

TDMS No. 20008 - 04
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: MICE/B6C3F1

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

Milk thistle extract
CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
Time Report Requested: 13:13:48
First Dose M/F: 03/25/03 / 03/25/03
Lab: SRI

F1_M3

C Number: C20008
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

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B6C3F1 MICE MALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice		1	1	1
Natural Death	5	3	6	
Survivors				
Terminal Sacrifice	45	46	43	49
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Intestine Large, Cecum	(48)	(47)	(49)	(50)
Edema	1 (2%)		1 (2%)	
Intestine Small, Ileum	(49)	(48)	(50)	(50)
Epithelium, Hyperplasia			1 (2%)	
Intestine Small, Jejunum	(49)	(49)	(46)	(50)
Hyperplasia, Lymphoid			1 (2%)	
Epithelium, Hyperplasia			1 (2%)	
Liver	(50)	(50)	(50)	(50)
Angiectasis				2 (4%)
Basophilic Focus	1 (2%)	1 (2%)	1 (2%)	1 (2%)
Clear Cell Focus	7 (14%)	3 (6%)	3 (6%)	
Cyst			1 (2%)	
Eosinophilic Focus	2 (4%)	1 (2%)	4 (8%)	1 (2%)
Hematopoietic Cell Proliferation	2 (4%)			
Hepatodiaphragmatic Nodule	1 (2%)			
Infiltration Cellular, Mixed Cell	1 (2%)		1 (2%)	
Mixed Cell Focus	10 (20%)	7 (14%)		3 (6%)
Necrosis, Focal	2 (4%)	3 (6%)	5 (10%)	
Necrosis, Diffuse			1 (2%)	
Thrombosis			1 (2%)	
Centrilobular, Necrosis	1 (2%)	2 (4%)	1 (2%)	
Hepatocyte, Vacuolization Cytoplasmic	7 (14%)	4 (8%)	1 (2%)	
Mesentery	(2)	(3)	(3)	(3)
Hemorrhage				1 (33%)
Fat, Necrosis	1 (50%)	2 (67%)	2 (67%)	1 (33%)
Pancreas	(49)	(49)	(49)	(50)
Basophilic Focus	1 (2%)			
Cyst			1 (2%)	1 (2%)
Acinus, Cytoplasmic Alteration	1 (2%)	1 (2%)	2 (4%)	4 (8%)
Salivary Glands	(50)	(50)	(50)	(50)
Atrophy				1 (2%)

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

B6C3F1 MICE MALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
Infiltration Cellular, Lymphocyte Stomach, Forestomach	(50)	(50)	1 (2%) (50)	(50)
Diverticulum		1 (2%)	1 (2%)	
Ulcer		1 (2%)		
Epithelium, Hyperplasia Stomach, Glandular	(49)	(50)	(50)	1 (2%) (50)
Erosion	2 (4%)	1 (2%)	1 (2%)	
Ulcer				1 (2%)
Epithelium, Hyperplasia	1 (2%)			
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	4 (8%)	1 (2%)		2 (4%)
Thrombosis	2 (4%)			
Myocardium, Necrosis	1 (2%)			
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Accessory Adrenal Cortical Nodule	7 (14%)	7 (14%)	4 (8%)	2 (4%)
Degeneration, Fatty				1 (2%)
Hyperplasia, Focal	4 (8%)	8 (16%)	6 (12%)	8 (16%)
Hypertrophy, Focal	13 (26%)	13 (26%)	12 (24%)	9 (18%)
Capsule, Hyperplasia	2 (4%)	2 (4%)	3 (6%)	5 (10%)
Adrenal Medulla	(49)	(50)	(49)	(49)
Hyperplasia		1 (2%)		
Islets, Pancreatic	(49)	(49)	(49)	(50)
Hyperplasia	1 (2%)	1 (2%)		
Parathyroid Gland	(50)	(50)	(50)	(50)
Cyst		2 (4%)	2 (4%)	1 (2%)
Pituitary Gland	(48)	(48)	(47)	(50)
Pars Distalis, Cyst	2 (4%)	3 (6%)	2 (4%)	3 (6%)
Pars Distalis, Hyperplasia, Focal	2 (4%)		1 (2%)	
Thyroid Gland	(48)	(49)	(50)	(50)
Follicle, Degeneration, Focal	6 (13%)	11 (22%)	3 (6%)	6 (12%)
GENERAL BODY SYSTEM				
Tissue NOS	(0)	(0)	(0)	(1)
GENITAL SYSTEM				

