5 | 6 | 7 | 6 | 7 | 7 | 6 | 7 | 7 | 1 |
| | 3 | 2 | 2 | 0 | 7 | 2 | 2 | 2 | 7 | 2 | 5 | 3 | 6 | 3 | 5 | 3 | 3 | 2 | 2 | 4 | 2 | 3 | 3.0 |
| | 0 | 9 | 9 | 5 | 2 | 9 | 9 | 8 | 9 | 9 | 3 | 0 | 4 | 2 | 8 | 0 | 2 | 8 | 9 | 7 | 9 | 0 | 4.0 |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|-----|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| Perforation | | | | | | | | | | | | | | | | | | | | | | | | 1 | 4.0 |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Inflammation | | | | | 4 | | | | | | | | | | | | | | | | | | | 1 | 4.0 |
| Necrosis | | | | | 4 | | | | | | | | | | | | | | | | | | | 1 | 4.0 |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Parasite Metazoan | | | | | | | | | | | | | | X | X | | | | | | | X | | 8 | |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Basophilic Focus | X | | X | | X | X | X | X | X | X | X | X | X | X | X | | X | X | X | X | X | X | | 41 | |
| Clear Cell Focus | | | X | | | | X | | X | | | | | | | | X | | X | | | | | 11 | |
| Eosinophilic Focus | | | X | | X | X | | | X | X | X | | | X | X | | X | X | X | | | X | | 24 | |
| Fatty Change, Diffuse | | | 1 | 3 | 3 | | | | | 1 | | | | 1 | | | | | | | 1 | | | 10 | 1.5 |
| Hepatodiaphragmatic Nodule | | | | | | | | | | | X | | | | | | | | | | | | | 1 | |
| Inflammation, Chronic Active | 1 | | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | 38 | 1.0 |
| Mixed Cell Focus | X | | | | | | | | | | X | | | | | | | X | | X | | X | | 9 | |
| Pigmentation, Hemosiderin | | | | | | | | | | | | | | | | | | | | | | | | 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS FEMALE
0.3 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | | |
|-------------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|-------|-------|--------|
| | 0730 | 0622 | 0729 | 0705 | 0672 | 0729 | 0728 | 0728 | 0578 | 0729 | 0673 | 0676 | 0533 | 0664 | 0532 | 0678 | 0672 | 0724 | 0679 | 0720 | | 0673 | 0709 | 0708 |
| ANIMAL ID | 00326 | 00332 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 |
| Bile Duct, Hyperplasia | | | | 2 | | | 1 | | | | 1 | | | | | 1 | | | 1 | | | | | |
| Hepatocyte, Hypertrophy | | | | | | | | | | | | | | | 1 | | | | | 1 | | 2 | | |
| Oval Cell, Hyperplasia | | | | 1 | | | | | | | | | | | | | | | | | | | | |
| Mesentery | + | | | | | | | | + | + | | | | | | | + | | | + | + | | | 7 |
| Fat, Necrosis | 2 | | | | | | | | 2 | 2 | | | | | | | 2 | | | 1 | 2 | | | 7 1.9 |
| Oral Mucosa | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Hyperplasia, Squamous | | | | | | | | | | | | | + | 4 | | | | | | | | | | 1 4.0 |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Atrophy | 2 | | | | 1 | | | | | | | | | | 1 | 1 | 1 | | | 1 | | 1 | | 16 1.3 |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Erosion | | | | | | | | | | | | | | | | | | | | | | | | 2 1.0 |
| Inflammation | | | | | 2 | | | | | | 3 | | | | | | 1 | | | | 2 | | | 7 2.1 |
| Ulcer | | | | | 2 | | | | | | 3 | | | | | | | | | | | | | 3 2.3 |
| Epithelium, Hyperplasia | | | | | 2 | | | | | | 3 | | | | | | 1 | | | | 1 | | | 8 1.8 |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Amyloid Deposition | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | 3 | | | 1 3.0 |
| Tooth | | + | | | + | | | | | | | | | | | | | | | + | | | | 4 |
| Malformation | | 1 | | | 1 | | | | | | | | | | | | | | | 1 | | | | 4 1.0 |

