TDMS No. 99020 - 06 Test Type: CHRONIC Route: GAVAGE Species/Strain: MICE/B6C3F1	P03: INCIDENCE RATES OF	NON-NEOPLASTIC LESIONS BY ANATOMIC SIT Pulegone CAS Number: 89-82-7 F1M3	E(a) Date Report Requested: 07/23/2008 Time Report Requested: 09:18:35 First Dose M/F: 04/15/03 / 04/14/03 Lab: BAT
C Number:	C99020		
Lock Date:	12/21/2005		
Cage Range:	ALL		
Date Range:	ALL		
Reasons For Removal:	25022 ACCK	25021 TSAC	25020 NATD
	25019 MSAC	25018 DACC	
Removal Date Range:	ALL		
Treatment Groups:	Include ALL		
Study Gender:	Both		
TDMSE Version:	2.0.0		

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

Pulegone

CAS Number: 89-82-7

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

Date Report Requested: 07/23/2008
 Time Report Requested: 09:18:35
 First Dose M/F: 04/15/03 / 04/14/03
 Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG	
isposition Summary					
Animals Initially in Study	50	50	50	50	
Early Deaths					
Accidently Killed		1			
Dosing Accident	_	1	_		
Moribund Sacrifice	7	8	7	8	
Natural Death	5	4	1	1	
Survivors Terminal Sacrifice	38	36	42	41	
Animals Examined Microscopically	50	50	42 50	50	
	50	30	30	30	
IMENTARY SYSTEM					
Esophagus	(50)	(50)	(50)	(50)	
Inflammation	2 (4%)	()	1 (2%)	1 (2%)	
Gallbladder	(49)	(49)	(50)	(50)	
Infiltration Cellular, Mononuclear Cell	1 (2%)				
Intestine Large, Cecum	(50)	(50)	(50)	(50)	
Hemorrhage		1 (2%)			
Intestine Small, Ileum	(50)	(50)	(50)	(50)	
Hyperplasia, Lymphoid	1 (2%)				
Inflammation		1 (2%)			
Epithelium, Hyperplasia	1 (2%)				
Intestine Small, Jejunum	(50)	(50)	(50)	(50)	
Hyperplasia, Lymphoid	1 (2%)				
Liver	(50)	(50)	(50)	(50)	
Angiectasis	1 (22())	2 (4%)	4 (00()	0 (100()	
Basophilic Focus	4 (8%)	5 (10%)	4 (8%)	6 (12%)	
Clear Cell Focus	15 (30%)	27 (54%)	28 (56%)	34 (68%)	
Eosinophilic Focus	7 (14%)	12 (24%)	20 (40%)	36 (72%)	
Fatty Change, Focal	3 (6%)	8 (16%)	20 (40%)	23 (46%)	
Fatty Change, Diffuse	38 (76%)	27 (54%)	21 (42%)	3 (6%)	
Hematopoietic Cell Proliferation Hemorrhage	3 (6%)		1 (2%)	2 (4%) 1 (2%)	
Hemorrhage Hepatodiaphragmatic Nodule	1 (2%)			I (2%)	
Inflammation	24 (48%)	21 (42%)	20 (40%)	29 (58%)	
Mixed Cell Focus	24 (48%) 18 (36%)	20 (40%)	20 (40%) 19 (38%)	29 (58%) 34 (68%)	
Necrosis	1 (2%)	8 (16%)	5 (10%)	26 (52%)	
Pigmentation	3 (6%)	0 (1070)	2 (4%)	1 (2%)	
Tension Lipidosis	5 (10%)	6 (12%)	7 (14%)	2 (4%)	
Bile Duct, Cyst			3 (6%)	14 (28%)	
Bile Duct, Fibrosis			0 (0 /0)	2 (4%)	

