

**TDMS No.** 88123 - 05  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** RATS/F 344

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**  
FORMAMIDE  
**CAS Number:** 75-12-7  
**Pathologist:** SELLS, D. - KURTZ, F.  
Final 1 Rats

**Date Report Requested:** 12/05/2005  
**Time Report Requested:** 14:23:30  
**First Dose M/F:** 03/21/01 / 03/20/01  
**Lab:** BAT

**C Number:** C88123B  
**Lock Date:** 11/20/2003  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL

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Date Report Requested: 12/05/2005  
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FISCHER 344 RATS MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
<b>Disposition Summary</b>				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	24	15	22	18
Natural Death		8	2	3
Survivors				
Terminal Sacrifice	26	27	26	29
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(49)	(50)	(50)
Inflammation	1 (2%)			1 (2%)
Intestine Large, Cecum	(49)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Parasite Metazoan	1 (2%)	2 (4%)	1 (2%)	1 (2%)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Parasite Metazoan	8 (16%)	9 (18%)	11 (22%)	10 (20%)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Hemorrhage			1 (2%)	
Inflammation, Chronic Active			1 (2%)	
Mineralization			1 (2%)	
Perforation			1 (2%)	
Ulcer			1 (2%)	
Liver	(50)	(50)	(50)	(50)
Angiectasis	3 (6%)	2 (4%)	2 (4%)	1 (2%)
Basophilic Focus	32 (64%)	34 (68%)	33 (66%)	30 (60%)
Clear Cell Focus	21 (42%)	19 (38%)	24 (48%)	16 (32%)
Degeneration, Cystic	7 (14%)	6 (12%)	2 (4%)	5 (10%)
Eosinophilic Focus	14 (28%)	16 (32%)	8 (16%)	13 (26%)
Fatty Change, Focal	9 (18%)	9 (18%)	12 (24%)	5 (10%)
Fatty Change, Diffuse	14 (28%)	14 (28%)	13 (26%)	9 (18%)
Hematopoietic Cell Proliferation	4 (8%)	4 (8%)	5 (10%)	5 (10%)
Hepatodiaphragmatic Nodule	4 (8%)	7 (14%)	8 (16%)	6 (12%)
Hyperplasia, Granulocytic				1 (2%)
Inflammation	38 (76%)	36 (72%)	38 (76%)	37 (74%)

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FISCHER 344 RATS MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Mixed Cell Focus	5 (10%)	10 (20%)	22 (44%)	7 (14%)
Necrosis	2 (4%)	4 (8%)	5 (10%)	6 (12%)
Pigmentation		1 (2%)		
Regeneration	1 (2%)		1 (2%)	
Thrombosis	1 (2%)			
Vacuolization Cytoplasmic, Focal			1 (2%)	
Vacuolization Cytoplasmic, Diffuse	1 (2%)			1 (2%)
Bile Duct, Cyst	1 (2%)			
Bile Duct, Fibrosis		1 (2%)		
Bile Duct, Hyperplasia	49 (98%)	48 (96%)	47 (94%)	44 (88%)
Centrilobular, Degeneration	10 (20%)	8 (16%)	8 (16%)	6 (12%)
Oval Cell, Hyperplasia	23 (46%)	15 (30%)	20 (40%)	12 (24%)
Serosa, Cyst	1 (2%)			
Serosa, Fibrosis	1 (2%)			
Mesentery	(10)	(12)	(7)	(10)
Hemorrhage			1 (14%)	
Fat, Necrosis	9 (90%)	10 (83%)	6 (86%)	10 (100%)
Oral Mucosa	(22)	(27)	(29)	(20)
Gingival, Hyperplasia, Squamous	21 (95%)	27 (100%)	29 (100%)	20 (100%)
Pancreas	(50)	(50)	(50)	(50)
Atrophy	1 (2%)			
Basophilic Focus			2 (4%)	
Cyst	1 (2%)			
Infiltration Cellular, Mononuclear Cell	4 (8%)	2 (4%)	7 (14%)	3 (6%)
Inflammation, Chronic Active	23 (46%)	24 (48%)	25 (50%)	27 (54%)
Vacuolization Cytoplasmic		1 (2%)		
Acinus, Atrophy	21 (42%)	21 (42%)	21 (42%)	24 (48%)
Acinus, Hyperplasia	2 (4%)	3 (6%)	1 (2%)	2 (4%)
Acinus, Hyperplasia, Focal	1 (2%)			
Duct, Cyst		2 (4%)	2 (4%)	1 (2%)
Salivary Glands	(50)	(50)	(50)	(50)
Vacuolization Cytoplasmic		1 (2%)		
Stomach, Forestomach	(50)	(50)	(50)	(50)
Edema				2 (4%)
Erosion				1 (2%)
Hyperplasia, Squamous				2 (4%)
Inflammation	1 (2%)	1 (2%)	2 (4%)	3 (6%)
Ulcer	1 (2%)	1 (2%)	1 (2%)	2 (4%)
Stomach, Glandular	(50)	(50)	(50)	(50)
Cyst		1 (2%)		
Edema	1 (2%)	1 (2%)		

