TDMS No. 99020 - 05	P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]	Date Report Requested: 05/21/2008
Test Type: CHRONIC Route: GAVAGE Species/Strain: RATS/F 344	F1 R2	Time Report Requested: 09:15:32 First Dose M/F: 04/09/03 / 04/10/03 Lab: BAT
C Number:	C99020	
Lock Date:	01/06/2006	
Cage Range:	ALL	
Date Range:	ALL	
Reasons For Removal:	ALL	
Removal Date Range:	ALL	
Treatment Groups:	Include ALL	

Study Gender:

TDMSE Version:

Both

2.0.0

TDMS No. 99020 - 05
Test Type: CHRONIC

Species/Strain: RATS/F 344

Route: GAVAGE

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

Date Report Requested: 05/21/2008

Pulegone

CAS Number: 89-82-7

Time Report Requested: 09:15:32 First Dose M/F: 04/09/03 / 04/10/03 Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 CHG 0 MG/KG	
Disposition Summary					
Animals Initially in Study Early Deaths	50	50	50	50	
Dosing Accident Moribund Sacrifice	8	1 10	12	35	
Natural Death	3	7	10	13	
Survivors	00	00	00	0	
Terminal Sacrifice Animals Examined Microscopically	39 50	32 50	28 50	2 50	
LIMENTARY SYSTEM					
Esophagus Perforation	(50)	(50) 1	(50)	(50)	
Periesophageal Tissue, Inflammation Intestine Large, Cecum Inflammation Mineralization	(50)	1 [2.0] (50)	(49) 6 [1.2]	(50) 21 [1.7] 4 [1.5]	
Ulcer Intestine Large, Colon Hemorrhage	(50)	(50) 1 [2.0]	(50)	3 [3.0] (50)	
Inflammation Parasite Metazoan	1 [1.0]	1 [3.0]	1 [3.0] 1	1 [1.0]	
Ulcer Intestine Large, Rectum Inflammation	(50)	(50)	1 [3.0] (50) 1 [1.0]	(50)	
Parasite Metazoan Intestine Small, Duodenum	2 (50)	1 (50)	(50)	1 (50)	
Diverticulum Erosion Inflammation Ulcer			1 1 [3.0]	2 [2.0] 1 [2.0] 1 [3.0]	
Epithelium, Hyperplasia Intestine Small, Ileum Intestine Small, Jejunum	(50) (50)	(50) (50)	(49) (50)	1 [2.0] (50) (50)	
Peyer's Patch, Hyperplasia Liver	1 [2.0] (50)	1 [3.0] (50)	(50)	(50)	

a - Number of animals examined microscopically at site and number of animals with lesion

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

Date Report Requested: 05/21/2008

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344

Pulegone

CAS Number: 89-82-7

Time Report Requested: 09:15:32 First Dose M/F: 04/09/03 / 04/10/03 Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 CHG 0 MG/KG	
Angiectasis			1 [2.0]		
Basophilic Focus	36	5	2	2	
Bile Stasis				1 [2.0]	
Clear Cell Focus	22	22	20	1	
Congestion		1 [2.0]			
Eosinophilic Focus	1	2	12	3	
Fatty Change	1 [2.0]	10 [1.4]	27 [1.4]	2 [1.0]	
Hematopoietic Cell Proliferation			1 [1.0]		
Hepatodiaphragmatic Nodule	6	6	2	3	
Inflammation	41 [1.0]	36 [1.0]	41 [1.2]	46 [1.3]	
Mixed Cell Focus	9	3	10	1	
Pigmentation, Bile		1 [1.0]			
Thrombosis			1 [2.0]		
Arteriole, Inflammation		1 [2.0]			
Bile Duct, Crystals			1 [4.0]		
Bile Duct, Cyst			11 [2.2]	9 [2.1]	
Bile Duct, Hyperplasia	29 [1.1]	15 [1.1]	37 [1.5]	50 [3.0]	
Centrilobular, Hepatocyte, Degeneration	3 [2.3]		1 [2.0]		
Hepatocyte, Cellular Alteration, Diffuse		2 [2.0]	21 [1.4]	46 [1.8]	
Hepatocyte, Degeneration, Cystic	1 [1.0]	1 [1.0]	3 [1.3]		
Hepatocyte, Necrosis		1 [3.0]	6 [1.2]	16 [1.8]	
Kupffer Cell, Pigmentation, Hemosiderin			1 [1.0]		
Oval Cell, Hyperplasia			8 [1.3]	44 [1.6]	
Portal, Fibrosis	8 [1.0]	6 [1.0]	13 [1.2]	43 [1.5]	
Mesentery	(9)	(11)	(11)	(4)	
Hemorrhage				1 [3.0]	
Inflammation		1 [3.0]			
Mineralization				1 [3.0]	
Necrosis	7 [2.9]	9 [2.9]	10 [3.0]	2 [3.0]	
Thrombosis				1 [3.0]	
Oral Mucosa	(0)	(1)	(3)	(0)	
Pharyngeal, Cyst			1 [4.0]		
Pharyngeal, Hyperplasia	()		1 [4.0]	<i>i</i> = - 1	
Pancreas	(50)	(50)	(50)	(50)	
Hemorrhage		1 [2.0]			
Inflammation			1 [2.0]		
Acinus, Atrophy	13 [1.6]	24 [1.4]	20 [1.4]	18 [1.2]	
Acinus, Atypia Cellular	1 [1.0]				
Acinus, Hyperplasia	11 [2.2]	8 [1.8]	7 [1.9]	1 [1.0]	
Duct, Cyst	4 [1.0]	5 [1.4]	1 [1.0]	5 [1.4]	

