

Experiment Number: 91005-01
Test Type: 18-33 DAYS
Route: GAVAGE
Species/Strain: Rat/F 344/N

**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: 10/15/2014
Time Report Requested: 17:57:17
First Dose M/F: NA / NA
Lab: BAT

C Number: C91005
Lock Date: 12/15/1992
Cage Range: All
Date Range: All
Reasons For Removal: All
Removal Date Range: All
Treatment Groups: All
Study Gender: Both
PWG Approval Date: NONE

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F 344/N Rat MALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Disposition Summary						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Moribund Sacrifice					1	
Natural Death				2	9	10
Survivors						
Terminal Sacrifice	10	10	10	8		
Animals Examined Microscopically	10	10	10	10	10	10
ALIMENTARY SYSTEM						
Esophagus	(10)	(0)	(0)	(9)	(9)	(9)
Intestine Large, Cecum	(10)	(0)	(0)	(9)	(10)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(9)	(10)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(9)	(10)	(10)
Intestine Small, Duodenum	(10)	(10)	(10)	(9)	(10)	(10)
Necrosis						6 [2.7]
Serosa, Inflammation						4 [2.3]
Intestine Small, Ileum	(10)	(10)	(10)	(9)	(10)	(10)
Necrosis						1 [2.0]
Intestine Small, Jejunum	(10)	(0)	(0)	(9)	(10)	(10)
Liver	(10)	(10)	(10)	(9)	(10)	(10)
Centrilobular, Necrosis				1 [3.0]	3 [3.0]	7 [2.9]
Hematopoietic Cell Proliferation		7 [1.0]	10 [1.0]	9 [1.0]	3 [1.0]	
Inflammation, Chronic Active		1 [1.0]				
Kupffer Cell, Pigmentation				5 [1.0]	4 [1.3]	
Serosa, Inflammation						1 [2.0]
Mesentery	(0)	(0)	(0)	(0)	(1)	(0)
Inflammation, Suppurative					1 [3.0]	
Pancreas	(10)	(0)	(0)	(9)	(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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Lab: BAT

F 344/N Rat MALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Atrophy	1 [1.0]			1 [1.0]		
Salivary Glands	(10)	(0)	(0)	(9)	(9)	(10)
Stomach, Forestomach	(10)	(10)	(10)	(9)	(10)	(10)
Hyperplasia				1 [2.0]		
Inflammation					2 [4.0]	
Inflammation, Chronic Active				1 [2.0]		
Stomach, Glandular	(10)	(10)	(10)	(9)	(10)	(10)
Inflammation, Chronic Active				1 [2.0]	1 [2.0]	
Mineralization	10 [1.0]	10 [1.0]	7 [1.0]	7 [1.0]	3 [1.0]	2 [1.0]
Necrosis					1 [4.0]	
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(0)	(9)	(10)	(10)
Heart	(10)	(10)	(10)	(9)	(10)	(10)
Inflammation, Chronic Active	8 [1.1]	6 [1.0]	6 [1.0]	3 [1.0]	6 [2.0]	4 [1.3]
Mineralization					1 [2.0]	
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(9)	(10)	(10)
Adrenal Medulla	(10)	(0)	(0)	(9)	(10)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(9)	(10)	(10)
Parathyroid Gland	(9)	(0)	(0)	(8)	(8)	(9)
Pituitary Gland	(10)	(0)	(0)	(10)	(10)	(10)
Thyroid Gland	(10)	(0)	(0)	(9)	(9)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Epididymis	(10)	(0)	(0)	(9)	(10)	(10)
Hypospermia					5 [1.0]	10 [1.0]

