

Experiment Number: 20107 - 02

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

Date Report Requested: 09/07/2016

Test Type: 90-DAY

N,N-Dimethyl-p-toluidine

Time Report Requested: 14:11:20

Route: GAVAGE

CAS Number: 99-97-8

First Dose M/F: 10/23/03 / 10/22/03

Species/Strain: MICE/B6C3F1

Lab: BAT

**NTP Study Number:** C20107  
**Lock Date:** 07/14/2004  
**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

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	15 MG/KG	30 MG/KG	60 MG/KG	125 MG/KG	250 MG/KG
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**Disposition Summary**

Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Moribund Sacrifice					1	
Natural Death					2	9
Survivors						
Terminal Sacrifice	10	10	10	10	7	1
Animals Examined Microscopically	10	10	10	10	10	10

## ALIMENTARY SYSTEM

Esophagus	(10)	(0)	(0)	(0)	(10)	(10)
Epithelium, Degeneration					1 [2.0]	
Gallbladder	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(10)	(10)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Hematopoietic Cell Proliferation			1 [2.0]	1 [2.0]		
Inflammation, Chronic Active	9 [1.0]	10 [1.1]	10 [1.2]	10 [1.1]	7 [1.3]	1 [1.0]
Tension Lipidosis						1 [2.0]
Hepatocyte, Fatty Change						8 [2.3]
Hepatocyte, Necrosis						4 [2.0]
Hepatocyte, Vacuolization Cytoplasmic	9 [2.0]	10 [3.0]	9 [2.6]	10 [2.6]	7 [2.6]	1 [3.0]
Mesentery	(0)	(0)	(0)	(0)	(1)	(0)
Artery, Fat, Thrombosis					1 [4.0]	
Fat, Inflammation, Chronic Active					1 [2.0]	
Fat, Necrosis					1 [4.0]	
Pancreas	(10)	(0)	(0)	(0)	(10)	(10)
Salivary Glands	(10)	(0)	(0)	(0)	(10)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(10)	(10)
Stomach, Glandular	(10)	(0)	(0)	(0)	(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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N,N-Dimethyl-p-toluidine

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Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	15 MG/KG	30 MG/KG	60 MG/KG	125 MG/KG	250 MG/KG
Inflammation, Chronic Active Tooth Malformation	1 [1.0] (1) 1 [2.0]	(0)	(0)	(0)	(0)	(0)
<b>CARDIOVASCULAR SYSTEM</b>						
Blood Vessel	(10)	(0)	(0)	(0)	(10)	(10)
Heart Mineralization	(10)	(0)	(0)	(0)	(10) 1 [1.0]	(10) 2 [1.0]
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(0)	(0)	(0)	(10)	(9)
Accessory Adrenal Cortical Nodule Subcapsular, Hyperplasia	2 [1.0]				1 [1.0] 2 [1.0]	1 [2.0]
Adrenal Medulla	(10)	(0)	(0)	(0)	(10)	(9)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(10)	(10)
Parathyroid Gland	(10)	(0)	(0)	(0)	(7)	(9)
Pituitary Gland	(10)	(0)	(0)	(0)	(10)	(9)
Thyroid Gland	(10)	(0)	(0)	(0)	(10)	(10)
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Coagulating Gland	(0)	(0)	(0)	(0)	(1)	(0)
Inflammation, Chronic Active					1 [2.0]	
Epididymis	(10)	(0)	(0)	(0)	(10)	(10)
Inflammation, Chronic Active					1 [3.0]	
Necrosis					1 [3.0]	
Preputial Gland	(10)	(0)	(0)	(0)	(10)	(10)

