C Number:	C88105
Lock Date:	01/21/2005
Cage Range:	ALL
Date Range:	ALL
Reasons For Removal:	ALL
Removal Date Range:	ALL
Treatment Groups:	Include ALL

FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Dosing Accident		1		2
Moribund Sacrifice	14	9	14	11
Natural Death	1	6	3	7
Survivors				
Terminal Sacrifice	35	34	33	30
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Perforation				2 (4%)
Intestine Large, Cecum	(49)	(46)	(50)	(45)
Inflammation, Acute		1 (2%)		
Intestine Large, Colon	(50)	(46)	(50)	(47)
Parasite Metazoan	1 (2%)	1 (2%)	2 (4%)	
Intestine Large, Rectum	(50)	(46)	(50)	(48)
Parasite Metazoan	4 (8%)	1 (2%)		
Intestine Small, Duodenum	(50)	(46)	(50)	(45)
Inflammation, Acute				1 (2%)
Intestine Small, Ileum	(50)	(46)	(50)	(45)
Intestine Small, Jejunum	(50)	(46)	(50)	(45)
Inflammation, Chronic			1 (2%)	
Liver	(50)	(50)	(50)	(48)
Angiectasis	1 (2%)			2 (4%)
Basophilic Focus	43 (86%)	34 (68%)	26 (52%)	18 (38%)
Clear Cell Focus	27 (54%)	20 (40%)	19 (38%)	14 (29%)
Degeneration, Cystic	4 (8%)	1 (2%)	2 (4%)	4 (8%)
Eosinophilic Focus	8 (16%)	2 (4%)		2 (4%)
Fatty Change	2 (4%)	1 (2%)	2 (4%)	2 (4%)
Hematopoietic Cell Proliferation		1 (2%)		
Hepatodiaphragmatic Nodule	5 (10%)	3 (6%)	3 (6%)	3 (6%)
Infarct				1 (2%)
Malformation		1 (2%)		
Mixed Cell Focus	6 (12%)	4 (8%)	6 (12%)	2 (4%)
Necrosis	1 (2%)			

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

FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Bile Duct, Hyperplasia	39 (78%)	39 (78%)	32 (64%)	24 (50%)
Centrilobular, Necrosis	2 (4%)	1 (2%)		1 (2%)
Hepatocyte, Vacuolization Cytoplasmic				1 (2%)
Mesentery	(12)	(18)	(7)	(11)
Fat, Hemorrhage	1 (8%)			
Fat, Necrosis	10 (83%)	17 (94%)	7 (100%)	9 (82%)
Oral Mucosa	(1)	(0)	(1)	(3)
Pancreas	(50)	(50)	(50)	(49)
Basophilic Focus	1 (2%)	1 (2%)		
Metaplasia, Hepatocyte	1 (2%)			
Acinus, Atrophy	22 (44%)	21 (42%)	17 (34%)	10 (20%)
Acinus, Hyperplasia	21 (42%)	12 (24%)	13 (26%)	19 (39%)
Salivary Glands	(50)	(50)	(49)	(50)
Hyperplasia	1 (2%)			
Stomach, Forestomach	(50)	(49)	(50)	(49)
Hyperplasia, Squamous	2 (4%)	1 (2%)	3 (6%)	5 (10%)
Inflammation	1 (2%)			
Ulcer	3 (6%)	1 (2%)	4 (8%)	2 (4%)
Stomach, Glandular	(50)	(46)	(50)	(45)
Atrophy	2 (4%)	3 (7%)	2 (4%)	3 (7%)
Inflammation, Chronic Active			1 (2%)	
Mineralization				1 (2%)
Necrosis		1 (2%)	1 (2%)	
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	48 (96%)	44 (88%)	47 (94%)	46 (92%)
Thrombosis	1 (2%)	2 (4%)		
Pericardium, Inflammation, Acute				1 (2%)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(49)
Degeneration, Cystic	2 (4%)			
Hyperplasia	31 (62%)	22 (44%)	21 (42%)	31 (63%)
Hypertrophy	5 (10%)	1 (2%)	4 (8%)	1 (2%)
Vacuolization Cytoplasmic		2 (4%)		
Adrenal Medulla	(50)	(50)	(50)	(49)
Hyperplasia	24 (48%)	18 (36%)	16 (32%)	15 (31%)