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

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

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

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

| DAY ON TEST | FISCHER 344 RATS FEMALE | | | | | | | | | | | | | | | | | | | | * TOTALS | | |
|-------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|------|--------|
| | 0730 | 0622 | 0729 | 0720 | 0672 | 0772 | 0772 | 0772 | 0572 | 0767 | 0766 | 0767 | 0667 | 0565 | 0666 | 0767 | 0666 | 0767 | 0766 | 0767 | | 0667 | 0767 |
| 0.3 G/KG | 0026 | 0033 | 0032 | 0033 | 0032 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 50 |
| ANIMAL ID | 0032 | 0033 | 0032 | 0033 | 0032 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 45 1.9 |

| | | | | | | | | | | | | | | | | | | | | | | | |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Cardiomyopathy | 1 | | 1 | | 2 | 3 | 2 | 2 | 2 | 1 | 2 | 2 | | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 45 1.9 |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Degeneration, Cystic | | | | | 4 | | | | | | | | | | | | | 1 | | | 1 | 1 | 7 1.6 |
| Hypertrophy | | | | | | | | | | 2 | | | | | | | | | | | | | 1 2.0 |
| Metaplasia, Osseous | | | | | | | | | | | | | | | | | | | | | | 2 | 1 2.0 |
| Necrosis | | | | | | | | | | | | | | | | | | | | | 1 | | 1 1.0 |
| Zona Fasciculata, Hyperplasia | | | | | | 1 | | 1 | | | 2 | | | | | | | | | | 1 | | 4 1.3 |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Hyperplasia | | | | | | | | | | | | | | | | | | | 1 | | | | 1 1.0 |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Hyperplasia | | | | | 1 | | | 1 | | | | | | | | | | | | | | | 3 1.3 |
| Parathyroid Gland | + | + | + | + | + | + | + | + | M | + | M | + | + | + | + | + | + | + | + | + | + | M | 44 |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Pars Distalis, Angiectasis | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Pars Distalis, Hyperplasia | 3 | 2 | 2 | | | 3 | 2 | | | | | | 4 | | 4 | | | 3 | | | 2 | | 16 2.3 |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| C-cell, Hyperplasia | | | 3 | | | 3 | 2 | | | | | | | | | | 3 | | | | 1 | | 6 2.3 |
| Follicular Cell, Hyperplasia | | | | | | 1 | | | | | | 4 | | | | | | | | 3 | | | 4 2.5 |

GENERAL BODY 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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

| DAY ON TEST | FISCHER 344 RATS FEMALE | | | | | | | | | | | | | | | | | | | | * TOTALS | | | |
|-------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|------|------|------|
| | 0730 | 0622 | 0729 | 0720 | 0672 | 0722 | 0722 | 0728 | 0579 | 0729 | 0673 | 0763 | 0532 | 0653 | 0733 | 0632 | 0724 | 0679 | 0723 | 0679 | | 0733 | 0700 | 0700 |
| 0.3 G/KG | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | | | |
| | 0032 | 0032 | 0032 | 0032 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | |
| | 67 | 78 | 90 | 01 | 22 | 33 | 44 | 55 | 66 | 77 | 88 | 99 | 00 | 11 | 22 | 33 | 44 | 55 | 66 | 77 | 88 | 99 | 00 | |

