

TDMS No. 20116 - 04
Test Type: CHRONIC
Route: DOSED WATER
Species/Strain: MICE/B6C3F1/NCTR

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
Aloe vera whole leaf extract (native)
CAS Number: ALOEVLEAFEXT

Date Report Requested: 01/15/2010
Time Report Requested: 14:39:08
First Dose M/F: 04/19/05 / 04/19/05
Lab: NCTR

C Number: C20116B
Lock Date: 09/08/2009
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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Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE CONTROL WATER ALOEWHOLLEAF 1.0 ALOEWHOLLEAF 2.0 ALOEWHOLLEAF 3.0

Disposition Summary

| | | | | |
|---|-----------|-----------|-----------|-----------|
| Animals Initially In Study | 48 | 48 | 48 | 48 |
| Early Deaths | | | | |
| Moribund Sacrifice | 16 | 16 | 23 | 15 |
| Natural Death | | 2 | 4 | 4 |
| Survivors | | | | |
| Natural Death | 1 | 1 | | 1 |
| Terminal Sacrifice | 31 | 28 | 21 | 28 |
| Animals Examined Microscopically | 48 | 47 | 48 | 48 |

ALIMENTARY SYSTEM

| | | | | |
|-----------------------------------|---------|----------|----------|----------|
| Esophagus | (48) | (46) | (47) | (47) |
| Gallbladder | (46) | (43) | (45) | (43) |
| Intestine Large, Ascending Colon | (47) | (44) | (45) | (42) |
| Goblet Cell, Hyperplasia | 2 (4%) | 16 (36%) | 20 (44%) | 19 (45%) |
| Intestine Large, Cecum | (47) | (44) | (44) | (43) |
| Hyperplasia, Lymphoid | 2 (4%) | | | |
| Goblet Cell, Hyperplasia | | | | 1 (2%) |
| Intestine Large, Descending Colon | (47) | (44) | (45) | (43) |
| Goblet Cell, Hyperplasia | | 7 (16%) | 12 (27%) | 17 (40%) |
| Intestine Large, Transverse Colon | (47) | (44) | (45) | (43) |
| Goblet Cell, Hyperplasia | 4 (9%) | 14 (32%) | 21 (47%) | 22 (51%) |
| Intestine Small, Duodenum | (47) | (44) | (44) | (44) |
| Intestine Small, Ileum | (47) | (44) | (45) | (43) |
| Hyperplasia, Lymphoid | 1 (2%) | | | |
| Intestine Small, Jejunum | (47) | (44) | (43) | (43) |
| Hyperplasia, Lymphoid | | | 1 (2%) | 1 (2%) |
| Liver | (47) | (46) | (47) | (46) |
| Angiectasis | | | | 1 (2%) |
| Basophilic Focus | 8 (17%) | 6 (13%) | 5 (11%) | 5 (11%) |
| Basophilic Focus, Multiple | | | | 1 (2%) |
| Congestion | 1 (2%) | | | |
| Cyst | 1 (2%) | | | 1 (2%) |
| Deformity | 1 (2%) | | | |

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

| C57BL/6N XC3H/HEN MTV-NCTR MICE MALE | CONTROL WATER | ALOEWHOLLEAF 1.0 | ALOEWHOLLEAF 2.0 | ALOEWHOLLEAF 3.0 |
|--|---------------|------------------|------------------|------------------|
| Degeneration, Cystic | 1 (2%) | | | |
| Eosinophilic Focus | 1 (2%) | | | |
| Fatty Change | 1 (2%) | | | |
| Infiltration Cellular, Lymphocyte | 1 (2%) | 1 (2%) | 2 (4%) | 4 (9%) |
| Infiltration Cellular, Polymorphonuclear | | | | 1 (2%) |
| Inflammation, Chronic Active | 1 (2%) | 1 (2%) | 1 (2%) | 3 (7%) |
| Karyomegaly | | | | 1 (2%) |
| Mixed Cell Focus | 3 (6%) | | | |
| Necrosis | | 1 (2%) | 1 (2%) | 1 (2%) |
| Tension Lipidosis | | 7 (15%) | 4 (9%) | 2 (4%) |
| Thrombus | | 1 (2%) | | |
| Vacuolization Cytoplasmic | 3 (6%) | 2 (4%) | 2 (4%) | 2 (4%) |
| Mesentery | (0) | (4) | (2) | (4) |
| Fat, Necrosis | | 4 (100%) | 2 (100%) | 3 (75%) |
| Pancreas | (47) | (46) | (47) | (45) |
| Infiltration Cellular, Lymphocyte | 2 (4%) | 3 (7%) | 1 (2%) | 4 (9%) |
| Vacuolization Cytoplasmic | 1 (2%) | 2 (4%) | 3 (6%) | 1 (2%) |
| Acinus, Degeneration | 3 (6%) | 2 (4%) | | |
| Duct, Dilatation | | | 1 (2%) | |
| Salivary Glands | (48) | (45) | (46) | (45) |
| Infiltration Cellular, Lymphocyte | 39 (81%) | 31 (69%) | 23 (50%) | 29 (64%) |
| Stomach, Forestomach | (47) | (45) | (45) | (44) |
| Epithelium, Hyperplasia | 1 (2%) | | | |
| Stomach, Glandular | (47) | (44) | (45) | (45) |
| Inflammation, Chronic Active | | | 1 (2%) | 1 (2%) |
| Epithelium, Hyperplasia | 1 (2%) | 2 (5%) | 3 (7%) | 2 (4%) |