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

FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Islets, Pancreatic	(50)	(49)	(50)	(49)
Hyperplasia	1 (2%)		1 (2%)	
Pituitary Gland	(50)	(48)	(47)	(47)
Hemorrhage				1 (2%)
Pars Distalis, Angiectasis	6 (12%)		3 (6%)	2 (4%)
Pars Distalis, Hyperplasia	18 (36%)	20 (42%)	15 (32%)	16 (34%)
Thyroid Gland	(50)	(49)	(50)	(47)
C-cell, Hyperplasia	9 (18%)	5 (10%)	7 (14%)	9 (19%)
Follicular Cell, Hyperplasia	3 (6%)	3 (6%)		5 (11%)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Epididymis	(50)	(50)	(50)	(50)
Granuloma Sperm		1 (2%)		
Preputial Gland	(50)	(49)	(50)	(50)
Cyst		1 (2%)		
Hyperplasia	1 (2%)	2 (4%)	1 (2%)	4 (8%)
Inflammation, Chronic Active		1 (2%)		
Prostate	(50)	(49)	(50)	(50)
Hyperplasia	10 (20%)	9 (18%)	15 (30%)	11 (22%)
Inflammation, Chronic Active	3 (6%)	1 (2%)		3 (6%)
Seminal Vesicle	(50)	(49)	(50)	(49)
Hyperplasia				1 (2%)
Testes	(50)	(50)	(50)	(50)
Atrophy	1 (2%)	4 (8%)	3 (6%)	
Interstitial Cell, Hyperplasia	7 (14%)	2 (4%)	4 (8%)	1 (2%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(49)	(50)	(50)
Hyperplasia, Reticulum Cell			1 (2%)	
Lymph Node	(3)	(4)	(4)	(4)
Deep Cervical, Hyperplasia, Lymphoid			1 (25%)	
Mediastinal, Ectasia	1 (33%)			
Pancreatic, Inflammation, Chronic Active			1 (25%)	
Lymph Node, Mesenteric	(50)	(48)	(50)	(47)

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

FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Spleen	(50)	(46)	(50)	(47)
Fibrosis	2 (4%)		2 (4%)	
Hematopoietic Cell Proliferation	3 (6%)	3 (7%)	1 (2%)	2 (4%)
Hemorrhage	1 (2%)			
Hyperplasia, Lymphoid		1 (2%)		
Inflammation, Acute		1 (2%)		
Necrosis	2 (4%)	1 (2%)	1 (2%)	
Thymus	(47)	(43)	(49)	(48)
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(49)	(50)	(50)
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion		2 (4%)		2 (4%)
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(0)	(2)	(0)	(1)
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Hydrocephalus	2 (4%)			
Thrombosis		1 (2%)		
Meninges, Hemorrhage			1 (2%)	
Peripheral Nerve	(0)	(1)	(1)	(0)
Spinal Cord	(0)	(1)	(1)	(0)
Hemorrhage			1 (100%)	
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Foreign Body			3 (6%)	1 (2%)
Inflammation, Chronic Active		1 (2%)	1 (2%)	
Metaplasia, Squamous	1 (2%)	2 (4%)		
Thrombosis		1 (2%)		
Alveolar Epithelium, Hyperplasia	27 (54%)	20 (40%)	16 (32%)	25 (50%)
Alveolus, Infiltration Cellular, Histiocyte				1 (2%)

