

TDMS No. 99020 - 06  
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: 04/23/2009  
Time Report Requested: 10:38:13  
First Dose M/F: 04/15/03 / 04/14/03  
Lab: BAT

F1\_Rev1\_M3

**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:** 2.1.0

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B6C3F1 MICE MALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>Disposition Summary</b>				
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	50	50

**ALIMENTARY 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		2 (4%)		
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	3 (6%)		1 (2%)	2 (4%)
Hemorrhage				1 (2%)
Hepatodiaphragmatic Nodule	1 (2%)			
Inflammation	24 (48%)	21 (42%)	20 (40%)	29 (58%)
Mixed Cell Focus	18 (36%)	20 (40%)	19 (38%)	34 (68%)
Necrosis	1 (2%)	8 (16%)	5 (10%)	26 (52%)
Pigmentation	3 (6%)		2 (4%)	1 (2%)
Tension Lipidosis	5 (10%)	6 (12%)	7 (14%)	2 (4%)
Bile Duct, Cyst			3 (6%)	14 (28%)
Bile Duct, Fibrosis				2 (4%)

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

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		11 (22%)	23 (46%)	46 (92%)
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%)
Peridental Tissue, Inflammation			1 (3%)	
Pulp, Inflammation	1 (3%)	1 (3%)	1 (3%)	1 (5%)
<b>CARDIOVASCULAR SYSTEM</b>				
Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	1 (2%)			
Infiltration Cellular, Mononuclear Cell	4 (8%)		1 (2%)	1 (2%)
Inflammation	1 (2%)			
Mineralization	1 (2%)	1 (2%)	1 (2%)	4 (8%)
<b>ENDOCRINE SYSTEM</b>				

B6C3F1 MICE MALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Adrenal Cortex	(50)	(50)	(50)	(50)
Degeneration, Cystic			1 (2%)	
Hypertrophy	17 (34%)	9 (18%)	8 (16%)	4 (8%)
Vacuolization Cytoplasmic		1 (2%)		1 (2%)
Subcapsular, Hyperplasia	39 (78%)	40 (80%)	47 (94%)	44 (88%)
Zona Fasciculata, Hyperplasia	1 (2%)			
Adrenal Medulla	(50)	(50)	(50)	(50)
Hyperplasia		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%)

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Coagulating Gland	(1)	(1)	(0)	(1)
Hyperplasia	1 (100%)			
Inflammation				1 (100%)
Epididymis	(50)	(50)	(50)	(50)
Cyst		1 (2%)		
Granuloma Sperm			1 (2%)	
Infiltration Cellular, Mononuclear Cell	23 (46%)	27 (54%)	20 (40%)	20 (40%)
Inflammation	2 (4%)			
Mineralization		1 (2%)		
Preputial Gland	(50)	(50)	(50)	(50)
Cyst				2 (4%)
Infiltration Cellular, Mononuclear Cell	10 (20%)	15 (30%)	12 (24%)	7 (14%)
Inflammation	4 (8%)	4 (8%)	3 (6%)	4 (8%)
Duct, Ectasia	1 (2%)	1 (2%)	3 (6%)	3 (6%)
Prostate	(50)	(50)	(50)	(50)
Infiltration Cellular, Mononuclear Cell	23 (46%)	30 (60%)	23 (46%)	14 (28%)
Inflammation	1 (2%)		1 (2%)	1 (2%)
Epithelium, Hyperplasia	6 (12%)	3 (6%)		
Seminal Vesicle	(50)	(50)	(50)	(50)
Atrophy		1 (2%)		
Dilatation		1 (2%)		

B6C3F1 MICE MALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Testes	(50)	(50)	(50)	(50)
Cyst		1 (2%)		
Mineralization		2 (4%)	1 (2%)	
Germinal Epithelium, Atrophy	2 (4%)	2 (4%)	3 (6%)	
<b>HEMATOPOIETIC SYSTEM</b>				
Bone Marrow	(50)	(50)	(50)	(50)
Atrophy, Focal				1 (2%)
Hemorrhage				1 (2%)
Myelofibrosis	2 (4%)		3 (6%)	1 (2%)
Lymph Node	(1)	(3)	(0)	(2)
Lymph Node, Mandibular	(50)	(50)	(50)	(50)
Atrophy	1 (2%)	4 (8%)	3 (6%)	2 (4%)
Hyperplasia, Lymphoid	1 (2%)	1 (2%)		
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				1 (2%)
Hematopoietic Cell Proliferation	29 (58%)	32 (64%)	23 (46%)	23 (46%)
Hyperplasia, Lymphoid	2 (4%)	3 (6%)		
Lymphoid Follicle, Atrophy	1 (2%)		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%)		
<b>INTEGUMENTARY SYSTEM</b>				
Skin	(50)	(50)	(50)	(50)
Inflammation		1 (2%)	2 (4%)	
Ulcer		1 (2%)	2 (4%)	
Epidermis, Hyperplasia			1 (2%)	
Subcutaneous Tissue, Hemorrhage		1 (2%)		
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone	(50)	(50)	(50)	(50)
Fracture		1 (2%)		
Osteosclerosis		1 (2%)		1 (2%)

