

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

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

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus Epithelium, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 1 | |
| Epithelium, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | |
| Muscularis, Degeneration | | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Intestine Large, Colon Parasite Metazoan | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 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 | | 1 | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hepatodiaphragmatic Nodule Inflammation, Chronic Active | 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

| 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 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 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 | 2 | 2 | 2 | 8 | |
| 9 | 7 | 1 | 8 | 7 | 0 | 9 | 9 | 7 | 8 | 7 | 2 | 8 | 7 | 9 | 4 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 8 | 8 | 7 | 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 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 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 | 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 | 5 | | |

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 | 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:

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 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 | 0 | ANIMAL ID | males (cont...) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|--------------------|
| | 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 | | |
| FISCHER 344 RATS MALE | 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 | 0 | 0 |
| 0.0 G/KG | 9 | 7 | 1 | 8 | 7 | 0 | 9 | 9 | 7 | 8 | 7 | 2 | 8 | 7 | 9 | 4 | 7 | 7 | 7 | 8 | 8 | 8 | 7 | 8 | 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 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 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 | 2 | 2 | 2 | 2 | 2 | 0 | 0 |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 1 | 1 |
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |
| Skeletal Muscle | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| NERVOUS SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Peripheral Nerve | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Spinal Cord | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| RESPIRATORY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Inflammation, Chronic Active | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Thrombosis | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Alveolar Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Alveolar Epithelium, Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Alveolar Epithelium, Metaplasia, Squamous | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Alveolus, Infiltration Cellular, Histiocyte | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Foreign Body | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Olfactory Epithelium, Metaplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Respiratory Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 X .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
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1-4 .. Lesion qualified as:
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 Lab: BAT

| FISCHER 344 RATS MALE 0.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | ANIMAL ID | males (cont...) |
|-----------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-----------|--------------------|
| | 0729 | 0729 | 0678 | 0778 | 0776 | 0667 | 0777 | 0777 | 0777 | 0777 | 0577 | 0777 | 0777 | 0777 | 0577 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | | |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| SPECIAL SENSES SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Cornea, Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Iris, Synechia | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lens, Cataract | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Retina, Degeneration | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Retina, Retinal Detachment | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| URINARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Accumulation, Hyaline Droplet | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infarct | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Nephropathy | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Cortex, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Papilla, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pelvis, Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Ureter | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Urethra | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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
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|---------------------------------------|-------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|-----------|--------------------|
| FISCHER 344 RATS MALE 0.0 G/KG | 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 | 07 | 05 | ANIMAL ID | males (cont...) |
| | ANIMAL ID | 29 | 27 | 51 | 28 | 27 | 10 | 29 | 29 | 27 | 88 | 27 | 28 | 22 | 28 | 27 | 49 | 27 | 27 | 88 | 88 | 27 | 27 | 28 | 28 | 45 | | |

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
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| 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 | |

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 | | | | | | | | | | | | | | | | | | | | | | | | | 2 | |
| Inflammation, Chronic Active | 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 | | | 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

| FISCHER 344 RATS MALE 0.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-----------|-----------------|------------|------------|
| | 0728 | 0728 | 0729 | 0601 | 0722 | 0722 | 0609 | 0501 | 0728 | 0609 | 0728 | 0727 | 0727 | 0727 | 0727 | 0727 | 0502 | 0722 | 0722 | 0509 | | | 0722 | 0607 | 0606 | 0727 | 0727 |
| ANIMAL ID | 00026 | 00007 | 00008 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | * TOTALS | | |
| Hyperplasia | | | 3 | | | 1 | | 3 | 2 | 3 | 1 | 4 | | | | | | 1 | | | 3 | | | | 16 | 2.4 | |
| Lymph Node | | | + | | | | | | | | | | | | | | | | | | | | | | 4 | | |
| Mediastinal, Hyperplasia, Lymphoid | | | 2 | | | | | | | | | | | | | | | | | | | | | | 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 | M | M | M | M | 0 | | |
| Lymph Node, Mesenteric Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | 2.0 | |
| Spleen | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | | |
| Accessory Spleen | | | | | | | | | | | | | | | | | | | | | | | | | 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 | 1 | | | | 1 | 31 | 1.1 | | |
| Lymphoid Follicle, Atrophy | | | | 4 | | | | | | | | | | | | 3 | | | | | | | | | 2 | 3.5 | |
| Thymus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 | | |
| Atrophy | 4 | 3 | 4 | 4 | 3 | 3 | 3 | 3 | 3 | 4 | 3 | 3 | 4 | 3 | 3 | 4 | 3 | 4 | 4 | 3 | M | + | + | + | 47 | 3.3 | |
| INTEGUMENTARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | | |
| Subcutaneous Tissue, Fibrosis | | | 4 | | | | | | | | | | | | | | | | | | | | | | 1 | 4.0 | |
| 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 0.0 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
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 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
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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 | 078 | 078 | 079 | 061 | 072 | 072 | 069 | 051 | 072 | 068 | 072 | 072 | 072 | 072 | 072 | 050 | 072 | 072 | 057 | 066 | 066 | 072 | 072 | * TOTALS |
| | 0.0 G/KG | 002 | 002 | 002 | 002 | 003 | 003 | 003 | 003 | 003 | 003 | 003 | 003 | 003 | 004 | 004 | 004 | 004 | 004 | 004 | 004 | 004 | 004 | 005 | |
| | ANIMAL ID | 006 | 007 | 008 | 009 | 010 | 011 | 012 | 013 | 014 | 015 | 016 | 017 | 018 | 019 | 020 | 021 | 022 | 023 | 024 | 025 | 026 | 027 | 028 | |

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

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 | | | | | | | | | | | | | | | | | | | | | | | |
| Basophilic Focus | | | 1 | | | | | | | | | | | | | | | | | | | | |
| Clear Cell Focus | X | X | X | X | | X | X | X | X | | X | | | | X | X | X | X | | | X | | |
| Degeneration, Cystic | | X | X | X | | X | X | | X | X | | | | | X | X | X | X | | | X | | |
| Eosinophilic Focus | | | | | | | | | | | | | | | | | | | | | | | |
| Fatty Change, Diffuse | | X | X | X | | X | | | | | | | | | | | | | | | | | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | |
| Hepatodiaphragmatic Nodule | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Chronic Active | | X | | | | X | | X | | X | | | | X | | X | | X | | | X | | |
| Mixed Cell Focus | 1 | 1 | 1 | 1 | | 1 | 1 | | 1 | 1 | 1 | 1 | | 1 | 1 | | 1 | 1 | 1 | | 1 | 1 | 1 |
| Necrosis | | | | | X | X | X | | | | X | | | | | | | | | | | X | |
| | | | | | | | | | | | | | | | | | | | | | | | |

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

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

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...) |
|---------------------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|--------------------|
| | 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 | 7 | 6 | 7 | 7 | 1 | 5 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 7 | | |
| | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 0 | 2 | 7 | 2 | 2 | 6 | 7 | 2 | 2 | 8 | 2 | 2 | 8 | 2 | 2 | 8 | | |
| | 8 | 7 | 7 | 7 | 4 | 7 | 9 | 9 | 8 | 9 | 8 | 8 | 8 | 1 | 8 | 8 | 9 | 7 | 8 | 3 | 7 | 6 | 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 | 0 | 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 | 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 | | |
| 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 | | |
| Centrilobular, Fatty Change | 2 | 1 | | | | | 2 | | | 1 | | 1 | | | | | | 1 | | | | | 2 | | |
| Centrilobular, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hepatocyte, Hypertrophy | | | | | | | | | | | | 1 | | | | | | | | | | | | | |
| Oval Cell, Hyperplasia | | | | | 2 | | | | | | | | | | | | | | | | | | | | |
| Mesentery | | | | | | | | | | + | + | | | | + | | | | + | | | | | | |
| Fat, Necrosis | | | | | | | | | | 1 | 2 | | | | 1 | | | | | 2 | | | | | |
| Oral Mucosa | | | | | | | | | | | | | | | | | | | | | | | + | | |
| Hyperplasia, Squamous | | | | | | | | | | | | | | | | | | | | | | | 3 | | |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Atrophy | | 1 | 1 | 1 | | | | 1 | 1 | | | | | | 1 | 1 | | | | | | | | | |
| Basophilic Focus | | | | | | | | | | | | | | | | | | | | | | X | | | |
| Acinus, Hyperplasia | | | | | 1 | | | | | | | | | | | | | 1 | 1 | | | 2 | 1 | | |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | 2 | | | |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Inflammation | | | | | 2 | | | | | | | | | | | | | | | | | | | | |
| Mineralization | | | | | | | | | | | | | 1 | | | | | | | | | | | | |
| Epithelium, Hyperplasia | | | | | 2 | | | | | | | 1 | | | | | | | | | | | | | |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Inflammation | | | | | 1 | | | | | | | | | | | | | | | | | | | | |
| Epithelium, Necrosis | | | | | | | | | | | | | | 2 | | | | | | | | | | | |
| 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 MALE | DAY ON TEST | | | | | | | | | | | | | | | | | | | | ANIMAL ID | | | | | | | |
|-----------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-----------|------|------|------|------|------|------|------|
| | 078 | 077 | 072 | 072 | 071 | 072 | 079 | 070 | 070 | 070 | 067 | 077 | 071 | 057 | 077 | 076 | 078 | 077 | 067 | 077 | | | 066 | 077 | 077 | | | |
| 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 | 0076 | 0077 | 0078 |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

C-cell, Hyperplasia
 Follicular Cell, Hyperplasia

3 1 2 1

4

males
(cont...)