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 FORMAMIDE  
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FISCHER 344 RATS MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Erosion		3 (6%)		1 (2%)
Hyperplasia	1 (2%)			
Inflammation				1 (2%)
Mineralization	1 (2%)	1 (2%)		
Ulcer			1 (2%)	
Tongue	(0)	(1)	(0)	(0)
Tooth	(25)	(32)	(30)	(25)
Malformation	1 (4%)			
Peridontal Tissue, Inflammation	24 (96%)	32 (100%)	30 (100%)	25 (100%)
<b>CARDIOVASCULAR SYSTEM</b>				
Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	48 (96%)	50 (100%)	48 (96%)	45 (90%)
Thrombosis	3 (6%)	2 (4%)	2 (4%)	1 (2%)
Atrium, Thrombosis	1 (2%)			
Endocardium, Hyperplasia				1 (2%)
<b>ENDOCRINE SYSTEM</b>				
Adrenal Cortex	(50)	(50)	(50)	(50)
Angiectasis	9 (18%)	18 (36%)	20 (40%)	11 (22%)
Degeneration, Cystic	2 (4%)			1 (2%)
Hematopoietic Cell Proliferation	1 (2%)	1 (2%)	1 (2%)	
Hyperplasia	12 (24%)	6 (12%)	9 (18%)	13 (26%)
Hypertrophy	7 (14%)	8 (16%)	10 (20%)	7 (14%)
Infiltration Cellular, Mononuclear Cell		1 (2%)	9 (18%)	9 (18%)
Vacuolization Cytoplasmic	31 (62%)	29 (58%)	33 (66%)	29 (58%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Angiectasis		2 (4%)		
Hyperplasia	12 (24%)	13 (26%)	15 (30%)	21 (42%)
Infiltration Cellular, Mononuclear Cell	2 (4%)	2 (4%)	1 (2%)	
Islets, Pancreatic	(50)	(50)	(50)	(50)
Hyperplasia	4 (8%)	4 (8%)	3 (6%)	2 (4%)
Parathyroid Gland	(48)	(49)	(49)	(49)
Hyperplasia			1 (2%)	
Pituitary Gland	(50)	(50)	(50)	(50)
Angiectasis	13 (26%)	18 (36%)	20 (40%)	19 (38%)
Cyst	3 (6%)	2 (4%)	3 (6%)	4 (8%)

