



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: 12:38:07  
 First Dose M/F: NA / 10/06/03  
 Lab: BAT

SPRAGUE-DAWLEY RATS FEMALE	0 NG/KG	1000 NG/KG 67	10,000 NG/ KG 67	50,000 NG/ KG 67	100,000 NG /KG 67	200,000 NG /KG 67
<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%)
Hepatocyte, Multinucleate						2 (20%)
Hepatodiaphragmatic Nodule	1 (10%)					
Inflammation, Suppurative					2 (20%)	10 (100%)
Inflammation, Chronic Active	8 (80%)	9 (90%)	8 (80%)	9 (90%)	10 (100%)	10 (100%)
Necrosis	1 (10%)			1 (10%)	1 (10%)	
Necrosis, Focal						6 (60%)
Pigmentation					2 (20%)	1 (10%)
Toxic Hepatopathy						10 (100%)
Bile Duct, Hyperplasia					1 (10%)	1 (10%)
Hepatocyte, Hypertrophy			1 (10%)	1 (10%)	3 (30%)	10 (100%)
Oval Cell, Hyperplasia						1 (10%)
Portal Vein, Fibrosis, Focal					1 (10%)	
Pancreas	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Mononuclear Cell					1 (10%)	
Inflammation		1 (10%)			1 (10%)	
Acinus, Atrophy, Focal		1 (10%)				
Stomach, Forestomach	(10)	(10)	(10)	(10)	(10)	(10)
Epithelium, Hyperkeratosis	1 (10%)					
Tooth	(1)	(0)	(0)	(0)	(0)	(0)
Gingiva, Inflammation	1 (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)
Hypertrophy		2 (20%)	1 (10%)	1 (10%)	1 (10%)	
Zona Fasciculata, Vacuolization		1 (10%)				
Cytoplasmic						
Thyroid Gland	(10)	(10)	(10)	(10)	(10)	(10)
Follicular Cell, Hypertrophy	1 (10%)					7 (70%)
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Clitoral Gland	(10)	(0)	(1)	(0)	(0)	(10)
Cyst			1 (100%)			
Inflammation, Chronic Active	6 (60%)					6 (60%)
Ovary	(10)	(10)	(10)	(10)	(10)	(10)
Atrophy				1 (10%)		
Uterus	(10)	(10)	(10)	(10)	(10)	(10)
Endometrium, Hyperplasia, Cystic				1 (10%)		
<b>HEMATOPOIETIC SYSTEM</b>						
Spleen	(10)	(10)	(10)	(10)	(10)	(10)
Pigmentation, Hemosiderin	10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)	9 (90%)
Thymus	(10)	(10)	(10)	(10)	(10)	(10)
Atrophy						1 (10%)
<b>INTEGUMENTARY SYSTEM</b>						
None						
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(0)	(0)	(0)	(1)	(10)
Rib, Fracture					1 (100%)	

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<b>NERVOUS SYSTEM</b>						
None						
<b>RESPIRATORY SYSTEM</b>						
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic Active	1 (10%)	1 (10%)			1 (10%)	1 (10%)
Alveolar Epithelium, Hyperplasia			1 (10%)			
Alveolus, Infiltration Cellular, Histiocyte	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)
Infiltration Cellular, Mononuclear Cell	1 (10%)					
<b>URINARY SYSTEM</b>						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Mineralization	4 (40%)	5 (50%)	4 (40%)	6 (60%)	5 (50%)	5 (50%)
Nephropathy	6 (60%)	6 (60%)	3 (30%)	6 (60%)	7 (70%)	5 (50%)

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