

**TDMS No.** 99024 - 07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** RATS/F 344

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**

Androstenedione  
**CAS Number:** 63-05-8

**Date Report Requested:** 08/08/2008  
**Time Report Requested:** 08:20:33  
**First Dose M/F:** 02/03/03 / 02/03/03  
**Lab:** SRI

F1\_R2

**C Number:** C99024C  
**Lock Date:** 06/29/2006  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 2.0.0

FISCHER 344 RATS MALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Disposition Summary</b>				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	22	9	17	13
Natural Death	7	8	4	10
Survivors				
Natural Death	1			
Terminal Sacrifice	20	33	29	27
Animals Examined Microscopically	50	50	50	50

## ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Foreign Body	1 (2%)			
Inflammation, Suppurative	1 (2%)			
Intestine Large, Cecum	(47)	(46)	(47)	(48)
Edema			1 (2%)	
Intestine Large, Colon	(44)	(43)	(47)	(44)
Edema	2 (5%)	1 (2%)	4 (9%)	
Fibrosis	1 (2%)			
Intestine Large, Rectum	(46)	(46)	(47)	(47)
Hemorrhage			1 (2%)	
Intestine Small, Duodenum	(48)	(47)	(49)	(47)
Hemorrhage			1 (2%)	
Intestine Small, Ileum	(44)	(46)	(47)	(44)
Intestine Small, Jejunum	(44)	(44)	(47)	(42)
Hemorrhage			1 (2%)	
Liver	(50)	(50)	(50)	(50)
Angiectasis		1 (2%)		1 (2%)
Basophilic Focus	17 (34%)	29 (58%)	29 (58%)	33 (66%)
Clear Cell Focus	13 (26%)	21 (42%)	23 (46%)	14 (28%)
Clear Cell Focus, Multiple				3 (6%)
Degeneration, Cystic	10 (20%)	3 (6%)	12 (24%)	7 (14%)
Eosinophilic Focus	3 (6%)	10 (20%)	7 (14%)	13 (26%)
Hematopoietic Cell Proliferation		1 (2%)		
Hemorrhage			1 (2%)	
Hepatodiaphragmatic Nodule	7 (14%)	8 (16%)	7 (14%)	10 (20%)
Infiltration Cellular, Mixed Cell	10 (20%)	3 (6%)	11 (22%)	4 (8%)
Inflammation, Chronic	1 (2%)			
Mixed Cell Focus	1 (2%)	2 (4%)	1 (2%)	4 (8%)
Necrosis, Focal	4 (8%)		1 (2%)	1 (2%)
Tension Lipidosis	1 (2%)			

FISCHER 344 RATS MALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
Thrombosis			1 (2%)	
Bile Duct, Hyperplasia	44 (88%)	44 (88%)	40 (80%)	43 (86%)
Hepatocyte, Hyperplasia	1 (2%)		2 (4%)	2 (4%)
Hepatocyte, Vacuolization Cytoplasmic	25 (50%)	18 (36%)	14 (28%)	9 (18%)
Kupffer Cell, Pigmentation	1 (2%)			
Mesentery	(18)	(13)	(12)	(18)
Accessory Spleen	4 (22%)	1 (8%)		3 (17%)
Hemorrhage		1 (8%)		
Inflammation, Suppurative	1 (6%)			
Inflammation, Granulomatous	1 (6%)			
Fat, Necrosis	13 (72%)	10 (77%)	10 (83%)	15 (83%)
Pancreas	(50)	(50)	(50)	(50)
Atrophy	17 (34%)	30 (60%)	19 (38%)	21 (42%)
Cyst	5 (10%)	3 (6%)	7 (14%)	
Infiltration Cellular, Lymphocyte				1 (2%)
Acinus, Cytoplasmic Alteration	4 (8%)	3 (6%)	2 (4%)	2 (4%)
Acinus, Hyperplasia, Focal	1 (2%)	3 (6%)	3 (6%)	2 (4%)
Arteriole, Inflammation, Chronic		1 (2%)		
Salivary Glands	(50)	(50)	(50)	(50)
Atrophy				1 (2%)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Edema	4 (8%)	7 (14%)	4 (8%)	4 (8%)
Erosion	1 (2%)			
Hemorrhage			1 (2%)	
Inflammation, Chronic Active		1 (2%)		
Ulcer	6 (12%)	7 (14%)	4 (8%)	5 (10%)
Epithelium, Hyperplasia	5 (10%)	6 (12%)	3 (6%)	5 (10%)
Stomach, Glandular	(50)	(50)	(50)	(50)
Edema				1 (2%)
Erosion	6 (12%)	2 (4%)	4 (8%)	5 (10%)
Ulcer	2 (4%)	1 (2%)	2 (4%)	1 (2%)
Epithelium, Cyst	1 (2%)			1 (2%)
Epithelium, Hyperplasia	1 (2%)		2 (4%)	2 (4%)
Muscularis, Hyperplasia				1 (2%)
Tongue	(1)	(0)	(0)	(2)
Hyperplasia, Squamous				2 (100%)
Tooth	(0)	(0)	(1)	(0)
Malformation			1 (100%)	

