

**TDMS No.** 99020 - 05  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** RATS/F 344/N

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**

Pulegone  
**CAS Number:** 89-82-7

**Date Report Requested:** 02/11/2009  
**Time Report Requested:** 09:57:45  
**First Dose M/F:** 04/09/03 / 04/10/03  
**Lab:** BAT

F1\_Rev.1\_R2

**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:** Both  
**TDMSE Version:** 2.1.0

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FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 MG/KG Stop
<b>Disposition Summary</b>				
Animals Initially in Study	50	50	50	50
Early Deaths				
Dosing Accident		1		
Moribund Sacrifice	8	10	12	35
Natural Death	3	7	10	13
Survivors				
Terminal Sacrifice	39	32	28	2
Animals Examined Microscopically	50	50	50	50

**ALIMENTARY SYSTEM**

Esophagus	(50)	(50)	(50)	(50)
Perforation		1 (2%)		
Periesophageal Tissue, Inflammation		1 (2%)		
Intestine Large, Cecum	(50)	(50)	(49)	(50)
Inflammation			6 (12%)	21 (42%)
Mineralization				4 (8%)
Ulcer				3 (6%)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Hemorrhage		1 (2%)		
Inflammation		1 (2%)	1 (2%)	1 (2%)
Parasite Metazoan	1 (2%)		1 (2%)	
Ulcer			1 (2%)	
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Inflammation			1 (2%)	
Parasite Metazoan	2 (4%)	1 (2%)		1 (2%)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Diverticulum			1 (2%)	
Erosion				2 (4%)
Inflammation			1 (2%)	1 (2%)
Ulcer				1 (2%)
Epithelium, Hyperplasia				1 (2%)
Intestine Small, Ileum	(50)	(50)	(49)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Peyer's Patch, Hyperplasia	1 (2%)	1 (2%)		
Liver	(50)	(50)	(50)	(50)
Angiectasis			1 (2%)	
Basophilic Focus	36 (72%)	5 (10%)	2 (4%)	2 (4%)
Bile Stasis				1 (2%)
Clear Cell Focus	22 (44%)	22 (44%)	20 (40%)	1 (2%)
Congestion		1 (2%)		

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

FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 MG/KG Stop
Eosinophilic Focus	1 (2%)	2 (4%)	12 (24%)	3 (6%)
Fatty Change	1 (2%)	10 (20%)	27 (54%)	2 (4%)
Hematopoietic Cell Proliferation			1 (2%)	
Hepatodiaphragmatic Nodule	6 (12%)	6 (12%)	2 (4%)	3 (6%)
Inflammation	41 (82%)	36 (72%)	41 (82%)	46 (92%)
Mixed Cell Focus	9 (18%)	3 (6%)	10 (20%)	1 (2%)
Pigmentation, Bile		1 (2%)		
Thrombosis			1 (2%)	
Arteriole, Inflammation		1 (2%)		
Bile Duct, Crystals			1 (2%)	
Bile Duct, Cyst			11 (22%)	9 (18%)
Bile Duct, Hyperplasia	29 (58%)	15 (30%)	37 (74%)	50 (100%)
Centrilobular, Hepatocyte, Degeneration	3 (6%)		1 (2%)	
Hepatocyte, Cellular Alteration, Diffuse		2 (4%)	21 (42%)	46 (92%)
Hepatocyte, Degeneration, Cystic	1 (2%)	1 (2%)	3 (6%)	
Hepatocyte, Necrosis		1 (2%)	6 (12%)	16 (32%)
Kupffer Cell, Pigmentation, Hemosiderin			1 (2%)	
Oval Cell, Hyperplasia			8 (16%)	44 (88%)
Portal, Fibrosis	8 (16%)	6 (12%)	13 (26%)	43 (86%)
Mesentery	(9)	(11)	(11)	(4)
Hemorrhage				1 (25%)
Inflammation		1 (9%)		
Mineralization				1 (25%)
Necrosis	7 (78%)	9 (82%)	10 (91%)	2 (50%)
Thrombosis				1 (25%)
Oral Mucosa	(0)	(1)	(3)	(0)
Pharyngeal, Cyst			1 (33%)	
Pharyngeal, Hyperplasia			1 (33%)	
Pancreas	(50)	(50)	(50)	(50)
Hemorrhage		1 (2%)		
Inflammation			1 (2%)	
Acinus, Atrophy	13 (26%)	24 (48%)	20 (40%)	18 (36%)
Acinus, Atypia Cellular	1 (2%)			
Acinus, Hyperplasia	11 (22%)	8 (16%)	7 (14%)	1 (2%)
Duct, Cyst	4 (8%)	5 (10%)	1 (2%)	5 (10%)
Salivary Glands	(50)	(49)	(50)	(50)
Atrophy				1 (2%)
Basophilic Focus	1 (2%)			
Hyperplasia	1 (2%)			
Stomach, Forestomach	(50)	(50)	(50)	(50)
Erosion				1 (2%)
Inflammation	2 (4%)	4 (8%)	8 (16%)	23 (46%)
Mineralization		1 (2%)		4 (8%)
Perforation				5 (10%)
Ulcer		2 (4%)	7 (14%)	16 (32%)
Epithelium, Hyperplasia	16 (32%)	21 (42%)	20 (40%)	23 (46%)

