

**TDMS No.** 20107 - 04

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

**Date Report Requested:** 03/10/2011

**Test Type:** CHRONIC

N,N-Dimethyl-p-toluidine

**Time Report Requested:** 11:42:39

**Route:** GAVAGE

**CAS Number:** 99-97-8

**First Dose M/F:** 10/26/04 / 10/25/04

**Species/Strain:** MICE/B6C3F1

**Lab:** BAT

F1\_M3

**C Number:** C20107  
**Lock Date:** 02/26/2008  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 2.3.0  
**PWG Approval Date:** NONE

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First Dose M/F: 10/26/04 / 10/25/04

Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
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**Disposition Summary**

<b>Animals Initially In Study</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>
<b>Early Deaths</b>				
<b>Dosing Accident</b>	<b>2</b>			
<b>Moribund Sacrifice</b>	<b>5</b>	<b>4</b>	<b>11</b>	<b>14</b>
<b>Natural Death</b>	<b>9</b>	<b>10</b>	<b>8</b>	
<b>Survivors</b>				
<b>Natural Death</b>	<b>1</b>			
<b>Terminal Sacrifice</b>	<b>33</b>	<b>36</b>	<b>31</b>	<b>36</b>
<b>Animals Examined Microscopically</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>

**ALIMENTARY SYSTEM**

Esophagus	(50)	(50)	(50)	(50)
Necrosis	1 [4.0]			
Perforation	1			
Periesophageal Tissue, Inflammation	2 [1.5]			
Gallbladder	(49)	(50)	(47)	(49)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Peyer's Patch, Hyperplasia		1 [3.0]		
Liver	(50)	(50)	(50)	(50)
Angiectasis	3 [1.0]	1 [1.0]		
Basophilic Focus	5	11	8	2
Clear Cell Focus	15	22	15	7
Eosinophilic Focus	25	30	39	43
Fatty Change		3 [2.7]	1 [2.0]	2 [2.0]
Hematopoietic Cell Proliferation	4 [1.3]	1 [1.0]	4 [1.8]	1 [2.0]
Inflammation, Chronic Active	23 [1.0]	22 [1.0]	18 [1.2]	19 [1.1]
Mineralization		1 [1.0]	1 [1.0]	1 [2.0]
Mitotic Alteration	1 [1.0]	1 [1.0]	2 [1.0]	1 [2.0]

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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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Mixed Cell Focus	21	25	17	12
Necrosis	9 [1.6]	8 [2.5]	7 [1.9]	10 [2.0]
Pigmentation		3 [1.0]	2 [2.0]	2 [1.5]
Bile Duct, Cyst		1 [1.0]	1 [2.0]	
Bile Duct, Hyperplasia	1 [1.0]	1 [1.0]	2 [1.0]	
Centrilobular, Degeneration	1 [2.0]		1 [3.0]	
Hepatocyte, Hypertrophy	1 [1.0]	9 [1.2]	11 [1.9]	16 [2.1]
Hepatocyte, Karyomegaly	1 [1.0]			
Kupffer Cell, Hyperplasia				1 [2.0]
Oval Cell, Hyperplasia	1 [1.0]		1 [2.0]	2 [1.0]
Mesentery	(4)	(3)	(5)	(2)
Inflammation, Suppurative	1 [4.0]			
Fat, Necrosis	2 [2.0]	3 [1.7]	5 [2.0]	2 [3.0]
Vein, Thrombosis	1 [3.0]			
Pancreas	(50)	(50)	(50)	(50)
Atrophy		1 [1.0]	1 [4.0]	1 [4.0]
Basophilic Focus			1 [1.0]	
Inflammation			1 [1.0]	
Acinus, Hyperplasia				1 [1.0]
Duct, Cyst			1 [4.0]	2 [3.0]
Salivary Glands	(50)	(50)	(50)	(50)
Fibrosis	1 [1.0]			
Stomach, Forestomach	(50)	(50)	(50)	(50)
Erosion	2 [1.0]	1 [2.0]		
Hemorrhage				1 [3.0]
Inflammation	13 [1.8]	12 [2.4]	13 [2.6]	8 [2.1]
Necrosis				1 [1.0]
Ulcer	5 [1.4]	4 [2.0]	5 [2.0]	5 [2.2]
Epithelium, Hyperplasia	14 [2.3]	14 [2.7]	17 [2.5]	11 [2.5]
Stomach, Glandular	(50)	(50)	(50)	(50)
Inflammation		1 [3.0]	1 [1.0]	
Mineralization			1 [2.0]	
Epithelium, Necrosis	1 [1.0]	1 [2.0]	1 [2.0]	
Tongue	(2)	(0)	(0)	(0)
Angiectasis	1 [3.0]			
Cyst	1 [2.0]			

