

TDMS No. 20304 - 01  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/SD

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

Date Report Requested: 07/15/2008  
Time Report Requested: 10:22:40  
First Dose M/F: NA / 03/26/04  
Lab: BAT

TEF evaluation (PCB 118)  
CAS Number: 31508-00-6

C\_T\_nostop

**C Number:** C20304

**Lock Date:** 10/12/2006

**Cage Range:** ALL

**Date Range:** ALL

**Reasons For Removal:** 25022 ACCK                                  25021 TSAC                                  25020 NATD  
25019 MSAC    25018 DACC

**Removal Date Range:** ALL

**Treatment Groups:** Include 001 0 UG/KG                                  Include 002 10 UG/KG                                  Include 003 30 UG/KG  
Include 004 100 UG/KG                                  Include 005 220 UG/KG                                  Include 006 460 UG/KG  
Include 007 1000 UG/KG                                  Include 008 4600 UG/KG

**Study Gender:** Female

**TDMSE Version:** 2.0.0

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SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG
<b>Disposition Summary</b>						
Animals Initially in Study	80	30	30	80	80	80
Early Deaths						
Dosing Accident				1		
Moribund Sacrifice	27			22	22	17
Natural Death	4	2		9	5	5
Survivors						
Terminal Sacrifice	21			20	25	30
Animals Examined Microscopically	52	2		52	52	52

**ALIMENTARY SYSTEM**

Esophagus	(51)	(2)	(0)	(52)	(52)	(52)
Ulcer						1 (2%)
Muscularis, Degeneration						
Muscularis, Inflammation				3 (6%)		1 (2%)
Intestine Large, Cecum	(52)	(2)	(0)	(51)	(51)	(52)
Degeneration, Fatty						
Inflammation					1 (2%)	1 (2%)
Ulcer					1 (2%)	
Artery, Inflammation, Chronic Active						1 (2%)
Intestine Large, Colon	(52)	(2)	(0)	(52)	(52)	(52)
Parasite Metazoan	1 (2%)					
Artery, Inflammation, Chronic Active						1 (2%)
Intestine Large, Rectum	(52)	(2)	(0)	(52)	(52)	(52)
Inflammation				1 (2%)		
Parasite Metazoan	2 (4%)			2 (4%)	3 (6%)	2 (4%)
Artery, Inflammation, Chronic Active	1 (2%)					2 (4%)
Intestine Small, Duodenum	(52)	(2)	(0)	(52)	(52)	(52)
Inflammation						
Ulcer						
Intestine Small, Ileum	(52)	(2)	(0)	(51)	(50)	(52)
Artery, Inflammation, Chronic Active						
Intestine Small, Jejunum	(52)	(2)	(0)	(52)	(50)	(52)
Inflammation, Chronic Active						
Artery, Inflammation, Chronic Active						
Liver	(52)	(2)	(0)	(51)	(52)	(52)
Angiectasis				1 (2%)	1 (2%)	2 (4%)
Basophilic Focus	11 (21%)			5 (10%)	8 (15%)	4 (8%)
Basophilic Focus, Multiple	4 (8%)			2 (4%)	3 (6%)	2 (4%)
Cholangiofibrosis				2 (4%)	2 (4%)	3 (6%)
Clear Cell Focus	6 (12%)			3 (6%)	4 (8%)	5 (10%)

