

Experiment Number: 20725 - 04
Test Type: CHRONIC
Route: RESPIRATORY EXPOSURE WHOLE BODY
Species/Strain: MICE/B6C3F1

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
2,3-Butanedione
CAS Number: 431-03-8

Date Report Requested: 04/15/2016
Time Report Requested: 10:33:42
First Dose M/F: 08/31/09 / 08/31/09
Lab: BNW

F1_Mice

NTP Study Number: C20725
Lock Date: 10/11/2012
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 3.0.2.3_002
PWG Approval Date: 01/25/2016

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B6C3F1 MICE MALE	Control	12.5 ppm	25 ppm	50 ppm
Disposition Summary				
Animals Initially In Study	50	50	50	50
Early Deaths				
Accidentally Killed		1		
Moribund Sacrifice	6	5	4	14
Natural Death	9	5	9	11
Survivors				
Terminal Sacrifice	35	39	37	25
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Epithelium, Hyperplasia		1 (2%)		
Periesophageal Tissue, Inflammation, Chronic Active				3 (6%)
Submucosa, Inflammation, Chronic Active				1 (2%)
Gallbladder	(45)	(42)	(43)	(43)
Inflammation				1 (2%)
Intestine Large, Cecum	(46)	(48)	(47)	(48)
Inflammation	7 (15%)		2 (4%)	
Intestine Large, Colon	(46)	(47)	(48)	(47)
Intestine Large, Rectum	(46)	(46)	(45)	(49)
Inflammation				1 (2%)
Intestine Small, Duodenum	(45)	(47)	(44)	(44)
Inflammation	1 (2%)			
Necrosis	1 (2%)			
Intestine Small, Ileum	(45)	(47)	(44)	(46)
Hemorrhage				1 (2%)
Hyperplasia, Lymphoid	1 (2%)	1 (2%)	2 (5%)	
Inflammation	3 (7%)		1 (2%)	
Intestine Small, Jejunum	(44)	(46)	(43)	(43)
Hyperplasia, Lymphoid	1 (2%)		1 (2%)	1 (2%)
Inflammation	1 (2%)	1 (2%)		
Liver	(50)	(50)	(50)	(50)

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B6C3F1 MICE MALE	Control	12.5 ppm	25 ppm	50 ppm
Basophilic Focus	7 (14%)	5 (10%)	7 (14%)	6 (12%)
Clear Cell Focus	2 (4%)	5 (10%)	5 (10%)	
Cyst	1 (2%)	1 (2%)		
Eosinophilic Focus	4 (8%)	6 (12%)	4 (8%)	4 (8%)
Hematopoietic Cell Proliferation				1 (2%)
Hepatodiaphragmatic Nodule	1 (2%)			
Mixed Cell Focus	4 (8%)	7 (14%)	2 (4%)	1 (2%)
Pigmentation, Ceroid	1 (2%)			
Syncytial Alteration		1 (2%)		
Tension Lipidosis		2 (4%)		1 (2%)
Thrombosis		1 (2%)		
Hepatocyte, Degeneration	2 (4%)			
Hepatocyte, Necrosis	4 (8%)	5 (10%)	1 (2%)	3 (6%)
Mesentery	(4)	(1)	(5)	(0)
Hemorrhage	1 (25%)			
Artery, Thrombosis	1 (25%)			
Fat, Necrosis	1 (25%)	1 (100%)	2 (40%)	
Pancreas	(48)	(48)	(50)	(50)
Necrosis			1 (2%)	
Acinus, Atrophy	2 (4%)		1 (2%)	
Salivary Glands	(50)	(49)	(50)	(50)
Stomach, Forestomach	(48)	(48)	(49)	(50)
Inflammation	2 (4%)	1 (2%)	1 (2%)	
Necrosis			1 (2%)	
Epithelium, Hyperplasia	3 (6%)	2 (4%)	1 (2%)	1 (2%)
Stomach, Glandular	(47)	(48)	(49)	(49)
Inflammation	3 (6%)	4 (8%)	2 (4%)	
Mineralization			1 (2%)	
Epithelium, Hyperplasia	1 (2%)			
Tooth	(2)	(2)	(1)	(0)
Dysplasia	2 (100%)	2 (100%)	1 (100%)	

CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
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B6C3F1 MICE MALE	Control	12.5 ppm	25 ppm	50 ppm
Inflammation	2 (4%)			1 (2%)
Heart	(50)	(50)	(50)	(49)
Cardiomyopathy	4 (8%)	1 (2%)	8 (16%)	3 (6%)
Inflammation, Acute	1 (2%)		1 (2%)	3 (6%)
Inflammation, Chronic Active			1 (2%)	5 (10%)
Mineralization		1 (2%)		
Necrosis	1 (2%)			3 (6%)
Polyarteritis	3 (6%)			1 (2%)
Thrombosis	1 (2%)			
Valve, Inflammation, Chronic Active	1 (2%)			