B6C3F1 MICE MALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
Epididymis	(50)	(50)	(50)	(50)
Granuloma Sperm		1 (2%)		1 (2%)
Preputial Gland	(50)	(50)	(50)	(49)
Cyst	19 (38%)	28 (56%)	26 (52%)	20 (41%)
Inflammation, Chronic	12 (24%)	12 (24%)	17 (34%)	14 (29%)
Prostate	(50)	(50)	(50)	(50)
Inflammation, Chronic			1 (2%)	
Seminal Vesicle	(50)	(50)	(50)	(50)
Degeneration	1 (2%)			
Testes	(50)	(50)	(50)	(50)
Germinal Epithelium, Atrophy	2 (4%)	1 (2%)		1 (2%)
Interstitial Cell, Hyperplasia				1 (2%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(49)	(49)	(49)	(50)
Angiectasis			1 (2%)	
Hyperplasia	13 (27%)	14 (29%)	13 (27%)	17 (34%)
Lymph Node	(2)	(1)	(2)	(0)
Mediastinal, Hematopoietic Cell Proliferation	1 (50%)			
Mediastinal, Hyperplasia, Lymphoid	1 (50%)			
Pancreatic, Fibrosis	1 (50%)			
Pancreatic, Hematopoietic Cell Proliferation	1 (50%)			
Pancreatic, Hyperplasia, Lymphoid	1 (50%)			
Lymph Node, Mandibular	(48)	(45)	(49)	(47)
Atrophy	1 (2%)	1 (2%)		
Hyperplasia, Lymphoid	3 (6%)	2 (4%)	1 (2%)	1 (2%)
Pigmentation			1 (2%)	2 (4%)
Lymph Node, Mesenteric	(47)	(44)	(48)	(48)
Atrophy	1 (2%)	1 (2%)		1 (2%)
Hematopoietic Cell Proliferation	2 (4%)	3 (7%)	2 (4%)	1 (2%)
Hemorrhage		3 (7%)	1 (2%)	1 (2%)
Hyperplasia, Lymphoid	2 (4%)	3 (7%)	4 (8%)	1 (2%)
Spleen	(50)	(50)	(49)	(50)
Hematopoietic Cell Proliferation	16 (32%)	11 (22%)	12 (24%)	4 (8%)
Necrosis	1 (2%)			
Lymphoid Follicle, Atrophy	1 (2%)	1 (2%)		2 (4%)
Lymphoid Follicle, Hyperplasia	2 (4%)		3 (6%)	2 (4%)
Red Pulp, Atrophy		1 (2%)		
Thymus	(45)	(46)	(49)	(40)
Atrophy	4 (9%)	5 (11%)	5 (10%)	1 (3%)
Cyst	4 (9%)	2 (4%)	4 (8%)	6 (15%)
INTEGUMENTARY SYSTEM				

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B6C3F1 MICE MALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion			1 (2%)	
Edema	1 (2%)			
Ulcer	1 (2%)			
Epidermis, Hyperplasia	1 (2%)			
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(49)
Fracture	1 (2%)			
Necrosis		1 (2%)		
Femur, Osteopetrosis				1 (2%)
Skeletal Muscle	(1)	(2)	(1)	(0)
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Infiltration Cellular, Lymphoid			1 (2%)	
Peripheral Nerve	(1)	(1)	(1)	(1)
Atrophy	1 (100%)	1 (100%)		1 (100%)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Edema		1 (2%)		
Foreign Body	2 (4%)		1 (2%)	
Hemorrhage	3 (6%)	3 (6%)	3 (6%)	3 (6%)
Infiltration Cellular, Histiocyte	6 (12%)	6 (12%)	4 (8%)	4 (8%)
Infiltration Cellular, Lymphocyte	1 (2%)	2 (4%)		
Inflammation, Chronic		1 (2%)	1 (2%)	
Thrombosis			1 (2%)	1 (2%)
Alveolar Epithelium, Hyperplasia	2 (4%)	7 (14%)	3 (6%)	5 (10%)
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)
Cataract				1 (2%)
Inflammation, Chronic	1 (2%)			
Cornea, Hyperplasia	1 (2%)			
Harderian Gland	(50)	(50)	(50)	(50)
Hyperplasia, Focal	3 (6%)	2 (4%)		1 (2%)

