

TDMS No. 88105 - 04
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
 ISOEUGENOL
 CAS Number: 97-54-1
 Pathologist: Blackshear, P. - GRUMBEIN, S.

Date Report Requested: 10/04/2006
 Time Report Requested: 13:43:51
 First Dose M/F: 05/09/02 / 05/08/02
 Lab: BNW

B6C3F1 MICE MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	7	10	5	7
Natural Death	4	2	9	16
Survivors				
Terminal Sacrifice	39	38	36	27
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Gallbladder	(44)	(47)	(46)	(38)
Hyperplasia				1 (3%)
Intestine Large, Colon	(48)	(49)	(46)	(46)
Intestine Small, Jejunum	(47)	(48)	(46)	(42)
Necrosis		1 (2%)		
Ulcer				1 (2%)
Liver	(50)	(50)	(50)	(50)
Angiectasis			1 (2%)	
Basophilic Focus	5 (10%)	5 (10%)	3 (6%)	7 (14%)
Clear Cell Focus	16 (32%)	26 (52%)	29 (58%)	13 (26%)
Eosinophilic Focus	8 (16%)	13 (26%)	11 (22%)	5 (10%)
Hepatodiaphragmatic Nodule			2 (4%)	
Infarct	2 (4%)	1 (2%)		
Necrosis	1 (2%)		2 (4%)	5 (10%)
Mesentery	(5)	(4)	(4)	(1)
Fat, Necrosis	5 (100%)	3 (75%)	4 (100%)	
Pancreas	(50)	(50)	(50)	(49)
Atrophy	2 (4%)	1 (2%)	2 (4%)	
Hemorrhage		1 (2%)		
Hyperplasia				1 (2%)
Necrosis, Fatty			1 (2%)	
Duct, Cyst			1 (2%)	
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(49)	(50)	(49)
Hyperplasia, Squamous	7 (14%)	8 (16%)	8 (16%)	14 (29%)
Inflammation	5 (10%)	8 (16%)	9 (18%)	14 (29%)
Metaplasia, Hepatocyte		1 (2%)		

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B6C3F1 MICE MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Ulcer	1 (2%)	4 (8%)	4 (8%)	9 (18%)
Stomach, Glandular Atrophy	(50)	(49)	(49)	(44)
Hyperplasia			1 (2%)	1 (2%)
Inflammation		1 (2%)	3 (6%)	3 (7%)
Inflammation, Acute			1 (2%)	2 (5%)
Metaplasia, Hepatocyte		1 (2%)		
Mineralization	1 (2%)			
Ulcer		1 (2%)	4 (8%)	5 (11%)
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	9 (18%)	11 (22%)	14 (28%)	12 (24%)
Inflammation, Suppurative	1 (2%)		1 (2%)	
Mineralization	1 (2%)			2 (4%)
Thrombosis	1 (2%)	1 (2%)	1 (2%)	
Artery, Inflammation, Chronic Active	1 (2%)	2 (4%)		1 (2%)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(49)
Hyperplasia	13 (26%)	16 (32%)	12 (24%)	7 (14%)
Hypertrophy	13 (26%)	13 (26%)	14 (28%)	6 (12%)
Adrenal Medulla	(50)	(50)	(50)	(49)
Hyperplasia		1 (2%)	2 (4%)	
Islets, Pancreatic	(50)	(50)	(50)	(49)
Hyperplasia	3 (6%)		1 (2%)	
Pituitary Gland	(50)	(48)	(50)	(48)
Pars Distalis, Hyperplasia	1 (2%)	3 (6%)	3 (6%)	
Thyroid Gland	(50)	(49)	(50)	(49)
Follicular Cell, Hyperplasia		2 (4%)		1 (2%)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				

