C Number:	C03098C
Lock Date:	05/13/1992
Cage Range:	All
Date Range:	All
Reasons For Removal:	All
Removal Date Range:	All
Treatment Groups:	All
Study Gender:	Both
PWG Approval Date	03/13/1995

B6C3F1 Mouse MALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
Disposition Summary				
Animals Initially In Study	**60**	**50**	**60**	**50**
Scheduled Sacrifice	**10**		**10**	
Early Deaths				
Natural Death	**1**	**2**	**2**	**1**
Survivors				
Moribund Sacrifice		**11**		**5**
Natural Death		**9**		**7**
Terminal Sacrifice	**49**	**28**	**48**	**37**
Animals Examined Microscopically	**60**	**50**	**60**	**50**
ALIMENTARY SYSTEM				
Esophagus	(60)	(50)	(60)	(50)
Periesoph Tiss, Inflammation, Suppurative	1 (2%)			
Gallbladder	(60)	(50)	(58)	(49)
Inflammation, Acute				1 (2%)
Intestine Large, Cecum	(60)	(50)	(59)	(50)
Intestine Large, Colon	(60)	(50)	(60)	(49)
Intestine Large, Rectum	(59)	(50)	(59)	(50)
Intestine Small, Duodenum	(60)	(50)	(59)	(50)
Intestine Small, Ileum	(59)	(50)	(60)	(49)
Intestine Small, Jejunum	(60)	(50)	(60)	(49)
Hyperplasia, Lymphoid	1 (2%)	1 (2%)	1 (2%)	5 (10%)
Inflammation, Chronic Active		1 (2%)		
Liver	(60)	(50)	(60)	(50)
Basophilic Focus		1 (2%)		1 (2%)
Bile Duct, Cyst				2 (4%)
Bile Duct, Hyperplasia, Cystic	1 (2%)			
Clear Cell Focus	1 (2%)			
Eosinophilic Focus	1 (2%)	1 (2%)		1 (2%)

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

B6C3F1 Mouse MALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
Hematopoietic Cell Proliferation		1 (2%)		
Hepatodiaphragmatic Nodule		1 (2%)		
Hyperplasia, Lymphoid		2 (4%)		
Mixed Cell Focus		2 (4%)	1 (2%)	
Necrosis	1 (2%)	1 (2%)	1 (2%)	
Mesentery	(1)	(5)	(0)	(1)
Artery, Inflammation, Chronic Active				1 (100%)
Fat, Inflammation, Chronic Active		3 (60%)		
Fat, Necrosis		2 (40%)		
Fibrosis	1 (100%)			
Pancreas	(60)	(50)	(60)	(50)
Acinus, Atrophy		2 (4%)	1 (2%)	
Acinus, Hyperplasia, Focal				1 (2%)
Artery, Inflammation, Chronic Active		2 (4%)		
Duct, Ectasia		1 (2%)		
Inflammation, Chronic Active		1 (2%)		
Salivary Glands	(60)	(50)	(60)	(50)
Stomach, Forestomach	(60)	(50)	(60)	(50)
Cyst				2 (4%)
Hyperplasia, Focal	44 (73%)	25 (50%)	38 (63%)	33 (66%)
Hyperplasia, Mast Cell				3 (6%)
Stomach, Glandular	(60)	(50)	(60)	(50)
Dysplasia	1 (2%)	1 (2%)	2 (3%)	3 (6%)
Hyperplasia		1 (2%)		
Tongue	(1)	(0)	(0)	(1)
Mineralization	1 (100%)			
Tooth	(2)	(3)	(0)	(7)
Dysplasia	2 (100%)	3 (100%)		6 (86%)
Inflammation, Chronic Active				1 (14%)