a - Number of animals examined microscopically at site and number of animals with lesion

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

Date Report Requested: 05/21/2008

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344

Pulegone

CAS Number: 89-82-7

Time Report Requested: 09:15:32 First Dose M/F: 04/09/03 / 04/10/03 Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 CHG 0 MG/KG	
Salivary Glands	(50)	(49)	(50)	(50)	
Atrophy	1			1 [1.0]	
Basophilic Focus Hyperplasia	1 [2.0]				
Stomach, Forestomach	(50)	(50)	(50)	(50)	
Erosion	(50)	(50)	(50)	1 [3.0]	
Inflammation	2 [1.5]	4 [1.8]	8 [1.9]	23 [2.1]	
Mineralization	2 [1.0]	1 [2.0]	0[1.0]	4 [2.0]	
Perforation		1 [2:0]		5	
Ulcer		2 [2.0]	7 [3.1]	16 [3.1]	
Epithelium, Hyperplasia	16 [1.3]	21 [1.3]	20 [2.0]	23 [2.3]	
Stomach, Glandular	(50)	(50)	(50)	(50)	
Erosion	(00)	(00)	2 [2.5]	(00)	
Inflammation	1 [1.0]	3 [1.0]	1 [1.0]	6 [1.2]	
Mineralization	1 - 1	1 [2.0]	4 [2.0]	21 [1.7]	
Ulcer		1 [4.0]			
Epithelium, Hyperplasia			1 [1.0]		
Serosa, Inflammation				1 [1.0]	
Tongue	(0)	(1)	(2) (0)	(0)	
Tooth	(0) (0)	(1) (2)	(0)	(0)	
Peridontal Tissue, Inflammation		1 [2.0]			
CARDIOVASCULAR SYSTEM					
Blood Vessel	(50)	(50)	(50)	(50)	
Dilatation	()	()	()	1 [3.0]	
Mineralization			1 [2.0]	24 [2.0]	
Heart	(50)	(50)	(50)	(50)	
Cardiomyopathy	44 [2.4]	44 [2.1]	48 [2.2]	50 [2.2]	
Mineralization			1 [3.0]	23 [1.6]	
Artery, Inflammation	1 [1.0]				
Atrium, Thrombosis			1 [4.0]		
Endocardium, Bacterium			2		
Endocardium, Inflammation			1 [2.0]		
Valve, Thrombosis		1 [1.0]			
ENDOCRINE SYSTEM					
Adrenal Cortex	(50)	(50)	(50)	(50)	
				· · ·	

a - Number of animals examined microscopically at site and number of animals with lesion