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F 344/N Rat MALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Inflammation, Chronic Active Preputial Gland	1 [1.0] (10)	(0)	(0)	(9)	(10)	(10)
Inflammation, Chronic Active Prostate	8 [1.4] (10)	(0)	(0)	7 [1.6] (9)	2 [1.0] (10)	5 [1.6] (10)
Inflammation, Chronic Active Seminal Vesicle	1 [2.0] (10)	(0)	(0)	(9)	(9)	(10)
Testes	(10)	(1)	(0)	(9)	(10)	(10)
Atrophy		1 [4.0]				
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Hyperplasia		8 [1.3]	10 [2.0]	10 [2.0]	10 [1.9]	10 [2.0]
Lymph Node, Mandibular	(10)	(0)	(0)	(9)	(9)	(9)
Lymph Node, Mesenteric	(10)	(0)	(0)	(9)	(10)	(10)
Spleen	(10)	(10)	(10)	(9)	(10)	(10)
Capsule, Fibrosis			9 [1.0]	7 [1.0]		
Hematopoietic Cell Proliferation		10 [1.0]	10 [1.9]	9 [2.2]	8 [1.5]	1 [1.0]
Lymph Follic, Depletion Cellular					9 [2.2]	9 [2.4]
Pigmentation		10 [1.9]	10 [1.9]	7 [1.0]	2 [2.0]	
Thymus	(10)	(10)	(10)	(9)	(9)	(9)
Atrophy					1 [4.0]	
Hemorrhage					2 [2.0]	3 [1.7]
Necrosis				1 [3.0]	7 [2.4]	9 [2.1]
INTEGUMENTARY SYSTEM						
Mammary Gland	(9)	(0)	(0)	(8)	(8)	(8)
Skin	(10)	(0)	(0)	(10)	(10)	(10)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(10)	(10)	(10)
Periosteum, Inflammation, Chronic Active	1 [2.0]					

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First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat MALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(10)	(9)	(10)
Peripheral Nerve	(0)	(0)	(0)	(0)	(2)	(0)
Spinal Cord	(0)	(0)	(0)	(0)	(2)	(0)
RESPIRATORY SYSTEM						
Lung	(10)	(0)	(0)	(9)	(10)	(10)
Inflammation, Chronic Active	2 [1.0]					
Nose	(9)	(10)	(10)	(10)	(10)	(10)
Foreign Body		1				
Inflammation, Suppurative		3 [1.3]	3 [2.7]	3 [2.3]	4 [2.0]	2 [2.0]
Trachea	(10)	(0)	(0)	(9)	(9)	(10)
Inflammation, Chronic Active	1 [1.0]					
SPECIAL SENSES SYSTEM						
Eye	(0)	(0)	(0)	(0)	(2)	(1)
Cornea, Degeneration						1 [2.0]
URINARY SYSTEM						
Kidney	(10)	(10)	(10)	(9)	(10)	(10)
Casts Protein				1 [2.0]		
Mineralization	9 [1.0]	10 [1.0]	10 [1.0]	9 [1.0]	7 [1.0]	9 [1.0]
Nephropathy	6 [1.0]	7 [1.0]	5 [1.0]	5 [1.0]		
Renal Tubule, Pigmentation				6 [1.0]		
Urinary Bladder	(10)	(10)	(10)	(9)	(9)	(10)

END OF MALE DATA

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

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F 344/N Rat FEMALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Disposition Summary						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Moribund Sacrifice				1	4	1
Natural Death				3	6	9
Survivors						
Terminal Sacrifice	10	10	10	6		
Animals Examined Microscopically	10	10	10	10	10	10
ALIMENTARY SYSTEM						
Esophagus	(10)	(0)	(0)	(10)	(9)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(10)	(10)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(10)	(10)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(10)	(10)	(10)
Intestine Small, Duodenum	(10)	(10)	(10)	(10)	(10)	(10)
Necrosis						7 [3.1]
Serosa, Inflammation						4 [2.0]
Intestine Small, Ileum	(10)	(10)	(10)	(10)	(9)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(10)	(9)	(10)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Centrilobular, Necrosis				4 [3.0]	3 [3.0]	9 [2.1]
Hematopoietic Cell Proliferation		2 [1.0]	10 [1.0]	10 [1.0]	4 [1.3]	
Hepatodiaphragmatic Nodule					1	
Kupffer Cell, Pigmentation			1 [1.0]	9 [1.0]	4 [1.0]	
Mesentery	(0)	(0)	(0)	(0)	(1)	(0)
Accessory Spleen					1	
Pancreas	(10)	(0)	(0)	(10)	(10)	(10)
Salivary Glands	(10)	(0)	(0)	(9)	(8)	(10)
Stomach, Forestomach	(10)	(10)	(10)	(10)	(10)	(10)