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(49)	(50)	(50)
Hyperplasia	1 (2%)			
Inflammation, Suppurative				1 (2%)
Vacuolization Cytoplasmic	1 (2%)			
Zona Fasciculata, Hypertrophy, Focal	23 (46%)	26 (53%)	35 (70%)	9 (18%)
Adrenal Medulla	(50)	(48)	(50)	(50)
Hyperplasia			3 (6%)	
Islets, Pancreatic	(48)	(48)	(49)	(50)
Hyperplasia	1 (2%)	1 (2%)	4 (8%)	
Parathyroid Gland	(40)	(39)	(44)	(37)
Pituitary Gland	(50)	(49)	(50)	(50)
Pars Distalis, Hyperplasia	1 (2%)	2 (4%)		
Thyroid Gland	(50)	(49)	(50)	(50)
Cyst	1 (2%)			
Inflammation, Chronic Active	1 (2%)			2 (4%)
Follicular Cell, Hyperplasia		1 (2%)		1 (2%)

GENERAL BODY SYSTEM

Tissue NOS	(0)	(0)	(0)	(1)
Inflammation, Chronic Active				1 (100%)

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B6C3F1 MICE MALE	Control	12.5 ppm	25 ppm	50 ppm
GENITAL SYSTEM				
Epididymis	(49)	(49)	(50)	(49)
Exfoliated Germ Cell	32 (65%)	23 (47%)	25 (50%)	26 (53%)
Granuloma Sperm	1 (2%)	2 (4%)		1 (2%)
Infiltration Cellular, Lymphoid	1 (2%)			
Inflammation	3 (6%)	2 (4%)	1 (2%)	1 (2%)
Preputial Gland	(50)	(49)	(50)	(49)
Ectasia		2 (4%)	2 (4%)	1 (2%)
Inflammation	1 (2%)	3 (6%)	5 (10%)	3 (6%)
Prostate	(49)	(49)	(49)	(50)
Inflammation		2 (4%)		1 (2%)
Seminal Vesicle	(49)	(49)	(50)	(50)
Dilatation	2 (4%)			
Testes	(49)	(49)	(50)	(49)
Interstitial Cell, Hyperplasia			1 (2%)	1 (2%)
Seminiferous Tubule, Degeneration	14 (29%)	6 (12%)	13 (26%)	6 (12%)

HEMATOPOIETIC SYSTEM

Bone Marrow	(48)	(47)	(50)	(49)
Infiltration Cellular, Mast Cell			1 (2%)	
Necrosis	1 (2%)			
Myeloid Cell, Hyperplasia	9 (19%)	8 (17%)	20 (40%)	39 (80%)
Lymph Node	(5)	(1)	(3)	(8)
Deep Cervical, Ectasia				1 (13%)
Deep Cervical, Hematopoietic Cell Proliferation				1 (13%)
Deep Cervical, Hyperplasia, Lymphoid				4 (50%)
Deep Cervical, Infiltration Cellular, Plasma Cell				1 (13%)
Pancreatic, Ectasia			1 (33%)	
Pancreatic, Hyperplasia, Lymphoid				1 (13%)
Renal, Ectasia	1 (20%)		1 (33%)	
Renal, Hematopoietic Cell Proliferation				1 (13%)
Lymph Node, Bronchial	(34)	(43)	(38)	(31)

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B6C3F1 MICE MALE	Control	12.5 ppm	25 ppm	50 ppm
Ectasia				1 (3%)
Hematopoietic Cell Proliferation			1 (3%)	
Hyperplasia, Lymphoid		1 (2%)	3 (8%)	2 (6%)
Infiltration Cellular, Plasma Cell				1 (3%)
Inflammation, Chronic Active				2 (6%)
Pigmentation				3 (10%)
Lymph Node, Mandibular	(36)	(33)	(30)	(32)
Ectasia				4 (13%)
Hematopoietic Cell Proliferation				3 (9%)
Hyperplasia, Lymphoid	2 (6%)	5 (15%)	11 (37%)	10 (31%)
Infiltration Cellular, Plasma Cell	1 (3%)		2 (7%)	14 (44%)
Lymph Node, Mediastinal	(37)	(33)	(38)	(32)
Hematopoietic Cell Proliferation			1 (3%)	1 (3%)
Hyperplasia, Lymphoid				2 (6%)
Infiltration Cellular, Plasma Cell			1 (3%)	2 (6%)
Inflammation, Chronic Active				2 (6%)
Lymph Node, Mesenteric	(47)	(47)	(49)	(47)
Ectasia	1 (2%)		1 (2%)	
Hematopoietic Cell Proliferation	4 (9%)	1 (2%)		2 (4%)
Hyperplasia, Lymphoid	7 (15%)	1 (2%)	2 (4%)	
Inflammation			1 (2%)	
Spleen	(48)	(49)	(50)	(50)
Angiectasis		1 (2%)		
Congestion				1 (2%)
Hematopoietic Cell Proliferation	11 (23%)	12 (24%)	15 (30%)	25 (50%)
Hyperplasia, Lymphoid		4 (8%)	1 (2%)	3 (6%)
Inflammation	1 (2%)			2 (4%)
Necrosis				2 (4%)
Lymphoid Follicle, Atrophy				2 (4%)
Thymus	(43)	(42)	(44)	(30)
Atrophy	10 (23%)	5 (12%)	2 (5%)	5 (17%)
Cyst	1 (2%)			1 (3%)
Ectopic Parathyroid Gland	6 (14%)	4 (10%)	11 (25%)	4 (13%)
Inflammation, Chronic Active	1 (2%)			3 (10%)