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

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FISCHER 344 RATS MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Pars Distalis, Hyperplasia	24 (48%)	23 (46%)	19 (38%)	18 (36%)
Pars Intermedia, Hyperplasia		1 (2%)		
Pars Nervosa, Rathke's Cleft, Hyperplasia, Tubular				1 (2%)
Thyroid Gland	(50)	(50)	(50)	(50)
Inflammation	1 (2%)			
C-cell, Hyperplasia	22 (44%)	18 (36%)	17 (34%)	18 (36%)
Follicle, Cyst				1 (2%)
Follicular Cell, Hyperplasia			2 (4%)	1 (2%)
<b>GENERAL BODY SYSTEM</b>				
None				
<b>GENITAL SYSTEM</b>				
Coagulating Gland	(0)	(1)	(1)	(0)
Inflammation		1 (100%)		
Epididymis	(50)	(50)	(50)	(50)
Infiltration Cellular, Mononuclear Cell	1 (2%)			
Inflammation	1 (2%)		1 (2%)	
Preputial Gland	(50)	(50)	(50)	(50)
Inflammation	50 (100%)	47 (94%)	45 (90%)	46 (92%)
Duct, Ectasia	7 (14%)	14 (28%)	2 (4%)	4 (8%)
Prostate	(50)	(50)	(50)	(50)
Cyst	1 (2%)	1 (2%)		
Inflammation	28 (56%)	29 (58%)	35 (70%)	30 (60%)
Epithelium, Degeneration				1 (2%)
Epithelium, Hyperplasia	6 (12%)	7 (14%)	7 (14%)	5 (10%)
Epithelium, Vacuolization Cytoplasmic	1 (2%)			
Seminal Vesicle	(50)	(50)	(50)	(49)
Dilatation	1 (2%)			
Inflammation		1 (2%)		
Testes	(50)	(50)	(50)	(50)
Artery, Inflammation, Chronic Active				1 (2%)
Germinal Epithelium, Atrophy	2 (4%)	1 (2%)	1 (2%)	1 (2%)
Germinal Epithelium, Degeneration	1 (2%)		1 (2%)	
Interstitial Cell, Hyperplasia	4 (8%)	1 (2%)	1 (2%)	1 (2%)

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FISCHER 344 RATS MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
<b>HEMATOPOIETIC SYSTEM</b>				
Bone Marrow	(50)	(50)	(50)	(50)
Atrophy	4 (8%)	5 (10%)	3 (6%)	3 (6%)
Hyperplasia	19 (38%)	24 (48%)	22 (44%)	29 (58%)
Lymph Node	(7)	(8)	(8)	(5)
Deep Cervical, Ectasia		1 (13%)		3 (60%)
Deep Cervical, Hemorrhage		2 (25%)		
Deep Cervical, Hyperplasia				1 (20%)
Deep Cervical, Hyperplasia, Plasma Cell				1 (20%)
Mediastinal, Ectasia		2 (25%)	1 (13%)	
Mediastinal, Hemorrhage		1 (13%)		
Lymph Node, Mandibular	(0)	(1)	(0)	(3)
Ectasia				1 (33%)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Ectasia	7 (14%)	4 (8%)	3 (6%)	5 (10%)
Hemorrhage			1 (2%)	
Hyperplasia, Histiocytic				1 (2%)
Spleen	(50)	(50)	(50)	(50)
Accessory Spleen			1 (2%)	
Fibrosis		1 (2%)		
Hematopoietic Cell Proliferation	41 (82%)	34 (68%)	36 (72%)	43 (86%)
Hyperplasia, Granulocytic				1 (2%)
Hyperplasia, Histiocytic		1 (2%)	3 (6%)	
Hyperplasia, Lymphoid, Focal		1 (2%)		
Hyperplasia, Focal		1 (2%)		1 (2%)
Pigmentation	29 (58%)	31 (62%)	32 (64%)	34 (68%)
Capsule, Fibrosis				1 (2%)
Capsule, Hemorrhage				1 (2%)
Lymphoid Follicle, Atrophy		1 (2%)		1 (2%)
Lymphoid Follicle, Depletion Cellular		2 (4%)		
Red Pulp, Atrophy		1 (2%)		
Thymus	(49)	(45)	(47)	(48)
Atrophy	46 (94%)	40 (89%)	41 (87%)	42 (88%)
<b>INTEGUMENTARY SYSTEM</b>				
Mammary Gland	(50)	(48)	(50)	(50)
Cyst	2 (4%)	4 (8%)	2 (4%)	3 (6%)
Hyperplasia	3 (6%)	3 (6%)	2 (4%)	3 (6%)