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N,N-Dimethyl-p-toluidine

Time Report Requested: 11:42:39

Route: GAVAGE

CAS Number: 99-97-8

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Tooth	(37)	(38)	(34)	(30)
Dysplasia	34	36	34	26

## CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
Inflammation			1 [2.0]	
Mineralization				1 [3.0]
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	8 [1.0]	7 [1.1]	10 [1.3]	13 [1.1]
Inflammation	2 [2.0]			1 [1.0]
Mineralization		1 [1.0]	2 [2.5]	5 [1.4]
Atrium, Thrombosis		1 [2.0]		
Valve, Thrombosis	1 [3.0]			

## ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Hypertrophy	3 [1.0]	3 [1.3]	1 [1.0]	1 [1.0]
Adrenal Medulla	(50)	(50)	(50)	(50)
Hyperplasia	1 [1.0]			1 [1.0]
Islets, Pancreatic	(50)	(50)	(50)	(50)
Hyperplasia	12 [1.5]	5 [1.2]	2 [1.0]	1 [1.0]
Parathyroid Gland	(40)	(43)	(45)	(42)
Amyloid Deposition			1 [2.0]	
Pituitary Gland	(50)	(50)	(49)	(50)
Pars Distalis, Hyperplasia	1 [1.0]	1 [1.0]		
Thyroid Gland	(50)	(50)	(50)	(50)

## GENERAL BODY SYSTEM

None

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B6C3F1 MICE MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>GENITAL SYSTEM</b>				
Coagulating Gland	(0)	(1)	(0)	(0)
Inflammation		1 [2.0]		
Epididymis	(50)	(50)	(50)	(50)
Angiectasis				1 [2.0]
Granuloma Sperm		2 [2.5]		
Inflammation				1 [2.0]
Preputial Gland	(50)	(50)	(50)	(50)
Atrophy	1 [4.0]			
Ectasia	7 [2.0]	6 [2.0]	7 [2.0]	8 [2.1]
Inflammation		1 [3.0]	1 [3.0]	1 [3.0]
Prostate	(50)	(50)	(50)	(50)
Inflammation	1 [1.0]	1 [2.0]	1 [1.0]	1 [2.0]
Epithelium, Hyperplasia	1 [1.0]			
Seminal Vesicle	(50)	(50)	(50)	(50)
Inflammation	1 [4.0]	1 [1.0]		
Mineralization	1 [1.0]			
Testes	(50)	(50)	(50)	(50)
Hyperplasia, Oncocytic		1 [1.0]		
Germinal Epithelium, Degeneration		2 [1.5]	3 [1.3]	
Germinal Epithelium, Mineralization			1 [1.0]	
Interstitial Cell, Hyperplasia	1 [1.0]			1 [1.0]

**HEMATOPOIETIC SYSTEM**

Bone Marrow	(50)	(50)	(50)	(50)
Atrophy	3 [1.7]		1 [1.0]	
Hyperplasia	8 [2.0]	6 [1.3]	9 [2.0]	9 [2.0]
Necrosis			1 [2.0]	
Thrombosis		1 [2.0]		
Lymph Node	(2)	(3)	(4)	(0)
Lymph Node, Mandibular	(50)	(50)	(49)	(50)
Atrophy	5 [1.8]	4 [1.5]	6 [1.3]	3 [2.0]
Hyperplasia, Lymphoid	2 [2.5]	1 [3.0]	1 [2.0]	