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B6C3F1 MICE MALE	Control	12.5 ppm	25 ppm	50 ppm
INTEGUMENTARY SYSTEM				
Mammary Gland	(1)	(0)	(0)	(1)
Skin	(50)	(49)	(50)	(49)
Hyperkeratosis			1 (2%)	
Inflammation, Chronic Active	1 (2%)	1 (2%)	2 (4%)	1 (2%)
Pigmentation, Melanin		1 (2%)		
Epidermis, Hyperplasia		2 (4%)	1 (2%)	
Epidermis, Necrosis			1 (2%)	
Epidermis, Ulcer	1 (2%)	1 (2%)	1 (2%)	
Subcutaneous Tissue, Cyst Epithelial Inclusion			1 (2%)	
Subcutaneous Tissue, Inflammation, Suppurative			1 (2%)	
Subcutaneous Tissue, Necrosis			1 (2%)	
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Fibro-Osseous Lesion	1 (2%)	1 (2%)	3 (6%)	2 (4%)
Maxilla, Osteomalacia				1 (2%)
Skeletal Muscle	(2)	(4)	(5)	(2)
Degeneration		1 (25%)		1 (50%)
Hemorrhage, Acute		2 (50%)		
Inflammation		1 (25%)		1 (50%)
Necrosis, Acute		1 (25%)		
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Infiltration Cellular, Lymphocyte			2 (4%)	
Inflammation, Acute	1 (2%)		1 (2%)	
Inflammation, Chronic Active				1 (2%)
Necrosis, Chronic	1 (2%)			
Peripheral Nerve	(0)	(2)	(1)	(1)
Degeneration		1 (50%)	1 (100%)	1 (100%)

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B6C3F1 MICE MALE	Control	12.5 ppm	25 ppm	50 ppm
Spinal Cord	(0)	(2)	(1)	(1)
RESPIRATORY SYSTEM				
Larynx	(49)	(49)	(49)	(50)
Inflammation, Suppurative	2 (4%)			
Inflammation, Chronic Active	4 (8%)	2 (4%)	11 (22%)	42 (84%)
Artery, Inflammation, Chronic Active				1 (2%)
Lumen, Exudate				2 (4%)
Respiratory Epithelium, Hyperplasia	1 (2%)			11 (22%)
Respiratory Epithelium, Metaplasia, Squamous	3 (6%)		6 (12%)	50 (100%)
Respiratory Epithelium, Necrosis	2 (4%)	1 (2%)	9 (18%)	34 (68%)
Respiratory Epithelium, Regeneration				32 (64%)
Squamous Epithelium, Hyperplasia	3 (6%)	7 (14%)	15 (31%)	42 (84%)
Lung	(50)	(49)	(50)	(50)
Foreign Body				1 (2%)
Inflammation, Suppurative				3 (6%)
Inflammation, Chronic Active	1 (2%)		2 (4%)	
Mineralization	1 (2%)			
Thrombosis	2 (4%)	1 (2%)		2 (4%)
Alveolar Epithelium, Hyperplasia	1 (2%)	1 (2%)		
Alveolar Epithelium, Hyperplasia, Focal	3 (6%)	3 (6%)	4 (8%)	
Alveolus, Infiltration Cellular, Histiocyte	7 (14%)	2 (4%)	3 (6%)	9 (18%)
Bronchiole, Epithelium, Hyperplasia	1 (2%)		1 (2%)	2 (4%)
Bronchus, Inflammation, Suppurative				1 (2%)
Bronchus, Epithelium, Necrosis				2 (4%)
Bronchus, Epithelium, Regeneration				34 (68%)
Interstitial, Fibrosis	1 (2%)		1 (2%)	
Mediastinum, Inflammation, Suppurative				3 (6%)
Mediastinum, Inflammation, Chronic Active	1 (2%)			8 (16%)
Mediastinum, Necrosis				1 (2%)
Pleura, Inflammation, Suppurative				2 (4%)
Pleura, Inflammation, Chronic Active			1 (2%)	
Nose	(49)	(48)	(50)	(50)
Foreign Body			3 (6%)	