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|-----|
| Clitoral Gland Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 5 | 2.0 |
| Ovary Cyst | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 6 | 2.3 |
| Uterus Endometrium, Hyperplasia, Adenomatous | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 | 2.0 |
| Endometrium, Hyperplasia, Cystic | | | | | | | | | | | | | | | | | | 1 | | 4 | | 1 | | | 6 | 2.0 |
| Stroma, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|-----|
| Bone Marrow Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 19 | 2.2 |
| Inflammation, Histiocytic | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Myelofibrosis | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Lymph Node | | | | | | | | | | | | | | | | | | | | | | | | | 3 | |
| Lymph Node, Mandibular | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | M | 0 | | |
| Lymph Node, Mesenteric Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 | 3.0 |
| Spleen Accessory Spleen | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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

| DAY ON TEST | FISCHER 344 RATS FEMALE | | | | | | | | | | | | | | | | | | | | ANIMAL ID | * TOTALS | | | | | |
|-----------------------------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-----------|----------|------|------|------|-----|-----|
| | 0730 | 0629 | 0729 | 0720 | 0672 | 0772 | 0772 | 0772 | 0579 | 0779 | 0663 | 0763 | 0553 | 0663 | 0773 | 0663 | 0773 | 0773 | 0667 | 0776 | | | 0777 | 0677 | 0777 | | |
| 0.3 G/KG | 0026 | 0037 | 0039 | 0035 | 0032 | 0039 | 0032 | 0039 | 0038 | 0039 | 0030 | 0034 | 0030 | 0030 | 0030 | 0030 | 0030 | 0030 | 0030 | 0030 | 0030 | 0030 | 0030 | 0036 | | | |
| Hematopoietic Cell Proliferation | | | | | | | 1 | | | | | | 2 | 1 | | | | | 1 | | | | 2 | 1 | 17 | 1.1 | |
| Hyperplasia, Histiocytic | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 | |
| Pigmentation, Hemosiderin | | | | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | | 2 | 1 | 1 | 41 | 1.1 | |
| Lymphoid Follicle, Atrophy | | | | | | | 4 | | | | | 1 | | | | | | | | | | | | | 4 | 2.3 | |
| Thymus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | | | |
| Atrophy | 3 | | 3 | 3 | 4 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 47 | 3.1 |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 | |
| INTEGUMENTARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Galactocele | | | | | | | 4 | | | | | | | | | | | | | | | | | | 1 | 4.0 | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | 3 | | | 2 | 3.0 | |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Epidermis, Hyperkeratosis | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 | |
| MUSCULOSKELETAL SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Skeletal Muscle | | | | | | | | | | | | | | | | | | | | | | | | | 1 | | |
| NERVOUS SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Hemorrhage | | 1 | | | | | | | | 1 | | | | | | | | | | | | | | | 2 | 1.0 | |
| Infiltration Cellular, Mixed Cell | | | | | | | | | | | | | | | | | | | | 1 | | | | | 1 | 1.0 | |
| Necrosis | | 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