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FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 MG/KG Stop
Stomach, Glandular	(50)	(50)	(50)	(50)
Erosion			2 (4%)	
Inflammation	1 (2%)	3 (6%)	1 (2%)	6 (12%)
Mineralization		1 (2%)	4 (8%)	21 (42%)
Ulcer		1 (2%)		
Epithelium, Hyperplasia			1 (2%)	
Serosa, Inflammation				1 (2%)
Tongue	(0)	(1)	(2)	(0)
Tooth	(0)	(2)	(0)	(0)
Peridental Tissue, Inflammation		1 (50%)		
<b>CARDIOVASCULAR SYSTEM</b>				
Blood Vessel	(50)	(50)	(50)	(50)
Dilatation				1 (2%)
Mineralization			1 (2%)	24 (48%)
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	44 (88%)	44 (88%)	48 (96%)	50 (100%)
Mineralization			1 (2%)	23 (46%)
Artery, Inflammation	1 (2%)			
Atrium, Thrombosis			1 (2%)	
Endocardium, Bacterium			2 (4%)	
Endocardium, Inflammation			1 (2%)	
Valve, Thrombosis		1 (2%)		
<b>ENDOCRINE SYSTEM</b>				
Adrenal Cortex	(50)	(50)	(50)	(50)
Degeneration, Cystic	1 (2%)		2 (4%)	
Hematopoietic Cell Proliferation		1 (2%)		
Hyperplasia	27 (54%)	16 (32%)	23 (46%)	18 (36%)
Hypertrophy	11 (22%)	12 (24%)	16 (32%)	9 (18%)
Vacuolization Cytoplasmic		1 (2%)	1 (2%)	
Adrenal Medulla	(50)	(50)	(50)	(50)
Hyperplasia	22 (44%)	19 (38%)	30 (60%)	31 (62%)
Infiltration Cellular, Mononuclear Cell		1 (2%)		
Islets, Pancreatic	(50)	(50)	(50)	(50)
Hyperplasia				1 (2%)
Parathyroid Gland	(49)	(44)	(45)	(48)
Hyperplasia			3 (7%)	36 (75%)
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Angiectasis	2 (4%)			
Pars Distalis, Cyst	2 (4%)		1 (2%)	1 (2%)
Pars Distalis, Hyperplasia	22 (44%)	24 (48%)	18 (36%)	14 (28%)