CARDIOVASCULAR SYSTEM

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

B6C3F1 Mouse MALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
Blood Vessel	(60)	(50)	(60)	(50)
Heart	(60)	(50)	(60)	(50)
Atrium, Thrombosis				1 (2%)
Degeneration		1 (2%)		
Inflammation, Chronic Active	1 (2%)			
Mineralization		1 (2%)		1 (2%)
Valve, Inflammation, Chronic Active				1 (2%)
ENDOCRINE SYSTEM				
Adrenal Cortex	(60)	(50)	(60)	(50)
Accessory Adrenal Cortical Nodule	4 (7%)	1 (2%)		1 (2%)
Capsule, Hyperplasia		3 (6%)		1 (2%)
Capsule, Hyperplasia, Adenomatous	6 (10%)			
Hematopoietic Cell Proliferation		1 (2%)		
Hemorrhage		1 (2%)		
Hyperplasia	14 (23%)	6 (12%)	6 (10%)	12 (24%)
Adrenal Medulla	(60)	(50)	(59)	(50)
Hyperplasia		3 (6%)		1 (2%)
Islets, Pancreatic	(60)	(50)	(59)	(50)
Hyperplasia	1 (2%)	3 (6%)		
Parathyroid Gland	(49)	(50)	(54)	(47)
Cyst				1 (2%)
Hyperplasia, Focal				1 (2%)
Pituitary Gland	(58)	(47)	(38)	(47)
Cyst			1 (3%)	
Pars Distalis, Cyst		3 (6%)		1 (2%)
Pars Distalis, Hyperplasia		2 (4%)		3 (6%)
Thyroid Gland	(60)	(50)	(60)	(50)
Follicular Cel, Hyperplasia	1 (2%)	6 (12%)		2 (4%)
Inflammation		1 (2%)		
Inflammation, Chronic Active				1 (2%)

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

B6C3F1 Mouse MALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
GENERAL BODY SYSTEM				
Tissue NOS	(0)	(0)	(0)	(1)
GENITAL SYSTEM				
Epididymis	(60)	(50)	(60)	(50)
Granuloma Sperm		7 (14%)		6 (12%)
Inflammation, Chronic Active		1 (2%)		
Spermatocele				1 (2%)
Preputial Gland	(60)	(50)	(59)	(50)
Degeneration				1 (2%)
Duct, Ectasia	24 (40%)	24 (48%)	10 (17%)	15 (30%)
Inflammation, Chronic Active	2 (3%)	7 (14%)	1 (2%)	6 (12%)
Prostate	(60)	(50)	(60)	(50)
Seminal Vesicle	(60)	(50)	(60)	(50)
Testes	(60)	(50)	(60)	(50)
Atrophy	1 (2%)	9 (18%)		7 (14%)
Hypoplasia	1 (2%)			
Interstit Cell, Hyperplasia		1 (2%)		
HEMATOPOIETIC SYSTEM				
Bone Marrow	(60)	(50)	(60)	(50)
Erythroid Cell, Hyperplasia				3 (6%)
Hyperplasia, Mast Cell	1 (2%)			
Myelofibrosis		2 (4%)		
Myeloid Cell, Hyperplasia		6 (12%)		1 (2%)
Lymph Node	(0)	(4)	(0)	(4)
Lymph Node, Bronchial	(0)	(0)	(3)	(0)
Lymph Node, Mandibular	(60)	(48)	(59)	(47)
Hyperplasia, Lymphoid				1 (2%)
Lymph Node, Mediastinal	(1)	(7)	(0)	(3)
Lymph Node, Mesenteric	(60)	(49)	(59)	(46)

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

B6C3F1 Mouse MALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
Angiectasis		5 (10%)		5 (11%)
Hyperplasia, Lymphoid				2 (4%)
Hyperplasia, Plasma Cell				1 (2%)
Spleen	(60)	(50)	(60)	(50)
Depletion Lymphoid		2 (4%)	1 (2%)	1 (2%)
Hematopoietic Cell Proliferation	2 (3%)	15 (30%)	1 (2%)	11 (22%)
Hyperplasia, Lymphoid		1 (2%)		1 (2%)
Hyperplasia, Plasma Cell				1 (2%)
Thrombosis		1 (2%)		
Thymus	(55)	(34)	(55)	(38)
Atrophy		13 (38%)	1 (2%)	9 (24%)
INTEGUMENTARY SYSTEM				
Mammary Gland	(1)	(0)	(0)	(0)
Skin	(60)	(48)	(60)	(50)
Subcut Tiss, Inflammation, Chronic Active		2 (4%)		
MUSCULOSKELETAL SYSTEM				
Bone	(60)	(50)	(60)	(50)
Skeletal Muscle	(0)	(0)	(0)	(1)
NERVOUS SYSTEM				
Brain	(60)	(50)	(60)	(50)
Infiltration Cellular, Lymphocyte			1 (2%)	
Peripheral Nerve	(0)	(1)	(0)	(1)
Spinal Cord	(0)	(1)	(0)	(1)
RESPIRATORY SYSTEM				
Lung	(60)	(50)	(60)	(50)
Alveolar Epith, Hyperplasia	5 (8%)	4 (8%)	1 (2%)	7 (14%)
Bronchiectasis, Focal	1 (2%)			
Bronchiole, Hyperplasia		1 (2%)	1 (2%)	