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

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SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG
Clear Cell Focus, Multiple	9 (17%)			7 (14%)	3 (6%)	9 (17%)
Degeneration, Cystic	1 (2%)				1 (2%)	
Eosinophilic Focus	5 (10%)			5 (10%)	4 (8%)	4 (8%)
Eosinophilic Focus, Multiple				3 (6%)	5 (10%)	11 (21%)
Fatty Change, Focal	2 (4%)			1 (2%)	6 (12%)	4 (8%)
Fatty Change, Diffuse	1 (2%)			2 (4%)	1 (2%)	9 (17%)
Hematopoietic Cell Proliferation	19 (37%)			20 (39%)	21 (40%)	28 (54%)
Hepatodiaphragmatic Nodule				1 (2%)	2 (4%)	1 (2%)
Hyperplasia, Nodular						
Inflammation	21 (40%)			30 (59%)	35 (67%)	36 (69%)
Mixed Cell Focus	6 (12%)			5 (10%)	7 (13%)	6 (12%)
Mixed Cell Focus, Multiple	15 (29%)			14 (27%)	22 (42%)	30 (58%)
Necrosis	1 (2%)			2 (4%)	1 (2%)	2 (4%)
Pigmentation	1 (2%)			5 (10%)	12 (23%)	41 (79%)
Toxic Hepatopathy					3 (6%)	14 (27%)
Bile Duct, Cyst	2 (4%)			3 (6%)	5 (10%)	6 (12%)
Bile Duct, Fibrosis	2 (4%)			1 (2%)		3 (6%)
Bile Duct, Hyperplasia	5 (10%)			6 (12%)	7 (13%)	8 (15%)
Capsule, Inflammation	1 (2%)					
Centrilobular, Degeneration	1 (2%)			2 (4%)	4 (8%)	3 (6%)
Hepatocyte, Hypertrophy				12 (24%)	15 (29%)	20 (38%)
Hepatocyte, Multinucleated				1 (2%)	3 (6%)	21 (40%)
Oval Cell, Hyperplasia				12 (24%)	9 (17%)	29 (56%)
Mesentery	(2)	(0)	(0)	(1)	(3)	(3)
Hemorrhage						1 (33%)
Artery, Inflammation, Chronic Active	1 (50%)					2 (67%)
Artery, Thrombosis						
Fat, Necrosis						
Oral Mucosa	(1)	(0)	(0)	(0)	(1)	(1)
Gingival, Cyst						
Gingival, Hyperplasia, Squamous						1 (100%)
Pancreas	(52)	(2)	(0)	(52)	(52)	(52)
Degeneration	1 (2%)					
Inflammation, Chronic Active				1 (2%)	2 (4%)	2 (4%)
Acinus, Atrophy, Focal	4 (8%)			2 (4%)	3 (6%)	4 (8%)
Acinus, Atrophy, Diffuse						
Acinus, Hyperplasia				2 (4%)		
Acinus, Vacuolization Cytoplasmic						
Artery, Inflammation, Chronic Active	1 (2%)			2 (4%)	1 (2%)	7 (13%)
Duct, Dilatation						
Duct, Inflammation						
Duct, Necrosis						
Salivary Glands	(51)	(2)	(0)	(51)	(52)	(51)
Degeneration						
Stomach, Forestomach	(52)	(2)	(0)	(52)	(52)	(52)
Hyperplasia, Squamous				3 (6%)		

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SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG
Inflammation	2 (4%)			1 (2%)		
Ulcer	2 (4%)					
Artery, Inflammation, Chronic Active						
Stomach, Glandular	(52)	(2)	(0)	(52)	(52)	(52)
Cyst	1 (2%)					
Erosion				1 (2%)		1 (2%)
Mineralization						
Artery, Inflammation, Chronic Active				1 (2%)		
Artery, Mineralization						
Glands, Cyst					1 (2%)	
Tooth	(10)	(0)	(0)	(5)	(5)	(5)
Peridental Tissue, Inflammation	7 (70%)			5 (100%)	5 (100%)	5 (100%)
<b>CARDIOVASCULAR SYSTEM</b>						
Blood Vessel	(52)	(2)	(0)	(52)	(52)	(52)
Aorta, Mineralization				1 (2%)		
Heart	(52)	(2)	(0)	(52)	(52)	(52)
Cardiomyopathy	13 (25%)			19 (37%)	14 (27%)	16 (31%)
Inflammation						
Artery, Inflammation, Chronic Active						
Artery, Mineralization				1 (2%)	1 (2%)	1 (2%)
Coronary Artery, Thrombosis				1 (2%)		
Endocardium, Hyperplasia				1 (2%)		
Endocardium, Infiltration Cellular				1 (2%)		
Epicardium, Fibrosis						
Epicardium, Inflammation				1 (2%)		
Myocardium, Mineralization				1 (2%)		
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(52)	(2)	(0)	(52)	(52)	(51)
Angiectasis						1 (2%)
Atrophy	1 (2%)					2 (4%)
Degeneration, Cystic	9 (17%)			8 (15%)	9 (17%)	12 (24%)
Hematopoietic Cell Proliferation	1 (2%)					
Hyperplasia	14 (27%)			18 (35%)	13 (25%)	16 (31%)
Hypertrophy	37 (71%)			37 (71%)	39 (75%)	43 (84%)
Inflammation					1 (2%)	
Necrosis				1 (2%)	2 (4%)	
Vacuolization Cytoplasmic	10 (19%)			12 (23%)	13 (25%)	12 (24%)
Adrenal Medulla	(52)	(2)	(0)	(52)	(52)	(52)
Hyperplasia	11 (21%)			12 (23%)	14 (27%)	16 (31%)
Necrosis						

