

**Experiment Number:** 91005-02  
**Test Type:** 18-33 DAYS  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

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

**Test Compound:** Methylene blue trihydrate

**CAS Number:** 7220-79-3

**Date Report Requested:** 10/21/2014

**Time Report Requested:** 08:56:06

**First Dose M/F:** NA / NA

**Lab:** BAT

<b>C Number:</b>	C91005
<b>Lock Date:</b>	12/16/1992
<b>Cage Range:</b>	All
<b>Date Range:</b>	All
<b>Reasons For Removal:</b>	All
<b>Removal Date Range:</b>	All
<b>Treatment Groups:</b>	All
<b>Study Gender:</b>	Both
<b>PWG Approval Date</b>	NONE

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B6C3F1 Mouse MALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Disposition Summary</b>						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Moribund Sacrifice			1	2	4	1
Natural Death			1	8	6	9
Survivors						
Terminal Sacrifice	10	10	8			
Animals Examined Microscopically	10	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>						
Esophagus	(10)	(0)	(10)	(10)	(10)	(10)
Gallbladder	(10)	(0)	(8)	(9)	(10)	(10)
Intestine Large, Cecum	(10)	(0)	(10)	(10)	(10)	(10)
Intestine Large, Colon	(10)	(0)	(10)	(9)	(10)	(10)
Intestine Large, Rectum	(10)	(0)	(10)	(10)	(10)	(10)
Intestine Small, Duodenum	(10)	(0)	(10)	(10)	(10)	(10)
Intestine Small, Ileum	(10)	(0)	(10)	(9)	(10)	(10)
Intestine Small, Jejunum	(10)	(0)	(10)	(10)	(10)	(10)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Centrilobular, Degeneration			1 (10%)			
Hematopoietic Cell Proliferation		5 (50%)	6 (60%)	8 (80%)	1 (10%)	
Kupffer Cell, Erythrophagocytosis						1 (10%)
Kupffer Cell, Pigmentation		9 (90%)	10 (100%)	10 (100%)	10 (100%)	9 (90%)
Mineralization			1 (10%)			
Necrosis					4 (40%)	3 (30%)
Necrosis, Focal				1 (10%)		
Periportal, Degeneration		6 (60%)	5 (50%)	3 (30%)	3 (30%)	1 (10%)
Periportal, Pigmentation				1 (10%)	2 (20%)	
Pigmentation		1 (10%)				
Pancreas	(10)	(0)	(10)	(10)	(10)	(10)

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

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B6C3F1 Mouse MALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Salivary Glands	(10)	(0)	(10)	(10)	(10)	(10)
Stomach, Forestomach	(10)	(10)	(10)	(10)	(10)	(10)
Hyperplasia, Squamous, Focal			1 (10%)	2 (20%)	1 (10%)	
Inflammation, Chronic Active				2 (20%)		
Inflammation, Focal					1 (10%)	
Ulcer, Focal				2 (20%)	6 (60%)	
Stomach, Glandular	(10)	(0)	(10)	(10)	(9)	(10)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(10)	(10)	(10)	(10)
Heart	(10)	(10)	(10)	(10)	(10)	(10)
Mineralization		2 (20%)	4 (40%)			
Myocardium, Degeneration, Chronic, Focal				1 (10%)		
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(10)	(10)	(10)	(10)
Adrenal Medulla	(10)	(0)	(10)	(10)	(10)	(9)
Islets, Pancreatic	(10)	(0)	(10)	(10)	(10)	(10)
Parathyroid Gland	(9)	(0)	(7)	(8)	(8)	(6)
Pituitary Gland	(9)	(0)	(10)	(10)	(10)	(10)
Thyroid Gland	(10)	(0)	(10)	(10)	(10)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Epididymis	(10)	(0)	(10)	(10)	(10)	(10)
Preputial Gland	(10)	(0)	(10)	(10)	(10)	(10)
Prostate	(10)	(0)	(10)	(10)	(10)	(10)
Seminal Vesicle	(10)	(0)	(10)	(10)	(10)	(10)
Testes	(10)	(0)	(10)	(10)	(10)	(10)
Germinal Epith, Degeneration					4 (40%)	