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Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Necrosis	1 [2.0]			
Lymph Node, Mesenteric	(50)	(50)	(49)	(50)
Atrophy	13 [2.2]	9 [2.4]	14 [2.5]	15 [2.3]
Hyperplasia, Lymphoid				2 [2.5]
Spleen	(48)	(50)	(49)	(50)
Atrophy	4 [2.5]	11 [2.2]	11 [2.4]	6 [1.8]
Hematopoietic Cell Proliferation	15 [2.3]	18 [2.2]	23 [2.4]	22 [2.5]
Hyperplasia, Lymphoid	5 [2.2]	9 [1.9]	6 [2.0]	9 [2.0]
Necrosis, Lymphoid	1 [2.0]			
Pigmentation	38 [1.0]	34 [1.1]	25 [1.0]	44 [1.6]
Red Pulp, Atrophy	4 [2.0]	1 [1.0]	2 [1.5]	2 [1.5]
Thymus	(48)	(48)	(48)	(49)
Atrophy	41 [3.1]	47 [3.2]	47 [3.1]	48 [3.0]
Hyperplasia, Lymphoid	1 [3.0]			1 [2.0]
Infiltration Cellular, Mast Cell				1 [2.0]
Necrosis	2 [3.5]			

## INTEGUMENTARY SYSTEM

Skin	(50)	(50)	(50)	(50)
Inflammation	3 [3.0]	1 [3.0]	1 [3.0]	1 [2.0]
Ulcer	4 [3.5]	1 [3.0]	1 [4.0]	2 [3.0]
Dermis, Fibrosis	2 [2.0]			1 [4.0]
Epidermis, Hyperplasia	1 [2.0]		1 [2.0]	1 [2.0]
Hair Follicle, Hyperkeratosis				1 [2.0]

## MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Fibrosis	1 [1.0]			
Fracture		1		
Osteopetrosis		1 [2.0]		
Skeletal Muscle	(0)	(1)	(2)	(2)
Inflammation				1 [2.0]

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Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
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## NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
Hemorrhage			1 [2.0]	
Hydrocephalus			1 [2.0]	1 [1.0]
Necrosis			1 [2.0]	
Olfactory Lobe, Atrophy		1 [3.0]		5 [1.2]

## RESPIRATORY SYSTEM

Lung	(50)	(50)	(50)	(50)
Foreign Body	1			
Hemorrhage				1 [2.0]
Inflammation, Chronic Active				1 [3.0]
Alveolar Epithelium, Hyperplasia	3 [1.0]	8 [1.9]	3 [1.3]	
Alveolar Epithelium, Metaplasia	1 [1.0]		1 [2.0]	
Alveolus, Infiltration Cellular, Histiocyte	1 [2.0]	2 [1.5]	2 [2.5]	10 [1.2]
Artery, Inflammation		1 [3.0]		
Bronchiole, Epithelium, Hyperplasia		1 [2.0]		
Bronchiole, Epithelium, Regeneration			1 [1.0]	1 [1.0]
Bronchus, Necrosis			1 [1.0]	
Bronchus, Epithelium, Regeneration				1 [1.0]
Mediastinum, Inflammation	1 [3.0]			
Perivascular, Infiltration Cellular, Lymphoid			1 [2.0]	
Serosa, Inflammation	1 [3.0]			
Nose	(49)	(50)	(50)	(50)
Foreign Body		1		
Hyperplasia		1 [1.0]		
Inflammation	13 [1.1]	12 [1.0]	10 [1.0]	20 [1.1]
Polyp, Inflammatory	3	2		
Glands, Olfactory Epithelium, Dilatation	4 [1.0]	11 [1.0]	7 [1.0]	48 [1.8]
Glands, Olfactory Epithelium, Hyperplasia	4 [1.0]	9 [1.1]	7 [1.3]	49 [2.1]
Glands, Olfactory Epithelium, Metaplasia, Respiratory	5 [1.0]	5 [1.0]	6 [1.0]	48 [1.7]

