

**Experiment Number:** 91005-04  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

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

**Test Compound:** Methylene blue trihydrate  
**CAS Number:** 7220-79-3

**Date Report Requested:** 10/17/2014  
**Time Report Requested:** 22:13:24  
**First Dose M/F:** NA / NA  
**Lab:** BAT

<b>C Number:</b>	C91005B
<b>Lock Date:</b>	05/12/1994
<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 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
<b>Disposition Summary</b>					
Animals Initially In Study	10	10	10	10	10
Early Deaths					
Dosing Accident					1
Survivors					
Terminal Sacrifice	10	10	10	10	9
Animals Examined Microscopically	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>					
Esophagus	(10)	(0)	(0)	(0)	(10)
Gallbladder	(10)	(0)	(0)	(0)	(8)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(9)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(10)
Intestine Small, Duodenum	(9)	(0)	(0)	(0)	(7)
Intestine Small, Ileum	(9)	(0)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(10)
Liver	(10)	(10)	(10)	(10)	(10)
Hematopoietic Cell Proliferation				10 [1.0]	10 [1.0]
Hepatocyte, Necrosis				1 [2.0]	
Inflammation, Chronic Active	3 [1.0]	3 [1.0]	1 [1.0]	4 [1.0]	3 [1.0]
Kupffer Cell, Pigmentation			10 [1.0]	10 [2.0]	10 [2.9]
Pancreas	(10)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active					1 [3.0]
Salivary Glands	(10)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active					1 [4.0]
Stomach, Glandular	(10)	(0)	(0)	(0)	(10)
<b>CARDIOVASCULAR SYSTEM</b>					

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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Lab: BAT

B6C3F1 Mouse MALE	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Blood Vessel	(10)	(0)	(0)	(0)	(10)
Heart	(10)	(0)	(0)	(0)	(10)
ENDOCRINE SYSTEM					
Adrenal Cortex	(10)	(0)	(0)	(0)	(10)
Adrenal Medulla	(10)	(0)	(0)	(0)	(9)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(10)
Parathyroid Gland	(9)	(0)	(0)	(0)	(4)
Cyst	2 [1.5]				
Pituitary Gland	(10)	(0)	(0)	(0)	(10)
Thyroid Gland	(10)	(0)	(0)	(0)	(10)
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
Epididymis	(10)	(0)	(0)	(0)	(10)
Preputial Gland	(10)	(0)	(0)	(0)	(10)
Prostate	(10)	(0)	(0)	(0)	(10)
Seminal Vesicle	(10)	(0)	(0)	(0)	(10)
Testes	(10)	(0)	(0)	(0)	(10)
HEMATOPOIETIC SYSTEM					
Bone Marrow	(10)	(10)	(10)	(10)	(10)
Pigmentation		10 [1.0]	10 [1.4]	10 [1.9]	9 [2.7]
Lymph Node, Mandibular	(9)	(0)	(0)	(0)	(10)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(9)
Spleen	(10)	(10)	(10)	(10)	(10)
Capsule, Fibrosis					1 [2.0]
Pigmentation		10 [1.6]	10 [2.0]	10 [2.6]	9 [3.0]
Red Pulp, Hematopoietic Cell Proliferation		10 [2.1]	10 [2.0]	10 [2.9]	10 [4.0]

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B6C3F1 Mouse MALE	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Thymus	(9)	(0)	(0)	(0)	(9)
INTEGUMENTARY SYSTEM					
Skin	(10)	(0)	(0)	(0)	(10)
MUSCULOSKELETAL SYSTEM					
Bone	(10)	(0)	(0)	(0)	(10)
NERVOUS SYSTEM					
Brain	(10)	(0)	(0)	(0)	(10)
RESPIRATORY SYSTEM					
Lung	(10)	(0)	(0)	(0)	(10)
Nose	(10)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM					
None					
URINARY SYSTEM					
Kidney	(10)	(0)	(0)	(1)	(10)
Cyst				1 [2.0]	
Inflammation, Suppurative					1 [2.0]
Renal Tubule, Pigmentation					9 [2.8]
Urinary Bladder	(10)	(10)	(10)	(10)	(10)

