

TDMs No. 20226 - 01

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**

Date Report Requested: 05/28/2009

Test Type: 26-WEEK

Chitosan

Time Report Requested: 08:46:11

Route: DOSED FEED

CAS Number: 9012-76-4

First Dose M/F: 08/31/06 / 09/01/06

Species/Strain: RATS/SD

Lab: BAT

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

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Species/Strain: RATS/SD

Lab: BAT

SPRAGUE-DAWLEY RATS MALE	0 %	1 %	3 %	9 %
Disposition Summary				
Animals Initially in Study	10	10	10	10
Early Deaths				
Survivors				
Terminal Sacrifice	10	10	10	10
Animals Examined Microscopically	10	10	10	10
ALIMENTARY SYSTEM				
Liver	(10)	(10)	(10)	(10)
Degeneration, Cystic				1 [1.0]
Hematopoietic Cell Proliferation	2 [1.0]	3 [1.0]	3 [1.0]	6 [1.0]
Inflammation, Chronic Active	10 [1.0]	10 [1.0]	10 [1.0]	9 [1.0]
Periportal, Fatty Change	6 [1.7]	3 [1.7]	6 [1.3]	3 [1.0]
Pancreas	(10)	(0)	(0)	(10)
Basophilic Focus	1			
Inflammation	2 [1.0]			1 [1.0]
Stomach, Forestomach	(10)	(0)	(0)	(10)
Epithelium, Hyperplasia	3 [1.0]			1 [1.0]
CARDIOVASCULAR SYSTEM				
Blood Vessel	(10)	(0)	(0)	(10)
Inflammation				1 [1.0]
Heart	(10)	(0)	(0)	(10)
Cardiomyopathy	5 [1.0]			3 [1.3]
Mineralization				1 [1.0]
ENDOCRINE SYSTEM				
Adrenal Cortex	(10)	(1)	(0)	(10)
Vacuolization Cytoplasmic				1 [1.0]
Parathyroid Gland	(10)	(10)	(10)	(10)
Hyperplasia	1 [1.0]			
Pituitary Gland	(10)	(0)	(0)	(10)
Cyst	1			

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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Thyroid Gland	(10)	(0)	(0)	(10)
C-cell, Hyperplasia				1 [1.0]
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Preputial Gland	(10)	(0)	(0)	(10)
Inflammation				1 [1.0]
Inflammation, Chronic Active				2 [1.0]
Prostate	(10)	(10)	(10)	(10)
Inflammation	8 [1.6]	9 [1.1]	10 [1.4]	10 [1.5]
Testes	(10)	(0)	(0)	(10)
Mineralization				1 [1.0]
HEMATOPOIETIC SYSTEM				
Lymph Node, Mandibular	(10)	(0)	(0)	(10)
Infiltration Cellular, Plasma Cell	1 [2.0]			2 [1.0]
Spleen	(10)	(0)	(0)	(10)
Hematopoietic Cell Proliferation	5 [1.0]			2 [1.0]
Thymus	(10)	(0)	(0)	(10)
Atrophy	1 [1.0]			
INTEGUMENTARY SYSTEM				
Skin	(10)	(0)	(0)	(10)
Hemorrhage				1 [3.0]
Mineralization				1 [2.0]
Ulcer				1 [4.0]
MUSCULOSKELETAL SYSTEM				
Skeletal Muscle	(0)	(0)	(0)	(1)
Inflammation, Granulomatous				1 [3.0]

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NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
Lung	(10)	(0)	(0)	(10)
Hemorrhage	2 [1.0]			
Inflammation, Chronic Active	2 [1.0]			4 [1.0]
Nose	(10)	(0)	(0)	(10)
Inflammation	1 [1.0]			
Goblet Cell, Hyperplasia				1 [2.0]
SPECIAL SENSES SYSTEM				
Eye	(10)	(1)	(0)	(10)
Choroid, Fibrosis		1 [2.0]		
Lens, Cataract		1 [3.0]		
Harderian Gland	(10)	(0)	(0)	(10)
Hyperplasia				1 [1.0]
Infiltration Cellular, Lymphocyte	2 [1.0]			1 [1.0]
URINARY SYSTEM				
Kidney	(10)	(10)	(10)	(10)
Infarct			1 [2.0]	
Mineralization	2 [1.0]	4 [1.0]	3 [1.0]	5 [1.0]
Nephropathy	9 [1.0]	9 [1.0]	9 [1.2]	9 [1.3]
Cortex, Cyst	1 [2.0]			
Pelvis, Dilatation	2 [1.5]		1 [2.0]	
Pelvis, Inflammation	1 [2.0]			
Urinary Bladder	(10)	(0)	(0)	(10)
Transitional Epithelium, Hyperplasia				1 [1.0]

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*** END OF MALE ***

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Disposition Summary				
Animals Initially in Study	10	10	10	10
Early Deaths				
Survivors				
Terminal Sacrifice	10	10	10	10
Animals Examined Microscopically	10	10	10	10
ALIMENTARY SYSTEM				
Liver	(10)	(10)	(10)	(10)
Hematopoietic Cell Proliferation	1 [1.0]	1 [1.0]	2 [1.0]	1 [1.0]
Inflammation, Chronic Active	9 [1.0]	9 [1.0]	9 [1.0]	10 [1.0]
Periportal, Fatty Change	7 [1.1]	4 [1.0]	4 [1.0]	
Pancreas	(10)	(0)	(0)	(10)
Atrophy				1 [1.0]
Inflammation	1 [1.0]			
Inflammation, Chronic Active				1 [1.0]
CARDIOVASCULAR SYSTEM				
Heart	(10)	(0)	(0)	(10)
Cardiomyopathy	1 [1.0]			
ENDOCRINE SYSTEM				
Pituitary Gland	(10)	(0)	(0)	(10)
Rathke's Cleft, Hyperplasia	1 [2.0]			
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Clitoral Gland	(10)	(0)	(0)	(10)

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Inflammation, Chronic Active	2 [2.0]			
HEMATOPOIETIC SYSTEM				
Spleen	(10)	(0)	(0)	(10)
Hematopoietic Cell Proliferation	1 [1.0]			
Thymus	(10)	(0)	(0)	(10)
Atrophy	1 [1.0]			
INTEGUMENTARY SYSTEM				
Mammary Gland	(10)	(0)	(0)	(10)
MUSCULOSKELETAL SYSTEM				
None				
NERVOUS SYSTEM				
Brain	(10)	(0)	(0)	(10)
Developmental Malformation	1			
RESPIRATORY SYSTEM				
Lung	(10)	(0)	(0)	(10)
Mineralization				1 [1.0]
Alveolar Epithelium, Hyperplasia				1 [1.0]
Alveolus, Infiltration Cellular, Histiocyte	2 [1.0]			
Artery, Mineralization	1 [1.0]			1 [1.0]
Nose	(10)	(0)	(0)	(10)
Goblet Cell, Hyperplasia	1 [2.0]			
SPECIAL SENSES SYSTEM				
Harderian Gland	(10)	(0)	(0)	(10)
Infiltration Cellular, Lymphocyte	1 [1.0]			1 [1.0]

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URINARY SYSTEM				
Kidney	(10)	(10)	(10)	(10)
Mineralization	8 [1.0]	8 [1.0]	5 [1.0]	6 [1.0]
Nephropathy	5 [1.0]	6 [1.0]	5 [1.0]	

*** END OF REPORT ***

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