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B6C3F1 MICE MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Coagulating Gland	(0)	(1)	(0)	(0)
Epididymis	(50)	(50)	(50)	(50)
Granuloma Sperm		1 (2%)		1 (2%)
Inflammation, Acute		1 (2%)	1 (2%)	
Necrosis			1 (2%)	
Preputial Gland	(50)	(50)	(50)	(50)
Ectasia	5 (10%)	4 (8%)	5 (10%)	6 (12%)
Inflammation, Granulomatous		1 (2%)		
Prostate	(50)	(50)	(50)	(50)
Inflammation, Chronic Active		1 (2%)		1 (2%)
Seminal Vesicle	(49)	(50)	(50)	(48)
Dilatation		1 (2%)		
Testes	(50)	(50)	(50)	(50)
Atrophy	1 (2%)	1 (2%)		4 (8%)
Inflammation, Suppurative		1 (2%)		
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Atrophy			1 (2%)	
Hyperplasia, Reticulum Cell				1 (2%)
Necrosis		1 (2%)		
Lymph Node	(1)	(0)	(2)	(2)
Lymph Node, Mandibular	(49)	(49)	(50)	(47)
Lymph Node, Mesenteric	(48)	(50)	(50)	(48)
Spleen	(50)	(50)	(50)	(49)
Depletion Cellular				2 (4%)
Hematopoietic Cell Proliferation			1 (2%)	1 (2%)
Thymus	(48)	(48)	(48)	(42)
INTEGUMENTARY SYSTEM				
Skin	(50)	(50)	(50)	(50)
Inflammation, Acute	1 (2%)			
Inflammation, Chronic Active		3 (6%)	1 (2%)	2 (4%)
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Arthrosis	1 (2%)			

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B6C3F1 MICE MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Skeletal Muscle	(1)	(0)	(0)	(0)
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Inflammation, Granulomatous				1 (2%)
Necrosis		2 (4%)		
RESPIRATORY SYSTEM				
Lung	(50)	(49)	(50)	(50)
Thrombosis	1 (2%)		1 (2%)	
Alveolar Epithelium, Hyperplasia	3 (6%)	4 (8%)	4 (8%)	2 (4%)
Alveolus, Infiltration Cellular, Histiocyte		1 (2%)		
Bronchiole, Hyperplasia	1 (2%)		1 (2%)	
Nose	(50)	(50)	(50)	(50)
Polyp, Inflammatory		1 (2%)		
Glands, Hyperplasia	3 (6%)	34 (68%)	49 (98%)	48 (96%)
Olfactory Epithelium, Accumulation, Hyaline Droplet		6 (12%)	26 (52%)	19 (38%)
Olfactory Epithelium, Atrophy	5 (10%)	13 (26%)	36 (72%)	41 (82%)
Olfactory Epithelium, Degeneration	1 (2%)	1 (2%)	7 (14%)	6 (12%)
Olfactory Epithelium, Inflammation, Granulomatous				1 (2%)
Olfactory Epithelium, Metaplasia, Squamous			2 (4%)	1 (2%)
Olfactory Epithelium, Respiratory Metaplasia	4 (8%)	31 (62%)	47 (94%)	49 (98%)
Pleura	(0)	(1)	(0)	(0)
SPECIAL SENSES SYSTEM				
Eye	(48)	(48)	(46)	(43)
Inflammation, Acute		1 (2%)		
Cornea, Inflammation, Chronic Active		1 (2%)	1 (2%)	
Harderian Gland	(49)	(50)	(50)	(49)
Hyperplasia	3 (6%)	4 (8%)	4 (8%)	4 (8%)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(49)

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B6C3F1 MICE MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Infarct	1 (2%)	1 (2%)	2 (4%)	1 (2%)
Inflammation, Suppurative Metaplasia, Osseous		2 (4%)		2 (4%)
Nephropathy	47 (94%)	48 (96%)	1 (2%) 47 (94%)	47 (96%)
Renal Tubule, Hyperplasia	2 (4%)	2 (4%)	1 (2%)	2 (4%)
Urinary Bladder Inflammation, Chronic Active	(49)	(50) 1 (2%)	(50)	(45)

