

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: 06/24/2008

Time Report Requested: 13:42:49

First Dose M/F: NA / 03/26/04

Lab: BAT

53 Wk_SSAC_R8

C Number: C20304

Lock Date: 10/12/2006

Cage Range: ALL

Date Range: ALL

Reasons For Removal: 25017 SSAC

Removal Date Range: 30-Mar-2005 - 30-Mar-2005

Treatment Groups: Include 001 0 UG/KG

Include 002 10 UG/KG

Include 003 30 UG/KG

Include 004 100 UG/KG

Include 005 220 UG/KG

Include 006 460 UG/KG

Include 007 1000 UG/KG

Include 008 4600 UG/KG

Study Gender: Female

TDMSE Version: 2.0.0

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| SPRAGUE-DAWLEY RATS FEMALE | 0 UG/KG | 10 UG/KG | 30 UG/KG | 100 UG/KG | 220 UG/KG | 460 UG/KG |
|----------------------------------|---------|----------|----------|-----------|-----------|-----------|
| Disposition Summary | | | | | | |
| Animals Initially in Study | 80 | 30 | 30 | 80 | 80 | 80 |
| Scheduled Sacrifice | 8 | 8 | 10 | 8 | 8 | 8 |
| Early Deaths | | | | | | |
| Survivors | | | | | | |
| Animals Examined Microscopically | 8 | 8 | 10 | 8 | 8 | 8 |

ALIMENTARY SYSTEM

| | | | | | | |
|-----------------------------------|----------|---------|---------|---------|----------|----------|
| Liver | (8) | (8) | (10) | (8) | (8) | (8) |
| Cholangiofibrosis | | 1 (13%) | | | | |
| Clear Cell Focus | 1 (13%) | 3 (38%) | 2 (20%) | 4 (50%) | 2 (25%) | 5 (63%) |
| Clear Cell Focus, Multiple | 3 (38%) | 1 (13%) | 1 (10%) | 1 (13%) | 3 (38%) | |
| Eosinophilic Focus | | | | | | |
| Eosinophilic Focus, Multiple | | | | | | |
| Fatty Change, Diffuse | | | | | | |
| Hepatodiaphragmatic Nodule | | | | | | |
| Hyperplasia, Nodular | | | | | | |
| Inflammation | 8 (100%) | 7 (88%) | 8 (80%) | 5 (63%) | 8 (100%) | 8 (100%) |
| Mixed Cell Focus | 1 (13%) | | | | | 1 (13%) |
| Mixed Cell Focus, Multiple | | | | | | |
| Necrosis | | | | | | 1 (13%) |
| Pigmentation | | | | | | 4 (50%) |
| Toxic Hepatopathy | | | | | | |
| Bile Duct, Cyst | | | 1 (10%) | 1 (13%) | | |
| Bile Duct, Hyperplasia | 1 (13%) | | | | | |
| Centrilobular, Degeneration | | | | | | |
| Hepatocyte, Hypertrophy | 2 (25%) | | 4 (40%) | 5 (63%) | 6 (75%) | 7 (88%) |
| Hepatocyte, Multinucleated | | | | | | |
| Oval Cell, Hyperplasia | | | | | | |
| Pancreas | (8) | (8) | (10) | (8) | (8) | (8) |
| Basophilic Focus | 1 (13%) | | | | | |
| Acinus, Vacuolization Cytoplasmic | | | | | | |
| Stomach, Forestomach | (8) | (0) | (0) | (0) | (0) | (0) |
| Stomach, Glandular | (8) | (0) | (0) | (0) | (0) | (0) |

