F1_Rev.1_M3

C Number:	C20005
Lock Date:	10/10/2006
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

B6C3F1 MICE MALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG

Disposition Summary

Animals Initially in Study	50	50	50	50
Early Deaths				
Accidently Killed				1
Moribund Sacrifice	12	10	8	8
Natural Death	6	7	4	8
Survivors				
Moribund Sacrifice		1		
Natural Death				1
Terminal Sacrifice	32	32	38	32
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Arteriole, Periesophageal Tissue, Inflammation		1 (2%)		
Periesophageal Tissue, Inflammation			1 (2%)	
Gallbladder	(49)	(50)	(49)	(50)
Cyst	1 (2%)		1 (2%)	
Inflammation				2 (4%)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Inflammation		1 (2%)		
Intestine Large, Colon	(50)	(50)	(50)	(50)
Serosa, Inflammation	1 (2%)			
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Inflammation			1 (2%)	1 (2%)
Serosa, Inflammation	1 (2%)			
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Inflammation			1 (2%)	
Peyer's Patch, Hyperplasia				2 (4%)
Serosa, Inflammation	1 (2%)			
Liver	(50)	(50)	(50)	(50)
Amyloid Deposition	1 (2%)			
Angiectasis	1 (2%)	1 (2%)		
Basophilic Focus	3 (6%)	3 (6%)	4 (8%)	1 (2%)
Clear Cell Focus	11 (22%)	21 (42%)	21 (42%)	16 (32%)
Eosinophilic Focus	17 (34%)	16 (32%)	18 (36%)	21 (42%)
Fibrosis	1 (2%)			
Hyperplasia, Regenerative	1 (2%)			
Infarct				1 (2%)

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

B6C3F1 MICE MALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Infiltration Cellular, Lymphocyte			1 (2%)	
Inflammation	8 (16%)	4 (8%)	7 (14%)	3 (6%)
Mixed Cell Focus	8 (16%)	6 (12%)	5 (10%)	5 (10%)
Tension Lipidosis	2 (4%)	3 (6%)	3 (6%)	1 (2%)
Thrombosis			1 (2%)	
Bile Duct, Inflammation				1 (2%)
Hepatocyte, Atypia Cellular	1 (2%)	1 (2%)		
Hepatocyte, Necrosis	3 (6%)	4 (8%)	4 (8%)	1 (2%)
Hepatocyte, Vacuolization Cytoplasmic, Diffuse	12 (24%)	15 (30%)	11 (22%)	17 (34%)
Kupffer Cell, Pigmentation, Hemosiderin		1 (2%)		
Mesentery	(3)	(4)	(6)	(0)
Necrosis	2 (67%)	2 (50%)	4 (67%)	
Artery, Inflammation		1 (25%)		
Pancreas	(50)	(50)	(50)	(50)
Basophilic Focus	1 (2%)	1 (2%)	1 (2%)	
Infiltration Cellular, Lipocyte	1 (2%)			
Salivary Glands	(50)	(50)	(50)	(50)
Infiltration Cellular, Mononuclear Cell			1 (2%)	
Stomach, Forestomach	(50)	(50)	(50)	(50)
Erosion			1 (2%)	
Inflammation	1 (2%)		2 (4%)	
Ulcer	2 (4%)	1 (2%)	5 (10%)	1 (2%)
Epithelium, Diverticulum	1 (2%)			
Epithelium, Hyperplasia	5 (10%)	4 (8%)	3 (6%)	2 (4%)
Epithelium, Hyperplasia, Focal		1 (2%)		
Stomach, Glandular	(50)	(50)	(50)	(50)
Inflammation			1 (2%)	
Ulcer	1 (2%)		1 (2%)	
Epithelium, Mineralization		1 (2%)	1 (2%)	1 (2%)
Tooth	(13)	(15)	(9)	(13)
Dysplasia	11 (85%)	11 (73%)	8 (89%)	10 (77%)
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(48)	(50)	(50)
Inflammation		1 (2%)		
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	42 (84%)	43 (86%)	45 (90%)	41 (82%)
Hemorrhage		1 (2%)		
Inflammation		2 (4%)		
Mineralization	1 (2%)		1 (2%)	
Artery, Inflammation		3 (6%)		
Artery, Mineralization		1 (2%)		
Ventricle, Thrombosis				1 (2%)