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B6C3F1 MICE MALE	Control	12.5 ppm	25 ppm	50 ppm
Inflammation, Suppurative	2 (4%)	4 (8%)	47 (94%)	50 (100%)
Glands, Olfactory Epithelium, Inflammation, Acute		1 (2%)		
Glands, Respiratory Epithelium, Cyst		1 (2%)		5 (10%)
Glands, Sinus, Metaplasia, Respiratory			1 (2%)	13 (26%)
Lamina Propria, Fibrosis			44 (88%)	50 (100%)
Lateral Wall, Inflammation, Chronic Active	5 (10%)	8 (17%)	5 (10%)	2 (4%)
Mucosa, Regeneration			47 (94%)	47 (94%)
Nasopharyngeal Duct, Polyp, Inflammatory				1 (2%)
Olfactory Epithelium, Accumulation, Hyaline Droplet	1 (2%)		1 (2%)	2 (4%)
Olfactory Epithelium, Atrophy		14 (29%)	48 (96%)	38 (76%)
Olfactory Epithelium, Metaplasia, Respiratory	1 (2%)		39 (78%)	45 (90%)
Olfactory Epithelium, Metaplasia, Squamous	1 (2%)			
Olfactory Epithelium, Necrosis				19 (38%)
Respiratory Epithelium, Accumulation, Hyaline Droplet	3 (6%)	1 (2%)	6 (12%)	7 (14%)
Respiratory Epithelium, Cyst		1 (2%)		
Respiratory Epithelium, Hyperplasia	1 (2%)			8 (16%)
Respiratory Epithelium, Metaplasia, Squamous		6 (13%)	47 (94%)	50 (100%)
Respiratory Epithelium, Necrosis			34 (68%)	50 (100%)
Respiratory Epithelium, Regeneration			2 (4%)	
Septum, Perforation			3 (6%)	11 (22%)
Turbinate, Atrophy		8 (17%)	49 (98%)	50 (100%)
Turbinate, Necrosis			4 (8%)	27 (54%)
Trachea	(48)	(49)	(49)	(49)
Inflammation, Chronic Active			2 (4%)	45 (92%)
Necrosis				47 (96%)
Carina, Epithelium, Hyperplasia				1 (2%)
Carina, Epithelium, Necrosis				1 (2%)
Carina, Submucosa, Fibrosis				16 (33%)
Carina, Submucosa, Inflammation, Chronic Active				4 (8%)
Carina, Submucosa, Mineralization				15 (31%)
Epithelium, Hyperplasia				6 (12%)
Epithelium, Metaplasia, Squamous				5 (10%)
Epithelium, Regeneration				45 (92%)

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Lumen, Exudate				4 (8%)
Submucosa, Fibrosis				46 (94%)

SPECIAL SENSES SYSTEM

	(49)	(49)	(50)	(50)
Eye				
Phthisis Bulbi				1 (2%)
Anterior Chamber, Inflammation, Suppurative				5 (10%)
Cornea, Edema				1 (2%)
Cornea, Inflammation, Acute	2 (4%)		1 (2%)	17 (34%)
Cornea, Mineralization				5 (10%)
Cornea, Neovascularization				1 (2%)
Cornea, Epithelium, Hyperplasia	1 (2%)			9 (18%)
Cornea, Epithelium, Ulcer				3 (6%)
Lens, Cataract	1 (2%)	1 (2%)		2 (4%)
Harderian Gland	(50)	(49)	(50)	(50)
Hyperplasia	2 (4%)	3 (6%)	1 (2%)	2 (4%)

URINARY SYSTEM

	(49)	(50)	(50)	(50)
Kidney				
Cyst	1 (2%)	2 (4%)	1 (2%)	
Infarct	2 (4%)	1 (2%)	2 (4%)	1 (2%)
Infiltration Cellular, Lymphocyte		1 (2%)		
Inflammation	1 (2%)		2 (4%)	1 (2%)
Metaplasia, Osseous	2 (4%)	2 (4%)	4 (8%)	2 (4%)
Mineralization		1 (2%)		
Nephropathy	34 (69%)	26 (52%)	25 (50%)	10 (20%)
Pigmentation, Hemosiderin			1 (2%)	
Papilla, Necrosis				1 (2%)
Pelvis, Dilatation		1 (2%)	1 (2%)	
Urinary Bladder	(49)	(48)	(50)	(49)
Angiectasis	1 (2%)			
Hyperplasia, Lymphoid			1 (2%)	
Inflammation		1 (2%)		

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Mineralization				1 (2%)

*** END OF MALE ***

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B6C3F1 MICE FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Disposition Summary				
Animals Initially In Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	10	6	4	15
Natural Death	4	4	4	17
Survivors				
Moribund Sacrifice				1
Terminal Sacrifice	36	40	42	17
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Epithelium, Hyperplasia		1 (2%)		
Periesophageal Tissue, Inflammation, Chronic Active				9 (18%)
Gallbladder	(42)	(45)	(45)	(37)
Hyperplasia		1 (2%)		
Inflammation				3 (8%)
Ulcer		1 (2%)		
Intestine Large, Cecum	(47)	(49)	(50)	(41)
Inflammation	2 (4%)		2 (4%)	
Inflammation, Granulomatous	1 (2%)			
Necrosis		1 (2%)		
Intestine Large, Colon	(47)	(49)	(50)	(46)
Intestine Large, Rectum	(49)	(49)	(46)	(43)
Inflammation		1 (2%)		
Intestine Small, Duodenum	(47)	(48)	(49)	(38)
Inflammation	1 (2%)	2 (4%)		
Necrosis	1 (2%)			
Intestine Small, Ileum	(47)	(48)	(49)	(39)
Hyperplasia, Lymphoid		1 (2%)	1 (2%)	
Inflammation	1 (2%)			
Necrosis	1 (2%)	1 (2%)		
Ulcer	1 (2%)			