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

Date Report Requested: 05/21/2008

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344

Pulegone

CAS Number: 89-82-7

Time Report Requested: 09:15:32 First Dose M/F: 04/09/03 / 04/10/03 Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 CHG 0 MG/KG	
Degeneration, Cystic	1 [1.0]		2 [2.5]		
Hematopoietic Cell Proliferation		1 [1.0]			
Hyperplasia	27 [1.6]	16 [1.4]	23 [1.5]	18 [1.6]	
Hypertrophy	11 [1.7]	12 [1.3]	16 [1.6]	9 [1.6]	
Vacuolization Cytoplasmic		1 [2.0]	1 [2.0]		
Adrenal Medulla	(50)	(50)	(50)	(50)	
Hyperplasia	22 [1.7]	19 [1.6]	30 [1.9]	31 [1.8]	
Infiltration Cellular, Mononuclear Cell		1 [1.0]			
Islets, Pancreatic	(50)	(50)	(50)	(50)	
Hyperplasia				1 [2.0]	
Parathyroid Gland	(49)	(44)	(45)	(48)	
Hyperplasia		. ,	3 [2.3]	36 [2.5]	
Pituitary Gland	(50)	(50)	(50)	(50)	
Pars Distalis, Angiectasis	2 [2.5]				
Pars Distalis, Cyst	2 [2.5]		1 [3.0]	1 [2.0]	
Pars Distalis, Hyperplasia	22 [1.9]	24 [1.6]	18 [1.9]	14 [1.4]	
Pars Distalis, Pigmentation	1 [1.0]				
Pars Intermedia, Cyst			1 [3.0]		
Rathke's Cleft, Cyst	1 [4.0]				
Thyroid Gland	(50)	(50)	(44)	(47)	
Ć-cell, Hyperplasia	32 [1.2]	34 [1.3]	28 [1.1]	20 [1.1]	
Follicle, Cyst				1 [2.0]	
Follicular Cell, Hyperplasia	1 [1.0]				
ENERAL BODY SYSTEM					
None					
ENITAL SYSTEM					
Epididymis	(50)	(50)	(50)	(49)	
Fibrosis				1 [2.0]	
Granuloma Sperm	2 [2.0]	2 [3.0]	2 [2.0]	2 [2.5]	
Inflammation	1 [2.0]	1 [1.0]	1 [1.0]	2 [2.0]	
Preputial Gland	(50)	(50)	(50)	(50)	
Inflammation	9 [1.6]	14 [1.3]	13 [1.2]	8 [1.5]	
Mineralization		_		1 [1.0]	
	10 01 0	1 [2.0]		1 [2.0]	
Duct, Ectasia Prostate	3 [2.3] (50)	(50)	(50)	(49)	

a - Number of animals examined microscopically at site and number of animals with lesion

TDMS No. 99020 - 05 Test Type: CHRONIC

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

Date Report Requested: 05/21/2008

Route: GAVAGE

Species/Strain: RATS/F 344

Pulegone CAS Number: 89-82-7 Time Report Requested: 09:15:32 First Dose M/F: 04/09/03 / 04/10/03 Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 CHG 0 MG/KG	
Atrophy Inflammation Mineralization	9 [2.1]	11 [2.3]	1 [2.0] 10 [2.1]	3 [1.7] 1 [2.0]	
Epithelium, Cyst Epithelium, Hyperplasia Seminal Vesicle Atrophy Inflammation	15 [1.1] (50)	6 [1.3] (50)	2 [2.0] 12 [1.1] (50) 1 [2.0]	3 [1.0] (49) 1 [2.0]	
Mineralization Epithelium, Hyperplasia Testes Cyst	(50) 1 [4.0]	1 [2.0] (50)	1 [2.0] (50)	1 [2.0] 1 [2.0] (49)	
Inflammation Mineralization Germinal Epithelium, Atrophy Interstitial Cell, Hyperplasia	3 [2.3] 1 [2.0]	1 [1.0] 4 [2.5]	2 [1.0] 5 [2.4] 2 [1.5]	1 [2.0] 4 [3.0] 1 [2.0]	
HEMATOPOIETIC SYSTEM					
Bone Marrow Hyperplasia Lymph Node Hematopoietic Cell Proliferation	(50) 10 [3.1] (2) 1 [1.0]	(50) 8 [3.0] (8)	(50) 9 [2.0] (3)	(50) 6 [2.8] (6)	
Deep Cervical, Hemorrhage Mediastinal, Degeneration, Cystic Mediastinal, Hemorrhage Mediastinal, Hyperplasia, Plasma Cell	L - J	2 [3.5] 3 [3.0]		2 [2.5] 2 [2.5]	
Mediastinal, Infiltration Cellular, Histiocyte Pancreatic, Degeneration, Cystic Pancreatic, Hemorrhage				1 [2.0] 1 [2.0] 1 [3.0]	
Lymph Node, Mesenteric Degeneration, Cystic Fibrosis Hemorrhage	(50) 1 [2.0]	(50) 1 [3.0]	(50)	(50) 2 [2.0] 1 [2.0]	
Infiltration Cellular, Histiocyte Mineralization Spleen Congestion	(50)	(50)	1 [2.0] (50) 1 [3.0]	1 [2.0] 1 [2.0] 1 [2.0] (50)	

a - Number of animals examined microscopically at site and number of animals with lesion