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

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

Pulegone

CAS Number: 89-82-7

Date Report Requested: 07/23/2008 Time Report Requested: 09:18:35 First Dose M/F: 04/15/03 / 04/14/03 Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG	
Bile Duct, Hyperplasia			1 (2%)	35 (70%)	
Centrilobular, Degeneration		1 (2%)			
Centrilobular, Vacuolization Cytoplasmic		1 (2%)	1 (2%)		
Centrilobular, Hepatocyte, Hypertrophy		10 (20%)	22 (44%)	46 (92%)	
Hepatocyte, Hypertrophy		1 (2%)	1 (2%)		
Oval Cell, Hyperplasia	1 (2%)		1 (2%)	36 (72%)	
Serosa, Inflammation, Chronic Active		1 (2%)			
Vein, Intravascular Hepatocyte	3 (6%)	1 (2%)	15 (30%)	47 (94%)	
Mesentery	(4)	(2)	(3)	(0)	
Fat, Necrosis	3 (75%)	1 (50%)	3 (100%)		
Pancreas	(50)	(50)	(50)	(50)	
Cyst	1 (2%)				
Cytoplasmic Alteration, Focal		2 (4%)	1 (2%)	1 (2%)	
Infiltration Cellular, Mononuclear Cell	5 (10%)	5 (10%)	4 (8%)	7 (14%)	
Acinus, Atrophy	1 (2%)	1 (2%)		1 (2%)	
Salivary Glands	(50)	(50)	(50)	(50)	
Atrophy			1 (2%)		
Infiltration Cellular, Mononuclear Cell	40 (80%)	32 (64%)	30 (60%)	33 (66%)	
Stomach, Forestomach	(50)	(50)	(50)	(50)	
Hyperplasia, Squamous	7 (14%)	10 (20%)	27 (54%)	41 (82%)	
Inflammation	3 (6%)	9 (18%)	24 (48%)	39 (78%)	
Mineralization		1 (2%)			
Ulcer		3 (6%)	9 (18%)	22 (44%)	
Artery, Inflammation, Chronic Active	1 (2%)				
Stomach, Glandular	(50)	(50)	(50)	(50)	
Erosion				1 (2%)	
Mineralization	2 (4%)	1 (2%)			
Epithelium, Hyperplasia		1 (2%)			
Glands, Cyst	4 (8%)	4 (8%)	3 (6%)	5 (10%)	
Glands, Hyperplasia	1 (2%)	1 (2%)			
Tooth	(37)	(37)	(35)	(20)	
Dysplasia	37 (100%)	37 (100%)	35 (100%)	20 (100%)	
Peridontal Tissue, Inflammation			1 (3%)		
Pulp, Inflammation	1 (3%)	1 (3%)	1 (3%)	1 (5%)	
CARDIOVASCULAR SYSTEM					
Blood Vessel	(50)	(50)	(50)	(50)	
Heart	(50)	(50)	(50)	(50)	
Cardiomyopathy	1 (2%)	(50)	(30)	(50)	
Infiltration Cellular, Mononuclear Cell	4 (8%)		1 (2%)	1 (2%)	
Inflammation	4 (8%) 1 (2%)		1 (270)	1 (2 /0)	
Mineralization	1 (2%)	1 (2%)	1 (2%)	4 (8%)	
IVIII IEI AIIZALIULI	1 (270)	1 (270)	I (270)	4 (0%)	

