TDMS No. 20226 - 01
Test Type: 26-WEEK
Route: DOSED FEED
Species/Strain: RATS/SD

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

Chitosan

CAS Number: 9012-76-4

Lab: B

F1_R8

C Number: C20226

Lock Date: 05/07/2008

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

Date Report Requested: 05/28/2009 Time Report Requested: 08:46:11 First Dose M/F: 08/31/06 / 09/01/06

Lab: BAT

Chitosan

CAS Number: 9012-76-4

Date Report Requested: 05/28/2009 Time Report Requested: 08:46:11 First Dose M/F: 08/31/06 / 09/01/06

Lab: BAT

| SPRAGUE-DAWLEY RATS MALE | 0 % | 1 % | 3 % | 9 % | |
|---|--|------------------------------------|------------------------------------|--|--|
| Disposition Summary | | | | | |
| Animals Initially in Study Early Deaths | 10 | 10 | 10 | 10 | |
| Survivors Terminal Sacrifice Animals Examined Microscopically | 10 10 | 10 10 | 10 10 | 10 10 | |
| LIMENTARY SYSTEM | | | | | |
| Liver Degeneration, Cystic Hematopoietic Cell Proliferation Inflammation, Chronic Active Periportal, Fatty Change Pancreas Basophilic Focus Inflammation Stomach, Forestomach Epithelium, Hyperplasia | (10) 2 (20%) 10 (100%) 6 (60%) (10) 1 (10%) 2 (20%) (10) 3 (30%) | (10) 3 (30%) 10 (100%) 3 (30%) (0) | (10) 3 (30%) 10 (100%) 6 (60%) (0) | (10) 1 (10%) 6 (60%) 9 (90%) 3 (30%) (10) 1 (10%) (10) 1 (10%) | |
| CARDIOVASCULAR SYSTEM | | | | | |
| Blood Vessel Inflammation Heart Cardiomyopathy Mineralization | (10) (10) 5 (50%) | (0) | (O) (O) | (10) 1 (10%) (10) 3 (30%) 1 (10%) | |
| ENDOCRINE SYSTEM | | | | | |
| Adrenal Cortex Vacuolization Cytoplasmic Parathyroid Gland Hyperplasia Pituitary Gland Cyst | (10) (10) 1 (10%) (10) 1 (10%) | (1) (10) (0) | (0) (10) (0) | (10) 1 (10%) (10) (10) | |
| Thyroid Gland C-cell, Hyperplasia | (10) | (0) | (0) | (10) 1 (10%) | |

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| SPRAGUE-DAWLEY RATS MALE | 0 % | 1 % | 3 % | 9 % | |
|---|---|-------------------------------|---------------------------------|--|--|
| GENERAL BODY SYSTEM | | | | | |
| None | | | | | |
| GENITAL SYSTEM | | | | | |
| Preputial Gland Inflammation Inflammation, Chronic Active Prostate Inflammation Testes Mineralization | (10) (10) 8 (80%) (10) | (0) (10) 9 (90%) (0) | (0) (10) 10 (100%) (0) | (10) 1 (10%) 2 (20%) (10) 10 (100%) (10) 1 (10%) | |
| HEMATOPOIETIC SYSTEM | | | | | |
| Lymph Node, Mandibular Infiltration Cellular, Plasma Cell Spleen Hematopoietic Cell Proliferation Thymus Atrophy | (10) 1 (10%) (10) 5 (50%) (10) 1 (10%) | (0) (0) (0) | (0) (0) (0) | (10) 2 (20%) (10) 2 (20%) (10) | |
| NTEGUMENTARY SYSTEM | | | | | |
| Skin Hemorrhage Mineralization Ulcer | (10) | (0) | (0) | (10) 1 (10%) 1 (10%) 1 (10%) | |
| MUSCULOSKELETAL SYSTEM | | | | | |
| Skeletal Muscle Inflammation, Granulomatous | (0) | (0) | (0) | (1) 1 (100%) | |
| NERVOUS SYSTEM | | | | | |
| None | | | | | |

