

TDMS No. 88123 - 07
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
FORMAMIDE
CAS Number: 75-12-7
Pathologist: RYAN, M. - Blackshear, P.
F1_M3

Date Report Reqsted: 05/04/2006
Time Report Reqsted: 11:47:08
First Dose M/F: 10/04/01 / 10/03/01
Lab: BAT

C Number: C88123B
Lock Date: 05/24/2004
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL

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B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	4	8	6	14
Natural Death	7		8	3
Survivors				
Terminal Sacrifice	39	42	36	33
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Artery, Inflammation, Chronic			1 (2%)	
Muscularis, Inflammation, Chronic	1 (2%)			
Gallbladder	(45)	(48)	(45)	(46)
Cyst		1 (2%)		
Inflammation, Chronic		1 (2%)	1 (2%)	3 (7%)
Ulcer				1 (2%)
Epithelium, Cytoplasmic Alteration		1 (2%)		2 (4%)
Epithelium, Hyperplasia		1 (2%)	2 (4%)	
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Edema		1 (2%)		
Hemorrhage			1 (2%)	
Artery, Inflammation, Chronic			1 (2%)	
Intestine Large, Colon	(50)	(50)	(50)	(50)
Hemorrhage			1 (2%)	
Artery, Inflammation, Chronic	1 (2%)			
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Artery, Inflammation, Chronic		1 (2%)		
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Artery, Inflammation, Chronic	1 (2%)			
Epithelium, Hyperplasia, Focal				1 (2%)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Inflammation, Granulomatous		1 (2%)		
Inflammation, Chronic				1 (2%)
Peyer's Patch, Hyperplasia, Lymphoid	2 (4%)			1 (2%)
Liver	(50)	(50)	(50)	(50)

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

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Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Angiectasis			1 (2%)	
Basophilic Focus	2 (4%)	4 (8%)	3 (6%)	4 (8%)
Clear Cell Focus	29 (58%)	27 (54%)	21 (42%)	8 (16%)
Eosinophilic Focus	16 (32%)	21 (42%)	14 (28%)	9 (18%)
Fatty Change	31 (62%)	25 (50%)	15 (30%)	1 (2%)
Fibrosis				1 (2%)
Hematopoietic Cell Proliferation	1 (2%)			
Hepatodiaphragmatic Nodule				1 (2%)
Inflammation, Acute	1 (2%)			1 (2%)
Inflammation, Chronic	16 (32%)	16 (32%)	11 (22%)	15 (30%)
Mineralization	1 (2%)	1 (2%)		
Mixed Cell Focus	10 (20%)	12 (24%)	13 (26%)	11 (22%)
Necrosis	5 (10%)	9 (18%)	7 (14%)	11 (22%)
Tension Lipidosis	4 (8%)	5 (10%)	1 (2%)	6 (12%)
Bile Duct, Dilatation		1 (2%)		
Bile Duct, Hyperplasia		1 (2%)		
Centrilobular, Degeneration	1 (2%)			
Centrilobular, Necrosis	1 (2%)			1 (2%)
Serosa, Hyperplasia		1 (2%)		
Vein, Thrombosis				1 (2%)
Mesentery	(3)	(1)	(1)	(1)
Inflammation, Chronic	1 (33%)			
Artery, Inflammation, Chronic	1 (33%)		1 (100%)	
Fat, Necrosis	1 (33%)	1 (100%)		
Oral Mucosa	(7)	(5)	(5)	(7)
Inflammation, Chronic				1 (14%)
Gingival, Inflammation, Chronic	7 (100%)	5 (100%)	5 (100%)	6 (86%)
Pancreas	(50)	(50)	(50)	(50)
Acinus, Atrophy	1 (2%)	3 (6%)		2 (4%)
Acinus, Cytoplasmic Alteration		1 (2%)	1 (2%)	1 (2%)
Duct, Cyst			1 (2%)	1 (2%)
Duct, Inflammation, Chronic		1 (2%)		
Salivary Glands	(50)	(50)	(50)	(50)
Inflammation, Granulomatous	1 (2%)			
Artery, Parotid Gland, Inflammation, Chronic			1 (2%)	
Artery, Parotid Gland, Mineralization			1 (2%)	1 (2%)
Parotid Gland, Atrophy				1 (2%)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Hemorrhage			1 (2%)	
Inflammation, Chronic	1 (2%)			
Ulcer	1 (2%)		1 (2%)	1 (2%)

