

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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

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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DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1
	6	6	6	6	6	6	6	6	6	6
	9	9	9	9	9	9	9	9	9	9
SPRAGUE-DAWLEY RATS MALE	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
0 %	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	1
	1	2	3	4	5	6	7	8	9	0
	* TOTALS									

ALIMENTARY SYSTEM

Esophagus	+	+	+	+	+	+	+	+	+	+	10
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	10
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	10
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	10
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	10
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	10
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	10
Liver	+	+	+	+	+	+	+	+	+	+	10
Hematopoietic Cell Proliferation				1			1				2 1.0
Inflammation, Chronic Active	1	1	1	1	1	1	1	1	1	1	10 1.0
Periportal, Fatty Change		3	1	2			1		1	2	6 1.7
Pancreas	+	+	+	+	+	+	+	+	+	+	10
Basophilic Focus							X				1
Inflammation					1		1				2 1.0
Salivary Glands	+	+	+	+	+	+	+	+	+	+	10

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1) Minimal 3) Moderate

2) Mild 4) Marked

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	6	6	6	6	6	6	6	6	6	6
	9	9	9	9	9	9	9	9	9	9
SPRAGUE-DAWLEY RATS MALE	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
0 %	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	1
	1	2	3	4	5	6	7	8	9	0
										* TOTALS

Stomach, Forestomach Epithelium, Hyperplasia	+	+	+	+	+	+	+	+	+	+	10	3	1.0
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	10		

CARDIOVASCULAR SYSTEM

Blood Vessel	+	+	+	+	+	+	+	+	+	+	10		
Heart Cardiomyopathy	+	+	+	+	+	+	+	+	+	+	10	5	1.0

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	10		
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	10		
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	10		
Parathyroid Gland Hyperplasia	+	+	+	+	+	+	+	+	+	+	10	1	1.0
Pituitary Gland Cyst	+	+	+	+	+	+	+	+	+	X	10		1

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	6	6	6	6	6	6	6	6	6	6	
	9	9	9	9	9	9	9	9	9	9	
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0 %	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	1	
	1	2	3	4	5	6	7	8	9	0	* TOTALS

Thyroid Gland	+	+	+	+	+	+	+	+	+	+	10
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GENERAL BODY SYSTEM
 NONE

GENITAL SYSTEM

Epididymis	+	+	+	+	+	+	+	+	+	+	10
Preputial Gland	+	+	+	+	+	+	+	+	+	+	10
Prostate	+	+	+	+	+	+	+	+	+	+	10
Inflammation	2	2	1		2	2	1	2		1	8 1.6
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	10
Testes	+	+	+	+	+	+	+	+	+	+	10

HEMATOPOIETIC SYSTEM

Bone Marrow	+	+	+	+	+	+	+	+	+	+	10
Lymph Node, Mandibular	+	+	+	+	+	+	+	+	+	+	10
Infiltration Cellular, Plasma Cell								2			1 2.0

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<hr/>											
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	0	0	0	0	0	0	0	0	0	1	
	1	2	3	4	5	6	7	8	9	0	* TOTALS

Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	10
Spleen	+	+	+	+	+	+	+	+	+	+	10
Hematopoietic Cell Proliferation		1		1	1		1		1		5 1.0
Thymus	+	+	+	+	+	+	+	+	+	+	10
Atrophy		1									1 1.0

INTEGUMENTARY SYSTEM

Mammary Gland	+	+	+	+	+	+	+	+	+	+	10
Skin	+	+	+	+	+	+	+	+	+	+	10

MUSCULOSKELETAL SYSTEM

Bone	+	+	+	+	+	+	+	+	+	+	10
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NERVOUS SYSTEM

Brain	+	+	+	+	+	+	+	+	+	+	10
Peripheral Nerve	+	+	+	+	+	+	+	+	+	+	10

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	9	9	9	9	9	9	9	9	9	9		
.....												
SPRAGUE-DAWLEY RATS MALE	0	0	0	0	0	0	0	0	0	0		
ANIMAL ID	0	0	0	0	0	0	0	0	0	0		
0 %	0	0	0	0	0	0	0	0	0	0		
	0	0	0	0	0	0	0	0	0	0	1	
	1	2	3	4	5	6	7	8	9	0		* TOTALS