| FISCHER 344 RATS FEMALE | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | | |
|---|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|----------|------------------|------------------|------------------|
| | 0
7
3
0 | 0
6
2
9 | 0
7
2
9 | 0
7
0
5 | 0
6
7
2 | 0
7
2
9 | 0
7
2
9 | 0
7
2
8 | 0
5
7
9 | 0
7
6
9 | 0
6
5
3 | 0
7
6
0 | 0
6
5
4 | 0
5
6
2 | 0
6
7
8 | 0
7
2
9 | 0
6
4
7 | 0
7
2
9 | 0
6
3
0 | 0
7
3
9 | | 0
6
3
8 | 0
7
3
0 | 0
7
0
2 |
| 0.3 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 | |
| | 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 | 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 | 0 | |
| Peripheral Nerve | + | | | | | | | | | | | | | | | | | | | | 1 | | | |
| Spinal Cord | + | | | | | | | | | | | | | | | | | | | | 1 | | | |
| Hemorrhage | 3 | | | | | | | | | | | | | | | | | | | | 1 3.0 | | | |
| Necrosis | 2 | | | | | | | | | | | | | | | | | | | | 1 2.0 | | | |
| RESPIRATORY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | |
| Lung | + | | | | | | | | | | | | | | | | | | | | 50 | | | |
| Inflammation, Chronic Active | | | | | | | | | | | | | | | | | | | | | 1 2.0 | | | |
| Alveolar Epithelium, Hyperplasia | 1 | | | | | | | | | | | | | | | | | | | | 6 1.8 | | | |
| Alveolus, Infiltration Cellular, Histiocyte | 1 2 1 1 1 | | | | | | | | | | | | | | | | | | | | 12 1.1 | | | |
| Nose | + | | | | | | | | | | | | | | | | | | | | 50 | | | |
| Inflammation | 2 1 1 2 1 | | | | | | | | | | | | | | | | | | | | 9 1.7 | | | |
| Glands, Dilatation | | | | | | | | | | | | | | | | | | | | | 1 3.0 | | | |
| Olfactory Epithelium, Metaplasia | | | | | | | | | | | | | | | | | | | | | 1 3.0 | | | |
| Respiratory Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | 1 2.0 | | | |
| Trachea | + | | | | | | | | | | | | | | | | | | | | 50 | | | |
| Peritracheal Tissue, Inflammation | | | | | | | | | | | | | | | | | | | | | 1 3.0 | | | |
| SPECIAL SENSES SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | |
| Eye | + | | | | | | | | | | | | | | | | | | | | 50 | | | |
| Synechia | | | | | | | | | | | | | | | | | | | | | 1 4.0 | | | |
| Cornea, Inflammation | | | | | | | | | | | | | | | | | | | | | 2 3.0 | | | |
| Lens, Cataract | | | | | | | | | | | | | | | | | | | | | 1 4.0 | | | |
| Retina, Degeneration | 1 2 | | | | | | | | | | | | | | | | | | | | 5 2.4 | | | |
| Retina, Dysplasia | 2 | | | | | | | | | | | | | | | | | | | | 1 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| DAY ON TEST | FISCHER 344 RATS FEMALE | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|--|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|--------|
| | 0730 | 0622 | 0722 | 0707 | 0672 | 0772 | 0772 | 0772 | 0575 | 0776 | 0767 | 0676 | 0565 | 0666 | 0777 | 0666 | 0777 | 0666 | 0777 | 0666 | | 0777 |
| 0.3 G/KG | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | |
| | 0032 | 0039 | 0039 | 0005 | 0002 | 0009 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | |
| Retina, Gliosis | | | | | | | 2 | | | | | | | | | 2 | | | | | 2 | 3 2.0 |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| URINARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | |
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Accumulation, Hyaline Droplet | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Infarct | 2 | | | | | | | | | | 1 | | | | | | | | 2 | | | 4 2.0 |
| Mineralization | 1 | | 1 | 1 | 2 | 1 | 1 | | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 45 1.0 |
| Nephropathy | 1 | 1 | 1 | | 3 | 1 | 1 | 1 | 1 | | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 37 1.1 |
| Papilla, Necrosis | | | | | | | | | | | 1 | | | | | | | | | | | 1 1.0 |
| Pelvis, Inflammation | 2 | | | | | | | | | | 2 | | | 1 | | | | | 1 | | | 5 1.4 |
| Pelvis, Transitional Epithelium, Hyperplasia | 2 | | | | | | | | | | 2 | | | | | | | | 1 | | | 4 1.5 |
| Pelvis, Transitional Epithelium, Metaplasia | 2 | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Renal Tubule, Dilatation | 2 | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Renal Tubule, Necrosis | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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

| | | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | 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 | | |
| | | 7 | 7 | 6 | 7 | 7 | 4 | 7 | 7 | 7 | 7 | 7 | 7 | 1 | 7 | 6 | 6 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 6 | | |
| FISCHER 344 RATS FEMALE | | 3 | 2 | 8 | 3 | 3 | 8 | 3 | 3 | 2 | 2 | 3 | 3 | 2 | 1 | 3 | 2 | 1 | 3 | 8 | 3 | 3 | 3 | 2 | 8 | | |
| | | 0 | 8 | 8 | 0 | 0 | 9 | 0 | 0 | 8 | 8 | 0 | 0 | 9 | 1 | 0 | 9 | 6 | 0 | 8 | 0 | 9 | 0 | 0 | 7 | | |
| | 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 | | |
| | 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 | | | |
| | | 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 | | | |
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | | | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Colon
Parasite Metazoan | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | | | | | | X | | | | | | | | | X | | | | | | | | X | |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Angiectasis | | 1 | | | | | | 1 | | | | | | | | | | | | | | 2 | | |
| Basophilic Focus | | | X | | X | | | | | | | | | X | | X | | X | | | | | X | |
| Clear Cell Focus | X | | | | | | X | | | | X | | | | | | | | | | | | | |
| Degeneration, Cystic | | | | | | | | | | | | | | | | | | | 1 | | | | | |
| Eosinophilic Focus | X | X | | X | X | | | X | | X | X | | X | | X | | X | | | | X | X | X | |
| Fatty Change, Diffuse | 2 | 1 | | | | | | | | 1 | | 1 | | | | | | 1 | | 1 | | | 1 | |
| Hepatodiaphragmatic Nodule | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Chronic Active | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | | | | 1 | | 1 | 1 | 1 |
| Mixed Cell Focus | | X | | | | | | | | | | | | | | | | | | | | | | |
| Pigmentation, Hemosiderin | | | | | | | | | | | | | | | | | | | | | | | | |
| Bile Duct, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | 1 | | |
| Centrilobular, Fatty Change | | | | | | | | | | | | | | | | | | | | | | | | |

* .. 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------|-------------|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|------------------------------|---|
| FISCHER 344 RATS FEMALE | 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 | females
(cont...) | |
| | | | 7 | 7 | 6 | 7 | 7 | 4 | 7 | 7 | 7 | 7 | 7 | 7 | 1 | 7 | 6 | 6 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 6 | | |
| | | | 3 | 2 | 8 | 3 | 3 | 8 | 3 | 3 | 2 | 2 | 3 | 3 | 2 | 1 | 3 | 2 | 1 | 3 | 8 | 3 | 2 | 3 | 3 | 2 | | 8 |
| | | | 0 | 8 | 8 | 0 | 0 | 9 | 0 | 0 | 8 | 8 | 0 | 0 | 9 | 1 | 0 | 9 | 6 | 0 | 8 | 0 | 9 | 0 | 0 | 8 | | 7 |
| 1.0 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 | 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 | | |
| | | | 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 | | |

Atrium, Thrombosis

2

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Degeneration, Cystic | | | | | | | | | | | | | 1 | | | | | | | | | | | | 1 |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | 4 |
| Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Zona Fasciculata, Hyperplasia | | | | 1 | | | | | | 1 | 2 | | 1 | | | | | | | | | | | | |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Parathyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Pars Distalis, Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Pars Distalis, Hyperplasia | | | | 2 | 4 | 2 | | 1 | 1 | 1 | | | | 1 | | | | | 4 | | | | | | 4 |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| C-cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Follicle, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | |
| Follicular Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 |

GENERAL BODY SYSTEM

NONE

* .. 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 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/21/2010