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SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG
Islets, Pancreatic	(52)	(2)	(0)	(52)	(52)	(52)
Hyperplasia				1 (2%)		
Parathyroid Gland	(47)	(2)	(0)	(46)	(47)	(50)
Hyperplasia				1 (2%)		
Pituitary Gland	(52)	(2)	(0)	(52)	(52)	(52)
Angiectasis	1 (2%)			1 (2%)		
Cyst				1 (2%)		
Pars Distalis, Cyst						
Pars Distalis, Hyperplasia	10 (19%)			6 (12%)	13 (25%)	13 (25%)
Thyroid Gland	(51)	(2)	(0)	(51)	(51)	(51)
Infiltration Cellular, Lymphocyte						
Inflammation	1 (2%)					
C-cell, Hyperplasia	10 (20%)			14 (27%)	10 (20%)	6 (12%)
Follicular Cell, Hyperplasia						
Follicular Cell, Hypertrophy	6 (12%)			7 (14%)	13 (25%)	18 (35%)

**GENERAL BODY SYSTEM**

None

**GENITAL SYSTEM**

Clitoral Gland	(52)	(2)	(0)	(52)	(51)	(52)
Hyperplasia, Squamous					1 (2%)	
Inflammation	41 (79%)	1 (50%)		38 (73%)	39 (76%)	40 (77%)
Duct, Cyst	26 (50%)			39 (75%)	31 (61%)	35 (67%)
Ovary	(52)	(2)	(0)	(52)	(52)	(52)
Cyst	8 (15%)			10 (19%)	13 (25%)	14 (27%)
Fibrosis						1 (2%)
Inflammation						2 (4%)
Pigmentation						1 (2%)
Bilateral, Cyst					1 (2%)	
Uterus	(52)	(2)	(0)	(52)	(52)	(52)
Adenomyosis						1 (2%)
Cyst					1 (2%)	1 (2%)
Hemorrhage						
Inflammation	4 (8%)			6 (12%)	6 (12%)	8 (15%)
Metaplasia, Squamous	29 (56%)			26 (50%)	27 (52%)	34 (65%)
Thrombosis	1 (2%)					2 (4%)
Ulcer						
Artery, Inflammation, Chronic Active						1 (2%)
Cervix, Cyst						
Endometrium, Hyperplasia, Cystic	28 (54%)			27 (52%)	22 (42%)	23 (44%)
Epithelium, Hyperplasia						