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

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 Lab: BAT

B6C3F1 Mouse FEMALE	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
<b>Disposition Summary</b>					
Animals Initially In Study	10	10	10	10	10
Early Deaths					
Dosing Accident		1			
Survivors					
Terminal Sacrifice	10	9	10	10	10
Animals Examined Microscopically	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>					
Esophagus	(9)	(1)	(0)	(0)	(10)
Perforation		1			
Gallbladder	(8)	(0)	(0)	(0)	(10)
Intestine Large, Cecum	(10)	(1)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(1)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(1)	(0)	(0)	(10)
Intestine Small, Duodenum	(8)	(1)	(0)	(0)	(9)
Intestine Small, Ileum	(8)	(0)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(1)	(0)	(0)	(10)
Liver	(10)	(10)	(10)	(10)	(10)
Hematopoietic Cell Proliferation		1 [1.0]	2 [1.0]	10 [1.0]	9 [1.7]
Inflammation, Chronic Active	8 [1.0]	6 [1.0]	7 [1.0]	10 [1.0]	9 [1.0]
Kupffer Cell, Pigmentation			9 [1.0]	10 [2.0]	10 [3.0]
Pancreas	(10)	(1)	(0)	(0)	(10)
Duct, Cyst	1 [2.0]				
Salivary Glands	(10)	(1)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(1)	(0)	(0)	(10)
Stomach, Glandular	(10)	(1)	(0)	(0)	(10)
<b>CARDIOVASCULAR SYSTEM</b>					
Blood Vessel	(10)	(1)	(0)	(0)	(10)

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<b>B6C3F1 Mouse FEMALE</b>	<b>0 MG/KG</b>	<b>25 MG/KG</b>	<b>50 MG/KG</b>	<b>100 MG/KG</b>	<b>200 MG/KG</b>
Heart	(10)	(1)	(0)	(0)	(10)
Pericardium, Inflammation, Chronic Active		1 [2.0]			
<b>ENDOCRINE SYSTEM</b>					
Adrenal Cortex	(10)	(1)	(0)	(0)	(10)
Adrenal Medulla	(10)	(1)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(1)	(0)	(0)	(10)
Parathyroid Gland	(8)	(0)	(0)	(0)	(6)
Pituitary Gland	(9)	(0)	(0)	(0)	(10)
Pars Distalis, Hyperplasia	1 [2.0]				
Thyroid Gland	(10)	(1)	(0)	(0)	(10)
<b>GENERAL BODY SYSTEM</b>					
None					
<b>GENITAL SYSTEM</b>					
Clitoral Gland	(10)	(1)	(0)	(0)	(10)
Ovary	(9)	(1)	(0)	(0)	(10)
Uterus	(10)	(1)	(0)	(0)	(10)
<b>HEMATOPOIETIC SYSTEM</b>					
Bone Marrow	(10)	(1)	(4)	(10)	(10)
Pigmentation			4 [1.0]	10 [1.5]	10 [1.8]
Lymph Node, Mandibular	(10)	(1)	(0)	(0)	(10)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(10)
Spleen	(10)	(10)	(10)	(10)	(10)
Pigmentation		9 [2.0]	9 [2.0]	10 [2.1]	10 [3.0]
Red Pulp, Hematopoietic Cell Proliferation		9 [1.8]	10 [1.9]	10 [2.8]	10 [3.9]
Thymus	(10)	(1)	(0)	(0)	(10)
Necrosis		1 [3.0]			
<b>INTEGUMENTARY SYSTEM</b>					

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Mammary Gland	(10)	(1)	(0)	(0)	(10)
Skin	(10)	(1)	(0)	(0)	(10)
<b>MUSCULOSKELETAL SYSTEM</b>					
Bone	(10)	(1)	(0)	(0)	(10)
<b>NERVOUS SYSTEM</b>					
Brain	(10)	(1)	(0)	(0)	(10)
<b>RESPIRATORY SYSTEM</b>					
Lung	(10)	(1)	(0)	(0)	(10)
Mediastinum, Serosa, Inflammation, Chronic Active		1 [2.0]			
Nose	(10)	(1)	(0)	(0)	(10)
Trachea	(9)	(1)	(0)	(0)	(10)
<b>SPECIAL SENSES SYSTEM</b>					
None					
<b>URINARY SYSTEM</b>					
Kidney	(10)	(1)	(0)	(4)	(10)
Pigmentation					1 [3.0]
Renal Tubule, Pigmentation				4 [1.0]	10 [2.4]
Urinary Bladder	(9)	(10)	(9)	(10)	(10)

**\*\* 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)