Spinal Cord	+	+	+	+	+	+	+	+	+	+		10

RESPIRATORY SYSTEM												

Lung	+	+	+	+	+	+	+	+	+	+		10
Hemorrhage			1	1								2 1.0
Inflammation, Chronic Active					1			1				2 1.0

Nose	+	+	+	+	+	+	+	+	+	+		10
Inflammation	1											1 1.0

Trachea	+	+	+	+	+	+	+	+	+	+		10

SPECIAL SENSES SYSTEM												

Eye	+	+	+	+	+	+	+	+	+	+		10

Harderian Gland	+	+	+	+	+	+	+	+	+	+		10
Infiltration Cellular, Lymphocyte	1			1								2 1.0

URINARY SYSTEM												

Kidney	+	+	+	+	+	+	+	+	+	+		10
Mineralization								1	1			2 1.0
Nephropathy	1	1	1		1	1	1	1	1	1		9 1.0
Cortex, Cyst							2					1 2.0

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	9	9	9	9	9	9	9	9	9	9	9	
<hr/>												
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0 %	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	1	
	1	2	3	4	5	6	7	8	9	0		
											* TOTALS	
Pelvis, Dilatation						2				1		2 1.5
Pelvis, Inflammation								2				1 2.0
<hr/>												
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	10	

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	1	1	1	1	1	1	1	1	1	1
	6	6	6	6	6	6	6	6	6	6
	9	9	9	9	9	9	9	9	9	9
SPRAGUE-DAWLEY RATS MALE	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
1 %	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	2
	1	2	3	4	5	6	7	8	9	0
	* TOTALS									

ALIMENTARY SYSTEM

Liver	+	+	+	+	+	+	+	+	+	+	10
Hematopoietic Cell Proliferation							1	1		1	3 1.0
Inflammation, Chronic Active	1	1	1	1	1	1	1	1	1	1	10 1.0
Periportal, Fatty Change	2								2	1	3 1.7

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

Adrenal Cortex										+	1
Parathyroid Gland	+	+	+	+	+	+	+	+	+	+	10

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

Prostate	+	+	+	+	+	+	+	+	+	+	10
Inflammation	1	1	1		1	1	1	1	1	2	9 1.1

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DAY ON TEST	1	1	1	1	1	1	1	1	1	1	
	6	6	6	6	6	6	6	6	6	6	
	9	9	9	9	9	9	9	9	9	9	
.....											
SPRAGUE-DAWLEY RATS MALE	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	
1 %	0	0	0	0	0	0	0	0	0	0	
	1	1	1	1	1	1	1	1	1	2	
	1	2	3	4	5	6	7	8	9	0	* TOTALS

HEMATOPOIETIC SYSTEM

NONE

INTEGUMENTARY SYSTEM

NONE

MUSCULOSKELETAL SYSTEM

NONE

NERVOUS SYSTEM

NONE

RESPIRATORY SYSTEM

NONE

SPECIAL SENSES SYSTEM

Eye		+		1	
Choroid, Fibrosis		2			1 2.0
Lens, Cataract		3			1 3.0

URINARY SYSTEM

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	9	9	9	9	9	9	9	9	9	9
<hr/>										
SPRAGUE-DAWLEY RATS MALE	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
1 %	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	2
	1	2	3	4	5	6	7	8	9	0
										* TOTALS
Kidney	+	+	+	+	+	+	+	+	+	+
Mineralization	1		1					1		1
Nephropathy	1	1	1		1	1	1	1	1	1
										10
										4 1.0
										9 1.0

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	9	9	9	9	9	9	9	9	9	9
<hr/>										
SPRAGUE-DAWLEY RATS MALE	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
3 %	0	0	0	0	0	0	0	0	0	0
	2	2	2	2	2	2	2	2	2	3
	1	2	3	4	5	6	7	8	9	0
										* TOTALS