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

Date Report Requested: 05/21/2008

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344

Pulegone

CAS Number: 89-82-7

Time Report Requested: 09:15:32 First Dose M/F: 04/09/03 / 04/10/03 Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 CHG 0 MG/KG	
Depletion Cellular Fibrosis Hyperplasia, Lymphoid Hyperplasia, Reticulum Cell Infarct Thrombosis	3 [2.3]	1 [2.0] 2 [2.0] 2 [2.0]	1 [2.0] 2 [1.5] 1 [1.0] 1 [3.0] 1 [3.0]		
Lymphoid Follicle, Depletion Cellular Thymus Atrophy Ectopic Parathyroid Gland	(50)	(48)	1 [3.0] (48) 1 [3.0]	(47) 1 [4.0] 1 [2.0]	
Hemorrhage Inflammation Mineralization	1 [3.0]	1 [2.0]		1 [1.0]	
INTEGUMENTARY SYSTEM					
Mammary Gland Hyperplasia Inflammation Duct, Dilatation Skin Cyst Epithelial Inclusion Inflammation, Chronic Active Dermis, Fibrosis Hair Follicle, Cyst	(50) 1 [2.0] 1 [2.0] (50) 1 [3.0] 1 [4.0]	(50) 1 [3.0] (50) 6 1 [2.0]	(50) 3 [3.3] (50) 1 [3.0] 1 [2.0]	(50) (50) 1	
MUSCULOSKELETAL SYSTEM					
Bone Fibrous Osteodystrophy Skeletal Muscle	(50) (0)	(50) (0)	(50) 2 [3.0] (1)	(50) 34 [2.3] (0)	
NERVOUS SYSTEM					
Brain Hemorrhage Hydrocephalus Cerebrum, Compression	(50)	(50) 2 [2.5] 2 [1.5]	(50) 1 [3.0] 1 [3.0]	(50)	

a - Number of animals examined microscopically at site and number of animals with lesion

IS No. 99020 - 05 t Type: CHRONIC ite: GAVAGE acies/Strain: RATS/F 344	P18: INCIDENCE RA	Date Report Requested: 05/21/2008 Time Report Requested: 09:15:32 First Dose M/F: 04/09/03 / 04/10/03 Lab: BAT			
FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 CHG 0 MG/KG	
Cerebrum, Necrosis Meninges, Inflammation			1 [2.0]	1 [2.0]	
RESPIRATORY SYSTEM					
Lung Congestion	(50) 2 [3.0]	(50) 1 [3.0]	(50)	(50)	
Edema Hemorrhage Inflammation Inflammation, Chronic Active	1 [2.0]	1 [1.0]	1 [2.0] 1 [3.0] 1 [2.0] 1 [2.0]	1 [2.0]	
Metaplasia, Squamous Necrosis Alveolar Epithelium, Hyperplasia Alveolus, Inflammation, Histiocyte	1 [1.0] 11 [1.8]	9 [2.0]	1 [3.0] 11 [1.5]	11 [1.5] 1 [1.0]	
Alveolus, Inflammation, Histiocytic Arteriole, Inflammation Arteriole, Necrosis	27 [1.3]	35 [1.1] 1 [2.0]	37 [1.2] 1 [2.0] 1 [2.0]	36 [1.1]	
Interstitium, Mineralization Serosa, Hyperplasia	2 [2.0]	1 [1.0]	2 [1.5]	16 [1.6]	
Vein, Inflammation Nose Inflammation Glands, Dilatation Goblet Cell, Hyperplasia	(50) 25 [1.9] 3 [1.3]	(50) 23 [1.4] 2 [1.5]	(46) 30 [1.6] 1 [2.0]	1 [2.0] (50) 28 [1.6] 1 [1.0]	
Olfactory Epithelium, Degeneration Olfactory Epithelium, Metaplasia, Respiratory	1 [1.0] 2 [2.0]	5 [1.0] 3 [1.3]	33 [1.6] 6 [1.0]	19 [1.6]	
Respiratory Epithelium, Hyperplasia Turbinate, Inflammation Trachea Inflammation	(50) 2 [1.0]	(50) 3 [1.0]	1 [2.0] 1 [2.0] (50) 3 [1.0]	(50) 3 [1.3]	
Peritracheal Tissue, Inflammation SPECIAL SENSES SYSTEM Eye	(50)	1 [2.0]	(50)	(50)	
Inflammation Synechia	(00)	(00)		3 [2.0] 1 [2.0]	

a - Number of animals examined microscopically at site and number of animals with lesion

IS No. 99020 - 05	P18: INCIDENCE RA	P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]				
t Type: CHRONIC te: GAVAGE cies/Strain: RATS/F 344		Time Report Requested: 09:15:32 First Dose M/F: 04/09/03 / 04/10/03 Lab: BAT				
FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 CHG 0 MG/KG		
Cornea, Inflammation				2 [1.5]		
Harderian Gland	(50)	(50)	(50)	(50)		
Infiltration Cellular, Mononuclear Cell Inflammation	2 [2.0]		2 [1.5]	1 [3.0]		
Epithelium, Hyperplasia	3 [2.3]		5 [2.4]	6 [2.0]		
JRINARY SYSTEM						
Kidney	(50)	(50)	(50)	(50)		
Cyst			2 [2.5]	7 [2.1]		
Glomerulopathy, Hyaline		1 [2 0]	9 [1.1]	24 [1.6]		
Hydronephrosis Inflammation		1 [2.0] 1 [3.0]	2 [2.0]			
Nephropathy	45 [1.9]	45 [1.9]	50 [2.9]	50 [4.0]		
Thrombosis	- 1 - 1	- 1 - 1	1 [3.0]			
Cortex, Mineralization	1 [1.0]	2 [1.0]	2 [1.5]	21 [2.1]		
Pelvis, Dilatation	1 [2.0]					
Renal Tubule, Pigmentation Transitional Epithelium, Hyperplasia	1 [3.0] 1 [4.0]					
Urinary Bladder	(50)	(50)	(50)	(49)		
Hemorrhage	(00)	1 [2.0]	(00)	(10)		
Inflammation	1 [1.0]	1 [2.0]		1 [3.0]		
Ulcer		1 [3.0]				
Transitional Epithelium, Hyperplasia		1 [2.0]				