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

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B6C3F1 MICE MALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Cyst	8 (16%)	10 (20%)	5 (10%)	7 (14%)
Hydronephrosis			1 (2%)	
Infarct	4 (8%)	3 (6%)		2 (4%)
Infiltration Cellular, Lymphocyte	3 (6%)	2 (4%)	3 (6%)	
Metaplasia, Osseous		3 (6%)	5 (10%)	
Nephropathy	45 (90%)	49 (98%)	47 (94%)	49 (98%)
Renal Tubule, Accumulation, Hyaline Droplet	1 (2%)			
Renal Tubule, Hyperplasia	5 (10%)	1 (2%)	1 (2%)	4 (8%)
Renal Tubule, Necrosis		1 (2%)		
Renal Tubule, Pigmentation				1 (2%)
Urinary Bladder	(50)	(50)	(49)	(50)
Calculus Gross Observation	2 (4%)			
Dilatation			1 (2%)	
Infiltration Cellular, Lymphocyte			1 (2%)	
Transitional Epithelium, Hyperplasia	1 (2%)			

*** END OF MALE ***

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B6C3F1 MICE FEMALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Accidently Killed				1
Moribund Sacrifice	3	2	2	3
Natural Death	7	5	6	1
Survivors				
Natural Death		1		
Terminal Sacrifice	40	42	42	45
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Intestine Large, Cecum	(48)	(48)	(49)	(50)
Edema	1 (2%)	1 (2%)		1 (2%)
Hyperplasia, Lymphoid	1 (2%)			
Intestine Small, Duodenum	(49)	(47)	(47)	(49)
Epithelium, Hyperplasia				1 (2%)
Intestine Small, Ileum	(46)	(49)	(48)	(49)
Peyer's Patch, Necrosis				1 (2%)
Intestine Small, Jejunum	(49)	(45)	(48)	(49)
Peyer's Patch, Inflammation, Suppurative	1 (2%)		1 (2%)	
Liver	(50)	(50)	(50)	(50)
Angiectasis	1 (2%)	2 (4%)		
Basophilic Focus	1 (2%)			
Clear Cell Focus		1 (2%)	1 (2%)	1 (2%)
Hematopoietic Cell Proliferation	1 (2%)	4 (8%)	1 (2%)	6 (12%)
Infiltration Cellular, Lymphocyte		2 (4%)	1 (2%)	
Infiltration Cellular, Mixed Cell		3 (6%)	2 (4%)	
Mixed Cell Focus	1 (2%)	1 (2%)	1 (2%)	
Necrosis, Focal	3 (6%)	1 (2%)		
Necrosis, Diffuse				1 (2%)
Centrilobular, Necrosis	1 (2%)	1 (2%)		1 (2%)
Hepatocyte, Vacuolization Cytoplasmic	1 (2%)	1 (2%)	3 (6%)	
Kupffer Cell, Hyperplasia	1 (2%)	1 (2%)	1 (2%)	1 (2%)
Kupffer Cell, Pigmentation				1 (2%)
Mesentery	(5)	(2)	(1)	(3)
Fat, Necrosis	3 (60%)	2 (100%)		3 (100%)
Oral Mucosa	(0)	(0)	(1)	(0)
Pancreas	(49)	(48)	(49)	(50)
Atrophy	2 (4%)	1 (2%)	1 (2%)	1 (2%)
Cyst	2 (4%)		1 (2%)	1 (2%)