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Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Glands, Respiratory Epithelium, Dilatation	17 [1.0]	19 [1.0]	13 [1.0]	41 [1.8]
Glands, Respiratory Epithelium, Hyperplasia	4 [1.0]	2 [1.0]	2 [1.0]	11 [1.1]
Glands, Respiratory Epithelium, Metaplasia, Respiratory	2 [1.5]	2 [1.0]	2 [1.0]	10 [1.1]
Nasolacrimal Duct, Hyperplasia, Regenerative Nerve, Atrophy	2 [1.0]	7 [1.1]	4 [1.3]	4 [1.0] 42 [2.0]
Olfactory Epithelium, Accumulation, Hyaline Droplet	12 [1.2]	14 [1.3]	10 [1.0]	4 [1.0]
Olfactory Epithelium, Metaplasia, Respiratory	10 [1.3]	10 [1.3]	5 [1.2]	49 [2.3]
Olfactory Epithelium, Necrosis	1 [1.0]	3 [1.3]	3 [1.0]	8 [1.5]
Respiratory Epithelium, Accumulation, Hyaline Droplet	24 [1.1]	25 [1.2]	24 [1.2]	25 [1.2]
Respiratory Epithelium, Hyperplasia	37 [1.2]	35 [1.4]	32 [1.1]	30 [1.3]
Respiratory Epithelium, Necrosis		1 [1.0]	1 [1.0]	1 [2.0]
Transitional Epithelium, Hyperplasia				1 [1.0]
Transitional Epithelium, Necrosis				1 [2.0]
Vomer nasal Organ, Necrosis		1 [2.0]	2 [1.0]	3 [1.0]
Trachea Necrosis	(50)	(50)	(50)	(50) 1 [2.0]

## SPECIAL SENSES SYSTEM

Ear	(1)	(0)	(0)	(0)
External Ear, Inflammation	1 [2.0]			
External Ear, Necrosis	1 [2.0]			
Eye	(50)	(50)	(50)	(50)
Cornea, Inflammation	3 [2.0]	1 [2.0]	4 [2.3]	
Lens, Cataract			1 [2.0]	
Optic Nerve, Atrophy		1 [2.0]		
Harderian Gland	(50)	(50)	(50)	(50)
Atrophy			1 [2.0]	
Hyperplasia	1 [1.0]	4 [2.5]	1 [1.0]	1 [2.0]
Zymbal's Gland	(1)	(0)	(0)	(0)

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Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Accumulation, Hyaline Droplet	1 [2.0]			
Infarct	3 [1.7]	2 [1.5]		2 [1.5]
Inflammation	2 [2.5]	1 [3.0]		
Mineralization	5 [1.2]	7 [1.0]	9 [1.0]	6 [1.2]
Nephropathy	39 [1.6]	41 [1.6]	43 [1.5]	37 [1.3]
Pigmentation			2 [2.5]	
Cortex, Cyst	3 [1.0]	2 [1.5]	1 [1.0]	2 [1.5]
Papilla, Necrosis	1 [3.0]	1 [2.0]		
Pelvis, Dilatation	2 [1.5]		1 [2.0]	1 [2.0]
Renal Tubule, Dilatation				1 [4.0]
Renal Tubule, Hyperplasia				1 [1.0]
Renal Tubule, Necrosis			2 [2.0]	1 [1.0]
Ureter	(1)	(0)	(0)	(0)
Inflammation	1 [2.0]			
Necrosis	1 [2.0]			
Urethra	(0)	(1)	(0)	(0)
Inflammation		1 [3.0]		
Necrosis		1 [1.0]		
Urinary Bladder	(50)	(50)	(50)	(50)
Calculus Gross Observation				2
Inflammation				1 [4.0]
Transitional Epithelium, Hyperplasia				1 [3.0]

