

**TDMS No.** 96011 - 06  
**Test Type:** CHRONIC  
**Route:** RESPIRATORY EXPOSURE WHOLE BODY  
**Species/Strain:** MICE/B6C3F1

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

CUMENE

**CAS Number:** 98-82-8

**Pathologist:** PIERCE, J. - GRUMBEIN, S.

F1 Mice

**Date Report Requested:** 02/27/2006  
**Time Report Requested:** 15:28:27  
**First Dose M/F:** 06/11/01 / 06/11/01  
**Lab:** BNW

**C Number:** C96011

**Lock Date:** 12/30/2003

**Cage Range:** ALL

**Date Range:** ALL

**Reasons For Removal:** 25021 TSAC

25020 NATD

25019 MSAC

**Removal Date Range:** ALL

**Treatment Groups:** Include ALL

B6C3F1 MICE MALE	CONTROL	250 PPM	500 PPM	1000 PPM
<b>Disposition Summary</b>				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	7	9	13	20
Natural Death	5	7	7	7
Survivors				
Terminal Sacrifice	38	34	30	23
Animals Examined Microscopically	50	50	50	50
<b>ALIMENTARY SYSTEM</b>				
Gallbladder	(43)	(32)	(37)	(38)
Degeneration, Hyaline	1 (2%)			
Hyperplasia	1 (2%)			
Intestine Large, Cecum	(49)	(47)	(44)	(44)
Infiltration Cellular, Histiocyte				1 (2%)
Inflammation, Acute				1 (2%)
Intestine Large, Colon	(50)	(46)	(45)	(48)
Intestine Small, Duodenum	(49)	(44)	(43)	(44)
Intestine Small, Ileum	(49)	(46)	(43)	(44)
Necrosis			1 (2%)	
Peyer's Patch, Inflammation, Acute	1 (2%)			
Intestine Small, Jejunum	(48)	(46)	(43)	(44)
Peyer's Patch, Hyperplasia		1 (2%)		
Liver	(50)	(50)	(50)	(50)
Angiectasis	1 (2%)	3 (6%)	1 (2%)	
Basophilic Focus	7 (14%)	5 (10%)	4 (8%)	5 (10%)
Clear Cell Focus	24 (48%)	11 (22%)	20 (40%)	11 (22%)
Eosinophilic Focus	6 (12%)	5 (10%)	16 (32%)	14 (28%)
Hepatodiaphragmatic Nodule				1 (2%)
Inflammation, Granulomatous	1 (2%)		1 (2%)	
Mixed Cell Focus	2 (4%)	3 (6%)	1 (2%)	1 (2%)
Necrosis	2 (4%)	4 (8%)	4 (8%)	1 (2%)
Tension Lipidosis	1 (2%)	1 (2%)	2 (4%)	
Centrilobular, Necrosis	1 (2%)	4 (8%)		
Mesentery	(3)	(7)	(6)	(3)
Thrombosis	1 (33%)			
Fat, Necrosis	3 (100%)	6 (86%)	6 (100%)	3 (100%)

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B6C3F1 MICE MALE	CONTROL	250 PPM	500 PPM	1000 PPM
Pancreas	(50)	(50)	(49)	(49)
Atrophy		1 (2%)		
Duct, Cyst	1 (2%)			
Stomach, Forestomach	(50)	(50)	(50)	(49)
Inflammation		2 (4%)	1 (2%)	5 (10%)
Ulcer	1 (2%)	4 (8%)	6 (12%)	6 (12%)
Epithelium, Erosion		1 (2%)		1 (2%)
Epithelium, Hyperplasia	2 (4%)	7 (14%)	8 (16%)	13 (27%)
Stomach, Glandular	(50)	(48)	(48)	(48)
Mineralization		1 (2%)		
Necrosis		2 (4%)		1 (2%)
Tongue	(1)	(0)	(0)	(0)
Tooth	(15)	(8)	(8)	(6)
Malformation	14 (93%)	7 (88%)	8 (100%)	6 (100%)

## CARDIOVASCULAR SYSTEM

Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	10 (20%)	18 (36%)	13 (26%)	17 (34%)
Inflammation, Acute				2 (4%)
Mineralization		1 (2%)		1 (2%)
Necrosis				1 (2%)
Thrombosis	1 (2%)		1 (2%)	2 (4%)
Artery, Inflammation, Chronic Active	1 (2%)		1 (2%)	1 (2%)

## ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(49)	(50)
Atrophy				1 (2%)
Degeneration		1 (2%)		
Hyperplasia	14 (28%)	15 (30%)	12 (24%)	8 (16%)
Hypertrophy	29 (58%)	16 (32%)	14 (29%)	9 (18%)
Adrenal Medulla	(50)	(50)	(48)	(50)
Hyperplasia	2 (4%)	1 (2%)		
Islets, Pancreatic	(50)	(50)	(49)	(49)
Hyperplasia	1 (2%)	3 (6%)	1 (2%)	
Hypertrophy			1 (2%)	
Pituitary Gland	(48)	(49)	(49)	(49)
Pars Distalis, Hyperplasia	1 (2%)	1 (2%)	3 (6%)	1 (2%)
Thyroid Gland	(50)	(50)	(49)	(50)

B6C3F1 MICE MALE	CONTROL	250 PPM	500 PPM	1000 PPM
Follicular Cell, Hyperplasia	7 (14%)	7 (14%)	7 (14%)	11 (22%)
<b>GENERAL BODY SYSTEM</b>				
None				
<b>GENITAL SYSTEM</b>				
Epididymis	(50)	(50)	(49)	(50)
Angiectasis		1 (2%)		
Granuloma Sperm		2 (4%)		1 (2%)
Preputial Gland	(49)	(50)	(50)	(50)
Ectasia		1 (2%)	1 (2%)	
Inflammation, Chronic Active	1 (2%)			
Prostate	(50)	(49)	(48)	(49)
Angiectasis	1 (2%)			
Hyperplasia		1 (2%)		1 (2%)
Infiltration Cellular, Polymorphonuclear				1 (2%)
Artery, Inflammation, Chronic Active	1 (2%)			
Testes	(50)	(50)	(49)	(50)
Atrophy	5 (10%)	3 (6%)	1 (2%)	1 (2%)
<b>HEMATOPOIETIC SYSTEM</b>				
Bone Marrow	(50)	(50)	(49)	(49)
Thrombosis		1 (2%)		
Lymph Node	(0)	(0)	(1)	(2)
Iliac, Infiltration Cellular, Mixed Cell			1 (100%)	
Lymph Node, Bronchial	(45)	(41)	(45)	(35)
Lymph Node, Mandibular	(34)	(35)	(22)	(25)
Infiltration Cellular, Plasma Cell	1 (3%)			
Lymph Node, Mediastinal	(37)	(42)	(40)	(39)
Lymph Node, Mesenteric	(48)	(47)	(46)	(44)
Infiltration Cellular, Mixed Cell			1 (2%)	
Infiltration Cellular, Plasma Cell	1 (2%)		1 (2%)	
Spleen	(50)	(50)	(49)	(50)
Hematopoietic Cell Proliferation	3 (6%)	1 (2%)	2 (4%)	
Infiltration Cellular, Plasma Cell	1 (2%)			
Thymus	(45)	(44)	(38)	(44)

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Species/Strain: MICE/B6C3F1

Pathologist: PIERCE, J. - GRUMBEIN, S.

Lab: BNW

B6C3F1 MICE MALE	CONTROL	250 PPM	500 PPM	1000 PPM
Artery, Inflammation			1 (3%)	
<b>INTEGUMENTARY SYSTEM</b>				
Skin	(50)	(50)	(49)	(50)
Cyst Epithelial Inclusion		1 (2%)		
Inflammation, Acute				1 (2%)
Inflammation, Chronic Active	1 (2%)	2 (4%)	6 (12%)	3 (6%)
Ulcer				1 (2%)
Epidermis, Abscess				1 (2%)
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone	(50)	(50)	(50)	(50)
Hyperostosis	1 (2%)			
Skeletal Muscle	(0)	(0)	(1)	(0)
<b>NERVOUS SYSTEM</b>				
Brain	(50)	(50)	(50)	(50)
Degeneration		1 (2%)		
Gliosis				1 (2%)
Necrosis			1 (2%)	
Ventricle, Infiltration Cellular, Polymorphonuclear				1 (2%)
<b>RESPIRATORY SYSTEM</b>				
Larynx	(50)	(49)	(50)	(50)
Metaplasia, Squamous				1 (2%)
Lung	(50)	(50)	(50)	(50)
Thrombosis		1 (2%)	1 (2%)	1 (2%)
Alveolar Epithelium, Bronchiole, Metaplasia	5 (10%)	43 (86%)	42 (84%)	39 (78%)
Alveolar Epithelium, Hyperplasia	3 (6%)	3 (6%)	4 (8%)	
Alveolus, Infiltration Cellular, Histiocyte	2 (4%)	3 (6%)		1 (2%)
Bronchiole, Hyperplasia		11 (22%)	17 (34%)	18 (36%)
Bronchus, Inflammation, Acute			1 (2%)	
Bronchus, Necrosis				1 (2%)