Time Report Requested: 09:10:56

First Dose M/F: 08/18/04 / 08/19/04

Lab: BAT

| FISCHER 344 RATS FEMALE
1.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | females
(cont...) |
|---|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|----------------------|
| | 0
7
3
0 | 0
7
2
8 | 0
6
8
8 | 0
7
3
0 | 0
7
3
0 | 0
4
8
9 | 0
7
3
0 | 0
7
3
0 | 0
7
2
8 | 0
7
2
8 | 0
7
3
0 | 0
7
3
0 | 0
7
2
8 | 0
7
3
0 | 0
7
2
8 | 0
7
3
0 | 0
7
2
8 | 0
7
3
0 | 0
7
2
8 | 0
7
3
0 | 0
7
2
8 | 0
7
3
0 | 0
7
2
8 | 0
7
3
0 | | |
| ANIMAL ID | 0
0
3
5
1 | 0
0
3
5
2 | 0
0
3
5
3 | 0
0
3
5
4 | 0
0
3
5
5 | 0
0
3
5
6 | 0
0
3
5
7 | 0
0
3
5
8 | 0
0
3
5
9 | 0
0
3
5
0 | 0
0
3
5
1 | 0
0
3
6
2 | 0
0
3
6
3 | 0
0
3
6
4 | 0
0
3
6
5 | 0
0
3
6
6 | 0
0
3
6
7 | 0
0
3
6
8 | 0
0
3
6
9 | 0
0
3
7
0 | 0
0
3
7
1 | 0
0
3
7
2 | 0
0
3
7
3 | 0
0
3
7
4 | 0
0
3
7
5 | |
| Atrophy | 2 | 3 | 3 | 3 | | 2 | 3 | 3 | 3 | 3 | 2 | 4 | 3 | | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | |
| INTEGUMENTARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| MUSCULOSKELETAL SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| NERVOUS SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| RESPIRATORY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Congestion | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Chronic Active | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Alveolar Epithelium, Hyperplasia | 1 | | 1 | | | | | 1 | | | 1 | | | | 1 | | | | | | | | | 1 | | |
| Alveolus, Infiltration Cellular, Histiocyte | 1 | 1 | | 1 | | 1 | | 1 | 1 | | 1 | | | | 1 | | | | | 1 | | | | | | |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Inflammation | 1 | | | 2 | | 1 | | 1 | | | | | | | 1 | | | | | | | | | | | |
| Pleura | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mesothelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 2 | |

* .. 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 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
CAS Number: 9000-38-8

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

| FISCHER 344 RATS FEMALE
1.0 G/KG | 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 |
|-------------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | ANIMAL ID | 0730 | 0730 | 0688 | 0733 | 0733 | 0489 | 0733 | 0733 | 0732 | 0732 | 0733 | 0732 | 0131 | 0732 | 0661 | 0663 | 0738 | 0683 | 0739 | 0732 | 0733 | 0733 | 0732 |
| Urinary Bladder | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS FEMALE
1.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | |
|-------------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|-------|-------|
| | 078 | 073 | 072 | 073 | 064 | 070 | 072 | 065 | 064 | 079 | 078 | 074 | 070 | 077 | 077 | 072 | 078 | 073 | 072 | 073 | | 073 | 059 |
| ANIMAL ID | 00376 | 00377 | 00378 | 00379 | 00380 | 00381 | 00382 | 00383 | 00384 | 00385 | 00386 | 00387 | 00388 | 00389 | 00390 | 00391 | 00392 | 00393 | 00394 | 00395 | 00396 | 00397 | 00398 |
| Centrilobular, Necrosis | | | | | | | | | 2 | | | | | | | | | | | | | | |
| Hepatocyte, Hypertrophy | 2 | 2 | | 2 | | | 1 | | 1 | 2 | 2 | | | 2 | 3 | 2 | | 1 | | 1 | 2 | 2 | 2 |
| Mesentery | + | | | + | | | | | + | | | | | | | | | | | + | + | | |
| Fat, Necrosis | 2 | | | 1 | | | | | 1 | | | | | | | | | | | 1 | 2 | | |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Atrophy | | 1 | | | | | | | | | 1 | | | | | 1 | | 1 | | | 1 | 1 | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Acinus, Metaplasia, Hepatocyte | | | | | | | | | | | | | | | | | | | | | | | 4 |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Atrophy | | | | | | | | | | 2 | | | | | | | | | | | | | |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation | | | | 1 | | 3 | | 2 | | | 3 | 2 | 1 | 2 | | | 1 | | | 2 | | | |
| Ulcer | | | | | | 3 | | 1 | | | 3 | 2 | | 4 | | | | | | | | | |
| Epithelium, Hyperplasia | | | | | | 3 | 2 | 2 | | | 3 | 2 | 3 | | | 2 | 1 | | | 2 | 1 | | 2 |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Tooth | | | | | | | | | | | | | | | | | | | | | | | |
| Malformation | | | | | | | | | | | 1 | | | | | | 3 | | | | | | |
| Peridontal Tissue, Inflammation | | | | | | | | | | | | | | | | | 3 | | | | | | |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Blood Vessel | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cardiomyopathy | 1 | 2 | 2 | 2 | 2 | 2 | 1 | 2 | 3 | 2 | 1 | | 2 | 2 | 2 | 1 | 2 | | 3 | 1 | 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