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

B6C3F1 MICE MALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Hyperplasia	10 (20%)	16 (32%)	16 (32%)	6 (12%)
Hypertrophy	28 (56%)	24 (48%)	31 (62%)	35 (70%)
Subcapsular, Hyperplasia, Focal	1 (2%)			
Adrenal Medulla	(50)	(50)	(50)	(50)
Hyperplasia	2 (4%)		1 (2%)	
Islets, Pancreatic	(50)	(50)	(50)	(50)
Hyperplasia	38 (76%)	38 (76%)	38 (76%)	40 (80%)
Parathyroid Gland	(49)	(48)	(45)	(48)
Cyst			1 (2%)	
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Cyst	2 (4%)	1 (2%)	1 (2%)	5 (10%)
Pars Distalis, Hyperplasia	3 (6%)	4 (8%)	2 (4%)	3 (6%)
Pars Intermedia, Hyperplasia	1 (2%)			
Thyroid Gland	(50)	(50)	(50)	(50)
Follicle, Cyst	1 (2%)		2 (4%)	
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Epididymis	(50)	(50)	(50)	(50)
Granuloma Sperm	2 (4%)	4 (8%)	1 (2%)	1 (2%)
Inflammation	2 (4%)	4 (8%)	6 (12%)	2 (4%)
Preputial Gland	(50)	(50)	(50)	(50)
Inflammation	5 (10%)	6 (12%)	4 (8%)	8 (16%)
Duct, Ectasia	9 (18%)	7 (14%)	6 (12%)	12 (24%)
Prostate	(50)	(50)	(50)	(50)
Inflammation	3 (6%)		2 (4%)	
Epithelium, Hyperplasia				1 (2%)
Seminal Vesicle	(50)	(50)	(50)	(50)
Dilatation			1 (2%)	
Inflammation				1 (2%)
Testes	(50)	(50)	(50)	(50)
Mineralization	3 (6%)			
Germinal Epithelium, Atrophy	2 (4%)	4 (8%)	5 (10%)	4 (8%)
Interstitial Cell, Hyperplasia		1 (2%)		

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

B6C3F1 MICE MALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Hyperplasia	1 (2%)		1 (2%)	
Lymph Node	(2)	(2)	(2)	(1)
Inguinal, Hyperplasia, Plasma Cell				1 (100%)
Lymph Node, Mandibular	(50)	(50)	(50)	(50)
Hyperplasia, Plasma Cell	1 (2%)			
Lymph Node, Mesenteric	(50)	(49)	(50)	(50)
Hemorrhage		1 (2%)		
Hyperplasia, Lymphoid	1 (2%)			1 (2%)
Hyperplasia, Plasma Cell	1 (2%)		1 (2%)	
Necrosis		1 (2%)		
Artery, Inflammation		1 (2%)		
Spleen	(50)	(50)	(50)	(50)
Hematopoietic Cell Proliferation	2 (4%)	5 (10%)	7 (14%)	6 (12%)
Hyperplasia, Lymphoid	7 (14%)	11 (22%)	11 (22%)	4 (8%)
Lymphoid Follicle, Atrophy	5 (10%)	7 (14%)	1 (2%)	4 (8%)
Red Pulp, Atrophy	1 (2%)			
Vein, Inflammation		1 (2%)		
Thymus	(47)	(50)	(50)	(49)
Cyst			1 (2%)	
Inflammation		1 (2%)		
Arteriole, Inflammation		1 (2%)		
INTEGUMENTARY SYSTEM				
Skin	(50)	(50)	(50)	(50)
Inflammation		1 (2%)		2 (4%)
Ulcer	2 (4%)	1 (2%)	1 (2%)	2 (4%)
Subcutaneous Tissue, Edema		1 (2%)		
MUSCULOSKELETAL SYSTEM				
Skeletal Muscle	(1)	(1)	(0)	(0)
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Hemorrhage		1 (2%)		
Hippocampus, Neuron, Necrosis			1 (2%)	