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

Experiment Number: 20725 - 04

Test Type: CHRONIC

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: MICE/B6C3F1

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

2,3-Butanedione

CAS Number: 431-03-8

Date Report Requested: 04/15/2016

Time Report Requested: 10:33:42

First Dose M/F: 08/31/09 / 08/31/09

Lab: BNW

B6C3F1 MICE FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Intestine Small, Jejunum	(46)	(49)	(49)	(39)
Liver	(50)	(50)	(50)	(50)
Amyloid Deposition			1 (2%)	
Angiectasis	1 (2%)			1 (2%)
Basophilic Focus	1 (2%)	3 (6%)	3 (6%)	1 (2%)
Clear Cell Focus	1 (2%)	7 (14%)	3 (6%)	
Cyst	1 (2%)		1 (2%)	2 (4%)
Eosinophilic Focus	4 (8%)	4 (8%)		1 (2%)
Fatty Change		1 (2%)	2 (4%)	
Fibrosis, Focal		1 (2%)		
Hematopoietic Cell Proliferation		1 (2%)	1 (2%)	1 (2%)
Hepatodiaphragmatic Nodule				1 (2%)
Hyperplasia, Lymphoid		2 (4%)	4 (8%)	
Infiltration Cellular, Lymphocyte				1 (2%)
Inflammation			1 (2%)	
Mixed Cell Focus	2 (4%)			
Tension Lipidosis				1 (2%)
Centrilobular, Hepatocyte, Hypertrophy				1 (2%)
Hepatocyte, Degeneration		1 (2%)		
Hepatocyte, Necrosis	3 (6%)	4 (8%)	1 (2%)	1 (2%)
Kupffer Cell, Hypertrophy				1 (2%)
Mesentery	(6)	(10)	(4)	(1)
Fat, Necrosis	4 (67%)	9 (90%)	4 (100%)	
Pancreas	(50)	(50)	(50)	(47)
Cyst	1 (2%)			1 (2%)
Inflammation, Chronic Active	1 (2%)	1 (2%)	1 (2%)	
Necrosis		1 (2%)		
Acinus, Atrophy	1 (2%)	2 (4%)	1 (2%)	
Salivary Glands	(49)	(50)	(50)	(50)
Inflammation, Chronic Active				3 (6%)
Stomach, Forestomach	(50)	(50)	(50)	(49)
Infiltration Cellular, Lymphoid			1 (2%)	
Inflammation	3 (6%)	1 (2%)	3 (6%)	
Mineralization	1 (2%)			
Epithelium, Hyperplasia	3 (6%)	2 (4%)	2 (4%)	1 (2%)
Stomach, Glandular	(49)	(50)	(50)	(46)

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Experiment Number: 20725 - 04
 Test Type: CHRONIC
 Route: RESPIRATORY EXPOSURE WHOLE BODY
 Species/Strain: MICE/B6C3F1

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
 2,3-Butanedione
 CAS Number: 431-03-8

Date Report Requested: 04/15/2016
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 Lab: BNW

B6C3F1 MICE FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Cyst	1 (2%)			
Degeneration		1 (2%)		
Infiltration Cellular, Lymphoid	1 (2%)		1 (2%)	
Inflammation	5 (10%)		1 (2%)	2 (4%)
Mineralization	3 (6%)			1 (2%)
Necrosis	1 (2%)			
Tooth	(1)	(0)	(0)	(0)
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)
Inflammation	1 (2%)	1 (2%)		3 (6%)
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	4 (8%)	1 (2%)	2 (4%)	4 (8%)
Inflammation, Acute	2 (4%)			2 (4%)
Inflammation, Chronic Active		2 (4%)	1 (2%)	7 (14%)
Mineralization		1 (2%)		1 (2%)
Necrosis	1 (2%)			2 (4%)
Polyarteritis	1 (2%)			3 (6%)
Valve, Inflammation, Chronic Active				1 (2%)
Valve, Thrombosis	1 (2%)			
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Accessory Adrenal Cortical Nodule	1 (2%)			
Angiectasis				2 (4%)
Hematopoietic Cell Proliferation				1 (2%)
Hemorrhage				1 (2%)
Hyperplasia			1 (2%)	1 (2%)
Hypertrophy				2 (4%)
Inflammation, Chronic Active			1 (2%)	
Necrosis	1 (2%)		1 (2%)	
Vacuolization Cytoplasmic	1 (2%)	1 (2%)		
Zona Fasciculata, Hyperplasia, Focal		1 (2%)		

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Experiment Number: 20725 - 04

Test Type: CHRONIC

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: MICE/B6C3F1

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

2,3-Butanedione

CAS Number: 431-03-8

Date Report Requested: 04/15/2016

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First Dose M/F: 08/31/09 / 08/31/09