CARDIOVASCULAR SYSTEM

Blood Vessel	(2)	(3)	(1)	(0)
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	47 (94%)	47 (94%)	48 (96%)	48 (96%)
Thrombosis	6 (12%)	3 (6%)	3 (6%)	2 (4%)

FISCHER 344 RATS MALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>ENDOCRINE SYSTEM</b>				
Adrenal Cortex	(50)	(50)	(50)	(50)
Accessory Adrenal Cortical Nodule	1 (2%)	3 (6%)	1 (2%)	1 (2%)
Degeneration, Fatty	22 (44%)	27 (54%)	25 (50%)	21 (42%)
Hyperplasia, Focal	5 (10%)	4 (8%)	3 (6%)	1 (2%)
Hypertrophy, Focal	3 (6%)	3 (6%)	2 (4%)	4 (8%)
Hypertrophy, Diffuse				1 (2%)
Necrosis	1 (2%)			
Bilateral, Necrosis		1 (2%)		
Adrenal Medulla	(50)	(50)	(50)	(50)
Hyperplasia	5 (10%)	8 (16%)	6 (12%)	10 (20%)
Infiltration Cellular, Lymphocyte				1 (2%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Hyperplasia	5 (10%)	4 (8%)	2 (4%)	9 (18%)
Parathyroid Gland	(48)	(50)	(50)	(48)
Cyst		1 (2%)		
Hyperplasia				1 (2%)
Pituitary Gland	(50)	(50)	(49)	(50)
Pars Distalis, Angiectasis	1 (2%)	1 (2%)		2 (4%)
Pars Distalis, Cyst	2 (4%)	3 (6%)	1 (2%)	4 (8%)
Pars Distalis, Hyperplasia, Focal	13 (26%)	15 (30%)	21 (43%)	18 (36%)
Pars Intermedia, Angiectasis				1 (2%)
Pars Intermedia, Cyst			2 (4%)	
Pars Intermedia, Hyperplasia, Focal			1 (2%)	
Rathke's Cleft, Cyst			1 (2%)	
Thyroid Gland	(50)	(50)	(50)	(50)
Ultimobranchial Cyst	1 (2%)	1 (2%)	2 (4%)	
C-cell, Hyperplasia	32 (64%)	33 (66%)	26 (52%)	20 (40%)
Follicle, Cyst		1 (2%)	5 (10%)	1 (2%)
Follicular Cell, Hyperplasia		2 (4%)	2 (4%)	1 (2%)
<b>GENERAL BODY SYSTEM</b>				
Tissue NOS	(0)	(0)	(1)	(0)
<b>GENITAL SYSTEM</b>				
Coagulating Gland	(0)	(3)	(2)	(0)
Inflammation, Suppurative		1 (33%)		
Epithelium, Hyperplasia		1 (33%)		
Epididymis	(50)	(50)	(50)	(50)

FISCHER 344 RATS MALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
Atrophy	1 (2%)			
Degeneration	1 (2%)			
Inflammation, Chronic				1 (2%)
Penis	(0)	(1)	(0)	(0)
Inflammation, Chronic		1 (100%)		
Preputial Gland	(50)	(50)	(50)	(50)
Cyst	4 (8%)	2 (4%)		7 (14%)
Fibrosis				1 (2%)
Hyperplasia	1 (2%)	1 (2%)		1 (2%)
Inflammation, Chronic	47 (94%)	48 (96%)	41 (82%)	43 (86%)
Prostate	(50)	(50)	(50)	(50)
Inflammation, Chronic	25 (50%)	24 (48%)	20 (40%)	20 (40%)
Epithelium, Hyperplasia	9 (18%)	18 (36%)	9 (18%)	12 (24%)
Seminal Vesicle	(50)	(50)	(50)	(50)
Testes	(50)	(50)	(50)	(50)
Malformation				1 (2%)
Thrombosis	1 (2%)			
Germinal Epithelium, Atrophy	9 (18%)	8 (16%)	10 (20%)	11 (22%)
Interstitial Cell, Hyperplasia	4 (8%)	2 (4%)	2 (4%)	2 (4%)