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

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FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 MG/KG Stop
Pars Distalis, Pigmentation	1 (2%)			
Pars Intermedia, Cyst			1 (2%)	
Rathke's Cleft, Cyst	1 (2%)			
Thyroid Gland	(50)	(50)	(44)	(47)
C-cell, Hyperplasia	32 (64%)	34 (68%)	28 (64%)	20 (43%)
Follicle, Cyst				1 (2%)
Follicular Cell, Hyperplasia	1 (2%)			
<b>GENERAL BODY SYSTEM</b>				
None				
<b>GENITAL SYSTEM</b>				
Epididymis	(50)	(50)	(50)	(49)
Fibrosis				1 (2%)
Granuloma Sperm	2 (4%)	2 (4%)	2 (4%)	2 (4%)
Inflammation	1 (2%)	1 (2%)	1 (2%)	2 (4%)
Preputial Gland	(50)	(50)	(50)	(50)
Inflammation	9 (18%)	14 (28%)	13 (26%)	8 (16%)
Mineralization				1 (2%)
Duct, Ectasia	3 (6%)	1 (2%)		1 (2%)
Prostate	(50)	(50)	(50)	(49)
Atrophy			1 (2%)	
Inflammation	9 (18%)	11 (22%)	10 (20%)	3 (6%)
Mineralization				1 (2%)
Epithelium, Cyst			2 (4%)	
Epithelium, Hyperplasia	15 (30%)	6 (12%)	12 (24%)	3 (6%)
Seminal Vesicle	(50)	(50)	(50)	(49)
Atrophy			1 (2%)	
Inflammation		1 (2%)		1 (2%)
Mineralization				1 (2%)
Epithelium, Hyperplasia			1 (2%)	
Testes	(50)	(50)	(50)	(49)
Cyst	1 (2%)			
Inflammation		1 (2%)	2 (4%)	
Mineralization				1 (2%)
Germinal Epithelium, Atrophy	3 (6%)	4 (8%)	5 (10%)	4 (8%)
Interstitial Cell, Hyperplasia	1 (2%)		2 (4%)	1 (2%)
<b>HEMATOPOIETIC SYSTEM</b>				
Bone Marrow	(50)	(50)	(50)	(50)

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FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 MG/KG Stop
Hyperplasia	10 (20%)	8 (16%)	9 (18%)	6 (12%)
Lymph Node	(2)	(8)	(3)	(6)
Hematopoietic Cell Proliferation	1 (50%)			
Deep Cervical, Hemorrhage				2 (33%)
Mediastinal, Degeneration, Cystic		2 (25%)		
Mediastinal, Hemorrhage				2 (33%)
Mediastinal, Hyperplasia, Plasma Cell		3 (38%)		
Mediastinal, Infiltration Cellular, Histiocyte				1 (17%)
Pancreatic, Degeneration, Cystic				1 (17%)
Pancreatic, Hemorrhage				1 (17%)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Degeneration, Cystic	1 (2%)			
Fibrosis				2 (4%)
Hemorrhage		1 (2%)		1 (2%)
Infiltration Cellular, Histiocyte			1 (2%)	1 (2%)
Mineralization				1 (2%)
Spleen	(50)	(50)	(50)	(50)
Congestion			1 (2%)	
Depletion Cellular		1 (2%)		
Fibrosis		2 (4%)	1 (2%)	
Hyperplasia, Lymphoid	3 (6%)	2 (4%)	2 (4%)	
Hyperplasia, Reticulum Cell			1 (2%)	
Infarct			1 (2%)	
Thrombosis			1 (2%)	
Lymphoid Follicle, Depletion Cellular			1 (2%)	
Thymus	(50)	(48)	(48)	(47)
Atrophy			1 (2%)	1 (2%)
Ectopic Parathyroid Gland				1 (2%)
Hemorrhage	1 (2%)			
Inflammation		1 (2%)		
Mineralization				1 (2%)
<b>INTEGUMENTARY SYSTEM</b>				
Mammary Gland	(50)	(50)	(50)	(50)
Hyperplasia	1 (2%)			
Inflammation	1 (2%)			
Duct, Dilatation		1 (2%)	3 (6%)	
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion		6 (12%)	1 (2%)	1 (2%)
Inflammation, Chronic Active	1 (2%)	1 (2%)		
Dermis, Fibrosis			1 (2%)	
Hair Follicle, Cyst	1 (2%)			