*** END OF MALE ***

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B6C3F1 MICE FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Accidently Killed	2			1
Moribund Sacrifice	5	7	5	5
Natural Death	8	4	7	11
Survivors				
Terminal Sacrifice	34	39	38	33
Animals Examined Microscopically	49	50	50	50
ALIMENTARY SYSTEM				
Gallbladder	(42)	(47)	(47)	(40)
Degeneration, Hyaline			1 (2%)	
Intestine Large, Cecum	(46)	(47)	(45)	(42)
Inflammation, Acute				1 (2%)
Necrosis				1 (2%)
Intestine Large, Colon	(47)	(47)	(47)	(47)
Intestine Large, Rectum	(47)	(48)	(45)	(46)
Necrosis				1 (2%)
Intestine Small, Duodenum	(42)	(47)	(45)	(40)
Intestine Small, Ileum	(45)	(47)	(46)	(44)
Intestine Small, Jejunum	(44)	(48)	(45)	(45)
Liver	(49)	(50)	(49)	(50)
Amyloid Deposition			1 (2%)	
Angiectasis	2 (4%)	2 (4%)	2 (4%)	
Basophilic Focus	5 (10%)	4 (8%)	8 (16%)	4 (8%)
Clear Cell Focus	1 (2%)	1 (2%)	2 (4%)	
Eosinophilic Focus	5 (10%)	5 (10%)	4 (8%)	1 (2%)
Fatty Change	3 (6%)	1 (2%)	1 (2%)	
Hematopoietic Cell Proliferation	1 (2%)	1 (2%)		
Inflammation, Chronic				1 (2%)
Mineralization				2 (4%)
Mixed Cell Focus	1 (2%)			
Necrosis	3 (6%)		1 (2%)	8 (16%)
Hepatocyte, Mitotic Alteration			1 (2%)	
Mesentery	(15)	(14)	(14)	(6)
Fat, Hemorrhage			1 (7%)	

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B6C3F1 MICE FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Fat, Necrosis	14 (93%)	14 (100%)	13 (93%)	6 (100%)
Pancreas	(47)	(50)	(47)	(49)
Amyloid Deposition		2 (4%)		
Atrophy		1 (2%)	1 (2%)	
Basophilic Focus	1 (2%)	2 (4%)	1 (2%)	1 (2%)
Hyperplasia				1 (2%)
Duct, Cyst	1 (2%)	1 (2%)		
Salivary Glands	(49)	(50)	(50)	(50)
Necrosis		1 (2%)		
Stomach, Forestomach	(48)	(50)	(49)	(50)
Hyperplasia, Squamous	2 (4%)	8 (16%)	5 (10%)	8 (16%)
Inflammation	2 (4%)	8 (16%)	5 (10%)	8 (16%)
Ulcer	2 (4%)	4 (8%)	3 (6%)	4 (8%)
Stomach, Glandular	(46)	(48)	(47)	(48)
Amyloid Deposition		1 (2%)		
Inflammation		1 (2%)	1 (2%)	6 (13%)
Mineralization	1 (2%)			
Ulcer		1 (2%)	1 (2%)	7 (15%)
CARDIOVASCULAR SYSTEM				
Blood Vessel	(2)	(1)	(1)	(2)
Mineralization	1 (50%)			1 (50%)
Heart	(49)	(50)	(50)	(50)
Cardiomyopathy	2 (4%)	2 (4%)		3 (6%)
Inflammation, Suppurative		1 (2%)		2 (4%)
Mineralization	3 (6%)	2 (4%)	2 (4%)	5 (10%)
Thrombosis		1 (2%)		2 (4%)
ENDOCRINE SYSTEM				
Adrenal Cortex	(48)	(50)	(49)	(50)
Amyloid Deposition		1 (2%)	1 (2%)	
Hyperplasia	4 (8%)	2 (4%)	4 (8%)	2 (4%)
Hypertrophy		1 (2%)	3 (6%)	1 (2%)
Necrosis				1 (2%)
Vacuolization Cytoplasmic	1 (2%)			
Adrenal Medulla	(48)	(50)	(49)	(50)
Hyperplasia	1 (2%)		1 (2%)	2 (4%)
Islets, Pancreatic	(47)	(50)	(48)	(49)

