

TDMS No. 20304 - 01
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/SD

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

TEF evaluation (PCB 118)
CAS Number: 31508-00-6

Date Report Requested: 07/14/2008
Time Report Requested: 15:09:47
First Dose M/F: NA / 03/26/04
Lab: BAT

C Number: C20304
Lock Date: 10/12/2006
Cage Range: ALL
Date Range: ALL
Reasons For Removal: 25022 ACCK 25021 TSAC 25020 NATD
25019 MSAC
Removal Date Range: ALL
Treatment Groups: Include 001 0 UG/KG Include 008 4600 UG/KG Include 009 4600 UG/KG STOP
Study Gender: Female
TDMSE Version: 2.0.0

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| SPRAGUE-DAWLEY RATS FEMALE | 0 UG/KG | 4600 UG/KG | 4600 UG/KG STOP |
|----------------------------------|---------|------------|-----------------|
| Disposition Summary | | | |
| Animals Initially in Study | 80 | 80 | 50 |
| Early Deaths | | | |
| Accidently Killed | | | 1 |
| Moribund Sacrifice | 27 | 16 | 18 |
| Natural Death | 4 | 11 | 6 |
| Survivors | | | |
| Moribund Sacrifice | | | 1 |
| Terminal Sacrifice | 21 | 25 | 24 |
| Animals Examined Microscopically | 52 | 52 | 50 |

ALIMENTARY SYSTEM

| | | | |
|--------------------------------------|----------|----------|----------|
| Esophagus | (51) | (52) | (50) |
| Muscularis, Inflammation | | | 1 (2%) |
| Intestine Large, Cecum | (52) | (48) | (49) |
| Artery, Inflammation, Chronic Active | | 1 (2%) | 2 (4%) |
| Intestine Large, Colon | (52) | (48) | (49) |
| Parasite Metazoan | 1 (2%) | 1 (2%) | 1 (2%) |
| Artery, Inflammation, Chronic Active | | 1 (2%) | 2 (4%) |
| Intestine Large, Rectum | (52) | (50) | (49) |
| Parasite Metazoan | 2 (4%) | 3 (6%) | 2 (4%) |
| Artery, Inflammation, Chronic Active | 1 (2%) | 1 (2%) | 5 (10%) |
| Intestine Small, Duodenum | (52) | (48) | (49) |
| Intestine Small, Ileum | (52) | (47) | (49) |
| Intestine Small, Jejunum | (52) | (48) | (49) |
| Liver | (52) | (49) | (49) |
| Angiectasis | | 2 (4%) | 1 (2%) |
| Basophilic Focus | 11 (21%) | 1 (2%) | 5 (10%) |
| Basophilic Focus, Multiple | 4 (8%) | | 4 (8%) |
| Cholangiofibrosis | | 22 (45%) | 10 (20%) |
| Clear Cell Focus | 6 (12%) | | 3 (6%) |
| Clear Cell Focus, Multiple | 9 (17%) | | 10 (20%) |
| Degeneration, Cystic | 1 (2%) | 2 (4%) | 4 (8%) |
| Eosinophilic Focus | 5 (10%) | | 7 (14%) |
| Eosinophilic Focus, Multiple | | 41 (84%) | 13 (27%) |
| Fatty Change, Focal | 2 (4%) | | 9 (18%) |
| Fatty Change, Diffuse | 1 (2%) | 48 (98%) | 8 (16%) |
| Hematopoietic Cell Proliferation | 19 (37%) | 21 (43%) | 31 (63%) |
| Hepatodiaphragmatic Nodule | | | 1 (2%) |
| Hyperplasia, Nodular | | 43 (88%) | 4 (8%) |
| Inflammation | 21 (40%) | 44 (90%) | 47 (96%) |