Lab: BNW

B6C3F1 MICE FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Zona Fasciculata, Hypertrophy, Focal	2 (4%)		2 (4%)	3 (6%)
Adrenal Medulla	(50)	(50)	(49)	(50)
Hyperplasia	2 (4%)	4 (8%)	1 (2%)	2 (4%)
Islets, Pancreatic	(49)	(50)	(49)	(48)
Hyperplasia		1 (2%)		
Parathyroid Gland	(38)	(39)	(46)	(46)
Hyperplasia			1 (2%)	
Pituitary Gland	(49)	(49)	(50)	(48)
Pars Distalis, Angiectasis	3 (6%)	1 (2%)	1 (2%)	
Pars Distalis, Hyperplasia	15 (31%)	7 (14%)	6 (12%)	1 (2%)
Pars Distalis, Inflammation, Suppurative			1 (2%)	
Pars Intermedia, Angiectasis			1 (2%)	
Thyroid Gland	(50)	(49)	(48)	(50)
Inflammation, Chronic Active				9 (18%)
Mineralization				1 (2%)
Follicular Cell, Hyperplasia		2 (4%)	1 (2%)	

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(47)	(49)	(48)	(44)
Ovary	(49)	(50)	(49)	(50)
Angiectasis			1 (2%)	
Cyst	15 (31%)	17 (34%)	12 (24%)	12 (24%)
Hemorrhage		1 (2%)	1 (2%)	
Hyperplasia, Tubular		1 (2%)		
Inflammation	2 (4%)	1 (2%)	3 (6%)	6 (12%)
Mineralization		1 (2%)	1 (2%)	
Necrosis		1 (2%)	1 (2%)	
Uterus	(50)	(50)	(50)	(50)
Angiectasis	1 (2%)	4 (8%)	2 (4%)	
Hemorrhage	1 (2%)			

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Experiment Number: 20725 - 04
 Test Type: CHRONIC
 Route: RESPIRATORY EXPOSURE WHOLE BODY
 Species/Strain: MICE/B6C3F1

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
 2,3-Butanedione
 CAS Number: 431-03-8

Date Report Requested: 04/15/2016
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 Lab: BNW

B6C3F1 MICE FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Inflammation	4 (8%)	2 (4%)		
Thrombosis	1 (2%)	3 (6%)	1 (2%)	
Artery, Necrosis	1 (2%)			
Endometrium, Hyperplasia, Cystic	42 (84%)	43 (86%)	47 (94%)	30 (60%)

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(49)
Myeloid Cell, Hyperplasia	3 (6%)	2 (4%)	7 (14%)	33 (67%)
Lymph Node	(11)	(10)	(11)	(7)
Deep Cervical, Hyperplasia, Lymphoid			1 (9%)	4 (57%)
Deep Cervical, Infiltration Cellular, Plasma Cell				1 (14%)
Iliac, Ectasia		1 (10%)		
Lumbar, Ectasia	1 (9%)	1 (10%)	1 (9%)	
Lumbar, Hyperplasia	1 (9%)			
Lumbar, Hyperplasia, Lymphoid	1 (9%)		1 (9%)	
Renal, Amyloid Deposition	1 (9%)			
Renal, Ectasia			1 (9%)	
Renal, Hyperplasia, Lymphoid	2 (18%)	1 (10%)		
Renal, Necrosis	1 (9%)			
Lymph Node, Bronchial	(40)	(42)	(43)	(43)
Ectasia	1 (3%)			
Hematopoietic Cell Proliferation		1 (2%)		1 (2%)
Hyperplasia, Lymphoid	5 (13%)	7 (17%)	4 (9%)	1 (2%)
Inflammation, Chronic Active				5 (12%)
Necrosis, Lymphoid		1 (2%)		1 (2%)
Lymph Node, Mandibular	(39)	(47)	(45)	(39)
Amyloid Deposition	1 (3%)			
Ectasia		1 (2%)		3 (8%)
Hematopoietic Cell Proliferation			2 (4%)	1 (3%)
Hyperplasia, Lymphoid	4 (10%)	5 (11%)	12 (27%)	12 (31%)
Hyperplasia, Plasma Cell				2 (5%)
Infiltration Cellular, Plasma Cell	1 (3%)			5 (13%)
Infiltration Cellular, Polymorphonuclear				1 (3%)
Inflammation, Suppurative				1 (3%)

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Species/Strain: MICE/B6C3F1

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
 2,3-Butanedione
CAS Number: 431-03-8