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B6C3F1 MICE MALE	CONTROL	250 PPM	500 PPM	1000 PPM
Nose	(50)	(50)	(49)	(48)
Inflammation, Suppurative	2 (4%)	2 (4%)	9 (18%)	6 (13%)
Polyp, Inflammatory	1 (2%)			
Glands, Olfactory Epithelium, Hyperplasia	3 (6%)	11 (22%)	9 (18%)	23 (48%)
Olfactory Epithelium, Accumulation, Hyaline Droplet	1 (2%)			
Olfactory Epithelium, Atrophy	4 (8%)	13 (26%)	11 (22%)	38 (79%)
Olfactory Epithelium, Hyperplasia, Atypical			5 (10%)	11 (23%)
Olfactory Epithelium, Hyperplasia, Basal Cell			15 (31%)	33 (69%)
Respiratory Epithelium, Accumulation, Hyaline Droplet	1 (2%)			
Respiratory Epithelium, Metaplasia, Squamous	1 (2%)	1 (2%)	1 (2%)	5 (10%)
Vomer nasal Organ, Inflammation, Suppurative			1 (2%)	
Pleura	(0)	(0)	(0)	(2)
Trachea	(50)	(50)	(49)	(50)
Necrosis				1 (2%)
<b>SPECIAL SENSES SYSTEM</b>				
Eye	(49)	(50)	(49)	(48)
Cataract	1 (2%)	1 (2%)		1 (2%)
Cornea, Inflammation, Chronic Active		2 (4%)	1 (2%)	4 (8%)
Cornea, Mineralization				1 (2%)
Harderian Gland	(48)	(50)	(49)	(50)
Hyperplasia	2 (4%)	2 (4%)	1 (2%)	1 (2%)
Hypertrophy				1 (2%)
Inflammation, Chronic	1 (2%)			
Necrosis				1 (2%)
<b>URINARY SYSTEM</b>				
Kidney	(50)	(50)	(50)	(50)
Infarct	1 (2%)	4 (8%)	3 (6%)	7 (14%)
Inflammation, Suppurative				1 (2%)
Metaplasia, Osseous	3 (6%)	1 (2%)		1 (2%)
Mineralization	1 (2%)	1 (2%)		2 (4%)
Nephropathy	47 (94%)	44 (88%)	45 (90%)	41 (82%)

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<b>B6C3F1 MICE MALE</b>	<b>CONTROL</b>	<b>250 PPM</b>	<b>500 PPM</b>	<b>1000 PPM</b>
Artery, Inflammation, Chronic Active	1 (2%)			1 (2%)
Capsule, Fibrosis		1 (2%)		
Perirenal Tissue, Thrombosis				1 (2%)
Renal Tubule, Cyst	1 (2%)		1 (2%)	
Renal Tubule, Hyperplasia		2 (4%)		
Renal Tubule, Necrosis				1 (2%)
Renal Tubule, Pigmentation				1 (2%)
Urinary Bladder	(50)	(48)	(49)	(48)

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\*\*\* END OF MALE \*\*\*

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Species/Strain: MICE/B6C3F1

Pathologist: PIERCE, J. - GRUMBEIN, S.

Lab: BNW

B6C3F1 MICE FEMALE	CONTROL	125 PPM	250 PPM	500 PPM
<b>Disposition Summary</b>				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	8	10	8	12
Natural Death	5	4	3	3
Survivors				
Natural Death				1
Terminal Sacrifice	37	36	39	34
Animals Examined Microscopically	50	50	50	50

## ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Gallbladder	(38)	(41)	(44)	(37)
Intestine Large, Cecum	(46)	(47)	(49)	(47)
Intestine Large, Colon	(47)	(50)	(50)	(48)
Intestine Small, Duodenum	(46)	(47)	(49)	(48)
Necrosis	1 (2%)			
Intestine Small, Ileum	(46)	(47)	(49)	(47)
Intestine Small, Jejunum	(46)	(47)	(49)	(47)
Hyperplasia, Lymphoid			1 (2%)	
Liver	(50)	(50)	(50)	(50)
Angiectasis		1 (2%)	1 (2%)	
Basophilic Focus	3 (6%)	3 (6%)	4 (8%)	1 (2%)
Clear Cell Focus	4 (8%)	6 (12%)	1 (2%)	5 (10%)
Cyst	1 (2%)			1 (2%)
Eosinophilic Focus	8 (16%)	11 (22%)	7 (14%)	14 (28%)
Erythrophagocytosis				1 (2%)
Fatty Change	1 (2%)			
Hematopoietic Cell Proliferation		1 (2%)		
Inflammation, Granulomatous	1 (2%)			
Mixed Cell Focus		1 (2%)		1 (2%)
Necrosis	4 (8%)	3 (6%)	3 (6%)	2 (4%)
Tension Lipidosis	3 (6%)	3 (6%)	4 (8%)	4 (8%)
Centrilobular, Necrosis	2 (4%)	1 (2%)		1 (2%)
Mesentery	(11)	(12)	(11)	(9)
Inflammation, Chronic Active			1 (9%)	
Fat, Hemorrhage		1 (8%)		