*** END OF MALE ***

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)

TDMS No. 99020 - 05
Test Type: CHRONIC

Species/Strain: RATS/F 344

Route: GAVAGE

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

Date Report Requested: 05/21/2008

Pulegone

CAS Number: 89-82-7

Time Report Requested: 09:15:32 First Dose M/F: 04/09/03 / 04/10/03 Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths Dosing Accident		1		1
Moribund Sacrifice	13	8	7	29
Natural Death Survivors	6	4	5	20
Terminal Sacrifice	31	37 50	38 50	50
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus Inflammation	(50)	(50) 1 [2.0]	(50)	(50) 1 [1.0]
Muscularis, Degeneration		1 [1.0]		1[1.0]
Periesophageal Tissue, Inflammation	(50)	1 [4.0]	(40)	(45)
Intestine Large, Cecum Inflammation	(50)	(50) 1 [1.0]	(49) 3 [1.0]	(45) 12 [1.8]
Ulcer	(50)			1 [3.0]
Intestine Large, Colon Inflammation	(50)	(50)	(49)	(45) 1 [1.0]
Mineralization				1 [2.0]
Parasite Metazoan Ulcer	3	2	1 [4.0]	
Intestine Large, Rectum	(50)	(50)	(50)	(49)
Erosion Inflammation				1 [2.0] 1 [1.0]
Parasite Metazoan	4	6	7	1
Intestine Small, Ileum Parasite Metazoan	(50)	(50)	(49)	(45) 1
Intestine Small, Jejunum	(50)	(50)	(49)	(45)
Peyer's Patch, Hyperplasia Liver	(50)	(50)	1 [2.0] (50)	(47)
Angiectasis		5 [1.4]		
Basophilic Focus Clear Cell Focus	44	21 12	3 4	2 1
Fatty Change	8 7 [1.3]	12 25 [1.4]	4 35 [1.9]	1 11 [2.0]

a - Number of animals examined microscopically at site and number of animals with lesion

TD

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

Date Report Requested: 05/21/2008

Pulegone

CAS Number: 89-82-7

Time Report Requested: 09:15:32 First Dose M/F: 04/09/03 / 04/10/03 Lab: BAT

DMS No. 99020 - 05	P18
	1.0

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344

FISCHER 344 RATS FEMALE	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG	
Hepatodiaphragmatic Nodule	3	6	7	2	
Inflammation	35 [1.2]	31 [1.1]	37 [1.5]	33 [1.2]	
Mixed Cell Focus	5		4		
Bile Duct, Cyst	1 [3.0]	6 [2.3]	38 [2.3]	13 [1.8]	
Bile Duct, Hyperplasia	5 [1.0]	4 [1.3]	49 [3.2]	43 [3.7]	
Centrilobular, Hepatocyte, Degeneration		1 [2.0]			
Hepatocyte, Cellular Alteration, Diffuse		4 [2.0]	45 [1.5]	43 [1.9]	
Hepatocyte, Necrosis	4 [1.5]	2 [1.5]	20 [1.7]	15 [2.0]	
Hepatocyte, Regeneration				1 [3.0]	
Oval Cell, Hyperplasia			45 [1.7]	43 [1.8]	
Portal, Fibrosis		3 [1.0]	28 [1.3]	35 [1.4]	
Serosa, Fibrosis			1 [2.0]		
Serosa, Hemorrhage			3 [3.0]		
Serosa, Inflammation			1 [2.0]		
Mesentery	(6)	(12)	(5)	(1)	
Necrosis	5 [3.0]	12 [2.9]	5 [3.2]	1 [3.0]	
Oral Mucosa	(1)	(0)	(0)	(2)	
Pharyngeal, Hyperplasia	1 [3.0]			2 [2.0]	
Pancreas	(50)	(50)	(49)	(46)	
Atypia Cellular	()	()	1 [2.0]		
Basophilic Focus		1	.[]		
Inflammation			2 [2.0]		
Acinus, Atrophy	11 [1.4]	12 [1.2]	15 [1.1]	17 [1.5]	
Acinus, Hyperplasia	7 [1.6]	1 [1.0]	1 [1.0]	2 [1.0]	
Duct, Cyst	2 [1.5]	4 [1.0]	3 [1.0]	3 [1.0]	
Salivary Glands	(50)	(50)	(50)	(49)	
Inflammation	1 [1.0]	(00)	1 [1.0]	(10)	
Mineralization	1 [1.0]		1 [1.0]		
Stomach, Forestomach	(50)	(50)	(49)	(46)	
Erosion	(00)	1 [3.0]	(13)	(10)	
Inflammation	3 [1.3]	3 [1.7]	7 [2.0]	3 [2.0]	
Mineralization	1 [1.0]	5[1.7]	7 [2:0]	5 [2.0]	
Ulcer	3 [2.0]	1 [3.0]	3 [2.7]	3 [2.7]	
Epithelium, Hyperplasia	3 [2.0] 11 [2.0]	7 [2.1]	15 [2.0]	9 [1.7]	
Stomach, Glandular	(50)	(50)	(49)	(46)	
Erosion	(50) 1 [1.0]	(50)	(49)	(46) 3 [2.0]	
Inflammation	1[1.0]				
	1 [2 0]	2 [4 2]	1 [4 0]	1 [1.0]	
Mineralization	1 [2.0]	3 [1.3]	1 [1.0]	13[2.2]	
Epithelium, Hyperplasia	(0)	(4)	(4)	1 [2.0]	
Tongue	(0)	(1)	(1)	(0)	