B6C3F1 MICE MALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Skeletal Muscle	(1)	(0)	(0)	(0)
<b>NERVOUS SYSTEM</b>				
Brain	(50)	(50)	(50)	(50)
Arteriole, Infiltration Cellular, Lymphoid		1 (2%)		
Meninges, Infiltration Cellular, Lymphoid		1 (2%)		
<b>RESPIRATORY SYSTEM</b>				
Lung	(50)	(50)	(50)	(50)
Hemorrhage	1 (2%)			
Inflammation		5 (10%)	2 (4%)	1 (2%)
Alveolar Epithelium, Hyperplasia	2 (4%)	7 (14%)	2 (4%)	9 (18%)
Alveolus, Infiltration Cellular, Histiocyte	2 (4%)	4 (8%)	3 (6%)	3 (6%)
Serosa, Inflammation		2 (4%)		
Nose	(50)	(50)	(50)	(50)
Inflammation	2 (4%)	3 (6%)	2 (4%)	22 (44%)
Polyp, Inflammatory		2 (4%)		
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				1 (2%)
Olfactory Epithelium, Metaplasia	1 (2%)	5 (10%)	3 (6%)	44 (88%)
Olfactory Epithelium, Necrosis				1 (2%)
Respiratory Epithelium, Hyperplasia	39 (78%)	38 (76%)	42 (84%)	40 (80%)
<b>SPECIAL SENSES SYSTEM</b>				
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%)
<b>URINARY SYSTEM</b>				
Kidney	(50)	(50)	(50)	(50)
Accumulation, Hyaline Droplet	1 (2%)			

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B6C3F1 MICE MALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
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				1 (2%)

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

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B6C3F1 MICE FEMALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>Disposition Summary</b>				
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

ALIMENTARY SYSTEM

Esophagus	(49)	(50)	(50)	(50)
Perforation				1 (2%)
Periesophageal Tissue, Inflammation		1 (2%)		
Gallbladder	(48)	(50)	(50)	(50)
Infiltration Cellular, Mononuclear Cell	1 (2%)	2 (4%)		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		1 (2%)		
Intestine Small, Duodenum	(49)	(50)	(50)	(50)
Artery, Inflammation, Chronic Active		1 (2%)		
Intestine Small, Ileum	(49)	(50)	(50)	(50)
Artery, Inflammation, Chronic Active		1 (2%)		
Intestine Small, Jejunum	(49)	(50)	(50)	(50)
Artery, Inflammation, Chronic Active		1 (2%)		
Liver	(49)	(50)	(50)	(50)
Angiectasis		1 (2%)	3 (6%)	1 (2%)
Basophilic Focus	1 (2%)	3 (6%)		1 (2%)
Clear Cell Focus		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				2 (4%)
Hematopoietic Cell Proliferation	1 (2%)			1 (2%)
Inflammation	40 (82%)	40 (80%)	14 (28%)	31 (62%)
Mineralization				1 (2%)
Mixed Cell Focus	4 (8%)	8 (16%)	16 (32%)	20 (40%)
Necrosis	5 (10%)	2 (4%)	4 (8%)	27 (54%)
Pigmentation				46 (92%)
Tension Lipidosis	5 (10%)	5 (10%)	4 (8%)	

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



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			2 (4%)	47 (94%)
Centrilobular, Hepatocyte, Hypertrophy		4 (8%)	12 (24%)	29 (58%)
Oval Cell, Hyperplasia			3 (6%)	46 (92%)
Portal, Fibrosis				1 (2%)
Vein, Hypertrophy				1 (2%)
Vein, Intravascular Hepatocyte		2 (4%)	20 (40%)	46 (92%)
Mesentery	(6)	(12)	(11)	(2)
Necrosis	2 (33%)			
Artery, Inflammation, Chronic Active		1 (8%)		
Fat, Necrosis	4 (67%)	11 (92%)	10 (91%)	1 (50%)
Pancreas	(49)	(50)	(50)	(50)
Atrophy				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%)		
Artery, Inflammation, Chronic Active		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%)

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B6C3F1 MICE FEMALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>ENDOCRINE SYSTEM</b>				
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				1 (2%)
Degeneration	1 (2%)			
Pars Distalis, Cyst		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%)		1 (2%)	
C-cell, Hyperplasia		1 (2%)		
Follicle, Cyst	1 (2%)			
Follicular Cell, Hyperplasia	1 (2%)			1 (2%)
<b>GENERAL BODY SYSTEM</b>				
None				
<b>GENITAL SYSTEM</b>				
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%)			
Decidual Reaction		1 (2%)		
Infiltration Cellular, Mononuclear Cell				1 (2%)