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

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| SPRAGUE-DAWLEY RATS FEMALE | 0 UG/KG | 4600 UG/KG | 4600 UG/KG STOP |
|--------------------------------------|----------|------------|-----------------|
| Mixed Cell Focus | 6 (12%) | 1 (2%) | 2 (4%) |
| Mixed Cell Focus, Multiple | 15 (29%) | 6 (12%) | 34 (69%) |
| Necrosis | 1 (2%) | 22 (45%) | 14 (29%) |
| Pigmentation | 1 (2%) | 48 (98%) | 43 (88%) |
| Toxic Hepatopathy | | 46 (94%) | 36 (73%) |
| Bile Duct, Cyst | 2 (4%) | 21 (43%) | 14 (29%) |
| Bile Duct, Fibrosis | 2 (4%) | | 7 (14%) |
| Bile Duct, Hyperplasia | 5 (10%) | 40 (82%) | 25 (51%) |
| Capsule, Inflammation | 1 (2%) | | |
| Centrilobular, Degeneration | 1 (2%) | 1 (2%) | 2 (4%) |
| Hepatocyte, Hypertrophy | | 48 (98%) | 30 (61%) |
| Hepatocyte, Multinucleated | | 43 (88%) | 32 (65%) |
| Oval Cell, Hyperplasia | | 46 (94%) | 29 (59%) |
| Mesentery | (2) | (9) | (9) |
| Artery, Inflammation, Chronic Active | 1 (50%) | 8 (89%) | 5 (56%) |
| Artery, Thrombosis | | 1 (11%) | |
| Fat, Necrosis | | 1 (11%) | |
| Oral Mucosa | (1) | (3) | (0) |
| Gingival, Cyst | | 1 (33%) | |
| Pancreas | (52) | (47) | (49) |
| Amyloid Deposition | | | 1 (2%) |
| Degeneration | 1 (2%) | | |
| Inflammation, Chronic Active | | 2 (4%) | 4 (8%) |
| Acinus, Atrophy, Focal | 4 (8%) | 1 (2%) | 4 (8%) |
| Acinus, Atrophy, Diffuse | | 1 (2%) | |
| Acinus, Vacuolization Cytoplasmic | | 42 (89%) | 10 (20%) |
| Artery, Inflammation, Chronic Active | 1 (2%) | 12 (26%) | 5 (10%) |
| Duct, Dilatation | | 3 (6%) | |
| Duct, Inflammation | | 2 (4%) | |
| Duct, Necrosis | | 1 (2%) | |
| Stomach, Forestomach | (52) | (51) | (49) |
| Hyperplasia, Squamous | | 3 (6%) | 5 (10%) |
| Inflammation | 2 (4%) | 1 (2%) | 4 (8%) |
| Ulcer | 2 (4%) | | 3 (6%) |
| Artery, Inflammation, Chronic Active | | 1 (2%) | 1 (2%) |
| Stomach, Glandular | (52) | (51) | (49) |
| Cyst | 1 (2%) | | |
| Erosion | | | 2 (4%) |
| Mineralization | | | 1 (2%) |
| Artery, Inflammation, Chronic Active | | 1 (2%) | |
| Tongue | (0) | (0) | (1) |
| Degeneration | | | 1 (100%) |
| Tooth | (10) | (7) | (7) |
| Peridental Tissue, Inflammation | 7 (70%) | 6 (86%) | 7 (100%) |

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| SPRAGUE-DAWLEY RATS FEMALE | 0 UG/KG | 4600 UG/KG | 4600 UG/KG STOP |
|--------------------------------------|----------|------------|-----------------|
| CARDIOVASCULAR SYSTEM | | | |
| Blood Vessel | (52) | (51) | (50) |
| Heart | (52) | (50) | (50) |
| Cardiomyopathy | 13 (25%) | 16 (32%) | 19 (38%) |
| Inflammation | | 1 (2%) | |
| Artery, Inflammation, Chronic Active | | 1 (2%) | |
| Coronary Artery, Thrombosis | | 1 (2%) | |
| Endocardium, Hyperplasia | | 2 (4%) | |
| Epicardium, Fibrosis | | 1 (2%) | |
| ENDOCRINE SYSTEM | | | |
| Adrenal Cortex | (52) | (49) | (49) |
| Atrophy | 1 (2%) | 35 (71%) | 4 (8%) |
| Degeneration, Cystic | 9 (17%) | 8 (16%) | 12 (24%) |
| Fibrosis | | | 1 (2%) |
| Hematopoietic Cell Proliferation | 1 (2%) | | |
| Hyperplasia | 14 (27%) | 13 (27%) | 21 (43%) |
| Hypertrophy | 37 (71%) | 34 (69%) | 38 (78%) |
| Necrosis | | | 4 (8%) |
| Vacuolization Cytoplasmic | 10 (19%) | 18 (37%) | 21 (43%) |
| Adrenal Medulla | (52) | (49) | (49) |
| Hyperplasia | 11 (21%) | 1 (2%) | 16 (33%) |
| Parathyroid Gland | (47) | (47) | (49) |
| Pituitary Gland | (52) | (52) | (50) |
| Angiectasis | 1 (2%) | | |
| Vacuolization Cytoplasmic | | | 1 (2%) |
| Pars Distalis, Hyperplasia | 10 (19%) | 10 (19%) | 10 (20%) |
| Thyroid Gland | (51) | (49) | (50) |
| Infiltration Cellular, Lymphocyte | | 1 (2%) | |
| Inflammation | 1 (2%) | | |
| C-cell, Hyperplasia | 10 (20%) | 11 (22%) | 9 (18%) |
| Follicular Cell, Hypertrophy | 6 (12%) | 23 (47%) | 12 (24%) |
| GENERAL BODY SYSTEM | | | |
| None | | | |
| GENITAL SYSTEM | | | |
| Clitoral Gland | (52) | (49) | (48) |
| Hyperplasia, Squamous | | | 1 (2%) |

