

Experiment Number: 20727 - 02

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**

Date Report Requested: 10/16/2015

Test Type: 90-DAY

ortho-Phthalaldehyde

Time Report Requested: 12:33:56

Route: RESPIRATORY EXPOSURE WHOLE BODY

CAS Number: 643-79-8

First Dose M/F: 01/19/09 / 01/19/09

Species/Strain: MICE/B6C3F1

Lab: BNW

F1_Rev.2_M3

NTP Study Number: C20727
Lock Date: 08/21/2009
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: NONE

Test Type: 90-DAY

ortho-Phthalaldehyde

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First Dose M/F: 01/19/09 / 01/19/09

Species/Strain: MICE/B6C3F1

Lab: BNW

B6C3F1 MICE MALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
Disposition Summary						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Moribund Sacrifice					5	2
Natural Death						8
Survivors						
Terminal Sacrifice	10	10	10	10	5	
Animals Examined Microscopically	10	10	10	10	10	10
ALIMENTARY SYSTEM						
Esophagus	(10)	(0)	(0)	(10)	(10)	(10)
Inflammation, Chronic Active						1 [2.0]
Necrosis						1 [3.0]
Gallbladder	(10)	(0)	(0)	(9)	(9)	(3)
Inflammation, Neutrophil	4 [1.0]					
Intestine Large, Cecum	(10)	(0)	(0)	(10)	(10)	(7)
Intestine Large, Colon	(10)	(0)	(0)	(10)	(10)	(8)
Intestine Large, Rectum	(10)	(0)	(0)	(10)	(10)	(7)
Intestine Small, Duodenum	(10)	(0)	(0)	(10)	(10)	(3)
Intestine Small, Ileum	(10)	(0)	(0)	(10)	(10)	(3)
Intestine Small, Jejunum	(10)	(0)	(0)	(10)	(10)	(3)
Liver	(10)	(0)	(0)	(10)	(10)	(10)
Necrosis					2 [1.0]	
Pancreas	(10)	(0)	(0)	(10)	(10)	(10)
Salivary Glands	(10)	(0)	(0)	(10)	(10)	(9)
Stomach, Forestomach	(10)	(0)	(0)	(10)	(10)	(9)
Hyperplasia, Squamous					1 [1.0]	
Stomach, Glandular	(10)	(0)	(0)	(10)	(10)	(8)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(0)	(10)	(0)	(2)
Heart	(10)	(0)	(0)	(10)	(10)	(10)

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

b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

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Species/Strain: MICE/B6C3F1

Lab: BNW

B6C3F1 MICE MALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(10)	(10)	(10)
Adrenal Medulla	(10)	(0)	(0)	(10)	(10)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(10)	(10)	(10)
Parathyroid Gland	(7)	(0)	(0)	(7)	(6)	(4)
Pituitary Gland	(10)	(0)	(0)	(9)	(10)	(9)
Thyroid Gland	(10)	(0)	(0)	(10)	(9)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Epididymis	(10)	(10)	(10)	(10)	(10)	(10)
Duct, Exfoliated Germ Cell					4 [1.3]	1 [1.0]
Preputial Gland	(10)	(0)	(0)	(10)	(10)	(10)
Inflammation, Chronic Active					1 [4.0]	
Prostate	(10)	(0)	(0)	(10)	(10)	(9)
Seminal Vesicle	(10)	(0)	(0)	(10)	(10)	(10)
Inflammation, Chronic					1 [2.0]	
Testes	(10)	(10)	(10)	(10)	(10)	(10)
Germinal Epithelium, Depletion Cellular, Focal		1 [1.0]				
Germinal Epithelium, Depletion Cellular, Multifocal		1 [1.0]	1 [1.0]		7 [1.3]	
Interstitial Cell, Atrophy					3 [2.0]	
Seminiferous Tubule, Dilatation, Focal		2 [1.0]				
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(0)	(0)	(10)	(10)	(10)
Hyperplasia				2 [1.0]	5 [1.4]	7 [1.9]