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

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

Pulegone

CAS Number: 89-82-7

Date Report Requested: 07/23/2008 Time Report Requested: 09:18:35 First Dose M/F: 04/15/03 / 04/14/03 Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG	
NDOCRINE SYSTEM					
Adrenal Cortex	(50)	(50)	(50)	(50)	
Degeneration, Cystic	47 (0.49()	0 (100()	1 (2%)	4 (00()	
Hypertrophy Vacuolization Cytoplasmic	17 (34%)	9 (18%)	8 (16%)	4 (8%)	
Subcapsular, Hyperplasia	39 (78%)	1 (2%) 40 (80%)	47 (94%)	1 (2%) 44 (88%)	
Zona Fasciculata, Hyperplasia	1 (2%)	40 (80%)	47 (94%)	44 (88%)	
Adrenal Medulla	(50)	(50)	(50)	(50)	
Hyperplasia	(50)	2 (4%)	1 (2%)	2 (4%)	
Islets, Pancreatic	(50)	(50)	(50)	(50)	
Hyperplasia	20 (40%)	17 (34%)	21 (42%)	2 (4%)	
Pituitary Gland	(50)	(50)	(50)	(50)	
Cyst	1 (2%)	(()	1 (2%)	
Pars Distalis, Hyperplasia			1 (2%)		
Thyroid Gland	(50)	(50)	(50)	(50)	
Infiltration Cellular, Mononuclear Cell	1 (2%)			1 (2%)	
Follicular Cell, Hyperplasia				1 (2%)	
ENERAL BODY SYSTEM					
None	(1)	(1)	(0)	(1)	
None ENITAL SYSTEM Coagulating Gland Hyperplasia	(1) 1 (100%)	(1)	(0)	(1)	
None ENITAL SYSTEM Coagulating Gland Hyperplasia Inflammation	1 (100%)			1 (100%)	
None ENITAL SYSTEM Coagulating Gland Hyperplasia Inflammation Epididymis	(1) 1 (100%) (50)	(50)	(0) (50)		
None ENITAL SYSTEM Coagulating Gland Hyperplasia Inflammation Epididymis Cyst	1 (100%)		(50)	1 (100%)	
None ENITAL SYSTEM Coagulating Gland Hyperplasia Inflammation Epididymis Cyst Granuloma Sperm	1 (100%) (50)	(50) 1 (2%)	(50) 1 (2%)	1 (100%) (50)	
None ENITAL SYSTEM Coagulating Gland Hyperplasia Inflammation Epididymis Cyst Granuloma Sperm Infiltration Cellular, Mononuclear Cell	1 (100%) (50) 23 (46%)	(50)	(50)	1 (100%)	
None ENITAL SYSTEM Coagulating Gland Hyperplasia Inflammation Epididymis Cyst Granuloma Sperm Infiltration Cellular, Mononuclear Cell Inflammation	1 (100%) (50)	(50) 1 (2%) 27 (54%)	(50) 1 (2%)	1 (100%) (50)	
None ENITAL SYSTEM Coagulating Gland Hyperplasia Inflammation Epididymis Cyst Granuloma Sperm Infiltration Cellular, Mononuclear Cell Inflammation Mineralization	1 (100%) (50) 23 (46%) 2 (4%)	(50) 1 (2%) 27 (54%) 1 (2%)	(50) 1 (2%) 20 (40%)	1 (100%) (50) 20 (40%)	
None ENITAL SYSTEM Coagulating Gland Hyperplasia Inflammation Epididymis Cyst Granuloma Sperm Infiltration Cellular, Mononuclear Cell Inflammation Mineralization Preputial Gland	1 (100%) (50) 23 (46%)	(50) 1 (2%) 27 (54%)	(50) 1 (2%)	1 (100%) (50) 20 (40%) (50)	
None ENITAL SYSTEM Coagulating Gland Hyperplasia Inflammation Epididymis Cyst Granuloma Sperm Infiltration Cellular, Mononuclear Cell Inflammation Mineralization Preputial Gland Cyst	1 (100%) (50) 23 (46%) 2 (4%) (50)	(50) 1 (2%) 27 (54%) 1 (2%) (50)	(50) 1 (2%) 20 (40%) (50)	1 (100%) (50) 20 (40%) (50) 2 (4%)	
None ENITAL SYSTEM Coagulating Gland Hyperplasia Inflammation Epididymis Cyst Granuloma Sperm Infiltration Cellular, Mononuclear Cell Inflammation Mineralization Preputial Gland Cyst Infiltration Cellular, Mononuclear Cell	1 (100%) (50) 23 (46%) 2 (4%) (50) 10 (20%)	(50) 1 (2%) 27 (54%) 1 (2%) (50) 15 (30%)	(50) 1 (2%) 20 (40%) (50) 12 (24%)	1 (100%) (50) 20 (40%) (50) 2 (4%) 7 (14%)	
None ENITAL SYSTEM Coagulating Gland Hyperplasia Inflammation Epididymis Cyst Granuloma Sperm Infiltration Cellular, Mononuclear Cell Inflammation Mineralization Preputial Gland Cyst	1 (100%) (50) 23 (46%) 2 (4%) (50) 10 (20%) 4 (8%)	(50) 1 (2%) 27 (54%) 1 (2%) (50) 15 (30%) 4 (8%)	(50) 1 (2%) 20 (40%) (50)	1 (100%) (50) 20 (40%) (50) 2 (4%) 7 (14%) 4 (8%)	
None ENITAL SYSTEM Coagulating Gland Hyperplasia Inflammation Epididymis Cyst Granuloma Sperm Infiltration Cellular, Mononuclear Cell Inflammation Mineralization Preputial Gland Cyst Infiltration Cellular, Mononuclear Cell Inflammation Duct, Ectasia Prostate	1 (100%) (50) 23 (46%) 2 (4%) (50) 10 (20%)	(50) 1 (2%) 27 (54%) 1 (2%) (50) 15 (30%)	(50) 1 (2%) 20 (40%) (50) 12 (24%) 3 (6%) 3 (6%)	1 (100%) (50) 20 (40%) (50) 2 (4%) 7 (14%)	
None ENITAL SYSTEM Coagulating Gland Hyperplasia Inflammation Epididymis Cyst Granuloma Sperm Infiltration Cellular, Mononuclear Cell Inflammation Preputial Gland Cyst Infiltration Cellular, Mononuclear Cell Inflammation Duct, Ectasia	1 (100%) (50) 23 (46%) 2 (4%) (50) 10 (20%) 4 (8%) 1 (2%) (50) 23 (46%)	(50) 1 (2%) 27 (54%) 1 (2%) (50) 15 (30%) 4 (8%) 1 (2%)	(50) 1 (2%) 20 (40%) (50) 12 (24%) 3 (6%) 3 (6%) (50) 23 (46%)	1 (100%) (50) 20 (40%) (50) 2 (4%) 7 (14%) 4 (8%) 3 (6%) (50) 14 (28%)	
None ENITAL SYSTEM Coagulating Gland Hyperplasia Inflammation Epididymis Cyst Granuloma Sperm Infiltration Cellular, Mononuclear Cell Inflammation Mineralization Preputial Gland Cyst Infiltration Cellular, Mononuclear Cell Inflammation Duct, Ectasia Prostate	1 (100%) (50) 23 (46%) 2 (4%) (50) 10 (20%) 4 (8%) 1 (2%) (50)	(50) 1 (2%) 27 (54%) 1 (2%) (50) 15 (30%) 4 (8%) 1 (2%) (50)	(50) 1 (2%) 20 (40%) (50) 12 (24%) 3 (6%) 3 (6%) (50)	1 (100%) (50) 20 (40%) 2 (4%) 7 (14%) 4 (8%) 3 (6%) (50)	