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SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG
Vagina	(7)	(0)	(0)	(0)	(0)	(1)
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(52)	(2)	(0)	(52)	(52)	(52)
Atrophy	4 (8%)			1 (2%)	1 (2%)	
Hyperplasia	31 (60%)	2 (100%)		30 (58%)	30 (58%)	32 (62%)
Myelofibrosis					1 (2%)	
Necrosis						
Lymph Node	(0)	(0)	(0)	(2)	(1)	(1)
Bronchial, Ectasia						
Bronchial, Hemorrhage						
Mediastinal, Hemorrhage				1 (50%)		
Lymph Node, Mandibular	(51)	(2)	(0)	(51)	(52)	(51)
Atrophy						
Hyperplasia, Lymphoid					1 (2%)	1 (2%)
Hyperplasia, Plasma Cell	24 (47%)	1 (50%)		34 (67%)	36 (69%)	33 (65%)
Lymph Node, Mesenteric	(52)	(2)	(0)	(51)	(52)	(52)
Atrophy	1 (2%)			1 (2%)		
Ectasia						
Hemorrhage						
Hyperplasia, Plasma Cell	1 (2%)					
Spleen	(52)	(2)	(0)	(52)	(52)	(52)
Hematopoietic Cell Proliferation	42 (81%)			39 (75%)	39 (75%)	39 (75%)
Hemorrhage	1 (2%)					
Necrosis	1 (2%)					1 (2%)
Pigmentation	39 (75%)			35 (67%)	31 (60%)	36 (69%)
Capsule, Hemorrhage						1 (2%)
Lymphoid Follicle, Atrophy	3 (6%)			4 (8%)	2 (4%)	2 (4%)
Red Pulp, Atrophy				2 (4%)	2 (4%)	1 (2%)
Thymus	(51)	(2)	(0)	(51)	(51)	(50)
Atrophy	41 (80%)			38 (75%)	44 (86%)	44 (88%)
Cyst				2 (4%)	1 (2%)	
Hemorrhage				1 (2%)	1 (2%)	
Inflammation		1 (50%)		1 (2%)		
Artery, Inflammation, Chronic Active						
<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(52)	(2)	(0)	(51)	(52)	(52)
Cyst	1 (2%)			2 (4%)		2 (4%)
Hyperplasia	4 (8%)			5 (10%)	4 (8%)	5 (10%)
Inflammation, Granulomatous					2 (4%)	1 (2%)
Inflammation, Chronic Active				1 (2%)		

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SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG
Skin	(52)	(2)	(0)	(51)	(52)	(52)
Cyst Epithelial Inclusion					1 (2%)	1 (2%)
Hyperkeratosis				1 (2%)		
Hyperplasia, Squamous				2 (4%)		
Inflammation				3 (6%)		
<b>MUSCULOSKELETAL SYSTEM</b>						
Skeletal Muscle	(0)	(0)	(0)	(1)	(0)	(0)
<b>NERVOUS SYSTEM</b>						
Brain	(52)	(2)	(0)	(52)	(52)	(52)
Angiectasis					1 (2%)	
Gliosis	1 (2%)					1 (2%)
Hemorrhage	3 (6%)					1 (2%)
Hydrocephalus	1 (2%)			2 (4%)	1 (2%)	
Necrosis	2 (4%)					
Vacuolization Cytoplasmic				1 (2%)		
Meninges, Inflammation						1 (2%)
Spinal Cord	(0)	(0)	(0)	(0)	(1)	(0)
Nerve, Degeneration						
<b>RESPIRATORY SYSTEM</b>						
Lung	(51)	(2)	(0)	(52)	(52)	(52)
Congestion						
Hemorrhage						1 (2%)
Inflammation	5 (10%)			3 (6%)	5 (10%)	3 (6%)
Metaplasia, Squamous	1 (2%)					1 (2%)
Pigmentation					1 (2%)	
Proteinosis	1 (2%)					
Alveolar Epithelium, Hyperplasia	4 (8%)			2 (4%)		
Alveolar Epithelium, Metaplasia, Bronchiolar	6 (12%)			7 (13%)	14 (27%)	18 (35%)
Alveolus, Infiltration Cellular, Histiocyte	36 (71%)			35 (67%)	37 (71%)	39 (75%)
Artery, Mediastinum, Inflammation, Chronic						
Active						
Serosa, Inflammation				1 (2%)		
Nose	(52)	(2)	(0)	(52)	(52)	(52)
Cyst	1 (2%)					
Inflammation	1 (2%)			5 (10%)	5 (10%)	3 (6%)
Nasolacrimal Duct, Inflammation, Suppurative						
Olfactory Epithelium, Degeneration	1 (2%)			1 (2%)		