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FISCHER 344 RATS MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion			1 (2%)	
Edema	1 (2%)			
Hemorrhage	1 (2%)			
Inflammation	3 (6%)			
Ulcer	1 (2%)			
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone	(50)	(50)	(50)	(50)
Hyperplasia, Granulocytic				1 (2%)
<b>NERVOUS SYSTEM</b>				
Brain	(50)	(50)	(50)	(50)
Edema				1 (2%)
Hemorrhage	2 (4%)	1 (2%)	2 (4%)	1 (2%)
Hydrocephalus			1 (2%)	1 (2%)
Mineralization		1 (2%)	1 (2%)	1 (2%)
<b>RESPIRATORY SYSTEM</b>				
Lung	(50)	(50)	(50)	(50)
Hemorrhage		2 (4%)		
Inflammation	1 (2%)	2 (4%)	4 (8%)	3 (6%)
Metaplasia, Squamous		1 (2%)	1 (2%)	
Alveolar Epithelium, Hyperplasia	10 (20%)	12 (24%)	10 (20%)	16 (32%)
Alveolus, Infiltration Cellular, Histiocyte	27 (54%)	33 (66%)	31 (62%)	31 (62%)
Artery, Thrombosis		1 (2%)		
Vein, Hemorrhage			1 (2%)	
Vein, Inflammation				1 (2%)
Nose	(50)	(50)	(50)	(50)
Glands, Hyperplasia			1 (2%)	
Lateral Wall, Inflammation	6 (12%)	4 (8%)	7 (14%)	11 (22%)
Nasolacrimal Duct, Inflammation	2 (4%)	4 (8%)	4 (8%)	5 (10%)
Nasopharyngeal Duct, Inflammation	1 (2%)	2 (4%)	1 (2%)	1 (2%)
Nasopharyngeal Duct, Ulcer		1 (2%)		
Olfactory Epithelium, Metaplasia	1 (2%)		1 (2%)	
Respiratory Epithelium, Hyperplasia	19 (38%)	20 (40%)	25 (50%)	24 (48%)

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FISCHER 344 RATS MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Septum, Inflammation	15 (30%)	11 (22%)	18 (36%)	17 (34%)
Turbinate, Inflammation	11 (22%)	4 (8%)	18 (36%)	16 (32%)
Trachea	(50)	(50)	(50)	(50)
Inflammation	3 (6%)	1 (2%)	4 (8%)	2 (4%)

SPECIAL SENSES SYSTEM

Eye	(50)	(50)	(50)	(50)
Choroid, Hyperplasia		1 (2%)		
Ciliary Body, Iris, Inflammation		1 (2%)	1 (2%)	
Cornea, Inflammation		1 (2%)	1 (2%)	
Lens, Degeneration	1 (2%)	2 (4%)		5 (10%)
Retina, Atrophy	2 (4%)	3 (6%)		3 (6%)
Retina, Degeneration	2 (4%)		1 (2%)	4 (8%)
Retina, Necrosis	1 (2%)			
Sclera, Mineralization	27 (54%)	30 (60%)	26 (52%)	22 (44%)
Harderian Gland	(50)	(50)	(50)	(50)
Hyperplasia		1 (2%)	2 (4%)	
Infiltration Cellular, Lymphoid	1 (2%)			
Infiltration Cellular, Mononuclear Cell	3 (6%)			
Inflammation	9 (18%)	8 (16%)	4 (8%)	10 (20%)
Zymbal's Gland	(0)	(0)	(1)	(1)