CARDIOVASCULAR SYSTEM

| | | | | |
|------------------------------|--------|------|--------|--------|
| Blood Vessel | (48) | (47) | (47) | (47) |
| Heart | (48) | (47) | (47) | (47) |
| Cardiomyopathy | 2 (4%) | | 2 (4%) | 1 (2%) |
| Inflammation, Chronic Active | 1 (2%) | | | |

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

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C57BL/6N XC3H/HEN MTV-NCTR MICE MALE CONTROL WATER ALOEWHOLLEAF 1.0 ALOEWHOLLEAF 2.0 ALOEWHOLLEAF 3.0

ENDOCRINE SYSTEM

| | | | | |
|-----------------------------------|----------|----------|----------|----------|
| Adrenal Cortex | (48) | (44) | (46) | (45) |
| Accessory Adrenal Cortical Nodule | 3 (6%) | | | 1 (2%) |
| Cyst | | | | 1 (2%) |
| Hematopoietic Cell Proliferation | | | 1 (2%) | |
| Hypertrophy | | 1 (2%) | | 1 (2%) |
| Mineralization | 1 (2%) | | | |
| Subcapsular, Hyperplasia | 43 (90%) | 34 (77%) | 32 (70%) | 35 (78%) |
| Adrenal Medulla | (47) | (44) | (46) | (44) |
| Hyperplasia | 4 (9%) | 2 (5%) | 5 (11%) | 4 (9%) |
| Islets, Pancreatic | (47) | (46) | (46) | (45) |
| Hyperplasia | 9 (19%) | 3 (7%) | 1 (2%) | 2 (4%) |
| Parathyroid Gland | (44) | (46) | (42) | (41) |
| Cyst | 1 (2%) | | | |
| Infiltration Cellular, Lymphocyte | | | 1 (2%) | |
| Pituitary Gland | (48) | (45) | (45) | (45) |
| Pars Distalis, Cyst | | 1 (2%) | 4 (9%) | 3 (7%) |
| Pars Intermedia, Hyperplasia | 1 (2%) | | | |
| Thyroid Gland | (47) | (46) | (47) | (45) |
| Cyst | | 1 (2%) | | |
| Ectopic Thymus | 1 (2%) | | | |
| Infiltration Cellular, Lymphocyte | 1 (2%) | 3 (7%) | 1 (2%) | 3 (7%) |
| Inflammation, Chronic Active | | | 2 (4%) | |
| Follicle, Degeneration | 6 (13%) | 6 (13%) | 3 (6%) | 4 (9%) |
| Follicular Cell, Hyperplasia | | 1 (2%) | | |

GENERAL BODY SYSTEM

| | | | | |
|------------|-----|-----|---------|-----|
| Tissue NOS | (1) | (1) | (3) | (0) |
| Cyst | | | 1 (33%) | |

GENITAL SYSTEM

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

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Lab: NCTR

| C57BL/6N XC3H/HEN MTV-NCTR MICE MALE | CONTROL WATER | ALOEWHOLLEAF 1.0 | ALOEWHOLLEAF 2.0 | ALOEWHOLLEAF 3.0 |
|--------------------------------------|---------------|------------------|------------------|------------------|
| Coagulating Gland | (1) | (1) | (0) | (0) |
| Lumen, Dilatation | 1 (100%) | | | |
| Epididymis | (48) | (44) | (46) | (45) |
| Atrophy | | | 1 (2%) | |
| Degeneration | 1 (2%) | | | |
| Fibrosis | | | 1 (2%) | |
| Hypospermia | 1 (2%) | 2 (5%) | 2 (4%) | |
| Infiltration Cellular, Lymphocyte | | 2 (5%) | | |
| Inflammation, Chronic Active | | | | 1 (2%) |
| Spermatocoele | | 1 (2%) | 1 (2%) | |
| Serosa, Hyperplasia | | | | 1 (2%) |
| Penis | (0) | (1) | (0) | (0) |
| Inflammation, Chronic Active | | 1 (100%) | | |
| Necrosis | | 1 (100%) | | |
| Ulcer | | 1 (100%) | | |
| Preputial Gland | (47) | (44) | (46) | (45) |
| Cyst | 4 (9%) | 6 (14%) | 5 (11%) | 4 (9%) |
| Degeneration | 15 (32%) | 11 (25%) | 10 (22%) | 17 (38%) |
| Infiltration Cellular, Lymphocyte | 3 (6%) | 4 (9%) | 4 (9%) | 5 (11%) |
| Inflammation, Suppurative | 2 (4%) | 6 (14%) | 6 (13%) | 1 (2%) |
| Inflammation, Chronic Active | 1 (2%) | 4 (9%) | 4 (9%) | |
| Bilateral, Cyst | | | 1 (2%) | |
| Duct, Ectasia | 3 (6%) | 6 (14%) | 3 (7%) | |
| Fat, Necrosis | 1 (2%) | | 1 (2%) | 1 (2%) |
| Prostate | (47) | (44) | (46) | (44) |
| Infiltration Cellular, Lymphocyte | 7 (15%) | 7 (16%) | 6 (13%) | 6 (14%) |
| Inflammation, Suppurative | | | 1 (2%) | |
| Inflammation, Chronic Active | | | | 1 (2%) |
| Seminal Vesicle | (48) | (44) | (47) | (44) |
| Atrophy | | | 1 (2%) | |
| Infiltration Cellular, Lymphocyte | | 1 (2%) | | |
| Inflammation, Suppurative | | | 1 (2%) | |
| Inflammation, Chronic Active | 1 (2%) | | | |
| Lumen, Dilatation | 5 (10%) | 4 (9%) | 4 (9%) | 5 (11%) |
| Testes | (47) | (44) | (45) | (44) |
| Interstitial Cell, Hyperplasia | | 1 (2%) | | 1 (2%) |