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Olfactory Epithelium, Metaplasia						
Respiratory Epithelium, Degeneration, Focal	1 (2%)					
Respiratory Epithelium, Hyperplasia	5 (10%)			5 (10%)	7 (13%)	7 (13%)
Respiratory Epithelium, Necrosis						1 (2%)
Trachea	(51)	(2)	(0)	(52)	(52)	(52)
Inflammation						
<b>SPECIAL SENSES SYSTEM</b>						
Eye	(52)	(2)	(0)	(52)	(52)	(52)
Cornea, Inflammation	1 (2%)			1 (2%)	1 (2%)	1 (2%)
Retina, Atrophy	1 (2%)					
Harderian Gland	(52)	(2)	(0)	(52)	(52)	(52)
Hyperplasia				1 (2%)	2 (4%)	
Infiltration Cellular, Mononuclear Cell	7 (13%)			10 (19%)	3 (6%)	10 (19%)
Vacuolization Cytoplasmic						
<b>URINARY SYSTEM</b>						
Kidney	(52)	(2)	(0)	(52)	(52)	(52)
Accumulation, Hyaline Droplet	1 (2%)				1 (2%)	
Calculus Micro Observation Only	3 (6%)					2 (4%)
Cyst				2 (4%)		
Dilatation						1 (2%)
Inflammation						
Mineralization	25 (48%)			28 (54%)	30 (58%)	18 (35%)
Necrosis					1 (2%)	
Nephropathy	42 (81%)			40 (77%)	46 (88%)	44 (85%)
Pigmentation	2 (4%)			3 (6%)	3 (6%)	4 (8%)
Artery, Inflammation, Chronic Active	1 (2%)					
Capsule, Inflammation, Chronic Active						
Pelvis, Dilatation				1 (2%)		1 (2%)
Pelvis, Inflammation				1 (2%)		
Renal Tubule, Hyperplasia						1 (2%)
Transitional Epithelium, Hyperplasia						
Ureter	(0)	(0)	(0)	(0)	(0)	(0)
Urinary Bladder	(52)	(2)	(0)	(52)	(52)	(52)
Hyperplasia				1 (2%)		
Inflammation				1 (2%)		



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SPRAGUE-DAWLEY RATS FEMALE	1000 UG/KG	4600 UG/KG
<b>Disposition Summary</b>		
Animals Initially in Study	80	80
Early Deaths		
Dosing Accident		
Moribund Sacrifice	16	16
Natural Death	8	11
Survivors		
Terminal Sacrifice	28	25
Animals Examined Microscopically	52	52

#### ALIMENTARY SYSTEM

Esophagus	(52)	(52)
Ulcer		
Muscularis, Degeneration	1 (2%)	
Muscularis, Inflammation		
Intestine Large, Cecum	(52)	(48)
Degeneration, Fatty	1 (2%)	
Inflammation		
Ulcer		
Artery, Inflammation, Chronic Active	3 (6%)	1 (2%)
Intestine Large, Colon	(52)	(48)
Parasite Metazoan	1 (2%)	1 (2%)
Artery, Inflammation, Chronic Active	3 (6%)	1 (2%)
Intestine Large, Rectum	(52)	(50)
Inflammation		
Parasite Metazoan	1 (2%)	3 (6%)
Artery, Inflammation, Chronic Active	5 (10%)	1 (2%)
Intestine Small, Duodenum	(52)	(48)
Inflammation	1 (2%)	
Ulcer	1 (2%)	
Intestine Small, Ileum	(52)	(47)
Artery, Inflammation, Chronic Active	1 (2%)	
Intestine Small, Jejunum	(52)	(48)
Inflammation, Chronic Active	1 (2%)	
Artery, Inflammation, Chronic Active	1 (2%)	
Liver	(52)	(49)
Angiectasis		2 (4%)
Basophilic Focus	8 (15%)	1 (2%)
Basophilic Focus, Multiple	1 (2%)	
Cholangiofibrosis	2 (4%)	22 (45%)
Clear Cell Focus	2 (4%)	