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Accumulation, Hyaline Droplet	2 (4%)	1 (2%)	3 (6%)	1 (2%)
Cyst	1 (2%)	1 (2%)	1 (2%)	
Mineralization	37 (74%)	43 (86%)	43 (86%)	44 (88%)
Necrosis		1 (2%)		
Nephropathy	49 (98%)	48 (96%)	50 (100%)	47 (94%)
Pigmentation	8 (16%)	7 (14%)	3 (6%)	4 (8%)
Renal Tubule, Degeneration	1 (2%)			
Transitional Epithelium, Hyperplasia		1 (2%)	1 (2%)	
Urinary Bladder	(50)	(50)	(50)	(50)
Hemorrhage		1 (2%)	1 (2%)	
Inflammation		1 (2%)	1 (2%)	
Ulcer		1 (2%)		
Transitional Epithelium, Hyperplasia			1 (2%)	



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<b>FISCHER 344 RATS MALE</b>	<b>0 MG/KG</b>	<b>20 MG/KG</b>	<b>40 MG/KG</b>	<b>80 MG/KG</b>
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\*\*\* END OF MALE \*\*\*

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FISCHER 344 RATS FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
<b>Disposition Summary</b>				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	10	16	14	14
Natural Death	2	4	2	4
Survivors				
Natural Death		1		
Terminal Sacrifice	38	29	34	32
Animals Examined Microscopically	50	50	50	50

#### ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(50)	(49)	(50)	(50)
Erosion		1 (2%)		
Inflammation			1 (2%)	1 (2%)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Parasite Metazoan				1 (2%)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Parasite Metazoan	4 (8%)	7 (14%)	7 (14%)	3 (6%)
Intestine Small, Ileum	(50)	(50)	(50)	(49)
Liver	(50)	(50)	(50)	(50)
Angiectasis	4 (8%)	1 (2%)	4 (8%)	2 (4%)
Basophilic Focus	44 (88%)	46 (92%)	47 (94%)	45 (90%)
Clear Cell Focus	7 (14%)	6 (12%)	5 (10%)	5 (10%)
Degeneration, Cystic				1 (2%)
Eosinophilic Focus	10 (20%)	8 (16%)	11 (22%)	14 (28%)
Fatty Change, Focal	12 (24%)	8 (16%)	10 (20%)	8 (16%)
Fatty Change, Diffuse	7 (14%)	5 (10%)	7 (14%)	4 (8%)
Hematopoietic Cell Proliferation	4 (8%)	3 (6%)	6 (12%)	2 (4%)
Hepatodiaphragmatic Nodule	3 (6%)	7 (14%)	3 (6%)	5 (10%)
Inflammation	39 (78%)	45 (90%)	46 (92%)	41 (82%)
Mixed Cell Focus	19 (38%)	12 (24%)	15 (30%)	18 (36%)
Necrosis	3 (6%)	1 (2%)		4 (8%)
Regeneration				1 (2%)
Vacuolization Cytoplasmic, Focal		3 (6%)	3 (6%)	2 (4%)
Vacuolization Cytoplasmic, Diffuse			2 (4%)	1 (2%)
Bile Duct, Cyst		1 (2%)	2 (4%)	