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<b>MUSCULOSKELETAL SYSTEM</b>				
Bone	(50)	(50)	(50)	(50)
Fibrous Osteodystrophy			2 (4%)	34 (68%)
Skeletal Muscle	(0)	(0)	(1)	(0)
<b>NERVOUS SYSTEM</b>				
Brain	(50)	(50)	(50)	(50)
Hemorrhage		2 (4%)	1 (2%)	
Hydrocephalus		2 (4%)		
Cerebrum, Compression			1 (2%)	
Cerebrum, Necrosis			1 (2%)	
Meninges, Inflammation				1 (2%)
<b>RESPIRATORY SYSTEM</b>				
Lung	(50)	(50)	(50)	(50)
Congestion	2 (4%)	1 (2%)		
Edema			1 (2%)	
Hemorrhage	1 (2%)		1 (2%)	1 (2%)
Inflammation		1 (2%)	1 (2%)	
Inflammation, Chronic Active			1 (2%)	
Metaplasia, Squamous	1 (2%)			
Necrosis			1 (2%)	
Alveolar Epithelium, Hyperplasia	11 (22%)	9 (18%)	11 (22%)	11 (22%)
Alveolus, Inflammation, Histiocyte				1 (2%)
Alveolus, Inflammation, Histiocytic	27 (54%)	35 (70%)	37 (74%)	36 (72%)
Arteriole, Inflammation		1 (2%)	1 (2%)	
Arteriole, Necrosis			1 (2%)	
Interstitial, Mineralization		1 (2%)	2 (4%)	16 (32%)
Serosa, Hyperplasia	2 (4%)			
Vein, Inflammation				1 (2%)
Nose	(50)	(50)	(46)	(50)
Inflammation	25 (50%)	23 (46%)	30 (65%)	28 (56%)
Glands, Dilatation		2 (4%)	1 (2%)	1 (2%)
Goblet Cell, Hyperplasia	3 (6%)			
Olfactory Epithelium, Degeneration	1 (2%)	5 (10%)	33 (72%)	19 (38%)
Olfactory Epithelium, Metaplasia, Respiratory	2 (4%)	3 (6%)	6 (13%)	
Respiratory Epithelium, Hyperplasia			1 (2%)	
Turbinate, Inflammation			1 (2%)	
Trachea	(50)	(50)	(50)	(50)
Inflammation	2 (4%)	3 (6%)	3 (6%)	3 (6%)

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FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 MG/KG Stop
Peritracheal Tissue, Inflammation		1 (2%)		
<b>SPECIAL SENSES SYSTEM</b>				
Eye	(50)	(50)	(50)	(50)
Inflammation				3 (6%)
Synechia				1 (2%)
Cornea, Inflammation				2 (4%)
Harderian Gland	(50)	(50)	(50)	(50)
Infiltration Cellular, Mononuclear Cell				1 (2%)
Inflammation	2 (4%)		2 (4%)	
Epithelium, Hyperplasia	3 (6%)		5 (10%)	6 (12%)
<b>URINARY SYSTEM</b>				
Kidney	(50)	(50)	(50)	(50)
Cyst			2 (4%)	7 (14%)
Glomerulopathy, Hyaline			9 (18%)	24 (48%)
Hydronephrosis		1 (2%)		
Inflammation		1 (2%)	2 (4%)	
Nephropathy	45 (90%)	45 (90%)	50 (100%)	50 (100%)
Thrombosis			1 (2%)	
Cortex, Mineralization	1 (2%)	2 (4%)	2 (4%)	21 (42%)
Pelvis, Dilatation	1 (2%)			
Renal Tubule, Pigmentation	1 (2%)			
Transitional Epithelium, Hyperplasia	1 (2%)			
Urinary Bladder	(50)	(50)	(50)	(49)
Hemorrhage		1 (2%)		
Inflammation	1 (2%)	1 (2%)		1 (2%)
Ulcer		1 (2%)		
Transitional Epithelium, Hyperplasia		1 (2%)		