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B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Artery, Inflammation, Chronic	1 (2%)			
Epithelium, Hyperplasia, Focal	1 (2%)		1 (2%)	
Epithelium, Vacuolization Cytoplasmic		1 (2%)		
Stomach, Glandular	(50)	(50)	(50)	(50)
Hemorrhage, Acute		1 (2%)		
Inflammation, Chronic			4 (8%)	1 (2%)
Mineralization			1 (2%)	
Ulcer			1 (2%)	3 (6%)
Epithelium, Glands, Ectasia		1 (2%)		
Epithelium, Glands, Hyperplasia, Focal			1 (2%)	
Epithelium, Hyperplasia, Focal		1 (2%)		
Glands, Ectasia		1 (2%)	2 (4%)	2 (4%)
Tooth	(15)	(14)	(9)	(2)
Dysplasia	2 (13%)	1 (7%)	2 (22%)	
Malformation	14 (93%)	13 (93%)	7 (78%)	2 (100%)
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)
Aorta, Inflammation, Chronic	1 (2%)			
Heart	(50)	(50)	(50)	(50)
Thrombosis				1 (2%)
Artery, Inflammation, Chronic	1 (2%)	1 (2%)	2 (4%)	
Atrium, Thrombosis	1 (2%)	1 (2%)		3 (6%)
Epicardium, Hyperplasia	1 (2%)			
Epicardium, Infiltration Cellular, Mononuclear Cell	1 (2%)			
Myocardium, Infiltration Cellular, Mononuclear Cell	9 (18%)	10 (20%)	2 (4%)	12 (24%)
Myocardium, Mineralization			2 (4%)	2 (4%)
Myocardium, Necrosis	3 (6%)	1 (2%)	1 (2%)	4 (8%)
Myocardium, Necrosis, Focal		1 (2%)		
Nerve, Inflammation, Chronic				1 (2%)
Ventricle, Atrophy			1 (2%)	
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(49)	(50)
Angiectasis		1 (2%)	1 (2%)	1 (2%)
Hyperplasia	2 (4%)			2 (4%)

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B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Hypertrophy	15 (30%)	17 (34%)	17 (35%)	13 (26%)
Pigmentation	1 (2%)			2 (4%)
Vacuolization Cytoplasmic				1 (2%)
Vacuolization Cytoplasmic, Focal	17 (34%)	14 (28%)	11 (22%)	16 (32%)
Subcapsular, Hyperplasia	50 (100%)	49 (98%)	42 (86%)	45 (90%)
Subcapsular, Hypertrophy, Focal	1 (2%)			
Adrenal Medulla	(50)	(50)	(50)	(50)
Hyperplasia, Focal	2 (4%)	1 (2%)	1 (2%)	3 (6%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Hyperplasia	35 (70%)	24 (48%)	24 (48%)	9 (18%)
Parathyroid Gland	(43)	(39)	(46)	(47)
Right, Atrophy				1 (2%)
Pituitary Gland	(50)	(50)	(50)	(49)
Angiectasis	1 (2%)			
Cyst	5 (10%)	2 (4%)	2 (4%)	2 (4%)
Pars Distalis, Hyperplasia, Focal	3 (6%)	4 (8%)	1 (2%)	
Thyroid Gland	(50)	(50)	(50)	(50)
Cyst	2 (4%)	3 (6%)	2 (4%)	5 (10%)
Inflammation, Granulomatous	1 (2%)			
Inflammation, Chronic		1 (2%)		1 (2%)
C-cell, Hyperplasia				1 (2%)
Follicle, Hyperplasia	1 (2%)			
Follicle, Hyperplasia, Focal	12 (24%)	15 (30%)	8 (16%)	8 (16%)

