TDMS No. 99020 - 05 Test Type: CHRONIC Route: GAVAGE Species/Strain: RATS/F 344	Ρ	PO3: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a) Pulegone CAS Number: 89-82-7 F1_R2	Date Report Requested: 05/21/2008 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:

Date Range:

Reasons For Removal:

Removal Date Range:

Treatment Groups:

Study Gender:

TDMSE Version:

ALL

ALL

ALL

ALL

Both

2.0.0

Include ALL

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344

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

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 MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 CHG 0 MG/KG
Disposition Summary				
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	(00)	1 (2%)	(00)	(00)
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			4 (201)	2 (4%)
Inflammation			1 (2%)	1 (2%)
				1 (2%)
Epithelium, Hyperplasia	(50)	(50)	(40)	1 (2%)
Intestine Small, Ileum	(50) (50)	(50)	(49)	(50)
Intestine Small, Jejunum		(50)	(50)	(50)
Peyer's Patch, Hyperplasia Liver	1 (2%) (50)	1 (2%) (50)	(50)	(50)
Angiectasis	(50)	(50)	(50) 1 (2%)	(50)
Basophilic Focus	36 (72%)	5 (10%)	2 (4%)	2 (4%)
Bile Stasis	30 (1270)	5(10%)	2 (4 /0)	1 (2%)
Clear Cell Focus	22 (44%)	22 (44%)	20 (40%)	1 (2%)
Congestion	ZZ (7770)	1 (2%)	20 (70/0)	i (∠ /0)

Test Type: CHRONIC

Route: GAVAGE

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Species/Strain: RATS/F 344

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

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 MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 CHG 0 MG/KG	
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%)	e ((e c ()	
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	(22())	2 (4%)	21 (42%)	46 (92%)	
Hepatocyte, Degeneration, Cystic	1 (2%)	1 (2%)	3 (6%)	(0.00)	
Hepatocyte, Necrosis		1 (2%)	6 (12%)	16 (32%)	
Kupffer Cell, Pigmentation, Hemosiderin			1 (2%)	11 (2021)	
Oval Cell, Hyperplasia	0 (100()	0 (100()	8 (16%)	44 (88%)	
Portal, Fibrosis	8 (16%)	6 (12%)	13 (26%)	43 (86%)	
Mesentery	(9)	(11)	(11)	(4)	
Hemorrhage		4 (00()		1 (25%)	
Inflammation		1 (9%)		4 (050()	
Mineralization	7 (700()	0 (000()	10 (010()	1 (25%)	
Necrosis	7 (78%)	9 (82%)	10 (91%)	2 (50%)	
Thrombosis	(0)	(4)	(2)	1 (25%)	
Oral Mucosa Pharyngeal, Cyst	(0)	(1)	(3) 1 (33%)	(0)	
Pharyngeal, Hyperplasia Pancreas	(50)	(50)	1 (33%) (50)	(50)	
Hemorrhage	(50)	(50) 1 (2%)	(50)	(50)	
Inflammation		1 (2%)	1 (2%)		
Acinus, Atrophy	13 (26%)	24 (48%)	20 (40%)	18 (36%)	
Acinus, Atophy Acinus, Atypia Cellular	1 (2%)	24 (40%)	20 (4078)	18 (30%)	
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	(50)	(43)	(30)	1 (2%)	
Basophilic Focus	1 (2%)			1 (270)	
Hyperplasia	1 (2%)				
Stomach, Forestomach	(50)	(50)	(50)	(50)	
Erosion	(00)	(00)		1 (2%)	
Inflammation	2 (4%)	4 (8%)	8 (16%)	23 (46%)	
Mineralization	- (770)	1 (2%)		4 (8%)	
Perforation		. (270)		5 (10%)	
Ulcer		2 (4%)	7 (14%)	16 (32%)	
Epithelium, Hyperplasia	16 (32%)	21 (42%)	20 (40%)	23 (46%)	
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Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344

