| | |
|---|---|
| **C Number:** | C96011 |
| **Lock Date:** | 01/28/2004 |
| **Cage Range:** | ALL |
| **Date Range:** | ALL |
| **Reasons For Removal:** | ALL |
| **Removal Date Range:** | ALL |
| **Treatment Groups:** | Include ALL |

| FISCHER 344 RATS MALE | CONTROL | 250 PPM | 500 PPM | 1000 PPM |
|---|---|---|---|---|
| **Disposition Summary** | | | | |
| **Animals Initially in Study** | 50 | 50 | 50 | 50 |
| **Early Deaths** | | | | |
| **Moribund Sacrifice** | 20 | 24 | 21 | 24 |
| **Natural Death** | 4 | 3 | 2 | 2 |
| **Survivors** | | | | |
| **Terminal Sacrifice** | 26 | 23 | 27 | 24 |
| **Animals Examined Microscopically** | 50 | 50 | 50 | 50 |
| ALIMENTARY SYSTEM | | | | |
| Esophagus | (50) | (50) | (50) | (50) |
| Foreign Body | | 1 (2%) | | |
| Intestine Large, Cecum | (49) | (49) | (49) | (49) |
| Intestine Large, Colon | (49) | (50) | (50) | (50) |
| Diverticulum | 1 (2%) | | | |
| Intestine Large, Rectum | (49) | (50) | (50) | (50) |
| Intestine Small, Duodenum | (49) | (49) | (49) | (49) |
| Intestine Small, Ileum | (49) | (47) | (48) | (49) |
| Intestine Small, Jejunum | (48) | (47) | (48) | (49) |
| Inflammation, Chronic Active | 1 (2%) | | | |
| Thrombosis | 1 (2%) | | | |
| Ulcer | 1 (2%) | | | |
| Liver | (50) | (50) | (50) | (50) |
| Angiectasis | | 1 (2%) | | |
| Basophilic Focus | 7 (14%) | 4 (8%) | 8 (16%) | 6 (12%) |
| Clear Cell Focus | 12 (24%) | 6 (12%) | 11 (22%) | 11 (22%) |
| Degeneration, Cystic | 3 (6%) | 1 (2%) | 4 (8%) | 6 (12%) |
| Eosinophilic Focus | | 1 (2%) | 3 (6%) | |
| Eosinophilic Focus, Multiple | | | 1 (2%) | |
| Fatty Change, Diffuse | | 1 (2%) | | |
| Hepatodiaphragmatic Nodule | 3 (6%) | 8 (16%) | 2 (4%) | 3 (6%) |
| Inflammation, Suppurative | | 1 (2%) | | |
| Mixed Cell Focus | 1 (2%) | | 3 (6%) | 1 (2%) |
| Necrosis | 3 (6%) | 3 (6%) | 3 (6%) | 3 (6%) |
| Vacuolization Cytoplasmic | 6 (12%) | 2 (4%) | 3 (6%) | 2 (4%) |
| Bile Duct, Hyperplasia | 7 (14%) | 4 (8%) | 12 (24%) | 7 (14%) |
| Hepatocyte, Regeneration | 1 (2%) | | | |

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

| FISCHER 344 RATS MALE | CONTROL | 250 PPM | 500 PPM | 1000 PPM |
|---|---|---|---|---|
| Oval Cell, Hyperplasia | | | | 1 (2%) |
| Periportal, Inflammation, Chronic | | | 2 (4%) | |
| Mesentery | (7) | (13) | (10) | (6) |
| Hemorrhage | | 1 (8%) | | 1 (17%) |
| Necrosis | 6 (86%) | 10 (77%) | 10 (100%) | 3 (50%) |
| Fat, Hemorrhage | 1 (14%) | | | 1 (17%) |
| Fat, Necrosis | | 1 (8%) | | |
| Pancreas | (50) | (50) | (50) | (50) |
| Hyperplasia | | | | 1 (2%) |
| Vacuolization Cytoplasmic | | 1 (2%) | | |
| Acinus, Atrophy | 2 (4%) | 2 (4%) | 2 (4%) | 2 (4%) |
| Acinus, Hyperplasia | | | 1 (2%) | 3 (6%) |
| Stomach, Forestomach | (50) | (50) | (50) | (50) |
| Hemorrhage | 1 (2%) | | | |
| Inflammation, Suppurative | | | 2 (4%) | |
| Necrosis | 1 (2%) | | | |
| Ulcer | 3 (6%) | 7 (14%) | 1 (2%) | 8 (16%) |
| Epithelium, Hyperplasia | 6 (12%) | 11 (22%) | 7 (14%) | 10 (20%) |
| Stomach, Glandular | (50) | (50) | (50) | (50) |
| Erosion | 2 (4%) | 1 (2%) | 1 (2%) | 2 (4%) |
| Hyperplasia, Lymphoid | | | 1 (2%) | |
| Mineralization | 1 (2%) | | | |
| Ulcer | 3 (6%) | | 1 (2%) | 1 (2%) |
| Tongue | (1) | (3) | (1) | (3) |
| Epithelium, Hyperplasia | 1 (100%) | 2 (67%) | 1 (100%) | 3 (100%) |
| Tooth | (0) | (1) | (0) | (0) |
| Inflammation | | 1 (100%) | | |
| **CARDIOVASCULAR SYSTEM** | | | | |
| Blood Vessel | (1) | (1) | (1) | (0) |
| Mineralization | 1 (100%) | | | |
| Heart | (50) | (50) | (50) | (50) |
| Cardiomyopathy | 9 (18%) | 7 (14%) | 12 (24%) | 11 (22%) |
| Atrium, Thrombosis | 3 (6%) | 6 (12%) | 4 (8%) | 4 (8%) |
| Valve, Cardiomyopathy | 1 (2%) | | | |
| Valve, Hemorrhage | | | 1 (2%) | |
| Valve, Thrombosis | 1 (2%) | | | |
| Ventricle, Hypertrophy | | | | 1 (2%) |