GENERAL BODY SYSTEM

Tissue NOS

GENITAL SYSTEM

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

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone Marrow Hemorrhage Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | 2 | | | | | | | 3 | | | | | 4 | 3 | | | 3 | 1 | | | | 4 | | | | 3 | 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
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TDMS No. 20007 - 05
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 Species/Strain: RATS/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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 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 | |
| | | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 1 | 5 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 6 | 7 | 6 | 7 | 7 | 7 |
| | | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 0 | 2 | 7 | 2 | 2 | 6 | 7 | 8 | 2 | 2 | 8 | 2 | 2 | 7 | 2 | 2 | 6 | 6 | 2 | 1 | 4 |
| 0.1 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 |
| | | 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 | |
| | | 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...) | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node Mediastinal, Infiltration Cellular, Plasma Cell | + | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 |
| Lymph Node, Mesenteric Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 1 | + | + | + | + |
| Spleen | + | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Amyloid Deposition | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hematopoietic Cell Proliferation | 1 3 2 3 1 2 2 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pigmentation, Hemosiderin | 1 | 1 | 1 | 1 | 1 | 1 | | | 1 | 1 | 1 | 1 | | | 1 | 1 | | 1 | 1 | | | 1 | 1 | | | | |
| Lymphoid Follicle, Atrophy | 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 | 4 | 4 |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|-----|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Mammary Gland | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Skin | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Cyst Epithelial Inclusion | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | 1 X | | | | | | | | | | | | | | | | | | | | | | | | |

MUSCULOSKELETAL SYSTEM

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

* .. 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:
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TDMS No. 20007 - 05
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P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
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| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------------|
| FISCHER 344 RATS MALE | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | males (cont...) |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 1 | 5 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 6 | 7 | 7 | |
| 0.1 G/KG | 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 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | |

Harderian Gland

+ +

URINARY SYSTEM

Kidney

+ +

Mineralization

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 1 3

Pelvis, Dilatation

Pelvis, Transitional Epithelium, Hyperplasia

1

Ureter

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

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| FISCHER 344 RATS MALE | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|-----------------------|-------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|----------|-----|
| | 030 | 072 | 078 | 079 | 078 | 079 | 078 | 079 | 072 | 078 | 079 | 075 | 077 | 076 | 077 | 077 | 077 | 075 | 076 | 077 | | 077 |
| 0.1 G/KG | 007 | 007 | 007 | 007 | 008 | 008 | 008 | 008 | 008 | 008 | 008 | 008 | 008 | 008 | 008 | 008 | 008 | 008 | 008 | 008 | 008 | 50 |
| | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 50 |
| | 007 | 007 | 007 | 007 | 008 | 008 | 008 | 008 | 008 | 008 | 008 | 008 | 008 | 008 | 008 | 008 | 008 | 008 | 008 | 008 | 008 | 50 |
| | 006 | 007 | 008 | 009 | 000 | 001 | 002 | 003 | 004 | 005 | 006 | 007 | 008 | 009 | 000 | 001 | 002 | 003 | 004 | 005 | 006 | 50 |

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 | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | |
| Basophilic Focus | | X | 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 | |

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 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 | 00097 | 00098 | 00099 | 00100 | | | | | | | |
| 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 | | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 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 | | |
|------------------------------|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|--|
| 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 | | 3 | 7 | 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 | 7 | 8 | 9 | 8 | 9 | 8 | 9 | 8 | 9 | 8 | 9 | 8 | 9 | 8 | 9 | 8 | 9 | 8 | 9 | 8 | 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 | | |
| | 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 | | |
| | | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 | | |
| | | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | * 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 3 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 **5 1.4**

Necrosis

1 1.0

Zona Fasciculata, Hyperplasia

1 1 1 1 2 1 **6 1.2**

Adrenal Medulla

+ **50**

Hyperplasia

2 **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

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

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TDMS No. 20007 - 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 | 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 | |
| C-cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 12 |
| Follicular Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 1.9 |
| | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| | | | | | | | | | | | | | | | | | | | | | | | | | | 1.5 |

GENERAL BODY SYSTEM

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

GENITAL SYSTEM

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

HEMATOPOIETIC SYSTEM

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

* .. 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

| FISCHER 344 RATS MALE 0.1 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|---|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 4 | 2 | 2 | 2 | 0 | 2 | 2 | 7 | 7 | 5 | |
| | 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 | |
| | 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 | |
| Necrosis | 1 | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Lymph Node Mediastinal, Infiltration Cellular, Plasma Cell | + | | | | | | | | | | | | | | | | | | | | | 3 | 1 2.0 |
| Lymph Node, Mandibular | M | | | | | | | | | | | | | | | | | | | | | 0 | |
| Lymph Node, Mesenteric Atrophy | + | | | | | | | | | | | | | | | | | | | | | 50 | 2 1.0 |
| Spleen Amyloid Deposition | + | | | | | | | | | | | | | | | | | | | | | 50 | 1 2.0 |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | 3 | 10 2.2 |
| Pigmentation, Hemosiderin | 1 | | | | | | | | | | | | | | | | | | | | | 32 | 1.0 |
| Lymphoid Follicle, Atrophy | | | | | | | | | | | | | | | | | | | | | | 2 | 2.5 |
| Thymus Atrophy | + | | | | | | | | | | | | | | | | | | | | | 50 | 49 3.2 |
| INTEGUMENTARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | |
| Mammary Gland | + | | | | | | | | | | | | | | | | | | | | | 50 | |
| Skin Cyst Epithelial Inclusion | + | | | | | | | | | | | | | | | | | | | | | 50 | 1 |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | 1 | 2 1.0 |
| MUSCULOSKELETAL SYSTEM | | | | | | | | | | | | | | | | | | | | | | | |
| Bone | + | | | | | | | | | | | | | | | | | | | | | 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 | | |
|-------------|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|----|----|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 0 | |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 50 | |
| 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 1 | |
| 0 | 7 | 8 | 9 | 8 | 9 | 8 | 9 | 9 | 5 | 7 | 8 | 6 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 6 | 7 | 7 | 1 |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 50 |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 1 |
| 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 0 |

NERVOUS SYSTEM

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

RESPIRATORY SYSTEM

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

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Ear | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Lens, Cataract | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Retina, Degeneration | | | | | | | | | | | | 1 | | | | | | | | | 1 | | 6 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
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TDMS No. 20007 - 05
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 Species/Strain: RATS/F 344/N

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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 | | |
| 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 | 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 | 47 1.2 | | |
| Pelvis, Dilatation | | | | | | | | | | 2 | | | | | | | | | | | | | | 1 2.0 | | |
| Pelvis, Transitional Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | | |
| Ureter | | | | | | | | | | | | | | | | | | | | | | + | | 1 | | |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |

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 Lab: BAT

| FISCHER 344 RATS MALE | 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 | 0777 | 0777 | 0777 | 0777 | | |
| 0.3 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 | 0011001100110011001100110011 | |

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 |
| Clear Cell Focus | 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 |
| 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 | 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

| | | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------|-----------|-------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|-----------|
| | | 07 | 07 | 06 | 06 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 06 | 07 | 07 | 07 | 07 | 07 | 07 | |
| FISCHER 344 RATS MALE | ANIMAL ID | 2 | 7 | 6 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 0 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | |
| | | 9 | 7 | 4 | 0 | 8 | 7 | 8 | 8 | 9 | 9 | 8 | 8 | 1 | 8 | 7 | 2 | 9 | 8 | 8 | 9 | 7 | 7 | 8 |
| 0.3 G/KG | | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | males |
| | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | (cont...) |
| | | 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 | |
| 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

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

| 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 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 0 | | |
| 2 | 2 | 6 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 0 | 8 | 8 | 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 | 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 | | | |
| 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 | 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 | 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 | |
| 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
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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 | 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 | 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 | 7 | | | |
| | | 2 | 2 | 6 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 0 | 8 | 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 | 7 | 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 | | | |
| | | 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 | | | |
| | | 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
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 BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
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| | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|-----------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|------------------------|
| FISCHER 344 RATS MALE | 0.3 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 | |
| | | | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| | | | 2 | 2 | 6 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 0 | 8 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| | | | 9 | 7 | 4 | 0 | 8 | 7 | 8 | 8 | 9 | 8 | 8 | 8 | 1 | 8 | 7 | 2 | 9 | 8 | 8 | 9 | 7 | 7 | 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 | |
| | | 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 | 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 | |
| | | | | | | | | | | | | | | | | | | | | | | | | | males (cont...) |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | | | 2 | | | | | | 1 | | | 2 | 3 | 1 | 2 | 3 | 4 | | 1 | 2 | 2 | | | |
| Lymph Node | | | | | | | | | | | | | | | | | | | | | | | | |
| Mediastinal, Ectasia | | | | | | | | | | | | | | | | | | | | | | | | |
| Mediastinal, Infiltration Cellular, Plasma Cell | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Spleen | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hematopoietic Cell Proliferation | | | 1 | | | | | 1 | | | | | | | | 3 | | | | | | | | |
| Pigmentation, Hemosiderin | 1 | 1 | | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 | 1 | 1 | 1 |
| Lymphoid Follicle, Atrophy | | | | 2 | | | | | | | | | 4 | | | | | | | | | | | |
| Lymphoid Follicle, Hyperplasia | | | | | | | | | | | | | | | | 3 | | | | | | | | |
| Thymus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Atrophy | 4 | 4 | 3 | 3 | 3 | 3 | 3 | 4 | 3 | 3 | 3 | 3 | 4 | 4 | 3 | 3 | 4 | 3 | 3 | 3 | 4 | 4 | 4 | 3 |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Epidermis, Hyperplasia, Basal Cell | | | | | | | | | | | | | | | | | | | | | | | | |

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

| DAY ON TEST | FISCHER 344 RATS MALE | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0.3 G/KG | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| 2 | 2 | 6 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 0 | 8 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | |
| 9 | 7 | 4 | 0 | 8 | 7 | 8 | 8 | 8 | 9 | 9 | 8 | 8 | 1 | 8 | 7 | 2 | 9 | 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 | |
| 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 | |
| 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 | |

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 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 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 | | | | | | | | | | | | | | | | | | | | | | | | | 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 | 1 | |
| Nephropathy | 2 | 1 | 1 | 1 | 2 | 2 | 2 | 3 | 1 | 2 | 2 | 3 | 3 | 2 | 2 | 1 | 2 | 2 | | 1 | 2 | 1 | 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 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 | | | |
| 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 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Colon Parasite Metazoan | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 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 | | | | | | | 18 |
| Clear Cell Focus | 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 | 2.0 | | | |
| Centrilobular, Fatty Change | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 4 | 1.3 | |
| Hepatocyte, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 | |
| Hepatocyte, Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1.0 | |
| Oval Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 | |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 7 | |
| Thrombosis | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 6 | 1.7 |
| Pancreas | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 18 | 1.3 |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1.0 |
| Acinus, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 9 | 1.6 |
| Salivary Glands | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Stomach, Forestomach | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Erosion | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 9 | 2.8 |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Ulcer | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 6 | 3.0 |
| Epithelium, Dysplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1.0 |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 11 | 2.5 |
| Stomach, Glandular | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 1.7 |
| Epithelium, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2.0 |
| Tooth | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 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

| 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 | 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 | 00 | |
| 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

| 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 |
| 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 |
| | 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 | 55 |
| | 67 | 67 | 67 | 67 | 88 | 88 | 88 | 88 | 88 | 88 | 88 | 88 | 88 | 88 | 99 | 99 | 99 | 99 | 99 | 99 | 99 | 99 | 99 | 99 |

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 | 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 | 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 | 4 | 3 | 4 | | 3 | 3 | 4 | 3 | 3 | 3 | 4 | 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 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 1.0
 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 2 1 2 2 10 1.6
 Olfactory Epithelium, Metaplasia 1 2 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 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
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|-----------------------------------|-------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----------|----|----|----|----|
| | 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