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

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 MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 CHG 0 MG/KG	
Stomach, Glandular	(50)	(50)	(50)	(50)	
Erosion Inflammation Mineralization	1 (2%)	3 (6%) 1 (2%)	2 (4%) 1 (2%) 4 (8%)	6 (12%) 21 (42%)	
Ulcer Epithelium, Hyperplasia Serosa, Inflammation		1 (2%)	1 (2%)	1 (2%)	
Tongue Tooth Peridontal Tissue, Inflammation	(0) (0)	(1) (2) 1 (50%)	(2) (0)	(0) (0)	
ARDIOVASCULAR SYSTEM					
Blood Vessel Dilatation	(50)	(50)	(50)	(50) 1 (2%)	
Mineralization Heart	(50)	(50)	1 (2%) (50)	24 (48%) (50)	
Cardiomyopathy Mineralization	44 (88%)	44 (88%)	48 (96%) 1 (2%)	50 (100%) 23 (46%)	
Artery, Inflammation Atrium, Thrombosis	1 (2%)		1 (2%)	20 (1070)	
Endocardium, Bacterium			2 (4%)		
Endocardium, Inflammation Valve, Thrombosis		1 (2%)	1 (2%)		
NDOCRINE SYSTEM					
Adrenal Cortex	(50)	(50)	(50)	(50)	
Degeneration, Cystic Hematopoietic Cell Proliferation	1 (2%)	1 (2%)	2 (4%)		
Hyperplasia	27 (54%)	16 (32%)	23 (46%)	18 (36%)	
Hypertrophy Vacuolization Cytoplasmic	11 (22%)	12 (24%) 1 (2%)	16 (32%) 1 (2%)	9 (18%)	
Adrenal Medulla	(50)	(50)	(50)	(50)	
Hyperplasia	22 (44%)	19 (38%)	30 (60%)	31 (62%)	
Infiltration Cellular, Mononuclear Cell	(50)	1 (2%)	(50)	(50)	
Islets, Pancreatic Hyperplasia	(50)	(50)	(50)	(50) 1 (2%)	
Parathyroid Gland	(49)	(44)	(45)	(48)	
Hyperplasia			3 (7%)	36 (75%)	
Pituitary Gland	(50)	(50)	(50)	(50)	
Pars Distalis, Angiectasis Pars Distalis, Cyst	2 (4%) 2 (4%)		1 (2%)	1 (2%)	
Pars Distalis, Hyperplasia	22 (44%)	24 (48%)	18 (36%)	14 (28%)	

TDMS No. 99020 - 05 Test Type: CHRONIC Route: GAVAGE Species/Strain: RATS/F 344	P03: INCIDENC	Date Report Requested: 05/21/200 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	
Pars Distalis, Pigmentation Pars Intermedia, Cyst Rathke's Cleft, Cyst Thyroid Gland C-cell, Hyperplasia Follicle, Cyst Follicular Cell, Hyperplasia	1 (2%) 1 (2%) (50) 32 (64%) 1 (2%)	(50) 34 (68%)	1 (2%) (44) 28 (64%)	(47) 20 (43%) 1 (2%)	
GENERAL BODY SYSTEM					
GENITAL SYSTEM					
Epididymis Fibrosis Granuloma Sperm Inflammation Preputial Gland Inflammation Duct, Ectasia Prostate Atrophy Inflammation Mineralization Epithelium, Cyst Epithelium, Hyperplasia Seminal Vesicle Atrophy Inflammation Mineralization Epithelium, Hyperplasia Testes Cyst Inflammation Mineralization Germinal Epithelium, Atrophy Interstitial Cell, Hyperplasia	(50) 2 (4%) 1 (2%) (50) 9 (18%) 3 (6%) (50) 9 (18%) 15 (30%) (50) 1 (2%) 3 (6%) 1 (2%)	(50) $2 (4%)$ $1 (2%)$ (50) $14 (28%)$ $1 (2%)$ (50) $11 (22%)$ $6 (12%)$ (50) $1 (2%)$ (50) $1 (2%)$ $4 (8%)$	(50) $2 (4%)$ $1 (2%)$ (50) $13 (26%)$ (50) $1 (2%)$ $10 (20%)$ $2 (4%)$ $12 (24%)$ (50) $1 (2%)$ $1 (2%)$ $1 (2%)$ $2 (4%)$ $5 (10%)$ $2 (4%)$	(49) 1 (2%) 2 (4%) 2 (4%) (50) 8 (16%) 1 (2%) 1 (2%) 3 (6%) (49) 3 (6%) (49) 1 (2%) 1 (2%) (49) 1 (2%) 1 (2%) 4 (8%) 1 (2%)	
HEMATOPOIETIC SYSTEM Bone Marrow	(50)	(50)	(50)	(50)	