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FISCHER 344 RATS FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Bile Duct, Hyperplasia	27 (54%)	28 (56%)	15 (30%)	16 (32%)
Centrilobular, Degeneration	8 (16%)	7 (14%)	6 (12%)	5 (10%)
Oval Cell, Hyperplasia	13 (26%)	22 (44%)	16 (32%)	17 (34%)
Serosa, Inflammation		1 (2%)		
Mesentery	(18)	(16)	(12)	(9)
Fat, Necrosis	17 (94%)	16 (100%)	12 (100%)	9 (100%)
Oral Mucosa	(15)	(9)	(12)	(7)
Gingival, Hyperplasia, Squamous	14 (93%)	9 (100%)	12 (100%)	7 (100%)
Pancreas	(50)	(50)	(50)	(50)
Basophilic Focus	1 (2%)	1 (2%)		
Infiltration Cellular, Mononuclear Cell	9 (18%)	1 (2%)	6 (12%)	6 (12%)
Inflammation, Chronic Active	8 (16%)	12 (24%)	16 (32%)	14 (28%)
Vacuolization Cytoplasmic		1 (2%)		
Acinus, Atrophy	7 (14%)	9 (18%)	10 (20%)	14 (28%)
Acinus, Hyperplasia	1 (2%)			
Artery, Inflammation, Chronic Active			1 (2%)	
Duct, Cyst	3 (6%)	3 (6%)	5 (10%)	1 (2%)
Salivary Glands	(50)	(50)	(50)	(50)
Atrophy			1 (2%)	
Inflammation		1 (2%)	1 (2%)	
Necrosis				1 (2%)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Edema		2 (4%)		
Erosion			1 (2%)	
Hyperplasia, Squamous		1 (2%)	1 (2%)	
Inflammation	1 (2%)	2 (4%)	3 (6%)	
Mineralization				1 (2%)
Ulcer	1 (2%)	1 (2%)	2 (4%)	
Stomach, Glandular	(50)	(50)	(50)	(50)
Amyloid Deposition				1 (2%)
Mineralization			1 (2%)	1 (2%)
Glands, Cyst	2 (4%)	1 (2%)		
Tongue	(0)	(0)	(1)	(0)
Hyperplasia, Squamous			1 (100%)	
Tooth	(19)	(11)	(11)	(14)
Peridontal Tissue, Inflammation	19 (100%)	11 (100%)	11 (100%)	14 (100%)
<b>CARDIOVASCULAR SYSTEM</b>				
Blood Vessel	(50)	(50)	(50)	(50)

TDMS No. 88123 - 05  
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P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)  
 FORMAMIDE  
 CAS Number: 75-12-7  
 Pathologist: SELLS, D. - KURTZ, F.

Date Report Requested: 12/05/2005  
 Time Report Requested: 14:23:30  
 First Dose M/F: 03/21/01 / 03/20/01  
 Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Aorta, Inflammation, Focal		1 (2%)		
Heart	(50)	(50)	(50)	(50)
Angiectasis		1 (2%)		
Cardiomyopathy	44 (88%)	47 (94%)	40 (80%)	37 (74%)
Degeneration				1 (2%)
Inflammation	1 (2%)	1 (2%)	2 (4%)	
Thrombosis	1 (2%)			

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Angiectasis	39 (78%)	38 (76%)	38 (76%)	43 (86%)
Degeneration, Cystic	5 (10%)	7 (14%)	5 (10%)	10 (20%)
Hyperplasia	20 (40%)	22 (44%)	8 (16%)	15 (30%)
Hypertrophy	11 (22%)	10 (20%)	11 (22%)	13 (26%)
Infiltration Cellular, Mononuclear Cell	2 (4%)			
Necrosis				1 (2%)
Vacuolization Cytoplasmic	30 (60%)	16 (32%)	23 (46%)	19 (38%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Hyperplasia	3 (6%)	2 (4%)	4 (8%)	1 (2%)
Infiltration Cellular, Mononuclear Cell	3 (6%)		1 (2%)	
Necrosis				1 (2%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Parathyroid Gland	(46)	(47)	(46)	(47)
Pituitary Gland	(50)	(50)	(50)	(50)
Angiectasis	36 (72%)	25 (50%)	23 (46%)	24 (48%)
Cyst	9 (18%)	10 (20%)	12 (24%)	5 (10%)
Cytoplasmic Alteration				1 (2%)
Hemorrhage		1 (2%)		
Pars Distalis, Cyst	1 (2%)			1 (2%)
Pars Distalis, Hyperplasia	24 (48%)	21 (42%)	26 (52%)	25 (50%)
Pars Nervosa, Cyst				1 (2%)
Thyroid Gland	(50)	(50)	(50)	(50)
C-cell, Hyperplasia	24 (48%)	24 (48%)	34 (68%)	27 (54%)
Follicle, Cyst	1 (2%)			
Follicular Cell, Hyperplasia	2 (4%)			