a - Number of animals examined microscopically at site and number of animals with lesion

est Type: CHRONIC bute: GAVAGE becies/Strain: RATS/F 344		Time Report Requested: 09:15:32 First Dose M/F: 04/09/03 / 04/10/03 Lab: BAT			
FISCHER 344 RATS FEMALE	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG	
Tooth Dysplasia Peridontal Tissue, Inflammation	(1)	(0)	(2) 1 [4.0] 1 [2.0]	(1) 1 [2.0]	
CARDIOVASCULAR SYSTEM					
Blood Vessel Mineralization Heart Cardiomyopathy Hypertrophy Inflammation Mineralization Artery, Inflammation Atrium, Thrombosis Endocardium, Ventricle, Thrombosis Valve, Thrombosis	(50) (50) 48 [1.6]	(50) 1 [2.0] (50) 45 [2.0] 1 [2.0] 1 [2.0]	(50) (50) 47 [1.9] 1 [1.0] 1 [2.0]	(50) 20 [2.3] (50) 44 [2.0] 1 [2.0] 4 [2.5] 11 [2.0] 1 [3.0] 1 [3.0] 1 [3.0] 1 [4.0]	
ENDOCRINE SYSTEM					
Adrenal Cortex Degeneration, Cystic Hematopoietic Cell Proliferation Hemorrhage Hyperplasia	(50) 1 [3.0] 10 [1.5]	(50) 4 [1.5] 1 [2.0] 7 [1.4]	(50) 1 [3.0] 6 [1.3]	(49) 14 [1.5]	
Hypertrophy Adrenal Medulla Hyperplasia Mineralization	20 [1.6] (50) 6 [1.2] 1 [1.0]	14 [1.6] (50) 11 [1.1]	34 [1.6] (50) 17 [1.6]	20 [1.6] (49) 27 [1.7]	
Islets, Pancreatic Parathyroid Gland Cyst	(50) (46) 1 [1.0]	(50) (47)	(49) (49)	(46) (49)	
Hyperplasia Pituitary Gland Hemorrhage Pars Distalis, Angiectasis	(50)	1 [1.0] (50) 2 [3.0]	11 [2.0] (50) 1 [2.0]	31 [2.9] (50) 1 [3.0] 1 [2.0]	
Pars Distalis, Cyst Pars Distalis, Hyperplasia Rathke's Cleft, Cyst	4 [2.3] 17 [2.3] 1 [4.0]	26 [2.0]	24 [1.8]	1 [4.0] 12 [1.5]	

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH

Date Report Requested: 05/21/2008

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)