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344

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

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 MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 CHG 0 MG/KG	
		- /	- /		
Hyperplasia Lymph Node Hematopoietic Cell Proliferation	10 (20%) (2) 1 (50%)	8 (16%) (8)	9 (18%) (3)	6 (12%) (6)	
Deep Cervical, Hemorrhage Mediastinal, Degeneration, Cystic	1 (0070)	2 (25%)		2 (33%)	
Mediastinal, Hemorrhage Mediastinal, Hyperplasia, Plasma Cell Mediastinal, Infiltration Cellular, Histiocyte		3 (38%)		2 (33%) 1 (17%)	
Pancreatic, Degeneration, Cystic Pancreatic, Hemorrhage				1 (17%) 1 (17%) 1 (17%)	
Lymph Node, Mesenteric Degeneration, Cystic	(50) 1 (2%)	(50)	(50)	(50)	
Fibrosis Hemorrhage Infiltration Cellular, Histiocyte		1 (2%)	1 (2%)	2 (4%) 1 (2%) 1 (2%)	
Mineralization Spleen Congestion	(50)	(50)	(50) 1 (2%)	1 (2%) (50)	
Depletion Cellular Fibrosis Hyperplasia, Lymphoid Hyperplasia, Reticulum Cell	3 (6%)	1 (2%) 2 (4%) 2 (4%)	1 (2%) 2 (4%) 1 (2%)		
Infarct Thrombosis Lymphoid Follicle, Depletion Cellular	(50)	(40)	1 (2%) 1 (2%) 1 (2%)	(47)	
Thymus Atrophy Ectopic Parathyroid Gland	(50)	(48)	(48) 1 (2%)	(47) 1 (2%) 1 (2%)	
Hemorrhage Inflammation Mineralization	1 (2%)	1 (2%)		1 (2%)	
INTEGUMENTARY SYSTEM					
Mammary Gland Hyperplasia	(50) 1 (2%)	(50)	(50)	(50)	
Inflammation Duct, Dilatation Skin	1 (2%) (50)	1 (2%) (50)	3 (6%) (50)	(50)	
Cyst Epithelial Inclusion Inflammation, Chronic Active Dermis, Fibrosis	1 (2%)	6 (12%) 1 (2%)	1 (2%) 1 (2%)	1 (2%)	
Hair Follicle, Cyst	1 (2%)		× ,		

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Test Type: CHRONIC

Species/Strain: RATS/F 344

Route: GAVAGE

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

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 MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 CHG 0 MG/KG	
MUSCULOSKELETAL SYSTEM					
Bone Fibrous Osteodystrophy	(50)	(50)	(50)	(50) 34 (68%)	
Skeletal Muscle	(0)	(0)	2 (4%) (1)	(0)	
NERVOUS SYSTEM					
Brain	(50)	(50)	(50)	(50)	
Hemorrhage	()	2 (4%)	1 (2%)	()	
Hydrocephalus		2 (4%)			
Cerebrum, Compression			1 (2%)		
Cerebrum, Necrosis Meninges, Inflammation			1 (2%)	1 (2%)	
Meninges, milamination				1 (276)	
RESPIRATORY SYSTEM					
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	4 (00()		1 (2%)		
Metaplasia, Squamous Necrosis	1 (2%)		1 (2%)		
Alveolar Epithelium, Hyperplasia	11 (22%)	9 (18%)	11 (22%)	11 (22%)	
Alveolus, Inflammation, Histiocyte	11 (22 /0)	9 (10%)	11 (2270)	1 (2%)	
Alveolus, Inflammation, Histiocytic	27 (54%)	35 (70%)	37 (74%)	36 (72%)	
Arteriole, Inflammation	(0.70)	1 (2%)	1 (2%)		
Arteriole, Necrosis			1 (2%)		
Interstitium, 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 Goblet Cell, Hyperplasia	3 (6%)	2 (4%)	1 (2%)	1 (2%)	
Olfactory Epithelium, Degeneration	3 (6%) 1 (2%)	5 (10%)	33 (72%)	19 (38%)	
Olfactory Epithelium, Metaplasia, Respiratory	2 (4%)	3 (6%)	6 (13%)	13 (3070)	
Respiratory Epithelium, Hyperplasia	- (1/0)	0 (070)	1 (2%)		
Turbinate, Inflammation			1 (2%)		
Trachea	(50)	(50)	(50)	(50)	
Inflammation	2 (4%)	3 (6%)	3 (6%)	3 (6%)	