Route: GAVAGE

Test Type: CHRONIC

Species/Strain: MICE/B6C3F1

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

Pulegone

CAS Number: 89-82-7

Date Report Requested: 07/23/2008 Time Report Requested: 09:18:35 First Dose M/F: 04/15/03 / 04/14/03 Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG	
Seminal Vesicle Atrophy Dilatation	(50)	(50) 1 (2%) 1 (2%)	(50)	(50)	
Testes Cyst	(50)	(50) 1 (2%)	(50)	(50)	
Mineralization Germinal Epithelium, Atrophy	2 (4%)	2 (4%) 2 (4%)	1 (2%) 3 (6%)		
EMATOPOIETIC SYSTEM					
Bone Marrow Atrophy, Focal	(50)	(50)	(50)	(50) 1 (2%)	
Hemorrhage				1 (2%)	
Myelofibrosis	2 (4%)		3 (6%)	1 (2%)	
Lymph Node	(1)	(3)	(0)	(2)	
Lymph Node, Mandibular Atrophy	(50) 1 (2%)	(50) 4 (8%)	(50) 3 (6%)	(50) 2 (4%)	
Hyperplasia, Lymphoid	1 (2%)	1 (2%)	5 (078)	2 (478)	
Hyperplasia, Plasma Cell	2 (4%)	1 (2%)			
Lymph Node, Mesenteric	(47)	(49)	(45)	(44)	
Atrophy		1 (2%)	2 (4%)	3 (7%)	
Hyperplasia, Lymphoid	1 (2%)	()	(= -)	1 (2%)	
Spleen	(50)	(50)	(50)	(50)	
Atrophy Homotopoiotic Coll Broliferation	20 (58%)	22 (649/)	22 (460/)	1 (2%)	
Hematopoietic Cell Proliferation Hyperplasia, Lymphoid	29 (58%) 2 (4%)	32 (64%) 3 (6%)	23 (46%)	23 (46%)	
Lymphoid Follicle, Atrophy	1 (2%)	3 (678)	1 (2%)	3 (6%)	
Red Pulp, Atrophy	1 (2%)		1 (2%)	3 (6%)	
Thymus	(49)	(46)	(45)	(42)	
Atrophy	36 (73%)	35 (76%)	32 (71%)	30 (71%)	
Hyperplasia, Lymphoid		2 (4%)			
Necrosis, Lymphoid		2 (4%)			
NTEGUMENTARY SYSTEM					
Skin	(50)	(50)	(50)	(50)	
Inflammation	()	1 (2%)	2 (4%)	()	
Ulcer		1 (2%)	2 (4%)		
Epidermis, Hyperplasia			1 (2%)		
Subcutaneous Tissue, Hemorrhage		1 (2%)			

MUSCULOSKELETAL SYSTEM

Test Type: CHRONIC

Route: GAVAGE

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

Pulegone

CAS Number: 89-82-7

Date Report Requested: 07/23/2008 Time Report Requested: 09:18:35 First Dose M/F: 04/15/03 / 04/14/03 Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG	
Bone	(50)	(50)	(50)	(50)	
Fracture		1 (2%)			
Osteosclerosis	(4)	1 (2%)	$\langle 0 \rangle$	1 (2%)	
Skeletal Muscle	(1)	(0)	(0)	(0)	
NERVOUS SYSTEM					
Brain Arteriole, Infiltration Cellular, Lymphoid	(50)	(50) 1 (2%)	(50)	(50)	
Meninges, Infiltration Cellular, Lymphoid		1 (2%)			
RESPIRATORY SYSTEM					
Lung	(50)	(50)	(50)	(50)	
Hemorrhage	1 (2%)	F (400()	0 (40/)	1 (29())	
Inflammation	2 (40/)	5 (10%) 7 (14%)	2 (4%) 2 (4%)	1 (2%) 9 (18%)	
Alveolar Epithelium, Hyperplasia Alveolus, Infiltration Cellular, Histiocyte	2 (4%) 2 (4%)	4 (8%)	2 (4%) 3 (6%)		
Serosa, Inflammation	2 (4%)	4 (8%) 2 (4%)	3 (6%)	3 (6%)	
Nose	(50)	(50)	(50)	(50)	
Inflammation	2 (4%)	3 (6%)	2 (4%)	22 (44%)	
Polyp, Inflammatory	2 (470)	2 (4%)	2 (470)	22 (4470)	
Glands, Cyst		1 (2%)			
Nerve, Atrophy	1 (2%)	3 (6%)	3 (6%)	45 (90%)	
Olfactory Epithelium, Degeneration	3 (6%)	3 (6%)	11 (22%)	46 (92%)	
Olfactory Epithelium, Erosion	0 (070)	8 (870)	11 (2270)	1 (2%)	
Olfactory Epithelium, Metaplasia	1 (2%)	5 (10%)	3 (6%)	44 (88%)	
Olfactory Epithelium, Necrosis	. (=/3)	0 (1070)		1 (2%)	
Respiratory Epithelium, Hyperplasia	39 (78%)	38 (76%)	42 (84%)	40 (80%)	
SPECIAL SENSES SYSTEM					
Eye	(50)	(50)	(50)	(50)	
Atrophy				1 (2%)	
Cornea, Inflammation	1 (2%)		1 (2%)	3 (6%)	
Optic Nerve, Degeneration		1 (2%)			
Harderian Gland	(50)	(50)	(50)	(50)	
Infiltration Cellular, Mononuclear Cell	34 (68%)	27 (54%)	23 (46%)	17 (34%)	
Inflammation, Chronic Active		1 (2%)		- />	
Epithelium, Hyperplasia	1 (2%)	3 (6%)	1 (2%)	3 (6%)	

