

TDMS No. 99020 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

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

Pulegone

CAS Number: 89-82-7

Date Report Requested: 03/31/2009

Time Report Requested: 11:07:07

First Dose M/F: 02/18/02 / 02/19/02

Lab: BAT

F1_Rev1_R2

C Number: C99020
Lock Date: 09/27/2002
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.1.0

| FISCHER 344 RATS MALE | 0 MG/KG | 9.375 MG/KG | 18.75 MG/KG | 37.5 MG/KG | 75 MG/KG | 150 MG/KG |
|---------------------------------------|---------|-------------|-------------|------------|-----------|-----------|
| Disposition Summary | | | | | | |
| Animals Initially in Study | 10 | 10 | 10 | 10 | 10 | 10 |
| Early Deaths | | | | | | |
| Survivors | | | | | | |
| Terminal Sacrifice | 10 | 10 | 10 | 10 | 10 | 10 |
| Animals Examined Microscopically | 10 | 10 | 10 | 10 | 10 | 10 |
| ALIMENTARY SYSTEM | | | | | | |
| Intestine Large, Rectum | (10) | (0) | (0) | (0) | (0) | (10) |
| Parasite Metazoan | 1 (10%) | | | | | |
| Liver | (10) | (10) | (10) | (10) | (10) | (10) |
| Hepatodiaphragmatic Nodule | | 2 (20%) | 2 (20%) | 2 (20%) | | |
| Inflammation, Chronic Active | 1 (10%) | | | 1 (10%) | 1 (10%) | 1 (10%) |
| Mineralization | | | | 1 (10%) | | 1 (10%) |
| Pigmentation | | | | | | 1 (10%) |
| Bile Duct, Hyperplasia | | | | | 9 (90%) | 10 (100%) |
| Hepatocyte, Hypertrophy | | | | | 10 (100%) | 10 (100%) |
| Hepatocyte, Necrosis, Focal | | | | | | 6 (60%) |
| Oval Cell, Hyperplasia | | | | | | 10 (100%) |
| Periportal, Fibrosis | | | | | | 10 (100%) |
| Pancreas | (10) | (0) | (0) | (0) | (0) | (10) |
| Basophilic Focus | | | | | | 1 (10%) |
| Salivary Glands | (10) | (0) | (0) | (0) | (0) | (10) |
| Metaplasia, Squamous, Focal | | | | | | 1 (10%) |
| Stomach, Glandular | (10) | (10) | (10) | (10) | (10) | (10) |
| Mineralization | 5 (50%) | 3 (30%) | 5 (50%) | 2 (20%) | 3 (30%) | 9 (90%) |
| CARDIOVASCULAR SYSTEM | | | | | | |
| Heart | (10) | (10) | (10) | (10) | (10) | (10) |
| Cardiomyopathy | 9 (90%) | 8 (80%) | 8 (80%) | 9 (90%) | 7 (70%) | 7 (70%) |
| Mineralization | 1 (10%) | | | 1 (10%) | | 6 (60%) |
| Myocardium, Pigmentation, Hemosiderin | 1 (10%) | | | | | |
| ENDOCRINE SYSTEM | | | | | | |
| Adrenal Cortex | (10) | (0) | (0) | (0) | (0) | (10) |
| Accessory Adrenal Cortical Nodule | | | | | | 1 (10%) |
| Capsule, Fibrosis | 1 (10%) | | | | | |

| FISCHER 344 RATS MALE | 0 MG/KG | 9.375 MG/KG | 18.75 MG/KG | 37.5 MG/KG | 75 MG/KG | 150 MG/KG |
|-------------------------------|---------|-------------|-------------|------------|----------|-----------|
| Pituitary Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Chromophobe Cell, Hyperplasia | 1 (10%) | | | | | |
| Thyroid Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Cyst | | | | | | 1 (10%) |

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

| | | | | | | |
|---|---------|----------|-----|-----|-----|---------|
| Epididymis | (10) | (0) | (0) | (0) | (0) | (10) |
| Inflammation, Granulomatous | | | | | | 1 (10%) |
| Preputial Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Infiltration Cellular, Mononuclear Cell | | | | | | 1 (10%) |
| Inflammation, Suppurative | 1 (10%) | | | | | |
| Inflammation, Chronic Active | | | | | | 2 (20%) |
| Prostate | (10) | (0) | (0) | (0) | (0) | (10) |
| Inflammation, Suppurative | | | | | | 1 (10%) |
| Testes | (10) | (2) | (0) | (0) | (0) | (10) |
| Germinal Epithelium, Degeneration | | 2 (100%) | | | | |