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

B6C3F1 MICE FEMALE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Inflammation	1 (2%)	1 (2%)		
Metaplasia		1 (2%)		
Endometrium, Hyperplasia, Cystic	32 (65%)	32 (65%)	40 (80%)	35 (70%)
<b>HEMATOPOIETIC SYSTEM</b>				
Bone Marrow	(49)	(50)	(50)	(50)
Atrophy			1 (2%)	1 (2%)
Hyperplasia	2 (4%)	9 (18%)	4 (8%)	5 (10%)
Myelofibrosis	20 (41%)	17 (34%)	17 (34%)	14 (28%)
Necrosis			1 (2%)	
Lymph Node	(1)	(2)	(5)	(2)
Lymph Node, Mandibular	(49)	(50)	(49)	(50)
Atrophy		1 (2%)		2 (4%)
Hyperplasia, Lymphoid	2 (4%)		1 (2%)	2 (4%)
Pigmentation			1 (2%)	
Lymph Node, Mesenteric	(47)	(49)	(50)	(49)
Atrophy			2 (4%)	1 (2%)
Hyperplasia, Reticulum Cell			1 (2%)	
Spleen	(49)	(50)	(50)	(50)
Hematopoietic Cell Proliferation	24 (49%)	29 (58%)	25 (50%)	40 (80%)
Hyperplasia, Lymphoid	6 (12%)	3 (6%)	9 (18%)	3 (6%)
Necrosis				1 (2%)
Pigmentation		1 (2%)	3 (6%)	2 (4%)
Lymphoid Follicle, Atrophy				1 (2%)
Red Pulp, Atrophy	1 (2%)			1 (2%)
Thymus	(48)	(49)	(49)	(46)
Atrophy	28 (58%)	21 (43%)	20 (41%)	13 (28%)
Hyperplasia, Lymphoid	4 (8%)	5 (10%)	2 (4%)	1 (2%)
<b>INTEGUMENTARY SYSTEM</b>				
Mammary Gland	(49)	(50)	(50)	(50)
Skin	(49)	(50)	(50)	(50)
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone	(49)	(50)	(50)	(50)
Osteosclerosis			1 (2%)	1 (2%)
Cranium, Myelofibrosis			1 (2%)	
Skeletal Muscle	(0)	(0)	(1)	(1)

TDMS No. 99020 - 06  
 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: 04/23/2009  
 Time Report Requested: 10:38:13  
 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
<b>NERVOUS SYSTEM</b>				
Brain	(49)	(50)	(50)	(50)
Hemorrhage				1 (2%)
Infiltration Cellular, Mononuclear Cell	1 (2%)			
Necrosis			1 (2%)	
Hippocampus, Gliosis			1 (2%)	
<b>RESPIRATORY SYSTEM</b>				
Lung	(49)	(50)	(50)	(50)
Inflammation	2 (4%)	4 (8%)	2 (4%)	
Mineralization			1 (2%)	
Pigmentation				1 (2%)
Alveolar Epithelium, Hyperplasia	1 (2%)	3 (6%)	2 (4%)	7 (14%)
Mediastinum, Serosa, Inflammation				1 (2%)
Nose	(49)	(50)	(50)	(50)
Inflammation	2 (4%)	1 (2%)	4 (8%)	27 (54%)
Ulcer				1 (2%)
Glands, Cyst	1 (2%)			
Nerve, Atrophy		1 (2%)	2 (4%)	49 (98%)
Olfactory Epithelium, Degeneration		5 (10%)	22 (44%)	48 (96%)
Olfactory Epithelium, Metaplasia	1 (2%)	2 (4%)	4 (8%)	49 (98%)
Respiratory Epithelium, Metaplasia	1 (2%)			
<b>SPECIAL SENSES SYSTEM</b>				
Eye	(49)	(50)	(49)	(50)
Atrophy		2 (4%)	1 (2%)	3 (6%)
Cataract	1 (2%)			1 (2%)
Anterior Chamber, Inflammation				2 (4%)
Choroid, Sclera, Inflammation			1 (2%)	1 (2%)
Cornea, Inflammation	2 (4%)			9 (18%)
Cornea, Pigmentation				1 (2%)
Retina, Degeneration	1 (2%)			
Harderian Gland	(49)	(50)	(49)	(50)
Cyst	1 (2%)			
Infiltration Cellular, Mononuclear Cell	30 (61%)	22 (44%)	17 (35%)	15 (30%)
Inflammation, Chronic Active				1 (2%)
Epithelium, Hyperplasia	3 (6%)			4 (8%)
<b>URINARY SYSTEM</b>				

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

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%)			
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 \*\*\*