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

B6C3F1 Mouse MALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
Inflammation		1 (2%)		
Nose	(60)	(50)	(60)	(50)
Respirat Epith, Inflammation, Chronic Active	1 (2%)			
Trachea	(60)	(50)	(60)	(50)
SPECIAL SENSES SYSTEM				
Ear	(0)	(2)	(0)	(0)
Eye	(0)	(1)	(0)	(3)
Lens, Cataract		1 (100%)		2 (67%)
Harderian Gland	(26)	(24)	(26)	(23)
Hyperplasia	1 (4%)			
Inflammation, Chronic Active	2 (8%)		2 (8%)	
URINARY SYSTEM				
Kidney	(60)	(50)	(60)	(50)
Cyst		3 (6%)		1 (2%)
Hyperplasia, Mast Cell	1 (2%)			
Necrosis, Focal		1 (2%)		
Nephropathy	56 (93%)	40 (80%)	50 (83%)	40 (80%)
Renal Tubule, Hyperplasia	1 (2%)			1 (2%)
Urinary Bladder	(60)	(50)	(59)	(49)

END OF MALE DATA

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

B6C3F1 Mouse FEMALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
Disposition Summary				
Animals Initially In Study	**60**	**50**	**60**	**50**
Scheduled Sacrifice	**10**		**10**	
Early Deaths				
Dosing Accident			**1**	
Moribund Sacrifice	**2**	**4**	**2**	**3**
Natural Death	**1**	**1**	**3**	**2**
Survivors				
Dosing Accident				**1**
Moribund Sacrifice		**14**		**13**
Natural Death		**11**		**12**
Terminal Sacrifice	**47**	**20**	**44**	**19**
Animals Examined Microscopically	**60**	**50**	**60**	**50**
ALIMENTARY SYSTEM				
Esophagus	(59)	(50)	(60)	(50)
Periesoph Tiss, Degeneration			1 (2%)	
Periesoph Tiss, Hemorrhage				1 (2%)
Gallbladder	(60)	(50)	(60)	(49)
Inflammation, Chronic Active		1 (2%)		1 (2%)
Intestine Large, Cecum	(60)	(49)	(60)	(48)
Intestine Large, Colon	(60)	(49)	(60)	(50)
Intestine Large, Rectum	(60)	(50)	(60)	(49)
Intestine Small, Duodenum	(60)	(50)	(60)	(50)
Intestine Small, Ileum	(57)	(49)	(60)	(50)
Intestine Small, Jejunum	(60)	(50)	(60)	(49)
Hemorrhage				1 (2%)
Hyperplasia, Lymphoid		1 (2%)		
Liver	(60)	(50)	(60)	(50)
Angiectasis	1 (2%)			1 (2%)