TDMS No. 99020 - 05

OMS No. 99020 - 05 est Type: CHRONIC oute: GAVAGE becies/Strain: RATS/F 344	P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Pulegone CAS Number: 89-82-7				Date Report Requested: 05/21/2008 Time Report Requested: 09:15:32 First Dose M/F: 04/09/03 / 04/10/03 Lab: BAT
FISCHER 344 RATS FEMALE	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG	
Thyroid Gland Inflammation C-cell, Hyperplasia Follicle, Cyst	(50) 39 [1.3] 1 [2.0]	(50) 32 [1.2] 1 [3.0]	(50) 19 [1.1] 1 [3.0]	(49) 1 [2.0] 3 [1.0]	
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
Clitoral Gland Hyperplasia Inflammation Duct, Cyst Ovary Atrophy Cyst Hemorrhage Uterus Hemorrhage Hydrometra Inflammation Cervix, Cyst Endometrium, Cyst Endometrium, Hyperplasia, Cystic Vagina	(50) 3 [2.3] 6 [2.0] 2 [2.0] (50) 5 [1.2] 6 [2.7] (50) 2 [3.5] 1 [3.0] (0)	(50) 1 [2.0] 7 [2.3] 2 [3.0] (50) 5 [2.2] 4 [2.8] (50) 1 [3.0] 1 [1.0] 1 [2.0] 3 [2.0] (0)	(50) 1 [1.0] 1 [3.0] (49) 4 [2.8] 5 [3.2] (50) 1 [3.0] 2 [2.0] (1)	(49) 1 [2.0] 3 [1.3] (46) 16 [2.3] 5 [2.0] 1 [3.0] (47) 1 [3.0] 3 [2.7] 2 [2.5] 1 [3.0] 5 [1.8] (0)	
HEMATOPOIETIC SYSTEM Bone Marrow Hemorrhage Hyperplasia Infiltration Cellular, Histiocyte Myelofibrosis Lymph Node Deep Cervical, Hemorrhage Deep Cervical, Hyperplasia, Lymphoid	(50) 8 [3.1] 1 [2.0] (2)	(50) 8 [3.3] 1 [3.0] (3) 1 [3.0]	(50) 2 [2.0] 20 [3.0] 1 [3.0] (5) 1 [2.0]	(50) 38 [2.9] (11) 3 [2.7] 1 [2.0]	

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)

TDMS No. 99020 - 05 Test Type: CHRONIC

Species/Strain: RATS/F 344

Route: GAVAGE

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

Date Report Requested: 05/21/2008

Pulegone

CAS Number: 89-82-7

Time Report Requested: 09:15:32 First Dose M/F: 04/09/03 / 04/10/03 Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG
Deep Cervical, Hyperplasia, Plasma Cell	1 [2.0]			
Deep Cervical, Pigmentation, Hemosiderin			1 [2.0]	
Mediastinal, Degeneration, Cystic	1 [3.0]		1 [2.0]	
Mediastinal, Hemorrhage	1 [0:0]		1 [2.0]	2 [2.5]
Mediastinal, Hyperplasia, Plasma Cell			2 [3.0]	
Pancreatic, Hemorrhage				3 [2.7]
Pancreatic, Infiltration Cellular, Histiocyte			1 [3.0]	
Lymph Node, Mesenteric	(50)	(50)	(50)	(45)
Hemorrhage	2 [1.5]		1 [1.0]	18 [2.2]
Inflammation Necrosis, Lymphoid				2 [2.0] 1 [2.0]
Spleen	(50)	(50)	(50)	(46)
Accessory Spleen	(30)	(30)	(50)	(40)
Fibrosis			1 [2.0]	
Hematopoietic Cell Proliferation			1 [2.0]	2 [2.0]
Hemorrhage	1 [4.0]			1 [2.0]
Hyperplasia, Lymphoid	3 [2.7]		1 [2.0]	2 [2.0]
Necrosis, Lymphoid				1 [2.0]
Pigmentation, Hemosiderin	4 [0, 0]	1 [2.0]		
Thrombosis Capsule, Hemorrhage	1 [3.0]		4 [4 0]	
Thymus	(50)	(49)	1 [4.0] (47)	(47)
Atrophy	1 [2.0]	(43)	(47)	1 [3.0]
Cyst	1 [2:0]	1 [3.0]		1 [0:0]
Ectopic Parathyroid Gland		. [0.0]		1 [1.0]
Inflammation	1 [4.0]	1 [2.0]		
NTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(49)
Hyperplasia		2 [3.0]	4 [4 0]	
Inflammation Mineralization		1 [1.0]	1 [1.0]	
Duct, Dilatation	2 [3.0]	4 [3.5]	1 [4.0]	
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion	1	(00)	(00)	
Epidermis, Hyperplasia		1 [1.0]		
Hair Follicle, Atrophy				1 [2.0]

a - Number of animals examined microscopically at site and number of animals with lesion