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Hyperplasia	4 (8%)	4 (8%)	4 (8%)	7 (14%)
Myelofibrosis	1 (2%)	2 (4%)		
Lymph Node	(25)	(18)	(16)	(13)
Mediastinal, Angiectasis		1 (6%)		
Mediastinal, Ectasia	1 (4%)		2 (13%)	
Mediastinal, Fibrosis	1 (4%)			
Mediastinal, Hemorrhage		1 (6%)	1 (6%)	
Mediastinal, Hyperplasia, Histiocytic	1 (4%)			
Mediastinal, Hyperplasia, Lymphoid	3 (12%)	3 (17%)		
Pancreatic, Angiectasis				1 (8%)
Pancreatic, Atrophy	1 (4%)			
Pancreatic, Ectasia	3 (12%)	1 (6%)	2 (13%)	
Pancreatic, Hemorrhage	1 (4%)		1 (6%)	
Pancreatic, Hyperplasia, Histiocytic	7 (28%)		3 (19%)	2 (15%)
Pancreatic, Hyperplasia, Lymphoid	1 (4%)			
Pancreatic, Necrosis		1 (6%)		
Lymph Node, Mandibular	(1)	(0)	(1)	(2)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Atrophy	1 (2%)			
Ectasia	3 (6%)	5 (10%)	7 (14%)	5 (10%)
Fibrosis	1 (2%)			
Hemorrhage			2 (4%)	

FISCHER 344 RATS MALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
Hyperplasia, Histiocytic	25 (50%)	13 (26%)	25 (50%)	19 (38%)
Hyperplasia, Lymphoid	1 (2%)	2 (4%)	1 (2%)	1 (2%)
Infiltration Cellular, Eosinophil	1 (2%)			
Infiltration Cellular, Plasma Cell	1 (2%)			
Pigmentation				2 (4%)
Spleen	(50)	(50)	(50)	(50)
Accessory Spleen		1 (2%)	1 (2%)	
Fibrosis	6 (12%)	1 (2%)	4 (8%)	
Hematopoietic Cell Proliferation	2 (4%)		4 (8%)	2 (4%)
Hemorrhage	2 (4%)			
Hyperplasia, Histiocytic	1 (2%)			1 (2%)
Hyperplasia, Lymphoid	1 (2%)			
Necrosis	2 (4%)	1 (2%)	1 (2%)	
Pigmentation	12 (24%)	12 (24%)	8 (16%)	12 (24%)
Lymphoid Follicle, Hyperplasia		3 (6%)	4 (8%)	3 (6%)
Red Pulp, Hyperplasia			1 (2%)	
Thymus	(50)	(50)	(50)	(49)
Atrophy			2 (4%)	
Cyst			1 (2%)	
Hemorrhage		1 (2%)	1 (2%)	
Hyperplasia, Lymphoid	2 (4%)			
<b>INTEGUMENTARY SYSTEM</b>				
Mammary Gland	(48)	(50)	(50)	(50)
Cyst	8 (17%)	4 (8%)	4 (8%)	11 (22%)
Hyperplasia	38 (79%)	37 (74%)	33 (66%)	42 (84%)
Inflammation, Granulomatous	1 (2%)			
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion	3 (6%)	1 (2%)	1 (2%)	2 (4%)
Fibrosis		2 (4%)	1 (2%)	3 (6%)
Hyperkeratosis	5 (10%)	3 (6%)	6 (12%)	7 (14%)
Inflammation, Suppurative				1 (2%)
Inflammation, Granulomatous				1 (2%)
Inflammation, Chronic			1 (2%)	1 (2%)
Ulcer				1 (2%)
Epidermis, Hyperplasia	3 (6%)	1 (2%)	3 (6%)	3 (6%)
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone	(50)	(50)	(50)	(50)
Cranium, Osteopetrosis	1 (2%)			1 (2%)
Skeletal Muscle	(8)	(1)	(3)	(5)
Fibrosis	3 (38%)		2 (67%)	1 (20%)