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

B6C3F1 MICE MALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Meninges, Hemorrhage				1 (2%)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Hemorrhage	1 (2%)		2 (4%)	
Inflammation	4 (8%)	2 (4%)	2 (4%)	1 (2%)
Pigmentation, Hemosiderin				1 (2%)
Thrombosis	1 (2%)		2 (4%)	1 (2%)
Alveolar Epithelium, Hyperplasia	3 (6%)	1 (2%)	6 (12%)	
Alveolus, Infiltration Cellular, Histiocyte				1 (2%)
Arteriole, Inflammation	1 (2%)			
Nose	(50)	(49)	(49)	(50)
Inflammation	6 (12%)	5 (10%)	7 (14%)	6 (12%)
Polyp, Inflammatory		3 (6%)		
Trachea	(50)	(50)	(50)	(50)
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)
Cornea, Inflammation	3 (6%)	3 (6%)	1 (2%)	3 (6%)
Optic Nerve, Atrophy	1 (2%)			
Retina, Dysplasia	1 (2%)			1 (2%)
Retina, Hemorrhage		1 (2%)		
Harderian Gland	(50)	(50)	(50)	(50)
Hyperplasia		2 (4%)	1 (2%)	1 (2%)
Inflammation			1 (2%)	
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Cyst	9 (18%)	6 (12%)	7 (14%)	7 (14%)
Hydronephrosis	2 (4%)	2 (4%)	3 (6%)	3 (6%)
Infarct	1 (2%)		1 (2%)	4 (8%)
Inflammation	2 (4%)	2 (4%)	1 (2%)	1 (2%)
Metaplasia, Osseous			2 (4%)	
Mineralization			2 (4%)	
Nephropathy	48 (96%)	47 (94%)	48 (96%)	47 (94%)
Arteriole, Inflammation		1 (2%)		
Artery, Inflammation		2 (4%)	1 (2%)	
Papilla, Necrosis	1 (2%)			
Pelvis, Inflammation		1 (2%)		1 (2%)
Renal Tubule, Hyperplasia		2 (4%)	2 (4%)	

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

B6C3F1 MICE MALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Vein, Inflammation			1 (2%)	
Urinary Bladder	(50)	(50)	(50)	(50)
Inflammation	1 (2%)		1 (2%)	
Transitional Epithelium, Hyperplasia	1 (2%)			

*** END OF MALE ***

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

B6C3F1 MICE FEMALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG

Disposition Summary

Animals Initially in Study	50	50	50	50
Early Deaths				
Dosing Accident			1	4
Moribund Sacrifice	7	11	10	8
Natural Death	5	8	5	6
Survivors				
Terminal Sacrifice	38	31	34	32
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Perforation			2 (4%)	
Muscularis, Degeneration	1 (2%)			
Periesophageal Tissue, Inflammation			3 (6%)	1 (2%)
Gallbladder	(49)	(50)	(50)	(50)
Cyst		2 (4%)	1 (2%)	1 (2%)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(49)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Liver	(50)	(50)	(50)	(50)
Angiectasis	2 (4%)		2 (4%)	
Basophilic Focus	1 (2%)			2 (4%)
Clear Cell Focus	4 (8%)	3 (6%)	2 (4%)	2 (4%)
Eosinophilic Focus	15 (30%)	14 (28%)	3 (6%)	9 (18%)
Hyperplasia, Regenerative		1 (2%)		
Infiltration Cellular, Lymphocyte			1 (2%)	
Inflammation	14 (28%)	11 (22%)	10 (20%)	14 (28%)
Mixed Cell Focus	2 (4%)	5 (10%)	2 (4%)	2 (4%)
Tension Lipidosis	2 (4%)	5 (10%)	4 (8%)	8 (16%)
Thrombosis			1 (2%)	1 (2%)
Hepatocyte, Atypia Cellular		1 (2%)		
Hepatocyte, Necrosis	4 (8%)	2 (4%)		1 (2%)
Hepatocyte, Vacuolization Cytoplasmic, Diffuse	8 (16%)	10 (20%)	10 (20%)	5 (10%)
Mesentery	(8)	(9)	(7)	(4)
Inflammation			1 (14%)	
Necrosis	8 (100%)	8 (89%)	5 (71%)	4 (100%)
Fat, Necrosis			1 (14%)	