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

| FISCHER 344 RATS MALE | CONTROL | 250 PPM | 500 PPM | 1000 PPM |
|---|---|---|---|---|
| **ENDOCRINE SYSTEM** | | | | |
| Adrenal Cortex | (50) | (50) | (50) | (50) |
| Hyperplasia | 17 (34%) | 16 (32%) | 10 (20%) | 10 (20%) |
| Hypertrophy | | | 1 (2%) | |
| Vacuolization Cytoplasmic | 8 (16%) | 5 (10%) | 7 (14%) | 4 (8%) |
| Adrenal Medulla | (50) | (50) | (50) | (50) |
| Hyperplasia | 11 (22%) | 13 (26%) | 18 (36%) | 12 (24%) |
| Bilateral, Hyperplasia | | | | 1 (2%) |
| Islets, Pancreatic | (50) | (50) | (50) | (50) |
| Hyperplasia | 1 (2%) | 1 (2%) | | |
| Parathyroid Gland | (45) | (49) | (49) | (48) |
| Hyperplasia | 1 (2%) | 1 (2%) | | |
| Pituitary Gland | (50) | (50) | (49) | (50) |
| Cyst | | 1 (2%) | 2 (4%) | |
| Hemorrhage | 1 (2%) | 1 (2%) | 1 (2%) | 3 (6%) |
| Hyperplasia | 6 (12%) | 7 (14%) | 13 (27%) | 6 (12%) |
| Pars Intermedia, Hyperplasia | 1 (2%) | | | |
| Thyroid Gland | (50) | (50) | (50) | (50) |
| C-cell, Hyperplasia | 7 (14%) | 11 (22%) | 6 (12%) | 8 (16%) |
| Follicular Cell, Cyst | | 1 (2%) | | |
| Follicular Cell, Hyperplasia | | | 1 (2%) | |
| **GENERAL BODY SYSTEM** | | | | |
| Peritoneum | (2) | (2) | (4) | (2) |
| **GENITAL SYSTEM** | | | | |
| Epididymis | (50) | (50) | (50) | (50) |
| Preputial Gland | (50) | (50) | (50) | (50) |
| Cyst | 1 (2%) | | 2 (4%) | |
| Hyperplasia | | | | 1 (2%) |
| Inflammation, Suppurative | | | 1 (2%) | |
| Prostate | (50) | (50) | (50) | (50) |
| Hyperplasia | | 1 (2%) | 1 (2%) | 2 (4%) |
| Inflammation, Suppurative | 42 (84%) | 32 (64%) | 27 (54%) | 28 (56%) |
| Seminal Vesicle | (50) | (50) | (50) | (50) |
| Dilatation | | 1 (2%) | | |