ALIMENTARY SYSTEM

Liver	+	+	+	+	+	+	+	+	+	+	10
Hematopoietic Cell Proliferation					1			1		1	3 1.0
Inflammation, Chronic Active	1	1	1	1	1	1	1	1	1	1	10 1.0
Periportal, Fatty Change		1	1		1	1			2	2	6 1.3

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

Parathyroid Gland	+	+	+	+	+	+	+	+	+	+	10
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GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

Prostate	+	+	+	+	+	+	+	+	+	+	10
Inflammation	1	1	1	2	2	2	1	1	2	1	10 1.4

HEMATOPOIETIC SYSTEM

NONE

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	9	9	9	9	9	9	9	9	9	9	
SPRAGUE-DAWLEY RATS MALE	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	
3 %	0	0	0	0	0	0	0	0	0	0	
	2	2	2	2	2	2	2	2	2	3	
	1	2	3	4	5	6	7	8	9	0	* TOTALS

INTEGUMENTARY SYSTEM
 NONE

MUSCULOSKELETAL SYSTEM
 NONE

NERVOUS SYSTEM
 NONE

RESPIRATORY SYSTEM
 NONE

SPECIAL SENSES SYSTEM
 NONE

URINARY SYSTEM

Kidney	+	+	+	+	+	+	+	+	+	+	10
Infarct											1 2.0
Mineralization		1		1		1					3 1.0
Nephropathy	1	1	1	2	1	2		1	1	1	9 1.2
Pelvis, Dilatation						2					1 2.0

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	9	9	9	9	9	9	9	9	9	9
SPRAGUE-DAWLEY RATS MALE	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0
9 %	3	3	3	3	3	3	3	3	3	4
	1	2	3	4	5	6	7	8	9	0
	* TOTALS									

ALIMENTARY SYSTEM

Esophagus	+	+	+	+	+	+	+	+	+	+	10
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	10
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	10
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	10
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	10
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	10
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	10
Liver	+	+	+	+	+	+	+	+	+	+	10
Degeneration, Cystic					1						1 1.0
Hematopoietic Cell Proliferation				1	1	1	1		1	1	6 1.0
Inflammation, Chronic Active	1	1	1	1		1	1	1	1	1	9 1.0
Periportal, Fatty Change	1	1				1					3 1.0
Pancreas	+	+	+	+	+	+	+	+	+	+	10
Inflammation								1			1 1.0
Salivary Glands	+	+	+	+	+	+	+	+	+	+	10

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1
	6	6	6	6	6	6	6	6	6	6
	9	9	9	9	9	9	9	9	9	9
SPRAGUE-DAWLEY RATS MALE	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
9 %	0	0	0	0	0	0	0	0	0	0
	3	3	3	3	3	3	3	3	3	4
	1	2	3	4	5	6	7	8	9	0
	* TOTALS									

Stomach, Forestomach Epithelium, Hyperplasia	+	+	+	+	+	+	+	+	+	+	10	1 1.0
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	10	

CARDIOVASCULAR SYSTEM

Blood Vessel Inflammation	+	+	+	+	+	+	+	+	+	+	10	1 1.0
Heart Cardiomyopathy Mineralization	+	+	+	+	+	+	+	+	+	+	10	3 1.3
			1				2	1			1 1.0	

ENDOCRINE SYSTEM

Adrenal Cortex Vacuolization Cytoplasmic	+	+	+	+	+	+	+	+	+	+	10	1 1.0
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	10	
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	10	
Parathyroid Gland	+	+	+	+	+	+	+	+	+	+	10	

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
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 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
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TDMS No. 20226 - 01
 Test Type: 26-WEEK
 Route: DOSED FEED
 Species/Strain: RATS/SD

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	* TOTALS
	1	1	1	1	1	1	1	1	1	1	
	6	6	6	6	6	6	6	6	6	6	
	9	9	9	9	9	9	9	9	9	9	
SPRAGUE-DAWLEY RATS MALE	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	
9 %	0	0	0	0	0	0	0	0	0	0	
	3	3	3	3	3	3	3	3	3	4	
	1	2	3	4	5	6	7	8	9	0	
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	10
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	10
C-cell, Hyperplasia							1				1 1.0