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Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	15 MG/KG	30 MG/KG	60 MG/KG	125 MG/KG	250 MG/KG
Inflammation, Chronic Active Necrosis					1 [2.0] 1 [4.0]	
Prostate	(10)	(0)	(0)	(0)	(10)	(10)
Inflammation, Chronic Active Necrosis					1 [2.0] 1 [4.0]	
Seminal Vesicle	(10)	(0)	(0)	(0)	(10)	(10)
Inflammation, Chronic Active					1 [2.0]	
Testes	(10)	(0)	(0)	(0)	(10)	(10)
Germinal Epithelium, Degeneration					1 [2.0]	
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Lymph Node	(0)	(0)	(0)	(0)	(0)	(2)
Bronchial, Atrophy						1 [2.0]
Inguinal, Necrosis, Lymphoid						1 [2.0]
Lymph Node, Mandibular	(10)	(10)	(10)	(10)	(10)	(9)
Atrophy					2 [2.0]	2 [2.0]
Necrosis, Lymphoid						5 [2.0]
Lymph Node, Mesenteric	(10)	(10)	(10)	(10)	(10)	(9)
Atrophy					2 [3.0]	2 [2.0]
Necrosis, Lymphoid						5 [1.8]
Spleen	(10)	(10)	(10)	(10)	(10)	(10)
Atrophy					3 [3.3]	8 [3.0]
Hematopoietic Cell Proliferation					1 [2.0]	
Lymphoid Follicle, Necrosis						6 [2.2]
Thymus	(10)	(10)	(10)	(10)	(10)	(10)
Atrophy					3 [3.3]	3 [3.3]
Thymocyte, Necrosis					8 [2.0]	7 [3.7]
<b>INTEGUMENTARY SYSTEM</b>						
Skin	(10)	(0)	(0)	(0)	(10)	(10)
Subcutaneous Tissue, Inflammation, Chronic Active					1 [2.0]	

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Subcutaneous Tissue, Necrosis					1 [4.0]	
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(0)	(0)	(0)	(10)	(10)
<b>NERVOUS SYSTEM</b>						
Brain	(10)	(0)	(0)	(0)	(10)	(10)
<b>RESPIRATORY SYSTEM</b>						
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Alveolus, Infiltration Cellular, Histiocyte					2 [2.0]	
Bronchiole, Epithelium, Degeneration				1 [2.0]	10 [2.8]	8 [3.0]
Bronchiole, Epithelium, Regeneration				1 [2.0]	9 [2.7]	3 [3.3]
Bronchus, Epithelium, Regeneration					1 [3.0]	
Peribronchiolar, Inflammation, Chronic Active					9 [2.2]	6 [1.7]
Nose	(10)	(10)	(10)	(10)	(10)	(10)
Foreign Body						1
Inflammation, Chronic Active					1 [1.0]	8 [2.3]
Glands, Hyperplasia					7 [2.0]	1 [2.0]
Olfactory Epithelium, Degeneration					9 [2.9]	2 [2.0]
Olfactory Epithelium, Metaplasia					6 [2.3]	1 [4.0]
Olfactory Epithelium, Necrosis						1 [4.0]
Respiratory Epithelium, Degeneration					1 [2.0]	1 [2.0]
Respiratory Epithelium, Necrosis						1 [4.0]
Trachea	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic						1 [2.0]
Epithelium, Degeneration					2 [1.0]	
Epithelium, Hyperplasia					1 [4.0]	
Epithelium, Necrosis					2 [4.0]	8 [4.0]

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B6C3F1 MICE MALE	0 MG/KG	15 MG/KG	30 MG/KG	60 MG/KG	125 MG/KG	250 MG/KG
<hr/>						
SPECIAL SENSES SYSTEM						
Eye	(10)	(0)	(0)	(0)	(10)	(10)
Harderian Gland	(10)	(0)	(0)	(0)	(10)	(10)
<hr/>						
URINARY SYSTEM						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic Active	1 [1.0]			1 [1.0]		1 [2.0]
Mineralization	1 [1.0]				1 [1.0]	1 [1.0]
Nephropathy	1 [1.0]			1 [1.0]	2 [1.0]	
Urinary Bladder	(10)	(0)	(0)	(0)	(10)	(10)

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

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**Disposition Summary**

Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Moribund Sacrifice						1
Natural Death					2	9
Survivors						
Terminal Sacrifice	10	10	10	10	8	
Animals Examined Microscopically	10	10	10	10	10	10

## ALIMENTARY SYSTEM

Esophagus	(10)	(0)	(0)	(0)	(10)	(10)
Gallbladder	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(10)	(10)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic Active	10 [1.1]	10 [1.0]	10 [1.0]	10 [1.0]	7 [1.0]	1 [1.0]
Tension Lipidosis						1 [3.0]
Hepatocyte, Fatty Change						9 [2.7]
Hepatocyte, Necrosis	3 [1.3]	1 [1.0]			1 [2.0]	4 [2.3]
Hepatocyte, Vacuolization Cytoplasmic	10 [1.0]	10 [2.2]	9 [2.1]	9 [2.3]	8 [2.6]	
Pancreas	(10)	(0)	(0)	(0)	(10)	(10)
Salivary Glands	(10)	(0)	(0)	(0)	(10)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(10)	(10)
Stomach, Glandular	(10)	(0)	(0)	(0)	(10)	(10)