CARDIOVASCULAR SYSTEM

None

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| SPRAGUE-DAWLEY RATS FEMALE | 0 UG/KG | 10 UG/KG | 30 UG/KG | 100 UG/KG | 220 UG/KG | 460 UG/KG |
|----------------------------------|----------|----------|-----------|-----------|-----------|-----------|
| ENDOCRINE SYSTEM | | | | | | |
| Adrenal Cortex | (8) | (8) | (10) | (8) | (8) | (8) |
| Atrophy | | | | | | |
| Degeneration, Cystic | | | | 1 (13%) | | |
| Hyperplasia | 1 (13%) | | | | | |
| Hypertrophy | 5 (63%) | 7 (88%) | 6 (60%) | 4 (50%) | 5 (63%) | 5 (63%) |
| Vacuolization Cytoplasmic | 1 (13%) | | | | | |
| Adrenal Medulla | (8) | (8) | (10) | (8) | (8) | (8) |
| Pituitary Gland | (8) | (0) | (0) | (0) | (0) | (0) |
| Angiectasis | 1 (13%) | | | | | |
| Pars Distalis, Hyperplasia | 1 (13%) | | | | | |
| Thyroid Gland | (8) | (8) | (10) | (8) | (8) | (8) |
| C-cell, Hyperplasia | 1 (13%) | | | 1 (13%) | | 1 (13%) |
| Follicular Cell, Hypertrophy | 1 (13%) | | 1 (10%) | 1 (13%) | 1 (13%) | 5 (63%) |
| GENERAL BODY SYSTEM | | | | | | |
| None | | | | | | |
| GENITAL SYSTEM | | | | | | |
| Ovary | (8) | (0) | (0) | (0) | (0) | (0) |
| Uterus | (8) | (8) | (10) | (8) | (8) | (8) |
| Dilatation | | | | | | 1 (13%) |
| Inflammation | | 1 (13%) | | | | |
| Inflammation, Suppurative | 3 (38%) | 1 (13%) | 3 (30%) | 4 (50%) | 3 (38%) | 3 (38%) |
| Metaplasia, Squamous | 6 (75%) | 5 (63%) | 7 (70%) | 7 (88%) | 4 (50%) | 4 (50%) |
| Endometrium, Hyperplasia, Cystic | 4 (50%) | 3 (38%) | 6 (60%) | 5 (63%) | 4 (50%) | 3 (38%) |
| Vagina | (8) | (0) | (0) | (0) | (0) | (0) |
| Inflammation, Chronic Active | 1 (13%) | | | | | |
| Necrosis | 1 (13%) | | | | | |
| HEMATOPOIETIC SYSTEM | | | | | | |
| Spleen | (8) | (0) | (0) | (0) | (0) | (0) |
| Pigmentation | 8 (100%) | | | | | |
| Thymus | (8) | (8) | (10) | (8) | (8) | (8) |
| Atrophy | 8 (100%) | 8 (100%) | 10 (100%) | 8 (100%) | 8 (100%) | 8 (100%) |
| Cyst | 1 (13%) | | | | | |

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

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|---|----------------|---|-----------------|-----------|-----------|-----------|
| INTEGUMENTARY SYSTEM | | | | | | |
| Mammary Gland Cyst | (8) | (2) 2 (100%) | (2) | (1) | (2) | (0) |
| MUSCULOSKELETAL SYSTEM | | | | | | |
| None | | | | | | |
| NERVOUS SYSTEM | | | | | | |
| None | | | | | | |
| RESPIRATORY SYSTEM | | | | | | |
| Lung Inflammation | (8) 1 (13%) | (8) | (10) 1 (10%) | (8) | (8) | (8) |
| Alveolar Epithelium, Hyperplasia Alveolar Epithelium, Metaplasia, Bronchiolar Alveolus, Infiltration Cellular, Histiocyte | 2 (25%) | 2 (25%) | 4 (40%) | 2 (25%) | 3 (38%) | 4 (50%) |
| SPECIAL SENSES SYSTEM | | | | | | |
| None | | | | | | |
| URINARY SYSTEM | | | | | | |
| Kidney Infarct Nephropathy Pelvis, Dilatation Pelvis, Inflammation Transitional Epithelium, Hyperplasia | (0) | (1) 1 (100%) 1 (100%) 1 (100%) 1 (100%) 1 (100%) | (0) | (0) | (0) | (0) |

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Disposition Summary

| | | |
|----------------------------------|----|----|
| Animals Initially in Study | 80 | 80 |
| Scheduled Sacrifice | 8 | 8 |
| Early Deaths | | |
| Survivors | | |
| Animals Examined Microscopically | 8 | 8 |