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

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B6C3F1 MICE MALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
Lymph Node, Bronchial	(7)	(0)	(0)	(4)	(5)	(6)
Lymph Node, Mandibular	(4)	(0)	(0)	(6)	(9)	(5)
Lymph Node, Mediastinal	(4)	(0)	(0)	(1)	(4)	(3)
Lymph Node, Mesenteric	(10)	(0)	(0)	(10)	(10)	(7)
Spleen	(10)	(0)	(0)	(10)	(10)	(10)
Atrophy, Lymphoid						10 [1.9]
Thymus	(10)	(10)	(10)	(10)	(9)	(10)
Atrophy, Lymphoid					5 [1.4]	10 [2.7]
INTEGUMENTARY SYSTEM						
Skin	(10)	(10)	(10)	(9)	(10)	(10)
Hyperplasia, Squamous		1 [2.0]			9 [1.7]	4 [2.0]
Inflammation, Chronic Active				1 [1.0]	10 [1.8]	9 [1.1]
Ulcer					1 [1.0]	
Adnexa, Degeneration		2 [1.5]		4 [2.0]	1 [1.0]	6 [2.0]
Adnexa, Pinna, Degeneration						10 [2.0]
Epidermis, Necrosis						3 [2.0]
Epithelium, Hair Follicle, Parakeratosis		3 [1.0]	4 [1.0]	2 [1.0]	2 [1.5]	10 [1.8]
Epithelium, Hair Follicle, Pinna, Parakeratosis						10 [2.1]
Pinna, Hyperplasia, Squamous						10 [2.0]
Pinna, Inflammation, Chronic Active						10 [1.8]
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(10)	(10)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(10)	(10)	(10)
RESPIRATORY SYSTEM						

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Species/Strain: MICE/B6C3F1

Lab: BNW

B6C3F1 MICE MALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
Larynx	(10)	(10)	(9)	(10)	(10)	(10)
Inflammation, Chronic Active				4 [1.0]	10 [1.3]	10 [3.0]
Metaplasia, Squamous			1 [1.0]	10 [2.4]	10 [4.0]	8 [3.5]
Necrosis					1 [2.0]	10 [3.1]
Ulcer				1 [2.0]		
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Bronchiole, Goblet Cell, Hyperplasia					4 [1.0]	
Bronchus, Inflammation, Chronic Active					1 [2.0]	6 [1.5]
Bronchus, Metaplasia, Squamous					1 [2.0]	
Bronchus, Necrosis					2 [1.0]	9 [2.4]
Bronchus, Regeneration					1 [1.0]	1 [2.0]
Perivascular, Inflammation, Chronic Active					1 [1.0]	
Nose	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Suppurative		10 [2.1]	10 [2.7]	10 [4.0]	10 [3.2]	10 [1.9]
Glands, Olfactory Epithelium, Hyperplasia		10 [1.4]	10 [1.6]	7 [1.7]	6 [1.5]	
Glands, Respiratory Epithelium, Accumulation, Hyaline Droplet		7 [2.0]	10 [2.4]	6 [1.0]		
Olfactory Epithelium, Accumulation, Hyaline Droplet		10 [2.9]	10 [3.0]	10 [2.2]	9 [2.2]	
Olfactory Epithelium, Atrophy		10 [2.3]	10 [1.9]	10 [2.6]	10 [2.3]	10 [1.5]
Olfactory Epithelium, Metaplasia, Respiratory		1 [2.0]	8 [1.4]	10 [1.9]	4 [1.5]	
Olfactory Epithelium, Metaplasia, Squamous			2 [2.0]	1 [1.0]	2 [1.5]	
Olfactory Epithelium, Necrosis						5 [2.2]
Respiratory Epithelium, Accumulation, Hyaline Droplet		10 [3.0]	10 [3.5]	10 [3.8]	10 [2.0]	
Respiratory Epithelium, Metaplasia, Squamous		10 [1.7]	10 [2.1]	10 [2.7]	10 [2.4]	6 [1.2]
Respiratory Epithelium, Necrosis		2 [1.0]	6 [1.3]	5 [1.2]	9 [1.9]	10 [2.8]
Respiratory Epithelium, Regeneration			1 [1.0]		1 [2.0]	4 [1.3]
Respiratory Epithelium, Ulcer			3 [1.0]			
Turbinate, Atrophy		4 [1.0]	6 [1.7]	10 [2.8]	8 [2.4]	
Trachea	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic Active				1 [1.0]	9 [1.3]	10 [1.6]
Metaplasia, Squamous				3 [1.0]	10 [2.8]	3 [2.0]
Necrosis						9 [2.7]
Regeneration						5 [1.6]

