

TDMS No. 20304 - 01

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

Date Report Requested: 06/24/2008

Test Type: CHRONIC

TEF evaluation (PCB 118)

Time Report Requested: 13:42:49

Route: GAVAGE

CAS Number: 31508-00-6

First Dose M/F: NA / 03/26/04

Species/Strain: RATS/SD

Lab: BAT

53 Wk_SSAC_R8

C Number: C20304

Lock Date: 10/12/2006

Cage Range: ALL

Date Range: ALL

Reasons For Removal: 25017 SSAC

Removal Date Range: 30-Mar-2005 - 30-Mar-2005

Treatment Groups: Include 001 0 UG/KG

Include 002 10 UG/KG

Include 003 30 UG/KG

Include 004 100 UG/KG

Include 005 220 UG/KG

Include 006 460 UG/KG

Include 007 1000 UG/KG

Include 008 4600 UG/KG

Study Gender: Female

TDMSE Version: 2.0.0

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SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG
Disposition Summary						
Animals Initially in Study	80	30	30	80	80	80
Scheduled Sacrifice	8	8	10	8	8	8
Early Deaths						
Survivors						
Animals Examined Microscopically	8	8	10	8	8	8
ALIMENTARY SYSTEM						
Liver	(8)	(8)	(10)	(8)	(8)	(8)
Cholangiofibrosis		1 [1.0]				
Clear Cell Focus	1	3	2	4	2	5
Clear Cell Focus, Multiple	3	1	1	1	3	
Eosinophilic Focus						
Eosinophilic Focus, Multiple						
Fatty Change, Diffuse						
Hepatodiaphragmatic Nodule						
Hyperplasia, Nodular						
Inflammation	8 [1.1]	7 [1.0]	8 [1.0]	5 [1.0]	8 [1.0]	8 [1.1]
Mixed Cell Focus	1					1
Mixed Cell Focus, Multiple						
Necrosis						1 [1.0]
Pigmentation						4 [1.0]
Toxic Hepatopathy						
Bile Duct, Cyst			1 [2.0]	1 [1.0]		
Bile Duct, Hyperplasia	1 [1.0]					
Centrilobular, Degeneration						
Hepatocyte, Hypertrophy	2 [1.0]		4 [1.3]	5 [1.0]	6 [1.0]	7 [1.0]
Hepatocyte, Multinucleated						
Oval Cell, Hyperplasia						
Pancreas	(8)	(8)	(10)	(8)	(8)	(8)
Basophilic Focus	1					
Acinus, Vacuolization Cytoplasmic						
Stomach, Forestomach	(8)	(0)	(0)	(0)	(0)	(0)
Stomach, Glandular	(8)	(0)	(0)	(0)	(0)	(0)

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 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG
CARDIOVASCULAR SYSTEM						
None						
ENDOCRINE SYSTEM						
Adrenal Cortex	(8)	(8)	(10)	(8)	(8)	(8)
Atrophy						
Degeneration, Cystic				1 [1.0]		
Hyperplasia	1 [2.0]					
Hypertrophy	5 [1.0]	7 [1.1]	6 [1.0]	4 [1.3]	5 [1.2]	5 [1.0]
Vacuolization Cytoplasmic	1 [3.0]					
Adrenal Medulla	(8)	(8)	(10)	(8)	(8)	(8)
Pituitary Gland	(8)	(0)	(0)	(0)	(0)	(0)
Angiectasis	1 [2.0]					
Pars Distalis, Hyperplasia	1 [3.0]					
Thyroid Gland	(8)	(8)	(10)	(8)	(8)	(8)
C-cell, Hyperplasia	1 [1.0]			1 [1.0]		1 [1.0]
Follicular Cell, Hypertrophy	1 [1.0]		1 [1.0]	1 [1.0]	1 [1.0]	5 [1.2]
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Ovary	(8)	(0)	(0)	(0)	(0)	(0)
Uterus	(8)	(8)	(10)	(8)	(8)	(8)
Dilatation						1 [4.0]
Inflammation		1 [1.0]				
Inflammation, Suppurative	3 [1.7]	1 [1.0]	3 [1.0]	4 [1.0]	3 [1.0]	3 [1.0]
Metaplasia, Squamous	6 [2.5]	5 [1.6]	7 [1.6]	7 [1.3]	4 [2.0]	4 [2.0]
Endometrium, Hyperplasia, Cystic	4 [2.8]	3 [2.7]	6 [1.7]	5 [2.2]	4 [1.5]	3 [1.7]
Vagina	(8)	(0)	(0)	(0)	(0)	(0)
Inflammation, Chronic Active	1 [3.0]					
Necrosis	1 [2.0]					