\*\*\* END OF MALE \*\*\*



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FISCHER 344 RATS FEMALE	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 MG/KG Stop
<b>Disposition Summary</b>				
Animals Initially in Study	50	50	50	50
Early Deaths				
Dosing Accident		1		1
Moribund Sacrifice	13	8	7	29
Natural Death	6	4	5	20
Survivors				
Terminal Sacrifice	31	37	38	
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Inflammation		1 (2%)		1 (2%)
Muscularis, Degeneration		1 (2%)		
Periesophageal Tissue, Inflammation		1 (2%)		
Intestine Large, Cecum	(50)	(50)	(49)	(45)
Inflammation		1 (2%)	3 (6%)	12 (27%)
Ulcer				1 (2%)
Intestine Large, Colon	(50)	(50)	(49)	(45)
Inflammation				1 (2%)
Mineralization				1 (2%)
Parasite Metazoan	3 (6%)	2 (4%)		
Ulcer			1 (2%)	
Intestine Large, Rectum	(50)	(50)	(50)	(49)
Erosion				1 (2%)
Inflammation				1 (2%)
Parasite Metazoan	4 (8%)	6 (12%)	7 (14%)	1 (2%)
Intestine Small, Ileum	(50)	(50)	(49)	(45)
Parasite Metazoan				1 (2%)
Intestine Small, Jejunum	(50)	(50)	(49)	(45)
Peyer's Patch, Hyperplasia			1 (2%)	
Liver	(50)	(50)	(50)	(47)
Angiectasis		5 (10%)		
Basophilic Focus	44 (88%)	21 (42%)	3 (6%)	2 (4%)
Clear Cell Focus	8 (16%)	12 (24%)	4 (8%)	1 (2%)
Fatty Change	7 (14%)	25 (50%)	35 (70%)	11 (23%)
Hepatodiaphragmatic Nodule	3 (6%)	6 (12%)	7 (14%)	2 (4%)
Inflammation	35 (70%)	31 (62%)	37 (74%)	33 (70%)
Mixed Cell Focus	5 (10%)		4 (8%)	
Bile Duct, Cyst	1 (2%)	6 (12%)	38 (76%)	13 (28%)
Bile Duct, Hyperplasia	5 (10%)	4 (8%)	49 (98%)	43 (91%)

FISCHER 344 RATS FEMALE	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 MG/KG Stop
Centrilobular, Hepatocyte, Degeneration		1 (2%)		
Hepatocyte, Cellular Alteration, Diffuse		4 (8%)	45 (90%)	43 (91%)
Hepatocyte, Necrosis	4 (8%)	2 (4%)	20 (40%)	15 (32%)
Hepatocyte, Regeneration				1 (2%)
Oval Cell, Hyperplasia			45 (90%)	43 (91%)
Portal, Fibrosis		3 (6%)	28 (56%)	35 (74%)
Serosa, Fibrosis			1 (2%)	
Serosa, Hemorrhage			3 (6%)	
Serosa, Inflammation			1 (2%)	
Mesentery	(6)	(12)	(5)	(1)
Necrosis	5 (83%)	12 (100%)	5 (100%)	1 (100%)
Oral Mucosa	(1)	(0)	(0)	(2)
Pharyngeal, Hyperplasia	1 (100%)			2 (100%)
Pancreas	(50)	(50)	(49)	(46)
Atypia Cellular			1 (2%)	
Basophilic Focus		1 (2%)		
Inflammation			2 (4%)	
Acinus, Atrophy	11 (22%)	12 (24%)	15 (31%)	17 (37%)
Acinus, Hyperplasia	7 (14%)	1 (2%)	1 (2%)	2 (4%)
Duct, Cyst	2 (4%)	4 (8%)	3 (6%)	3 (7%)
Salivary Glands	(50)	(50)	(50)	(49)
Inflammation	1 (2%)		1 (2%)	
Mineralization	1 (2%)		1 (2%)	
Stomach, Forestomach	(50)	(50)	(49)	(46)
Erosion		1 (2%)		
Inflammation	3 (6%)	3 (6%)	7 (14%)	3 (7%)
Mineralization	1 (2%)			
Ulcer	3 (6%)	1 (2%)	3 (6%)	3 (7%)
Epithelium, Hyperplasia	11 (22%)	7 (14%)	15 (31%)	9 (20%)
Stomach, Glandular	(50)	(50)	(49)	(46)
Erosion	1 (2%)			3 (7%)
Inflammation				1 (2%)
Mineralization	1 (2%)	3 (6%)	1 (2%)	13 (28%)
Epithelium, Hyperplasia				1 (2%)
Tongue	(0)	(1)	(1)	(0)
Tooth	(1)	(0)	(2)	(1)
Dysplasia			1 (50%)	
Peridontal Tissue, Inflammation			1 (50%)	1 (100%)

CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
Mineralization		1 (2%)		20 (40%)
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	48 (96%)	45 (90%)	47 (94%)	44 (88%)

FISCHER 344 RATS FEMALE	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 MG/KG Stop
Hypertrophy		1 (2%)		1 (2%)
Inflammation				4 (8%)
Mineralization		1 (2%)	1 (2%)	11 (22%)
Artery, Inflammation				1 (2%)
Atrium, Thrombosis			1 (2%)	1 (2%)
Endocardium, Ventricle, Thrombosis				1 (2%)
Valve, Thrombosis				1 (2%)
<b>ENDOCRINE SYSTEM</b>				
Adrenal Cortex	(50)	(50)	(50)	(49)
Degeneration, Cystic	1 (2%)	4 (8%)		
Hematopoietic Cell Proliferation		1 (2%)		
Hemorrhage			1 (2%)	
Hyperplasia	10 (20%)	7 (14%)	6 (12%)	14 (29%)
Hypertrophy	20 (40%)	14 (28%)	34 (68%)	20 (41%)
Adrenal Medulla	(50)	(50)	(50)	(49)
Hyperplasia	6 (12%)	11 (22%)	17 (34%)	27 (55%)
Mineralization	1 (2%)			
Islets, Pancreatic	(50)	(50)	(49)	(46)
Parathyroid Gland	(46)	(47)	(49)	(49)
Cyst	1 (2%)			
Hyperplasia		1 (2%)	11 (22%)	31 (63%)
Pituitary Gland	(50)	(50)	(50)	(50)
Hemorrhage		2 (4%)		1 (2%)
Pars Distalis, Angiectasis			1 (2%)	1 (2%)
Pars Distalis, Cyst	4 (8%)			1 (2%)
Pars Distalis, Hyperplasia	17 (34%)	26 (52%)	24 (48%)	12 (24%)
Rathke's Cleft, Cyst	1 (2%)			
Thyroid Gland	(50)	(50)	(50)	(49)
Inflammation				1 (2%)
C-cell, Hyperplasia	39 (78%)	32 (64%)	19 (38%)	3 (6%)
Follicle, Cyst	1 (2%)	1 (2%)	1 (2%)	

**GENERAL BODY SYSTEM**

None

**GENITAL SYSTEM**

Clitoral Gland	(50)	(50)	(50)	(49)
Hyperplasia	3 (6%)	1 (2%)		1 (2%)
Inflammation	6 (12%)	7 (14%)	1 (2%)	3 (6%)

