

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:** 12:37:34

**Route:** GAVAGE

**CAS Number:** PCNCOMPARISN

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

**Species/Strain:** RATS/SD

**Pathologist:** VASCONCELOS, D.

**Lab:** BAT

F1 PCN 66

**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 002 1000 NG/KG 66	Include 003 10,000 NG/KG 66
	Include 004 50,000 NG/KG 66	Include 005 100,000 NG/KG 66	Include 006 200,000 NG/KG 66

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 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 [1.3]	10 [2.6]
Hepatocyte, Multinucleate					4 [1.0]	9 [1.6]
Hepatodiaphragmatic Nodule	1		1			
Inflammation, Suppurative				2 [1.0]	9 [1.4]	9 [1.4]
Inflammation, Chronic Active	8 [1.0]	9 [1.1]	10 [1.2]	10 [1.6]	10 [1.7]	10 [1.2]
Necrosis	1 [2.0]					
Necrosis, Focal					1 [1.0]	4 [1.0]
Pigmentation				4 [1.0]	3 [1.0]	5 [1.0]
Toxic Hepatopathy				1 [1.0]	10 [1.5]	10 [2.3]
Hepatocyte, Hypertrophy		4 [1.0]	6 [1.0]	10 [1.1]	10 [2.1]	10 [3.3]
Oval Cell, Hyperplasia						3 [1.0]
Pancreas	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Mononuclear Cell					1 [1.0]	
Acinus, Atrophy, Focal					2 [1.0]	1 [1.0]
Acinus, Atrophy, Diffuse					1 [1.0]	2 [1.5]
Acinus, Vacuolization Cytoplasmic						5 [1.0]
Stomach, Forestomach	(10)	(10)	(10)	(10)	(10)	(10)
Epithelium, Hyperkeratosis	1 [1.0]					2 [1.5]
Epithelium, Necrosis			1 [1.0]			
Tooth	(1)	(0)	(1)	(3)	(0)	(0)
Gingiva, Inflammation	1 [1.0]		1 [1.0]	3 [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)
Subcapsular, Hyperplasia					1 [1.0]	
Zona Fasciculata, Vacuolization						1 [1.0]
Cytoplasmic						
Parathyroid Gland	(10)	(0)	(0)	(1)	(0)	(8)
Infiltration Cellular, Mononuclear Cell				1 [1.0]		
Pigmentation, Ceroid				1 [1.0]		
Thyroid Gland	(10)	(10)	(10)	(10)	(10)	(10)
Follicular Cell, Hypertrophy	1 [1.0]		2 [1.0]	3 [1.0]	6 [1.0]	6 [1.0]
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Clitoral Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active	6 [1.5]					1 [1.0]
Ovary	(10)	(10)	(10)	(10)	(10)	(10)
Germinal Epithelium, Cyst		1 [3.0]				
<b>HEMATOPOIETIC SYSTEM</b>						
Spleen	(10)	(10)	(10)	(10)	(10)	(10)
Hematopoietic Cell Proliferation						1 [1.0]
Pigmentation, Hemosiderin	10 [1.0]	10 [1.2]	10 [1.0]	10 [1.0]	10 [1.0]	10 [1.3]
Thymus	(10)	(10)	(10)	(10)	(10)	(10)
Atrophy			1 [1.0]		5 [1.0]	9 [1.4]
<b>INTEGUMENTARY SYSTEM</b>						
Skin	(10)	(10)	(10)	(10)	(10)	(10)
Hair Follicle, Inflammation				1 [1.0]		

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<b>MUSCULOSKELETAL SYSTEM</b>						
None						
<b>NERVOUS SYSTEM</b>						
None						
<b>RESPIRATORY SYSTEM</b>						
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic Active	1 [1.0]		1 [1.0]			
Alveolar Epithelium, Hyperplasia					1 [1.0]	
Alveolar Epithelium, Metaplasia, Bronchiolar						2 [1.0]
Alveolus, Infiltration Cellular, Histiocyte	1 [1.0]	1 [1.0]	1 [1.0]	1 [1.0]	1 [1.0]	1 [1.0]
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Respiratory Epithelium, Inflammation	2 [1.5]					
<b>SPECIAL SENSES SYSTEM</b>						
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
Hyperplasia						3 [1.0]
Infiltration Cellular, Mononuclear Cell	1 [1.0]					3 [1.0]
<b>URINARY SYSTEM</b>						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Mineralization	4 [1.0]	6 [1.0]	6 [1.0]	7 [1.0]	5 [1.0]	8 [1.0]
Nephropathy	6 [1.0]	7 [1.0]	8 [1.0]	6 [1.0]	6 [1.2]	10 [1.0]

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

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