HEMATOPOIETIC SYSTEM

| | | | | | | |
|------------------------|---------|---------|---------|---------|-----------|-----------|
| Bone Marrow | (10) | (10) | (10) | (10) | (10) | (10) |
| Hyperplasia | 3 (30%) | 1 (10%) | 5 (50%) | 9 (90%) | 10 (100%) | 10 (100%) |
| Lymph Node, Mesenteric | (10) | (0) | (0) | (0) | (0) | (10) |
| Necrosis, Lymphoid | | | | | | 1 (10%) |
| Thymus | (10) | (0) | (0) | (10) | (10) | (10) |
| Atrophy | 2 (20%) | | | | 1 (10%) | 1 (10%) |

INTEGUMENTARY SYSTEM

None

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

| FISCHER 344 RATS MALE | 0 MG/KG | 9.375 MG/KG | 18.75 MG/KG | 37.5 MG/KG | 75 MG/KG | 150 MG/KG |
|---|---------|-------------|-------------|------------|----------|-----------|
| None | | | | | | |
| RESPIRATORY SYSTEM | | | | | | |
| Lung | (10) | (10) | (10) | (10) | (10) | (10) |
| Infiltration Cellular, Histiocyte | 6 (60%) | | 5 (50%) | 4 (40%) | 2 (20%) | 8 (80%) |
| Interstitial, Infiltration Cellular, Lymphocyte | 7 (70%) | | | 1 (10%) | 2 (20%) | 1 (10%) |
| SPECIAL SENSES SYSTEM | | | | | | |
| Eye | (10) | (0) | (0) | (0) | (0) | (10) |
| Inflammation, Acute | | | | | | 1 (10%) |
| Harderian Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Inflammation, Acute | | | | | | 1 (10%) |
| URINARY SYSTEM | | | | | | |
| Kidney | (10) | (10) | (10) | (10) | (10) | (10) |
| Accumulation, Hyaline Droplet | 3 (30%) | | 1 (10%) | 1 (10%) | | |
| Glomerulopathy, Hyaline | | | | | 2 (20%) | 10 (100%) |
| Infiltration Cellular, Lymphocyte | 1 (10%) | | 1 (10%) | 1 (10%) | | |
| Mineralization | 6 (60%) | 8 (80%) | 8 (80%) | 7 (70%) | 9 (90%) | 7 (70%) |
| Renal Tubule, Casts Protein | 7 (70%) | 4 (40%) | 6 (60%) | 6 (60%) | 4 (40%) | 10 (100%) |
| Renal Tubule, Regeneration | 9 (90%) | 9 (90%) | 10 (100%) | 10 (100%) | 3 (30%) | 9 (90%) |
| Urinary Bladder | (9) | (0) | (0) | (0) | (0) | (10) |
| Infiltration Cellular | 1 (11%) | | | | | |
| Mineralization | | | | | | 1 (10%) |