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

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B6C3F1 MICE FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
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**Disposition Summary**

<b>Animals Initially In Study</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>
<b>Early Deaths</b>				
<b>Dosing Accident</b>		<b>1</b>	<b>1</b>	<b>2</b>
<b>Moribund Sacrifice</b>	<b>3</b>	<b>1</b>	<b>7</b>	<b>10</b>
<b>Natural Death</b>	<b>4</b>	<b>8</b>	<b>3</b>	<b>6</b>
<b>Survivors</b>				
<b>Terminal Sacrifice</b>	<b>43</b>	<b>40</b>	<b>39</b>	<b>32</b>
<b>Animals Examined Microscopically</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>

## ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Foreign Body				1
Perforation			1	1
Epithelium, Inflammation				1 [1.0]
Muscularis, Degeneration			1 [1.0]	1 [1.0]
Muscularis, Inflammation	1 [1.0]			
Periesophageal Tissue, Hemorrhage			1 [4.0]	
Gallbladder	(50)	(50)	(49)	(49)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Fibrosis		1 [3.0]		
Lymphoid Tissue, Hyperplasia, Lymphoid	1 [3.0]			
Intestine Large, Colon	(50)	(50)	(50)	(50)
Fibrosis		1 [3.0]		
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Fibrosis		1 [3.0]		
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Fibrosis		1 [3.0]		
Peyer's Patch, Hyperplasia, Lymphoid		1 [4.0]		
Liver	(50)	(50)	(50)	(50)
Angiectasis	1 [2.0]			
Basophilic Focus	7	5	9	11

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Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Clear Cell Focus		2	2	3
Eosinophilic Focus	20	18	45	38
Fatty Change	1 [4.0]			8 [2.5]
Hematopoietic Cell Proliferation	2 [1.0]	4 [1.3]	2 [1.0]	3 [2.0]
Inflammation, Chronic Active	39 [1.1]	27 [1.0]	33 [1.1]	35 [1.0]
Mineralization				1 [1.0]
Mixed Cell Focus	3	9	7	7
Necrosis	1 [2.0]	8 [1.5]	4 [2.0]	10 [1.8]
Pigmentation	1 [3.0]	1 [1.0]	1 [1.0]	4 [1.0]
Bile Duct, Cyst	2 [2.0]	1 [2.0]	1 [3.0]	3 [3.0]
Hepatocyte, Hypertrophy		11 [1.6]	10 [1.6]	17 [1.9]
Kupffer Cell, Hyperplasia		1 [2.0]		1 [2.0]
Oval Cell, Hyperplasia				2 [1.5]
Serosa, Fibrosis		1 [3.0]		
Serosa, Inflammation, Chronic Active		1 [2.0]		
Mesentery	(3)	(8)	(9)	(6)
Inflammation, Chronic		1 [4.0]		
Fat, Necrosis	3 [2.0]	5 [2.4]	9 [2.8]	6 [2.0]
Pancreas	(50)	(50)	(50)	(50)
Atrophy	1 [3.0]		2 [2.0]	
Acinus, Hyperplasia				1 [1.0]
Acinus, Necrosis				1 [2.0]
Duct, Cyst			2 [3.5]	
Salivary Glands	(50)	(50)	(50)	(48)
Atrophy				1 [1.0]
Fibrosis				1 [2.0]
Stomach, Forestomach	(50)	(50)	(50)	(50)
Erosion		1 [1.0]		2 [1.5]
Fibrosis		1 [3.0]		
Inflammation	3 [3.0]	4 [2.0]	7 [2.3]	16 [2.3]
Necrosis	1 [1.0]			
Ulcer	2 [2.0]	2 [2.0]	4 [1.3]	7 [1.6]
Epithelium, Cyst		1 [1.0]		1 [2.0]
Epithelium, Hyperplasia	3 [2.7]	5 [2.8]	12 [2.2]	17 [2.6]
Stomach, Glandular	(50)	(50)	(50)	(50)
Mineralization	1 [1.0]			