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

| FISCHER 344 RATS MALE | CONTROL | 250 PPM | 500 PPM | 1000 PPM |
|---|---|---|---|---|
| Hyperplasia | | 1 (2%) | | |
| Testes | (50) | (50) | (50) | (50) |
| Necrosis | | | 1 (2%) | |
| Artery, Inflammation, Chronic Active | | 1 (2%) | 2 (4%) | |
| Bilateral, Interstitial Cell, Hyperplasia | | | | 1 (2%) |
| Germinal Epithelium, Atrophy | 6 (12%) | 5 (10%) | 3 (6%) | 6 (12%) |
| Interstitial Cell, Hyperplasia | 12 (24%) | 18 (36%) | 19 (38%) | 9 (18%) |
| HEMATOPOIETIC SYSTEM | | | | |
| Bone Marrow | (50) | (50) | (50) | (50) |
| Lymph Node | (7) | (10) | (8) | (14) |
| Deep Cervical, Ectasia | | 1 (10%) | | 1 (7%) |
| Deep Cervical, Hemorrhage | | | | 1 (7%) |
| Deep Cervical, Hyperplasia, Lymphoid | | | 1 (13%) | 2 (14%) |
| Pancreatic, Ectasia | | | 1 (13%) | 1 (7%) |
| Pancreatic, Hyperplasia, Lymphoid | | | 1 (13%) | |
| Pancreatic, Inflammation, Granulomatous | | | 1 (13%) | |
| Lymph Node, Bronchial | (7) | (12) | (11) | (8) |
| Ectasia | 1 (14%) | 1 (8%) | | |
| Hyperplasia, Lymphoid | 1 (14%) | 1 (8%) | 1 (9%) | |
| Lymph Node, Mandibular | (1) | (3) | (0) | (1) |
| Ectasia | 1 (100%) | 2 (67%) | | |
| Metaplasia, Osseous | 1 (100%) | | | |
| Lymph Node, Mediastinal | (34) | (32) | (34) | (34) |
| Angiectasis | | | | 1 (3%) |
| Hemorrhage | | 1 (3%) | | |
| Hyperplasia, Lymphoid | 1 (3%) | | 2 (6%) | |
| Inflammation, Suppurative | 1 (3%) | | | |
| Lymph Node, Mesenteric | (50) | (50) | (50) | (50) |
| Hemorrhage | | 2 (4%) | | 1 (2%) |
| Spleen | (50) | (50) | (50) | (50) |
| Accessory Spleen | | | | 1 (2%) |
| Fibrosis | 2 (4%) | 2 (4%) | 7 (14%) | 2 (4%) |
| Hematopoietic Cell Proliferation | | | | 1 (2%) |
| Hemorrhage | 4 (8%) | 4 (8%) | 2 (4%) | 4 (8%) |
| Necrosis | 1 (2%) | 3 (6%) | 1 (2%) | |
| Thymus | (49) | (49) | (50) | (50) |

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

| FISCHER 344 RATS MALE | CONTROL | 250 PPM | 500 PPM | 1000 PPM |
|---|---|---|---|---|
| **INTEGUMENTARY SYSTEM** | | | | |
| Mammary Gland | (50) | (50) | (50) | (50) |
| Galactocele | 2 (4%) | | 2 (4%) | 1 (2%) |
| Epithelium, Hyperplasia | 1 (2%) | | 1 (2%) | 1 (2%) |
| Skin | (50) | (50) | (50) | (50) |
| Cyst Epithelial Inclusion | 1 (2%) | 1 (2%) | | 2 (4%) |
| Hyperkeratosis | 1 (2%) | | 1 (2%) | |
| Inflammation, Chronic | | | | 1 (2%) |
| Ulcer | | | | 1 (2%) |
| **MUSCULOSKELETAL SYSTEM** | | | | |
| Bone | (50) | (50) | (50) | (50) |
| Hyperostosis | | | 1 (2%) | |
| Skeletal Muscle | (1) | (2) | (2) | (1) |
| **NERVOUS SYSTEM** | | | | |
| Brain | (50) | (50) | (50) | (50) |
| Compression | 7 (14%) | 16 (32%) | 6 (12%) | 6 (12%) |
| Hemorrhage | 5 (10%) | 7 (14%) | 3 (6%) | 1 (2%) |
| Necrosis | | 1 (2%) | | |
| Thrombosis | | 1 (2%) | | |
| **RESPIRATORY SYSTEM** | | | | |
| Larynx | (50) | (50) | (50) | (50) |
| Foreign Body | 6 (12%) | 3 (6%) | | 3 (6%) |
| Inflammation, Suppurative | 4 (8%) | 7 (14%) | 1 (2%) | 3 (6%) |
| Inflammation, Chronic | 1 (2%) | 1 (2%) | 1 (2%) | |
| Epiglottis, Hyperplasia | 1 (2%) | | | |
| Epiglottis, Metaplasia, Squamous | 1 (2%) | | 1 (2%) | 2 (4%) |
| Respiratory Epithelium, Hyperplasia | 3 (6%) | 2 (4%) | | 1 (2%) |
| Lung | (50) | (50) | (50) | (50) |
| Congestion | 1 (2%) | | | |
| Hemorrhage | 3 (6%) | 7 (14%) | 3 (6%) | |
| Inflammation | | | 1 (2%) | |
| Inflammation, Suppurative | 1 (2%) | 1 (2%) | | |