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| SPRAGUE-DAWLEY RATS MALE | 0 % | 1 % | 3 % | 9 % | |
|--|--------------------|----------------------|--------------------|-----------------|--|
| | | | | | |
| RESPIRATORY SYSTEM | | | | | |
| Lung | (10) | (0) | (0) | (10) | |
| Hemorrhage Inflammation, Chronic Active | 2 (20%) 2 (20%) | | | 4 (40%) | |
| Nose Inflammation | (10) 1 (10%) | (0) | (0) | (10) | |
| Goblet Cell, Hyperplasia | . (13/3) | | | 1 (10%) | |
| SPECIAL SENSES SYSTEM | | | | | |
| Eye | (10) | (1) | (0) | (10) | |
| Choroid, Fibrosis Lens, Cataract | | 1 (100%) 1 (100%) | | | |
| Harderian Gland Hyperplasia | (10) | (0) | (0) | (10) 1 (10%) | |
| Infiltration Cellular, Lymphocyte | 2 (20%) | | | 1 (10%) | |
| URINARY SYSTEM | | | | | |
| Kidney | (10) | (10) | (10) | (10) | |
| Infarct Mineralization | 2 (20%) | 4 (40%) | 1 (10%) 3 (30%) | 5 (50%) | |
| Nephropathy Cortex, Cyst | 9 (90%) 1 (10%) | 9 (90%) | 9 (90%) | 9 (90%) | |
| Pelvis, Dilatation Pelvis, Inflammation | 2 (20%) | | 1 (10%) | | |
| Urinary Bladder | 1 (10%) (10) | (0) | (0) | (10) | |
| Transitional Epithelium, Hyperplasia | | | | 1 (10%) | |

*** END OF MALE ***

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| SPRAGUE-DAWLEY RATS FEMALE | 0 % | 1 % | 3 % | 9 % | |
|---|--|--|--|---|--|
| | | | | | |
| Disposition Summary | | | | | |
| Animals Initially in Study Early Deaths Survivors | 10 | 10 | 10 | 10 | |
| Terminal Sacrifice Animals Examined Microscopically | 10 10 | 10 10 | 10 10 | 10 10 | |
| ALIMENTARY SYSTEM | | | | | |
| Liver Hematopoietic Cell Proliferation Inflammation, Chronic Active Periportal, Fatty Change Pancreas Atrophy Inflammation Inflammation, Chronic Active | (10) 1 (10%) 9 (90%) 7 (70%) (10) 1 (10%) | (10) 1 (10%) 9 (90%) 4 (40%) (0) | (10) 2 (20%) 9 (90%) 4 (40%) (0) | (10) 1 (10%) 10 (100%) (10) 1 (10%) | |
| CARDIOVASCULAR SYSTEM | | | | | |
| Heart Cardiomyopathy | (10) 1 (10%) | (0) | (0) | (10) | |
| ENDOCRINE SYSTEM | | | | | |
| Pituitary Gland Rathke's Cleft, Hyperplasia | (10) 1 (10%) | (0) | (0) | (10) | |
| GENERAL BODY SYSTEM | | | | | |
| None | | | | | |
| GENITAL SYSTEM | | | | | |
| Clitoral Gland Inflammation, Chronic Active | (10) 2 (20%) | (0) | (0) | (10) | |

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|---|---------------------------------------|----------------------------|----------------------------|----------------------------|--|
| HEMATOPOIETIC SYSTEM | | | | | |
| Spleen | (10) | (0) | (0) | (10) | |
| Hematopoietic Cell Proliferation Thymus Atrophy | 1 (10%) (10) 1 (10%) | (0) | (0) | (10) | |
| INTEGUMENTARY SYSTEM | | | | | |
| Mammary Gland | (10) | (0) | (0) | (10) | |
| MUSCULOSKELETAL SYSTEM | | | | | |
| None | | | | | |
| NERVOUS SYSTEM | | | | | |
| Brain Developmental Malformation | (10) 1 (10%) | (0) | (0) | (10) | |
| RESPIRATORY SYSTEM | | | | | |
| Lung Mineralization Alveolar Epithelium, Hyperplasia | (10) | (0) | (0) | (10) 1 (10%) 1 (10%) | |
| Alveolus, Infiltration Cellular, Histiocyte Artery, Mineralization Nose Goblet Cell, Hyperplasia | 2 (20%) 1 (10%) (10) 1 (10%) | (0) | (0) | 1 (10%) (10) | |
| SPECIAL SENSES SYSTEM | | | | | |
| Harderian Gland Infiltration Cellular, Lymphocyte | (10) 1 (10%) | (0) | (0) | (10) 1 (10%) | |
| URINARY SYSTEM | | | | | |
| Kidney Mineralization Nephropathy | (10) 8 (80%) 5 (50%) | (10) 8 (80%) 6 (60%) | (10) 5 (50%) 5 (50%) | (10) 6 (60%) | |

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*** END OF REPORT ***

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