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 Kava kava extract
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 Time Report Requested: 09:10:56
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 Lab: BAT

| FISCHER 344 RATS MALE 1.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | ANIMAL ID | males (cont...) | |
|-----------------------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------|
| | 07 27 | 07 27 | 05 56 | 05 89 | 07 28 | 07 29 | 06 29 | 07 79 | 07 79 | 04 73 | 06 78 | 06 70 | 07 79 | 06 79 | 07 74 | 06 65 | 06 67 | 07 77 | 06 79 | 07 77 | 00 03 | 07 22 | | | 07 28 |
| | 00 11 55 12 | 00 01 55 23 | 00 01 55 34 | 00 01 55 45 | 00 01 55 56 | 00 01 55 67 | 00 01 55 78 | 00 01 55 89 | 00 01 55 90 | 00 01 66 01 | 00 01 66 12 | 00 01 66 23 | 00 01 66 34 | 00 01 66 45 | 00 01 66 56 | 00 01 66 67 | 00 01 66 78 | 00 01 66 89 | 00 01 66 90 | 00 01 66 01 | 00 01 66 12 | 00 01 66 23 | 00 01 66 34 | 00 01 66 45 | |

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 | X | |
| Clear Cell Focus | | X | X | | X | | | | | | X | | X | X | | | | | X | | X | | X | X |
| Degeneration, Cystic | | | 1 | | | | | | 2 | | 1 | | | 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 | 1 | |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | |
| Pigmentation, Hemosiderin | | | | | | | | | | | | | 1 | | | | | | | | | | | |
| Tension Lipidosis | | | | 2 | | | | | | | | | | | | | | | | | | | | |

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 + .. Tissue examined microscopically
 X .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
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 BLANK .. Not examined microscopically
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Lab: BAT

| | | DAY ON TEST | | | | | | | | | | | | | | | | | | | | males (cont...) | | | | | | | | |
|--------------------------------|--|-------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|--------------------|----|----|----|----|----|----|----|----|
| FISCHER 344 RATS MALE | | 07 | 07 | 05 | 05 | 07 | 07 | 06 | 07 | 07 | 04 | 06 | 07 | 06 | 07 | 07 | 07 | 06 | 06 | 07 | 07 | | 06 | 07 | 00 | 07 | 00 | 07 | 00 | 07 |
| 1.0 G/KG | | 27 | 27 | 55 | 58 | 22 | 22 | 22 | 02 | 47 | 73 | 80 | 24 | 22 | 22 | 22 | 22 | 29 | 66 | 66 | 27 | | 27 | 27 | 27 | 33 | 22 | 77 | 88 | |
| 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 | 00 | 00 | 00 | |
| Bile Duct, Hyperplasia | | | | | 1 | | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 3 | 2 | 2 | 2 | | | | | | | 1 | | |
| Centrilobular, Fatty Change | | | 1 | | | 2 | 2 | | | | | 2 | | 1 | | 1 | | | | | 2 | | 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 | | | | | 3 | | | |
| 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 | 1 | | | | 3 | | | |
| Stomach, Glandular | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | 2 | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
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| 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 7 3 | 0 7 2 8 | 0 6 4 0 | 0 7 2 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 2 3 | 0 7 2 0 | 0 7 2 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 1 5 1 | | |

Epithelium, Necrosis

3

Tooth
Malformation

+
 1 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 1 1 1 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 |
| | 27 | 27 | 25 | 28 | 22 | 22 | 22 | 20 | 04 | 07 | 24 | 22 | 22 | 22 | 29 | 06 | 06 | 07 | 07 | 06 | 07 | 02 | 03 | 02 | 02 |
| | 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 |
| | 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 |
| | 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 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 35 |

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
 X .. Lesion present A .. Autolysis precludes evaluation
 I .. Insufficient tissue BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:
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| 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 4 8 | 0 6 2 0 | 0 7 2 9 | 0 7 2 7 | 0 6 9 4 | 0 6 6 5 | 0 7 2 7 | 0 6 7 9 | 0 7 2 7 | | | 0 0 3 0 | 0 7 2 7 | 0 0 2 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 | 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 | 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 | |

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

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 X .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
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 1-4 .. Lesion qualified as:
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 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

| | | DAY ON TEST | | | | | | | | | | | | | | | | | | | | males (cont...) | | | | |
|-----------------------|----------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|---|---|---|---|
| FISCHER 344 RATS MALE | 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 | | | |
| | | 7 | 7 | 5 | 5 | 7 | 7 | 6 | 7 | 7 | 4 | 6 | 7 | 6 | 7 | 7 | 6 | 6 | 7 | 7 | 6 | | 7 | 0 | 7 | 2 |
| | | 2 | 2 | 5 | 8 | 2 | 2 | 2 | 2 | 0 | 4 | 7 | 2 | 4 | 2 | 2 | 2 | 9 | 6 | 6 | 2 | 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 |
| | | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | | | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | |
| | | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 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
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| FISCHER 344 RATS MALE 1.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | ANIMAL ID | males (cont...) | | | | | | |
|---|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-----------|--------------------|--|--|---|--|--|--|
| | 0727 | 0727 | 0756 | 0758 | 0772 | 0776 | 0776 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | | | | | | | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0001 | | | | | | | |
| | 7 | 7 | 5 | 5 | 7 | 7 | 6 | 7 | 7 | 4 | 6 | 7 | 6 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 6 | 7 | 0 | 7 | 0002 | | | | | | | |
| | 2 | 2 | 5 | 8 | 2 | 2 | 2 | 2 | 0 | 4 | 7 | 2 | 4 | 2 | 2 | 2 | 9 | 6 | 2 | 2 | 7 | 2 | 3 | 2 | 0003 | | | | | | | |
| | 7 | 7 | 6 | 9 | 8 | 9 | 9 | 7 | 9 | 7 | 3 | 8 | 0 | 9 | 9 | 7 | 4 | 5 | 7 | 7 | 9 | 7 | 0 | 7 | 0004 | | | | | | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0005 | | | | | | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0006 | | | | | | | |
| | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0007 | | | | | | | |
| | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 0008 | | | | | | | |
| | 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 | 0009 | | | | | | |
| Alveolar Epithelium, Hyperplasia | 1 | | | | 1 | | | | 1 | | | | 2 | | | | 1 | | | | 2 | | | | | | | | | | | |
| Alveolar Epithelium, Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | | | 1 | | | | | | | |
| Alveolus, Infiltration Cellular, Histiocyte | 1 | | | | 2 | | | | 3 | | | | 1 | | | | | | | | | | | | | | | | | | | |
| Arteriole, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 | | | | | | | |
| Serosa, Inflammation, Acute | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | | | | | | |
| Foreign Body | | | | | | | | | | | | | | | | | | | | | | | | | X | | | | | | | |
| Inflammation | | | | | 1 | | | | 1 | | | | 2 | | | | 1 | | | | | | | | | | | | | | | |
| Olfactory Epithelium, Metaplasia | 1 | | | | 1 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Respiratory Epithelium, Hyperplasia | 1 | | | | | | | | 1 | | | | | | | | | | | | | | | | | | | | | | | |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | | | | | | |
| SPECIAL SENSES SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | | | | | | |
| Anterior Chamber, Inflammation | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Iris, Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | 1 | | | | | | | |
| Retina, Degeneration | 1 | | | | 2 | | | | 2 | | | | 2 | | | | 1 | | | | 1 | | | | 2 | | | | 3 | | | |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | | | | | | |
| URINARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | | | | | | |
| Accumulation, Hyaline Droplet | | | | | | | | | | | | | | | | | | | | | | | | | 1 | | | | | | | |
| Hyperplasia, Oncocytic | | | | | | | | | | | | | | | | | | | | | | | | | 1 | | | | | | | |
| Mineralization | 1 | 1 | 1 | 1 | | 1 | | 1 | | | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | | | | | | | | |
| Nephropathy | 3 | 3 | 2 | 4 | 4 | 3 | 4 | 4 | 4 | 2 | 4 | 4 | 3 | 3 | 4 | 2 | 4 | 3 | 4 | 3 | 2 | 3 | | | | | | | | | | |
| Cortex, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 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
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 BLANK .. Not examined microscopically

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| FISCHER 344 RATS MALE 1.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | ANIMAL ID | males (cont...) |
|--|-------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----------|--------------------|
| | 077 | 077 | 055 | 055 | 077 | 077 | 066 | 077 | 077 | 044 | 066 | 077 | 066 | 077 | 077 | 066 | 066 | 077 | 077 | 066 | 077 | 000 | 077 | 077 | | |
| | 27 | 27 | 56 | 89 | 28 | 29 | 22 | 29 | 04 | 73 | 24 | 20 | 29 | 09 | 09 | 04 | 65 | 27 | 27 | 79 | 23 | 27 | 07 | 001 | | |
| | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 001 | | |
| | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 11 | 001 | | |
| | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 66 | 66 | 66 | 66 | 66 | 66 | 66 | 66 | 66 | 66 | 66 | 77 | 77 | 77 | 77 | 001 | | |
| | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 00 | 01 | 02 | 03 | 04 | 05 | 06 | 07 | 08 | 09 | 00 | 01 | 02 | 03 | 04 | 001 | | |
| Pelvis, Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pelvis, Transitional Epithelium, Hyperplasia | | | | 2 | | | | 1 | 1 | 1 | | 1 | | | 1 | 1 | | 2 | | 1 | | | 2 | | | |
| Urinary Bladder Inflammation | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |

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|-----------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|
| | 0729 | 0729 | 0729 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | 0728 | |
| 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 | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---------|-------|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| 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 | | | | | 1 | | | | | | | | | | | | | | | | | | | | 1 1.0 | |
| Basophilic Focus | | X | X | X | | X | | | X | | | | | | | | | | X | | | | | | 13 | |
| Clear Cell Focus | | | | | | | | | | | | | X | X | | | | | X | | | X | | | 11 | |
| Degeneration, Cystic | | | | | | | | | | | | | | | | | | | | | | | | | 5 1.2 | |
| Eosinophilic Focus | X | | | | | | | | | | | X | | | | | | | X | | | | X | | 13 | |
| Fatty Change, Diffuse | 2 | | | | | | | | 2 | 2 | | | | | | | | | | | | | 1 | | 8 1.5 | |
| Fibrosis | | | | | | | | | | | | | | | | | | | | | | | 2 | | 1 2.0 | |
| Hepatodiaphragmatic Nodule | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Inflammation, Chronic Active | 1 | 1 | 1 | 1 | 1 | 1 | | | 1 | | 1 | | 1 | 1 | | | | 1 | 1 | 1 | 1 | | 1 | | 34 1.1 | |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 1 3.0 |
| Pigmentation, Hemosiderin | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2 1.0 |
| Tension Lipidosis | | | | | | | | | | | | | | | | | | | | | | | | | 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 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 | |
| Centrilobular, Fatty Change | | 1 | 2 | 2 | 2 | 2 | | 1 | | | | | | 2 | | 1 | | | 1 | 2 | | 2 | 2 | | |
| Centrilobular, Necrosis | | | | | | | | | | | 3 | | | | | | | | | | | | | | |
| Hepatocyte, Hypertrophy | | 1 | 1 | 1 | 1 | 1 | | 1 | 2 | 1 | | | 1 | | 2 | | | | 2 | | 1 | | | 2 | |
| Oval Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | |
| Oral Mucosa | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Atrophy | | | 1 | 3 | | | 1 | | 1 | | | | | | 1 | | | | 2 | | 1 | | | 1 | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | |
| Acinus, Hyperplasia | | | | | 2 | | | | | | | | | | | | | | | | | | | | |
| Acinus, Metaplasia, Hepatocyte | | | | | | | | | | | | 2 | | | | | | | | 1 | 2 | | | | |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Erosion | | | | | | | | | | | | | | | 1 | | | | | | | | | 1 | |
| Inflammation | 1 | 2 | | | | | 1 | | 3 | 2 | | 2 | | | | 1 | 1 | | 2 | | | 1 | | 2 | |
| Mineralization | | | | | | | 2 | | | | | | | | | | | | | | | | | | |
| Ulcer | 1 | 1 | | | | | 2 | | 3 | | | | | | | | | | | | | | | | |
| Epithelium, Dysplasia | | | | | | | | | | | | | | | | | | | | | | | | | |
| Epithelium, Hyperplasia | 1 | 3 | | | | | | 1 | 3 | 4 | | 3 | | | | 1 | 1 | | 4 | | | 1 | 1 | | |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation | | | 2 | | | | | | | | 1 | | | | | | | | | | | | 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 | | |
|--|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|----|-----|
| | 0729 | 0729 | 0729 | 0728 | 0727 | 0727 | 0727 | 0658 | 0568 | 0667 | 0474 | 0747 | 0474 | 0777 | 0777 | 0222 | 0222 | 0003 | 0028 | 0077 | 0077 | 0055 | 0077 | | | | |
| 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 | | | |
| Epithelium, Necrosis | 2 | | | | | | | | | | | | | | | | | | | | | | | | 2 | 3 | 2.3 |
| Tooth Malformation | | | | + | + | + | | | + | | | + | | | | | | | | | | | | | 11 | 11 | 1.1 |
| CARDIOVASCULAR SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Blood Vessel Mineralization | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 | 1.0 |
| Heart Cardiomyopathy | 2 | 1 | 2 | 3 | 2 | 2 | 3 | 2 | 2 | 3 | 2 | 2 | 1 | 2 | 2 | 2 | | | | | | | | | 50 | 46 | 2.3 |
| Heart Inflammation, Suppurative Atrium, Thrombosis | | | | | | | | 2 | | | | | | | | | | | | | | | | | 1 | 1 | 2.0 |
| | | | | | | | 2 | | | | | | | | | | | | | | | | | | 1 | 1 | 2.0 |
| ENDOCRINE SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Adrenal Cortex Hypertrophy | + | + | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 3 | 1.0 |
| Adrenal Cortex Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 | 2.0 |
| Adrenal Cortex Zona Fasciculata, Hyperplasia | | | 1 | | | | | | | | 2 | 1 | | | | | 1 | | | | | | | | 13 | 13 | 1.1 |
| Adrenal Medulla Hemorrhage | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 | 3.0 |
| Adrenal Medulla Hyperplasia | | | | | | | | | | | | | 1 | | 4 | | | | | | | | | | 10 | 10 | 1.9 |
| Adrenal Medulla Thrombosis | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 | 2.0 |
| Islets, Pancreatic Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 3 | 2.7 |
| Islets, Pancreatic Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 3 | 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
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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 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 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 | |
| | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | |
| Hyperplasia | | 3 | | | 1 | | | | | | | | | | | | | | | | | | 1 | 2 | 2 | 10 1.8 |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Pars Distalis, Hyperplasia | | | 1 | | | | | 1 | | | 1 | | | | 1 | | | | | | | 1 | 1 | 2 | 11 1.5 | |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| C-cell, Hyperplasia | | | | | | 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 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Inflammation | | | | | | | | | | | 2 | | | | | | | | | | | 1 | | | 2 1.5 | |
| Preputial Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | 4 | | 2 4.0 | |
| Duct, Hyperplasia, Atypical | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | |
| Prostate | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Atrophy | | | | | | | 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 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Atrophy | | | | | | | 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 | | | |
|-----------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|-------|-------|-------|
| | 079 | 079 | 077 | 078 | 077 | 078 | 078 | 069 | 058 | 066 | 066 | 044 | 074 | 045 | 072 | 077 | 077 | 029 | 020 | 072 | | 077 | 077 | 057 |
| ANIMAL ID | 00176 | 00077 | 00077 | 00078 | 00077 | 00078 | 00078 | 00078 | 00078 | 00078 | 00078 | 00078 | 00078 | 00078 | 00078 | 00078 | 00078 | 00078 | 00078 | 00078 | 00078 | 00078 | 00078 | 00078 |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| 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 | | | | | | | | | | | | | | | | | | | | | | | | | 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 | | | | | | | | | | | | | | | | | | | | | | | | | 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 | 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 | 3 | 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
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 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
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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 | 078 | 077 | 069 | 058 | 066 | 066 | 044 | 074 | 045 | 022 | 022 | 029 | 029 | 003 | 008 | | 007 | 008 | 007 | 005 |
| 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 |

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 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 | 063 | 060 | 044 | 074 | 047 | 074 | 077 | 077 | 022 | 000 | 027 | | 078 | 072 | 072 | 059 | 052 | 079 | 059 | 072 | 070 |
| ANIMAL ID | 00176 | 00077 | 00077 | 00077 | 00077 | 00077 | 00078 | 00089 | 00082 | 00083 | 00080 | 00044 | 00074 | 00047 | 00074 | 00077 | 00077 | 00022 | 00000 | 00027 | 00078 | 00072 | 00072 | 00059 | 00052 | 00079 | 00059 | 00072 | 00070 | |
| 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 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 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 | 3 | 3 | 3 | 4 | | | 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

| DAY ON TEST | FISCHER 344 RATS MALE | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|--|-----------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|---------------|
| | 07 | 07 | 07 | 07 | 07 | 07 | 06 | 05 | 06 | 06 | 04 | 07 | 04 | 07 | 07 | 07 | 07 | 00 | 07 | 07 | 07 | 07 | 05 | 07 | |
| 1.0 G/KG | 29 | 29 | 27 | 28 | 27 | 28 | 29 | 28 | 23 | 20 | 24 | 27 | 25 | 28 | 29 | 29 | 29 | 20 | 28 | 27 | 28 | 22 | 25 | 29 | |
| ANIMAL ID | 0017 | 0017 | 0018 | 0019 | 0020 | 0021 | 0022 | 0023 | 0024 | 0025 | 0026 | 0027 | 0028 | 0029 | 0030 | 0031 | 0032 | 0033 | 0034 | 0035 | 0036 | 0037 | 0038 | 0039 | |
| Pelvis, Inflammation | | | | | | | | | | 1 | | | | | | | | | | | | | | | 1 1.0 |
| Pelvis, Transitional Epithelium, Hyperplasia | | 1 | | | | 1 | | | | 2 | | 1 | | | | | | 1 | | | | | | | 15 1.3 |
| Urinary Bladder Inflammation | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 3 2 2.5 |

*** 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 0.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | females (cont...) |
|-------------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------------------|
| | 0705 | 0708 | 0713 | 0719 | 0722 | 0729 | 0730 | 0732 | 0733 | 0734 | 0735 | 0736 | 0737 | 0738 | 0739 | 0740 | 0741 | 0742 | 0743 | 0744 | 0745 | 0746 | 0747 | 0748 | | |
| 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 | 0025 | |

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 |
| Clear Cell Focus | | | | | | | | X | | | | X | | | | | | | | | | | X | X |
| Eosinophilic Focus | | | | X | X | X | X | | | X | 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

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 | | | | | | | | | | | | | | | | | | | | | | | | | ANIMAL ID | females (cont...) |
|-------------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-----------|----------------------|
| | 0705 | 0708 | 0709 | 0712 | 0713 | 0714 | 0715 | 0716 | 0717 | 0718 | 0719 | 0720 | 0721 | 0722 | 0723 | 0724 | 0725 | 0726 | 0727 | 0728 | 0729 | 0730 | 0731 | 0732 | 0733 | | |
| 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
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TDMS No. 20007 - 05
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 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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 Kava kava extract
 CAS Number: 9000-38-8

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

| FISCHER 344 RATS FEMALE | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | ANIMAL ID | females (cont...) |
|-------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|----------------------|
| | 0 7 0 5 | 0 7 2 8 | 0 7 3 0 | 0 7 2 9 | 0 7 2 9 | 0 7 2 9 | 0 7 3 0 | 0 7 2 9 | 0 7 3 0 | 0 5 2 6 | 0 7 3 0 | 0 7 3 0 | 0 7 3 0 | 0 6 2 8 | 0 7 3 0 | 0 7 2 9 | 0 7 2 9 | 0 7 2 9 | 0 7 2 9 | 0 5 2 9 | 0 7 2 8 | 0 0 2 9 | 0 7 0 9 | 0 7 2 8 | | |
| 0.0 G/KG | 0 0 2 0 1 | 0 0 0 2 2 | 0 0 0 2 3 | 0 0 0 2 4 | 0 0 0 2 5 | 0 0 0 2 6 | 0 0 0 2 7 | 0 0 0 2 8 | 0 0 0 2 9 | 0 0 0 2 0 | 0 0 0 2 1 | 0 0 0 2 2 | 0 0 0 2 3 | 0 0 0 2 4 | 0 0 0 2 5 | 0 0 0 2 6 | 0 0 0 2 7 | 0 0 0 2 8 | 0 0 0 2 9 | 0 0 0 2 0 | 0 0 0 2 1 | 0 0 0 2 2 | 0 0 0 2 3 | 0 0 0 2 4 | 0 0 0 2 5 | |

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
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1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
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TDMS No. 20007 - 05
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Kava kava extract
 CAS Number: 9000-38-8

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

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

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland Inflammation | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Ovary Cyst Cyst, Multiple | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Uterus Endometrium, Hyperplasia, Cystic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone Marrow Hemorrhage Hyperplasia Myelofibrosis Necrosis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 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 Inflammation | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 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

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

Atelectasis 4
 Congestion
 Inflammation, Chronic Active 2
 Alveolar Epithelium, Hyperplasia 1 1 1 1 1 1
 Alveolar Epithelium, Hypertrophy
 Alveolar Epithelium, Metaplasia
 Alveolar Epithelium, Metaplasia, Squamous 2
 Alveolus, Infiltration Cellular, Histiocyte 1 1 1 1 1 1 1
 Mediastinum, Foreign Body
 Mediastinum, Inflammation, Chronic Active 1

Nose +
 Cyst
 Foreign Body X
 Inflammation 1 1 1 1 1 1 1 1
 Olfactory Epithelium, Metaplasia 1