SPRAGUE-DAWLEY RATS FEMALE	1000 UG/KG	4600 UG/KG
Clear Cell Focus, Multiple	3 (6%)	
Degeneration, Cystic	1 (2%)	2 (4%)
Eosinophilic Focus	5 (10%)	
Eosinophilic Focus, Multiple	20 (38%)	41 (84%)
Fatty Change, Focal	3 (6%)	
Fatty Change, Diffuse	39 (75%)	48 (98%)
Hematopoietic Cell Proliferation	19 (37%)	21 (43%)
Hepatodiaphragmatic Nodule		
Hyperplasia, Nodular	12 (23%)	43 (88%)
Inflammation	43 (83%)	44 (90%)
Mixed Cell Focus	1 (2%)	1 (2%)
Mixed Cell Focus, Multiple	30 (58%)	6 (12%)
Necrosis	20 (38%)	22 (45%)
Pigmentation	50 (96%)	48 (98%)
Toxic Hepatopathy	33 (63%)	46 (94%)
Bile Duct, Cyst	6 (12%)	21 (43%)
Bile Duct, Fibrosis	2 (4%)	
Bile Duct, Hyperplasia	21 (40%)	40 (82%)
Capsule, Inflammation		
Centrilobular, Degeneration	6 (12%)	1 (2%)
Hepatocyte, Hypertrophy	44 (85%)	48 (98%)
Hepatocyte, Multinucleated	40 (77%)	43 (88%)
Oval Cell, Hyperplasia	40 (77%)	46 (94%)
Mesentery	(9)	(9)
Hemorrhage		
Artery, Inflammation, Chronic Active	5 (56%)	8 (89%)
Artery, Thrombosis		1 (11%)
Fat, Necrosis	1 (11%)	1 (11%)
Oral Mucosa	(1)	(3)
Gingival, Cyst		1 (33%)
Gingival, Hyperplasia, Squamous	1 (100%)	
Pancreas	(52)	(47)
Degeneration		
Inflammation, Chronic Active	3 (6%)	2 (4%)
Acinus, Atrophy, Focal	3 (6%)	1 (2%)
Acinus, Atrophy, Diffuse		1 (2%)
Acinus, Hyperplasia	1 (2%)	
Acinus, Vacuolization Cytoplasmic	4 (8%)	42 (89%)
Artery, Inflammation, Chronic Active	7 (13%)	12 (26%)
Duct, Dilatation		3 (6%)
Duct, Inflammation		2 (4%)
Duct, Necrosis		1 (2%)
Salivary Glands	(52)	(51)
Degeneration	1 (2%)	
Stomach, Forestomach	(52)	(51)
Hyperplasia, Squamous	2 (4%)	3 (6%)

TDMS No. 20304 - 01  
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P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)  
 TEF evaluation (PCB 118)  
 CAS Number: 31508-00-6

Date Report Requested: 07/15/2008  
 Time Report Requested: 10:22:40  
 First Dose M/F: NA / 03/26/04  
 Lab: BAT