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C57BL/6N XC3H/HEN MTV-NCTR MICE MALE CONTROL WATER ALOEWHOLLEAF 1.0 ALOEWHOLLEAF 2.0 ALOEWHOLLEAF 3.0

Seminiferous Tubule, Degeneration 4 (9%) 4 (9%) 11 (24%) 3 (7%)

HEMATOPOIETIC SYSTEM

| | | | | |
|---|----------|----------|----------|----------|
| Bone Marrow | (47) | (45) | (47) | (45) |
| Hyperplasia | 8 (17%) | 9 (20%) | 13 (28%) | 7 (16%) |
| Lymph Node | (11) | (5) | (9) | (7) |
| Axillary, Hyperplasia, Lymphoid | 3 (27%) | | 2 (22%) | 1 (14%) |
| Axillary, Infiltration Cellular, Plasma Cell | | | 1 (11%) | |
| Inguinal, Hyperplasia, Lymphoid | 2 (18%) | | 3 (33%) | 1 (14%) |
| Inguinal, Infiltration Cellular, Plasma Cell | | 1 (20%) | 2 (22%) | 1 (14%) |
| Lumbar, Erythrophagocytosis | | | | 1 (14%) |
| Lumbar, Hyperplasia, Lymphoid | | 1 (20%) | | 1 (14%) |
| Lumbar, Infiltration Cellular, Plasma Cell | | | | 1 (14%) |
| Mediastinal, Hyperplasia, Lymphoid | 2 (18%) | | | |
| Mediastinal, Infiltration Cellular, Plasma Cell | 1 (9%) | | | |
| Pancreatic, Erythrophagocytosis | | | | 1 (14%) |
| Pancreatic, Infiltration Cellular, Plasma Cell | | | | 1 (14%) |
| Renal, Erythrophagocytosis | | | | 1 (14%) |
| Renal, Hyperplasia, Lymphoid | 1 (9%) | | 1 (11%) | |
| Renal, Infiltration Cellular, Plasma Cell | | | 1 (11%) | 1 (14%) |
| Lymph Node, Mandibular | (47) | (44) | (45) | (44) |
| Hyperplasia, Lymphoid | 9 (19%) | 5 (11%) | 4 (9%) | 2 (5%) |
| Infiltration Cellular, Plasma Cell | | 1 (2%) | 1 (2%) | 1 (2%) |
| Pigmentation | | 1 (2%) | | |
| Lymph Node, Mesenteric | (48) | (45) | (45) | (43) |
| Angiectasis | 5 (10%) | 1 (2%) | 2 (4%) | 1 (2%) |
| Hematopoietic Cell Proliferation | 1 (2%) | | | 1 (2%) |
| Hemorrhage | 10 (21%) | 13 (29%) | 10 (22%) | 11 (26%) |
| Hyperplasia, Lymphoid | 28 (58%) | 17 (38%) | 17 (38%) | 23 (53%) |
| Infiltration Cellular, Histiocyte | | | 2 (4%) | 4 (9%) |
| Infiltration Cellular, Plasma Cell | | | | 2 (5%) |
| Infiltration Cellular, Polymorphonuclear | | 1 (2%) | 2 (4%) | 1 (2%) |
| Thrombus | | 1 (2%) | | 1 (2%) |
| Sinus, Dilatation | 6 (13%) | 2 (4%) | 4 (9%) | 2 (5%) |

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C57BL/6N XC3H/HEN MTV-NCTR MICE MALE CONTROL WATER ALOEWHOLLEAF 1.0 ALOEWHOLLEAF 2.0 ALOEWHOLLEAF 3.0

| | | | | |
|----------------------------------|----------|----------|----------|----------|
| Spleen | (48) | (45) | (46) | (44) |
| Angiectasis | 1 (2%) | | 1 (2%) | |
| Depletion Lymphoid | | | 1 (2%) | |
| Hematopoietic Cell Proliferation | 20 (42%) | 15 (33%) | 18 (39%) | 14 (32%) |
| Hyperplasia, Lymphoid | 24 (50%) | 21 (47%) | 20 (43%) | 22 (50%) |
| Pigmentation | | | 1 (2%) | |
| Thymus | (41) | (39) | (37) | (40) |
| Atrophy | 22 (54%) | 19 (49%) | 17 (46%) | 23 (58%) |
| Hyperplasia, Lymphoid | 2 (5%) | 1 (3%) | | 1 (3%) |
| Mineralization | | | 1 (3%) | |