URINARY SYSTEM

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

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

Pulegone

CAS Number: 89-82-7

Date Report Requested: 07/23/2008 Time Report Requested: 09:18:35 First Dose M/F: 04/15/03 / 04/14/03 Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG	
Kidney	(50)	(50)	(50)	(50)	
Accumulation, Hyaline Droplet	1 (2%)				
Cyst	9 (18%)	3 (6%)	4 (8%)		
Glomerulopathy, Hyaline	1 (2%)	19 (38%)	30 (60%)	44 (88%)	
Infarct	1 (2%)			1 (2%)	
Metaplasia, Osseous	3 (6%)	2 (4%)	2 (4%)	4 (8%)	
Mineralization	30 (60%)	34 (68%)	41 (82%)	38 (76%)	
Necrosis	(()	× ,	1 (2%)	
Nephropathy	45 (90%)	45 (90%)	49 (98%)	49 (98%)	
Pigmentation		(2 (4%)	(),	
Glomerulus, Congestion	9 (18%)	14 (28%)	17 (34%)	44 (88%)	
Papilla, Necrosis	1 (2%)	()		()	
Pelvis, Inflammation	1 (2%)			2 (4%)	
Renal Tubule, Hyperplasia	1 (2%)		1 (2%)	1 (2%)	
Urethra	(0)	(0)	(1)	(0)	
Urinary Bladder	(50)	(50)	(50)	(50)	
Infiltration Cellular, Mononuclear Cell	28 (56%)	19 (38%)	19 (38%)	31 (62%)	
Transitional Epithelium, Hyperplasia	(00,0)			1 (2%)	

*** END OF MALE ***

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

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

Pulegone

CAS Number: 89-82-7

Date Report Requested: 07/23/2008 Time Report Requested: 09:18:35 First Dose M/F: 04/15/03 / 04/14/03 Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG	
Disposition Summary					
Animals Initially in Study	50	50	50	50	
Early Deaths					
Dosing Accident				1	
Moribund Sacrifice	9	3	5	9	
Natural Death	5	6	7	3	
Survivors					
Terminal Sacrifice	35	41	38	37	
Animals Examined Microscopically	49	50	50	50	
LIMENTARY SYSTEM					
Esophagus	(49)	(50)	(50)	(50)	
Perforation	(-0)	(00)	(00)	1 (2%)	
Periesophageal Tissue, Inflammation		1 (2%)		. (270)	
Gallbladder	(48)	(50)	(50)	(50)	
Infiltration Cellular, Mononuclear Cell	1 (2%)	2 (4%)	(00)	1 (2%)	
Intestine Large, Cecum	(49)	(50)	(50)	(50)	
Intestine Large, Colon	(49)	(50)	(50)	(50)	
Intestine Large, Rectum	(49)	(50)	(50)	(50)	
Artery, Inflammation, Chronic Active	(+3)	1 (2%)	(00)	(00)	
Intestine Small, Duodenum	(49)	(50)	(50)	(50)	
Artery, Inflammation, Chronic Active	(+3)	1 (2%)	(00)	(00)	
Intestine Small, Ileum	(49)	(50)	(50)	(50)	
Artery, Inflammation, Chronic Active	(+3)	1 (2%)	(50)	(00)	
Intestine Small, Jejunum	(49)	(50)	(50)	(50)	
Artery, Inflammation, Chronic Active	(+3)	1 (2%)	(50)	(00)	
Liver	(49)	(50)	(50)	(50)	
Angiectasis	(+3)	1 (2%)	3 (6%)	1 (2%)	
Basophilic Focus	1 (2%)	3 (6%)	0 (0 /0)	1 (2%)	
Clear Cell Focus	1 (270)	6 (12%)	23 (46%)	32 (64%)	
Eosinophilic Focus	3 (6%)	7 (14%)	10 (20%)	31 (62%)	
Fatty Change, Focal	1 (2%)	2 (4%)	20 (40%)	12 (24%)	
Fatty Change, Diffuse	36 (73%)	31 (62%)	34 (68%)	3 (6%)	
Fibrosis	00 (1070)	01 (0270)		2 (4%)	
Hematopoietic Cell Proliferation	1 (2%)			1 (2%)	
Inflammation	40 (82%)	40 (80%)	14 (28%)	31 (62%)	
Mineralization		40 (0070)	14 (2070)	1 (2%)	
Mixed Cell Focus	4 (8%)	8 (16%)	16 (32%)	20 (40%)	
Necrosis	5 (10%)	2 (4%)	4 (8%)	27 (54%)	
Pigmentation	0 (10/0)	2 (470)	- (070)	46 (92%)	