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Epididymis	(50)	(50)	(50)	(50)
Granuloma Sperm	1 (2%)	1 (2%)		3 (6%)
Inflammation, Chronic	1 (2%)			1 (2%)
Artery, Inflammation, Chronic		1 (2%)		
Preputial Gland	(50)	(50)	(50)	(50)
Cyst	19 (38%)	11 (22%)	11 (22%)	10 (20%)
Infiltration Cellular, Lymphoid			1 (2%)	
Infiltration Cellular, Chronic				1 (2%)
Inflammation, Suppurative				1 (2%)
Inflammation, Granulomatous	1 (2%)	1 (2%)		

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Inflammation, Chronic	1 (2%)	4 (8%)		1 (2%)
Duct, Cyst		1 (2%)		
Prostate	(50)	(50)	(50)	(50)
Infiltration Cellular, Lymphoid			1 (2%)	
Inflammation, Suppurative	1 (2%)	1 (2%)		1 (2%)
Inflammation, Chronic		1 (2%)	1 (2%)	
Seminal Vesicle	(50)	(50)	(50)	(50)
Atrophy				2 (4%)
Fibrosis	1 (2%)		1 (2%)	
Inflammation, Suppurative	1 (2%)			
Inflammation, Chronic		1 (2%)		
Testes	(50)	(50)	(50)	(50)
Granuloma Sperm				1 (2%)
Artery, Inflammation, Chronic	1 (2%)		1 (2%)	
Artery, Mineralization		2 (4%)	5 (10%)	35 (70%)
Artery, Thrombosis			1 (2%)	
Germinal Epithelium, Degeneration	1 (2%)	4 (8%)	1 (2%)	4 (8%)
Germinal Epithelium, Inflammation, Chronic				1 (2%)
Germinal Epithelium, Mineralization		1 (2%)	1 (2%)	
Tunic, Inflammation, Chronic	1 (2%)			1 (2%)
Tunic, Mineralization	1 (2%)		5 (10%)	27 (54%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Hyperplasia	34 (68%)	39 (78%)	35 (70%)	34 (68%)
Lymph Node	(4)	(2)	(1)	(1)
Bronchial, Hyperplasia, Lymphoid	1 (25%)			
Lumbar, Hyperplasia, Lymphoid	1 (25%)			
Mediastinal, Hyperplasia, Lymphoid	2 (50%)			
Pancreatic, Hyperplasia		1 (50%)		
Renal, Hyperplasia, Lymphoid	2 (50%)			
Lymph Node, Mandibular	(49)	(48)	(49)	(48)
Atrophy	11 (22%)	5 (10%)	6 (12%)	13 (27%)
Hematopoietic Cell Proliferation	1 (2%)			
Hyperplasia, Lymphoid	2 (4%)	5 (10%)	5 (10%)	2 (4%)
Necrosis, Lymphoid	2 (4%)			1 (2%)
Lymph Node, Mesenteric	(50)	(47)	(50)	(49)
Atrophy	10 (20%)	3 (6%)	6 (12%)	14 (29%)
Hyperplasia, Lymphoid	4 (8%)	1 (2%)	4 (8%)	
Necrosis, Lymphoid	1 (2%)		1 (2%)	1 (2%)

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

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B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Spleen	(50)	(50)	(50)	(50)
Atrophy	2 (4%)	6 (12%)	3 (6%)	7 (14%)
Hematopoietic Cell Proliferation	14 (28%)	14 (28%)	20 (40%)	28 (56%)
Hyperplasia, Plasma Cell	1 (2%)			
Lymphoid Follicle, Hyperplasia	4 (8%)	1 (2%)	4 (8%)	
Lymphoid Follicle, Necrosis	1 (2%)			
Thymus	(47)	(46)	(50)	(46)
Atrophy	41 (87%)	39 (85%)	37 (74%)	44 (96%)
Cyst	19 (40%)	9 (20%)	15 (30%)	9 (20%)
Ectopic Parathyroid Gland			1 (2%)	
Hyperplasia, Lymphoid	1 (2%)		2 (4%)	
Necrosis	1 (2%)			
Epithelial Cell, Hyperplasia			1 (2%)	
INTEGUMENTARY SYSTEM				
Skin	(50)	(50)	(50)	(50)
Ulcer				3 (6%)
Subcutaneous Tissue, Edema				1 (2%)
Subcutaneous Tissue, Inflammation, Chronic	1 (2%)			
Subcutaneous Tissue, Necrosis			1 (2%)	
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Hyperostosis	1 (2%)	2 (4%)	2 (4%)	3 (6%)
Cranium, Hyperplasia		1 (2%)		
Skeletal Muscle	(1)	(1)	(0)	(2)
Inflammation, Granulomatous	1 (100%)			
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Compression	1 (2%)			
Cyst Epithelial Inclusion	1 (2%)			
Hemorrhage, Acute		1 (2%)		
Hydrocephalus	1 (2%)			
Necrosis		1 (2%)		
Artery, Inflammation, Chronic		1 (2%)	1 (2%)	
Meninges, Ventricle, Inflammation,	1 (2%)			