TDMS No. 99020 - 05 Test Type: CHRONIC Route: GAVAGE Species/Strain: RATS/F 344	P18: INCIDENCE RA	INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Pulegone CAS Number: 89-82-7			Date Report Requested: 05/21/2008 Time Report Requested: 09:15:32 First Dose M/F: 04/09/03 / 04/10/03 Lab: BAT	
FISCHER 344 RATS FEMALE	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG		
Subcutaneous Tissue, Inflammation		1 [4.0]				
MUSCULOSKELETAL SYSTEM						
Bone Fibrous Osteodystrophy Skeletal Muscle Hemorrhage	(50) (1)	(50) (0)	(50) 1 [2.0] (0)	(50) 27 [2.9] (1) 1 [3.0]		
NERVOUS SYSTEM						
Brain Hemorrhage Hydrocephalus Thrombosis	(50) 1 [2.0] 2 [2.0]	(50) 1 [2.0]	(50) 1 [4.0]	(50) 1 [4.0] 1 [1.0]		
RESPIRATORY SYSTEM						
Lung Bacterium Congestion Hemorrhage Inflammation Inflammation, Suppurative	(50) 1 [1.0]	(50) 3 [2.0]	(50) 1 [2.0]	(50) 1 12 [2.4] 1 [4.0]		
Pigmentation, Hepperature Pigmentation, Hepperature Thrombosis Alveolar Epithelium, Hyperplasia Alveolar Epithelium, Metaplasia, Squamous	8 [1.5]	14 [1.4] 1 [3.0]	10 [1.1]	1 [2.0] 1 [2.0] 1 [2.0] 12 [1.3]		
Alveolus, Inflammation, Histiocytic Arteriole, Inflammation Interstitium, Mineralization Perivascular, Inflammation	40 [1.0]	44 [1.0]	49 [1.0] 1 [2.0]	43 [1.1] 2 [2.0] 16 [1.7]		
Serosa, Inflammation Nose Inflammation Thrombosis Glands, Dilatation	(50) 12 [1.3]	1 [1.0] (50) 22 [1.7] 1 [3.0] 6 [1.2]	(50) 39 [2.2] 2 [3.0] 6 [1.5]	(41) 26 [2.5] 2 [3.0] 2 [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)

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

Date Report Requested: 05/21/2008

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344

Pulegone

CAS Number: 89-82-7

Time Report Requested: 09:15:32 First Dose M/F: 04/09/03 / 04/10/03 Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG	
Olfactory Epithelium, Degeneration Olfactory Epithelium, Metaplasia, Respiratory	2 [1.0] 1 [1.0]	40 [1.2] 8 [1.1]	48 [2.0] 46 [1.7]	37 [2.1] 36 [2.0]	
Olfactory Epithelium, Necrosis Respiratory Epithelium, Hyperplasia Respiratory Epithelium, Necrosis		1 [2.0]	4 [0.0]	1 [2.0] 1 [2.0]	
Septum, Fibrosis Turbinate, Inflammation Trachea Hemorrhage	(50)	(50)	1 [3.0] 1 [2.0] (50)	(50) 1 [3.0]	
Inflammation Perforation	5 [1.0]	1 [1.0]	1 [1.0]	3 [1.0] 1 [4.0]	
SPECIAL SENSES SYSTEM					
Eye Cataract Hemorrhage	(50) 1 [3.0]	(50) 3 [3.0]	(50) 2 [3.5]	(50) 1 [2.0] 3 [3.7]	
Inflammation Optic Nerve, Atrophy	1 [3.0]	1 [1.0]		9 [2.3] 1 [2.0]	
Retina, Atrophy Retina, Dysplasia	2 [3.0]	4 [3.8]	3 [3.7] 2 [2.0]	2 [2.0]	
Harderian Gland Inflammation	(50)	(50) 1 [1.0]	(50)	(50)	
Mineralization Epithelium, Hyperplasia Zymbal's Gland	(1)	(0)	1 [1.0] 1 [3.0] (1)	(0)	
URINARY SYSTEM					
Kidney Angiectasis	(50) 1 [2.0]	(50)	(50)	(49)	
Cyst Glomerulopathy, Hyaline Glomerulosclerosis	2 [2.0] 1 [2.0]	17 [1.0]	49 [2.2]	2 [2.5] 48 [3.3]	
Hemorrhage Inflammation Nephropathy Cortex, Mineralization	1 [2.0] 42 [1.2]	1 [1.0] 44 [1.3] 1 [2.0]	1 [1.0] 49 [2.9] 1 [2.0]	2 [3.0] 48 [3.4] 26 [2.0]	

a - Number of animals examined microscopically at site and number of animals with lesion

DMS No. 99020 - 05 est Type: CHRONIC pute: GAVAGE pecies/Strain: RATS/F 344	ONIC Pulegone CAS Number: 89-82-7 RATS/F 344			Date Report Requested: 05/21/2008 Time Report Requested: 09:15:32 First Dose M/F: 04/09/03 / 04/10/03 Lab: BAT	
FISCHER 344 RATS FEMALE				150 CHG 0 MG/KG	
Pelvis, Inflammation Renal Tubule, Degeneration		2 [2.0]	1 [3.0]		
Urinary Bladder	(50)	(49)	(50)	(47)	
Inflammation Transitional Epithelium, Hyperplasia	1 [1.0]		2 [1.0]	2 [1.5] 1 [1.0]	

*** END OF REPORT ***

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)