GENERAL BODY SYSTEM
 NONE

GENITAL SYSTEM

Epididymis	+	+	+	+	+	+	+	+	+	+	10
Preputial Gland	+	+	+	+	+	+	+	+	+	+	10
Inflammation	1										1 1.0
Inflammation, Chronic Active							1		1		2 1.0
Prostate	+	+	+	+	+	+	+	+	+	+	10
Inflammation	2	1	1	1	1	1	2	2	2	2	10 1.5
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	10
Testes	+	+	+	+	+	+	+	+	+	+	10
Mineralization							1				1 1.0

HEMATOPOIETIC SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

Page 15

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	* TOTALS
	1	1	1	1	1	1	1	1	1	1	
	6	6	6	6	6	6	6	6	6	6	
	9	9	9	9	9	9	9	9	9	9	
SPRAGUE-DAWLEY RATS MALE	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	
9 %	0	0	0	0	0	0	0	0	0	0	
	3	3	3	3	3	3	3	3	3	4	
	1	2	3	4	5	6	7	8	9	0	
Bone Marrow	+	+	+	+	+	+	+	+	+	+	10
Lymph Node, Mandibular Infiltration Cellular, Plasma Cell	+	+	+	+	+	+	+	+	+	+	10
	1						1				2 1.0
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	10
Spleen Hematopoietic Cell Proliferation	+	+	+	+	+	+	+	+	+	+	10
				1					1		2 1.0
Thymus	+	+	+	+	+	+	+	+	+	+	10
INTEGUMENTARY SYSTEM											
Mammary Gland	+	+	+	+	+	+	+	+	+	+	10
Skin Hemorrhage	+	+	+	+	+	+	+	+	+	+	10
Mineralization							3				1 3.0
Ulcer							2				1 2.0
							4				1 4.0
MUSCULOSKELETAL SYSTEM											
Bone	+	+	+	+	+	+	+	+	+	+	10
Skeletal Muscle							+				1

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

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

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1
	6	6	6	6	6	6	6	6	6	6
	9	9	9	9	9	9	9	9	9	9
SPRAGUE-DAWLEY RATS MALE	0	0	0	0	0	0	0	0	0	0
9 %	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	3	3	3	3	3	3	3	3	3	4
	1	2	3	4	5	6	7	8	9	0
										* TOTALS

Inflammation, Granulomatous 3 1 3.0

NERVOUS SYSTEM

Brain	+	+	+	+	+	+	+	+	+	+	10
Peripheral Nerve	+	+	+	+	+	+	+	+	+	+	10
Spinal Cord	+	+	+	+	+	+	+	+	+	+	10

RESPIRATORY SYSTEM

Lung	+	+	+	+	+	+	+	+	+	+	10
Inflammation, Chronic Active				1		1			1	1	4 1.0
Nose	+	+	+	+	+	+	+	+	+	+	10
Goblet Cell, Hyperplasia					2						1 2.0
Trachea	+	+	+	+	+	+	+	+	+	+	10

SPECIAL SENSES SYSTEM

Eye	+	+	+	+	+	+	+	+	+	+	10
Harderian Gland	+	+	+	+	+	+	+	+	+	+	10

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Page 17

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1	1	1
	6	6	6	6	6	6	6	6	6	6	6	6
	9	9	9	9	9	9	9	9	9	9	9	9
.....												
SPRAGUE-DAWLEY RATS MALE	0	0	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0
9 %	0	0	0	0	0	0	0	0	0	0	0	0
	3	3	3	3	3	3	3	3	3	3	3	4
	1	2	3	4	5	6	7	8	9	9	9	0
												* TOTALS
Hyperplasia	1											1 1.0
Infiltration Cellular, Lymphocyte	1											1 1.0
.....												
URINARY SYSTEM												
Kidney	+ + + + + + + + + +											10
Mineralization	1 1 1 1 1 1											5 1.0
Nephropathy	1 1 1 1 2 1 2 2 1											9 1.3
.....												
Urinary Bladder	+ + + + + + + + + +											10
Transitional Epithelium, Hyperplasia	1											1 1.0