FISCHER 344 RATS MALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>NERVOUS SYSTEM</b>				
Brain	(50)	(50)	(50)	(50)
Compression	13 (26%)	8 (16%)	7 (14%)	9 (18%)
Gliosis	1 (2%)			
Hemorrhage	3 (6%)		2 (4%)	4 (8%)
Necrosis				2 (4%)
Spinal Cord	(6)	(1)	(0)	(5)
<b>RESPIRATORY SYSTEM</b>				
Lung	(50)	(50)	(50)	(50)
Congestion			1 (2%)	
Foreign Body			1 (2%)	
Hemorrhage	1 (2%)	1 (2%)	1 (2%)	1 (2%)
Infiltration Cellular, Histiocyte	17 (34%)	17 (34%)	18 (36%)	18 (36%)
Inflammation, Granulomatous		1 (2%)	1 (2%)	1 (2%)
Inflammation, Chronic			1 (2%)	3 (6%)
Metaplasia, Osseous		1 (2%)	1 (2%)	
Alveolar Epithelium, Hyperplasia	6 (12%)	7 (14%)	8 (16%)	4 (8%)
Serosa, Cyst				1 (2%)
Nose	(50)	(50)	(50)	(50)
Foreign Body	5 (10%)	13 (26%)	5 (10%)	
Infiltration Cellular, Lymphocyte			1 (2%)	
Inflammation, Suppurative	3 (6%)	4 (8%)	1 (2%)	1 (2%)
Inflammation, Chronic	4 (8%)	3 (6%)	5 (10%)	1 (2%)
Nasolacrimal Duct, Inflammation, Chronic				1 (2%)
Respiratory Epithelium, Hyperplasia	8 (16%)	11 (22%)	7 (14%)	3 (6%)
Sinus, Inflammation, Suppurative	1 (2%)			
Vomeranasal Organ, Atrophy			1 (2%)	
<b>SPECIAL SENSES SYSTEM</b>				
Eye	(48)	(46)	(50)	(49)
Cataract	1 (2%)		1 (2%)	2 (4%)
Ciliary Body, Hyperplasia	1 (2%)			
Retina, Degeneration	1 (2%)	1 (2%)	1 (2%)	4 (8%)
Retina, Edema				1 (2%)
Sclera, Metaplasia, Osseous		3 (7%)	2 (4%)	1 (2%)
Harderian Gland	(50)	(50)	(50)	(50)
Infiltration Cellular, Lymphocyte			1 (2%)	
Inflammation, Chronic				1 (2%)

FISCHER 344 RATS MALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
Necrosis Zymbal's Gland	1 (2%) (0)	(0)	(1)	(0)
<b>URINARY SYSTEM</b>				
Kidney	(49)	(50)	(50)	(50)
Cyst				1 (2%)
Hydronephrosis				1 (2%)
Infarct	3 (6%)	1 (2%)		
Nephropathy	42 (86%)	48 (96%)	46 (92%)	44 (88%)
Renal Tubule, Accumulation, Hyaline Droplet	1 (2%)	1 (2%)		1 (2%)
Renal Tubule, Necrosis	1 (2%)	1 (2%)	2 (4%)	
Renal Tubule, Pigmentation	5 (10%)	2 (4%)	6 (12%)	6 (12%)
Urinary Bladder	(50)	(50)	(50)	(50)
Calculus Micro Observation Only		1 (2%)		
Hemorrhage				1 (2%)
Inflammation, Chronic		1 (2%)		
Transitional Epithelium, Hyperplasia		2 (4%)		

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



FISCHER 344 RATS FEMALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<b>Disposition Summary</b>				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	10	7	12	9
Natural Death	2	6	5	4
Survivors				
Natural Death		1		
Terminal Sacrifice	38	36	33	37
Animals Examined Microscopically	50	50	50	50