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Lab: BAT

F 344/N Rat FEMALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Hyperplasia				1 [3.0]	3 [3.0]	
Necrosis				1 [1.0]		1 [1.0]
Stomach, Glandular	(10)	(10)	(10)	(10)	(10)	(10)
Necrosis						4 [3.5]
Serosa, Inflammation					1 [1.0]	3 [2.0]
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(0)	(10)	(9)	(10)
Heart	(10)	(10)	(10)	(10)	(10)	(10)
Atrium, Thrombosis				2 [3.5]	2 [2.0]	
Inflammation, Chronic Active	1 [1.0]	3 [1.0]	2 [1.0]	7 [2.0]	7 [2.3]	3 [1.0]
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(10)	(10)	(10)
Hemorrhage						2 [1.5]
Adrenal Medulla	(10)	(0)	(0)	(10)	(10)	(9)
Islets, Pancreatic	(10)	(0)	(0)	(10)	(10)	(10)
Parathyroid Gland	(8)	(0)	(0)	(9)	(6)	(9)
Pituitary Gland	(10)	(0)	(0)	(9)	(9)	(10)
Thyroid Gland	(10)	(0)	(0)	(9)	(8)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(10)	(0)	(0)	(10)	(10)	(10)
Inflammation, Chronic Active	8 [1.5]			7 [1.6]	5 [1.4]	5 [1.6]
Ovary	(10)	(0)	(1)	(10)	(10)	(10)
Uterus	(10)	(0)	(0)	(10)	(10)	(10)
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)

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F 344/N Rat FEMALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Hyperplasia		10 [1.8]	10 [1.9]	10 [2.1]	10 [2.1]	10 [2.0]
Lymph Node, Mandibular	(10)	(0)	(0)	(9)	(8)	(10)
Lymph Node, Mesenteric	(10)	(0)	(0)	(10)	(10)	(10)
Spleen	(10)	(10)	(10)	(10)	(10)	(10)
Capsule, Fibrosis			7 [1.0]	4 [1.0]		
Hematopoietic Cell Proliferation		10 [1.0]	10 [2.0]	10 [2.4]	5 [2.6]	
Lymph Follic, Depletion Cellular					6 [1.5]	9 [2.2]
Pigmentation		10 [1.8]	10 [1.8]	9 [1.4]	3 [1.3]	
Thymus	(10)	(10)	(10)	(10)	(10)	(10)
Atrophy					2 [3.5]	
Hemorrhage				3 [3.0]	3 [1.7]	4 [1.3]
Necrosis				4 [3.5]	8 [2.1]	9 [3.2]
INTEGUMENTARY SYSTEM						
Mammary Gland	(10)	(0)	(0)	(10)	(10)	(10)
Skin	(10)	(0)	(0)	(10)	(10)	(10)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(10)	(10)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(9)	(9)	(10)
Peripheral Nerve	(0)	(0)	(0)	(1)	(2)	(1)
Spinal Cord	(0)	(0)	(0)	(1)	(2)	(1)
RESPIRATORY SYSTEM						
Lung	(10)	(0)	(0)	(10)	(10)	(10)
Inflammation, Chronic Active					2 [1.5]	
Thrombosis, Focal					1 [3.0]	
Nose	(10)	(10)	(10)	(10)	(9)	(10)
Foreign Body					1	

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F 344/N Rat 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, Suppurative Trachea	1 [1.0] (10)	7 [1.4] (0)	5 [1.6] (0)	2 [1.5] (10)	3 [2.0] (10)	4 [2.3] (10)
Inflammation, Chronic Active					1 [1.0]	
SPECIAL SENSES SYSTEM						
Eye	(0)	(0)	(0)	(1)	(1)	(2)
Cataract					1 [1.0]	1 [1.0]
URINARY SYSTEM						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Cyst	1 [2.0]					
Mineralization	10 [1.0]	10 [1.1]	10 [1.0]	10 [1.0]	10 [1.0]	10 [1.0]
Nephropathy	7 [1.0]	4 [1.0]	9 [1.0]	1 [1.0]	2 [1.0]	4 [1.0]
Renal Tubule, Pigmentation				8 [1.0]	1 [1.0]	
Urinary Bladder	(10)	(10)	(10)	(10)	(10)	(10)

**** END OF REPORT ****

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