INTEGUMENTARY SYSTEM

| | | | | |
|------------------------------|--------|---------|--------|--------|
| Skin | (48) | (47) | (46) | (48) |
| Fibrosis | | 1 (2%) | 4 (9%) | |
| Hemorrhage | | | | 1 (2%) |
| Hyperplasia, Basal Cell | | | 1 (2%) | |
| Inflammation, Suppurative | 1 (2%) | 2 (4%) | 3 (7%) | 1 (2%) |
| Inflammation, Chronic | | | 1 (2%) | |
| Inflammation, Chronic Active | 1 (2%) | 3 (6%) | 4 (9%) | 2 (4%) |
| Metaplasia, Osseous | | | 1 (2%) | |
| Mineralization | 1 (2%) | 1 (2%) | 1 (2%) | |
| Necrosis | | | | 1 (2%) |
| Ulcer | 1 (2%) | | 4 (9%) | 3 (6%) |
| Epithelium, Hyperplasia | 1 (2%) | 6 (13%) | 4 (9%) | 4 (8%) |

MUSCULOSKELETAL SYSTEM

| | | | | |
|-----------------|-----|-----|-----|-----|
| Skeletal Muscle | (1) | (1) | (3) | (0) |
|-----------------|-----|-----|-----|-----|

NERVOUS SYSTEM

| | | | | |
|-----------------|----------|----------|----------|----------|
| Brain, Cerebrum | (47) | (46) | (46) | (43) |
| Mineralization | 29 (62%) | 24 (52%) | 24 (52%) | 24 (56%) |

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C57BL/6N XC3H/HEN MTV-NCTR MICE MALE

CONTROL WATER

ALOEWHOLLEAF 1.0

ALOEWHOLLEAF 2.0

ALOEWHOLLEAF 3.0

RESPIRATORY SYSTEM

| | | | | |
|---------------------------------------|---------|----------|----------|----------|
| Lung | (48) | (47) | (46) | (47) |
| Congestion | | 1 (2%) | | |
| Infiltration Cellular, Histiocyte | 5 (10%) | | 2 (4%) | |
| Infiltration Cellular, Lymphocyte | | | | 1 (2%) |
| Inflammation, Chronic Active | 1 (2%) | | | |
| Thrombus | | 1 (2%) | | |
| Alveolar Epithelium, Hyperplasia | | 5 (11%) | 4 (9%) | 2 (4%) |
| Nose | (48) | (47) | (47) | (47) |
| Hyaline Droplet | 6 (13%) | 31 (66%) | 39 (83%) | 13 (28%) |
| Posterior To Upper Incisor, Dysplasia | 1 (2%) | | 1 (2%) | |
| Trachea | (48) | (47) | (46) | (45) |

SPECIAL SENSES SYSTEM

| | | | | |
|--------------------------------------|--------|--------|--------|--------|
| Eye | (47) | (43) | (44) | (43) |
| Cataract | | | 1 (2%) | 1 (2%) |
| Cornea, Hyperplasia | | 1 (2%) | | |
| Cornea, Inflammation, Chronic Active | | 1 (2%) | | |
| Harderian Gland | (48) | (44) | (46) | (44) |
| Infiltration Cellular, Lymphocyte | 1 (2%) | 2 (5%) | 3 (7%) | 2 (5%) |
| Inflammation, Chronic Active | | | | 1 (2%) |
| Acinus, Degeneration | | 1 (2%) | | 1 (2%) |
| Acinus, Dilatation | | | | 1 (2%) |
| Epithelium, Hyperplasia | | | 1 (2%) | |

URINARY SYSTEM

| | | | | |
|-------------------|------|--------|--------|--------|
| Kidney | (48) | (45) | (46) | (45) |
| Cyst | | 3 (7%) | 2 (4%) | |
| Cyst Multilocular | | | | 1 (2%) |
| Fibrosis | | | 1 (2%) | |

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|--|---------------|------------------|------------------|------------------|
| Hyaline Droplet | | | 3 (7%) | |
| Infiltration Cellular, Lymphocyte | 10 (21%) | 8 (18%) | 10 (22%) | 12 (27%) |
| Inflammation, Chronic Active | | | | 1 (2%) |
| Metaplasia, Osseous | 2 (4%) | | 2 (4%) | |
| Nephropathy | 26 (54%) | 18 (40%) | 17 (37%) | 20 (44%) |
| Pigmentation | | | 1 (2%) | |
| Pelvis, Dilatation | | 1 (2%) | 1 (2%) | |
| Urethra | (1) | (0) | (0) | (1) |
| Bulbourethral Gland, Dilatation | 1 (100%) | | | |
| Bulbourethral Gland, Infiltration Cellular, Lymphocyte | 1 (100%) | | | |
| Urinary Bladder | (48) | (45) | (45) | (44) |
| Infiltration Cellular, Lymphocyte | 3 (6%) | 2 (4%) | 2 (4%) | 2 (5%) |
| Inflammation, Chronic Active | | | | 1 (2%) |
| Lumen, Dilatation | 3 (6%) | 1 (2%) | 1 (2%) | 1 (2%) |

*** END OF MALE ***

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Disposition Summary

| | CONTROL WATER | ALOEWOLLEAF 1.0 | ALOEWOLLEAF 2.0 | ALOEWOLLEAF 3.0 |
|---|---------------|-----------------|-----------------|-----------------|
| Animals Initially In Study | 48 | 48 | 48 | 48 |
| Early Deaths | | | | |
| Moribund Sacrifice | 6 | 12 | 8 | 6 |
| Natural Death | 5 | 4 | 3 | 5 |
| Survivors | | | | |
| Moribund Sacrifice | 1 | 1 | | 1 |
| Natural Death | | 1 | 1 | 2 |
| Terminal Sacrifice | 35 | 30 | 36 | 34 |
| Animals Examined Microscopically | 47 | 48 | 48 | 48 |