## ALIMENTARY SYSTEM

Intestine Large, Rectum	(49)	(47)	(47)	(48)
Edema	1 (2%)			
Intestine Small, Ileum	(48)	(46)	(45)	(48)
Serosa, Inflammation, Chronic	1 (2%)			
Liver	(50)	(50)	(50)	(50)
Angiectasis		1 (2%)		1 (2%)
Basophilic Focus	47 (94%)	46 (92%)	42 (84%)	38 (76%)
Clear Cell Focus	14 (28%)	10 (20%)	11 (22%)	14 (28%)
Degeneration, Cystic				1 (2%)
Eosinophilic Focus	5 (10%)		4 (8%)	
Fibrosis	1 (2%)	1 (2%)		
Hematopoietic Cell Proliferation	1 (2%)			
Hemorrhage				1 (2%)
Hepatodiaphragmatic Nodule	10 (20%)	9 (18%)	11 (22%)	9 (18%)
Infiltration Cellular, Mixed Cell	21 (42%)	33 (66%)	32 (64%)	31 (62%)
Mixed Cell Focus	1 (2%)		2 (4%)	
Necrosis, Focal			1 (2%)	1 (2%)
Bile Duct, Hyperplasia	12 (24%)	16 (32%)	18 (36%)	24 (48%)
Centrilobular, Necrosis				1 (2%)
Hepatocyte, Vacuolization Cytoplasmic	6 (12%)	4 (8%)	7 (14%)	5 (10%)
Kupffer Cell, Pigmentation	2 (4%)			
Mesentery	(13)	(14)	(15)	(15)
Accessory Spleen	2 (15%)		3 (20%)	2 (13%)
Fat, Necrosis	12 (92%)	14 (100%)	14 (93%)	12 (80%)
Oral Mucosa	(0)	(1)	(0)	(0)
Pancreas	(50)	(50)	(50)	(50)
Atrophy	10 (20%)	10 (20%)	16 (32%)	26 (52%)
Cyst	3 (6%)	7 (14%)	4 (8%)	2 (4%)
Infiltration Cellular, Lymphocyte			1 (2%)	3 (6%)
Acinus, Cytoplasmic Alteration		4 (8%)	1 (2%)	2 (4%)

FISCHER 344 RATS FEMALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
Acinus, Hyperplasia, Focal Salivary Glands	(50)	(50)	1 (2%) (50)	3 (6%) (50)
Atrophy Vacuolization Cytoplasmic		1 (2%) 1 (2%)		
Stomach, Forestomach	(50)	(50)	(50)	(50)
Edema	1 (2%)	3 (6%)	2 (4%)	3 (6%)
Inflammation, Chronic Active	1 (2%)			
Ulcer	2 (4%)	2 (4%)	2 (4%)	2 (4%)
Epithelium, Hyperplasia	3 (6%)	1 (2%)	2 (4%)	6 (12%)
Stomach, Glandular	(50)	(50)	(50)	(50)
Edema				2 (4%)
Erosion				3 (6%)
Ulcer			2 (4%)	1 (2%)
Epithelium, Hyperplasia	1 (2%)	2 (4%)		1 (2%)
Tongue	(1)	(0)	(1)	(1)
Hyperkeratosis				1 (100%)
Epithelium, Hyperplasia	1 (100%)			
<b>CARDIOVASCULAR SYSTEM</b>				
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	46 (92%)	43 (86%)	43 (86%)	48 (96%)
Thrombosis		2 (4%)	1 (2%)	1 (2%)
<b>ENDOCRINE SYSTEM</b>				
Adrenal Cortex	(50)	(50)	(50)	(50)
Accessory Adrenal Cortical Nodule	1 (2%)	3 (6%)	1 (2%)	
Angiectasis	1 (2%)			
Degeneration, Fatty	15 (30%)	20 (40%)	24 (48%)	13 (26%)
Hematopoietic Cell Proliferation		2 (4%)		1 (2%)
Hyperplasia, Focal	1 (2%)	4 (8%)	1 (2%)	2 (4%)
Hypertrophy, Focal	12 (24%)	10 (20%)	9 (18%)	2 (4%)
Hypertrophy, Diffuse		1 (2%)		
Necrosis		1 (2%)		
Capsule, Developmental Malformation		1 (2%)		
Adrenal Medulla	(50)	(50)	(50)	(50)
Hyperplasia	1 (2%)	1 (2%)	3 (6%)	2 (4%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Hyperplasia		4 (8%)	1 (2%)	11 (22%)
Parathyroid Gland	(49)	(48)	(48)	(45)
Hyperplasia				1 (2%)
Pituitary Gland	(50)	(50)	(49)	(50)
Pars Distalis, Angiectasis		1 (2%)	1 (2%)	3 (6%)