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Lab: BNW

B6C3F1 MICE FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Lymph Node, Mediastinal	(40)	(38)	(41)	(33)
Hematopoietic Cell Proliferation		1 (3%)		
Hyperplasia, Lymphoid	1 (3%)	2 (5%)	2 (5%)	1 (3%)
Hyperplasia, Plasma Cell			1 (2%)	1 (3%)
Inflammation, Acute	1 (3%)			
Inflammation, Chronic Active				2 (6%)
Necrosis, Lymphoid		1 (3%)		1 (3%)
Lymph Node, Mesenteric	(49)	(50)	(50)	(45)
Ectasia		1 (2%)	1 (2%)	
Hematopoietic Cell Proliferation				2 (4%)
Hyperplasia, Lymphoid	2 (4%)	1 (2%)	2 (4%)	1 (2%)
Infiltration Cellular, Plasma Cell	1 (2%)			
Spleen	(50)	(50)	(50)	(48)
Amyloid Deposition			1 (2%)	
Angiectasis				1 (2%)
Hematopoietic Cell Proliferation	8 (16%)	14 (28%)	5 (10%)	11 (23%)
Hyperplasia, Lymphoid	10 (20%)	15 (30%)	10 (20%)	4 (8%)
Inflammation	1 (2%)	1 (2%)	1 (2%)	2 (4%)
Necrosis		1 (2%)	1 (2%)	3 (6%)
Lymphoid Follicle, Atrophy				1 (2%)
Thymus	(47)	(50)	(49)	(45)
Atrophy	4 (9%)	5 (10%)	2 (4%)	12 (27%)
Cyst		1 (2%)		
Ectopic Parathyroid Gland	4 (9%)	8 (16%)	4 (8%)	3 (7%)
Hyperplasia, Lymphoid	3 (6%)	4 (8%)	2 (4%)	1 (2%)
Inflammation, Chronic	2 (4%)			
Inflammation, Chronic Active				8 (18%)
INTEGUMENTARY SYSTEM				
Mammary Gland	(49)	(50)	(50)	(49)
Hyperplasia	1 (2%)			
Inflammation, Chronic	1 (2%)			
Skin	(50)	(50)	(50)	(50)
Erosion	1 (2%)			

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Experiment Number: 20725 - 04
 Test Type: CHRONIC
 Route: RESPIRATORY EXPOSURE WHOLE BODY
 Species/Strain: MICE/B6C3F1

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMICAL SITE(a)
 2,3-Butanedione
 CAS Number: 431-03-8

Date Report Requested: 04/15/2016
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 Lab: BNW

B6C3F1 MICE FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Fibrosis				1 (2%)
Inflammation, Chronic Active	1 (2%)	2 (4%)		3 (6%)
Epidermis, Hyperplasia	1 (2%)			1 (2%)
Subcutaneous Tissue, Necrosis				2 (4%)

MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Fibro-Osseous Lesion	13 (26%)	12 (24%)	17 (34%)	3 (6%)
Skeletal Muscle	(6)	(1)	(3)	(4)
Degeneration	2 (33%)		1 (33%)	1 (25%)
Inflammation		1 (100%)		

NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
Infiltration Cellular		1 (2%)		1 (2%)
Infiltration Cellular, Lymphocyte	2 (4%)		2 (4%)	5 (10%)
Inflammation, Acute	1 (2%)			1 (2%)
Inflammation, Chronic			1 (2%)	
Peripheral Nerve	(2)	(1)	(2)	(2)
Degeneration	1 (50%)		2 (100%)	1 (50%)
Spinal Cord	(2)	(1)	(2)	(2)

RESPIRATORY SYSTEM

Larynx	(49)	(50)	(50)	(49)
Inflammation, Chronic Active	4 (8%)	5 (10%)	22 (44%)	36 (73%)
Lumen, Exudate				4 (8%)
Respiratory Epithelium, Hyperplasia			4 (8%)	1 (2%)
Respiratory Epithelium, Metaplasia, Atypical, Squamous		1 (2%)		1 (2%)
Respiratory Epithelium, Metaplasia, Squamous	2 (4%)		6 (12%)	48 (98%)
Respiratory Epithelium, Necrosis	1 (2%)	1 (2%)	14 (28%)	32 (65%)

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Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: MICE/B6C3F1

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

2,3-Butanedione

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B6C3F1 MICE FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Respiratory Epithelium, Regeneration			3 (6%)	30 (61%)
Squamous Epithelium, Hyperplasia	4 (8%)	13 (26%)	34 (68%)	40 (82%)
Submucosa, Mineralization		1 (2%)		
Lung	(50)	(50)	(50)	(50)
Foreign Body				1 (2%)
Hematopoietic Cell Proliferation		1 (2%)		
Hemorrhage	1 (2%)			
Hyperplasia, Lymphoid	1 (2%)	1 (2%)		
Inflammation, Suppurative		1 (2%)		5 (10%)
Inflammation, Chronic Active	1 (2%)		1 (2%)	2 (4%)
Necrosis				1 (2%)
Alveolar Epithelium, Hyperplasia, Focal	3 (6%)			
Alveolus, Infiltration Cellular, Histiocyte	2 (4%)	3 (6%)	3 (6%)	4 (8%)
Alveolus, Inflammation, Suppurative				1 (2%)
Alveolus, Epithelium, Hyperplasia			1 (2%)	
Artery, Mediastinum, Inflammation, Chronic Active				1 (2%)
Bronchiole, Inflammation, Suppurative				1 (2%)
Bronchiole, Inflammation, Chronic				1 (2%)
Bronchiole, Epithelium, Hyperplasia	1 (2%)			2 (4%)
Bronchus, Inflammation, Suppurative				2 (4%)
Bronchus, Regeneration				1 (2%)
Bronchus, Epithelium, Degeneration				4 (8%)
Bronchus, Epithelium, Necrosis	2 (4%)			5 (10%)
Bronchus, Epithelium, Regeneration	2 (4%)			38 (76%)
Bronchus, Smooth Muscle, Mineralization				3 (6%)
Bronchus, Submucosa, Fibrosis				5 (10%)
Interstitial, Fibrosis				1 (2%)
Mediastinum, Inflammation, Suppurative		1 (2%)	1 (2%)	8 (16%)
Mediastinum, Inflammation, Chronic Active			1 (2%)	7 (14%)
Pleura, Inflammation, Suppurative				5 (10%)
Pleura, Inflammation, Chronic Active			1 (2%)	
Nose	(50)	(50)	(50)	(50)
Foreign Body			3 (6%)	3 (6%)
Inflammation, Suppurative	3 (6%)	20 (40%)	50 (100%)	50 (100%)
Glands, Respiratory Epithelium, Cyst				2 (4%)