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B6C3F1 MICE FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Hyperplasia	1 (2%)	1 (2%)	1 (2%)	2 (4%)
Pituitary Gland	(47)	(48)	(50)	(50)
Pars Distalis, Hyperplasia	9 (19%)	17 (35%)	6 (12%)	9 (18%)
Thyroid Gland	(48)	(50)	(49)	(50)
Follicular Cell, Hyperplasia	1 (2%)			1 (2%)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Clitoral Gland	(47)	(49)	(49)	(48)
Ovary	(48)	(50)	(50)	(50)
Angiectasis	2 (4%)			1 (2%)
Cyst	5 (10%)	12 (24%)	5 (10%)	4 (8%)
Thrombosis		1 (2%)		
Uterus	(48)	(50)	(50)	(50)
Angiectasis	2 (4%)	3 (6%)	2 (4%)	
Inflammation, Suppurative		1 (2%)		
Thrombosis			1 (2%)	
Endometrium, Hyperplasia, Cystic	24 (50%)	32 (64%)	19 (38%)	21 (42%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(48)	(49)	(50)	(50)
Necrosis		1 (2%)		
Lymph Node	(4)	(5)	(3)	(2)
Lymph Node, Mandibular	(49)	(50)	(50)	(50)
Lymph Node, Mesenteric	(47)	(49)	(47)	(50)
Hyperplasia, Lymphoid		1 (2%)		
Inflammation, Acute				1 (2%)
Spleen	(48)	(50)	(49)	(50)
Amyloid Deposition			1 (2%)	
Depletion Cellular				9 (18%)
Hematopoietic Cell Proliferation	1 (2%)	5 (10%)	2 (4%)	
Hyperplasia, Lymphoid		1 (2%)		
Necrosis	1 (2%)			
Thymus	(47)	(50)	(49)	(47)

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B6C3F1 MICE FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
INTEGUMENTARY SYSTEM				
Mammary Gland	(48)	(50)	(50)	(50)
Hyperplasia	1 (2%)			
Skin	(49)	(50)	(50)	(50)
Hemorrhage	1 (2%)			
Inflammation, Chronic Active			1 (2%)	
Necrosis	1 (2%)	1 (2%)		
MUSCULOSKELETAL SYSTEM				
Bone	(49)	(50)	(50)	(50)
Skeletal Muscle	(0)	(1)	(0)	(0)
NERVOUS SYSTEM				
Brain	(49)	(50)	(50)	(50)
Demyelination		2 (4%)		
Gliosis	1 (2%)			
Necrosis		1 (2%)		1 (2%)
Peripheral Nerve	(2)	(2)	(1)	(0)
Radicular Neuropathy	1 (50%)	1 (50%)	1 (100%)	
RESPIRATORY SYSTEM				
Lung	(48)	(50)	(50)	(50)
Hemorrhage		1 (2%)		
Inflammation, Suppurative		1 (2%)		
Mineralization	1 (2%)			
Thrombosis				1 (2%)
Alveolar Epithelium, Hyperplasia	2 (4%)	1 (2%)	4 (8%)	
Bronchiole, Hyperplasia				1 (2%)
Bronchiole, Necrosis				1 (2%)
Nose	(48)	(50)	(50)	(50)
Thrombosis				1 (2%)
Glands, Hyperplasia	6 (13%)	38 (76%)	49 (98%)	49 (98%)
Olfactory Epithelium, Accumulation, Hyaline Droplet		4 (8%)	18 (36%)	12 (24%)

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Olfactory Epithelium, Atrophy	3 (6%)	8 (16%)	36 (72%)	43 (86%)
Olfactory Epithelium, Degeneration			1 (2%)	2 (4%)
Olfactory Epithelium, Respiratory Metaplasia	6 (13%)	37 (74%)	49 (98%)	50 (100%)
Respiratory Epithelium, Necrosis				1 (2%)
SPECIAL SENSES SYSTEM				
Eye	(44)	(47)	(46)	(42)
Cataract			1 (2%)	1 (2%)
Degeneration			1 (2%)	1 (2%)
Harderian Gland	(46)	(50)	(49)	(48)
Hyperplasia	5 (11%)	5 (10%)	6 (12%)	2 (4%)
URINARY SYSTEM				
Kidney	(47)	(50)	(49)	(49)
Amyloid Deposition	1 (2%)	1 (2%)	1 (2%)	
Inflammation, Suppurative				1 (2%)
Nephropathy	23 (49%)	30 (60%)	22 (45%)	33 (67%)
Bilateral, Papilla, Necrosis		1 (2%)		4 (8%)
Papilla, Mineralization				1 (2%)
Papilla, Necrosis			1 (2%)	14 (29%)
Renal Tubule, Necrosis		1 (2%)		6 (12%)
Urinary Bladder	(47)	(49)	(47)	(46)

*** END OF REPORT ***