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Granulomatous Meninges, Infiltration Cellular, Lymphocyte Vein, Infiltration Cellular, Mononuclear Cell		1 (2%) 1 (2%)		
Peripheral Nerve Axon, Degeneration	(0)	(0)	(1) 1 (100%)	(0)
Spinal Cord Hemorrhage	(0)	(0)	(1) 1 (100%)	(0)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Fibrosis	1 (2%)			
Inflammation, Chronic			3 (6%)	1 (2%)
Metaplasia, Osseous			2 (4%)	
Alveolar Epithelium, Hyperplasia	2 (4%)	1 (2%)	4 (8%)	2 (4%)
Alveolus, Infiltration Cellular, Histiocyte	1 (2%)		1 (2%)	8 (16%)
Arteriole, Thrombosis	1 (2%)			
Artery, Mineralization	1 (2%)			
Bronchus, Hypertrophy	1 (2%)			
Serosa, Inflammation, Chronic				1 (2%)
Nose	(50)	(50)	(50)	(50)
Inflammation, Suppurative	4 (8%)	4 (8%)	1 (2%)	1 (2%)
Inflammation, Chronic		2 (4%)	1 (2%)	1 (2%)
Polyp, Inflammatory	1 (2%)	1 (2%)	1 (2%)	
Glands, Hyperplasia				1 (2%)
Glands, Hyperplasia, Focal	1 (2%)			
Glands, Inflammation, Suppurative	4 (8%)	1 (2%)	1 (2%)	
Nasolacrimal Duct, Infiltration Cellular, Polymorphonuclear	2 (4%)	5 (10%)	2 (4%)	2 (4%)
Nasopharyngeal Duct, Inflammation, Chronic				1 (2%)
Olfactory Epithelium, Amyloid Deposition	1 (2%)			
Olfactory Epithelium, Atrophy, Focal	8 (16%)	5 (10%)	1 (2%)	2 (4%)
Olfactory Epithelium, Metaplasia	1 (2%)			
Olfactory Epithelium, Metaplasia, Focal		1 (2%)		
Respiratory Epithelium, Atrophy, Focal		2 (4%)		
Respiratory Epithelium, Hyperplasia, Focal	1 (2%)	1 (2%)	1 (2%)	
Respiratory Epithelium, Metaplasia, Squamous		1 (2%)		
Vomeronasal Organ, Infiltration Cellular, Polymorphonuclear	2 (4%)	10 (20%)	3 (6%)	4 (8%)
Pleura	(1)	(0)	(0)	(0)