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

FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Bronchiole, Hyperplasia		1 (2%)	1 (2%)	1 (2%)
Perivascular, Inflammation, Chronic Active		1 (2%)		
Nose	(50)	(48)	(49)	(49)
Foreign Body	3 (6%)		3 (6%)	4 (8%)
Inflammation, Suppurative	12 (24%)	11 (23%)	13 (27%)	12 (24%)
Inflammation, Chronic	2 (4%)	1 (2%)	2 (4%)	2 (4%)
Thrombosis			1 (2%)	
Glands, Dilatation		2 (4%)	1 (2%)	2 (4%)
Nasolacrimal Duct, Cyst			1 (2%)	
Nasolacrimal Duct, Inflammation				1 (2%)
Olfactory Epithelium, Accumulation, Hyaline Droplet	50 (100%)	37 (77%)	42 (86%)	42 (86%)
Olfactory Epithelium, Atrophy	1 (2%)	5 (10%)	9 (18%)	13 (27%)
Olfactory Epithelium, Degeneration	1 (2%)		2 (4%)	6 (12%)
Olfactory Epithelium, Hyperplasia				1 (2%)
Olfactory Epithelium, Hyperplasia, Basal Cell			1 (2%)	
Olfactory Epithelium, Metaplasia, Respiratory	4 (8%)	6 (13%)	10 (20%)	15 (31%)
Olfactory Epithelium, Metaplasia, Squamous	1 (2%)	1 (2%)		
Respiratory Epithelium, Accumulation, Hyaline Droplet	3 (6%)	5 (10%)	1 (2%)	2 (4%)
Respiratory Epithelium, Hyperplasia	12 (24%)	3 (6%)	14 (29%)	8 (16%)
Respiratory Epithelium, Metaplasia, Squamous	1 (2%)	4 (8%)	3 (6%)	5 (10%)
Pleura	(0)	(0)	(0)	(2)
Inflammation, Acute				2 (100%)
Trachea	(50)	(49)	(50)	(48)
Epithelium, Necrosis		1 (2%)		
SPECIAL SENSES SYSTEM				
Eye	(50)	(46)	(50)	(45)
Cataract		1 (2%)		2 (4%)
Retina, Atrophy		1 (2%)	1 (2%)	2 (4%)
Harderian Gland	(50)	(47)	(50)	(45)
Hyperplasia	1 (2%)	5 (11%)	5 (10%)	1 (2%)
Inflammation, Chronic Active	1 (2%)			
Zymbal's Gland	(2)	(1)	(0)	(0)
URINARY SYSTEM				

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

FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Kidney	(50)	(48)	(50)	(49)
Cyst				1 (2%)
Degeneration, Mucoid, Focal				1 (2%)
Hyperplasia, Oncocytic				1 (2%)
Inflammation, Suppurative				1 (2%)
Nephropathy	49 (98%)	46 (96%)	47 (94%)	47 (96%)
Renal Tubule, Degeneration, Hyaline				1 (2%)
Transitional Epithelium, Hyperplasia		1 (2%)		2 (4%)
Urinary Bladder	(50)	(48)	(50)	(47)

*** END OF MALE ***

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

FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Dosing Accident		1		
Moribund Sacrifice	15	8	9	9
Natural Death	2	6	7	10
Survivors				
Moribund Sacrifice				1
Terminal Sacrifice	33	35	34	30
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Perforation		1 (2%)		
Intestine Large, Colon	(50)	(48)	(47)	(48)
Parasite Metazoan	2 (4%)	1 (2%)	1 (2%)	
Intestine Large, Rectum	(49)	(48)	(47)	(48)
Parasite Metazoan	1 (2%)	1 (2%)	1 (2%)	2 (4%)
Intestine Small, Ileum	(49)	(47)	(45)	(45)
Parasite Metazoan			1 (2%)	
Liver	(50)	(50)	(50)	(50)
Angiectasis			2 (4%)	3 (6%)
Basophilic Focus	50 (100%)	49 (98%)	48 (96%)	46 (92%)
Clear Cell Focus	12 (24%)	9 (18%)	9 (18%)	10 (20%)
Degeneration, Cystic	1 (2%)			
Eosinophilic Focus	2 (4%)	2 (4%)	5 (10%)	5 (10%)
Fatty Change	2 (4%)		1 (2%)	
Hepatodiaphragmatic Nodule	8 (16%)	11 (22%)	7 (14%)	4 (8%)
Mixed Cell Focus	5 (10%)	7 (14%)	3 (6%)	3 (6%)
Necrosis		1 (2%)		
Bile Duct, Hyperplasia	3 (6%)	4 (8%)	4 (8%)	4 (8%)
Hepatocyte, Mitotic Alteration				1 (2%)
Mesentery	(11)	(11)	(11)	(14)
Fat, Hemorrhage	1 (9%)			
Fat, Necrosis	11 (100%)	10 (91%)	11 (100%)	13 (93%)
Oral Mucosa	(0)	(1)	(0)	(1)
Pancreas	(50)	(49)	(48)	(50)