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

B6C3F1 Mouse FEMALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
Basophilic Focus	1 (2%)		2 (3%)	3 (6%)
Bile Duct, Cyst				2 (4%)
Bile Duct, Hyperplasia			1 (2%)	
Centrilobular, Necrosis	1 (2%)			
Clear Cell Focus				2 (4%)
Eosinophilic Focus		4 (8%)	1 (2%)	
Hematopoietic Cell Proliferation		1 (2%)		2 (4%)
Hyperplasia, Lymphoid	1 (2%)			
Inflammation, Focal		1 (2%)		
Mixed Cell Focus	2 (3%)			1 (2%)
Necrosis		2 (4%)	1 (2%)	1 (2%)
Serosa, Pigmentation, Hemosiderin	1 (2%)			
Mesentery	(2)	(6)	(0)	(6)
Pancreas	(60)	(49)	(60)	(50)
Acinus, Atrophy		4 (8%)	3 (5%)	3 (6%)
Acinus, Hyperplasia, Focal	3 (5%)			
Artery, Inflammation, Chronic Active		2 (4%)		
Duct, Ectasia		1 (2%)	1 (2%)	2 (4%)
Salivary Glands	(60)	(49)	(60)	(50)
Stomach, Forestomach	(60)	(50)	(60)	(50)
Cyst		1 (2%)		
Erosion	1 (2%)			
Hyperplasia, Focal	36 (60%)	23 (46%)	37 (62%)	29 (58%)
Infiltration Cellular, Mast Cell	1 (2%)			
Mineralization				1 (2%)
Stomach, Glandular	(60)	(50)	(60)	(50)
Dysplasia				1 (2%)
Erosion				1 (2%)
Mineralization				1 (2%)
Tooth	(0)	(2)	(0)	(2)

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

B6C3F1 Mouse FEMALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
Dysplasia		2 (100%)		1 (50%)
CARDIOVASCULAR SYSTEM				
Blood Vessel	(60)	(50)	(60)	(50)
Aorta, Inflammation		1 (2%)		
Aorta, Thrombosis		2 (4%)		
Inflammation, Chronic Active			1 (2%)	
Heart	(60)	(50)	(60)	(50)
Degeneration				1 (2%)
Inflammation, Chronic Active	1 (2%)			
Mineralization	2 (3%)	1 (2%)		
ENDOCRINE SYSTEM				
Adrenal Cortex	(59)	(50)	(60)	(50)
Accessory Adrenal Cortical Nodule	1 (2%)		1 (2%)	1 (2%)
Angiectasis		1 (2%)		2 (4%)
Capsule, Hyperplasia		1 (2%)		
Hyperplasia	2 (3%)	2 (4%)	1 (2%)	2 (4%)
Hypertrophy	1 (2%)			
Adrenal Medulla	(59)	(49)	(60)	(50)
Hyperplasia				1 (2%)
Islets, Pancreatic	(60)	(49)	(60)	(50)
Hyperplasia		1 (2%)		
Parathyroid Gland	(52)	(45)	(49)	(46)
Cyst			2 (4%)	1 (2%)
Pituitary Gland	(56)	(42)	(56)	(49)
Pars Distalis, Hyperplasia	2 (4%)	8 (19%)	4 (7%)	1 (2%)
Pars Intermed, Hyperplasia	1 (2%)			
Thyroid Gland	(60)	(50)	(59)	(50)
Follicular Cel, Hyperplasia	2 (3%)	9 (18%)		2 (4%)
Inflammation, Chronic Active	1 (2%)			

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

B6C3F1 Mouse FEMALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
GENERAL BODY SYSTEM				
Tissue NOS	(0)	(0)	(1)	(0)
GENITAL SYSTEM				
Clitoral Gland	(59)	(50)	(59)	(48)
Duct, Ectasia		2 (4%)		
Inflammation, Chronic Active		1 (2%)		1 (2%)
Ovary	(60)	(49)	(60)	(49)
Angiectasis		2 (4%)	1 (2%)	1 (2%)
Atrophy	1 (2%)			
Corpus Luteum, Hyperplasia		1 (2%)		
Cyst	14 (23%)	18 (37%)	9 (15%)	19 (39%)
Hemorrhage	1 (2%)			
Inflammation, Chronic Active		2 (4%)		
Thrombosis		1 (2%)		1 (2%)
Uterus	(60)	(49)	(60)	(49)
Hemorrhage		1 (2%)		
Hyperplasia, Cystic	16 (27%)	9 (18%)	17 (28%)	11 (22%)
Inflammation, Suppurative	1 (2%)			
Thrombosis		1 (2%)		
HEMATOPOIETIC SYSTEM				
Blood	(0)	(0)	(0)	(1)
Bone Marrow	(60)	(50)	(60)	(50)
Angiectasis		1 (2%)		
Erythroid Cell, Hyperplasia		4 (8%)	1 (2%)	1 (2%)
Myelofibrosis	7 (12%)	19 (38%)	13 (22%)	13 (26%)
Myeloid Cell, Hyperplasia	1 (2%)	9 (18%)	1 (2%)	7 (14%)
Lymph Node	(0)	(13)	(0)	(8)
Hematopoietic Cell Proliferation				1 (13%)
Hyperplasia, Lymphoid		1 (8%)		