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|----------------------------------|----------|------------|-----------------|
| Inflammation | 41 (79%) | 13 (27%) | 29 (60%) |
| Duct, Cyst | 26 (50%) | 30 (61%) | 28 (58%) |
| Ovary | (52) | (48) | (49) |
| Cyst | 8 (15%) | 7 (15%) | 10 (20%) |
| Inflammation | | 2 (4%) | 1 (2%) |
| Uterus | (52) | (49) | (49) |
| Adenomyosis | | 1 (2%) | |
| Cyst | | 1 (2%) | |
| Hemorrhage | | 1 (2%) | 2 (4%) |
| Inflammation | 4 (8%) | 4 (8%) | 10 (20%) |
| Metaplasia, Squamous | 29 (56%) | 5 (10%) | 23 (47%) |
| Thrombosis | 1 (2%) | | |
| Endometrium, Hyperplasia, Cystic | 28 (54%) | 9 (18%) | 21 (43%) |
| Vagina | (7) | (0) | (0) |

HEMATOPOIETIC SYSTEM

| | | | |
|--------------------------------------|----------|----------|----------|
| Bone Marrow | (52) | (52) | (50) |
| Atrophy | 4 (8%) | | |
| Hyperplasia | 31 (60%) | 47 (90%) | 43 (86%) |
| Necrosis | | 1 (2%) | |
| Lymph Node | (0) | (2) | (1) |
| Bronchial, Ectasia | | 1 (50%) | |
| Bronchial, Hemorrhage | | 1 (50%) | |
| Lymph Node, Mandibular | (51) | (51) | (50) |
| Atrophy | | 1 (2%) | |
| Hyperplasia, Lymphoid | | 1 (2%) | |
| Hyperplasia, Plasma Cell | 24 (47%) | 19 (37%) | 22 (44%) |
| Lymph Node, Mesenteric | (52) | (47) | (49) |
| Atrophy | 1 (2%) | | 1 (2%) |
| Ectasia | | 1 (2%) | |
| Hemorrhage | | | 2 (4%) |
| Hyperplasia, Plasma Cell | 1 (2%) | | |
| Spleen | (52) | (47) | (49) |
| Hematopoietic Cell Proliferation | 42 (81%) | 34 (72%) | 43 (88%) |
| Hemorrhage | 1 (2%) | | |
| Necrosis | 1 (2%) | | |
| Pigmentation | 39 (75%) | 28 (60%) | 31 (63%) |
| Lymphoid Follicle, Atrophy | 3 (6%) | 3 (6%) | 1 (2%) |
| Red Pulp, Atrophy | | 3 (6%) | |
| Thymus | (51) | (49) | (50) |
| Atrophy | 41 (80%) | 44 (90%) | 46 (92%) |
| Hemorrhage | | 3 (6%) | |
| Artery, Inflammation, Chronic Active | | 2 (4%) | |