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

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First Dose M/F: 01/19/09 / 01/19/09

Species/Strain: MICE/B6C3F1

Lab: BNW

B6C3F1 MICE MALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
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SPECIAL SENSES SYSTEM						
Eye	(10)	(10)	(10)	(10)	(10)	(10)
Cornea, Inflammation, Suppurative		1 [2.0]			1 [1.0]	4 [1.0]
Cornea, Necrosis					1 [1.0]	
Harderian Gland	(10)	(0)	(0)	(10)	(10)	(10)
<hr/>						
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(10)	(10)	(10)
Inflammation, Chronic Active					1 [4.0]	
Nephropathy	2 [1.0]			1 [1.0]	1 [1.0]	
Urinary Bladder	(10)	(0)	(0)	(10)	(10)	(10)

*** END OF MALE ***

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Species/Strain: MICE/B6C3F1

Lab: BNW

B6C3F1 MICE FEMALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
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Disposition Summary

Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Moribund Sacrifice					4	1
Natural Death						9
Survivors						
Terminal Sacrifice	10	10	10	10	6	
Animals Examined Microscopically	10	10	10	10	10	10

ALIMENTARY SYSTEM

Esophagus	(10)	(0)	(0)	(0)	(10)	(10)
Gallbladder	(10)	(0)	(0)	(0)	(9)	(1)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(10)	(4)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(10)	(3)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(10)	(4)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(10)	(2)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(10)	(2)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(10)	(2)
Liver	(10)	(0)	(0)	(0)	(10)	(10)
Necrosis					1 [2.0]	
Pancreas	(10)	(0)	(0)	(0)	(10)	(8)
Cyst					1	
Salivary Glands	(10)	(0)	(0)	(0)	(10)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(10)	(7)
Stomach, Glandular	(10)	(0)	(0)	(0)	(10)	(7)

CARDIOVASCULAR SYSTEM

Blood Vessel	(10)	(0)	(0)	(0)	(9)	(0)
Heart	(10)	(0)	(0)	(0)	(10)	(10)

ENDOCRINE SYSTEM

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B6C3F1 MICE FEMALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
Adrenal Cortex	(10)	(0)	(0)	(1)	(10)	(10)
Adrenal Medulla	(10)	(0)	(0)	(1)	(10)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(10)	(8)
Parathyroid Gland	(6)	(0)	(0)	(0)	(5)	(4)
Pituitary Gland	(10)	(0)	(0)	(0)	(10)	(7)
Thyroid Gland	(10)	(0)	(0)	(0)	(10)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(9)	(0)	(0)	(0)	(8)	(8)
Ovary	(10)	(0)	(0)	(0)	(10)	(10)
Cyst	1 [2.0]					
Uterus	(10)	(0)	(0)	(0)	(10)	(8)
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(0)	(0)	(0)	(10)	(7)
Hyperplasia					8 [2.0]	
Lymph Node	(0)	(0)	(0)	(1)	(0)	(0)
Deep Cervical, Hyperplasia, Lymphoid				1 [2.0]		
Lymph Node, Bronchial	(4)	(0)	(0)	(0)	(6)	(7)
Lymph Node, Mandibular	(7)	(0)	(0)	(0)	(8)	(4)
Lymph Node, Mediastinal	(4)	(0)	(0)	(0)	(3)	(2)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(10)	(6)
Spleen	(10)	(0)	(0)	(0)	(10)	(8)
Atrophy, Lymphoid					1 [1.0]	8 [1.6]
Thymus	(10)	(10)	(9)	(10)	(10)	(10)
Atrophy, Lymphoid					6 [2.0]	10 [2.6]