FISCHER 344 RATS FEMALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
Pars Distalis, Cyst	18 (36%)	12 (24%)	14 (29%)	13 (26%)
Pars Distalis, Hyperplasia, Focal	20 (40%)	20 (40%)	14 (29%)	19 (38%)
Pars Intermedia, Angiectasis	1 (2%)			
Rathke's Cleft, Cyst	3 (6%)	1 (2%)	4 (8%)	
Thyroid Gland	(50)	(50)	(50)	(50)
Ultimobranchial Cyst			2 (4%)	1 (2%)
C-cell, Hyperplasia	27 (54%)	33 (66%)	24 (48%)	25 (50%)
Follicle, Cyst		1 (2%)	2 (4%)	1 (2%)
Follicular Cell, Hyperplasia	1 (2%)			
<b>GENERAL BODY SYSTEM</b>				
None				
<b>GENITAL SYSTEM</b>				
Clitoral Gland	(50)	(50)	(50)	(50)
Cyst	6 (12%)	8 (16%)	8 (16%)	4 (8%)
Hyperplasia	3 (6%)	4 (8%)		3 (6%)
Inflammation, Suppurative	1 (2%)		1 (2%)	1 (2%)
Inflammation, Chronic	23 (46%)	26 (52%)	18 (36%)	24 (48%)
Ovary	(50)	(50)	(50)	(50)
Angiectasis				1 (2%)
Cyst	3 (6%)	5 (10%)	2 (4%)	1 (2%)
Infiltration Cellular, Histiocyte				1 (2%)
Bursa, Dilatation	6 (12%)	6 (12%)	2 (4%)	6 (12%)
Corpus Luteum, Hyperplasia		1 (2%)		
Follicle, Cyst				1 (2%)
Interstitial Cell, Cyst				1 (2%)
Uterus	(50)	(50)	(50)	(50)
Decidual Reaction			1 (2%)	
Hemorrhage		1 (2%)	1 (2%)	1 (2%)
Hyperplasia, Cystic	9 (18%)	8 (16%)	11 (22%)	14 (28%)
Inflammation, Suppurative	1 (2%)			
Thrombosis		1 (2%)		
Epithelium, Hyperplasia			2 (4%)	
<b>HEMATOPOIETIC SYSTEM</b>				
Bone Marrow	(50)	(50)	(50)	(50)
Atrophy		1 (2%)	1 (2%)	
Hyperplasia	3 (6%)	6 (12%)	5 (10%)	1 (2%)
Thrombosis		1 (2%)		

FISCHER 344 RATS FEMALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
Lymph Node	(5)	(10)	(16)	(10)
Congestion			1 (6%)	
Deep Cervical, Ectasia			1 (6%)	
Deep Cervical, Necrosis	1 (20%)			
Mediastinal, Ectasia		2 (20%)	1 (6%)	
Mediastinal, Hemorrhage		3 (30%)	1 (6%)	1 (10%)
Mediastinal, Hyperplasia, Lymphoid	2 (40%)	2 (20%)	3 (19%)	
Mediastinal, Infiltration Cellular, Mast Cell	1 (20%)			
Mediastinal, Pigmentation	1 (20%)			
Pancreatic, Ectasia			1 (6%)	
Pancreatic, Hemorrhage	1 (20%)	2 (20%)	3 (19%)	2 (20%)
Pancreatic, Hyperplasia, Histiocytic			1 (6%)	
Pancreatic, Pigmentation				1 (10%)
Lymph Node, Mandibular	(0)	(0)	(0)	(1)
Lymph Node, Mesenteric	(50)	(50)	(49)	(50)
Ectasia	2 (4%)		3 (6%)	4 (8%)
Hemorrhage			1 (2%)	
Hyperplasia, Histiocytic	29 (58%)	34 (68%)	24 (49%)	19 (38%)
Hyperplasia, Lymphoid		1 (2%)	1 (2%)	1 (2%)
Pigmentation	1 (2%)		2 (4%)	
Spleen	(50)	(49)	(50)	(50)
Fibrosis			1 (2%)	
Hematopoietic Cell Proliferation	5 (10%)	3 (6%)	6 (12%)	2 (4%)
Hemorrhage		1 (2%)	1 (2%)	1 (2%)
Hyperplasia, Lymphoid				1 (2%)
Infiltration Cellular, Mixed Cell				1 (2%)
Pigmentation	43 (86%)	44 (90%)	39 (78%)	36 (72%)
Lymphoid Follicle, Hyperplasia	1 (2%)	2 (4%)	3 (6%)	11 (22%)
Thymus	(50)	(50)	(49)	(50)
Atrophy				1 (2%)
Hemorrhage		1 (2%)		
<b>INTEGUMENTARY SYSTEM</b>				
Mammary Gland	(50)	(50)	(50)	(50)
Cyst	15 (30%)	3 (6%)	9 (18%)	3 (6%)
Hyperplasia	48 (96%)	40 (80%)	35 (70%)	23 (46%)
Inflammation, Suppurative				1 (2%)
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion		1 (2%)		1 (2%)
Hyperkeratosis		1 (2%)		2 (4%)
<b>MUSCULOSKELETAL SYSTEM</b>				