ALIMENTARY SYSTEM

| | CONTROL WATER | ALOEWOLLEAF 1.0 | ALOEWOLLEAF 2.0 | ALOEWOLLEAF 3.0 |
|-----------------------------------|---------------|-----------------|-----------------|-----------------|
| Gallbladder | (42) | (43) | (44) | (41) |
| Intestine Large, Ascending Colon | (43) | (43) | (44) | (43) |
| Goblet Cell, Hyperplasia | 1 (2%) | 15 (35%) | 20 (45%) | 25 (58%) |
| Intestine Large, Cecum | (42) | (43) | (44) | (42) |
| Hyperplasia, Lymphoid | 1 (2%) | | | |
| Goblet Cell, Hyperplasia | 1 (2%) | | 2 (5%) | 2 (5%) |
| Intestine Large, Descending Colon | (43) | (43) | (44) | (43) |
| Goblet Cell, Hyperplasia | | 4 (9%) | 7 (16%) | 17 (40%) |
| Intestine Large, Rectum | (43) | (43) | (44) | (42) |
| Intestine Large, Transverse Colon | (42) | (42) | (44) | (43) |
| Goblet Cell, Hyperplasia | 2 (5%) | 18 (43%) | 23 (52%) | 26 (60%) |
| Intestine Small, Duodenum | (43) | (43) | (44) | (42) |
| Intestine Small, Ileum | (42) | (43) | (44) | (42) |
| Hyperplasia, Lymphoid | | | 1 (2%) | 1 (2%) |
| Intestine Small, Jejunum | (42) | (43) | (44) | (42) |
| Liver | (45) | (44) | (46) | (46) |
| Autolysis | | | | 1 (2%) |
| Basophilic Focus | 1 (2%) | | 1 (2%) | 4 (9%) |
| Clear Cell Focus | | 1 (2%) | | |
| Cyst, Multiple | | | | 1 (2%) |
| Cytomegaly | | 1 (2%) | | |
| Eosinophilic Focus | 1 (2%) | | | 1 (2%) |

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

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE CONTROL WATER ALOEWHOLLEAF 1.0 ALOEWHOLLEAF 2.0 ALOEWHOLLEAF 3.0

| | | | | |
|--|----------|----------|----------|----------|
| Hematopoietic Cell Proliferation | 1 (2%) | 1 (2%) | | 2 (4%) |
| Infiltration Cellular, Lymphocyte | 10 (22%) | 6 (14%) | 6 (13%) | 9 (20%) |
| Inflammation, Chronic Active | 6 (13%) | 5 (11%) | 4 (9%) | 5 (11%) |
| Mixed Cell Focus | 1 (2%) | | 1 (2%) | 1 (2%) |
| Necrosis | 3 (7%) | 2 (5%) | 2 (4%) | 3 (7%) |
| Pigmentation | 1 (2%) | | 1 (2%) | |
| Tension Lipidosis | 7 (16%) | 5 (11%) | 2 (4%) | 5 (11%) |
| Vacuolization Cytoplasmic | 12 (27%) | 14 (32%) | 12 (26%) | 16 (35%) |
| Bile Duct, Hyperplasia | | 1 (2%) | | |
| Oval Cell, Hyperplasia | 1 (2%) | | | |
| Parenchyma, Degeneration | | | 1 (2%) | |
| Mesentery | (6) | (8) | (9) | (3) |
| Angiectasis | | | 1 (11%) | |
| Infiltration Cellular, Lymphocyte | | | 1 (11%) | |
| Inflammation, Chronic Active | | | 1 (11%) | |
| Fat, Hemorrhage | 1 (17%) | | | 1 (33%) |
| Fat, Infiltration Cellular, Histiocyte | | | | 1 (33%) |
| Fat, Necrosis | 6 (100%) | 8 (100%) | 8 (89%) | 2 (67%) |
| Oral Mucosa | (1) | (0) | (0) | (0) |
| Pancreas | (42) | (43) | (44) | (43) |
| Cyst | | | | 1 (2%) |
| Hemorrhage | | | | 1 (2%) |
| Infiltration Cellular, Lymphocyte | 11 (26%) | 4 (9%) | 13 (30%) | 15 (35%) |
| Vacuolization Cytoplasmic | 1 (2%) | 2 (5%) | | |
| Acinus, Degeneration | 1 (2%) | 1 (2%) | 1 (2%) | |
| Duct, Dilatation | | | 1 (2%) | 1 (2%) |
| Salivary Glands | (43) | (43) | (44) | (43) |
| Infiltration Cellular, Lymphocyte | 29 (67%) | 31 (72%) | 31 (70%) | 26 (60%) |
| Stomach, Forestomach | (43) | (44) | (45) | (42) |
| Keratin Cyst | 1 (2%) | 1 (2%) | | |
| Epithelium, Hyperplasia | | 2 (5%) | 1 (2%) | 1 (2%) |
| Stomach, Glandular | (43) | (44) | (45) | (42) |
| Cyst | 1 (2%) | | | |
| Erosion | | | | 1 (2%) |
| Inflammation, Chronic Active | | 1 (2%) | | |
| Epithelium, Hyperplasia | | 1 (2%) | 3 (7%) | 4 (10%) |