Trachea +

SPECIAL SENSES SYSTEM

Ear
 Eye +
 Cornea, Fibrosis 2
 Cornea, Inflammation
 Lens, Cataract 4
 Retina, Degeneration 4 3
 Retina, Gliosis

* .. 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 | females (cont...) | | |
| | | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 0 | 7 | 7 | | | |
| | | 0 | 2 | 3 | 2 | 2 | 2 | 3 | 2 | 0 | 3 | 3 | 3 | 2 | 3 | 2 | 0 | 2 | 2 | 2 | 1 | 2 | 0 | 2 | | 2 | |
| | | 5 | 8 | 0 | 9 | 9 | 9 | 0 | 9 | 6 | 0 | 0 | 0 | 8 | 1 | 0 | 9 | 5 | 9 | 8 | 9 | 0 | 8 | 9 | | 8 | |
| 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 | | | |
| | | 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 | | | |
| | | 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
 Infarct
 Mineralization
 Nephropathy
 Cortex, Cyst
 Medulla, Cyst
 Pelvis, Inflammation

+
 1
 1
 1
 2
 1

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
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 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 | 0709 | 0709 | 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 | 0022 | 0022 | |
| | 67 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Parasite Metazoan | | | | | X | | | | | X | X | | | | | | | | | | | | | | 3 |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Basophilic Focus | | X | X | X | X | X | X | | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | 44 |
| Clear Cell Focus | | | X | X | X | | X | | | | | | X | | | | X | | | | | X | X | | 12 |
| Eosinophilic Focus | | | | X | X | X | X | | | | | X | X | X | | | | | | | | X | | X | 23 |
| Fatty Change, Focal | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Fatty Change, Diffuse | | 1 | | | | | | | 1 | | | | | | 2 | | | 1 | | | | | 1 | 1 | 9 1.3 |
| Hematopoietic Cell Proliferation | | | | | | | | | | | 1 | | | | | | | | | | | | | | 1 1.0 |
| Hepatodiaphragmatic Nodule | | | | | | X | | X | | | | | X | | | | | X | | | | | | | 5 |
| 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 | 43 1.0 |
| Mixed Cell Focus | | | | | X | | X | X | | X | | X | | | | | | | | | | | X | | 15 |
| Necrosis | 4 | | | | | | | | | | | | | | | | | | | | | | | | 2 3.0 |
| Pigmentation, Hemosiderin | | | | | | | | | | | | | | | | | | | | | | | | | 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:
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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 | 0705 | 0707 | 0709 | 0711 | 0713 | 0715 | 0717 | 0719 | 0721 | 0723 | 0725 | 0727 | 0729 | 0731 | 0733 | 0735 | 0737 | 0739 | 0741 | | |
| | 0002 | 0004 | 0006 | 0008 | 0010 | 0012 | 0014 | 0016 | 0018 | 0020 | 0022 | 0024 | 0026 | 0028 | 0030 | 0032 | 0034 | 0036 | 0038 | 0040 | 0042 | 0044 | 0046 | | |
| Artery, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 2.0 |
| Bile Duct, Hyperplasia | | | | | | | | | 1 | | | 1 | | | | | | 1 | 1 | 1 | | | | 1 | 12 1.0 |
| Hepatocyte, Hypertrophy | | | 1 | | | 2 | | | | | | | | | 1 | | | | | | | | 2 | | 5 1.6 |
| Serosa, Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | 3 | 1 3.0 |
| Mesentery | + | | | | | | | + | | + | | | | | | | | | | | | | + | | 10 |
| Fat, Necrosis | 1 | | | | | | | 2 | | 2 | | | | | | | | | | | | | 1 | | 10 1.5 |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Atrophy | | 1 | | | | | | | | | | | | | 1 | | | | | | | | 1 | | 13 1.0 |
| Basophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Acinus, Hyperplasia | | | | | | | | 1 | | | | | | | | | | | | | | | | | 1 1.0 |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Hyperplasia, Atypical | | | | | | | | | | | | | | | | | | | | | | | 4 | | 1 4.0 |
| Inflammation | | 2 | | | | | | | | 3 | | | | | | | | | | | | | | | 5 2.0 |
| Ulcer | | 3 | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Epithelium, Hyperplasia | | 2 | | | | | | | | 3 | | | | | | 1 | | | | | | | | | 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
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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 | 0609 | 0605 | 0709 | 0702 | 0703 | 0700 | 0603 | 0708 | 0606 | 0604 | 0709 | 0607 | 0702 | 0708 | 0702 | | |
| ANIMAL ID | 0022 | 0022 | 0022 | 0022 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0034 | 0034 | 0034 | 0034 | 0034 | 0034 | 0034 | 0034 | 0034 | 0034 | | |
| 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 | 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:
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|--|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|---------------|
| | 0692 | 0450 | 0701 | 0733 | 0770 | 0773 | 0777 | 0779 | 0519 | 0669 | 0665 | 0772 | 0779 | 0777 | 0773 | 0673 | 0773 | 0676 | 0666 | 0772 | 0667 | 0777 | 0777 | 0777 | |
| ANIMAL ID | 00226 | 00227 | 00228 | 00229 | 00230 | 00231 | 00232 | 00233 | 00234 | 00235 | 00236 | 00237 | 00238 | 00239 | 00240 | 00241 | 00242 | 00243 | 00244 | 00245 | 00246 | 00247 | 00248 | 00249 | |
| 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
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 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 | 0707 | 0707 | 0707 | 0707 | 0707 | 0707 | 0707 | 0707 | 0707 | 0707 | 0707 | 0707 | 0707 | 0707 | 0707 | 0707 | | 0707 |
| ANIMAL ID | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 | 0022 |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----|-----|
| 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
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 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 |
|-------------------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|--|----------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 6 | 4 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 6 | 6 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 6 | 7 | 6 | 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 | | |
| | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | | |
| | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | | |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| URINARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | |
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Infarct | | | | | | | | | | | | | | | 1 | | | | | | | | 2 1.0 | | |
| Mineralization | | 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 | | | | | | | | | | | | | | 2 | | | | | | | | | 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
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TDMS No. 20007 - 05
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 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 | females (cont...) | | | | |
|-------------|-------------------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------------|----------------|----------------|----------------|----------|
| | 07 27 | 06 39 | 06 78 | 07 29 | 07 79 | 07 70 | 07 73 | 07 73 | 07 20 | 07 38 | 07 30 | 07 05 | 06 79 | 07 78 | 07 78 | 07 29 | 07 30 | 07 33 | 05 81 | 06 73 | | | 07 01 | 07 02 | 07 03 | 07 04 |
| 0.1 G/KG | 00 25 11 | 00 25 12 | 00 25 13 | 00 25 14 | 00 25 15 | 00 25 16 | 00 25 17 | 00 25 18 | 00 25 19 | 00 25 20 | 00 25 21 | 00 25 22 | 00 25 23 | 00 25 24 | 00 25 25 | 00 25 26 | 00 25 27 | 00 25 28 | 00 25 29 | 00 25 30 | 00 25 31 | 00 25 32 | 00 25 33 | 00 25 34 | 00 25 35 | |

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 |
| Basophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | X |
| Clear Cell Focus | | | | | | | | | | | | | | | | | | | | | | | | | X |
| Eosinophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | X |
| Fatty Change, Diffuse | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Hepatodiaphragmatic Nodule | | | | | | | | | | | | | | | | | | | | | | | | | X |
| Inflammation, Chronic Active | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Mixed Cell Focus | | | | | | | | | | | | | | | | | | | | | | | | | X |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | 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
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1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
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| FISCHER 344 RATS FEMALE 0.1 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | females (cont...) | | | | |
|-------------------------------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|----------------------|---------------|---------------|---------------|--------------|
| | 07 27 | 06 23 9 | 06 7 8 | 07 2 9 | 07 2 9 | 07 3 0 | 07 3 0 | 07 3 0 | 07 2 8 | 07 3 0 | 07 3 0 | 07 0 5 | 07 2 9 | 07 2 8 | 07 2 8 | 07 2 9 | 07 3 0 | 07 3 0 | 08 5 8 | 08 6 3 | 08 7 3 | 08 7 3 | 09 5 1 | | 09 5 1 | 09 5 2 | 09 7 8 | 09 7 8 |
| ANIMAL ID | 00 25 1 | 00 25 2 | 00 25 3 | 00 25 4 | 00 25 5 | 00 25 6 | 00 25 7 | 00 25 8 | 00 25 9 | 00 26 0 | 00 26 1 | 00 26 2 | 00 26 3 | 00 26 4 | 00 26 5 | 00 26 6 | 00 26 7 | 00 26 8 | 00 26 9 | 00 27 0 | 00 27 1 | 00 27 2 | 00 27 3 | 00 27 4 | 00 27 5 | 00 27 6 | 00 27 7 | |
| Bile Duct, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Bile Duct, Hyperplasia | 3 | | | 1 | | | | | | 1 | 1 | 2 | 1 | 2 | | | | | | | | | 1 | | | | | |
| Centrilobular, Necrosis | | | | | | | | | | | | | | 3 | | | | | | | | | | | | | | |
| Hepatocyte, Hypertrophy | | | | | | | | | | 1 | | | | | | | | | | | | | | | | | | |
| Oval Cell, Hyperplasia | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Serosa, Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Oral Mucosa | | | | | | | | | | | | | | | | | | | | | | | | | | | | + |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Atrophy | | 1 | | | | | | | | | 1 | | | | | 1 | | | | | | | 1 | | | | 2 | |
| Acinus, Hyperplasia | | | | 2 | | | | | | | | | | | | | | | | | | | | 1 | | | | |
| Acinus, Metaplasia, Hepatocyte | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Erosion | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Inflammation | 2 | 1 | | | | | | | | | | | | | 1 | 3 | | | | | | | | | | | | 3 |
| Ulcer | 4 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Epithelium, Hyperplasia | 2 | 2 | | | | | | | | | | | | | 1 | 1 | 4 | | | | | | | | | | | 4 |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Epithelium, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Tooth | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | + | | | | | | | | | | | | | | | | | | | | | | | | + |

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

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 Lab: BAT

| DAY ON TEST | FISCHER 344 RATS FEMALE | | | | | | | | | | | | | | | | | | | | | | | | ANIMAL ID | females (cont...) |
|--------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-----------|-------------------|
| | 0727 | 0667 | 0677 | 0727 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0677 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | | |
| | 27 | 33 | 78 | 29 | 29 | 30 | 33 | 33 | 28 | 30 | 05 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | |
| | 01 | 02 | 03 | 04 | 05 | 06 | 07 | 08 | 09 | 00 | 01 | 02 | 03 | 04 | 05 | 06 | 07 | 08 | 09 | 00 | 01 | 02 | 03 | 04 | 05 | |
| 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 |
| Atrium, Thrombosis | | | | | | | | | | | | | | | | | | | | | | | | |
| Valve, Thrombosis | 2 | | | | | | | | | | | | | | | | | | | | | | | |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Amyloid Deposition | | | | | | | | | | | | | | | | | | | | | | 2 | | |
| Degeneration, Cystic | | | | 1 | | | | | | | | 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 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