Route: GAVAGE

Test Type: CHRONIC

Species/Strain: RATS/F 344

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

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 MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 CHG 0 MG/KG	
Peritracheal Tissue, Inflammation		1 (2%)			
SPECIAL SENSES SYSTEM					
Eye Inflammation Synechia Cornea. Inflammation	(50)	(50)	(50)	(50) 3 (6%) 1 (2%) 2 (4%)	
Harderian Gland	(50)	(50)	(50)	(50)	
Infiltration Cellular, Mononuclear Cell Inflammation	2 (4%)		2 (4%)	1 (2%)	
Epithelium, Hyperplasia	3 (6%)		5 (10%)	6 (12%)	
JRINARY SYSTEM					
Kidney Cyst Glomerulopathy, Hyaline	(50)	(50)	(50) 2 (4%) 9 (18%)	(50) 7 (14%) 24 (48%)	
Hydronephrosis		1 (2%)		()	
Inflammation Nephropathy	45 (90%)	1 (2%) 45 (90%)	2 (4%) 50 (100%)	50 (100%)	
Thrombosis Cortex, Mineralization	1 (2%)	2 (4%)	1 (2%) 2 (4%)	21 (42%)	
Pelvis, Dilatation Renal Tubule, Pigmentation	1 (2%) 1 (2%)				
Transitional Epithelium, Hyperplasia Urinary Bladder	1 (2%) (50)	(50)	(50)	(49)	
Hemorrhage	(00)	1 (2%)	(50)	(+3)	
Inflammation	1 (2%)	1 (2%)		1 (2%)	
Ulcer Transitional Epithelium, Hyperplasia		1 (2%) 1 (2%)			

*** END OF MALE ***

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344

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

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	
Disposition Summary					
Animals Initially in Study Early Deaths	50	50	50	50	
Dosing Accident Moribund Sacrifice Natural Death	13 6	1 8 4	7 5	1 29 20	
Survivors	0	4	5	20	
Terminal Sacrifice Animals Examined Microscopically	31 50	37 50	38 50	50	
ALIMENTARY SYSTEM					
Esophagus Inflammation Muscularis, Degeneration	(50)	(50) 1 (2%) 1 (2%)	(50)	(50) 1 (2%)	
Periesophageal Tissue, Inflammation Intestine Large, Cecum Inflammation	(50)	1 (2%) (50) 1 (2%)	(49) 3 (6%)	(45) 12 (27%)	
Ulcer Intestine Large, Colon Inflammation	(50)	(50)	(49)	1 (2%) (45) 1 (2%)	
Mineralization Parasite Metazoan Ulcer	3 (6%)	2 (4%)	1 (2%)	1 (2%)	
Intestine Large, Rectum Erosion Inflammation	(50)	(50)	(50)	(49) 1 (2%) 1 (2%)	
Parasite Metazoan Intestine Small, Ileum Parasite Metazoan	4 (8%) (50)	6 (12%) (50)	7 (14%) (49)	1 (2%) (45) 1 (2%)	
Intestine Small, Jejunum Peyer's Patch, Hyperplasia	(50)	(50)	(49) 1 (2%)	(45)	
Liver Angiectasis Basophilic Focus	(50) 44 (88%)	(50) 5 (10%) 21 (42%)	(50) 3 (6%)	(47) 2 (4%)	
Clear Cell Focus Fatty Change	8 (16%) 7 (14%)	12 (24%) 25 (50%)	4 (8%) 35 (70%)	1 (2%) 11 (23%)	
Hepatodiaphragmatic Nodule Inflammation Mixed Cell Focus	3 (6%) 35 (70%) 5 (10%)	6 (12%) 31 (62%)	7 (14%) 37 (74%) 4 (8%)	2 (4%) 33 (70%)	
Bile Duct, Cyst Bile Duct, Hyperplasia	1 (2%) 5 (10%)	6 (12%) 4 (8%)	38 (76%) 49 (98%)	13 (28%) 43 (91%)	