*** END OF MALE ***

| FISCHER 344 RATS FEMALE | 0 MG/KG | 9.375 MG/KG | 18.75 MG/KG | 37.5 MG/KG | 75 MG/KG | 150 MG/KG |
|----------------------------------|---------|-------------|-------------|------------|----------|-----------|
| Disposition Summary | | | | | | |
| Animals Initially in Study | 10 | 10 | 10 | 10 | 10 | 10 |
| Early Deaths | | | | | | |
| Natural Death | | | | | | 1 |
| Survivors | | | | | | |
| Terminal Sacrifice | 10 | 10 | 10 | 10 | 10 | 9 |
| Animals Examined Microscopically | 10 | 10 | 10 | 10 | 10 | 10 |
| ALIMENTARY SYSTEM | | | | | | |
| Esophagus | (10) | (0) | (0) | (0) | (0) | (10) |
| Inflammation, Chronic | 1 (10%) | | | | | |
| Liver | (10) | (10) | (10) | (10) | (10) | (10) |
| Basophilic Focus | 1 (10%) | | | | | |
| Hepatodiaphragmatic Nodule | 1 (10%) | 2 (20%) | 2 (20%) | 2 (20%) | | 1 (10%) |
| Inflammation, Chronic Active | | 1 (10%) | | | | |
| Bile Duct, Hyperplasia | | | | | 1 (10%) | 10 (100%) |
| Hepatocyte, Hypertrophy | | | | | | 10 (100%) |
| Oval Cell, Hyperplasia | | | | | | 9 (90%) |
| Periportal, Fibrosis | | | | | | 9 (90%) |
| Serosa, Fibrosis | 1 (10%) | | | | | |
| Stomach, Glandular | (10) | (10) | (10) | (10) | (10) | (10) |
| Mineralization | | 3 (30%) | 2 (20%) | 2 (20%) | 6 (60%) | 7 (70%) |
| CARDIOVASCULAR SYSTEM | | | | | | |
| Heart | (10) | (10) | (10) | (10) | (10) | (10) |
| Cardiomyopathy | 6 (60%) | 3 (30%) | | 4 (40%) | 5 (50%) | 2 (20%) |
| Mineralization | | | | | | 1 (10%) |
| ENDOCRINE SYSTEM | | | | | | |
| Thyroid Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Cyst | | | | | | 1 (10%) |
| GENERAL BODY SYSTEM | | | | | | |
| None | | | | | | |

| FISCHER 344 RATS FEMALE | 0 MG/KG | 9.375 MG/KG | 18.75 MG/KG | 37.5 MG/KG | 75 MG/KG | 150 MG/KG |
|---|---------|-------------|-------------|------------|-----------|-----------|
| GENITAL SYSTEM | | | | | | |
| Clitoral Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Inflammation, Chronic Active | | | | | | 1 (10%) |
| Ovary | (10) | (10) | (10) | (10) | (10) | (10) |
| Cyst | 1 (10%) | 2 (20%) | 2 (20%) | 2 (20%) | 3 (30%) | 6 (60%) |
| Uterus | (10) | (10) | (10) | (10) | (10) | (10) |
| Dilatation | 2 (20%) | | | | | |
| HEMATOPOIETIC SYSTEM | | | | | | |
| Bone Marrow | (10) | (10) | (10) | (10) | (10) | (10) |
| Hyperplasia | 1 (10%) | 1 (10%) | 1 (10%) | 1 (10%) | 10 (100%) | 9 (90%) |
| Thymus | (10) | (0) | (0) | (0) | (10) | (10) |
| Atrophy | 1 (10%) | | | | | |
| INTEGUMENTARY SYSTEM | | | | | | |
| None | | | | | | |
| MUSCULOSKELETAL SYSTEM | | | | | | |
| None | | | | | | |
| NERVOUS SYSTEM | | | | | | |
| Brain | (10) | (10) | (10) | (10) | (10) | (10) |
| Cerebellum, Dysplasia | 1 (10%) | | | | | |
| RESPIRATORY SYSTEM | | | | | | |
| Lung | (10) | (10) | (10) | (10) | (10) | (10) |
| Infiltration Cellular, Histiocyte | 1 (10%) | | | 2 (20%) | 2 (20%) | 6 (60%) |
| Interstitial, Infiltration Cellular, Lymphocyte | 4 (40%) | | | | | |
| SPECIAL SENSES SYSTEM | | | | | | |
| None | | | | | | |

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|--|---------|-------------|-------------|------------|-----------|-----------|
| URINARY SYSTEM | | | | | | |
| Kidney | (10) | (10) | (10) | (10) | (10) | (10) |
| Glomerulopathy, Hyaline Mineralization | 6 (60%) | 10 (100%) | 9 (90%) | 9 (90%) | 10 (100%) | 8 (80%) |
| Nephropathy | | | | | | 9 (90%) |
| Renal Tubule, Casts Protein | 1 (10%) | | | | 2 (20%) | 1 (10%) |
| Renal Tubule, Regeneration | | 1 (10%) | | | | 6 (60%) |
| Urinary Bladder | (10) | (0) | (0) | (0) | (0) | (10) |
| Mineralization | 1 (10%) | | | | | |

*** END OF REPORT ***