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B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Hyperplasia	1 (100%)			
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)
Degeneration				1 (2%)
Anterior Chamber, Inflammation, Suppurative				1 (2%)
Cornea, Inflammation, Chronic	3 (6%)		2 (4%)	1 (2%)
Harderian Gland	(50)	(50)	(50)	(50)
Hyperplasia, Focal	4 (8%)	8 (16%)	5 (10%)	10 (20%)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Casts Protein	1 (2%)			
Fibrosis, Focal			1 (2%)	
Infarct	1 (2%)	1 (2%)	3 (6%)	
Inflammation, Suppurative				1 (2%)
Inflammation, Chronic		2 (4%)		1 (2%)
Metaplasia, Osseous	1 (2%)	1 (2%)	3 (6%)	4 (8%)
Mineralization	16 (32%)	15 (30%)	2 (4%)	5 (10%)
Necrosis				1 (2%)
Nephropathy	43 (86%)	46 (92%)	41 (82%)	45 (90%)
Artery, Inflammation, Chronic	2 (4%)	1 (2%)	1 (2%)	
Glomerulus, Inflammation, Chronic	1 (2%)			
Glomerulus, Necrosis, Fibrinoid	1 (2%)			
Papilla, Necrosis	1 (2%)			
Pelvis, Inflammation, Suppurative	1 (2%)			2 (4%)
Renal Tubule, Accumulation, Hyaline Droplet	1 (2%)			
Renal Tubule, Cyst	8 (16%)	5 (10%)	4 (8%)	5 (10%)
Renal Tubule, Hyperplasia	1 (2%)	2 (4%)	5 (10%)	1 (2%)
Renal Tubule, Mineralization			1 (2%)	
Vein, Infiltration Cellular, Lymphocyte		1 (2%)		
Urinary Bladder	(50)	(50)	(50)	(50)
Infiltration Cellular, Lymphoid	1 (2%)		1 (2%)	
Inflammation, Suppurative	1 (2%)			
Inflammation, Chronic		2 (4%)		1 (2%)
Artery, Inflammation, Chronic	1 (2%)		1 (2%)	
Artery, Mineralization	1 (2%)			

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Transitional Epithelium, Hyperplasia	1 (2%)			

*** END OF MALE ***

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B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Dosing Accident			1	
Moribund Sacrifice	7	8	8	8
Natural Death	5	3	10	3
Survivors				
Natural Death		1		
Terminal Sacrifice	38	38	31	39
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Inflammation, Suppurative			1 (2%)	
Perforation			1 (2%)	
Gallbladder	(47)	(45)	(46)	(49)
Cyst	1 (2%)			
Inflammation, Chronic	1 (2%)			
Epithelium, Cytoplasmic Alteration				1 (2%)
Intestine Large, Cecum	(49)	(50)	(50)	(50)
Edema	1 (2%)			
Lymphoid Tissue, Hyperplasia, Lymphoid			1 (2%)	
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Serosa, Inflammation, Chronic			1 (2%)	
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Inflammation, Chronic	1 (2%)			
Epithelium, Hyperplasia, Focal	1 (2%)			
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Epithelium, Cyst	1 (2%)			
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Artery, Peyer's Patch, Mineralization			1 (2%)	
Epithelium, Hyperplasia, Focal				1 (2%)
Liver	(50)	(50)	(50)	(50)
Angiectasis			2 (4%)	
Basophilic Focus			1 (2%)	2 (4%)
Clear Cell Focus	3 (6%)	2 (4%)	2 (4%)	2 (4%)

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

TDMS No. 88123 - 07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
 FORMAMIDE
 CAS Number: 75-12-7
 Pathologist: RYAN, M. - Blackshear, P.

Date Report Requested: 05/04/2006
 Time Report Requested: 11:47:08
 First Dose M/F: 10/04/01 / 10/03/01
 Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Eosinophilic Focus	12 (24%)	15 (30%)	8 (16%)	7 (14%)
Fatty Change	6 (12%)	7 (14%)	4 (8%)	2 (4%)
Hematopoietic Cell Proliferation	3 (6%)	4 (8%)	1 (2%)	1 (2%)
Infarct			1 (2%)	
Inflammation, Chronic	29 (58%)	27 (54%)	21 (42%)	21 (42%)
Mineralization				1 (2%)
Mixed Cell Focus	4 (8%)	5 (10%)	4 (8%)	6 (12%)
Necrosis	1 (2%)			2 (4%)
Tension Lipidosis	3 (6%)	9 (18%)	5 (10%)	6 (12%)
Centrilobular, Necrosis			1 (2%)	
Centrilobular, Vacuolization Cytoplasmic	1 (2%)			
Mesentery	(8)	(3)	(8)	(2)
Fat, Necrosis	5 (63%)	3 (100%)	8 (100%)	2 (100%)
Oral Mucosa	(1)	(0)	(0)	(0)
Gingival, Inflammation, Chronic	1 (100%)			
Pancreas	(49)	(49)	(50)	(50)
Hyperplasia, Lymphoid			1 (2%)	
Inflammation, Chronic			2 (4%)	
Acinus, Atrophy		1 (2%)	3 (6%)	2 (4%)
Acinus, Cytoplasmic Alteration	1 (2%)			1 (2%)
Artery, Thrombosis			1 (2%)	
Duct, Cyst			1 (2%)	3 (6%)
Duct, Cytoplasmic Alteration				1 (2%)
Duct, Inflammation, Chronic	1 (2%)		1 (2%)	
Salivary Glands	(49)	(50)	(50)	(50)
Atrophy, Diffuse				1 (2%)
Parotid Gland, Atrophy		1 (2%)	1 (2%)	
Stomach, Forestomach	(50)	(50)	(50)	(50)
Inflammation, Chronic	1 (2%)			
Epithelium, Hyperplasia	1 (2%)			1 (2%)
Stomach, Glandular	(50)	(50)	(50)	(50)
Inflammation, Chronic	1 (2%)	1 (2%)		1 (2%)
Ulcer		1 (2%)		
Epithelium, Glands, Cytoplasmic Alteration	1 (2%)			1 (2%)
Epithelium, Glands, Hyperplasia				1 (2%)
Glands, Ectasia	1 (2%)			
Glands, Hyperplasia	1 (2%)			
Tooth	(0)	(0)	(0)	(1)
Malformation				1 (100%)