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First Dose M/F: NA / NA

Lab: BAT

B6C3F1 Mouse MALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Pigmentation		10 (100%)	11 (110%)	10 (100%)	10 (100%)	7 (70%)
Lymph Node, Mandibular	(10)	(9)	(9)	(9)	(8)	(8)
Necrosis			1 (11%)	4 (44%)	4 (50%)	4 (50%)
Lymph Node, Mesenteric	(10)	(10)	(10)	(9)	(9)	(10)
Necrosis		7 (70%)	4 (40%)	8 (89%)	7 (78%)	7 (70%)
Spleen	(10)	(10)	(10)	(10)	(10)	(10)
Capsule, Fibrosis						1 (10%)
Congestion					6 (60%)	4 (40%)
Hematopoietic Cell Proliferation			1 (10%)			
Lymph Follic, Depletion Cellular		9 (90%)	9 (90%)	10 (100%)	10 (100%)	10 (100%)
Pigmentation		10 (100%)	9 (90%)	10 (100%)	9 (90%)	10 (100%)
Red Pulp, Hematopoietic Cell Proliferation	1 (10%)	10 (100%)	8 (80%)	10 (100%)	5 (50%)	5 (50%)
Thymus	(10)	(10)	(10)	(10)	(9)	(10)
Necrosis		7 (70%)	9 (90%)	10 (100%)	8 (89%)	8 (80%)
<b>INTEGUMENTARY SYSTEM</b>						
Skin	(10)	(0)	(10)	(10)	(10)	(10)
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(1)	(10)	(10)	(10)	(10)
Patella, Arthrosis, Chronic Active		1 (100%)				
<b>NERVOUS SYSTEM</b>						
Brain	(10)	(0)	(10)	(10)	(10)	(10)
Peripheral Nerve	(0)	(0)	(1)	(2)	(4)	(0)
Spinal Cord	(0)	(0)	(1)	(2)	(4)	(0)
<b>RESPIRATORY SYSTEM</b>						
Lung	(10)	(0)	(10)	(10)	(10)	(10)
Mediastinum, Foreign Body				1 (10%)		1 (10%)

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**Lab:** BAT

B6C3F1 Mouse MALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Mediastinum, Inflammation, Suppurative				1 (10%)		
Nose	(10)	(0)	(10)	(10)	(10)	(10)
Trachea	(10)	(0)	(10)	(10)	(10)	(10)
SPECIAL SENSES SYSTEM						
Eye	(0)	(0)	(0)	(2)	(0)	(3)
URINARY SYSTEM						
Kidney	(10)	(10)	(10)	(10)	(9)	(10)
Renal Tubule, Casts Protein					5 (56%)	3 (30%)
Renal Tubule, Degeneration					1 (11%)	1 (10%)
Renal Tubule, Necrosis			2 (20%)	1 (10%)	2 (22%)	2 (20%)
Renal Tubule, Pigmentation			4 (40%)	5 (50%)	5 (56%)	3 (30%)
Urinary Bladder	(10)	(10)	(10)	(9)	(8)	(10)
Muscularis, Degeneration				7 (78%)		1 (10%)
Transit Epithe, Degeneration			5 (50%)	9 (100%)	8 (100%)	9 (90%)
Transit Epithe, Pigmentation			4 (40%)	9 (100%)	3 (38%)	7 (70%)

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

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B6C3F1 Mouse FEMALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Disposition Summary</b>						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Moribund Sacrifice			1	6		3
Natural Death			1	4	10	7
Survivors						
Terminal Sacrifice	10	10	8			
Animals Examined Microscopically	10	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>						
Esophagus	(10)	(0)	(10)	(10)	(10)	(10)
Gallbladder	(10)	(0)	(8)	(10)	(10)	(10)
Intestine Large, Cecum	(10)	(0)	(10)	(10)	(10)	(10)
Intestine Large, Colon	(10)	(0)	(10)	(10)	(10)	(10)
Intestine Large, Rectum	(10)	(0)	(10)	(10)	(10)	(10)
Intestine Small, Duodenum	(10)	(0)	(10)	(10)	(10)	(10)
Intestine Small, Ileum	(10)	(0)	(10)	(10)	(10)	(10)
Intestine Small, Jejunum	(10)	(0)	(10)	(10)	(10)	(10)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Hematopoietic Cell Proliferation	2 (20%)	7 (70%)	10 (100%)	10 (100%)	9 (90%)	2 (20%)
Kupffer Cell, Pigmentation		10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)
Necrosis					3 (30%)	6 (60%)
Necrosis, Focal			1 (10%)	1 (10%)		
Periportal, Degeneration		6 (60%)		6 (60%)	1 (10%)	
Periportal, Necrosis				1 (10%)		
Periportal, Pigmentation				1 (10%)	1 (10%)	
Pancreas	(10)	(0)	(10)	(10)	(10)	(10)
Salivary Glands	(10)	(0)	(10)	(10)	(10)	(10)
Stomach, Forestomach	(10)	(10)	(10)	(10)	(9)	(10)
Hyperplasia, Squamous, Focal				5 (50%)	3 (33%)	