ALIMENTARY SYSTEM

| | | |
|-----------------------------------|----------|----------|
| Liver | (8) | (8) |
| Cholangiofibrosis | | 4 (50%) |
| Clear Cell Focus | 2 (25%) | |
| Clear Cell Focus, Multiple | 6 (75%) | |
| Eosinophilic Focus | | 3 (38%) |
| Eosinophilic Focus, Multiple | | 1 (13%) |
| Fatty Change, Diffuse | | 8 (100%) |
| Hepatodiaphragmatic Nodule | 1 (13%) | |
| Hyperplasia, Nodular | | 3 (38%) |
| Inflammation | 8 (100%) | 8 (100%) |
| Mixed Cell Focus | | |
| Mixed Cell Focus, Multiple | 1 (13%) | 7 (88%) |
| Necrosis | 2 (25%) | 1 (13%) |
| Pigmentation | 7 (88%) | 8 (100%) |
| Toxic Hepatopathy | | 8 (100%) |
| Bile Duct, Cyst | | |
| Bile Duct, Hyperplasia | | 6 (75%) |
| Centrilobular, Degeneration | 1 (13%) | |
| Hepatocyte, Hypertrophy | 8 (100%) | 8 (100%) |
| Hepatocyte, Multinucleated | 1 (13%) | 7 (88%) |
| Oval Cell, Hyperplasia | | 8 (100%) |
| Pancreas | (8) | (8) |
| Basophilic Focus | | |
| Acinus, Vacuolization Cytoplasmic | | 8 (100%) |
| Stomach, Forestomach | (0) | (8) |
| Stomach, Glandular | (0) | (8) |

CARDIOVASCULAR SYSTEM

None

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| ENDOCRINE SYSTEM | | |
| Adrenal Cortex | (8) | (8) |
| Atrophy | | 2 (25%) |
| Degeneration, Cystic | 1 (13%) | 3 (38%) |
| Hyperplasia | | 4 (50%) |
| Hypertrophy | 5 (63%) | 4 (50%) |
| Vacuolization Cytoplasmic | 1 (13%) | |
| Adrenal Medulla | (8) | (8) |
| Pituitary Gland | (0) | (8) |
| Angiectasis | | |
| Pars Distalis, Hyperplasia | | 1 (13%) |
| Thyroid Gland | (8) | (8) |
| C-cell, Hyperplasia | | |
| Follicular Cell, Hypertrophy | 5 (63%) | 7 (88%) |
| GENERAL BODY SYSTEM | | |
| None | | |
| GENITAL SYSTEM | | |
| Ovary | (0) | (8) |
| Uterus | (8) | (8) |
| Dilatation | 4 (50%) | |
| Inflammation | | |
| Inflammation, Suppurative | 5 (63%) | 2 (25%) |
| Metaplasia, Squamous | 3 (38%) | 4 (50%) |
| Endometrium, Hyperplasia, Cystic | 4 (50%) | 3 (38%) |
| Vagina | (0) | (8) |
| Inflammation, Chronic Active | | |
| Necrosis | | |
| HEMATOPOIETIC SYSTEM | | |
| Spleen | (0) | (8) |
| Pigmentation | | 8 (100%) |
| Thymus | (8) | (8) |
| Atrophy | 8 (100%) | 8 (100%) |
| Cyst | | |

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

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| INTEGUMENTARY SYSTEM | | |
| Mammary Gland Cyst | (1) | (8) |
| MUSCULOSKELETAL SYSTEM | | |
| None | | |
| NERVOUS SYSTEM | | |
| None | | |
| RESPIRATORY SYSTEM | | |
| Lung | (8) | (8) |
| Inflammation | | 1 (13%) |
| Alveolar Epithelium, Hyperplasia | | 1 (13%) |
| Alveolar Epithelium, Metaplasia, Bronchiolar | | 3 (38%) |
| Alveolus, Infiltration Cellular, Histiocyte | 3 (38%) | 3 (38%) |
| SPECIAL SENSES SYSTEM | | |
| None | | |
| URINARY SYSTEM | | |
| Kidney | (0) | (0) |
| Infarct | | |
| Nephropathy | | |
| Pelvis, Dilatation | | |
| Pelvis, Inflammation | | |
| Transitional Epithelium, Hyperplasia | | |

*** END OF REPORT ***