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 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 |
| | 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 | 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 |
| Follicular Cell, Hyperplasia | | | 1 | | | | | | | | | | | | | | | | | | | | | 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 |

* .. 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 | 0770 | 0770 | 0770 | 0770 | 0770 | 0770 | 0675 | 0779 | 0778 | 0778 | 0779 | 0770 | 0770 | 0561 | 0679 | | | 0701 | 0778 | 0773 | 0774 |
| Lymph Node, Mesenteric Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 3 | |
| Spleen Fibrosis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 1 | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | 1 | 1 | 1 | | | | | | | 1 | |
| Pigmentation, Hemosiderin | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymphoid Follicle, Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Thymus Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 3 | |
| INTEGUMENTARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Skin Epidermis, Hyperplasia, Basal Cell | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | |
| MUSCULOSKELETAL SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| NERVOUS SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Brain Hemorrhage | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| 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:
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TDMS No. 20007 - 05
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 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 2 8 | 0 7 3 0 | 0 7 3 0 | 0 7 3 0 | 0 7 3 0 | 0 7 3 0 | 0 6 7 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 |
| 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 | | | | | |
| 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 | 1 | 1 |
| Nephropathy | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |

* .. 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 | 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 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | 000 | |
| | 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 | | 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 | 6 | 6 | 7 | 6 | 0 | 7 | 6 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 7 |
| 0.1 G/KG | | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 0 | 8 | 1 | 2 | 0 | 0 | 3 | 3 | 3 | 2 | 0 | 2 | 3 | 2 | 3 | 2 |
| ANIMAL ID | | 9 | 9 | 8 | 9 | 8 | 9 | 1 | 8 | 5 | 9 | 5 | 5 | 0 | 2 | 0 | 9 | 5 | 9 | 0 | 8 | 2 | 9 | 0 |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 |
| | | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |
| | | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| | | | | | | | | | | | | | | | | | | | | | | * TOTALS | | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|--|---|---|---|---|---|---|---|---|---|-------|
| Esophagus | + | | | | | | | | | | | | | | | | | | | | | | 50 |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Intestine Large, Cecum | + | | | | | | | | | | | | | | | | | | | | | | 50 |
| Intestine Large, Colon | + | | | | | | | | | | | | | | | | | | | | | | 50 |
| Parasite Metazoan | | | | | | | | | | | | | | | | | | | | | | | 1 |
| 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 |
| Clear Cell Focus | | X | | X | X | X | | | | X | | | | | | X | | | | | X | X | |
| Eosinophilic Focus | | X | X | X | X | X | | | X | X | | | | X | X | X | | | X | X | | X | X |
| Fatty Change, Diffuse | | | | | | | | 2 | | | | 2 | | 1 | 1 | | | | | | | | 1 |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | 3 1.0 |
| Hepatodiaphragmatic Nodule | | | | | | | | | | | | | | | | | | | | | | | 6 |
| 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 | | | | X | | | X |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |

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 X .. Lesion present
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TDMS No. 20007 - 05
 Test Type: CHRONIC
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 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 | |

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 M .. Missing tissue
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TDMS No. 20007 - 05
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 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 | 070 | 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 |
| | 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 | 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 | 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 |
| | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 |
| | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 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 |

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 | 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 | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|-------------------------|------------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----|----------|
| | 079 | 072 | 078 | 079 | 078 | 079 | 077 | 077 | 077 | 061 | 066 | 075 | 066 | 000 | 073 | 066 | 077 | 077 | 077 | 062 | 067 | 077 | 077 | | |
| 0.1 G/KG | 0076 | 0077 | 0078 | 0079 | 0070 | 0071 | 0072 | 0073 | 0074 | 0075 | 0076 | 0077 | 0078 | 0079 | 0080 | 0081 | 0082 | 0083 | 0084 | 0085 | 0086 | 0087 | 0088 | 15 | |
| | C-cell, Hyperplasia | | | | | | 3 | | | | | | 1 | | | 3 | | | | | | | | | 1.9 |
| | Follicular Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 1.0 |

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Clitoral Gland | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Hyperplasia | | | | | | | | | | | 2 | | | | | | | | | | | | | | 3 |
| Inflammation | | | | | | | | | | | | | | 2 | | | | | | | | | | | 2 |
| Ovary | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Cyst | 1 | | | | 1 | | | | 4 | | | | | | | | | | | 2 | | | 1 | | 3 |
| Uterus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Congestion | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Endometrium, Hyperplasia, Cystic | | | | | | | | | | | 1 | | | | | | | | | | | 1 | | | 5 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Hyperplasia | | | | 1 | 1 | 1 | | | | 3 | | | 3 | | 4 | | | | | 3 | 1 | 3 | 3 | 2 | 27 |
| Myelofibrosis | | | | | | | | | | 2 | | | | | | | | | | | | | | | 1 |
| 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

| FISCHER 344 RATS FEMALE 0.1 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | | | |
|---|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|------|------|------|--------|-----|--|
| | 079 | 079 | 078 | 079 | 078 | 079 | 079 | 071 | 068 | 065 | 079 | 065 | 075 | 060 | 077 | 066 | 073 | 077 | 072 | 063 | | 077 | 066 | 077 | 077 | 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 | 0100 | | |
| Lymph Node, Mesenteric Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 | | |
| Spleen Fibrosis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | 3 1.7 | | |
| Pigmentation, Hemosiderin | | | | | | | | | | | | | | | | | | | | | | | | | 18 1.3 | | |
| Lymphoid Follicle, Atrophy | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | 2 | 1 | 1 | | | 1 | | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 37 1.1 | | |
| | | | | | | | | | 2 | | | | | | | | | | | | | | | | 1 2.0 | | |
| Thymus Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | | | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 43 3.0 | | |
| 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 | | |
| Brain Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | 3 1.7 | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | 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 | | | | | | | | |
|---|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|------|------|------|------|------|------|--------|--------|
| | 079 | 079 | 078 | 079 | 078 | 079 | 079 | 071 | 068 | 065 | 079 | 065 | 070 | 067 | 063 | 063 | 072 | 075 | 079 | 070 | | 068 | 062 | 073 | 063 | 072 | 067 | 077 | 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 | 0100 | 0101 | 0102 | 0103 | 0104 |
| 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 | 17 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 | 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 | 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

| FISCHER 344 RATS FEMALE | 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 | |
| 0.1 G/KG | 0076 | 0076 | 0078 | 0079 | 0078 | 0079 | 0079 | 0079 | 0079 | 0079 | 0079 | 0079 | 0079 | 0079 | 0079 | 0079 | 0079 | 0079 | 0079 | 0079 | 0079 | 0079 | 0079 | 0079 | |
| | 0027 | 0027 | 0027 | 0027 | 0027 | 0027 | 0027 | 0027 | 0027 | 0027 | 0027 | 0027 | 0027 | 0027 | 0027 | 0027 | 0027 | 0027 | 0027 | 0027 | 0027 | 0027 | 0027 | 0027 | |
| | 67 | 77 | 78 | 79 | 80 | 81 | 82 | 83 | 84 | 85 | 86 | 87 | 88 | 88 | 88 | 88 | 88 | 88 | 88 | 88 | 88 | 88 | 88 | 88 | |
| | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 3 4 |

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

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 | | | | | | | | | | | | | | | | | | | | | | | | ANIMAL ID | 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 | | | |
| 0.3 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 | 000000000000000000000000 | | |
| | 7 | 7 | 0 | 6 | 5 | 5 | 6 | 6 | 7 | 6 | 7 | 7 | 7 | 5 | 4 | 6 | 6 | 7 | 7 | 7 | 7 | 5 | 7 | 000000000000000000000000 | | |
| | 0 | 3 | 9 | 2 | 3 | 1 | 1 | 1 | 2 | 8 | 2 | 2 | 2 | 3 | 3 | 5 | 8 | 2 | 2 | 2 | 2 | 3 | 1 | 333333333333333333333333 | | |
| | 5 | 0 | 8 | 8 | 2 | 9 | 5 | 8 | 9 | 1 | 9 | 9 | 9 | 9 | 9 | 2 | 8 | 8 | 9 | 9 | 9 | 9 | 0 | 000000000000000000000000 | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 000000000000000000000000 | | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 333333333333333333333333 | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 000000000000000000000000 | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 1234567890123456789012345 | | |

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 | 1 | 3 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|---|---|---|---|---|---|---|---|
| Bone Marrow Hyperplasia Inflammation, Histiocytic Myelofibrosis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 4 | | 2 | 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 | | | | | | | | | | |
| 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
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 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
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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 | 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 5 3 9 | 0 4 3 9 | 0 6 5 8 | 0 6 8 8 | 0 7 2 8 | 0 7 2 9 | 0 7 2 9 | 0 5 3 0 | | | 0 7 1 8 | 0 5 3 0 | 0 7 3 0 | | |
| 0.3 G/KG | 0 0 3 0 1 | 0 0 3 0 2 | 0 0 3 0 3 | 0 0 3 0 4 | 0 0 3 0 5 | 0 0 3 0 6 | 0 0 3 0 7 | 0 0 3 0 8 | 0 0 3 0 9 | 0 0 3 1 0 | 0 0 3 1 1 | 0 0 3 1 2 | 0 0 3 1 3 | 0 0 3 1 4 | 0 0 3 1 5 | 0 0 3 1 6 | 0 0 3 1 7 | 0 0 3 1 8 | 0 0 3 1 9 | 0 0 3 2 0 | 0 0 3 2 1 | 0 0 3 2 2 | 0 0 3 2 3 | 0 0 3 2 4 | 0 0 3 2 5 | | |
| Hematopoietic Cell Proliferation | 1 | | 1 | | 1 | | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | | 1 | | 1 | | 1 | 1 | | | | | | |
| Hyperplasia, Histiocytic | | | | | | | 3 | | | | | | | | | | | | | | | | | | | | |
| Pigmentation, Hemosiderin | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 2 | 1 | 2 | 1 | | 1 | 1 | 1 | 2 | 1 | | | | |
| Lymphoid Follicle, Atrophy | | | | | | | | | | | | | 2 | | 2 | | | | | | | | | | | | |
| Thymus | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |
| Atrophy | 3 | 3 | | 3 | 3 | 3 | 3 | 4 | 3 | 3 | 3 | | 3 | 3 | 4 | 3 | 3 | 4 | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | |
| Inflammation | | | | | | | | | | | | | 2 | | | | | | | | | | | | | | |
| INTEGUMENTARY SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Galactocele | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | 3 | | | | |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Epidermis, Hyperkeratosis | | | | | | | | | 2 | | | | | | | | | | | | | | | | | | |
| MUSCULOSKELETAL SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Skeletal Muscle | | | | | | | | | | | | | | | | | | | | | | | | | + | | |
| NERVOUS SYSTEM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mixed Cell | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Necrosis | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 X .. Lesion present
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TDMS No. 20007 - 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 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 | |
| | 0 | 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 | |
| | 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 | |