*** END OF MALE DATA ***

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

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BLANK .. Not examined microscopically

Page 18

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

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

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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

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1
	6	6	6	6	6	6	6	6	6	6
	9	9	9	9	9	9	9	9	9	9
<hr/>										
SPRAGUE-DAWLEY RATS	0	0	0	0	0	0	0	0	0	0
FEMALE	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	4	4	4	4	4	4	4	4	4	5
0 %	1	2	3	4	5	6	7	8	9	0
	* TOTALS									

ALIMENTARY SYSTEM

Esophagus	+	+	+	+	+	+	+	+	+	+	10
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	10
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	10
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	10
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	10
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	10
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	10
Liver	+	+	+	+	+	+	+	+	+	+	10
Hematopoietic Cell Proliferation							1				1 1.0
Inflammation, Chronic Active	1	1	1	1	1	1		1	1	1	9 1.0
Periportal, Fatty Change			1	1	1	1	2	1		1	7 1.1
Pancreas	+	+	+	+	+	+	+	+	+	+	10
Inflammation		1									1 1.0
Salivary Glands	+	+	+	+	+	+	+	+	+	+	10

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+ .. Tissue examined microscopically

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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

DAY ON TEST		0	0	0	0	0	0	0	0	0	0	
		1	1	1	1	1	1	1	1	1	1	
		6	6	6	6	6	6	6	6	6	6	
		9	9	9	9	9	9	9	9	9	9	
SPRAGUE-DAWLEY RATS		0	0	0	0	0	0	0	0	0	0	
FEMALE		0	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	0	
ANIMAL ID		4	4	4	4	4	4	4	4	4	5	
0 %		1	2	3	4	5	6	7	8	9	0	* TOTALS
Stomach, Forestomach		+	+	+	+	+	+	+	+	+	+	10
Stomach, Glandular		+	+	+	+	+	+	+	+	+	+	10
CARDIOVASCULAR SYSTEM												
Blood Vessel		+	+	+	+	+	+	+	+	+	+	10
Heart		+	+	+	+	+	+	+	+	+	+	10
Cardiomyopathy							1					1 1.0
ENDOCRINE SYSTEM												
Adrenal Cortex		+	+	+	+	+	+	+	+	+	+	10
Adrenal Medulla		+	+	+	+	+	+	+	+	+	+	10
Islets, Pancreatic		+	+	+	+	+	+	+	+	+	+	10
Parathyroid Gland		+	+	+	+	+	+	+	+	+	+	10
Pituitary Gland		+	+	+	+	+	+	+	+	+	+	10
Rathke's Cleft, Hyperplasia											2	1 2.0
Thyroid Gland		+	+	+	+	+	+	+	+	+	+	10

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
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TDMS No. 20226 - 01
 Test Type: 26-WEEK
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 Lab: BAT

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	
	1	1	1	1	1	1	1	1	1	1	
	6	6	6	6	6	6	6	6	6	6	
	9	9	9	9	9	9	9	9	9	9	
SPRAGUE-DAWLEY RATS	0	0	0	0	0	0	0	0	0	0	
FEMALE	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	4	4	4	4	4	4	4	4	4	5	
0 %	1	2	3	4	5	6	7	8	9	0	* TOTALS

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

Clitoral Gland	+	+	+	+	+	+	+	+	+	+	10
Inflammation, Chronic Active	2							2			2 2.0
Ovary	+	+	+	+	+	+	+	+	+	+	10
Uterus	+	+	+	+	+	+	+	+	+	+	10

HEMATOPOIETIC SYSTEM

Bone Marrow	+	+	+	+	+	+	+	+	+	+	10
Lymph Node, Mandibular	+	+	+	+	+	+	+	+	+	+	10
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	10
Spleen	+	+	+	+	+	+	+	+	+	+	10
Hematopoietic Cell Proliferation							1				1 1.0
Thymus	+	+	+	+	+	+	+	+	+	+	10
Atrophy		1									1 1.0