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

FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Basophilic Focus	1 (2%)			
Acinus, Atrophy	9 (18%)	4 (8%)	2 (4%)	4 (8%)
Acinus, Hyperplasia	5 (10%)	2 (4%)		5 (10%)
Salivary Glands	(49)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(49)	(50)
Hyperplasia, Squamous	2 (4%)		1 (2%)	2 (4%)
Inflammation	1 (2%)			1 (2%)
Ulcer	1 (2%)		2 (4%)	2 (4%)
Stomach, Glandular	(50)	(47)	(46)	(47)
Atrophy	1 (2%)	3 (6%)		3 (6%)
Mineralization	3 (6%)	1 (2%)	2 (4%)	1 (2%)
Tongue	(0)	(0)	(1)	(0)
Tooth	(0)	(1)	(0)	(0)
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	41 (82%)	42 (84%)	38 (76%)	39 (78%)
Pericardium, Inflammation, Granulomatous				1 (2%)
Pericardium, Inflammation, Acute		1 (2%)		1 (2%)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(47)	(49)
Degeneration, Cystic		2 (4%)	4 (9%)	3 (6%)
Hyperplasia	25 (50%)	17 (34%)	18 (38%)	18 (37%)
Hypertrophy	4 (8%)	3 (6%)	2 (4%)	2 (4%)
Necrosis	1 (2%)	2 (4%)	1 (2%)	
Vacuolization Cytoplasmic				1 (2%)
Adrenal Medulla	(50)	(50)	(46)	(49)
Hyperplasia	5 (10%)	6 (12%)	5 (11%)	5 (10%)
Islets, Pancreatic	(50)	(49)	(47)	(49)
Parathyroid Gland	(47)	(44)	(48)	(44)
Hyperplasia	1 (2%)			
Pituitary Gland	(50)	(48)	(49)	(49)
Cyst	1 (2%)			
Pars Distalis, Angiectasis	3 (6%)	2 (4%)	2 (4%)	3 (6%)
Pars Distalis, Hyperplasia	17 (34%)	21 (44%)	21 (43%)	20 (41%)
Thyroid Gland	(50)	(46)	(46)	(48)
C-cell, Hyperplasia	9 (18%)	4 (9%)	7 (15%)	6 (13%)

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

FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Follicular Cell, Hyperplasia	2 (4%)	2 (4%)		
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Clitoral Gland	(48)	(50)	(49)	(50)
Hyperplasia	7 (15%)	5 (10%)	5 (10%)	4 (8%)
Inflammation, Chronic Active		1 (2%)		1 (2%)
Ovary	(50)	(50)	(49)	(50)
Cyst	1 (2%)	6 (12%)	1 (2%)	4 (8%)
Uterus	(50)	(50)	(49)	(50)
Inflammation, Acute			1 (2%)	
Necrosis	1 (2%)			
Endometrium, Hyperplasia, Cystic	2 (4%)		1 (2%)	
Vagina	(1)	(0)	(1)	(0)
Inflammation, Suppurative			1 (100%)	
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(49)	(49)	(49)
Hyperplasia, Reticulum Cell	1 (2%)	1 (2%)	1 (2%)	
Lymph Node	(0)	(3)	(3)	(3)
Deep Cervical, Ectasia		1 (33%)		1 (33%)
Deep Cervical, Hemorrhage				1 (33%)
Lymph Node, Mesenteric	(50)	(49)	(48)	(49)
Spleen	(50)	(49)	(49)	(49)
Hematopoietic Cell Proliferation		1 (2%)	2 (4%)	3 (6%)
Inflammation, Granulomatous			1 (2%)	1 (2%)
Necrosis				1 (2%)
Thymus	(47)	(47)	(46)	(49)
Inflammation, Acute				1 (2%)
INTEGUMENTARY SYSTEM				
Mammary Gland	(49)	(50)	(50)	(49)
Galactocele				1 (2%)