SPRAGUE-DAWLEY RATS FEMALE	1000 UG/KG	4600 UG/KG
Inflammation		1 (2%)
Ulcer		
Artery, Inflammation, Chronic Active	1 (2%)	1 (2%)
Stomach, Glandular	(52)	(51)
Cyst		
Erosion		
Mineralization	1 (2%)	
Artery, Inflammation, Chronic Active		1 (2%)
Artery, Mineralization		
Glands, Cyst		
Tooth	(4)	(7)
Peridental Tissue, Inflammation	4 (100%)	6 (86%)
<b>CARDIOVASCULAR SYSTEM</b>		
Blood Vessel	(52)	(51)
Aorta, Mineralization		
Heart	(52)	(50)
Cardiomyopathy	19 (37%)	16 (32%)
Inflammation	1 (2%)	1 (2%)
Artery, Inflammation, Chronic Active	1 (2%)	1 (2%)
Artery, Mineralization		
Coronary Artery, Thrombosis		1 (2%)
Endocardium, Hyperplasia	1 (2%)	2 (4%)
Endocardium, Infiltration Cellular		
Epicardium, Fibrosis		1 (2%)
Epicardium, Inflammation		
Myocardium, Mineralization		
<b>ENDOCRINE SYSTEM</b>		
Adrenal Cortex	(52)	(49)
Angiectasis		
Atrophy	9 (17%)	35 (71%)
Degeneration, Cystic	6 (12%)	8 (16%)
Hematopoietic Cell Proliferation	1 (2%)	
Hyperplasia	13 (25%)	13 (27%)
Hypertrophy	44 (85%)	34 (69%)
Inflammation		
Necrosis	3 (6%)	
Vacuolization Cytoplasmic	12 (23%)	18 (37%)
Adrenal Medulla	(52)	(49)
Hyperplasia	10 (19%)	1 (2%)
Necrosis	1 (2%)	

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SPRAGUE-DAWLEY RATS FEMALE	1000 UG/KG	4600 UG/KG
Islets, Pancreatic	(52)	(47)
Hyperplasia		
Parathyroid Gland	(50)	(47)
Hyperplasia		
Pituitary Gland	(52)	(52)
Angiectasis	1 (2%)	
Cyst		
Pars Distalis, Cyst	1 (2%)	
Pars Distalis, Hyperplasia	16 (31%)	10 (19%)
Thyroid Gland	(52)	(49)
Infiltration Cellular, Lymphocyte	1 (2%)	1 (2%)
Inflammation		
C-cell, Hyperplasia	12 (23%)	11 (22%)
Follicular Cell, Hyperplasia	1 (2%)	
Follicular Cell, Hypertrophy	21 (40%)	23 (47%)

#### GENERAL BODY SYSTEM

None

#### GENITAL SYSTEM

Clitoral Gland	(51)	(49)
Hyperplasia, Squamous		
Inflammation	35 (69%)	13 (27%)
Duct, Cyst	37 (73%)	30 (61%)
Ovary	(52)	(48)
Cyst	14 (27%)	7 (15%)
Fibrosis		
Inflammation	1 (2%)	2 (4%)
Pigmentation		
Bilateral, Cyst		
Uterus	(52)	(49)
Adenomyosis		1 (2%)
Cyst		1 (2%)
Hemorrhage	1 (2%)	1 (2%)
Inflammation	8 (15%)	4 (8%)
Metaplasia, Squamous	35 (67%)	5 (10%)
Thrombosis	1 (2%)	
Ulcer	2 (4%)	
Artery, Inflammation, Chronic Active		
Cervix, Cyst	1 (2%)	
Endometrium, Hyperplasia, Cystic	13 (25%)	9 (18%)
Epithelium, Hyperplasia	1 (2%)	

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SPRAGUE-DAWLEY RATS FEMALE	1000 UG/KG	4600 UG/KG
Vagina	(1)	(0)
<b>HEMATOPOIETIC SYSTEM</b>		
Bone Marrow	(52)	(52)
Atrophy	1 (2%)	
Hyperplasia	34 (65%)	47 (90%)
Myelofibrosis		
Necrosis		1 (2%)
Lymph Node	(0)	(2)
Bronchial, Ectasia		1 (50%)
Bronchial, Hemorrhage		1 (50%)
Mediastinal, Hemorrhage		
Lymph Node, Mandibular	(52)	(51)
Atrophy	1 (2%)	1 (2%)
Hyperplasia, Lymphoid	1 (2%)	1 (2%)
Hyperplasia, Plasma Cell	30 (58%)	19 (37%)
Lymph Node, Mesenteric	(52)	(47)
Atrophy	1 (2%)	
Ectasia		1 (2%)
Hemorrhage	1 (2%)	
Hyperplasia, Plasma Cell		
Spleen	(52)	(47)
Hematopoietic Cell Proliferation	32 (62%)	34 (72%)
Hemorrhage		
Necrosis		
Pigmentation	40 (77%)	28 (60%)
Capsule, Hemorrhage		
Lymphoid Follicle, Atrophy	3 (6%)	3 (6%)
Red Pulp, Atrophy	1 (2%)	3 (6%)
Thymus	(50)	(49)
Atrophy	46 (92%)	44 (90%)
Cyst		
Hemorrhage	1 (2%)	3 (6%)
Inflammation		
Artery, Inflammation, Chronic Active		2 (4%)
<b>INTEGUMENTARY SYSTEM</b>		
Mammary Gland	(52)	(50)
Cyst		
Hyperplasia		1 (2%)
Inflammation, Granulomatous		
Inflammation, Chronic Active		