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

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

Pulegone

CAS Number: 89-82-7

Date Report Requested: 07/23/2008 Time Report Requested: 09:18:35 First Dose M/F: 04/15/03 / 04/14/03 Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG	
Bile Duct, Cyst			4 (8%)	38 (76%)	
Bile Duct, Hyperplasia		0 (00()	2 (4%)	47 (94%)	
Centrilobular, Hepatocyte, Hypertrophy		3 (6%)	7 (14%)	18 (36%)	
Hepatocyte, Hypertrophy		1 (2%)	5 (10%)	11 (22%)	
Oval Cell, Hyperplasia			3 (6%)	46 (92%) 1 (2%)	
Portal, Fibrosis				1 (2%)	
Vein, Hypertrophy		2(40/)	20 (40%)		
Vein, Intravascular Hepatocyte Mesentery	(6)	2 (4%)	20 (40%) (11)	46 (92%)	
Necrosis	(6) 2 (33%)	(12)	(11)	(2)	
Artery, Inflammation, Chronic Active	2 (33%)	1 (8%)			
Fat, Necrosis	4 (67%)	11 (92%)	10 (91%)	1 (50%)	
Pancreas	(49)	(50)	(50)	(50)	
Atrophy	(49)	(50)	(30)	1 (2%)	
Cytoplasmic Alteration, Focal	1 (2%)	2 (4%)		2 (4%)	
Infiltration Cellular, Mononuclear Cell	12 (24%)	16 (32%)	15 (30%)	11 (22%)	
Acinus, Atrophy	1 (2%)	1 (2%)	13 (30 %)	11 (2270)	
Artery, Inflammation, Chronic Active	1 (270)	1 (2%)			
Salivary Glands	(49)	(50)	(49)	(50)	
Infiltration Cellular, Mononuclear Cell	39 (80%)	29 (58%)	28 (57%)	26 (52%)	
Stomach, Forestomach	(49)	(50)	(50)	(50)	
Hyperplasia, Squamous	13 (27%)	1 (2%)	10 (20%)	26 (52%)	
Inflammation	10 (20%)	(_,,,)	7 (14%)	20 (40%)	
Mineralization				1 (2%)	
Ulcer	8 (16%)		4 (8%)	10 (20%)	
Stomach, Glandular	(49)	(50)	(50)	(50)	
Mineralization			1 (2%)	× ,	
Artery, Inflammation, Chronic Active		1 (2%)			
Glands, Cyst	2 (4%)	3 (6%)	3 (6%)	2 (4%)	
Tongue	(0)	(0)	(0)	(1)	
Tooth	(3)	(1)	(2)	(1)	
Dysplasia	3 (100%)	1 (100%)	2 (100%)	1 (100%)	
Peridontal Tissue, Inflammation		1 (100%)			
CARDIOVASCULAR SYSTEM					
Blood Vessel	(49)	(50)	(50)	(50)	
Mineralization			1 (2%)		
Heart	(49)	(50)	(50)	(50)	
Cardiomyopathy	1 (2%)	2 (4%)	1 (2%)	5 (10%)	
Infiltration Cellular, Mononuclear Cell	1 (2%)				
Inflammation	1 (2%)	1 (2%)	1 (2%)	1 (2%)	
Mineralization	2 (4%)		2 (4%)	8 (16%)	
Necrosis				2 (4%)	
Ventricle, Thrombosis				1 (2%)	