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

| FISCHER 344 RATS MALE | CONTROL | 250 PPM | 500 PPM | 1000 PPM |
|---|---|---|---|---|
| Inflammation, Granulomatous | | 1 (2%) | | |
| Inflammation, Chronic | 3 (6%) | 3 (6%) | 6 (12%) | 5 (10%) |
| Thrombosis | | 1 (2%) | | |
| Alveolar Epithelium, Hyperplasia | 13 (26%) | 11 (22%) | 10 (20%) | 10 (20%) |
| Alveolar Epithelium, Metaplasia, Squamous | | | | 1 (2%) |
| Alveolar Epithelium, Metaplasia, Mucous | | | | 1 (2%) |
| Alveolus, Emphysema | | | | 1 (2%) |
| Alveolus, Foreign Body | | 1 (2%) | | |
| Alveolus, Infiltration Cellular, Histiocyte | 9 (18%) | 7 (14%) | 4 (8%) | 14 (28%) |
| Alveolus, Proteinosis | | | | 1 (2%) |
| Artery, Mineralization | 2 (4%) | | | |
| Artery, Thrombosis | 1 (2%) | | | |
| Bronchiole, Hyperplasia | | 1 (2%) | | |
| Bronchiole, Inflammation, Chronic | | 1 (2%) | 1 (2%) | |
| Interstitium, Fibrosis | | 2 (4%) | 1 (2%) | 1 (2%) |
| Nose | (50) | (50) | (49) | (50) |
| Foreign Body | 5 (10%) | 5 (10%) | 3 (6%) | 4 (8%) |
| Hyperplasia, Basal Cell | | | | 1 (2%) |
| Inflammation, Suppurative | 7 (14%) | 8 (16%) | 8 (16%) | 6 (12%) |
| Inflammation, Chronic | 5 (10%) | 1 (2%) | | |
| Epithelium, Nasolacrimal Duct, Metaplasia, Squamous | | 2 (4%) | 1 (2%) | |
| Glands, Olfactory Epithelium, Hyperplasia | 1 (2%) | | 1 (2%) | 1 (2%) |
| Glands, Respiratory Epithelium, Dilatation | 1 (2%) | 3 (6%) | 2 (4%) | 2 (4%) |
| Glands, Respiratory Epithelium, Hyperplasia | | | 2 (4%) | 4 (8%) |
| Goblet Cell, Olfactory Epithelium, Hyperplasia | | | 1 (2%) | |
| Goblet Cell, Hyperplasia | 3 (6%) | 11 (22%) | 7 (14%) | 5 (10%) |
| Nasolacrimal Duct, Inflammation, Suppurative | 2 (4%) | 2 (4%) | 3 (6%) | |
| Olfactory Epithelium, Degeneration | | | 1 (2%) | |
| Olfactory Epithelium, Degeneration, Hyaline | 3 (6%) | 2 (4%) | 1 (2%) | |
| Olfactory Epithelium, Hyperplasia, Basal Cell | | 19 (38%) | 27 (55%) | 26 (52%) |
| Olfactory Epithelium, Inflammation, Chronic | | | | 1 (2%) |
| Olfactory Epithelium, Metaplasia | 7 (14%) | 4 (8%) | 5 (10%) | 5 (10%) |
| Olfactory Epithelium, Necrosis | | 1 (2%) | | 1 (2%) |

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

| FISCHER 344 RATS MALE | CONTROL | 250 PPM | 500 PPM | 1000 PPM |
|---|---|---|---|---|
| Olfactory Epithelium, Ulcer | | | 2 (4%) | |
| Respiratory Epithelium, Degeneration, Hyaline | 1 (2%) | 1 (2%) | | |
| Respiratory Epithelium, Hyperplasia | | 15 (30%) | 16 (33%) | 23 (46%) |
| Respiratory Epithelium, Inflammation, Chronic | | | 1 (2%) | 2 (4%) |
| Respiratory Epithelium, Necrosis | | | | 1 (2%) |
| Squamous Epithelium, Hyperplasia | | | 1 (2%) | |
| Squamous Epithelium, Inflammation | | | 1 (2%) | |
| Vomeronasal Organ, Inflammation, Suppurative | 1 (2%) | | | |
| Pleura | (5) | (3) | (5) | (6) |
| Inflammation, Chronic | 4 (80%) | 3 (100%) | 4 (80%) | 6 (100%) |
| Mesothelium, Hyperplasia | 1 (20%) | | | |
| Trachea | (50) | (50) | (50) | (50) |
| Epithelium, Hyperplasia | | | | 1 (2%) |
| Glands, Cyst | | 1 (2%) | | |
| **SPECIAL SENSES SYSTEM** | | | | |
| Eye | (50) | (50) | (49) | (50) |
| Degeneration | | 1 (2%) | | |
| Inflammation, Chronic Active | | 1 (2%) | | |
| Bilateral, Lens, Cataract | 1 (2%) | 1 (2%) | | 1 (2%) |
| Bilateral, Retina, Atrophy | | 1 (2%) | 1 (2%) | |
| Ciliary Body, Iris, Inflammation, Suppurative | | | 1 (2%) | |
| Cornea, Inflammation, Suppurative | 2 (4%) | | | |
| Cornea, Inflammation, Chronic | | | | 1 (2%) |
| Lens, Cataract | 5 (10%) | 1 (2%) | 2 (4%) | 4 (8%) |
| Retina, Atrophy | 4 (8%) | | | 2 (4%) |
| Harderian Gland | (50) | (50) | (50) | (50) |
| Inflammation, Suppurative | | 1 (2%) | | |
| Inflammation, Chronic | 1 (2%) | 1 (2%) | | |
| Zymbal's Gland | (1) | (0) | (0) | (2) |
| **URINARY SYSTEM** | | | | |
| Kidney | (50) | (50) | (50) | (50) |
| Atrophy | | | | 1 (2%) |