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Test Type: CHRONIC

N,N-Dimethyl-p-toluidine

Time Report Requested: 11:42:39

Route: GAVAGE

CAS Number: 99-97-8

First Dose M/F: 10/26/04 / 10/25/04

Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Epithelium, Necrosis Glands, Dysplasia	1 [1.0]			1 [1.0]
Tongue	(0)	(0)	(0)	(1)
Cyst				1 [3.0]
Tooth	(13)	(10)	(7)	(4)
Dysplasia	13	10	4	4
Peridental Tissue, Pulp, Inflammation	1 [2.0]			

## CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(49)	(50)	(50)
Embolus Bacterial		1 [2.0]		
Inflammation				3 [1.7]
Media, Pulmonary Artery, Hyperplasia		1 [2.0]		
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	5 [1.2]	2 [1.0]	4 [1.3]	2 [1.0]
Inflammation				1 [3.0]
Mineralization	1 [1.0]	2 [1.0]	1 [3.0]	5 [2.8]
Necrosis			2 [2.5]	
Epicardium, Fibrosis				1 [2.0]
Valve, Thrombosis		1 [1.0]	1 [2.0]	
Ventricle, Thrombosis			1 [3.0]	

## ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Angiectasis		1 [2.0]		
Necrosis			2 [1.5]	
Vacuolization Cytoplasmic			1 [4.0]	
Adrenal Medulla	(50)	(50)	(50)	(50)
Hyperplasia	3 [2.3]			
Necrosis			1 [2.0]	
Islets, Pancreatic	(50)	(50)	(50)	(50)
Hyperplasia		1 [1.0]		2 [1.0]
Parathyroid Gland	(48)	(38)	(38)	(34)

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Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Pituitary Gland	(48)	(50)	(50)	(49)
Pars Distalis, Angiectasis				1 [1.0]
Pars Distalis, Hyperplasia	5 [2.2]	3 [1.3]	3 [2.0]	3 [1.7]
Pars Intermedia, Hyperplasia	1 [1.0]	1 [2.0]	1 [3.0]	2 [2.0]
Thyroid Gland	(50)	(50)	(50)	(50)
Atrophy		2 [2.0]		
Inflammation		1 [2.0]	1 [1.0]	
Follicle, Degeneration			1 [1.0]	
Follicular Cell, Hyperplasia		1 [3.0]		
Follicular Cell, Hypertrophy			1 [3.0]	

## GENERAL BODY SYSTEM

None

## GENITAL SYSTEM

Clitoral Gland	(50)	(50)	(50)	(49)
Ovary	(50)	(49)	(50)	(50)
Angiectasis	2 [4.0]		1 [2.0]	1 [3.0]
Atrophy	40 [3.6]	43 [3.3]	40 [3.6]	45 [3.7]
Cyst	4 [2.0]	6 [2.0]	4 [3.5]	2 [4.0]
Hemorrhage	2 [3.5]		1 [4.0]	
Inflammation		2 [4.0]		
Thrombosis	2 [4.0]			3 [3.3]
Oviduct	(0)	(1)	(0)	(0)
Uterus	(50)	(50)	(50)	(50)
Angiectasis	2 [2.5]	2 [3.0]	1 [3.0]	
Atrophy				1 [3.0]
Dilatation	13 [2.5]	13 [3.2]	6 [3.3]	10 [2.6]
Inflammation	1 [2.0]	3 [2.7]	2 [3.0]	
Thrombosis		1 [4.0]	1 [1.0]	
Endometrium, Hyperplasia, Cystic	25 [1.8]	17 [2.0]	11 [2.0]	9 [1.7]