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Page 21

1-4 .. Lesion qualified as:

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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

DAY ON TEST		0	0	0	0	0	0	0	0	0	0
		1	1	1	1	1	1	1	1	1	1
		6	6	6	6	6	6	6	6	6	6
		9	9	9	9	9	9	9	9	9	9
SPRAGUE-DAWLEY RATS		0	0	0	0	0	0	0	0	0	0
FEMALE		0	0	0	0	0	0	0	0	0	0
ANIMAL ID		0	0	0	0	0	0	0	0	0	0
		4	4	4	4	4	4	4	4	4	5
0 %		1	2	3	4	5	6	7	8	9	0
* TOTALS											

INTEGUMENTARY SYSTEM

Mammary Gland	+	+	+	+	+	+	+	+	+	+	10
Skin	+	+	+	+	+	+	+	+	+	+	10

MUSCULOSKELETAL SYSTEM

Bone	+	+	+	+	+	+	+	+	+	+	10
------	---	---	---	---	---	---	---	---	---	---	-----------

NERVOUS SYSTEM

Brain	+	+	+	+	+	+	+	+	+	+	10
Developmental Malformation		X									1
Peripheral Nerve	+	+	+	+	+	+	+	+	+	+	10
Spinal Cord	+	+	+	+	+	+	+	+	+	+	10

RESPIRATORY SYSTEM

Lung	+	+	+	+	+	+	+	+	+	+	10
Alveolus, Infiltration Cellular, Histiocyte			1					1			2 1.0

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+ .. Tissue examined microscopically

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Page 22

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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

DAY ON TEST		0	0	0	0	0	0	0	0	0	0	
		1	1	1	1	1	1	1	1	1	1	
		6	6	6	6	6	6	6	6	6	6	
		9	9	9	9	9	9	9	9	9	9	
SPRAGUE-DAWLEY RATS		0	0	0	0	0	0	0	0	0	0	
FEMALE		0	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	0	
ANIMAL ID		4	4	4	4	4	4	4	4	4	5	
0 %		1	2	3	4	5	6	7	8	9	0	* TOTALS
Artery, Mineralization		1										1 1.0
Nose		+ + + + + + + + + +										10
Goblet Cell, Hyperplasia		2										1 2.0
Trachea		+ + + + + + + + + +										10
SPECIAL SENSES SYSTEM												
Eye		+ + + + + + + + + +										10
Harderian Gland		+ + + + + + + + + +										10
Infiltration Cellular, Lymphocyte		1										1 1.0
URINARY SYSTEM												
Kidney		+ + + + + + + + + +										10
Mineralization		1 1 1 1 1 1 1 1 1 1										8 1.0
Nephropathy		1 1 1 1 1 1 1										5 1.0
Urinary Bladder		+ + + + + + + + + +										10

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 + .. Tissue examined microscopically
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 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL
 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

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1
	6	6	6	6	6	6	6	6	6	6
	9	9	9	9	9	9	9	9	9	9
<hr/>										
SPRAGUE-DAWLEY RATS	0	0	0	0	0	0	0	0	0	0
FEMALE	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	5	5	5	5	5	5	5	5	5	6
1 %	1	2	3	4	5	6	7	8	9	0
										* TOTALS

ALIMENTARY SYSTEM

Liver	+	+	+	+	+	+	+	+	+	+	10
Hematopoietic Cell Proliferation				1							1 1.0
Inflammation, Chronic Active	1	1		1	1	1	1	1	1	1	9 1.0
Periportal, Fatty Change		1		1			1		1		4 1.0