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

B6C3F1 MICE FEMALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Pancreas	(50)	(50)	(50)	(50)
Basophilic Focus		2 (4%)		
Hemorrhage		1 (2%)		
Infiltration Cellular, Lipocyte		3 (6%)		
Inflammation		2 (4%)		
Acinus, Hyperplasia	4 (8%)	1 (2%)	1 (2%)	
Artery, Inflammation			1 (2%)	
Duct, Cyst	1 (2%)			
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Infiltration Cellular, Mast Cell			1 (2%)	
Inflammation		1 (2%)	1 (2%)	
Ulcer			1 (2%)	
Epithelium, Hyperplasia	2 (4%)	2 (4%)	3 (6%)	4 (8%)
Epithelium, Hyperplasia, Focal		1 (2%)	2 (4%)	
Stomach, Glandular	(50)	(50)	(50)	(50)
Erosion		1 (2%)	1 (2%)	
Ulcer			1 (2%)	
Epithelium, Mineralization	1 (2%)	1 (2%)		
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)
Inflammation	1 (2%)		1 (2%)	1 (2%)
Mineralization		1 (2%)		
Media, Hyperplasia	1 (2%)			
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	35 (70%)	40 (80%)	38 (76%)	31 (62%)
Inflammation		2 (4%)	3 (6%)	1 (2%)
Mineralization		2 (4%)		
Artery, Inflammation				2 (4%)
Atrium, Thrombosis		1 (2%)		
Epicardium, Hyperplasia		1 (2%)		
Myocardium, Hyperplasia, Reticulum Cell	1 (2%)			
Valve, Thrombosis		2 (4%)		
Ventricle, Thrombosis	1 (2%)			1 (2%)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Hyperplasia	8 (16%)	1 (2%)	3 (6%)	6 (12%)
Hypertrophy	39 (78%)	40 (80%)	39 (78%)	39 (78%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Amyloid Deposition		1 (2%)		

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

B6C3F1 MICE FEMALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Hyperplasia	3 (6%)	3 (6%)	6 (12%)	2 (4%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Hyperplasia	16 (32%)	15 (30%)	17 (34%)	15 (30%)
Parathyroid Gland	(41)	(44)	(39)	(43)
Hyperplasia				1 (2%)
Pituitary Gland	(50)	(50)	(50)	(49)
Pars Distalis, Cyst		2 (4%)		
Pars Distalis, Hyperplasia	18 (36%)	18 (36%)	19 (38%)	18 (37%)
Thyroid Gland	(49)	(50)	(50)	(50)
Inflammation				1 (2%)
C-cell, Hyperplasia			1 (2%)	
Follicle, Cyst		1 (2%)	2 (4%)	1 (2%)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Clitoral Gland	(50)	(50)	(49)	(50)
Inflammation				1 (2%)
Ovary	(50)	(50)	(50)	(50)
Cyst	4 (8%)	7 (14%)	6 (12%)	2 (4%)
Hemorrhage		1 (2%)	2 (4%)	1 (2%)
Inflammation	2 (4%)		2 (4%)	
Thrombosis	1 (2%)			
Uterus	(50)	(50)	(50)	(50)
Angiectasis		1 (2%)		1 (2%)
Atrophy		1 (2%)		
Hemorrhage	1 (2%)			1 (2%)
Hydrometra			1 (2%)	
Inflammation	2 (4%)	2 (4%)	2 (4%)	
Thrombosis			1 (2%)	
Endometrium, Decidual Reaction			1 (2%)	
Endometrium, Hyperplasia, Cystic	47 (94%)	40 (80%)	35 (70%)	43 (86%)
Myometrium, Atypia Cellular	1 (2%)			
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(49)	(50)
Angiectasis	1 (2%)			
Hyperplasia			1 (2%)	2 (4%)
Lymph Node	(4)	(4)	(6)	(6)