TDMS No. 88123 - 07
 Test Type: CHRONIC
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 Species/Strain: MICE/B6C3F1

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
 FORMAMIDE
 CAS Number: 75-12-7
 Pathologist: RYAN, M. - Blackshear, P.

Date Report Requested: 05/04/2006
 Time Report Requested: 11:47:08
 First Dose M/F: 10/04/01 / 10/03/01
 Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Artery, Inflammation, Chronic	2 (4%)			
Atrium, Thrombosis			1 (2%)	1 (2%)
Coronary Artery, Inflammation, Chronic	1 (2%)			
Myocardium, Infiltration Cellular, Mononuclear Cell	2 (4%)	7 (14%)	4 (8%)	3 (6%)
Myocardium, Mineralization		3 (6%)	1 (2%)	
Myocardium, Necrosis			1 (2%)	
Ventricle, Thrombosis				1 (2%)
ENDOCRINE SYSTEM				
Adrenal Cortex	(49)	(50)	(49)	(50)
Angiectasis		1 (2%)		
Atrophy				1 (2%)
Hematopoietic Cell Proliferation	1 (2%)	1 (2%)		
Hyperplasia		2 (4%)		1 (2%)
Hypertrophy	1 (2%)	1 (2%)	4 (8%)	
Pigmentation		3 (6%)		
Vacuolization Cytoplasmic, Focal	3 (6%)		2 (4%)	
Subcapsular, Hyperplasia	49 (100%)	49 (98%)	48 (98%)	49 (98%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Angiectasis		1 (2%)		
Hyperplasia, Focal	1 (2%)	4 (8%)	1 (2%)	2 (4%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Hyperplasia	1 (2%)	1 (2%)	4 (8%)	
Parathyroid Gland	(42)	(32)	(35)	(42)
Cyst	1 (2%)			2 (5%)
Pituitary Gland	(50)	(50)	(49)	(50)
Angiectasis	2 (4%)	1 (2%)		
Cyst	3 (6%)	4 (8%)		1 (2%)
Fibrosis		1 (2%)		
Hemorrhage, Chronic		1 (2%)		
Pars Distalis, Hyperplasia, Focal	11 (22%)	11 (22%)	10 (20%)	10 (20%)
Pars Intermedia, Hyperplasia, Focal	1 (2%)		1 (2%)	1 (2%)
Thyroid Gland	(49)	(50)	(50)	(50)
Cyst	1 (2%)	1 (2%)	2 (4%)	
Infiltration Cellular, Lymphoid		1 (2%)		

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TDMS No. 88123 - 07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
 FORMAMIDE
 CAS Number: 75-12-7
 Pathologist: RYAN, M. - Blackshear, P.