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

TDMS No. 20116 - 04
 Test Type: CHRONIC
 Route: DOSED WATER
 Species/Strain: MICE/B6C3F1/NCTR

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

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Date Report Requested: 01/15/2010

Time Report Requested: 14:39:08

First Dose M/F: 04/19/05 / 04/19/05

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE CONTROL WATER ALOEWHOLLEAF 1.0 ALOEWHOLLEAF 2.0 ALOEWHOLLEAF 3.0

CARDIOVASCULAR SYSTEM

| | CONTROL WATER | ALOEWOLLEAF 1.0 | ALOEWOLLEAF 2.0 | ALOEWOLLEAF 3.0 |
|------------------------------|---------------|-----------------|-----------------|-----------------|
| Heart | (45) | (46) | (46) | (44) |
| Cardiomyopathy | 4 (9%) | 2 (4%) | 3 (7%) | |
| Inflammation, Chronic Active | | | 1 (2%) | |
| Mineralization | 1 (2%) | | | |

ENDOCRINE SYSTEM

| | CONTROL WATER | ALOEWOLLEAF 1.0 | ALOEWOLLEAF 2.0 | ALOEWOLLEAF 3.0 |
|-----------------------------------|---------------|-----------------|-----------------|-----------------|
| Adrenal Cortex | (44) | (43) | (44) | (44) |
| Vacuolization Cytoplasmic | 4 (9%) | 4 (9%) | 1 (2%) | 1 (2%) |
| Subcapsular, Hyperplasia | 43 (98%) | 43 (100%) | 43 (98%) | 44 (100%) |
| Adrenal Medulla | (44) | (42) | (44) | (44) |
| Hyperplasia | 1 (2%) | | 1 (2%) | |
| Pigmentation | | | | 1 (2%) |
| Islets, Pancreatic | (42) | (43) | (44) | (43) |
| Hyperplasia | 1 (2%) | 5 (12%) | 1 (2%) | 2 (5%) |
| Parathyroid Gland | (42) | (37) | (42) | (40) |
| Cyst | | 1 (3%) | 1 (2%) | |
| Infiltration Cellular, Lymphocyte | | | | 1 (3%) |
| Pituitary Gland | (43) | (38) | (41) | (44) |
| Thrombus | | | 1 (2%) | |
| Pars Distalis, Angiectasis | | | 1 (2%) | 1 (2%) |
| Pars Distalis, Cyst | | | 1 (2%) | 2 (5%) |
| Pars Distalis, Hyperplasia | 7 (16%) | 8 (21%) | 10 (24%) | 11 (25%) |
| Pars Intermedia, Angiectasis | | | 1 (2%) | |
| Thyroid Gland | (43) | (43) | (44) | (43) |
| Cyst | | 1 (2%) | 1 (2%) | |
| Ectopic Thymus | 2 (5%) | 1 (2%) | | |
| Infiltration Cellular, Lymphocyte | 3 (7%) | 1 (2%) | 2 (5%) | 6 (14%) |
| Inflammation, Suppurative | | | | 1 (2%) |
| Inflammation, Chronic Active | | | 1 (2%) | |
| Follicle, Degeneration | 6 (14%) | 10 (23%) | 9 (20%) | 6 (14%) |
| Follicular Cell, Hyperplasia | 3 (7%) | 1 (2%) | 1 (2%) | |

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TDMS No. 20116 - 04
 Test Type: CHRONIC
 Route: DOSED WATER
 Species/Strain: MICE/B6C3F1/NCTR

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

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Date Report Requested: 01/15/2010

Time Report Requested: 14:39:08

First Dose M/F: 04/19/05 / 04/19/05

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE CONTROL WATER ALOEWHOLLEAF 1.0 ALOEWHOLLEAF 2.0 ALOEWHOLLEAF 3.0

Follicular Cell, Hypertrophy 1 (2%)

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

| | | | | |
|----------------------------------|----------|-----------|----------|----------|
| Clitoral Gland | (44) | (44) | (44) | (42) |
| Degeneration | 43 (98%) | 44 (100%) | 43 (98%) | 40 (95%) |
| Ovary | (44) | (46) | (45) | (44) |
| Atrophy | 40 (91%) | 39 (85%) | 40 (89%) | 39 (89%) |
| Autolysis | | 1 (2%) | | |
| Cyst | 14 (32%) | 18 (39%) | 12 (27%) | 9 (20%) |
| Cyst, Multiple | 1 (2%) | | 2 (4%) | 2 (5%) |
| Hemorrhage | | | 1 (2%) | |
| Uterus | (46) | (45) | (44) | (45) |
| Angiectasis | | | 1 (2%) | |
| Autolysis | 1 (2%) | | | 1 (2%) |
| Edema | 1 (2%) | | | |
| Hydrometra | | 1 (2%) | | 1 (2%) |
| Thrombus | | 1 (2%) | 1 (2%) | 1 (2%) |
| Endometrium, Hyperplasia, Cystic | 43 (93%) | 44 (98%) | 43 (98%) | 43 (96%) |
| Lumen, Dilatation | 1 (2%) | | | |