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|--|----------|------------|-----------------|
| INTEGUMENTARY SYSTEM | | | |
| Mammary Gland | (52) | (50) | (50) |
| Cyst | 1 (2%) | | 5 (10%) |
| Hyperplasia | 4 (8%) | 1 (2%) | 4 (8%) |
| Inflammation, Granulomatous | | | 4 (8%) |
| Skin | (52) | (51) | (50) |
| MUSCULOSKELETAL SYSTEM | | | |
| Bone | (52) | (52) | (50) |
| Fracture | | | 1 (2%) |
| Skeletal Muscle | (0) | (0) | (2) |
| NERVOUS SYSTEM | | | |
| Brain | (52) | (52) | (50) |
| Gliosis | 1 (2%) | | |
| Hemorrhage | 3 (6%) | | 1 (2%) |
| Hydrocephalus | 1 (2%) | | |
| Necrosis | 2 (4%) | | |
| Spinal Cord | (0) | (1) | (0) |
| Nerve, Degeneration | | 1 (100%) | |
| RESPIRATORY SYSTEM | | | |
| Lung | (51) | (50) | (50) |
| Hemorrhage | | 1 (2%) | |
| Inflammation | 5 (10%) | 2 (4%) | 2 (4%) |
| Metaplasia, Squamous | 1 (2%) | 13 (26%) | |
| Pigmentation | | 1 (2%) | |
| Proteinosis | 1 (2%) | | |
| Alveolar Epithelium, Hyperplasia | 4 (8%) | | 3 (6%) |
| Alveolar Epithelium, Metaplasia, Bronchiolar | 6 (12%) | 40 (80%) | 32 (64%) |
| Alveolus, Infiltration Cellular, Histiocyte | 36 (71%) | 40 (80%) | 40 (80%) |
| Artery, Mediastinum, Inflammation, Chronic | | 1 (2%) | |
| Active | | | |
| Nose | (52) | (52) | (50) |
| Cyst | 1 (2%) | | |
| Inflammation | 1 (2%) | 23 (44%) | 8 (16%) |
| Glands, Cyst | | | 1 (2%) |

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|--|----------|------------|-----------------|
| Nasolacrimal Duct, Inflammation, Suppurative | | 1 (2%) | |
| Olfactory Epithelium, Degeneration | 1 (2%) | 1 (2%) | |
| Olfactory Epithelium, Metaplasia | | 1 (2%) | 1 (2%) |
| Respiratory Epithelium, Degeneration, Focal | 1 (2%) | | |
| Respiratory Epithelium, Hyperplasia | 5 (10%) | 27 (52%) | 11 (22%) |
| Respiratory Epithelium, Metaplasia, Squamous | | | 1 (2%) |
| Trachea | (51) | (52) | (50) |
| Inflammation | | 1 (2%) | |
| SPECIAL SENSES SYSTEM | | | |
| Eye | (52) | (52) | (50) |
| Cornea, Inflammation | 1 (2%) | | |
| Retina, Atrophy | 1 (2%) | 6 (12%) | |
| Harderian Gland | (52) | (52) | (50) |
| Infiltration Cellular, Mononuclear Cell | 7 (13%) | 13 (25%) | 11 (22%) |
| URINARY SYSTEM | | | |
| Kidney | (52) | (50) | (49) |
| Accumulation, Hyaline Droplet | 1 (2%) | | 2 (4%) |
| Amyloid Deposition | | | 1 (2%) |
| Calculus Micro Observation Only | 3 (6%) | | |
| Cyst | | 1 (2%) | 1 (2%) |
| Mineralization | 25 (48%) | 25 (50%) | 28 (57%) |
| Nephropathy | 42 (81%) | 46 (92%) | 48 (98%) |
| Pigmentation | 2 (4%) | 42 (84%) | 6 (12%) |
| Artery, Inflammation, Chronic Active | 1 (2%) | | 1 (2%) |
| Pelvis, Dilatation | | | 3 (6%) |
| Pelvis, Inflammation | | 2 (4%) | 2 (4%) |
| Transitional Epithelium, Hyperplasia | | 3 (6%) | |
| Ureter | (0) | (0) | (2) |
| Cyst | | | 2 (100%) |
| Urinary Bladder | (52) | (50) | (49) |
| Inflammation | | | 1 (2%) |

*** END OF REPORT ***