



TDMS No. 20306 - 02  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: RATS/SD

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)  
 PCN 66/67 COMPARISON STUDY  
 CAS Number: PCNCOMPARISN  
 Pathologist: VASCONCELOS, D.

Date Report Requested: 12/05/2005  
 Time Report Requested: 12:37:34  
 First Dose M/F: NA / 10/06/03  
 Lab: BAT

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	1000 NG/KG 66	10,000 NG/ KG 66	50,000 NG/ KG 66	100,000 NG /KG 66	200,000 NG /KG 66
<b>Disposition Summary</b>						
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
<b>ALIMENTARY SYSTEM</b>						
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Fatty Change					10 (100%)	10 (100%)
Hepatocyte, Multinucleate					4 (40%)	9 (90%)
Hepatodiaphragmatic Nodule	1 (10%)		1 (10%)			
Inflammation, Suppurative				2 (20%)	9 (90%)	9 (90%)
Inflammation, Chronic Active	8 (80%)	9 (90%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)
Necrosis	1 (10%)					
Necrosis, Focal					1 (10%)	4 (40%)
Pigmentation				4 (40%)	3 (30%)	5 (50%)
Toxic Hepatopathy				1 (10%)	10 (100%)	10 (100%)
Hepatocyte, Hypertrophy		4 (40%)	6 (60%)	10 (100%)	10 (100%)	10 (100%)
Oval Cell, Hyperplasia						3 (30%)
Pancreas	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Mononuclear Cell					1 (10%)	
Acinus, Atrophy, Focal					2 (20%)	1 (10%)
Acinus, Atrophy, Diffuse					1 (10%)	2 (20%)
Acinus, Vacuolization Cytoplasmic						5 (50%)
Stomach, Forestomach	(10)	(10)	(10)	(10)	(10)	(10)
Epithelium, Hyperkeratosis	1 (10%)					2 (20%)
Epithelium, Necrosis			1 (10%)			
Tooth	(1)	(0)	(1)	(3)	(0)	(0)
Gingiva, Inflammation	1 (100%)		1 (100%)	3 (100%)		
<b>CARDIOVASCULAR SYSTEM</b>						
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Cardiomyopathy						1 (10%)

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

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<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(10)	(10)	(10)	(10)	(10)
Subcapsular, Hyperplasia					1 (10%)	
Zona Fasciculata, Vacuolization						1 (10%)
Cytoplasmic						
Parathyroid Gland	(10)	(0)	(0)	(1)	(0)	(8)
Infiltration Cellular, Mononuclear Cell				1 (100%)		
Pigmentation, Ceroid				1 (100%)		
Thyroid Gland	(10)	(10)	(10)	(10)	(10)	(10)
Follicular Cell, Hypertrophy	1 (10%)		2 (20%)	3 (30%)	6 (60%)	6 (60%)
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Clitoral Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active	6 (60%)					1 (10%)
Ovary	(10)	(10)	(10)	(10)	(10)	(10)
Germinal Epithelium, Cyst		1 (10%)				
<b>HEMATOPOIETIC SYSTEM</b>						
Spleen	(10)	(10)	(10)	(10)	(10)	(10)
Hematopoietic Cell Proliferation						1 (10%)
Pigmentation, Hemosiderin	10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)
Thymus	(10)	(10)	(10)	(10)	(10)	(10)
Atrophy			1 (10%)		5 (50%)	9 (90%)
<b>INTEGUMENTARY SYSTEM</b>						
Skin	(10)	(10)	(10)	(10)	(10)	(10)
Hair Follicle, Inflammation				1 (10%)		
<b>MUSCULOSKELETAL SYSTEM</b>						

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None						
<b>NERVOUS SYSTEM</b>						
None						
<b>RESPIRATORY SYSTEM</b>						
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic Active	1 (10%)		1 (10%)			
Alveolar Epithelium, Hyperplasia					1 (10%)	
Alveolar Epithelium, Metaplasia, Bronchiolar						2 (20%)
Alveolus, Infiltration Cellular, Histiocyte	1 (10%)	1 (10%)	1 (10%)	1 (10%)	1 (10%)	1 (10%)
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Respiratory Epithelium, Inflammation	2 (20%)					
<b>SPECIAL SENSES SYSTEM</b>						
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
Hyperplasia						3 (30%)
Infiltration Cellular, Mononuclear Cell	1 (10%)					3 (30%)
<b>URINARY SYSTEM</b>						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Mineralization	4 (40%)	6 (60%)	6 (60%)	7 (70%)	5 (50%)	8 (80%)
Nephropathy	6 (60%)	7 (70%)	8 (80%)	6 (60%)	6 (60%)	10 (100%)

\*\*\* END OF REPORT \*\*\*