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B6C3F1 MICE FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Glands, Sinus, Metaplasia, Respiratory				12 (24%)
Lamina Propria, Fibrosis			47 (94%)	49 (98%)
Lateral Wall, Inflammation, Chronic Active	1 (2%)		1 (2%)	
Mucosa, Regeneration			39 (78%)	48 (96%)
Olfactory Epithelium, Accumulation, Hyaline Droplet	11 (22%)	11 (22%)	17 (34%)	2 (4%)
Olfactory Epithelium, Atrophy		41 (82%)	49 (98%)	45 (90%)
Olfactory Epithelium, Metaplasia, Respiratory		22 (44%)	46 (92%)	49 (98%)
Olfactory Epithelium, Necrosis			1 (2%)	20 (40%)
Respiratory Epithelium, Accumulation, Hyaline Droplet	18 (36%)	28 (56%)	28 (56%)	3 (6%)
Respiratory Epithelium, Hyperplasia		1 (2%)		2 (4%)
Respiratory Epithelium, Metaplasia, Squamous	1 (2%)	9 (18%)	48 (96%)	50 (100%)
Respiratory Epithelium, Necrosis	1 (2%)	5 (10%)	33 (66%)	50 (100%)
Septum, Perforation			6 (12%)	5 (10%)
Turbinate, Atrophy		32 (64%)	50 (100%)	50 (100%)
Turbinate, Necrosis			1 (2%)	11 (22%)
Pleura	(0)	(0)	(1)	(0)
Trachea	(50)	(49)	(50)	(50)
Inflammation, Chronic Active	1 (2%)		4 (8%)	42 (84%)
Necrosis			3 (6%)	48 (96%)
Carina, Inflammation, Chronic Active				1 (2%)
Carina, Epithelium, Regeneration				1 (2%)
Carina, Submucosa, Fibrosis				6 (12%)
Carina, Submucosa, Mineralization				5 (10%)
Epithelium, Hyperplasia			1 (2%)	1 (2%)
Epithelium, Metaplasia, Squamous				2 (4%)
Epithelium, Regeneration			9 (18%)	45 (90%)
Glands, Hyperplasia				1 (2%)
Lumen, Exudate				12 (24%)
Submucosa, Fibrosis				44 (88%)

SPECIAL SENSES SYSTEM

Ear	(0)	(0)	(0)	(1)
Inflammation, Suppurative				1 (100%)

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B6C3F1 MICE FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Eye	(50)	(49)	(50)	(49)
Anterior Chamber, Inflammation, Suppurative			4 (8%)	3 (6%)
Cornea, Fibrosis			1 (2%)	
Cornea, Inflammation, Acute	1 (2%)	2 (4%)	20 (40%)	23 (47%)
Cornea, Mineralization			13 (26%)	16 (33%)
Cornea, Necrosis				6 (12%)
Cornea, Epithelium, Hyperplasia	2 (4%)	2 (4%)	10 (20%)	9 (18%)
Cornea, Epithelium, Ulcer			10 (20%)	10 (20%)
Lens, Cataract				2 (4%)
Harderian Gland	(50)	(50)	(50)	(50)
Hyperplasia	2 (4%)	4 (8%)	1 (2%)	4 (8%)
Inflammation				1 (2%)
Pigmentation, Porphyrin				1 (2%)

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(49)
Amyloid Deposition			1 (2%)	
Cyst	1 (2%)			
Hyperplasia, Lymphoid	1 (2%)	3 (6%)	3 (6%)	
Infarct		3 (6%)	3 (6%)	2 (4%)
Inflammation				1 (2%)
Metaplasia, Osseous	1 (2%)	1 (2%)	1 (2%)	
Necrosis		1 (2%)		
Nephropathy	14 (28%)	15 (30%)	6 (12%)	6 (12%)
Capsule, Inflammation		1 (2%)		
Urinary Bladder	(50)	(50)	(50)	(49)
Hyperplasia, Lymphoid	1 (2%)	1 (2%)	1 (2%)	

*** END OF REPORT ***

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