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344

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

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	
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	. (0,0)	= (,	20 (10,0)	1 (2%)	
Oval Cell, Hyperplasia			45 (90%)	43 (91%)	
Portal, Fibrosis		3 (6%)	28 (56%)	35 (74%)	
Serosa, Fibrosis		0 (070)	1 (2%)	00 (1 170)	
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%)	(0)	(3)	2 (100%)	
Pancreas	(50)	(50)	(49)	(46)	
Atypia Cellular	(00)	(00)	1 (2%)	(10)	
Basophilic Focus		1 (2%)	. (= ,0)		
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%)	(00)	1 (2%)	(10)	
Mineralization	1 (2%)		1 (2%)		
Stomach, Forestomach	(50)	(50)	(49)	(46)	
Erosion	()	1 (2%)	(19)	()	
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)		
Tooth	(0) (1)	(1) (0)	(2)	(0) (1)	
Dysplasia			1 (50%)		
Peridontal Tissue, Inflammation			1 (50%)	1 (100%)	
CARDIOVASCULAR SYSTEM					
Blood Vessel	(50)	(50)	(50)	(50)	
Mineralization	x /	1 (2%)	x/	20 (40%)	
Heart	(50)	(50)	(50)	(50)	
Cardiomyopathy	48 (96%)	45 (90%)	47 (94%)	44 (88%)	
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Test Type: CHRONIC

Species/Strain: RATS/F 344

Route: GAVAGE

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

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

Adrenal Cortex (50) (50) (50) (49) Degeneration, Cystic 1 (2%) 4 (8%) 1 Hemorrhage 1 (2%) 1 (2%) 1 (2%) Hyperplasia 10 (20%) 7 (14%) 6 (12%) 14 (29%) Hyperplasia 10 (20%) 7 (14%) 6 (12%) 14 (29%) Hyperplasia (50) (50) (60) (50) (49) Adrenal Medulla (50) (50) (49) (49) Hyperplasia 6 (12%) 11 (22%) 17 (34%) 27 (55%) Mineralization 1 (2%) 11 (22%) 17 (34%) 27 (55%) Biets, Pancreatic (50) (50) (49) (49) Cyst 1 (2%) 11 (22%) 11 (22%) 31 (63%) Para Distalis, Angiectasis 1 (2%) 1 (2%) 1 (2%) 1 (2%) Para Distalis, Cyst 4 (8%) 1 (2%) 1 (2%) 1 (2%) Para Distalis, Cyst 1 (2%) 1 (2%) 1 (2%) 1 (2%) Para Distalis, Kyst 1 (2%) 1 (2%) 1 (2%) 1 (2%) <th>FISCHER 344 RATS FEMALE</th> <th>0 MG/KG</th> <th>37.5 MG/KG</th> <th>75.0 MG/KG</th> <th>150 CHG 0 MG/KG</th> <th></th>	FISCHER 344 RATS FEMALE	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG	
Mineralization 1 (2%) 1 (2%) 1 (2%) Artery, Information 1 (2%) 1 (2%) Artery, Information 1 (2%) 1 (2%) Endocardium, Ventrice, Thrombosis 1 (2%) 1 (2%) Valve, Thrombosis 1 (2%) 1 (2%) SUDOCRINE SYSTEM 1 (2%) 4 (8%) Artery, Informacion, Cysitc 1 (2%) 4 (8%) Hemotrhage 1 (2%) 1 (2%) Hyperplasia 10 (20%) 7 (14%) 6 (12%) Hyperplasia 10 (20%) 7 (14%) 3 4 (68%) Hyperplasia 6 (12%) 11 (2%) 14 (2%) Hyperplasia 6 (12%) 11 (2%) 17 (34%) 27 (5%) Mineralization 1 (2%) 11 (2%) 17 (34%) 27 (5%) Mineralization 1 (2%) 11 (2%) 13 (63%) 16 (2%) Parathyroid Gland (46) (47) (49) (49) Oyat 1 (2%) 11 (2%) 11 (2%) 16 (3%) Para Distalis, Appendasis 6 (12%) 12 (2%) 12 (2%) Para Distalis, Cyst 1 (2%) <td></td> <td></td> <td>1 (2%)</td> <td></td> <td>1 (2%)</td> <td></td>			1 (2%)		1 (2%)	
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	IIIIaIIIIIallOII	0 (1∠%)	7 (14%)	I (∠%)	3 (0%)	

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344

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

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	
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 Capsule, Hemorrhage	1 (2%)		1 (2%)		