1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

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

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

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

| FISCHER 344 RATS FEMALE
1.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | |
|-------------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|-------|-------|
| | 078 | 073 | 072 | 073 | 064 | 073 | 072 | 025 | 069 | 072 | 074 | 079 | 078 | 074 | 077 | 077 | 072 | 088 | 072 | 073 | | 073 | 039 |
| ANIMAL ID | 00376 | 00377 | 00378 | 00379 | 00380 | 00381 | 00382 | 00383 | 00384 | 00385 | 00386 | 00387 | 00388 | 00389 | 00390 | 00391 | 00392 | 00393 | 00394 | 00395 | 00396 | 00397 | 00398 |

Atrium, Thrombosis

1 2.0

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Degeneration, Cystic | | | | | | 1 | | | | | | | | | | | | | | | | 1 | | 6 1.2 |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 |
| Hypertrophy | | | | | | 1 | | | | | | | | | | | | | | | | 1 | | 3 1.0 |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | 2 2.0 |
| Zona Fasciculata, Hyperplasia | | | | 1 | | 1 | | | | 1 | | | | | | 1 | | | | | 1 | | | 9 1.1 |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Parathyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | M | 47 |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Pars Distalis, Angiectasis | | 2 | | | | | | | | | | | | | | | | | | | | | | 2 2.5 |
| Pars Distalis, Hyperplasia | | | 2 | 2 | | 4 | | | 2 | 3 | 1 | | | 1 | | | 1 | 2 | | 1 | | 1 | 1 | 23 2.0 |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| C-cell, Hyperplasia | 2 | | | | | | | | | | 1 | | | | | | | | | | 1 | | | 4 1.3 |
| Follicle, Cyst | | | | | | | | | | 1 | | | | | | | | | | | | | | 2 1.5 |
| Follicular Cell, Hyperplasia | | | | | | | | | | | | | | | | 4 | | | | | | | | 4 2.0 |

GENERAL BODY SYSTEM

NONE

* .. 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

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|-----------------|
| FISCHER 344 RATS FEMALE | 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 | * TOTALS |
| | | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 2 | 6 | 7 | 7 | 1 | 1 | 7 | 7 | 7 | 7 | 7 | 3 | 7 | 7 | 7 | 3 | 5 | |
| | | 2 | 3 | 2 | 3 | 6 | 3 | 2 | 6 | 9 | 2 | 2 | 9 | 4 | 3 | 3 | 3 | 2 | 2 | 8 | 2 | 2 | 3 | 3 | 5 | |
| 1.0 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 | * TOTALS | |
| | | 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 | | |
| | 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 | | |

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|-------------------------------|
| Clitoral Gland
Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | 1 1.0 |
| Ovary
Cyst | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 5 1.6 |
| Uterus
Hemorrhage
Endometrium, Hyperplasia, Cystic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 3.0
10 1.5 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|---|
| Bone Marrow
Hyperplasia
Myelofibrosis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 23 2.0
1 1.0 |
| Lymph Node | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 2 | |
| Lymph Node, Mandibular | 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 | |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Spleen
Fibrosis
Hematopoietic Cell Proliferation
Pigmentation, Hemosiderin
Lymphoid Follicle, Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 2 2.5
7 1.3
42 1.3
2 2.0 |
| Thymus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 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

2) Mild 4) Marked

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

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

| FISCHER 344 RATS FEMALE
1.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|-------------------------------------|-------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|---|-----------|------------|
| | 078 | 073 | 072 | 073 | 064 | 073 | 077 | 026 | 067 | 077 | 011 | 011 | 077 | 077 | 077 | 077 | 037 | 077 | 027 | 037 | 037 | 035 | | | |
| ANIMAL ID | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | | | |
| Atrophy | 2 | 3 | 3 | 3 | 3 | 3 | 4 | | | | | 3 | 3 | 2 | 1 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 45 | 2.9 |

