

TDMs No. 99020 - 03

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

Date Report Requested: 03/31/2009

Test Type: 90-DAY

Pulegone

Time Report Requested: 11:07:07

Route: GAVAGE

CAS Number: 89-82-7

First Dose M/F: 02/18/02 / 02/19/02

Species/Strain: RATS/F 344/N

Lab: BAT

F1_Rev1_R2

C Number: C99020
Lock Date: 09/27/2002
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.1.0

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FISCHER 344 RATS MALE	0 MG/KG	9.375 MG/KG	18.75 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Disposition Summary						
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
ALIMENTARY SYSTEM						
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(0)	(10)
Parasite Metazoan	1					
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Hepatodiaphragmatic Nodule		2	2	2		
Inflammation, Chronic Active	1 [1.0]			1 [1.0]	1 [1.0]	1 [2.0]
Mineralization				1 [1.0]		1 [1.0]
Pigmentation						1 [1.0]
Bile Duct, Hyperplasia					9 [1.0]	10 [2.0]
Hepatocyte, Hypertrophy					10 [1.0]	10 [1.9]
Hepatocyte, Necrosis, Focal						6 [1.0]
Oval Cell, Hyperplasia						10 [1.0]
Periportal, Fibrosis						10 [1.0]
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Basophilic Focus						1 [1.0]
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Metaplasia, Squamous, Focal						1 [1.0]
Stomach, Glandular	(10)	(10)	(10)	(10)	(10)	(10)
Mineralization	5 [1.0]	3 [1.0]	5 [1.8]	2 [1.0]	3 [1.0]	9 [1.1]
CARDIOVASCULAR SYSTEM						
Heart	(10)	(10)	(10)	(10)	(10)	(10)
Cardiomyopathy	9 [1.1]	8 [1.1]	8 [1.1]	9 [1.0]	7 [1.0]	7 [1.0]
Mineralization	1 [1.0]			1 [1.0]		6 [1.0]
Myocardium, Pigmentation, Hemosiderin	1 [1.0]					

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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ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Accessory Adrenal Cortical Nodule						1 [1.0]
Capsule, Fibrosis	1 [1.0]					
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Chromophobe Cell, Hyperplasia	1 [1.0]					
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
Cyst						1
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Epididymis	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Granulomatous						1 [2.0]
Preputial Gland	(10)	(0)	(0)	(0)	(0)	(10)
Infiltration Cellular, Mononuclear Cell						1 [1.0]
Inflammation, Suppurative	1 [1.0]					
Inflammation, Chronic Active						2 [1.0]
Prostate	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Suppurative						1 [1.0]
Testes	(10)	(2)	(0)	(0)	(0)	(10)
Germinal Epithelium, Degeneration		2 [2.5]				
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Hyperplasia	3 [1.0]	1 [1.0]	5 [1.0]	9 [1.2]	10 [1.9]	10 [2.7]
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Necrosis, Lymphoid						1 [1.0]
Thymus	(10)	(0)	(0)	(10)	(10)	(10)
Atrophy	2 [1.5]				1 [1.0]	1 [1.0]
INTEGUMENTARY SYSTEM						

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None						
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
None						
RESPIRATORY SYSTEM						
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Histiocyte	6 [1.0]		5 [1.0]	4 [1.0]	2 [1.0]	8 [1.0]
Interstitial, Infiltration Cellular, Lymphocyte	7 [1.0]			1 [1.0]	2 [1.0]	1 [1.0]
SPECIAL SENSES SYSTEM						
Eye	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Acute						1 [1.0]
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Acute						1 [1.0]
URINARY SYSTEM						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Accumulation, Hyaline Droplet	3 [1.0]		1 [1.0]	1 [1.0]		
Glomerulopathy, Hyaline					2 [1.0]	10 [1.0]
Infiltration Cellular, Lymphocyte	1 [1.0]		1 [1.0]	1 [1.0]		
Mineralization	6 [1.0]	8 [1.0]	8 [1.0]	7 [1.0]	9 [1.0]	7 [1.0]
Renal Tubule, Casts Protein	7 [1.0]	4 [1.5]	6 [1.0]	6 [1.0]	4 [1.0]	10 [2.7]
Renal Tubule, Regeneration	9 [1.0]	9 [1.0]	10 [1.0]	10 [1.0]	3 [1.0]	9 [1.0]
Urinary Bladder	(9)	(0)	(0)	(0)	(0)	(10)
Infiltration Cellular	1 [1.0]					
Mineralization						1 [1.0]

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*** END OF MALE ***

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Disposition Summary						
Animals Initially in Study	10	10	10	10	10	10
Early Deaths						
Natural Death						1
Survivors						
Terminal Sacrifice	10	10	10	10	10	9
Animals Examined Microscopically	10	10	10	10	10	10
ALIMENTARY SYSTEM						
Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic	1 [1.0]					
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Basophilic Focus	1					
Hepatodiaphragmatic Nodule	1	2	2	2		1
Inflammation, Chronic Active		1 [1.0]				
Bile Duct, Hyperplasia					1 [1.0]	10 [1.7]
Hepatocyte, Hypertrophy						10 [1.9]
Oval Cell, Hyperplasia						9 [1.0]
Periportal, Fibrosis						9 [1.0]
Serosa, Fibrosis	1 [1.0]					
Stomach, Glandular	(10)	(10)	(10)	(10)	(10)	(10)
Mineralization		3 [1.0]	2 [1.0]	2 [1.0]	6 [1.0]	7 [1.0]
CARDIOVASCULAR SYSTEM						
Heart	(10)	(10)	(10)	(10)	(10)	(10)
Cardiomyopathy	6 [1.0]	3 [1.0]		4 [1.0]	5 [1.0]	2 [1.0]
Mineralization						1 [1.0]
ENDOCRINE SYSTEM						
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
Cyst						1

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GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active						1 [1.0]
Ovary	(10)	(10)	(10)	(10)	(10)	(10)
Cyst	1	2	2	2	3	6
Uterus	(10)	(10)	(10)	(10)	(10)	(10)
Dilatation	2 [2.5]					
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Hyperplasia	1 [1.0]	1 [1.0]	1 [1.0]	1 [1.0]	10 [1.3]	9 [1.9]
Thymus	(10)	(0)	(0)	(0)	(10)	(10)
Atrophy	1 [2.0]					
INTEGUMENTARY SYSTEM						
None						
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
Brain	(10)	(10)	(10)	(10)	(10)	(10)
Cerebellum, Dysplasia	1 [2.0]					
RESPIRATORY SYSTEM						
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Histiocyte	1 [1.0]			2 [1.0]	2 [1.0]	6 [1.0]

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Interstitial, Infiltration Cellular, Lymphocyte	4 [1.0]					
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Glomerulopathy, Hyaline Mineralization	6 [1.0]	10 [1.0]	9 [1.0]	9 [1.0]	10 [1.0]	8 [1.0] 9 [1.1]
Nephropathy						1 [1.0]
Renal Tubule, Casts Protein	1 [1.0]				2 [1.0]	6 [1.0]
Renal Tubule, Regeneration		1 [1.0]				
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)
Mineralization	1 [1.0]					

*** END OF REPORT ***