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Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>HEMATOPOIETIC SYSTEM</b>				
Bone Marrow	(50)	(50)	(50)	(49)
Atrophy	1 [1.0]	2 [1.5]	2 [2.0]	3 [1.3]
Hyperplasia	5 [2.2]	14 [1.9]	15 [2.1]	14 [2.1]
Lymph Node	(7)	(3)	(5)	(4)
Lumbar, Hemorrhage				1 [3.0]
Mediastinal, Hyperplasia, Lymphoid			1 [3.0]	
Renal, Ectasia	2 [4.0]			
Renal, Hemorrhage		1 [4.0]		
Lymph Node, Mandibular	(50)	(50)	(50)	(48)
Atrophy	1 [3.0]	4 [3.0]	5 [2.0]	5 [2.4]
Hyperplasia, Lymphoid	3 [2.3]	5 [2.0]		3 [2.0]
Hyperplasia, Plasma Cell		1 [3.0]		
Lymph Node, Mesenteric	(49)	(49)	(49)	(50)
Angiectasis	1 [2.0]			
Atrophy	1 [2.0]	5 [2.0]	5 [2.2]	12 [2.9]
Hyperplasia, Lymphoid	7 [2.3]	3 [3.7]	1 [2.0]	
Infiltration Cellular, Plasma Cell			1 [3.0]	
Inflammation, Granulomatous				1 [4.0]
Necrosis				1 [1.0]
Spleen	(49)	(49)	(49)	(50)
Atrophy	3 [1.7]	8 [1.8]	1 [1.0]	6 [2.5]
Hematopoietic Cell Proliferation	18 [2.1]	23 [2.1]	24 [2.3]	21 [2.1]
Hyperplasia, Lymphoid	14 [2.1]	15 [1.7]	12 [2.0]	15 [1.8]
Infarct		1 [2.0]		
Infiltration Cellular, Plasma Cell	1 [3.0]			
Pigmentation	37 [1.1]	39 [1.0]	33 [1.2]	43 [1.1]
Capsule, Fibrosis		1 [3.0]		
Red Pulp, Atrophy				5 [3.2]
Thymus	(50)	(50)	(48)	(48)
Atrophy	46 [2.4]	46 [2.5]	39 [2.6]	43 [2.7]
Hyperplasia, Histiocytic		1 [2.0]		
Hyperplasia, Lymphoid	3 [1.7]			

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Route: GAVAGE

CAS Number: 99-97-8

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
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## INTEGUMENTARY SYSTEM

Mammary Gland	(50)	(50)	(50)	(50)
Skin	(50)	(50)	(50)	(50)
Hemorrhage			1 [4.0]	
Inflammation	1 [2.0]	2 [3.0]		1 [3.0]
Ulcer		2 [3.5]	2 [2.0]	1 [3.0]
Dermis, Fibrosis		1 [2.0]	1 [2.0]	
Epidermis, Hyperplasia	1 [2.0]		2 [2.5]	
Sebaceous Gland, Hyperplasia			1 [2.0]	

## MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Fibro-Osseous Lesion	3 [1.7]	5 [1.6]	6 [1.5]	11 [1.5]
Fracture				1
Osteopetrosis	1 [1.0]	1 [2.0]		1 [1.0]
Skeletal Muscle	(0)	(2)	(1)	(2)
Inflammation		1 [3.0]		

## NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(49)
Necrosis	1 [3.0]		1 [1.0]	
Olfactory Lobe, Atrophy				8 [1.6]
Peripheral Nerve	(0)	(0)	(1)	(0)
Spinal Cord	(0)	(0)	(1)	(0)

## RESPIRATORY SYSTEM

Lung	(50)	(50)	(50)	(50)
Foreign Body		1		2
Hemorrhage			1 [1.0]	
Inflammation		2 [2.5]		2 [4.0]