Date Report Requested: 05/04/2006
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 Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Inflammation, Suppurative		2 (4%)		
Inflammation, Granulomatous				1 (2%)
Inflammation, Chronic	1 (2%)	1 (2%)	1 (2%)	
Follicle, Hyperplasia, Focal	14 (29%)	6 (12%)	10 (20%)	5 (10%)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Clitoral Gland	(50)	(50)	(49)	(50)
Duct, Cyst				1 (2%)
Ovary	(50)	(50)	(50)	(49)
Angiectasis	2 (4%)	2 (4%)	1 (2%)	2 (4%)
Cyst	24 (48%)	19 (38%)	11 (22%)	23 (47%)
Mineralization		1 (2%)		
Thrombosis	1 (2%)	1 (2%)	2 (4%)	2 (4%)
Bilateral, Thrombosis	1 (2%)			
Follicle, Atrophy	33 (66%)	29 (58%)	35 (70%)	37 (76%)
Uterus	(50)	(50)	(50)	(50)
Angiectasis		2 (4%)	2 (4%)	1 (2%)
Dilatation				2 (4%)
Inflammation, Suppurative	1 (2%)	1 (2%)		
Inflammation, Chronic Active				1 (2%)
Thrombosis			1 (2%)	
Endometrium, Hyperplasia, Cystic	45 (90%)	48 (96%)	45 (90%)	42 (84%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Atrophy				1 (2%)
Hyperplasia	8 (16%)	10 (20%)	13 (26%)	5 (10%)
Infiltration Cellular, Histiocyte	1 (2%)			
Lymph Node	(8)	(4)	(6)	(5)
Bronchial, Hyperplasia, Lymphoid		1 (25%)		
Iliac, Necrosis		1 (25%)		
Lumbar, Hematopoietic Cell Proliferation	1 (13%)			
Lumbar, Hyperplasia, Lymphoid	1 (13%)			
Mediastinal, Hematopoietic Cell Proliferation	1 (13%)			

TDMS No. 88123 - 07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
 FORMAMIDE
 CAS Number: 75-12-7
 Pathologist: RYAN, M. - Blackshear, P.

Date Report Requested: 05/04/2006
 Time Report Requested: 11:47:08
 First Dose M/F: 10/04/01 / 10/03/01
 Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Mediastinal, Hyperplasia, Lymphoid	2 (25%)			
Mediastinal, Inflammation, Chronic			1 (17%)	
Renal, Hyperplasia, Lymphoid	1 (13%)			
Lymph Node, Mandibular	(49)	(50)	(50)	(50)
Atrophy	3 (6%)	2 (4%)	6 (12%)	4 (8%)
Hematopoietic Cell Proliferation	1 (2%)	1 (2%)		
Hyperplasia, Lymphoid	8 (16%)		5 (10%)	6 (12%)
Necrosis, Lymphoid	1 (2%)		1 (2%)	
Lymph Node, Mesenteric	(50)	(50)	(49)	(50)
Atrophy	7 (14%)	9 (18%)	8 (16%)	7 (14%)
Hematopoietic Cell Proliferation	1 (2%)			
Hyperplasia, Lymphoid	4 (8%)	1 (2%)	4 (8%)	3 (6%)
Infiltration Cellular, Polymorphonuclear			1 (2%)	
Inflammation, Suppurative				1 (2%)
Necrosis, Lymphoid	2 (4%)	1 (2%)	1 (2%)	
Spleen	(50)	(49)	(49)	(50)
Atrophy	1 (2%)	2 (4%)	1 (2%)	2 (4%)
Hematopoietic Cell Proliferation	17 (34%)	17 (35%)	15 (31%)	8 (16%)
Hyperplasia, Lymphoid				3 (6%)
Hyperplasia, Plasma Cell	1 (2%)		1 (2%)	
Lymphoid Follicle, Hyperplasia	3 (6%)	4 (8%)		2 (4%)
Lymphoid Follicle, Necrosis	3 (6%)			1 (2%)
Thymus	(49)	(50)	(49)	(50)
Angiectasis				1 (2%)
Atrophy	16 (33%)	19 (38%)	12 (24%)	17 (34%)
Cyst	7 (14%)	9 (18%)	7 (14%)	
Hyperplasia, Lymphoid	9 (18%)	11 (22%)	7 (14%)	8 (16%)
Necrosis, Lymphoid	1 (2%)	1 (2%)	1 (2%)	
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Hyperplasia, Cystic	1 (2%)	1 (2%)		
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion			1 (2%)	
Inflammation, Granulomatous			1 (2%)	
Ulcer			2 (4%)	
MUSCULOSKELETAL SYSTEM				

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P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
 FORMAMIDE
 CAS Number: 75-12-7
 Pathologist: RYAN, M. - Blackshear, P.