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B6C3F1 MICE FEMALE	CONTROL	125 PPM	250 PPM	500 PPM
Fat, Necrosis	11 (100%)	10 (83%)	10 (91%)	9 (100%)
Pancreas	(49)	(50)	(50)	(50)
Atrophy			1 (2%)	3 (6%)
Inflammation, Chronic Active	1 (2%)			
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(49)	(50)	(50)	(50)
Hemorrhage			1 (2%)	
Inflammation	1 (2%)			
Ulcer			1 (2%)	2 (4%)
Epithelium, Erosion				1 (2%)
Epithelium, Hyperplasia	1 (2%)	2 (4%)	2 (4%)	3 (6%)
Stomach, Glandular	(49)	(50)	(50)	(49)
Mineralization			1 (2%)	
Necrosis	1 (2%)			1 (2%)
<b>CARDIOVASCULAR SYSTEM</b>				
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	12 (24%)	17 (34%)	6 (12%)	7 (14%)
Inflammation, Chronic			1 (2%)	
Mineralization		1 (2%)	1 (2%)	
Thrombosis		1 (2%)		
<b>ENDOCRINE SYSTEM</b>				
Adrenal Cortex	(50)	(50)	(50)	(49)
Hyperplasia	5 (10%)	7 (14%)	7 (14%)	5 (10%)
Hypertrophy	2 (4%)	1 (2%)	1 (2%)	6 (12%)
Adrenal Medulla	(50)	(49)	(50)	(49)
Hyperplasia	1 (2%)	4 (8%)	2 (4%)	2 (4%)
Islets, Pancreatic	(49)	(50)	(50)	(50)
Hyperplasia	1 (2%)	1 (2%)	2 (4%)	3 (6%)
Pituitary Gland	(50)	(49)	(50)	(48)
Pars Distalis, Angiectasis	3 (6%)	1 (2%)	7 (14%)	1 (2%)
Pars Distalis, Hyperplasia	11 (22%)	19 (39%)	10 (20%)	6 (13%)
Thyroid Gland	(50)	(50)	(50)	(50)
Follicular Cell, Hyperplasia	15 (30%)	10 (20%)	16 (32%)	10 (20%)
<b>GENERAL BODY SYSTEM</b>				

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B6C3F1 MICE FEMALE	CONTROL	125 PPM	250 PPM	500 PPM
None				
<b>GENITAL SYSTEM</b>				
Ovary	(48)	(50)	(50)	(49)
Angiectasis	1 (2%)			
Cyst	9 (19%)	12 (24%)	14 (28%)	11 (22%)
Thrombosis	1 (2%)	1 (2%)		1 (2%)
Uterus	(50)	(50)	(50)	(50)
Angiectasis	1 (2%)	2 (4%)	1 (2%)	3 (6%)
Decidual Reaction	1 (2%)			
Inflammation, Suppurative	1 (2%)	2 (4%)		1 (2%)
Thrombosis	1 (2%)			2 (4%)
Endometrium, Hyperplasia, Cystic	8 (16%)	11 (22%)	18 (36%)	8 (16%)
<b>HEMATOPOIETIC SYSTEM</b>				
Bone Marrow	(49)	(50)	(50)	(50)
Lymph Node	(4)	(9)	(5)	(5)
Iliac, Ectasia	1 (25%)	1 (11%)		
Lumbar, Angiectasis		1 (11%)		
Lumbar, Ectasia	2 (50%)	1 (11%)	1 (20%)	1 (20%)
Lumbar, Hyperplasia, Lymphoid		2 (22%)		
Renal, Ectasia	1 (25%)			
Lymph Node, Bronchial	(39)	(36)	(40)	(46)
Lymph Node, Mandibular	(35)	(42)	(38)	(42)
Inflammation, Granulomatous	1 (3%)			
Lymph Node, Mediastinal	(44)	(40)	(42)	(40)
Hyperplasia, Lymphoid				1 (3%)
Lymph Node, Mesenteric	(46)	(46)	(48)	(48)
Spleen	(49)	(50)	(50)	(50)
Hematopoietic Cell Proliferation	1 (2%)	6 (12%)	2 (4%)	2 (4%)
Hyperplasia, Lymphoid	1 (2%)			1 (2%)
Thymus	(49)	(50)	(48)	(48)
<b>INTEGUMENTARY SYSTEM</b>				
Mammary Gland	(50)	(50)	(50)	(50)
Hyperplasia	1 (2%)			1 (2%)