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B6C3F1 MICE FEMALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
INTEGUMENTARY SYSTEM						
Mammary Gland	(10)	(0)	(0)	(0)	(9)	(9)
Skin	(10)	(10)	(10)	(10)	(10)	(10)
Hyperplasia, Squamous	3 [1.3]			6 [1.3]	9 [1.7]	6 [1.0]
Inflammation, Chronic Active	1 [1.0]	1 [1.0]	3 [1.0]	9 [1.1]	9 [1.9]	8 [1.3]
Adnexa, Degeneration	2 [1.0]			1 [1.0]		9 [1.3]
Adnexa, Pinna, Degeneration						10 [1.7]
Epidermis, Necrosis						5 [2.2]
Epithelium, Hair Follicle, Parakeratosis		3 [1.0]	7 [1.0]	9 [1.1]	10 [1.1]	10 [2.1]
Epithelium, Hair Follicle, Pinna, Parakeratosis						10 [2.0]
Pinna, Hyperplasia, Squamous						10 [1.5]
Pinna, Inflammation, Chronic Active						10 [1.4]
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(10)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(10)	(10)
RESPIRATORY SYSTEM						
Larynx	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic Active					9 [1.9]	10 [3.1]
Metaplasia, Squamous			3 [1.3]	10 [2.1]	10 [3.9]	8 [3.8]
Necrosis					3 [2.0]	9 [2.6]
Regeneration						3 [1.7]
Ulcer						1 [2.0]
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Bronchiole, Goblet Cell, Hyperplasia					6 [1.5]	
Bronchus, Inflammation, Chronic Active					6 [1.2]	8 [1.4]
Bronchus, Necrosis					2 [2.0]	8 [2.8]

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B6C3F1 MICE FEMALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
Bronchus, Regeneration						1 [1.0]
Bronchus, Ulcer						2 [2.5]
Nose	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Suppurative		10 [2.0]	10 [3.2]	10 [4.0]	10 [3.0]	6 [1.5]
Glands, Olfactory Epithelium, Hyperplasia		10 [2.1]	9 [2.1]	10 [1.5]	8 [2.0]	
Glands, Respiratory Epithelium, Accumulation, Hyaline Droplet		9 [2.1]	10 [2.1]	6 [2.0]	2 [1.0]	
Olfactory Epithelium, Accumulation, Hyaline Droplet		10 [3.0]	10 [2.8]	10 [2.0]	6 [1.3]	
Olfactory Epithelium, Atrophy		10 [2.3]	10 [2.1]	10 [2.6]	9 [2.4]	9 [1.8]
Olfactory Epithelium, Metaplasia, Respiratory		3 [1.3]	6 [1.2]	3 [1.0]	4 [2.3]	
Olfactory Epithelium, Necrosis		1 [1.0]			1 [2.0]	
Olfactory Epithelium, Regeneration					1 [2.0]	
Respiratory Epithelium, Accumulation, Hyaline Droplet		10 [3.0]	10 [3.3]	10 [3.6]	8 [2.0]	
Respiratory Epithelium, Metaplasia, Squamous		10 [2.0]	10 [2.7]	10 [2.7]	8 [2.6]	
Respiratory Epithelium, Necrosis		2 [1.0]	7 [1.1]	6 [1.3]	8 [1.5]	10 [2.5]
Respiratory Epithelium, Regeneration				1 [1.0]	3 [2.0]	6 [1.7]
Respiratory Epithelium, Ulcer						2 [1.0]
Turbinate, Atrophy		7 [1.0]	9 [2.1]	10 [3.3]	7 [3.1]	
Trachea	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic Active					10 [1.9]	10 [1.3]
Metaplasia, Squamous					9 [3.1]	2 [1.5]
Necrosis					2 [1.5]	10 [3.5]
Regeneration					1 [1.0]	2 [2.0]
Ulcer					1 [2.0]	
SPECIAL SENSES SYSTEM						
Eye	(10)	(10)	(10)	(10)	(10)	(8)
Cornea, Inflammation, Suppurative					2 [1.0]	3 [1.0]
Cornea, Necrosis						2 [1.5]
Harderian Gland	(10)	(0)	(0)	(0)	(10)	(9)

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

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Lab: BNW

B6C3F1 MICE FEMALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(0)	(10)	(10)
Nephropathy	1 [1.0]					
Urinary Bladder	(10)	(0)	(0)	(0)	(10)	(9)

*** END OF REPORT ***

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

b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)