Date Report Requested: 05/04/2006
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 Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Bone	(50)	(50)	(50)	(50)
Atrophy				1 (2%)
Hyperostosis	3 (6%)	6 (12%)	3 (6%)	2 (4%)
Skeletal Muscle	(2)	(5)	(5)	(0)
Fibrosis		3 (60%)		
Inflammation, Chronic			1 (20%)	
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Arteriole, Inflammation, Chronic	1 (2%)			
Artery, Meninges, Inflammation, Chronic				1 (2%)
Hypothalamus, Compression	1 (2%)	2 (4%)	1 (2%)	
Meninges, Infiltration Cellular, Lymphocyte	2 (4%)		1 (2%)	
Vein, Infiltration Cellular, Lymphocyte	1 (2%)			
Spinal Cord	(1)	(0)	(0)	(0)
Hemorrhage	1 (100%)			
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Hematopoietic Cell Proliferation		1 (2%)		
Inflammation, Granulomatous				1 (2%)
Inflammation, Focal, Chronic	1 (2%)			
Inflammation, Chronic	2 (4%)			
Metaplasia, Osseous	1 (2%)		1 (2%)	1 (2%)
Necrosis			1 (2%)	
Alveolar Epithelium, Hyperplasia	2 (4%)	5 (10%)	2 (4%)	
Alveolus, Infiltration Cellular, Histiocyte	1 (2%)	1 (2%)	1 (2%)	3 (6%)
Vein, Thrombosis			2 (4%)	
Nose	(50)	(50)	(50)	(50)
Inflammation, Suppurative		1 (2%)		
Inflammation, Chronic	1 (2%)		2 (4%)	
Glands, Hyperplasia	1 (2%)			
Glands, Inflammation, Suppurative			2 (4%)	
Nasolacrimal Duct, Infiltration Cellular, Polymorphonuclear	3 (6%)	1 (2%)	2 (4%)	1 (2%)
Olfactory Epithelium, Atrophy, Focal		2 (4%)	1 (2%)	1 (2%)
Respiratory Epithelium, Hyperplasia, Focal	1 (2%)			1 (2%)
Respiratory Epithelium, Necrosis			1 (2%)	

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 FORMAMIDE
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 Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Vomeronasal Organ, Infiltration Cellular, Polymorphonuclear	9 (18%)	11 (22%)	2 (4%)	5 (10%)
Pleura	(0)	(0)	(1)	(0)
SPECIAL SENSES SYSTEM				
Eye	(49)	(50)	(49)	(50)
Degeneration	1 (2%)	1 (2%)		
Cornea, Inflammation, Chronic	1 (2%)			1 (2%)
Retrolbulbar, Inflammation, Chronic	1 (2%)			
Harderian Gland	(49)	(50)	(50)	(50)
Fibrosis				1 (2%)
Hyperplasia, Focal	7 (14%)	4 (8%)	3 (6%)	5 (10%)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Hydronephrosis	1 (2%)	1 (2%)		
Hyperplasia, Lymphoid	1 (2%)			
Infarct	2 (4%)	1 (2%)	1 (2%)	
Infiltration Cellular, Lymphoid		1 (2%)		
Metaplasia, Osseous	1 (2%)	1 (2%)	1 (2%)	1 (2%)
Mineralization	6 (12%)	5 (10%)	1 (2%)	3 (6%)
Nephropathy	35 (70%)	23 (46%)	28 (56%)	38 (76%)
Arteriole, Inflammation, Chronic		1 (2%)		
Artery, Inflammation, Chronic	1 (2%)			
Glomerulus, Amyloid Deposition				1 (2%)
Renal Tubule, Accumulation, Hyaline Droplet	1 (2%)	2 (4%)		
Renal Tubule, Cyst				1 (2%)
Urinary Bladder	(50)	(50)	(50)	(50)
Artery, Inflammation, Chronic				1 (2%)

*** END OF REPORT ***