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

FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Hyperplasia	1 (2%)			
Skin	(50)	(50)	(50)	(50)
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Hyperostosis			1 (2%)	
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Hemorrhage			1 (2%)	
Hydrocephalus	1 (2%)			
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Cyst				1 (2%)
Inflammation, Acute	1 (2%)			3 (6%)
Inflammation, Chronic Active	2 (4%)	4 (8%)	3 (6%)	2 (4%)
Alveolar Epithelium, Hyperplasia	17 (34%)	11 (22%)	16 (32%)	14 (28%)
Alveolus, Infiltration Cellular, Histiocyte				1 (2%)
Bronchiole, Hyperplasia	1 (2%)		1 (2%)	1 (2%)
Nose	(50)	(49)	(49)	(49)
Foreign Body	1 (2%)			
Inflammation, Suppurative	3 (6%)	5 (10%)	2 (4%)	3 (6%)
Inflammation, Chronic	5 (10%)	4 (8%)		2 (4%)
Thrombosis	1 (2%)	1 (2%)	1 (2%)	
Glands, Dilatation	2 (4%)			2 (4%)
Glands, Hyperplasia		1 (2%)	1 (2%)	1 (2%)
Olfactory Epithelium, Accumulation, Hyaline Droplet	48 (96%)	36 (73%)	37 (76%)	33 (67%)
Olfactory Epithelium, Atrophy				4 (8%)
Olfactory Epithelium, Degeneration			1 (2%)	
Olfactory Epithelium, Metaplasia, Respiratory	5 (10%)	5 (10%)	9 (18%)	12 (24%)
Olfactory Epithelium, Metaplasia, Squamous	3 (6%)			1 (2%)
Respiratory Epithelium, Accumulation, Hyaline Droplet	4 (8%)	3 (6%)	2 (4%)	
Respiratory Epithelium, Hyperplasia	6 (12%)	9 (18%)	4 (8%)	6 (12%)

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

FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Respiratory Epithelium, Metaplasia, Squamous	2 (4%)	2 (4%)		2 (4%)
Respiratory Epithelium, Necrosis		1 (2%)		
Pleura	(0)	(0)	(0)	(1)
Inflammation, Suppurative				1 (100%)
Trachea	(50)	(49)	(48)	(49)
Inflammation, Suppurative				1 (2%)
SPECIAL SENSES SYSTEM				
Eye	(49)	(46)	(47)	(48)
Cataract			3 (6%)	
Cornea, Inflammation, Acute		1 (2%)		
Cornea, Mineralization	1 (2%)			
Retina, Atrophy	1 (2%)		3 (6%)	1 (2%)
Zymbal's Gland	(0)	(1)	(0)	(1)
URINARY SYSTEM				
Kidney	(50)	(49)	(47)	(50)
Infarct		1 (2%)		1 (2%)
Inflammation, Suppurative				2 (4%)
Nephropathy	41 (82%)	39 (80%)	40 (85%)	40 (80%)
Renal Tubule, Necrosis	1 (2%)			
Transitional Epithelium, Hyperplasia	1 (2%)		1 (2%)	2 (4%)
Urinary Bladder	(50)	(50)	(48)	(49)
Inflammation, Chronic Active				1 (2%)

*** END OF REPORT ***

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