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

B6C3F1 MICE FEMALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Hyperplasia			1 (17%)	
Iliac, Hemorrhage			1 (17%)	
Lumbar, Hyperplasia, Plasma Cell	1 (25%)			
Renal, Degeneration, Cystic				1 (17%)
Renal, Hemorrhage		2 (50%)	1 (17%)	
Lymph Node, Mandibular	(50)	(49)	(50)	(50)
Amyloid Deposition				1 (2%)
Hyperplasia			1 (2%)	1 (2%)
Hyperplasia, Lymphoid			1 (2%)	
Infiltration Cellular, Histiocyte			2 (4%)	
Lymph Node, Mesenteric	(49)	(50)	(50)	(50)
Degeneration, Cystic		1 (2%)		
Hemorrhage		1 (2%)		
Hyperplasia, Lymphoid		1 (2%)		
Infiltration Cellular, Histiocyte			2 (4%)	
Inflammation			2 (4%)	1 (2%)
Spleen	(50)	(50)	(49)	(50)
Amyloid Deposition			1 (2%)	
Atrophy				1 (2%)
Hematopoietic Cell Proliferation	4 (8%)	2 (4%)	2 (4%)	2 (4%)
Hyperplasia, Lymphoid	22 (44%)	23 (46%)	24 (49%)	12 (24%)
Hyperplasia, Plasma Cell			1 (2%)	
Infarct	1 (2%)			
Lymphoid Follicle, Atrophy	2 (4%)	1 (2%)	4 (8%)	3 (6%)
Thymus	(48)	(49)	(49)	(49)
Cyst	1 (2%)			
Hyperplasia, Lymphoid				1 (2%)
Infiltration Cellular, Mast Cell			1 (2%)	
Inflammation			1 (2%)	
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Hyperplasia, Focal		2 (4%)	3 (6%)	2 (4%)
Inflammation	1 (2%)			
Skin	(50)	(50)	(50)	(50)
Inflammation	1 (2%)		1 (2%)	
Ulcer	1 (2%)	1 (2%)		
Subcutaneous Tissue, Fibrosis	2 (4%)	4 (8%)	1 (2%)	1 (2%)
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Femur, Fibro-Osseous Lesion		4 (8%)	2 (4%)	4 (8%)

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

B6C3F1 MICE FEMALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Hydrocephalus		2 (4%)	1 (2%)	
Inflammation		1 (2%)		
Artery, Inflammation			1 (2%)	
Meninges, Inflammation			1 (2%)	
Spinal Cord	(0)	(1)	(1)	(1)
Degeneration				1 (100%)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Congestion				3 (6%)
Hemorrhage		1 (2%)	1 (2%)	
Inflammation	2 (4%)	6 (12%)	2 (4%)	6 (12%)
Thrombosis			2 (4%)	
Alveolar Epithelium, Hyperplasia	2 (4%)	3 (6%)	2 (4%)	1 (2%)
Alveolus, Infiltration Cellular, Histiocyte			2 (4%)	
Nose	(50)	(50)	(50)	(49)
Inflammation	1 (2%)		4 (8%)	3 (6%)
SPECIAL SENSES SYSTEM				
Eye	(49)	(50)	(50)	(50)
Developmental Malformation	1 (2%)			
Cornea, Inflammation	2 (4%)	1 (2%)	3 (6%)	
Optic Nerve, Degeneration				1 (2%)
Harderian Gland	(49)	(50)	(50)	(50)
Hyperplasia	2 (4%)	1 (2%)	1 (2%)	
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Cyst		1 (2%)		
Infarct		2 (4%)		6 (12%)
Inflammation	7 (14%)	2 (4%)		1 (2%)
Metaplasia, Osseous		3 (6%)	2 (4%)	
Mineralization		1 (2%)		
Nephropathy	39 (78%)	39 (78%)	38 (76%)	33 (66%)
Arteriole, Inflammation				1 (2%)

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

B6C3F1 MICE FEMALE	0 MG/KG	1250 MG/KG	2500 MG/KG	5000 MG/KG
Artery, Inflammation		1 (2%)	1 (2%)	
Urinary Bladder	(49)	(50)	(50)	(50)
Inflammation				1 (2%)

*** END OF REPORT ***

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