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

| FISCHER 344 RATS MALE | CONTROL | 250 PPM | 500 PPM | 1000 PPM |
|---|---|---|---|---|
| Infarct | | 1 (2%) | 2 (4%) | 1 (2%) |
| Infarct, Multiple | | 1 (2%) | | |
| Nephropathy | 47 (94%) | 47 (94%) | 47 (94%) | 50 (100%) |
| Bilateral, Renal Tubule, Cyst | | | 1 (2%) | |
| Bilateral, Infarct | | 1 (2%) | | |
| Capsule, Dilatation | | | 1 (2%) | |
| Glomerulus, Inflammation, Suppurative | | 1 (2%) | | |
| Papilla, Mineralization | 5 (10%) | 35 (70%) | 44 (88%) | 41 (82%) |
| Pelvis, Transitional Epithelium, Hyperplasia | 3 (6%) | 5 (10%) | 14 (28%) | 15 (30%) |
| Pelvis, Dilatation | | | 1 (2%) | 1 (2%) |
| Renal Tubule, Accumulation, Hyaline Droplet | | | 1 (2%) | 1 (2%) |
| Renal Tubule, Cyst | | 1 (2%) | 3 (6%) | 2 (4%) |
| Renal Tubule, Hyperplasia | | 3 (6%) | 8 (16%) | 6 (12%) |
| Renal Tubule, Hypertrophy | | | | 1 (2%) |
| Renal Tubule, Mineralization | 1 (2%) | | | |
| Ureter | (0) | (1) | (0) | (1) |
| Urethra | (0) | (0) | (1) | (1) |
| Transitional Epithelium, Hyperplasia | | | 1 (100%) | |
| Urinary Bladder | (50) | (50) | (49) | (50) |
| Calculus Gross Observation | | | 1 (2%) | |
| Hemorrhage | | 1 (2%) | | |
| Inflammation, Chronic | | | 1 (2%) | |
| Transitional Epithelium, Hyperplasia | 1 (2%) | | 4 (8%) | 2 (4%) |

*** END OF MALE ***

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

| FISCHER 344 RATS FEMALE | CONTROL | 250 PPM | 500 PPM | 1000 PPM |
|---|---|---|---|---|
| **Disposition Summary** | | | | |
| **Animals Initially in Study** | 50 | 50 | 50 | 50 |
| **Early Deaths** | | | | |
| **Moribund Sacrifice** | 23 | 18 | 17 | 15 |
| **Natural Death** | 6 | 5 | 2 | 3 |
| **Survivors** | | | | |
| **Terminal Sacrifice** | 21 | 27 | 31 | 32 |
| **Animals Examined Microscopically** | 50 | 50 | 50 | 50 |
| ALIMENTARY SYSTEM | | | | |
| Intestine Large, Cecum | (46) | (45) | (50) | (49) |
| Necrosis | | | | 1 (2%) |
| Intestine Large, Colon | (48) | (46) | (50) | (50) |
| Artery, Inflammation, Chronic | | | | 1 (2%) |
| Intestine Large, Rectum | (48) | (46) | (50) | (50) |
| Liver | (50) | (50) | (50) | (50) |
| Angiectasis | 1 (2%) | | 2 (4%) | |
| Basophilic Focus | 27 (54%) | 31 (62%) | 36 (72%) | 32 (64%) |
| Clear Cell Focus | 15 (30%) | 9 (18%) | 6 (12%) | 5 (10%) |
| Eosinophilic Focus | | | | 1 (2%) |
| Hepatodiaphragmatic Nodule | 6 (12%) | 6 (12%) | 4 (8%) | 6 (12%) |
| Inflammation, Granulomatous | 1 (2%) | | | |
| Mixed Cell Focus | | | 2 (4%) | 1 (2%) |
| Necrosis | | 1 (2%) | 1 (2%) | 3 (6%) |
| Vacuolization Cytoplasmic | 11 (22%) | 4 (8%) | 4 (8%) | 2 (4%) |
| Bile Duct, Hyperplasia | | | 1 (2%) | |
| Centrilobular, Congestion | | 1 (2%) | | |
| Periportal, Vacuolization Cytoplasmic | 1 (2%) | | | |
| Mesentery | (18) | (18) | (17) | (9) |
| Necrosis | 18 (100%) | 16 (89%) | 17 (100%) | 8 (89%) |
| Oral Mucosa | (0) | (0) | (1) | (1) |
| Pancreas | (50) | (49) | (50) | (50) |
| Fibrosis | | 1 (2%) | | |
| Hemorrhage | | 1 (2%) | | |
| Thrombosis | | | | 1 (2%) |
| Artery, Inflammation, Chronic | | | | 1 (2%) |
| Stomach, Forestomach | (50) | (50) | (50) | (50) |