HEMATOPOIETIC SYSTEM

| | | | | |
|--|---------|---------|---------|--------|
| Bone Marrow | (43) | (43) | (44) | (43) |
| Fibrosis | 1 (2%) | | | |
| Hyperplasia | 7 (16%) | 5 (12%) | 5 (11%) | 3 (7%) |
| Lymph Node | (14) | (15) | (12) | (13) |
| Axillary, Infiltration Cellular, Polymorphonuclear | | 1 (7%) | | |
| Iliac, Hyperplasia, Lymphoid | | | | 1 (8%) |
| Iliac, Infiltration Cellular, Plasma Cell | | | | 1 (8%) |

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TDMS No. 20116 - 04
 Test Type: CHRONIC
 Route: DOSED WATER
 Species/Strain: MICE/B6C3F1/NCTR

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

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Date Report Requested: 01/15/2010

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First Dose M/F: 04/19/05 / 04/19/05

Lab: NCTR

| C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE | CONTROL WATER | ALOEWHOLLEAF 1.0 | ALOEWHOLLEAF 2.0 | ALOEWHOLLEAF 3.0 |
|--|---------------|------------------|------------------|------------------|
| Iliac, Infiltration Cellular, Polymorphonuclear | | | | 1 (8%) |
| Lumbar, Hemorrhage | | | | 2 (15%) |
| Lumbar, Hyperplasia, Lymphoid | 3 (21%) | | 1 (8%) | 5 (38%) |
| Lumbar, Infiltration Cellular, Plasma Cell | 1 (7%) | | 1 (8%) | |
| Lumbar, Infiltration Cellular, Polymorphonuclear | 2 (14%) | 1 (7%) | | |
| Lumbar, Sinus, Dilatation | | | | 1 (8%) |
| Renal, Hemorrhage | | | | 1 (8%) |
| Renal, Hyperplasia, Lymphoid | 2 (14%) | | | 1 (8%) |
| Renal, Infiltration Cellular, Polymorphonuclear | 2 (14%) | | | |
| Lymph Node, Mandibular | (43) | (44) | (45) | (43) |
| Amyloid Deposition | | 1 (2%) | | |
| Hyperplasia, Lymphoid | 11 (26%) | 13 (30%) | 12 (27%) | 14 (33%) |
| Infiltration Cellular, Lymphocyte | | 1 (2%) | | |
| Infiltration Cellular, Plasma Cell | 1 (2%) | 2 (5%) | | |
| Infiltration Cellular, Polymorphonuclear | 1 (2%) | | 1 (2%) | |
| Lymph Node, Mesenteric | (43) | (45) | (43) | (42) |
| Amyloid Deposition | | 1 (2%) | | |
| Angiectasis | 1 (2%) | | 1 (2%) | |
| Hemorrhage | | 1 (2%) | | 2 (5%) |
| Hyperplasia, Lymphoid | 10 (23%) | 12 (27%) | 14 (33%) | 16 (38%) |
| Infiltration Cellular, Plasma Cell | 1 (2%) | 2 (4%) | | |
| Sinus, Dilatation | | | | 1 (2%) |
| Spleen | (44) | (46) | (45) | (44) |
| Amyloid Deposition | | 1 (2%) | | |
| Depletion Lymphoid | | | | 1 (2%) |
| Fibrosis, Stromal | 1 (2%) | | | |
| Hematopoietic Cell Proliferation | 16 (36%) | 13 (28%) | 9 (20%) | 12 (27%) |
| Hyperplasia, Lymphoid | 20 (45%) | 23 (50%) | 21 (47%) | 24 (55%) |
| Necrosis | | | 1 (2%) | |
| Pigmentation | 3 (7%) | 4 (9%) | 4 (9%) | 5 (11%) |
| Thrombus | 1 (2%) | | | |
| Thymus | (41) | (44) | (43) | (41) |
| Amyloid Deposition | | 1 (2%) | | |
| Atrophy | 10 (24%) | 14 (32%) | 17 (40%) | 10 (24%) |
| Cyst | | | | 1 (2%) |

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TDMS No. 20116 - 04
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 Species/Strain: MICE/B6C3F1/NCTR

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

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Date Report Requested: 01/15/2010

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First Dose M/F: 04/19/05 / 04/19/05

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE CONTROL WATER ALOEWHOLLEAF 1.0 ALOEWHOLLEAF 2.0 ALOEWHOLLEAF 3.0

| | | | | |
|------------------------------|---------|---------|---------|----------|
| Hyperplasia, Lymphoid | 8 (20%) | 7 (16%) | 8 (19%) | 12 (29%) |
| Necrosis | 1 (2%) | | | |
| Epithelial Cell, Hyperplasia | | | | 1 (2%) |

INTEGUMENTARY SYSTEM

| | | | | |
|-----------------------------------|--------|--------|--------|--------|
| Mammary Gland | (44) | (43) | (44) | (44) |
| Galactocele | 1 (2%) | | 1 (2%) | |
| Infiltration Cellular, Lymphocyte | | | 1 (2%) | 1 (2%) |
| Lactation | 2 (5%) | | 2 (5%) | |
| Alveolus, Hyperplasia | 4 (9%) | 3 (7%) | 3 (7%) | 3 (7%) |
| Skin | (44) | (46) | (45) | (44) |
| Fat, Necrosis | | | 1 (2%) | |