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Lab: BAT

B6C3F1 Mouse FEMALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Inflammation, Acute					1 (11%)	
Inflammation, Chronic Active				5 (50%)	3 (33%)	
Ulcer, Focal		1 (10%)		3 (30%)	4 (44%)	2 (20%)
Stomach, Glandular	(10)	(0)	(10)	(10)	(9)	(10)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(10)	(10)	(10)	(9)
Heart	(10)	(10)	(10)	(10)	(10)	(10)
Myocardium, Necrosis, Acute				3 (30%)	6 (60%)	6 (60%)
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(10)	(10)	(10)	(10)
Adrenal Medulla	(10)	(0)	(10)	(10)	(10)	(10)
Islets, Pancreatic	(10)	(0)	(10)	(10)	(10)	(10)
Parathyroid Gland	(9)	(0)	(8)	(10)	(9)	(7)
Cyst			1 (13%)			
Pituitary Gland	(9)	(0)	(10)	(9)	(9)	(10)
Thyroid Gland	(10)	(0)	(10)	(10)	(10)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(10)	(0)	(8)	(10)	(9)	(10)
Ovary	(10)	(1)	(10)	(10)	(9)	(10)
Periovarn Tiss, Cyst		1 (100%)				
Uterus	(10)	(0)	(10)	(10)	(10)	(10)
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Erythroid Cell, Hyperplasia						1 (10%)
Hyperplasia					1 (10%)	
Pigmentation		9 (90%)	10 (100%)	10 (100%)	10 (100%)	9 (90%)

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<b>B6C3F1 Mouse FEMALE</b>	<b>0 G/KG</b>	<b>0.125 G/KG</b>	<b>0.25 G/KG</b>	<b>0.5 G/KG</b>	<b>1.0 G/KG</b>	<b>2.0 G/KG</b>
Lymph Node, Mandibular	(10)	(10)	(9)	(8)	(8)	(10)
Necrosis		1 (10%)	1 (11%)	4 (50%)	5 (63%)	8 (80%)
Lymph Node, Mesenteric	(10)	(10)	(9)	(10)	(8)	(9)
Necrosis		5 (50%)	2 (22%)	7 (70%)	7 (88%)	9 (100%)
Spleen	(10)	(10)	(10)	(10)	(10)	(10)
Congestion						9 (90%)
Lymph Follic, Depletion Cellular		10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)
Pigmentation		10 (100%)	10 (100%)	10 (100%)	10 (100%)	8 (80%)
Red Pulp, Hematopoietic Cell Proliferation		10 (100%)	10 (100%)	10 (100%)	10 (100%)	
Thymus	(10)	(10)	(10)	(10)	(10)	(10)
Necrosis		6 (60%)	9 (90%)	10 (100%)	10 (100%)	10 (100%)
<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(10)	(0)	(10)	(10)	(8)	(10)
Skin	(10)	(0)	(10)	(10)	(9)	(10)
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(0)	(10)	(10)	(10)	(10)
<b>NERVOUS SYSTEM</b>						
Brain	(10)	(0)	(10)	(10)	(10)	(10)
Peripheral Nerve	(0)	(0)	(1)	(6)	(0)	(3)
Spinal Cord	(0)	(0)	(1)	(6)	(0)	(3)
<b>RESPIRATORY SYSTEM</b>						
Lung	(10)	(0)	(10)	(10)	(10)	(10)
Nose	(10)	(0)	(10)	(10)	(10)	(10)
Trachea	(10)	(0)	(10)	(10)	(10)	(10)
<b>SPECIAL SENSES SYSTEM</b>						
Eye	(0)	(0)	(0)	(1)	(0)	(2)
<b>URINARY SYSTEM</b>						

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



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<b>B6C3F1 Mouse FEMALE</b>	<b>0 G/KG</b>	<b>0.125 G/KG</b>	<b>0.25 G/KG</b>	<b>0.5 G/KG</b>	<b>1.0 G/KG</b>	<b>2.0 G/KG</b>
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Lymphocyte		1 (10%)				
Renal Tubule, Casts Protein				1 (10%)	4 (40%)	3 (30%)
Renal Tubule, Necrosis				3 (30%)	6 (60%)	3 (30%)
Renal Tubule, Pigmentation			4 (40%)	9 (90%)	8 (80%)	7 (70%)
Urinary Bladder	(9)	(10)	(9)	(10)	(10)	(10)
Infiltration Cellular, Lymphocyte, Diffuse		1 (10%)				
Transit Epithe, Degeneration			6 (67%)	9 (90%)	8 (80%)	8 (80%)
Transit Epithe, Hyperplasia					1 (10%)	1 (10%)
Transit Epithe, Pigmentation			3 (33%)	7 (70%)	7 (70%)	2 (20%)

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

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