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

| FISCHER 344 RATS FEMALE | CONTROL | 250 PPM | 500 PPM | 1000 PPM |
|---|---|---|---|---|
| Erosion | | | 1 (2%) | |
| Inflammation, Suppurative | | | | 1 (2%) |
| Inflammation, Chronic | | 1 (2%) | 1 (2%) | |
| Ulcer | 5 (10%) | 4 (8%) | 3 (6%) | 1 (2%) |
| Epithelium, Cyst | | | 1 (2%) | |
| Epithelium, Erosion | | 1 (2%) | | |
| Epithelium, Hyperplasia | 11 (22%) | 13 (26%) | 12 (24%) | 8 (16%) |
| Submucosa, Fibrosis | | | 1 (2%) | |
| Stomach, Glandular | (50) | (49) | (50) | (50) |
| Erosion | 1 (2%) | | | |
| Ulcer | | | 1 (2%) | |
| Epithelium, Hyperplasia | | | | 1 (2%) |
| Tongue | (1) | (2) | (2) | (3) |
| Epithelium, Hyperplasia | 1 (100%) | 2 (100%) | 2 (100%) | 3 (100%) |
| Tooth | (0) | (2) | (0) | (0) |
| Peridontal Tissue, Inflammation | | 2 (100%) | | |
| **CARDIOVASCULAR SYSTEM** | | | | |
| Heart | (50) | (50) | (50) | (50) |
| Cardiomyopathy | 1 (2%) | 2 (4%) | 2 (4%) | |
| Inflammation, Chronic | | | | 1 (2%) |
| Atrium, Thrombosis | | 2 (4%) | 2 (4%) | 1 (2%) |
| **ENDOCRINE SYSTEM** | | | | |
| Adrenal Cortex | (50) | (49) | (50) | (50) |
| Hemorrhage | 1 (2%) | | | |
| Hyperplasia | 9 (18%) | 9 (18%) | 13 (26%) | 12 (24%) |
| Necrosis | 2 (4%) | | | 1 (2%) |
| Vacuolization Cytoplasmic | 11 (22%) | 18 (37%) | 16 (32%) | 7 (14%) |
| Adrenal Medulla | (50) | (49) | (50) | (50) |
| Islets, Pancreatic | (50) | (49) | (50) | (50) |
| Parathyroid Gland | (49) | (45) | (48) | (47) |
| Hyperplasia | | 1 (2%) | | |
| Pituitary Gland | (50) | (50) | (50) | (49) |
| Cyst | 7 (14%) | 2 (4%) | 2 (4%) | 2 (4%) |
| Hemorrhage | 2 (4%) | 2 (4%) | 2 (4%) | |
| Hyperplasia | 10 (20%) | 13 (26%) | 6 (12%) | 16 (33%) |
| Thyroid Gland | (50) | (49) | (50) | (50) |

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

| FISCHER 344 RATS FEMALE | CONTROL | 250 PPM | 500 PPM | 1000 PPM |
|---|---|---|---|---|
| Ultimobranchial Cyst | 1 (2%) | | | |
| C-cell, Hyperplasia | 13 (26%) | 13 (27%) | 15 (30%) | 15 (30%) |
| Follicular Cell, Hyperplasia | | | 1 (2%) | |
| GENERAL BODY SYSTEM | | | | |
| Peritoneum | (0) | (0) | (1) | (0) |
| GENITAL SYSTEM | | | | |
| Clitoral Gland | (50) | (49) | (50) | (50) |
| Cyst | | 2 (4%) | 2 (4%) | 1 (2%) |
| Hyperplasia | 2 (4%) | 5 (10%) | 7 (14%) | 5 (10%) |
| Inflammation, Chronic | | 1 (2%) | 1 (2%) | 3 (6%) |
| Ovary | (50) | (49) | (50) | (50) |
| Cyst | 3 (6%) | 7 (14%) | 7 (14%) | 6 (12%) |
| Cyst, Multiple | | | 1 (2%) | |
| Uterus | (50) | (49) | (50) | (50) |
| Hemorrhage | 1 (2%) | 1 (2%) | 4 (8%) | 1 (2%) |
| Pigmentation | | | 1 (2%) | |
| Endometrium, Hyperplasia | 4 (8%) | 7 (14%) | 2 (4%) | 5 (10%) |
| Vagina | (2) | (0) | (0) | (0) |
| Epithelium, Hyperplasia, Adenomatous | 1 (50%) | | | |
| HEMATOPOIETIC SYSTEM | | | | |
| Lymph Node | (3) | (3) | (5) | (2) |
| Pancreatic, Infiltration Cellular, Histiocyte | | | 1 (20%) | |
| Pancreatic, Pigmentation | | | 1 (20%) | |
| Lymph Node, Bronchial | (7) | (9) | (8) | (5) |
| Ectasia | 2 (29%) | | | |
| Hemorrhage | | | | 1 (20%) |
| Hyperplasia, Lymphoid | | 1 (11%) | | 1 (20%) |
| Inflammation | 1 (14%) | | | |
| Lymph Node, Mandibular | (4) | (1) | (1) | (4) |
| Ectasia | | | | 1 (25%) |
| Hyperplasia, Lymphoid | | | | 1 (25%) |
| Lymph Node, Mediastinal | (30) | (28) | (26) | (31) |
| Angiectasis | | | 1 (4%) | |