Route: GAVAGE

Test Type: CHRONIC

Species/Strain: MICE/B6C3F1

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

Pulegone

CAS Number: 89-82-7

Date Report Requested: 07/23/2008 Time Report Requested: 09:18:35 First Dose M/F: 04/15/03 / 04/14/03 Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG	
NDOCRINE SYSTEM					
Adrenal Cortex	(49)	(50)	(50)	(50)	
Hypertrophy		1 (2%)	1 (2%)	1 (2%)	
Inflammation				1 (2%)	
Vacuolization Cytoplasmic	1 (2%)		1 (2%)		
Subcapsular, Hyperplasia	49 (100%)	50 (100%)	49 (98%)	49 (98%)	
Adrenal Medulla	(49)	(50)	(50)	(50)	
Hyperplasia	1 (2%)				
Islets, Pancreatic	(49)	(50)	(50)	(50)	
Hyperplasia	5 (10%)	2 (4%)	3 (6%)	1 (2%)	
Parathyroid Gland	(45)	(47)	(39)	(39)	
Infiltration Cellular, Lymphocyte	()	1 (2%)	()	()	
Pituitary Gland	(49)	(50)	(49)	(49)	
Angiectasis	3 (6%)	3 (6%)	1 (2%)	2 (4%)	
Cyst		0 (070)	. (= /0)	1 (2%)	
Degeneration	1 (2%)			(270)	
Pars Distalis, Cyst	1 (270)	2 (4%)			
Pars Distalis, Hyperplasia	7 (14%)	4 (8%)	5 (10%)	4 (8%)	
Thyroid Gland	(49)	(50)	(49)	(50)	
Infiltration Cellular, Mononuclear Cell	1 (2%)	(88)	1 (2%)	(00)	
C-cell, Hyperplasia	1 (270)	1 (2%)	1 (270)		
Follicle, Cyst	1 (2%)	1 (270)			
Follicular Cell, Hyperplasia	1 (2%)			1 (2%)	
	1 (270)			1 (270)	
ENERAL BODY SYSTEM					
None					
ENITAL SYSTEM					
Clitoral Gland	(47)	(50)	(49)	(49)	
Infiltration Cellular, Mononuclear Cell		. ,	1 (2%)	1 (2%)	
Inflammation		1 (2%)	1 (2%)	3 (6%)	
Ovary	(49)	(49)	(50)	(50)	
Angiectasis	1 (2%)	1 (2%)	1 (2%)	· · /	
Atrophy	11 (22%)	10 (20%)	24 (48%)	39 (78%)	
Cyst	6 (12%)	7 (14%)	9 (18%)	7 (14%)	
Uterus	(49)	(49)	(50)	(50)	
Angiectasis	3 (6%)	()	(00)	(00)	
Decidual Reaction	0 (070)	1 (2%)			
		· (~ / · /)			
Infiltration Cellular, Mononuclear Cell				1 (2%)	

est Type: CHRONIC Route: GAVAGE Species/Strain: MICE/B6C3F1		Time Report Requested: 09:18:35 First Dose M/F: 04/15/03 / 04/14/03 Lab: BAT			
B6C3F1 MICE FEMALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG	
Inflammation Metaplasia Endometrium, Hyperplasia, Cystic	1 (2%) 32 (65%)	1 (2%) 1 (2%) 32 (65%)	40 (80%)	35 (70%)	
HEMATOPOIETIC SYSTEM					
Bone Marrow Atrophy Hyperplasia Myelofibrosis Necrosis Lymph Node Lymph Node, Mandibular Atrophy Hyperplasia, Lymphoid Pigmentation Lymph Node, Mesenteric Atrophy Hyperplasia, Reticulum Cell Spleen Hematopoietic Cell Proliferation Hyperplasia, Lymphoid Necrosis Pigmentation Lymphoid Follicle, Atrophy Red Pulp, Atrophy Thymus Atrophy Hyperplasia, Lymphoid	(49) $(2) (4%)$ $(2) (41%)$ (1) (49) $(2) (4%)$ (47) (49) (24) (47) (49) (24) $(49%)$ $6 (12%)$ $1 (2%)$ (48) $(28) (58%)$ $4 (8%)$	(50) 9 (18%) 17 (34%) (2) (50) 1 (2%) (49) (50) 29 (58%) 3 (6%) 1 (2%) (49) 21 (43%) 5 (10%)	(50) 1 (2%) 4 (8%) 17 (34%) 1 (2%) (5) (49) 1 (2%) (50) 2 (4%) 1 (2%) (50) 25 (50%) 9 (18%) 3 (6%) (49) 20 (41%) 2 (4%)	(50) 1 (2%) 5 (10%) 14 (28%) (2) (50) 2 (4%) 2 (4%) (49) 1 (2%) (50) 40 (80%) 3 (6%) 1 (2%) 2 (4%) 1 (2%) 1 (2%) (46) 13 (28%) 1 (2%) (28%) 1 (2%) (28%) (2) (50) (2) (50) (2) (50) (2) (50) (4%) (4%) (4%) (4%) (50) (50) (50) (50) (50) (50) (50) (50) (50) (50) (50) (50) (4%) (50) (50) (50) (50) (50) (4%) (50) (50) (50) (50) (50) (50) (4%) (50) (
INTEGUMENTARY SYSTEM					
Mammary Gland Skin	(49) (49)	(50) (50)	(50) (50)	(50) (50)	
MUSCULOSKELETAL SYSTEM					
Bone Osteosclerosis Cranium, Myelofibrosis Skeletal Muscle	(49) (0)	(50)	(50) 1 (2%) 1 (2%) (1)	(50) 1 (2%) (1)	