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

NONE

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

NONE

HEMATOPOIETIC SYSTEM

NONE

INTEGUMENTARY SYSTEM

NONE

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

Page 24

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

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

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DAY ON TEST	0	0	0	0	0	0	0	0	0	0	
	1	1	1	1	1	1	1	1	1	1	
	6	6	6	6	6	6	6	6	6	6	
	9	9	9	9	9	9	9	9	9	9	
.....											
SPRAGUE-DAWLEY RATS	0	0	0	0	0	0	0	0	0	0	
FEMALE	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	5	5	5	5	5	5	5	5	5	6	
1 %	1	2	3	4	5	6	7	8	9	0	* TOTALS

MUSCULOSKELETAL SYSTEM
 NONE

NERVOUS SYSTEM
 NONE

RESPIRATORY SYSTEM
 NONE

SPECIAL SENSES SYSTEM
 NONE

URINARY SYSTEM

Kidney	+	+	+	+	+	+	+	+	+	+	10
Mineralization	1	1	1	1	1	1			1	1	8 1.0
Nephropathy	1			1			1	1	1	1	6 1.0

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
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DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1
	6	6	6	6	6	6	6	6	6	6
	9	9	9	9	9	9	9	9	9	9
<hr/>										
SPRAGUE-DAWLEY RATS	0	0	0	0	0	0	0	0	0	0
FEMALE	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	6	6	6	6	6	6	6	6	6	7
3 %	1	2	3	4	5	6	7	8	9	0
										* TOTALS

ALIMENTARY SYSTEM

Liver	+	+	+	+	+	+	+	+	+	+	10
Hematopoietic Cell Proliferation	1		1								2 1.0
Inflammation, Chronic Active	1	1	1	1	1	1	1	1	1		9 1.0
Periportal, Fatty Change		1	1					1	1		4 1.0

CARDIOVASCULAR SYSTEM

NONE

ENDOCRINE SYSTEM

NONE

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

NONE

HEMATOPOIETIC SYSTEM

NONE

INTEGUMENTARY SYSTEM

NONE

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

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Page 26

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 Species/Strain: RATS/SD

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DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1
	6	6	6	6	6	6	6	6	6	6
	9	9	9	9	9	9	9	9	9	9

**SPRAGUE-DAWLEY RATS
 FEMALE**

ANIMAL ID

3 %

0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0
6	6	6	6	6	6	6	6	6	6	7
1	2	3	4	5	6	7	8	9	9	0

*** TOTALS**

MUSCULOSKELETAL SYSTEM

NONE

NERVOUS SYSTEM

NONE

RESPIRATORY SYSTEM

NONE

SPECIAL SENSES SYSTEM

NONE

URINARY SYSTEM

Kidney	+	+	+	+	+	+	+	+	+	+	10
Mineralization	1	1		1	1			1			5 1.0
Nephropathy		1	1	1				1	1		5 1.0

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

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Page 27

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DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1
	6	6	6	6	6	6	6	6	6	6
	9	9	9	9	9	9	9	9	9	9
<hr/>										
SPRAGUE-DAWLEY RATS	0	0	0	0	0	0	0	0	0	0
FEMALE	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	7	7	7	7	7	7	7	7	7	8
9 %	1	2	3	4	5	6	7	8	9	0
										* TOTALS

ALIMENTARY SYSTEM

Esophagus	+	+	+	+	+	+	+	+	+	+	10
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	10
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	10
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	10
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	10
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	10
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	10
Liver	+	+	+	+	+	+	+	+	+	+	10
Hematopoietic Cell Proliferation						1					1 1.0
Inflammation, Chronic Active	1	1	1	1	1	1	1	1	1	1	10 1.0
Pancreas	+	+	+	+	+	+	+	+	+	+	10
Atrophy								1			1 1.0
Inflammation, Chronic Active					1						1 1.0
Salivary Glands	+	+	+	+	+	+	+	+	+	+	10

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DAY ON TEST		0	0	0	0	0	0	0	0	0	0	
		1	1	1	1	1	1	1	1	1	1	
		6	6	6	6	6	6	6	6	6	6	
		9	9	9	9	9	9	9	9	9	9	
SPRAGUE-DAWLEY RATS		0	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	0	
	FEMALE	0	0	0	0	0	0	0	0	0	0	
	9 %	7	7	7	7	7	7	7	7	7	8	
	ANIMAL ID	1	2	3	4	5	6	7	8	9	0	* TOTALS

Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	+	10
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	+	10

CARDIOVASCULAR SYSTEM

Blood Vessel	+	+	+	+	+	+	+	+	+	+	+	10
Heart	+	+	+	+	+	+	+	+	+	+	+	10

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	10
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	+	10
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	+	10
Parathyroid Gland	+	+	+	+	+	+	+	+	+	+	+	10
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	+	10
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	10

GENERAL BODY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
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 Page 29

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1
	6	6	6	6	6	6	6	6	6	6
	9	9	9	9	9	9	9	9	9	9
SPRAGUE-DAWLEY RATS FEMALE	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	7	7	7	7	7	7	7	7	7	8
9 %	1	2	3	4	5	6	7	8	9	0
										* TOTALS

NONE

GENITAL SYSTEM

Clitoral Gland	+	+	+	+	+	+	+	+	+	+	10
Ovary	+	+	+	+	+	+	+	+	+	+	10
Uterus	+	+	+	+	+	+	+	+	+	+	10

HEMATOPOIETIC SYSTEM

Bone Marrow	+	+	+	+	+	+	+	+	+	+	10
Lymph Node, Mandibular	+	+	+	+	+	+	+	+	+	+	10
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	10
Spleen	+	+	+	+	+	+	+	+	+	+	10
Thymus	+	+	+	+	+	+	+	+	+	+	10

INTEGUMENTARY SYSTEM

Mammary Gland	+	+	+	+	+	+	+	+	+	+	10
---------------	---	---	---	---	---	---	---	---	---	---	-----------

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DAY ON TEST	0	0	0	0	0	0	0	0	0	0	
	1	1	1	1	1	1	1	1	1	1	
	6	6	6	6	6	6	6	6	6	6	
	9	9	9	9	9	9	9	9	9	9	
SPRAGUE-DAWLEY RATS	0	0	0	0	0	0	0	0	0	0	
FEMALE	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	7	7	7	7	7	7	7	7	7	8	
9 %	1	2	3	4	5	6	7	8	9	0	* TOTALS

Skin	+	+	+	+	+	+	+	+	+	+	10
------	---	---	---	---	---	---	---	---	---	---	-----------

MUSCULOSKELETAL SYSTEM

Bone	+	+	+	+	+	+	+	+	+	+	10
------	---	---	---	---	---	---	---	---	---	---	-----------

NERVOUS SYSTEM

Brain	+	+	+	+	+	+	+	+	+	+	10
Peripheral Nerve	+	+	+	+	+	+	+	+	+	+	10
Spinal Cord	+	+	+	+	+	+	+	+	+	+	10

RESPIRATORY SYSTEM

Lung	+	+	+	+	+	+	+	+	+	+	10
Mineralization					1						1 1.0
Alveolar Epithelium, Hyperplasia						1					1 1.0
Artery, Mineralization									1		1 1.0
Nose	+	+	+	+	+	+	+	+	+	+	10
Trachea	+	+	+	+	+	+	+	+	+	+	10

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 Page 31

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DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1
	6	6	6	6	6	6	6	6	6	6
	9	9	9	9	9	9	9	9	9	9
.....										
SPRAGUE-DAWLEY RATS	0	0	0	0	0	0	0	0	0	0
FEMALE	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	7	7	7	7	7	7	7	7	7	8
9 %	1	2	3	4	5	6	7	8	9	0
										* TOTALS

SPECIAL SENSES SYSTEM

Eye	+	+	+	+	+	+	+	+	+	+	10
Harderian Gland	+	+	+	+	+	+	+	+	+	+	10
Infiltration Cellular, Lymphocyte						1					1 1.0

URINARY SYSTEM

Kidney	+	+	+	+	+	+	+	+	+	+	10
Mineralization		1	1		1	1			1	1	6 1.0
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	10

*** END OF REPORT ***

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

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Page 32

1-4 .. Lesion qualified as:

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2) Mild 4) Marked