B6C3F1 MICE FEMALE	CONTROL	125 PPM	250 PPM	500 PPM
Skin Inflammation, Chronic Active	(50)	(50) 1 (2%)	(50) 1 (2%)	(50)
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone Skeletal Muscle	(50) (1)	(50) (1)	(50) (1)	(50) (0)
<b>NERVOUS SYSTEM</b>				
Brain Necrosis Meninges, Infiltration Cellular, Mononuclear Cell	(50)	(50)	(50) 1 (2%)	(50) 1 (2%)
<b>RESPIRATORY SYSTEM</b>				
Larynx Inflammation, Suppurative Metaplasia, Squamous	(50) 1 (2%)	(49)	(50)	(50) 1 (2%)
Lung Foreign Body Hemorrhage Inflammation, Suppurative Thrombosis Alveolar Epithelium, Bronchiole, Hyperplasia Alveolar Epithelium, Bronchiole, Metaplasia Alveolar Epithelium, Hyperplasia Alveolar Epithelium, Metaplasia, Squamous Alveolus, Infiltration Cellular, Histiocyte Bronchiole, Hyperplasia	(50)	(50) 2 (4%) 2 (4%) 42 (84%)	(50) 1 (2%) 49 (98%)	(50) 1 (2%) 1 (2%) 14 (28%)
Nose Inflammation, Suppurative Glands, Olfactory Epithelium, Cyst Glands, Olfactory Epithelium, Hyperplasia Olfactory Epithelium, Atrophy	(50) 1 (2%) 4 (8%) 4 (8%)	(50) 1 (2%) 4 (8%) 11 (22%)	(50) 3 (6%) 4 (8%) 9 (18%)	(50) 7 (14%) 1 (2%) 11 (22%) 18 (36%)

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Olfactory Epithelium, Hyperplasia, Atypical			2 (4%)	10 (20%)
Olfactory Epithelium, Hyperplasia, Basal Cell		1 (2%)	11 (22%)	25 (50%)
Olfactory Epithelium, Necrosis		2 (4%)	2 (4%)	3 (6%)
Respiratory Epithelium, Accumulation, Hyaline Droplet		1 (2%)	1 (2%)	
Respiratory Epithelium, Metaplasia, Squamous			1 (2%)	6 (12%)
Respiratory Epithelium, Necrosis Turbinate, Necrosis			1 (2%)	2 (4%)
Pleura	(0)	(1)	(1)	(2)
Trachea	(50)	(50)	(50)	(50)
Inflammation, Suppurative				2 (4%)
<b>SPECIAL SENSES SYSTEM</b>				
Eye	(49)	(50)	(50)	(49)
Cataract	2 (4%)		1 (2%)	2 (4%)
Degeneration				1 (2%)
Cornea, Epithelium, Hyperplasia				1 (2%)
Cornea, Inflammation, Acute	1 (2%)		1 (2%)	
Cornea, Inflammation, Chronic Active	4 (8%)	1 (2%)	1 (2%)	2 (4%)
Cornea, Mineralization				1 (2%)
Harderian Gland	(50)	(49)	(50)	(50)
Atrophy	1 (2%)			
Hyperplasia	6 (12%)	2 (4%)	1 (2%)	1 (2%)
<b>URINARY SYSTEM</b>				
Kidney	(49)	(50)	(50)	(50)
Cyst		1 (2%)		
Infarct	1 (2%)	3 (6%)	2 (4%)	1 (2%)
Inflammation, Suppurative				1 (2%)
Metaplasia, Osseous	2 (4%)	3 (6%)	1 (2%)	
Nephropathy	36 (73%)	34 (68%)	34 (68%)	34 (68%)
Capsule, Fibrosis	1 (2%)		1 (2%)	
Renal Tubule, Karyomegaly	1 (2%)			
Renal Tubule, Necrosis	3 (6%)	1 (2%)		1 (2%)
Urinary Bladder	(48)	(48)	(49)	(48)
Inflammation, Chronic Active			1 (2%)	

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B6C3F1 MICE FEMALE	CONTROL	125 PPM	250 PPM	500 PPM
Artery, Inflammation, Chronic Active		1 (2%)		

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