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

B6C3F1 MICE FEMALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
Acinus, Cytoplasmic Alteration	2 (4%)	3 (6%)	1 (2%)	2 (4%)
Duct, Hyperplasia				1 (2%)
Salivary Glands	(50)	(50)	(49)	(50)
Atrophy				2 (4%)
Infiltration Cellular, Lymphocyte	7 (14%)	8 (16%)	8 (16%)	4 (8%)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Diverticulum		1 (2%)		
Erosion				1 (2%)
Epithelium, Hyperplasia	2 (4%)	2 (4%)	3 (6%)	
Stomach, Glandular	(50)	(48)	(50)	(50)
Cyst	4 (8%)	4 (8%)	2 (4%)	4 (8%)
Erosion	2 (4%)	1 (2%)		1 (2%)
Epithelium, Hyperplasia	1 (2%)	1 (2%)		
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy		1 (2%)		
Mineralization	1 (2%)	2 (4%)		
Artery, Inflammation, Chronic Active		1 (2%)		
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Accessory Adrenal Cortical Nodule	5 (10%)	6 (12%)	7 (14%)	7 (14%)
Cyst		1 (2%)		
Hypertrophy, Focal				2 (4%)
Capsule, Hyperplasia	2 (4%)			
Adrenal Medulla	(49)	(49)	(50)	(50)
Hyperplasia	2 (4%)	3 (6%)		1 (2%)
Islets, Pancreatic	(49)	(48)	(49)	(50)
Parathyroid Gland	(48)	(48)	(48)	(48)
Cyst	1 (2%)	1 (2%)		1 (2%)
Hyperplasia		1 (2%)		
Pituitary Gland	(49)	(49)	(48)	(48)
Pars Distalis, Angiectasis		1 (2%)		1 (2%)
Pars Distalis, Cyst		3 (6%)	2 (4%)	
Pars Distalis, Hyperplasia, Focal	5 (10%)	1 (2%)	1 (2%)	5 (10%)
Pars Intermedia, Hyperplasia			1 (2%)	
Thyroid Gland	(50)	(48)	(49)	(50)
Ectopic Thymus		1 (2%)		
Ultimobranchial Cyst				1 (2%)
Follicle, Cyst	1 (2%)			1 (2%)
Follicle, Degeneration, Focal	25 (50%)	19 (40%)	20 (41%)	13 (26%)

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B6C3F1 MICE FEMALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
Follicular Cell, Hyperplasia				3 (6%)
GENERAL BODY SYSTEM				
Tissue NOS	(0)	(1)	(0)	(1)
GENITAL SYSTEM				
Clitoral Gland	(47)	(47)	(49)	(47)
Cyst				1 (2%)
Inflammation, Chronic		3 (6%)		2 (4%)
Ovary	(46)	(50)	(48)	(49)
Angiectasis	1 (2%)	3 (6%)	3 (6%)	4 (8%)
Cyst	16 (35%)	10 (20%)	19 (40%)	19 (39%)
Hemorrhage	8 (17%)	12 (24%)	10 (21%)	10 (20%)
Corpus Luteum, Hyperplasia		1 (2%)		1 (2%)
Interstitial Cell, Hyperplasia		1 (2%)	1 (2%)	2 (4%)
Thecal Cell, Hyperplasia	1 (2%)			1 (2%)
Uterus	(50)	(50)	(50)	(50)
Angiectasis	1 (2%)	3 (6%)		6 (12%)
Hyperplasia, Cystic	47 (94%)	46 (92%)	46 (92%)	44 (88%)
Inflammation, Chronic		2 (4%)	2 (4%)	1 (2%)
Metaplasia, Squamous			2 (4%)	2 (4%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Hyperplasia	18 (36%)	21 (42%)	24 (48%)	18 (36%)
Hyperplasia, Neutrophil	1 (2%)			
Myelofibrosis			1 (2%)	
Lymph Node	(10)	(4)	(6)	(4)
Hematopoietic Cell Proliferation			1 (17%)	
Deep Cervical, Hemorrhage	1 (10%)			
Deep Cervical, Pigmentation	1 (10%)			
Iliac, Hematopoietic Cell Proliferation	1 (10%)		1 (17%)	1 (25%)
Iliac, Hyperplasia, Lymphoid		1 (25%)	3 (50%)	1 (25%)
Mediastinal, Hyperplasia, Lymphoid	1 (10%)			
Renal, Hematopoietic Cell Proliferation			1 (17%)	
Renal, Hyperplasia, Lymphoid		1 (25%)	3 (50%)	
Lymph Node, Mandibular	(48)	(49)	(46)	(47)
Angiectasis		1 (2%)		
Atrophy	1 (2%)		1 (2%)	
Ectasia	2 (4%)			

