TDMS No. 20226 - 01	P18: INCIDENCE RATE	ES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WI AVERAGE SEVERITY GRADES[b]	TH 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:

Treatment Groups:

Study Gender:

TDMSE Version:

ALL

Both

2.1.0

Include ALL

MS No. 20226 - 01 st Type: 26-WEEK oute: DOSED FEED secies/Strain: RATS/SD	P18: INCIDENCE RA	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 Survivors	10	10	10	10	
Terminal Sacrifice Animals Examined Microscopically	10 10	10 10	10 10	10 10	
ALIMENTARY SYSTEM					
Liver Degeneration, Cystic Hematopoietic Cell Proliferation Inflammation, Chronic Active Periportal, Fatty Change Pancreas	(10) 2 [1.0] 10 [1.0] 6 [1.7] (10)	(10) 3 [1.0] 10 [1.0] 3 [1.7] (0)	(10) 3 [1.0] 10 [1.0] 6 [1.3] (0)	(10) 1 [1.0] 6 [1.0] 9 [1.0] 3 [1.0] (10)	
Basophilic Focus Inflammation Stomach, Forestomach Epithelium, Hyperplasia	1 2 [1.0] (10) 3 [1.0]	(0)	(0)	1 [1.0] (10) 1 [1.0]	
CARDIOVASCULAR SYSTEM					
Blood Vessel Inflammation Heart Cardiomyopathy Mineralization	(10) (10) 5 [1.0]	(0) (0)	(0) (0)	(10) 1 [1.0] (10) 3 [1.3] 1 [1.0]	
ENDOCRINE SYSTEM					
Adrenal Cortex Vacuolization Cytoplasmic Parathyroid Gland Hyperplasia Pituitary Gland Cyst	(10) (10) 1 [1.0] (10) 1	(1) (10) (0)	(0) (10) (0)	(10) 1 [1.0] (10) (10)	

DMS No. 20226 - 01 est Type: 26-WEEK oute: DOSED FEED pecies/Strain: RATS/SD	AVERAGE SEVERITY GRADES[b] 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 %	
Thyroid Gland C-cell, Hyperplasia	(10)	(0)	(0)	(10) 1 [1.0]	
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
Preputial Gland Inflammation Inflammation, Chronic Active Prostate Inflammation Testes Mineralization	(10) (10) 8 [1.6] (10)	(0) (10) 9 [1.1] (0)	(0) (10) 10 [1.4] (0)	(10) 1 [1.0] 2 [1.0] (10) 10 [1.5] (10) 1 [1.0]	
HEMATOPOIETIC SYSTEM					
Lymph Node, Mandibular Infiltration Cellular, Plasma Cell Spleen Hematopoietic Cell Proliferation Thymus Atrophy	(10) 1 [2.0] (10) 5 [1.0] (10) 1 [1.0]	(0) (0) (0)	(0) (0) (0)	(10) 2 [1.0] (10) 2 [1.0] (10)	
INTEGUMENTARY SYSTEM					
Skin Hemorrhage Mineralization Ulcer	(10)	(0)	(0)	(10) 1 [3.0] 1 [2.0] 1 [4.0]	
MUSCULOSKELETAL SYSTEM					
Skeletal Muscle Inflammation, Granulomatous	(0)	(0)	(0)	(1) 1 [3.0]	

MS No. 20226 - 01 st Type: 26-WEEK oute: DOSED FEED secies/Strain: RATS/SD	P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] 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 %	
NERVOUS SYSTEM					
None					
RESPIRATORY SYSTEM					
Lung	(10)	(0)	(0)	(10)	
Hemorrhage Inflammation, Chronic Active Nose Inflammation	2 [1.0] 2 [1.0] (10) 1 [1.0]	(0)	(0)	4 [1.0] (10)	
Goblet Cell, Hyperplasia	.[]			1 [2.0]	
SPECIAL SENSES SYSTEM					
Eye Choroid, Fibrosis Lens, Cataract	(10)	(1) 1 [2.0] 1 [3.0]	(0)	(10)	
Harderian Gland Hyperplasia	(10)	(0)	(0)	(10) 1 [1.0]	
Infiltration Cellular, Lymphocyte	2 [1.0]			1 [1.0]	
URINARY SYSTEM					
Kidney	(10)	(10)	(10)	(10)	
Infarct Mineralization Nephropathy Cortex, Cyst	2 [1.0] 9 [1.0] 1 [2.0]	4 [1.0] 9 [1.0]	1 [2.0] 3 [1.0] 9 [1.2]	5 [1.0] 9 [1.3]	
Pelvis, Dilatation	2 [1.5]		1 [2.0]		
Pelvis, Inflammation Urinary Bladder Transitional Epithelium, Hyperplasia	1 [2.0] (10)	(0)	(0)	(10) 1 [1.0]	