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 | | | | | | | | | | | | | | | | | | | | | | 2 | |
| Retina, Dysplasia | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 X .. Lesion present
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 A .. Autolysis precludes evaluation
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 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
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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 | females (cont...) | | | | |
|-------------|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|----------------------|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | 0 | | | |
| 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 | |
| 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 | 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 | 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 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 0 | 0 |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 0 | 0 |

Retina, Gliosis

Harderian Gland

URINARY SYSTEM

Kidney

Accumulation, Hyaline Droplet

Infarct

Mineralization

Nephropathy

Papilla, Necrosis

Pelvis, Inflammation

Pelvis, Transitional Epithelium, Hyperplasia

Pelvis, Transitional Epithelium, Metaplasia

Renal Tubule, Dilatation

Renal Tubule, Necrosis

Urinary Bladder

| | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Accumulation, Hyaline Droplet | | | | | | | | | | | | | | | | | 2 | | | | | | |
| Infarct | | | | | | | | | | | | | | | | | | | | | 3 | | |
| Mineralization | 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 |
| Papilla, Necrosis | | | | | | | | | | | | | | | | | | | | | | | |
| Pelvis, Inflammation | | | | | | | | | | | | | | | 1 | | | | | | | | |
| Pelvis, Transitional Epithelium, Hyperplasia | | | | | | | | | | | | | | 1 | | | | | | | | | |
| Pelvis, Transitional Epithelium, Metaplasia | | | | | | | | | | | | | | | | | | | | | | | |
| Renal Tubule, Dilatation | | | | | | | | | | | | | | | | | | | | | | | |
| Renal Tubule, Necrosis | | | | | | | | | | | | | | | | 3 | | | | | | | |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
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TDMS No. 20007 - 05
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 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
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 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 | 0727 | 0647 | | 0777 | 0677 | 0767 | 0777 | 0677 |
| 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 | 00333 | 00333 |

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 | 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 | 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
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1-4 .. Lesion qualified as:
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 2) Mild 4) Marked

| DAY ON TEST | FISCHER 344 RATS FEMALE | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | | | | | |
|-------------------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|------|------|------|------|------|------|-----|-----|
| | 0730 | 0622 | 0722 | 0700 | 0672 | 0772 | 0772 | 0772 | 0572 | 0762 | 0762 | 0562 | 0662 | 0732 | 0632 | 0532 | 0632 | 0722 | 0722 | 0642 | | 0722 | 0672 | 0672 | 0672 | 0672 | 0672 | | |
| ANIMAL ID | 0.3 G/KG | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | | | | | |
| | 0032 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | | |
| Bile Duct, Hyperplasia | | | | 2 | | | 1 | | | | 1 | | | | | | | 1 | | | 1 | | | | | | 10 | 1.3 | |
| Hepatocyte, Hypertrophy | | | | | | | | | | | | | | | | | 1 | | | | | 1 | | | 2 | | 3 | 1.3 | |
| Oval Cell, Hyperplasia | | | | 1 | | | | | | | | | | | | | | | | | | | | | | | 2 | 1.0 | |
| 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 | | | | | | | | | | | | | | | | | | | | | | | | | | | 7 | 2.1 | |
| Ulcer | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 2.3 | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | 8 | 1.8 | |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Amyloid Deposition | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 1 | 3.0 | |
| Tooth | | | | | | | | | | | | | | | | | | | | | | | | | | | 4 | | |
| Malformation | | | | | | | | | | | | | | | | | | | | | | | | | | | 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 | 0665 | 0566 | 0773 | 0663 | 0772 | 0772 | 0664 | 0772 | | 0663 | 0773 | 0660 |
| ANIMAL ID | 00326 | 00332 | 00332 | 00332 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 |
| 0.3 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 |

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

| FISCHER 344 RATS FEMALE 0.3 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | | |
|-------------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|-------|-------|-------|-------|-------|
| | 0730 | 0622 | 0729 | 0720 | 0672 | 0772 | 0772 | 0772 | 0572 | 0762 | 0762 | 0672 | 0662 | 0552 | 0662 | 0732 | 0632 | 0722 | 0722 | 0662 | | 0772 | 0662 | 0772 | 0672 | 0772 |
| ANIMAL ID | 00326 | 00332 | 00332 | 00332 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 | 00333 |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 0 |

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|-----|
| Clitoral Gland Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| | | | | | | | | | | | 2 | | | | | | | | | | | | | | | | 5 | 2.0 | |
| Ovary Cyst | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| | | | | | | 1 | | | | | | | | | | | | | | | | | | | | | 6 | 2.3 | |
| Uterus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Endometrium, Hyperplasia, Adenomatous | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Endometrium, Hyperplasia, Cystic | | | | | | | | | | | | | | | | | | | | | | | | | | | | 6 | 2.0 |
| Stroma, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|-----|-----|
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | |
| Hyperplasia | 2 | 4 | | 3 | 1 | | | | 1 | | | | | | 1 | | | | | | | | | | | | | 19 | 2.2 | |
| Inflammation, Histiocytic | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 | |
| Myelofibrosis | | | | | 2 | | | | | | | | | | | | | | | | | | | | | | | 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 | M | M | M | 0 | | |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| Spleen | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Accessory Spleen | | | X | | | | | | | | | | | | | | | | | | | | | | | | | 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

| FISCHER 344 RATS FEMALE 0.3 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|-------------------------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----------|-------|
| | 0730 | 0622 | 0729 | 0705 | 0672 | 0772 | 0722 | 0729 | 0708 | 0759 | 0779 | 0663 | 0673 | 0534 | 0662 | 0673 | 0633 | 0628 | 0779 | 0664 | 0779 | 0673 | 0677 | 0700 | | 0700 |
| ANIMAL ID | 00326 | 00032 | 00032 | 00032 | 00033 | 00033 | 00033 | 00033 | 00033 | 00033 | 00033 | 00033 | 00033 | 00033 | 00033 | 00033 | 00033 | 00033 | 00033 | 00033 | 00033 | 00033 | 00033 | 00033 | 00033 | 00033 |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|--|--|---|---|---|---|---|---|---|---|---|---|---|---|---|--|--|--|---|---|---|--|---|---|---|---------------|--------------|
| 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 | 3 | 2 | 3 | 3 | 47 3.1 |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Galactocoele | | | | | 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 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

| DAY ON TEST | FISCHER 344 RATS FEMALE | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | | | |
|-------------|-------------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|------|------|------|------|------|------|
| | 0730 | 0622 | 0729 | 0705 | 0672 | 0772 | 0772 | 0772 | 0572 | 0757 | 0667 | 0766 | 0555 | 0667 | 0733 | 0636 | 0533 | 0633 | 0722 | 0722 | | 0677 | 0776 | 0777 | 0667 | 0777 | 0677 |
| ANIMAL ID | 0032 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 | 0033 |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 0 | 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 1.0 | |
| Alveolar Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 6 1.8 | |
| Alveolus, Infiltration Cellular, Histiocyte | 1 | | | 2 | | | | 1 | | | | 1 | | | | | | | | | | | | | | | |
| Nose | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | |
| Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | | 2 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 | | | | | | | | | | | | | | | | | | | | | | | | | | 5 2.4 | |
| Retina, Dysplasia | 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 | | | | | | | | | | | | | | | | | | | | ANIMAL ID | females (cont...) |
|--|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-----------|----------------------|
| | 0730 | 0728 | 0768 | 0773 | 0777 | 0747 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | | |
| Centrilobular, Necrosis Hepatocyte, Hypertrophy | 2 | 1 | 3 | 2 | 3 | | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | | 2 | | 2 | 2 | 1 | 1 | 1 |
| Mesentery Fat, Necrosis | | + | 3 | | | | | | | | | | | | | | + | + | | | + | |
| Pancreas Atrophy Inflammation Acinus, Metaplasia, Hepatocyte | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | | | | 2 | | 3 | 1 | 1 | | 1 | 3 | | | 1 | | | | 1 | | | 1 | 3 |
| | | | | | 2 | | | | | | | 1 | | | | | | 1 | | | 1 | 1 |
| Salivary Glands Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Stomach, Forestomach Inflammation Ulcer Epithelium, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | | | | | | | | | | | | | 1 | | 1 | | | | | | 2 | 2 |
| | | | | | | | | | | | | | | 1 | | 2 | | | | | 3 | 3 |
| | | | | | | | | 1 | | | | 1 | | | 2 | | | | | | 3 | 3 |
| | | | | | | | | | | | | | | | | | | | | | | 1 |
| | | | | | | | | | | | | | | | | | | | | | | 2 |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Tooth Malformation Peridontal Tissue, Inflammation | | | | | | | | | | | | | | | | | | | | | | |

CARDIOVASCULAR SYSTEM

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

| FISCHER 344 RATS FEMALE | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | ANIMAL ID | females (cont...) | | |
|-------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-----------|-------------------|-------|------|
| | 0730 | 0738 | 0768 | 0773 | 0774 | 0778 | 0779 | 0780 | 0782 | 0783 | 0784 | 0785 | 0786 | 0787 | 0788 | 0789 | 0790 | 0791 | 0792 | 0793 | 0794 | 0795 | 0796 | 0797 | | | 0798 | 0799 |
| 1.0 G/KG | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 00351 | |

Atrium, Thrombosis

2

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Degeneration, Cystic | | | | | | | | | | | | 1 | | | | 2 | | | | | | | | | | 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 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pars Distalis, Hyperplasia | | | | 2 | 4 | 2 | | 1 | 1 | 1 | | | 3 | | | 1 | | | | | 4 | | | 4 | | 2 |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| C-cell, Hyperplasia | 1 | | | | | | | | | | | | | | | | | | | | | | | | | |
| Follicle, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Follicular Cell, Hyperplasia | | | | 1 | | | | | 1 | | | | | | | | | | | | | | | | | 2 |

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 9 | 0 4 8 0 | 0 7 3 0 | 0 7 3 0 | 0 7 2 8 | 0 7 3 8 | 0 7 3 0 | 0 7 2 8 | 0 7 3 0 | 0 1 3 1 | 0 7 2 0 | 0 6 1 9 | 0 6 3 6 | 0 7 8 0 | 0 7 3 0 | 0 7 2 0 | | 0 7 3 0 | 0 7 3 0 | 0 7 2 8 | 0 6 8 7 |
| | 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 6 0 | 0 0 3 6 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 |