FISCHER 344 RATS FEMALE	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 MG/KG Stop
Duct, Cyst	2 (4%)	2 (4%)	1 (2%)	
Ovary	(50)	(50)	(49)	(46)
Atrophy	5 (10%)	5 (10%)	4 (8%)	16 (35%)
Cyst	6 (12%)	4 (8%)	5 (10%)	5 (11%)
Hemorrhage				1 (2%)
Uterus	(50)	(50)	(50)	(47)
Hemorrhage	2 (4%)	1 (2%)		1 (2%)
Hydrometra			1 (2%)	3 (6%)
Inflammation		1 (2%)		2 (4%)
Cervix, Cyst				1 (2%)
Endometrium, Cyst		1 (2%)		
Endometrium, Hyperplasia, Cystic	1 (2%)	3 (6%)	2 (4%)	5 (11%)
Vagina	(0)	(0)	(1)	(0)

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Hemorrhage			2 (4%)	
Hyperplasia	8 (16%)	8 (16%)	20 (40%)	38 (76%)
Infiltration Cellular, Histiocyte	1 (2%)			
Myelofibrosis		1 (2%)	1 (2%)	
Lymph Node	(2)	(3)	(5)	(11)
Deep Cervical, Hemorrhage		1 (33%)		3 (27%)
Deep Cervical, Hyperplasia, Lymphoid			1 (20%)	1 (9%)
Deep Cervical, Hyperplasia, Plasma Cell	1 (50%)			
Deep Cervical, Pigmentation, Hemosiderin			1 (20%)	
Mediastinal, Degeneration, Cystic	1 (50%)		1 (20%)	
Mediastinal, Hemorrhage				2 (18%)
Mediastinal, Hyperplasia, Plasma Cell			2 (40%)	
Pancreatic, Hemorrhage				3 (27%)
Pancreatic, Infiltration Cellular, Histiocyte			1 (20%)	
Lymph Node, Mesenteric	(50)	(50)	(50)	(45)
Hemorrhage	2 (4%)		1 (2%)	18 (40%)
Inflammation				2 (4%)
Necrosis, Lymphoid				1 (2%)
Spleen	(50)	(50)	(50)	(46)
Accessory Spleen		1 (2%)		
Fibrosis			1 (2%)	
Hematopoietic Cell Proliferation			1 (2%)	2 (4%)
Hemorrhage	1 (2%)			1 (2%)
Hyperplasia, Lymphoid	3 (6%)		1 (2%)	2 (4%)
Necrosis, Lymphoid				1 (2%)
Pigmentation, Hemosiderin		1 (2%)		
Thrombosis	1 (2%)			
Capsule, Hemorrhage			1 (2%)	

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344/N

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**

Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 02/11/2009  
 Time Report Requested: 09:57:45  
 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 MG/KG Stop
Thymus	(50)	(49)	(47)	(47)
Atrophy	1 (2%)			1 (2%)
Cyst		1 (2%)		
Ectopic Parathyroid Gland				1 (2%)
Inflammation	1 (2%)	1 (2%)		
<b>INTEGUMENTARY SYSTEM</b>				
Mammary Gland	(50)	(50)	(50)	(49)
Hyperplasia		2 (4%)		
Inflammation			1 (2%)	
Mineralization		1 (2%)		
Duct, Dilatation	2 (4%)	4 (8%)	1 (2%)	
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion	1 (2%)			
Epidermis, Hyperplasia		1 (2%)		
Hair Follicle, Atrophy				1 (2%)
Subcutaneous Tissue, Inflammation		1 (2%)		
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone	(50)	(50)	(50)	(50)
Fibrous Osteodystrophy			1 (2%)	27 (54%)
Skeletal Muscle	(1)	(0)	(0)	(1)
Hemorrhage				1 (100%)
<b>NERVOUS SYSTEM</b>				
Brain	(50)	(50)	(50)	(50)
Hemorrhage	1 (2%)		1 (2%)	1 (2%)
Hydrocephalus	2 (4%)	1 (2%)		
Thrombosis				1 (2%)
<b>RESPIRATORY SYSTEM</b>				
Lung	(50)	(50)	(50)	(50)
Bacterium				1 (2%)
Congestion			1 (2%)	
Hemorrhage				12 (24%)
Inflammation	1 (2%)	3 (6%)		
Inflammation, Suppurative				1 (2%)
Pigmentation, Hemosiderin				1 (2%)