GENERAL BODY SYSTEM

None

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FISCHER 344 RATS FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
<b>GENITAL SYSTEM</b>				
Clitoral Gland	(50)	(50)	(50)	(49)
Cyst	1 (2%)			1 (2%)
Hyperplasia	5 (10%)	7 (14%)	6 (12%)	8 (16%)
Inflammation	36 (72%)	39 (78%)	43 (86%)	37 (76%)
Duct, Cyst	11 (22%)	14 (28%)	23 (46%)	16 (33%)
Ovary	(50)	(50)	(50)	(50)
Congestion				1 (2%)
Cyst	9 (18%)		9 (18%)	5 (10%)
Necrosis			1 (2%)	
Uterus	(50)	(50)	(50)	(50)
Adenomyosis	1 (2%)		1 (2%)	2 (4%)
Cyst	1 (2%)		1 (2%)	
Decidual Reaction			1 (2%)	
Hemorrhage		1 (2%)		
Inflammation			4 (8%)	1 (2%)
Endometrium, Hyperplasia, Cystic	8 (16%)	7 (14%)	6 (12%)	5 (10%)
Vagina	(0)	(2)	(0)	(0)
Inflammation		1 (50%)		
<b>HEMATOPOIETIC SYSTEM</b>				
Bone Marrow	(50)	(50)	(50)	(50)
Atrophy	1 (2%)	2 (4%)	1 (2%)	1 (2%)
Hyperplasia	14 (28%)	16 (32%)	18 (36%)	13 (26%)
Hyperplasia, Histiocytic	1 (2%)			
Inflammation, Granulomatous	1 (2%)			
Myelofibrosis	1 (2%)	1 (2%)		1 (2%)
Lymph Node	(6)	(5)	(3)	(2)
Ectasia			1 (33%)	
Hyperplasia, Lymphoid	1 (17%)			
Deep Cervical, Ectasia	1 (17%)	2 (40%)		
Deep Cervical, Hyperplasia, Plasma Cell		1 (20%)		
Mediastinal, Ectasia	1 (17%)			
Mediastinal, Hyperplasia, Lymphoid		1 (20%)		
Mediastinal, Inflammation			1 (33%)	
Lymph Node, Mandibular	(1)	(0)	(1)	(1)
Ectasia	1 (100%)			1 (100%)

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

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FISCHER 344 RATS FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Ectasia	2 (4%)	1 (2%)	4 (8%)	
Hyperplasia, Histiocytic			1 (2%)	
Hyperplasia, Lymphoid	1 (2%)	1 (2%)		
Spleen	(50)	(50)	(50)	(50)
Hematopoietic Cell Proliferation	40 (80%)	32 (64%)	40 (80%)	40 (80%)
Hyperplasia, Lymphoid, Focal			1 (2%)	
Pigmentation	39 (78%)	39 (78%)	41 (82%)	38 (76%)
Capsule, Thrombosis				1 (2%)
Thymus	(48)	(47)	(47)	(46)
Atrophy	45 (94%)	44 (94%)	43 (91%)	45 (98%)
Pigmentation		1 (2%)		
<b>INTEGUMENTARY SYSTEM</b>				
Mammary Gland	(50)	(50)	(50)	(50)
Cyst	24 (48%)	19 (38%)	20 (40%)	6 (12%)
Hyperplasia	15 (30%)	7 (14%)	7 (14%)	7 (14%)
Hyperplasia, Atypical		1 (2%)		
Skin	(50)	(50)	(50)	(50)
Hyperplasia, Squamous		1 (2%)		
Inflammation	1 (2%)	1 (2%)	1 (2%)	
Ulcer		1 (2%)		
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone	(50)	(50)	(50)	(50)
Osteopetrosis	1 (2%)	1 (2%)		
Skeletal Muscle	(1)	(0)	(1)	(0)
Cyst			1 (100%)	
<b>NERVOUS SYSTEM</b>				
Brain	(50)	(50)	(50)	(50)
Gliosis			2 (4%)	
Hemorrhage		2 (4%)	1 (2%)	1 (2%)
Mineralization	1 (2%)			