## CARDIOVASCULAR SYSTEM

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

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Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	15 MG/KG	30 MG/KG	60 MG/KG	125 MG/KG	250 MG/KG
Mineralization						2 [1.0]
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(0)	(0)	(0)	(10)	(10)
Accessory Adrenal Cortical Nodule	1					
Subcapsular, Hyperplasia	10 [1.4]				8 [1.8]	
Adrenal Medulla	(10)	(0)	(0)	(0)	(10)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(10)	(10)
Parathyroid Gland	(9)	(0)	(0)	(0)	(7)	(6)
Pituitary Gland	(10)	(0)	(0)	(0)	(10)	(9)
Thyroid Gland	(10)	(0)	(0)	(0)	(10)	(10)
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Clitoral Gland	(10)	(0)	(0)	(0)	(10)	(10)
Ovary	(10)	(0)	(0)	(0)	(10)	(10)
Cyst	1					
Uterus	(10)	(0)	(0)	(0)	(10)	(10)
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Lymph Node	(0)	(0)	(0)	(0)	(0)	(3)
Inguinal, Necrosis, Lymphoid						2 [2.5]
Renal, Necrosis, Lymphoid						1 [2.0]
Lymph Node, Mandibular	(10)	(10)	(10)	(10)	(10)	(8)
Atrophy						3 [2.7]
Necrosis, Lymphoid					3 [1.7]	2 [2.0]

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B6C3F1 MICE FEMALE	0 MG/KG	15 MG/KG	30 MG/KG	60 MG/KG	125 MG/KG	250 MG/KG
Lymph Node, Mesenteric Atrophy	(10)	(10)	(10)	(10)	(10)	(9) 5 [2.8]
Necrosis, Lymphoid					2 [2.0]	4 [2.3]
Spleen	(10)	(10)	(10)	(10)	(10)	(10)
Atrophy					2 [3.0]	7 [2.6]
Hematopoietic Cell Proliferation				1 [2.0]	1 [2.0]	
Lymphoid Follicle, Necrosis					2 [2.0]	6 [2.0]
Thymus	(10)	(10)	(10)	(10)	(10)	(10)
Atrophy					2 [3.0]	6 [3.0]
Inflammation, Chronic Active Thymocyte, Necrosis	1 [1.0]		1 [1.0]		10 [2.0]	8 [3.1]
<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(10)	(0)	(0)	(0)	(10)	(10)
Skin	(10)	(0)	(0)	(0)	(10)	(10)
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(0)	(0)	(0)	(10)	(10)
Skeletal Muscle	(0)	(0)	(0)	(0)	(0)	(1)
Inflammation, Chronic Active						1 [1.0]
<b>NERVOUS SYSTEM</b>						
Brain	(10)	(0)	(0)	(0)	(10)	(10)
<b>RESPIRATORY SYSTEM</b>						
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Alveolus, Infiltration Cellular, Histiocyte					7 [2.0]	
Bronchiole, Epithelium, Degeneration					6 [2.5]	9 [2.6]
Bronchiole, Epithelium, Regeneration			1 [2.0]	1 [1.0]	7 [3.1]	

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B6C3F1 MICE FEMALE	0 MG/KG	15 MG/KG	30 MG/KG	60 MG/KG	125 MG/KG	250 MG/KG
Bronchus, Epithelium, Degeneration Peribronchiolar, Inflammation, Chronic Active		1 [2.0]	1 [2.0]	1 [2.0]	10 [2.3]	1 [2.0] 10 [2.0]
Nose Inflammation, Chronic Active	(10)	(10)	(10)	(10)	(10) 1 [2.0]	(10) 8 [2.0]
Glands, Dilatation	2 [2.0]					
Glands, Hyperplasia					7 [2.1]	
Olfactory Epithelium, Degeneration				5 [1.8]	8 [2.5]	
Olfactory Epithelium, Metaplasia					4 [2.5]	
Trachea Epithelium, Necrosis	(10)	(10)	(10)	(10)	(10) 2 [4.0]	(10) 10 [4.0]
<b>SPECIAL SENSES SYSTEM</b>						
Eye Cornea, Inflammation, Chronic Active	(10)	(0)	(0)	(0)	(10)	(10) 2 [2.0]
Harderian Gland	(9)	(0)	(0)	(0)	(10)	(10)
<b>URINARY SYSTEM</b>						
Kidney Inflammation, Chronic Active	(10) 2 [1.0]	(10)	(10)	(10)	(10)	(10)
Urinary Bladder	(10)	(0)	(0)	(0)	(10)	(9)

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

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