B6C3F1 MICE FEMALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
Hematopoietic Cell Proliferation	1 (2%)		1 (2%)	1 (2%)
Hemorrhage	1 (2%)			
Hyperplasia, Lymphoid	4 (8%)	3 (6%)	1 (2%)	3 (6%)
Pigmentation	2 (4%)	4 (8%)	1 (2%)	7 (15%)
Lymph Node, Mesenteric	(49)	(47)	(49)	(50)
Atrophy	2 (4%)		1 (2%)	2 (4%)
Ectasia		1 (2%)	1 (2%)	
Hematopoietic Cell Proliferation	2 (4%)	2 (4%)		
Hemorrhage	1 (2%)			
Hyperplasia, Lymphoid	3 (6%)	5 (11%)	2 (4%)	1 (2%)
Spleen	(50)	(48)	(49)	(50)
Fibrosis			1 (2%)	
Hematopoietic Cell Proliferation	20 (40%)	17 (35%)	17 (35%)	11 (22%)
Hemorrhage	1 (2%)			
Hyperplasia, Lymphoid		1 (2%)		
Necrosis	1 (2%)			
Lymphoid Follicle, Atrophy	1 (2%)		1 (2%)	
Lymphoid Follicle, Hyperplasia	6 (12%)	9 (19%)	8 (16%)	6 (12%)
Thymus	(49)	(47)	(46)	(49)
Angiectasis		1 (2%)		
Atrophy	6 (12%)	1 (2%)	5 (11%)	3 (6%)
Hyperplasia, Lymphoid	9 (18%)	5 (11%)	6 (13%)	
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Hyperplasia	5 (10%)	5 (10%)	5 (10%)	4 (8%)
Necrosis	1 (2%)			
Skin	(50)	(50)	(50)	(50)
Edema	2 (4%)		1 (2%)	1 (2%)
Hyperkeratosis			1 (2%)	
Inflammation, Chronic				1 (2%)
Epidermis, Hyperplasia			1 (2%)	
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Fibro-Osseous Lesion	8 (16%)	15 (30%)	19 (38%)	17 (34%)
Fibrosis		1 (2%)		
Fracture			1 (2%)	1 (2%)
Skeletal Muscle	(3)	(2)	(0)	(3)
Atrophy	1 (33%)			
Inflammation, Acute	1 (33%)			

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B6C3F1 MICE FEMALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Compression	1 (2%)			1 (2%)
Hemorrhage	1 (2%)			
Necrosis	1 (2%)			
Peripheral Nerve	(3)	(0)	(0)	(0)
Atrophy	1 (33%)			
Spinal Cord	(3)	(0)	(0)	(0)
Hemorrhage	1 (33%)			
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Edema	1 (2%)			
Hemorrhage	2 (4%)	4 (8%)	2 (4%)	7 (14%)
Infiltration Cellular, Histiocyte	1 (2%)	4 (8%)	1 (2%)	1 (2%)
Infiltration Cellular, Lymphocyte	3 (6%)	1 (2%)	6 (12%)	5 (10%)
Infiltration Cellular, Polymorphonuclear	1 (2%)			
Inflammation, Chronic	2 (4%)			
Thrombosis			1 (2%)	
Alveolar Epithelium, Hyperplasia	1 (2%)	3 (6%)	3 (6%)	1 (2%)
Arteriole, Hypertrophy		1 (2%)		
Nose	(50)	(50)	(50)	(50)
Inflammation, Chronic		2 (4%)		1 (2%)
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)
Cataract	1 (2%)		1 (2%)	
Inflammation, Chronic	1 (2%)		2 (4%)	
Cornea, Hyperplasia	1 (2%)		2 (4%)	
Retina, Degeneration	1 (2%)			
Harderian Gland	(50)	(50)	(50)	(50)
Hyperplasia, Focal		1 (2%)		
URINARY SYSTEM				
Kidney	(50)	(49)	(50)	(50)
Cyst		1 (2%)	1 (2%)	1 (2%)
Hyperplasia, Lymphoid				1 (2%)

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Time Report Requested: 13:13:48

First Dose M/F: 03/25/03 / 03/25/03

Lab: SRI

B6C3F1 MICE FEMALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
Infarct	2 (4%)			
Infiltration Cellular, Lymphocyte	4 (8%)	2 (4%)	2 (4%)	11 (22%)
Metaplasia, Osseous	4 (8%)			3 (6%)
Mineralization		1 (2%)		
Nephropathy	10 (20%)	7 (14%)	13 (26%)	10 (20%)
Renal Tubule, Accumulation, Hyaline Droplet	2 (4%)	1 (2%)		1 (2%)
Renal Tubule, Dilatation, Diffuse			1 (2%)	
Renal Tubule, Necrosis		2 (4%)		
Renal Tubule, Pigmentation			1 (2%)	
Urinary Bladder	(50)	(50)	(50)	(50)
Edema		1 (2%)		
Infiltration Cellular, Lymphocyte	2 (4%)	3 (6%)	5 (10%)	3 (6%)

*** END OF REPORT ***