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Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Alveolar Epithelium, Hyperplasia	2 [3.0]	3 [2.3]	8 [1.5]	2 [1.0]
Alveolus, Infiltration Cellular, Histiocyte	1 [1.0]			7 [1.4]
Bronchiole, Epithelium, Necrosis				1 [1.0]
Bronchiole, Epithelium, Regeneration				5 [1.8]
Bronchus, Necrosis				5 [1.6]
Bronchus, Epithelium, Regeneration				5 [2.0]
Nose	(50)	(49)	(50)	(50)
Inflammation	3 [1.0]	7 [1.0]	3 [1.0]	32 [1.3]
Glands, Lateral Wall, Dilatation				2 [1.5]
Glands, Olfactory Epithelium, Dilatation	13 [1.0]	14 [1.1]	20 [1.0]	46 [2.3]
Glands, Olfactory Epithelium, Hyperplasia	2 [1.0]	14 [1.0]	14 [1.1]	50 [2.2]
Glands, Olfactory Epithelium, Metaplasia, Respiratory	2 [1.0]	5 [1.0]	7 [1.0]	44 [2.3]
Glands, Respiratory Epithelium, Dilatation	10 [1.0]	17 [1.0]	15 [1.1]	33 [1.4]
Glands, Respiratory Epithelium, Hyperplasia		2 [1.0]	12 [1.2]	13 [1.2]
Glands, Respiratory Epithelium, Metaplasia, Respiratory			10 [1.0]	10 [1.4]
Nasolacrimal Duct, Hyperplasia, Regenerative				4 [2.5]
Nerve, Atrophy				41 [2.3]
Olfactory Epithelium, Accumulation, Hyaline Droplet	2 [1.0]	5 [1.0]	8 [1.0]	15 [1.1]
Olfactory Epithelium, Degeneration				1 [1.0]
Olfactory Epithelium, Metaplasia, Respiratory	1 [1.0]	6 [1.0]	14 [1.1]	46 [2.9]
Olfactory Epithelium, Necrosis			3 [1.3]	6 [2.3]
Respiratory Epithelium, Accumulation, Hyaline Droplet	33 [1.2]	34 [1.1]	39 [1.2]	36 [1.1]
Respiratory Epithelium, Hyperplasia	11 [1.0]	15 [1.0]	11 [1.0]	30 [1.2]
Respiratory Epithelium, Hyperplasia, Regenerative				3 [1.3]
Respiratory Epithelium, Necrosis				5 [2.0]
Transitional Epithelium, Hyperplasia, Regenerative				1 [2.0]
Transitional Epithelium, Necrosis				2 [2.0]
Vomeronasal Organ, Necrosis				4 [1.5]
Trachea	(50)	(50)	(50)	(50)
Inflammation				1 [2.0]
Glands, Hyperplasia				1 [2.0]

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B6C3F1 MICE FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
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## SPECIAL SENSES SYSTEM

Eye	(50)	(50)	(50)	(49)
Fibrosis			1 [2.0]	
Cornea, Inflammation		1 [2.0]	1 [3.0]	3 [1.7]
Lens, Cataract			1 [4.0]	
Optic Nerve, Atrophy			1 [2.0]	
Harderian Gland	(50)	(50)	(50)	(49)
Fibrosis		1 [2.0]		
Hyperplasia	4 [2.8]	2 [2.5]		2 [2.5]
Inflammation	1 [3.0]			

## URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Accumulation, Hyaline Droplet		2 [2.5]	1 [4.0]	
Infarct	4 [1.8]	3 [1.3]	4 [1.5]	
Inflammation			1 [2.0]	2 [2.5]
Mineralization		1 [1.0]		3 [1.0]
Nephropathy	13 [1.0]	15 [1.2]	15 [1.1]	17 [1.2]
Cortex, Cyst				1 [1.0]
Papilla, Necrosis				1 [3.0]
Renal Tubule, Necrosis	1 [4.0]		2 [3.0]	2 [1.5]
Urinary Bladder	(50)	(50)	(50)	(50)

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

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