FISCHER 344 RATS FEMALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
Bone	(50)	(50)	(50)	(50)
Hyperostosis				1 (2%)
Skeletal Muscle	(0)	(1)	(0)	(0)
Inflammation, Chronic		1 (100%)		
<b>NERVOUS SYSTEM</b>				
Brain	(50)	(50)	(50)	(50)
Compression	6 (12%)	10 (20%)	4 (8%)	5 (10%)
Hemorrhage	1 (2%)			1 (2%)
Hydrocephalus	1 (2%)	1 (2%)		
<b>RESPIRATORY SYSTEM</b>				
Lung	(50)	(50)	(50)	(50)
Congestion		1 (2%)		
Emphysema		1 (2%)		
Hemorrhage		1 (2%)		
Infiltration Cellular, Histiocyte	31 (62%)	37 (74%)	26 (52%)	27 (54%)
Inflammation, Chronic	1 (2%)	1 (2%)	1 (2%)	1 (2%)
Pigmentation		1 (2%)		
Alveolar Epithelium, Hyperplasia	12 (24%)	13 (26%)	11 (22%)	10 (20%)
Artery, Hypertrophy		1 (2%)		
Nose	(50)	(50)	(50)	(50)
Foreign Body	6 (12%)	4 (8%)	6 (12%)	3 (6%)
Inflammation, Suppurative	3 (6%)	2 (4%)	3 (6%)	
Inflammation, Chronic	3 (6%)	2 (4%)	1 (2%)	
Respiratory Epithelium, Hyperplasia	7 (14%)	8 (16%)	1 (2%)	1 (2%)
<b>SPECIAL SENSES SYSTEM</b>				
Ear	(0)	(1)	(0)	(0)
Inflammation, Suppurative		1 (100%)		
Eye	(49)	(48)	(47)	(49)
Atrophy	1 (2%)	1 (2%)		1 (2%)
Cataract	3 (6%)			1 (2%)
Cornea, Inflammation, Chronic		1 (2%)		
Retina, Degeneration		1 (2%)	3 (6%)	
Sclera, Metaplasia, Osseous	1 (2%)		1 (2%)	
Harderian Gland	(50)	(50)	(50)	(50)
Infiltration Cellular, Lymphocyte			1 (2%)	
Zymbal's Gland	(0)	(0)	(1)	(0)

TDMS No. 99024 - 07

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Androstenedione

CAS Number: 63-05-8

Date Report Requested: 08/08/2008

Time Report Requested: 08:20:33

First Dose M/F: 02/03/03 / 02/03/03

Lab: SRI

---

FISCHER 344 RATS FEMALE	0 MG/KG	10 MG/KG	20 MG/KG	50 MG/KG
<hr/>				
URINARY SYSTEM				
Kidney	(50)	(49)	(50)	(50)
Cyst	2 (4%)			1 (2%)
Glomerulosclerosis		1 (2%)	1 (2%)	
Infarct	2 (4%)		1 (2%)	
Nephropathy	48 (96%)	44 (90%)	43 (86%)	43 (86%)
Renal Tubule, Accumulation, Hyaline Droplet	3 (6%)			2 (4%)
Renal Tubule, Necrosis				1 (2%)
Renal Tubule, Pigmentation	1 (2%)		2 (4%)	3 (6%)
Renal Tubule, Vacuolization Cytoplasmic		1 (2%)		
Urinary Bladder	(50)	(50)	(50)	(50)

---

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