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

FISCHER 344 RATS FEMALE	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 MG/KG Stop
Thrombosis				1 (2%)
Alveolar Epithelium, Hyperplasia	8 (16%)	14 (28%)	10 (20%)	12 (24%)
Alveolar Epithelium, Metaplasia, Squamous		1 (2%)		
Alveolus, Inflammation, Histiocytic	40 (80%)	44 (88%)	49 (98%)	43 (86%)
Arteriole, Inflammation				2 (4%)
Interstitial, Mineralization				16 (32%)
Perivascular, Inflammation			1 (2%)	
Serosa, Inflammation		1 (2%)		
Nose	(50)	(50)	(50)	(41)
Inflammation	12 (24%)	22 (44%)	39 (78%)	26 (63%)
Thrombosis		1 (2%)	2 (4%)	2 (5%)
Glands, Dilatation		6 (12%)	6 (12%)	2 (5%)
Olfactory Epithelium, Degeneration	2 (4%)	40 (80%)	48 (96%)	37 (90%)
Olfactory Epithelium, Metaplasia, Respiratory	1 (2%)	8 (16%)	46 (92%)	36 (88%)
Olfactory Epithelium, Necrosis				1 (2%)
Respiratory Epithelium, Hyperplasia		1 (2%)		
Respiratory Epithelium, Necrosis				1 (2%)
Septum, Fibrosis			1 (2%)	
Turbinate, Inflammation			1 (2%)	
Trachea	(50)	(50)	(50)	(50)
Hemorrhage				1 (2%)
Inflammation	5 (10%)	1 (2%)	1 (2%)	3 (6%)
Perforation				1 (2%)
<b>SPECIAL SENSES SYSTEM</b>				
Eye	(50)	(50)	(50)	(50)
Cataract	1 (2%)	3 (6%)	2 (4%)	1 (2%)
Hemorrhage				3 (6%)
Inflammation	1 (2%)	1 (2%)		9 (18%)
Optic Nerve, Atrophy				1 (2%)
Retina, Atrophy	2 (4%)	4 (8%)	3 (6%)	2 (4%)
Retina, Dysplasia			2 (4%)	
Harderian Gland	(50)	(50)	(50)	(50)
Inflammation		1 (2%)		
Mineralization			1 (2%)	
Epithelium, Hyperplasia			1 (2%)	
Zymbal's Gland	(1)	(0)	(1)	(0)
<b>URINARY SYSTEM</b>				
Kidney	(50)	(50)	(50)	(49)
Angiectasis	1 (2%)			
Cyst	2 (4%)			2 (4%)

TDMS No. 99020 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344/N

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Pulegone

CAS Number: 89-82-7

Date Report Requested: 02/11/2009

Time Report Requested: 09:57:45

First Dose M/F: 04/09/03 / 04/10/03

Lab: BAT

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FISCHER 344 RATS FEMALE	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 MG/KG Stop
Glomerulopathy, Hyaline		17 (34%)	49 (98%)	48 (98%)
Glomerulosclerosis	1 (2%)			
Hemorrhage	1 (2%)			
Inflammation		1 (2%)	1 (2%)	2 (4%)
Nephropathy	42 (84%)	44 (88%)	49 (98%)	48 (98%)
Cortex, Mineralization		1 (2%)	1 (2%)	26 (53%)
Pelvis, Inflammation			1 (2%)	
Renal Tubule, Degeneration		2 (4%)		
Urinary Bladder	(50)	(49)	(50)	(47)
Inflammation	1 (2%)			2 (4%)
Transitional Epithelium, Hyperplasia			2 (4%)	1 (2%)

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