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SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG
HEMATOPOIETIC SYSTEM						
Spleen	(8)	(0)	(0)	(0)	(0)	(0)
Pigmentation	8 [1.3]					
Thymus	(8)	(8)	(10)	(8)	(8)	(8)
Atrophy	8 [1.8]	8 [2.5]	10 [2.3]	8 [1.9]	8 [2.1]	8 [2.4]
Cyst	1 [2.0]					
INTEGUMENTARY SYSTEM						
Mammary Gland	(8)	(2)	(2)	(1)	(2)	(0)
Cyst		2 [3.0]				
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
None						
RESPIRATORY SYSTEM						
Lung	(8)	(8)	(10)	(8)	(8)	(8)
Inflammation	1 [1.0]		1 [1.0]			
Alveolar Epithelium, Hyperplasia						
Alveolar Epithelium, Metaplasia,						
Bronchiolar						
Alveolus, Infiltration Cellular, Histiocyte	2 [1.5]	2 [1.0]	4 [1.3]	2 [1.5]	3 [1.0]	4 [1.0]
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
Kidney	(0)	(1)	(0)	(0)	(0)	(0)

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SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG
Infarct		1 [2.0]				
Nephropathy		1 [2.0]				
Pelvis, Dilatation		1 [2.0]				
Pelvis, Inflammation		1 [2.0]				
Transitional Epithelium, Hyperplasia		1 [2.0]				

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Disposition Summary		
Animals Initially in Study	80	80
Scheduled Sacrifice	8	8
Early Deaths		
Survivors		
Animals Examined Microscopically	8	8
ALIMENTARY SYSTEM		
Liver	(8)	(8)
Cholangiofibrosis		4 [1.8]
Clear Cell Focus	2	
Clear Cell Focus, Multiple	6	
Eosinophilic Focus		3
Eosinophilic Focus, Multiple		1
Fatty Change, Diffuse		8 [2.8]
Hepatodiaphragmatic Nodule	1	
Hyperplasia, Nodular		3
Inflammation	8 [1.3]	8 [1.8]
Mixed Cell Focus		
Mixed Cell Focus, Multiple	1	7
Necrosis	2 [1.0]	1 [1.0]
Pigmentation	7 [1.3]	8 [1.8]
Toxic Hepatopathy		8 [2.0]
Bile Duct, Cyst		
Bile Duct, Hyperplasia		6 [1.2]
Centrilobular, Degeneration	1 [2.0]	
Hepatocyte, Hypertrophy	8 [1.1]	8 [2.9]
Hepatocyte, Multinucleated	1 [1.0]	7 [1.1]
Oval Cell, Hyperplasia		8 [1.4]
Pancreas	(8)	(8)
Basophilic Focus		
Acinus, Vacuolization Cytoplasmic		8 [1.4]
Stomach, Forestomach	(0)	(8)
Stomach, Glandular	(0)	(8)

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SPRAGUE-DAWLEY RATS FEMALE

1000 UG/KG

4600 UG/KG

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

Adrenal Cortex	(8)	(8)
Atrophy		2 [2.0]
Degeneration, Cystic	1 [2.0]	3 [3.0]
Hyperplasia		4 [1.8]
Hypertrophy	5 [1.4]	4 [1.3]
Vacuolization Cytoplasmic	1 [1.0]	
Adrenal Medulla	(8)	(8)
Pituitary Gland	(0)	(8)
Angiectasis		
Pars Distalis, Hyperplasia		1 [2.0]
Thyroid Gland	(8)	(8)
C-cell, Hyperplasia		
Follicular Cell, Hypertrophy	5 [1.4]	7 [2.0]

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Ovary	(0)	(8)
Uterus	(8)	(8)
Dilatation	4 [4.0]	
Inflammation		
Inflammation, Suppurative	5 [1.0]	2 [1.0]
Metaplasia, Squamous	3 [2.0]	4 [1.0]
Endometrium, Hyperplasia, Cystic	4 [2.0]	3 [2.3]
Vagina	(0)	(8)
Inflammation, Chronic Active		
Necrosis		

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HEMATOPOIETIC SYSTEM		
Spleen	(0)	(8)
Pigmentation		8 [1.8]
Thymus	(8)	(8)
Atrophy	8 [2.3]	8 [2.5]
Cyst		
INTEGUMENTARY SYSTEM		
Mammary Gland	(1)	(8)
Cyst		
MUSCULOSKELETAL SYSTEM		
None		
NERVOUS SYSTEM		
None		
RESPIRATORY SYSTEM		
Lung	(8)	(8)
Inflammation		1 [1.0]
Alveolar Epithelium, Hyperplasia		1 [1.0]
Alveolar Epithelium, Metaplasia,		3 [1.3]
Bronchiolar		
Alveolus, Infiltration Cellular, Histiocyte	3 [1.0]	3 [1.0]
SPECIAL SENSES SYSTEM		
None		
URINARY SYSTEM		
Kidney	(0)	(0)

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Pelvis, Dilatation
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*** END OF REPORT ***