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FISCHER 344 RATS FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
<b>RESPIRATORY SYSTEM</b>				
Lung	(50)	(50)	(50)	(50)
Inflammation	5 (10%)	2 (4%)	5 (10%)	8 (16%)
Metaplasia, Squamous	1 (2%)		1 (2%)	
Alveolar Epithelium, Hyperplasia	12 (24%)	6 (12%)	15 (30%)	6 (12%)
Alveolus, Infiltration Cellular, Histiocyte	45 (90%)	43 (86%)	46 (92%)	43 (86%)
Serosa, Fibrosis			1 (2%)	
Nose	(50)	(50)	(50)	(50)
Glands, Cyst	1 (2%)			
Lateral Wall, Inflammation	4 (8%)	5 (10%)	3 (6%)	2 (4%)
Nasolacrimal Duct, Inflammation	6 (12%)	6 (12%)	5 (10%)	2 (4%)
Nasopharyngeal Duct, Inflammation		3 (6%)		
Nerve, Degeneration			1 (2%)	
Olfactory Epithelium, Metaplasia			1 (2%)	2 (4%)
Respiratory Epithelium, Hyperplasia	37 (74%)	31 (62%)	25 (50%)	22 (44%)
Septum, Inflammation	10 (20%)	9 (18%)	12 (24%)	6 (12%)
Turbinate, Inflammation	20 (40%)	11 (22%)	12 (24%)	9 (18%)
Trachea	(50)	(50)	(50)	(50)
Inflammation	7 (14%)	6 (12%)	3 (6%)	7 (14%)
<b>SPECIAL SENSES SYSTEM</b>				
Eye	(50)	(50)	(50)	(50)
Atrophy		1 (2%)		
Inflammation		1 (2%)		
Anterior Chamber, Ciliary Body Iris, Inflammation				1 (2%)
Cornea, Inflammation			2 (4%)	1 (2%)
Iris, Inflammation			1 (2%)	
Lens, Degeneration		2 (4%)	1 (2%)	3 (6%)
Retina, Atrophy		1 (2%)	1 (2%)	2 (4%)
Retina, Degeneration		1 (2%)	1 (2%)	
Sclera, Mineralization	5 (10%)	2 (4%)		
Harderian Gland	(50)	(50)	(50)	(50)
Degeneration		1 (2%)		
Infiltration Cellular, Mononuclear Cell		1 (2%)		1 (2%)
Inflammation	13 (26%)	11 (22%)	17 (34%)	17 (34%)
Zymbal's Gland	(0)	(0)	(0)	(1)

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FISCHER 344 RATS FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Accumulation, Hyaline Droplet	1 (2%)			
Cyst			1 (2%)	
Infarct	3 (6%)			2 (4%)
Infiltration Cellular, Mononuclear Cell		1 (2%)		
Inflammation	2 (4%)			
Mineralization	43 (86%)	42 (84%)	36 (72%)	43 (86%)
Nephropathy	44 (88%)	45 (90%)	46 (92%)	45 (90%)
Pigmentation	3 (6%)	6 (12%)	2 (4%)	2 (4%)
Pelvis, Inflammation, Suppurative			1 (2%)	
Transitional Epithelium, Hyperplasia	4 (8%)		1 (2%)	1 (2%)
Urinary Bladder	(50)	(50)	(50)	(50)
Infiltration Cellular, Mononuclear Cell			1 (2%)	1 (2%)
Inflammation	1 (2%)	1 (2%)		

\*\*\* END OF REPORT \*\*\*