TDMS No. 99020 - 05 Test Type: CHRONIC Route: GAVAGE Species/Strain: RATS/F 344	P03: INCIDENC		DPLASTIC LESIONS E ulegone nber: 89-82-7	3Y ANATOMIC SITE(a)	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	
Thymus Atrophy Cyst Ectopic Parathyroid Gland Inflammation	(50) 1 (2%) 1 (2%)	(49) 1 (2%) 1 (2%)	(47)	(47) 1 (2%) 1 (2%)	
INTEGUMENTARY SYSTEM Mammary Gland Hyperplasia Inflammation	(50)	(50) 2 (4%)	(50)	(49)	
Mineralization Mineralization Duct, Dilatation Skin Cyst Epithelial Inclusion Epidermis, Hyperplasia Hair Follicle, Atrophy Subcutaneous Tissue, Inflammation	2 (4%) (50) 1 (2%)	1 (2%) 4 (8%) (50) 1 (2%) 1 (2%)	1 (2%) 1 (2%) (50)	(50) 1 (2%)	
MUSCULOSKELETAL SYSTEM Bone Fibrous Osteodystrophy Skeletal Muscle Hemorrhage	(50) (1)	(50) (0)	(50) 1 (2%) (0)	(50) 27 (54%) (1) 1 (100%)	
NERVOUS SYSTEM Brain Hemorrhage Hydrocephalus Thrombosis	(50) 1 (2%) 2 (4%)	(50) 1 (2%)	(50) 1 (2%)	(50) 1 (2%) 1 (2%)	
RESPIRATORY SYSTEM Lung Bacterium Congestion Hemorrhage Inflammation Inflammation, Suppurative Pigmentation, Hemosiderin	(50) 1 (2%)	(50) 3 (6%)	(50) 1 (2%)	(50) 1 (2%) 12 (24%) 1 (2%) 1 (2%)	

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344

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

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	
Thrombosis	a ((aa()		(0.00)	1 (2%)	
Alveolar Epithelium, Hyperplasia	8 (16%)	14 (28%)	10 (20%)	12 (24%)	
Alveolar Epithelium, Metaplasia, Squamous Alveolus, Inflammation, Histiocytic	40 (000/)	1 (2%) 44 (88%)	40 (08%)	43 (86%)	
Arteriole, Inflammation	40 (80%)	44 (88%)	49 (98%)	43 (86%) 2 (4%)	
Interstitium, Mineralization				16 (32%)	
Perivascular, Inflammation			1 (2%)	10 (3278)	
Serosa, Inflammation		1 (2%)	1 (276)		
Nose	(50)	(50)	(50)	(41)	
Inflammation	12 (24%)	22 (44%)	39 (78%)	26 (63%)	
Thrombosis	12 (2170)	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%)	
SPECIAL SENSES SYSTEM					
Eye	(50)	(50)	(50)	(50)	
Cataract	1 (2%)	3 (6%)	2 (4%)	1 (2%)	
Hemorrhage	1 (00())	4 (00()		3 (6%)	
	1 (2%)	1 (2%)		9 (18%)	
Optic Nerve, Atrophy Retina, Atrophy	2 (4%)	4 (8%)	3 (6%)	1 (2%) 2 (4%)	
Retina, Aliophy Retina, Dysplasia	2 (4%)	4 (8%)	2 (4%)	2 (4%)	
Harderian Gland	(50)	(50)	(50)	(50)	
Inflammation	(50)	1 (2%)	(56)	(30)	
Mineralization		1 (270)	1 (2%)		
Epithelium, Hyperplasia			1 (2%)		
Zymbal's Gland	(1)	(0)	(1)	(0)	
	(.)	(0)	(-)	(0)	
URINARY SYSTEM					
Kidney	(50)	(50)	(50)	(49)	
Angiectasis	1 (2%)	(30)	(00)	()	
Cyst	2 (4%)			2 (4%)	
-,	- (,			_ (,	

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344

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

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	
Glomerulopathy, Hyaline Glomerulosclerosis	1 (2%)	17 (34%)	49 (98%)	48 (98%)	
Hemorrhage	1 (2%)	(00)	(22())		
Inflammation Nephropathy	42 (84%)	1 (2%) 44 (88%)	1 (2%) 49 (98%)	2 (4%) 48 (98%)	
Cortex, Mineralization	42 (0470)	1 (2%)	1 (2%)	26 (53%)	
Pelvis, Inflammation		0 (40()	1 (2%)		
Renal Tubule, Degeneration Jrinary Bladder	(50)	2 (4%) (49)	(50)	(47)	
Inflammation	1 (2%)	()		2 (4%)	
Transitional Epithelium, Hyperplasia			2 (4%)	1 (2%)	

*** END OF REPORT ***