

TDMS No. 20306 - 02

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

**Date Report Requested:** 12/05/2005

**Test Type:** 90-DAY

PCN 66/67 COMPARISON STUDY

**Time Report Requested:** 12:38:07

**Route:** GAVAGE

**CAS Number:** PCNCOMPARISN

**First Dose M/F:** NA / 10/06/03

**Species/Strain:** RATS/SD

**Pathologist:** VASCONCELOS, D.

**Lab:** BAT

F1 PCN 67

**C Number:** C20306

**Lock Date:** 10/07/2004

**Cage Range:** ALL

**Date Range:** ALL

**Reasons For Removal:** ALL

**Removal Date Range:** ALL

<b>Treatment Groups:</b>	Include 001 0 NG/KG	Include 007 1000 NG/KG 67	Include 008 10,000 NG/KG 67
	Include 009 50,000 NG/KG 67	Include 010 100,000 NG/KG 67	Include 011 200,000 NG/KG 67

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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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 [3.0]
Hepatocyte, Multinucleate						2 [1.0]
Hepatodiaphragmatic Nodule	1					
Inflammation, Suppurative					2 [1.0]	10 [1.0]
Inflammation, Chronic Active	8 [1.0]	9 [1.0]	8 [1.0]	9 [1.0]	10 [1.1]	10 [1.5]
Necrosis	1 [2.0]			1 [3.0]	1 [3.0]	
Necrosis, Focal						6 [1.0]
Pigmentation					2 [1.5]	1 [2.0]
Toxic Hepatopathy						10 [1.9]
Bile Duct, Hyperplasia					1 [2.0]	1 [2.0]
Hepatocyte, Hypertrophy			1 [1.0]	1 [1.0]	3 [1.3]	10 [2.3]
Oval Cell, Hyperplasia						1 [1.0]
Portal Vein, Fibrosis, Focal					1 [2.0]	
Pancreas	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Mononuclear Cell					1 [1.0]	
Inflammation		1 [1.0]			1 [1.0]	
Acinus, Atrophy, Focal		1 [1.0]				
Stomach, Forestomach	(10)	(10)	(10)	(10)	(10)	(10)
Epithelium, Hyperkeratosis	1 [1.0]					
Tooth	(1)	(0)	(0)	(0)	(0)	(0)
Gingiva, Inflammation	1 [1.0]					
<b>CARDIOVASCULAR SYSTEM</b>						
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Cardiomyopathy						1 [1.0]

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<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(10)	(10)	(10)	(10)	(10)
Hypertrophy		2 [1.5]	1 [1.0]	1 [2.0]	1 [1.0]	
Zona Fasciculata, Vacuolization		1 [1.0]				
Cytoplasmic						
Thyroid Gland	(10)	(10)	(10)	(10)	(10)	(10)
Follicular Cell, Hypertrophy	1 [1.0]					7 [1.0]
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Clitoral Gland	(10)	(0)	(1)	(0)	(0)	(10)
Cyst			1 [1.0]			
Inflammation, Chronic Active	6 [1.5]					6 [1.2]
Ovary	(10)	(10)	(10)	(10)	(10)	(10)
Atrophy				1 [1.0]		
Uterus	(10)	(10)	(10)	(10)	(10)	(10)
Endometrium, Hyperplasia, Cystic				1 [2.0]		
<b>HEMATOPOIETIC SYSTEM</b>						
Spleen	(10)	(10)	(10)	(10)	(10)	(10)
Pigmentation, Hemosiderin	10 [1.0]	10 [1.0]	10 [1.0]	10 [1.0]	10 [1.0]	9 [1.0]
Thymus	(10)	(10)	(10)	(10)	(10)	(10)
Atrophy						1 [1.0]
<b>INTEGUMENTARY SYSTEM</b>						
None						
<b>MUSCULOSKELETAL SYSTEM</b>						

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Bone Rib, Fracture	(10)	(0)	(0)	(0)	(1) 1 [1.0]	(10)
<b>NERVOUS SYSTEM</b>						
None						
<b>RESPIRATORY SYSTEM</b>						
Lung Inflammation, Chronic Active Alveolar Epithelium, Hyperplasia Alveolus, Infiltration Cellular, Histiocyte	(10) 1 [1.0]	(10) 1 [1.0]	(10) 1 [1.0]	(10)	(10) 1 [1.0]	(10) 1 [1.0]
Nose Respiratory Epithelium, Inflammation	(10) 2 [1.5]	(0)	(0)	1 [1.0] (0)	(0)	1 [1.0] (10)
<b>SPECIAL SENSES SYSTEM</b>						
Harderian Gland Infiltration Cellular, Mononuclear Cell	(10) 1 [1.0]	(0)	(0)	(0)	(0)	(10)
<b>URINARY SYSTEM</b>						
Kidney Mineralization Nephropathy	(10) 4 [1.0] 6 [1.0]	(10) 5 [1.0] 6 [1.2]	(10) 4 [1.0] 3 [1.3]	(10) 6 [1.0] 6 [1.0]	(10) 5 [1.0] 7 [1.0]	(10) 5 [1.0] 5 [1.0]

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

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