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

B6C3F1 Mouse FEMALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
Lymph Node, Bronchial	(0)	(0)	(1)	(1)
Lymph Node, Mandibular	(60)	(45)	(58)	(47)
Hematopoietic Cell Proliferation				1 (2%)
Hyperplasia, Lymphoid	1 (2%)	1 (2%)	1 (2%)	
Lymph Node, Mediastinal	(2)	(12)	(4)	(11)
Lymph Node, Mesenteric	(51)	(43)	(60)	(48)
Angiectasis		3 (7%)		1 (2%)
Hyperplasia, Lymphoid			1 (2%)	
Spleen	(60)	(50)	(60)	(50)
Depletion Lymphoid				1 (2%)
Hematopoietic Cell Proliferation	3 (5%)	21 (42%)	7 (12%)	17 (34%)
Hyperplasia, Lymphoid	1 (2%)	2 (4%)		
Thymus	(55)	(37)	(59)	(42)
Atrophy	1 (2%)	9 (24%)	1 (2%)	5 (12%)
Hyperplasia, Lymphoid			2 (3%)	
INTEGUMENTARY SYSTEM				
Mammary Gland	(60)	(49)	(60)	(49)
Hyperplasia		1 (2%)		
Skin	(60)	(50)	(60)	(50)
Subcut Tiss, Inflammation, Chronic Active		1 (2%)		1 (2%)
MUSCULOSKELETAL SYSTEM				
Bone	(60)	(50)	(60)	(50)
Skeletal Muscle	(2)	(0)	(0)	(0)
NERVOUS SYSTEM				
Brain	(60)	(50)	(60)	(50)
Granuloma, Focal				1 (2%)
Neuron, Necrosis		1 (2%)		
Peripheral Nerve	(0)	(1)	(3)	(0)
Spinal Cord	(0)	(1)	(1)	(0)

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

B6C3F1 Mouse FEMALE	0 MG/KG 104/WEEK	0 MG/KG 20%/36M	25 MG/KG104/WEEK	25 MG/KG20%/36M
RESPIRATORY SYSTEM				
Lung	(60)	(50)	(60)	(50)
Alveolar Epith, Hyperplasia	1 (2%)		4 (7%)	4 (8%)
Infiltration Cellular, Histiocyte	2 (3%)			
Infiltration Cellular, Lymphocyte		1 (2%)		
Inflammation, Chronic Active			1 (2%)	1 (2%)
Nose	(60)	(50)	(59)	(50)
Infiltration Cellular, Mast Cell		1 (2%)		
Trachea	(60)	(50)	(59)	(50)
SPECIAL SENSES SYSTEM				
Ear	(0)	(1)	(1)	(1)
Eye	(0)	(1)	(0)	(3)
Lens, Cataract		1 (100%)		3 (100%)
Harderian Gland	(24)	(22)	(26)	(25)
Hyperplasia				1 (4%)
Inflammation, Chronic Active			1 (4%)	
URINARY SYSTEM				
Kidney	(60)	(50)	(60)	(50)
Cytoplasmic Alteration		1 (2%)	1 (2%)	
Infiltration Cellular, Lymphocyte		1 (2%)		
Nephropathy	16 (27%)	19 (38%)	6 (10%)	13 (26%)
Pelvis, Inflammation, Chronic Active				1 (2%)
Renal Tubule, Necrosis	1 (2%)			
Urinary Bladder	(60)	(49)	(60)	(49)
Inflammation, Chronic Active		1 (2%)		1 (2%)

** END OF REPORT **

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