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

| FISCHER 344 RATS FEMALE | CONTROL | 250 PPM | 500 PPM | 1000 PPM |
|---|---|---|---|---|
| Hemorrhage | | | 1 (4%) | 1 (3%) |
| Hyperplasia, Histiocytic | | | 1 (4%) | |
| Hyperplasia, Lymphoid | | | 1 (4%) | 2 (6%) |
| Inflammation, Suppurative | | | | 1 (3%) |
| Lymph Node, Mesenteric | (48) | (49) | (49) | (50) |
| Ectasia | | | 1 (2%) | |
| Hemorrhage | 2 (4%) | | | |
| Hyperplasia, Lymphoid | | 1 (2%) | | |
| Infiltration Cellular, Histiocyte | | 1 (2%) | | |
| Necrosis | | | | 1 (2%) |
| Spleen | (50) | (50) | (50) | (50) |
| Atrophy | | | | 1 (2%) |
| Fibrosis | | | 3 (6%) | |
| Hematopoietic Cell Proliferation | | 1 (2%) | 2 (4%) | 2 (4%) |
| Necrosis | | | | 2 (4%) |
| Capsule, Fibrosis | 1 (2%) | | | |
| Thymus | (48) | (46) | (50) | (50) |
| Hyperplasia, Tubular | | | 1 (2%) | |
| **INTEGUMENTARY SYSTEM** | | | | |
| Mammary Gland | (50) | (50) | (50) | (50) |
| Galactocele | 3 (6%) | | | 2 (4%) |
| Hyperplasia | 1 (2%) | | | |
| Inflammation, Suppurative | | 1 (2%) | | |
| Epithelium, Hyperplasia | | | 1 (2%) | 1 (2%) |
| Skin | (50) | (50) | (50) | (50) |
| Cyst Epithelial Inclusion | | 1 (2%) | | |
| Hyperkeratosis | 1 (2%) | 1 (2%) | | 1 (2%) |
| Inflammation, Chronic | | | | 1 (2%) |
| Ulcer | | 3 (6%) | | 2 (4%) |
| Sebaceous Gland, Hemorrhage | | 1 (2%) | | |
| Subcutaneous Tissue, Fibrosis | | | | 1 (2%) |
| Subcutaneous Tissue, Inflammation, Suppurative | | 1 (2%) | | |
| **MUSCULOSKELETAL SYSTEM** | | | | |
| Bone | (50) | (50) | (50) | (50) |
| Hyperostosis | | 1 (2%) | | |

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

| FISCHER 344 RATS FEMALE | CONTROL | 250 PPM | 500 PPM | 1000 PPM |
|---|---|---|---|---|
| Maxilla, Fracture | | | 1 (2%) | |
| Maxilla, Inflammation, Chronic Active | | | | 1 (2%) |
| Skeletal Muscle | (1) | (0) | (1) | (1) |
| **NERVOUS SYSTEM** | | | | |
| Brain | (50) | (49) | (50) | (50) |
| Compression | 12 (24%) | 9 (18%) | 4 (8%) | 5 (10%) |
| Demyelination | | | | 1 (2%) |
| Gliosis | | | | 1 (2%) |
| Hemorrhage | 1 (2%) | 3 (6%) | 2 (4%) | 3 (6%) |
| Inflammation, Chronic Active | | | | 1 (2%) |
| Necrosis | 1 (2%) | | | |
| Thrombosis | | 1 (2%) | 1 (2%) | |
| Medulla, Meninges, Inflammation, Suppurative | 1 (2%) | | | |
| Medulla, Neuron, Necrosis | | | | 1 (2%) |
| Neuron, Degeneration | | | | 1 (2%) |
| Spinal Cord | (0) | (1) | (1) | (1) |
| Gliosis | | | | 1 (100%) |
| Inflammation, Chronic Active | | | | 1 (100%) |
| **RESPIRATORY SYSTEM** | | | | |
| Larynx | (50) | (49) | (50) | (50) |
| Foreign Body | 2 (4%) | 1 (2%) | 2 (4%) | |
| Inflammation, Suppurative | 3 (6%) | 3 (6%) | 4 (8%) | 1 (2%) |
| Inflammation, Chronic | 2 (4%) | | 2 (4%) | 2 (4%) |
| Respiratory Epithelium, Hyperplasia | | 1 (2%) | | 1 (2%) |
| Lung | (50) | (50) | (50) | (50) |
| Cyst, Squamous | | | | 1 (2%) |
| Hemorrhage | 2 (4%) | 1 (2%) | 2 (4%) | |
| Inflammation, Suppurative | 1 (2%) | | | |
| Inflammation, Chronic | 11 (22%) | 10 (20%) | 8 (16%) | 16 (32%) |
| Thrombosis | | | 1 (2%) | |
| Alveolar Epithelium, Hyperplasia | 3 (6%) | 1 (2%) | 5 (10%) | 7 (14%) |
| Alveolar Epithelium, Metaplasia, Squamous | | | | 1 (2%) |
| Alveolus, Infiltration Cellular, Histiocyte | 16 (32%) | 6 (12%) | 11 (22%) | 14 (28%) |
| Alveolus, Proteinosis | | | | 2 (4%) |