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SPRAGUE-DAWLEY RATS FEMALE	1000 UG/KG	4600 UG/KG
Skin	(52)	(51)
Cyst Epithelial Inclusion		
Hyperkeratosis		
Hyperplasia, Squamous		
Inflammation		
<b>MUSCULOSKELETAL SYSTEM</b>		
Skeletal Muscle	(1)	(0)
<b>NERVOUS SYSTEM</b>		
Brain	(52)	(52)
Angiectasis		
Gliosis		
Hemorrhage		
Hydrocephalus		
Necrosis		
Vacuolization Cytoplasmic		
Meninges, Inflammation		
Spinal Cord	(0)	(1)
Nerve, Degeneration		1 (100%)
<b>RESPIRATORY SYSTEM</b>		
Lung	(52)	(50)
Congestion	1 (2%)	
Hemorrhage		1 (2%)
Inflammation	2 (4%)	2 (4%)
Metaplasia, Squamous	1 (2%)	13 (26%)
Pigmentation		1 (2%)
Proteinosis		
Alveolar Epithelium, Hyperplasia		
Alveolar Epithelium, Metaplasia, Bronchiolar	24 (46%)	40 (80%)
Alveolus, Infiltration Cellular, Histiocyte	34 (65%)	40 (80%)
Artery, Mediastinum, Inflammation, Chronic		1 (2%)
Active		
Serosa, Inflammation		
Nose	(52)	(52)
Cyst		
Inflammation	5 (10%)	23 (44%)
Nasolacrimal Duct, Inflammation, Suppurative		1 (2%)
Olfactory Epithelium, Degeneration		1 (2%)

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

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SPRAGUE-DAWLEY RATS FEMALE	1000 UG/KG	4600 UG/KG
Olfactory Epithelium, Metaplasia		1 (2%)
Respiratory Epithelium, Degeneration, Focal		
Respiratory Epithelium, Hyperplasia	14 (27%)	27 (52%)
Respiratory Epithelium, Necrosis		
Trachea	(52)	(52)
Inflammation		1 (2%)
<b>SPECIAL SENSES SYSTEM</b>		
Eye	(52)	(52)
Cornea, Inflammation		
Retina, Atrophy	1 (2%)	6 (12%)
Harderian Gland	(52)	(52)
Hyperplasia		
Infiltration Cellular, Mononuclear Cell	4 (8%)	13 (25%)
Vacuolization Cytoplasmic	1 (2%)	
<b>URINARY SYSTEM</b>		
Kidney	(52)	(50)
Accumulation, Hyaline Droplet		
Calculus Micro Observation Only	1 (2%)	
Cyst		1 (2%)
Dilatation		
Inflammation	1 (2%)	
Mineralization	22 (42%)	25 (50%)
Necrosis		
Nephropathy	44 (85%)	46 (92%)
Pigmentation	6 (12%)	42 (84%)
Artery, Inflammation, Chronic Active	1 (2%)	
Capsule, Inflammation, Chronic Active	1 (2%)	
Pelvis, Dilatation	1 (2%)	
Pelvis, Inflammation	2 (4%)	2 (4%)
Renal Tubule, Hyperplasia		
Transitional Epithelium, Hyperplasia	3 (6%)	3 (6%)
Ureter	(1)	(0)
Urinary Bladder	(52)	(50)
Hyperplasia		
Inflammation	1 (2%)	

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