GENITAL SYSTEM

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

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone Marrow Hyperplasia Myelofibrosis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| | | | | | 3 | 2 | | | | | | | | | 2 | | 1 | 1 | | 1 | 3 | 1 | 1 | 2 | |
| 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 | | |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Spleen Fibrosis Hematopoietic Cell Proliferation Pigmentation, Hemosiderin Lymphoid Follicle, Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | 1 | | | 1 | 1 | 2 | | 1 | 1 | 2 | 2 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 2 | 1 | | 2 | 2 | 2 |
| Thymus | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |

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 + .. Tissue examined microscopically
 X .. Lesion present
 I .. Insufficient tissue

M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically

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

TDMS No. 20007 - 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...) |
|-------------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------------------|
| | 0730 | 0728 | 0726 | 0724 | 0722 | 0720 | 0718 | 0716 | 0714 | 0712 | 0710 | 0708 | 0706 | 0704 | 0702 | 0630 | 0628 | 0626 | 0624 | 0622 | 0620 | 0618 | 0616 | 0614 | 0612 | |
| 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 | |

Atrophy 2 3 3 3 2 3 3 3 3 2 4 3 3 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 2

Inflammation, Chronic Active 1 1 1

Alveolar Epithelium, Hyperplasia 1 1 1 4

Alveolus, Infiltration Cellular, Histiocyte 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
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 Lab: BAT

| FISCHER 344 RATS FEMALE 1.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | ANIMAL ID | females (cont...) | | | | | |
|-------------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-----------|----------------------|------|------|------|------|------|
| | 0730 | 0738 | 0768 | 0773 | 0774 | 0778 | 0779 | 0780 | 0781 | 0782 | 0783 | 0784 | 0785 | 0786 | 0787 | 0788 | 0789 | 0790 | 0791 | 0792 | | | 0793 | 0794 | 0795 | 0796 | 0797 |
| | 0 | 0 | 0 | 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 | 7 | 1 | 7 | 6 | 6 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 8 |
| | 3 | 2 | 8 | 3 | 3 | 8 | 3 | 3 | 2 | 2 | 3 | 3 | 2 | 1 | 3 | 2 | 1 | 3 | 8 | 3 | 3 | 3 | 3 | 2 | 8 | 7 | 8 |
| | 0 | 8 | 8 | 0 | 0 | 9 | 0 | 0 | 8 | 8 | 0 | 0 | 9 | 1 | 0 | 9 | 6 | 0 | 8 | 0 | 9 | 0 | 0 | 0 | 8 | 7 | 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 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 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 | 5 | 5 |

Trachea +

SPECIAL SENSES SYSTEM

Ear +

Eye +

Cornea, Fibrosis
 Cornea, Inflammation 2
 Lens, Cataract 1 4
 Posterior Chamber, Inflammation 1
 Retina, Degeneration 2 1 2 4 2
 Retina, Gliosis 2

Harderian Gland +

Zymbal's Gland

URINARY SYSTEM

Kidney +

Accumulation, Hyaline Droplet 3
 Infarct 2
 Mineralization 1
 Nephropathy 3 1 1 1 1 1 1 1 1 1 2 1 1 1 1 2 1 3 2 1 1 1
 Papilla, Necrosis
 Pelvis, Inflammation 2 2 1
 Pelvis, Transitional Epithelium, Hyperplasia 1 1 1
 Renal Tubule, Necrosis

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 + .. Tissue examined microscopically
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 I .. Insufficient tissue
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 BLANK .. Not examined microscopically
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TDMS No. 20007 - 05
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 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
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 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|-------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|------------------------------|
| FISCHER 344 RATS FEMALE 1.0 G/KG | DAY ON TEST | 07 | 07 | 06 | 07 | 07 | 04 | 07 | 07 | 07 | 07 | 07 | 07 | 07 | 01 | 07 | 06 | 06 | 07 | 06 | 07 | 07 | 07 | 07 | 06 | females (cont...) |
| | | 30 | 28 | 88 | 30 | 30 | 89 | 30 | 30 | 28 | 28 | 30 | 30 | 21 | 30 | 29 | 66 | 08 | 38 | 30 | 29 | 30 | 33 | 28 | 78 | |
| | 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 | |

Urinary Bladder

+ +

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 Lab: BAT

| FISCHER 344 RATS FEMALE | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|-------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|
| | 078 | 073 | 072 | 073 | 064 | 070 | 072 | 065 | 069 | 064 | 078 | 074 | 073 | 070 | 077 | 072 | 078 | 073 | 072 | 073 | 073 | 039 | 055 | 059 | |
| 1.0 G/KG | 0076 | 0037 | 0027 | 0037 | 0004 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 50 |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|--------|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Parasite Metazoan | X | | | | | | | | | | | | | | | X | X | | | | | | | 6 | |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | 3 1.3 |
| Basophilic Focus | | | | | X | X | | | X | X | | | | X | | | | | | | | | | | 11 |
| Clear Cell Focus | X | X | | | | | X | | | | | | | | | | | | X | | X | | | | 8 |
| Degeneration, Cystic | | | | | | | X | | | | | | | X | X | X | | X | X | X | X | | | | 1 1.0 |
| Eosinophilic Focus | | X | | X | | | X | | | | | | X | X | X | | X | X | X | X | | | | | 23 |
| Fatty Change, Diffuse | 1 | | | | | | | | | 1 | 1 | | | | | | 1 | | | | | | | | 11 1.1 |
| Hepatodiaphragmatic Nodule | | X | | | | | X | | | | | | | | | | | | | | | | | | 2 |
| Inflammation, Chronic Active | 1 | 1 | | 1 | | 1 | 1 | | 1 | 1 | | 1 | 1 | | | 1 | 1 | 1 | 1 | 1 | 1 | | | 35 1.0 | |
| Mixed Cell Focus | | | | | | | X | | | | | | | | | | | X | | | | | | | 3 |
| Pigmentation, Hemosiderin | | | | | | 2 | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Bile Duct, Hyperplasia | | | | 1 | | 1 | 1 | 1 | | | | | | | 1 | 1 | 1 | 1 | 1 | | | | 2 | | 10 1.1 |
| Centrilobular, Fatty Change | | | | | | | | | | | | | | | 2 | | | | 2 | | | | | | 2 2.0 |

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 Kava kava extract
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 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 | 065 | 064 | 079 | 078 | 074 | 071 | 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 |

* .. 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 2 |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| C-cell, Hyperplasia | | 2 | | | | | | | | | | 1 | | | | | | | | | 1 | | 4 1.3 |
| Follicle, Cyst | | | | | | | | | 1 | | | | | | | | | | | | | 2 | 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 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 2 | 6 | 7 | 7 | 1 | 1 | 7 | 7 | 7 | 7 | 7 | 3 | 7 | 7 | 7 | 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 | 0 | |
| | 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 | 4 | |
| | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | |

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|-----|
| Clitoral Gland Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | 49 | 1 | 1.0 |
| Ovary Cyst | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 5 | 1.6 |
| Uterus Hemorrhage | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 | 3.0 |
| Endometrium, Hyperplasia, Cystic | | | | 1 | 1 | | | | | | | | | 1 | 3 | | | 2 | | | | 1 | | | | | 10 | 1.5 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|-----|-----|
| Bone Marrow Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 23 | 2.0 | |
| Myelofibrosis | | | 4 | | 3 | 2 | | | | 2 | 1 | | | | 1 | | 1 | 4 | | 2 | | 3 | 1 | | | 3 | | 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 | M | M | | | 0 |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | 50 |
| Spleen Fibrosis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 2 | 2.5 |
| Hematopoietic Cell Proliferation | 1 | | | | | | | | | 3 | | | | | 1 | | | | | | | 1 | | | | | | 7 | 1.3 |
| Pigmentation, Hemosiderin | 1 | 2 | | 1 | 1 | | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | | 42 | 1.3 | |
| Lymphoid Follicle, Atrophy | | | | | | | | | | | | | | 2 | | | | | | | | | | 2 | | | | 2 | 2.0 |
| Thymus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | | | 48 | |

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

+ .. Tissue examined microscopically

X .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

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 | 069 | 074 | 079 | 078 | 011 | 011 | 077 | 077 | 077 | 077 | 037 | 077 | 077 | 037 | 053 | 055 | |
| 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 | 00399 | 00400 |

Atrophy 2 3 3 3 3 3 4 3 3 2 1 3 3 3 3 3 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 2 7 1.6
 Alveolus, Infiltration Cellular, Histiocyte 1 1 1 1 16 1.0
 Nose + 50
 Inflammation 2 1 1 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 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
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TDMS No. 20007 - 05
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 Kava kava extract
 CAS Number: 9000-38-8

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 Lab: BAT

| FISCHER 344 RATS FEMALE 1.0 G/KG | DAY ON TEST | | | | | | | | | | | | | | | | | | | | * TOTALS | | | |
|--|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| | 0 7 2 8 | 0 7 3 0 | 0 7 2 9 | 0 7 3 0 | 0 6 6 4 | 0 7 3 0 | 0 7 2 9 | 0 2 6 5 | 0 6 9 4 | 0 7 2 9 | 0 7 2 8 | 0 1 9 4 | 0 1 4 0 | 0 7 3 0 | 0 7 3 0 | 0 7 2 1 | 0 7 2 8 | 0 3 8 0 | 0 7 2 9 | 0 7 3 0 | | 0 7 3 0 | 0 3 9 9 | 0 5 5 9 |
| ANIMAL ID | 0 0 3 7 6 | 0 0 3 7 7 | 0 0 3 7 8 | 0 0 3 7 9 | 0 0 3 8 0 | 0 0 3 8 1 | 0 0 3 8 2 | 0 0 3 8 3 | 0 0 3 8 4 | 0 0 3 8 5 | 0 0 3 8 6 | 0 0 3 8 7 | 0 0 3 8 8 | 0 0 3 8 9 | 0 0 3 9 0 | 0 0 3 9 1 | 0 0 3 9 2 | 0 0 3 9 3 | 0 0 3 9 4 | 0 0 3 9 5 | 0 0 3 9 6 | 0 0 3 9 7 | 0 0 3 9 8 | 0 0 3 9 9 |
| 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 | 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
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Kava kava extract
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| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|-----------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|---|
| FISCHER 344 RATS FEMALE 1.0 G/KG | DAY ON TEST | 078 | 078 | 079 | 079 | 064 | 070 | 072 | 065 | 074 | 079 | 078 | 074 | 070 | 077 | 077 | 073 | 078 | 079 | 079 | 073 | 077 | 073 | 059 | 059 | |
| | ANIMAL ID | 00376 | 00378 | 00379 | 00380 | 00381 | 00382 | 00383 | 00384 | 00385 | 00386 | 00387 | 00388 | 00389 | 00390 | 00391 | 00392 | 00393 | 00394 | 00395 | 00396 | 00397 | 00398 | 00399 | 00400 | |
| | Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| * TOTALS | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 50 | | | | | | | | | | | | | | | | | | | | | | | | | | |

*** END OF REPORT ***

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 X .. Lesion present
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