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

| FISCHER 344 RATS FEMALE | CONTROL | 250 PPM | 500 PPM | 1000 PPM |
|---|---|---|---|---|
| Bronchiole, Hyperplasia | | 3 (6%) | | 1 (2%) |
| Bronchiole, Inflammation, Chronic | 1 (2%) | 1 (2%) | | 3 (6%) |
| Interstitium, Fibrosis | 1 (2%) | | | |
| Nose | (50) | (48) | (50) | (50) |
| Foreign Body | | 4 (8%) | 2 (4%) | 3 (6%) |
| Hyperplasia, Basal Cell | | | | 1 (2%) |
| Inflammation, Suppurative | 1 (2%) | 3 (6%) | 1 (2%) | 2 (4%) |
| Inflammation, Chronic | 1 (2%) | 3 (6%) | 4 (8%) | 1 (2%) |
| Inflammation, Chronic Active | | | 1 (2%) | |
| Glands, Respiratory Epithelium, Dilatation | 1 (2%) | | | |
| Goblet Cell, Hyperplasia | 4 (8%) | 6 (13%) | 1 (2%) | 5 (10%) |
| Nasolacrimal Duct, Inflammation, Suppurative | 4 (8%) | 3 (6%) | 2 (4%) | 1 (2%) |
| Nasolacrimal Duct, Inflammation, Chronic | 1 (2%) | | | |
| Olfactory Epithelium, Degeneration, Hyaline | 2 (4%) | 1 (2%) | | |
| Olfactory Epithelium, Hyperplasia | | | 1 (2%) | |
| Olfactory Epithelium, Hyperplasia, Basal Cell | | 14 (29%) | 25 (50%) | 31 (62%) |
| Olfactory Epithelium, Inflammation, Granulomatous | | 1 (2%) | | |
| Olfactory Epithelium, Metaplasia | | 1 (2%) | | 2 (4%) |
| Olfactory Epithelium, Necrosis | | | 1 (2%) | |
| Respiratory Epithelium, Degeneration, Hyaline | 1 (2%) | | 3 (6%) | |
| Respiratory Epithelium, Hyperplasia | | | 4 (8%) | 6 (12%) |
| Respiratory Epithelium, Metaplasia, Squamous | | 1 (2%) | | |
| Turbinate, Necrosis | | | 1 (2%) | |
| Pleura | (15) | (16) | (16) | (20) |
| Inflammation, Chronic | 15 (100%) | 15 (94%) | 14 (88%) | 20 (100%) |
| Mesothelium, Hyperplasia | | 1 (6%) | | |
| Trachea | (50) | (49) | (50) | (50) |
| Glands, Cyst | | | 1 (2%) | |
| SPECIAL SENSES SYSTEM | | | | |
| Eye | (50) | (49) | (50) | (50) |
| Bilateral, Lens, Cataract | 1 (2%) | | | |
| Bilateral, Retina, Atrophy | 1 (2%) | 1 (2%) | 1 (2%) | |

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

| FISCHER 344 RATS FEMALE | CONTROL | 250 PPM | 500 PPM | 1000 PPM |
|---|---|---|---|---|
| Cornea, Epithelium, Hyperplasia | | | | 1 (2%) |
| Cornea, Inflammation | | | | 1 (2%) |
| Cornea, Inflammation, Suppurative | 1 (2%) | | | |
| Lens, Cataract | 5 (10%) | 2 (4%) | 5 (10%) | 3 (6%) |
| Retina, Atrophy | 3 (6%) | 5 (10%) | 8 (16%) | 2 (4%) |
| Harderian Gland | (50) | (49) | (50) | (50) |
| Inflammation, Chronic | 1 (2%) | | 1 (2%) | 1 (2%) |
| Zymbal's Gland | (1) | (0) | (1) | (1) |
| URINARY SYSTEM | | | | |
| Kidney | (50) | (50) | (50) | (50) |
| Infarct, Multiple | | | 1 (2%) | |
| Nephropathy | 38 (76%) | 37 (74%) | 41 (82%) | 44 (88%) |
| Artery, Inflammation, Chronic Active | | | | 1 (2%) |
| Papilla, Mineralization | 6 (12%) | 3 (6%) | 4 (8%) | 6 (12%) |
| Pelvis, Transitional Epithelium, Hyperplasia | 1 (2%) | 1 (2%) | 6 (12%) | 1 (2%) |
| Pelvis, Transitional Epithelium, Mineralization | 23 (46%) | 27 (54%) | 27 (54%) | 22 (44%) |
| Pelvis, Dilatation | 1 (2%) | | | |
| Renal Tubule, Accumulation, Hyaline Droplet | 1 (2%) | | 1 (2%) | |
| Renal Tubule, Cyst | 1 (2%) | | 1 (2%) | 1 (2%) |
| Renal Tubule, Pigmentation | 1 (2%) | | | |
| Urinary Bladder | (50) | (49) | (50) | (50) |
| Transitional Epithelium, Hyperplasia | 1 (2%) | 2 (4%) | 2 (4%) | 1 (2%) |

*** END OF REPORT ***

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