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

Date Report Requested: 07/23/2008

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

TDMS No. 99020 - 06

TDMS No. 99020 - 06 Test Type: CHRONIC Route: GAVAGE Species/Strain: MICE/B6C3F1 B6C3F1 MICE FEMALE	P03: INCIDENCI	Date Report Requested: 07/23/200 Time Report Requested: 09:18:35 First Dose M/F: 04/15/03 / 04/14/03 Lab: BAT			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG	
NERVOUS SYSTEM					
Brain	(49)	(50)	(50)	(50)	
Hemorrhage	4 (00()			1 (2%)	
Infiltration Cellular, Mononuclear Cell Necrosis Hippocampus, Gliosis	1 (2%)		1 (2%) 1 (2%)		
RESPIRATORY SYSTEM					
Lung	(49)	(50)	(50)	(50)	
Inflammation	2 (4%)	4 (8%)	2 (4%)	()	
Mineralization			1 (2%)	1 (00())	
Pigmentation Alveolar Epithelium, Hyperplasia	1 (2%)	3 (6%)	2 (4%)	1 (2%) 7 (14%)	
Mediastinum, Serosa, Inflammation	1 (270)	0 (070)	2 (470)	1 (2%)	
Nose	(49)	(50)	(50)	(50)	
Inflammation	2 (4%)	1 (2%)	4 (8%)	27 (54%)	
Ulcer Glands, Cyst	1 (2%)			1 (2%)	
Nerve, Atrophy	1 (270)	1 (2%)	2 (4%)	49 (98%)	
Olfactory Epithelium, Degeneration		5 (Ì0%́)	22 (44%)	48 (96%)	
Olfactory Epithelium, Metaplasia	1 (2%)	2 (4%)	4 (8%)	49 (98%)	
Respiratory Epithelium, Metaplasia	1 (2%)				
SPECIAL SENSES SYSTEM					
Eye	(49)	(50)	(49)	(50)	
Atrophy		2 (4%)	1 (2%)	3 (6%)	
Cataract Anterior Chamber, Inflammation	1 (2%)			1 (2%) 2 (4%)	
Choroid, Sclera, Inflammation			1 (2%)	1 (2%)	
Cornea, Inflammation	2 (4%)			9 (18%)	
Cornea, Pigmentation	4 (001)			1 (2%)	
Retina, Degeneration Harderian Gland	1 (2%) (49)	(50)	(49)	(50)	
Cyst	(49) 1 (2%)	(30)	(49)	(50)	
Infiltration Cellular, Mononuclear Cell	30 (61%)	22 (44%)	17 (35%)	15 (30%)	
Inflammation, Chronic Active	- (a))			1 (2%)	
Epithelium, Hyperplasia	3 (6%)			4 (8%)	

URINARY SYSTEM

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

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

Pulegone

CAS Number: 89-82-7

Date Report Requested: 07/23/2008 Time Report Requested: 09:18:35 First Dose M/F: 04/15/03 / 04/14/03 Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG	
Kidney	(49)	(50)	(50)	(50)	
Accumulation, Hyaline Droplet	2 (4%)			ζ, γ.	
Cyst	, , , , , , , , , , , , , , , , , , ,		2 (4%)		
Glomerulopathy, Hyaline		3 (6%)	15 (30%)	41 (82%)	
Infarct	3 (6%)	2 (4%)	1 (2%)	1 (2%)	
Metaplasia, Osseous	1 (2%)	2 (4%)	2 (4%)	4 (8%)	
Mineralization	1 (2%)		3 (6%)	20 (40%)	
Nephropathy	13 (27%)	19 (38%)	12 (24%)	25 (50%)	
Pigmentation	1 (2%)	1 (2%)		· · · ·	
Vacuolization Cytoplasmic	, , , , , , , , , , , , , , , , , , ,	1 (2%)	2 (4%)		
Glomerulus, Congestion	5 (10%)	2 (4%)	12 (24%)	37 (74%)	
Papilla, Mineralization	1 (2%)			· · · ·	
Papilla, Necrosis	3 (6%)	1 (2%)	1 (2%)		
Pelvis, Dilatation	, , , , , , , , , , , , , , , , , , ,	1 (2%)	. ,		
Urinary Bladder	(49)	(49)	(50)	(50)	
Infiltration Cellular, Mononuclear Cell	37 (76%)	33 (67%)	30 (60%)	30 (60%)	
Artery, Inflammation, Chronic Active	· · ·	1 (2%)	. ,	· · ·	

*** END OF REPORT ***