MUSCULOSKELETAL SYSTEM

| | | | | |
|---|--------|--------|---------|--------|
| Bone, Femur | (47) | (46) | (48) | (46) |
| Fibro-Osseous Lesion | 1 (2%) | 1 (2%) | 2 (4%) | 1 (2%) |
| Skeletal Muscle | (0) | (2) | (2) | (0) |
| Diaphragm, Inflammation, Chronic Active | | | 1 (50%) | |

NERVOUS SYSTEM

| | | | | |
|-----------------------------------|----------|----------|----------|----------|
| Brain, Brain Stem | (43) | (44) | (44) | (43) |
| Compression | 2 (5%) | 1 (2%) | 2 (5%) | 1 (2%) |
| Brain, Cerebellum | (43) | (44) | (44) | (43) |
| Infiltration Cellular, Lymphocyte | | | | 1 (2%) |
| Brain, Cerebrum | (43) | (44) | (44) | (43) |
| Infiltration Cellular, Lymphocyte | | | | 1 (2%) |
| Mineralization | 24 (56%) | 30 (68%) | 24 (55%) | 27 (63%) |

RESPIRATORY SYSTEM

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| C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE | CONTROL WATER | ALOEWHOLLEAF 1.0 | ALOEWHOLLEAF 2.0 | ALOEWHOLLEAF 3.0 |
|--|---------------|------------------|------------------|------------------|
|--|---------------|------------------|------------------|------------------|

| | | | | |
|-----------------------------------|----------|----------|----------|---------|
| Lung | (45) | (45) | (46) | (44) |
| Autolysis | 1 (2%) | | 1 (2%) | |
| Congestion | | | | 1 (2%) |
| Hemorrhage | 2 (4%) | 1 (2%) | | |
| Infiltration Cellular, Histiocyte | 5 (11%) | 4 (9%) | 3 (7%) | 1 (2%) |
| Infiltration Cellular, Lymphocyte | 4 (9%) | 2 (4%) | 2 (4%) | 3 (7%) |
| Inflammation, Chronic | | 1 (2%) | | |
| Inflammation, Chronic Active | 2 (4%) | 1 (2%) | | 1 (2%) |
| Metaplasia, Osseous | | 1 (2%) | | |
| Mineralization | | | 1 (2%) | |
| Alveolar Epithelium, Hyperplasia | | | 2 (4%) | 1 (2%) |
| Nose | (45) | (44) | (45) | (45) |
| Hyaline Droplet | 12 (27%) | 12 (27%) | 17 (38%) | 9 (20%) |
| Inflammation, Chronic Active | 1 (2%) | | | |

SPECIAL SENSES SYSTEM

| | | | | |
|--------------------------------------|----------|---------|---------|---------|
| Eye | (42) | (43) | (44) | (42) |
| Cataract | 2 (5%) | | 2 (5%) | |
| Phthisis Bulbi | | 1 (2%) | | |
| Cornea, Inflammation, Chronic Active | 1 (2%) | | | |
| Cornea, Ulcer | 1 (2%) | | | |
| Harderian Gland | (43) | (43) | (44) | (43) |
| Hyperplasia | | | | 1 (2%) |
| Infiltration Cellular, Lymphocyte | 6 (14%) | 5 (12%) | 5 (11%) | 5 (12%) |
| Epithelium, Hyperplasia | | 2 (5%) | | |
| Lacrimal Gland | (1) | (0) | (0) | (0) |
| Infiltration Cellular, Lymphocyte | 1 (100%) | | | |

URINARY SYSTEM

| | | | | |
|--------------------|--------|--------|------|--------|
| Kidney | (44) | (43) | (46) | (44) |
| Amyloid Deposition | 1 (2%) | 1 (2%) | | 2 (5%) |
| Autolysis | 1 (2%) | | | 1 (2%) |
| Cyst, Multiple | | 1 (2%) | | |

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TDMS No. 20116 - 04
Test Type: CHRONIC
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Species/Strain: MICE/B6C3F1/NCTR

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

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

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Lab: NCTR

| C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE | CONTROL WATER | ALOEWHOLLEAF 1.0 | ALOEWHOLLEAF 2.0 | ALOEWHOLLEAF 3.0 |
|--|---------------|------------------|------------------|------------------|
| Hyaline Droplet | 3 (7%) | 1 (2%) | 1 (2%) | 1 (2%) |
| Infiltration Cellular, Histiocyte | 1 (2%) | | | |
| Infiltration Cellular, Lymphocyte | 22 (50%) | 23 (53%) | 22 (48%) | 27 (61%) |
| Metaplasia, Osseous | | | 3 (7%) | 2 (5%) |
| Nephropathy | 5 (11%) | 6 (14%) | 7 (15%) | 6 (14%) |
| Polyarteritis | | | | 1 (2%) |
| Pelvis, Dilatation | | 1 (2%) | 2 (4%) | |
| Pelvis, Mineralization | | 1 (2%) | | |
| Transitional Epithelium, Hyperplasia | | 1 (2%) | | |
| Urinary Bladder | (43) | (43) | (44) | (42) |
| Infiltration Cellular, Lymphocyte | 22 (51%) | 22 (51%) | 22 (50%) | 25 (60%) |
| Lumen, Dilatation | | | 1 (2%) | |

*** END OF REPORT ***

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