INTEGUMENTARY SYSTEM

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

MUSCULOSKELETAL SYSTEM

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

NERVOUS SYSTEM

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

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|------------|------------|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Congestion | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Inflammation, Chronic Active | | | | | | 1 | 1 | | | | | | | | | | | | | | | | | | | | | | 7 | 1.0 |
| Alveolar Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 7 | 1.6 |
| Alveolus, Infiltration Cellular, Histiocyte | 1 | 1 | | | | | 1 | | | | | | | | | | | | | | | | | | | | | | 16 | 1.0 |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 8 | 1.3 |
| Pleura | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Mesothelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

| FISCHER 344 RATS FEMALE
1.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | |
|--|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|-------|--------|
| | 078 | 079 | 070 | 071 | 072 | 073 | 074 | 075 | 076 | 077 | 078 | 079 | 080 | 081 | 082 | 083 | 084 | 085 | 086 | 087 | | 088 | 089 |
| ANIMAL ID | 00376 | 00377 | 00378 | 00379 | 00380 | 00381 | 00382 | 00383 | 00384 | 00385 | 00386 | 00387 | 00388 | 00389 | 00390 | 00391 | 00392 | 00393 | 00394 | 00395 | 00396 | 00397 | |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| SPECIAL SENSES SYSTEM | | | | | | | | | | | | | | | | | | | | | | | |
| Ear | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Cornea, Fibrosis | | | | | | | | | | | | | | | | | | | | | 2 | | 1 2.0 |
| Cornea, Inflammation | | | | | | | | | | | | | | | | | | | | | 2 | | 2 2.0 |
| Lens, Cataract | | | | | | | | | | | | | | | | | | | | | 1 | | 3 2.0 |
| Posterior Chamber, Inflammation | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Retina, Degeneration | | | 1 | | | | 1 | | 1 | | | | | | 1 | | | | | | 3 | 1 | 12 1.7 |
| Retina, Gliosis | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Zymbal's Gland | | | | | | | | | | | | | | | | | | | | | + | | 1 |
| URINARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | |
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Accumulation, Hyaline Droplet | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Infarct | | 2 | | | | | | | | | | | | 2 | | | | | | | | | 3 2.0 |
| Mineralization | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 46 1.0 |
| Nephropathy | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 43 1.2 |
| Papilla, Necrosis | | | | 1 | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Pelvis, Inflammation | | | | | | | | | | | | | | | 2 | | | | | | | | 4 1.8 |
| Pelvis, Transitional Epithelium, Hyperplasia | | 1 | | | | | | | | | | | | 2 | | 1 | | | | | | | 6 1.2 |
| Renal Tubule, Necrosis | | | | | | | | | | | | 2 | | | | | | | | | | 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

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

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

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

| DAY ON TEST | FISCHER 344 RATS FEMALE | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|-----------------|-------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|----------|
| | 078 | 077 | 077 | 077 | 067 | 077 | 077 | 022 | 066 | 077 | 077 | 011 | 011 | 077 | 077 | 077 | 077 | 077 | 033 | 077 | 077 | 077 | 033 | 055 | |
| 1.0 G/KG | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | | | | |
| | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | |
| | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | 333 | | |
| | 777 | 777 | 777 | 778 | 778 | 778 | 778 | 778 | 778 | 778 | 778 | 778 | 778 | 778 | 778 | 778 | 778 | 778 | 778 | 778 | 778 | 778 | 778 | | |
| | 667 | 668 | 669 | 660 | 661 | 662 | 663 | 664 | 665 | 666 | 667 | 668 | 669 | 660 | 661 | 662 | 663 | 664 | 665 | 666 | 667 | 668 | 669 | | |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |

*** END OF REPORT ***

* .. 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