TDMS No. 20226 - 01 Test Type: 26-WEEK	P18: INCIDENCE RAT	AVERAGE SEVI	F NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requester AVERAGE SEVERITY GRADES[b] Chitosan Time Report Request		
Route: DOSED FEED Species/Strain: RATS/SD		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 %	

*** END OF MALE ***

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)

MS No. 20226 - 01 st Type: 26-WEEK ute: DOSED FEED ecies/Strain: RATS/SD	P18: INCIDENCE RA	Date Report Requested: 05/28/200 Time Report Requested: 08:46:11 First Dose M/F: 08/31/06 / 09/01/06 Lab: BAT			
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	(10) 1 [1.0]	(10) 1 [1.0]	(10) 2 [1.0]	(10) 1 [1.0]	
Inflammation, Chronic Active Periportal, Fatty Change	9 [1.0] 7 [1.1]	9 [1.0] 4 [1.0]	9 [1.0] 4 [1.0]	10 [1.0]	
Pancreas Atrophy	(10)	(0)	(0)	(10) 1 [1.0]	
Inflammation Inflammation, Chronic Active	1 [1.0]			1 [1.0]	
CARDIOVASCULAR SYSTEM					
Heart Cardiomyopathy	(10) 1 [1.0]	(0)	(0)	(10)	
ENDOCRINE SYSTEM					
Pituitary Gland Rathke's Cleft, Hyperplasia	(10) 1 [2.0]	(0)	(0)	(10)	
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
Clitoral Gland	(10)	(0)	(0)	(10)	

MS No. 20226 - 01 st Type: 26-WEEK ute: DOSED FEED ecies/Strain: RATS/SD	P18: INCIDENCE RAT	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 FEMALE	0 %	1 %	3 %	9 %	
Inflammation, Chronic Active	2 [2.0]				
HEMATOPOIETIC SYSTEM					
Spleen	(10)	(0)	(0)	(10)	
Hematopoietic Cell Proliferation Thymus Atrophy	1 [1.0] (10) 1 [1.0]	(0)	(0)	(10)	
INTEGUMENTARY SYSTEM					
Mammary Gland	(10)	(0)	(0)	(10)	
MUSCULOSKELETAL SYSTEM None					
NERVOUS SYSTEM					
Brain Developmental Malformation	(10) 1	(0)	(0)	(10)	
RESPIRATORY SYSTEM					
Lung Mineralization Alveolar Epithelium, Hyperplasia	(10)	(0)	(0)	(10) 1 [1.0] 1 [1.0]	
Alveolus, Infiltration Cellular, Histiocyte Artery, Mineralization	2 [1.0] 1 [1.0]			1 [1.0]	
Nose Goblet Cell, Hyperplasia	(10) 1 [2.0]	(0)	(0)	(10)	
SPECIAL SENSES SYSTEM					
Harderian Gland Infiltration Cellular, Lymphocyte	(10) 1 [1.0]	(0)	(0)	(10) 1 [1.0]	

TDMS No. 20226 - 01 Test Type: 26-WEEK Route: DOSED FEED Species/Strain: RATS/SD	P18: INCIDENCE RA	AVERAGE SEVERITY GRADES[b] Chitosan Time Report			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 FEMALE	0 %	1 %	3 %	9 %	
URINARY SYSTEM					
Kidney Mineralization Nephropathy	(10) 8 [1.0] 5 [1.0]	(10) 8 [1.0] 6 [1.0]	(10) 5 [1.0] 5 [1.0]	(10) 6 [1.0]	

*** END OF REPORT ***