

Experiment Number: 20107-01
Test Type: 90-DAY
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: N,N-Dimethyl-p-toluidine
CAS Number: 99-97-8

Date Report Requested: 10/22/2014
Time Report Requested: 11:56:52
First Dose M/F: NA / NA
Lab: BAT

C Number:	C20107
Lock Date:	07/14/2004
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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Lab: BAT

F 344/N Rat MALE	0	MG/KG	62.5	MG/KG	125	MG/KG	250	MG/KG	500	MG/KG	1000	MG/KG
Disposition Summary												
Animals Initially In Study	10		10		10		10		10		10	
Early Deaths												
Moribund Sacrifice									1		1	
Natural Death											9	
Survivors												
Terminal Sacrifice	10		10		10		10		9			
Animals Examined Microscopically	10		10		10		10		10		10	
ALIMENTARY SYSTEM												
Esophagus	(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)	
Hyperplasia, Lymphoid	1 [1.0]											
Liver	(10)		(10)		(10)		(10)		(10)		(10)	
Basophilic Focus									2			
Bile Duct, Hyperplasia							3 [1.0]		1 [1.0]			
Centrilobular, Fatty Change									1 [1.0]		2 [1.0]	
Centrilobular, Hepatocyte, Necrosis									1 [3.0]		10 [2.9]	
Fatty Change, Focal	1 [1.0]											
Hematopoietic Cell Proliferation	4 [1.0]		8 [1.0]		10 [1.0]		8 [1.0]		7 [1.0]			
Hepatocyte, Hypertrophy			2 [1.0]		9 [1.0]		10 [1.2]		10 [1.8]		10 [1.8]	
Hepatocyte, Necrosis	3 [1.0]		3 [1.0]		5 [1.0]		3 [1.0]		5 [1.0]			
Hepatodiaphragmatic Nodule					1		1		1 [3.0]			
Inflammation, Chronic Active	7 [1.0]		10 [1.0]		9 [1.0]		6 [1.0]		7 [1.1]		2 [1.0]	

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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Lab: BAT

F 344/N Rat MALE	0	MG/KG	62.5	MG/KG	125	MG/KG	250	MG/KG	500	MG/KG	1000	MG/KG
Pigmentation			4 [1.0]		7 [1.0]		9 [1.0]		9 [1.0]			
Pancreas	(10)		(0)		(0)		(0)		(10)		(10)	
Infiltration Cellular, Lymphocyte	9 [1.8]								6 [2.0]			
Salivary Glands	(10)		(0)		(0)		(0)		(10)		(10)	
Fibrosis									1 [2.0]			
Stomach, Forestomach	(10)		(10)		(10)		(10)		(10)		(10)	
Hemorrhage											1 [2.0]	
Hyperplasia, Squamous							2 [1.0]		2 [2.0]			
Inflammation					1 [1.0]				5 [1.4]		9 [2.4]	
Mineralization									1 [1.0]		1 [1.0]	
Ulcer					1 [2.0]				1 [3.0]		7 [2.1]	
Stomach, Glandular	(10)		(0)		(0)		(0)		(10)		(10)	
Inflammation									1 [1.0]			
Ulcer											1 [2.0]	
CARDIOVASCULAR SYSTEM												
Blood Vessel	(10)		(0)		(0)		(0)		(10)		(10)	
Heart	(10)		(0)		(0)		(0)		(10)		(10)	
Cardiomyopathy	10 [1.4]								6 [1.0]		1 [1.0]	
ENDOCRINE SYSTEM												
Adrenal Cortex	(10)		(0)		(0)		(0)		(10)		(10)	
Mineralization									1 [2.0]			
Vacuolization Cytoplasmic	10 [1.1]								1 [1.0]			
Adrenal Medulla	(10)		(0)		(0)		(0)		(10)		(10)	
Islets, Pancreatic	(10)		(0)		(0)		(0)		(10)		(10)	
Parathyroid Gland	(9)		(0)		(0)		(0)		(8)		(7)	
Pituitary Gland	(10)		(0)		(0)		(0)		(10)		(9)	
Thyroid Gland	(10)		(0)		(0)		(0)		(10)		(10)	
GENERAL BODY SYSTEM												

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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Route: GAVAGE

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

Test Compound: N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 10/22/2014

Time Report Requested: 11:56:52

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat MALE	0	MG/KG	62.5	MG/KG	125	MG/KG	250	MG/KG	500	MG/KG	1000	MG/KG
None												
GENITAL SYSTEM												
Epididymis	(10)		(0)		(0)		(0)		(10)		(10)	
Inflammation	2 [1.0]											
Preputial Gland	(10)		(0)		(0)		(0)		(10)		(10)	
Duct, Ectasia	1 [2.0]											
Prostate	(10)		(0)		(0)		(0)		(10)		(10)	
Epithelium, Hyperplasia	2 [1.5]								2 [1.0]			
Inflammation, Chronic Active									1 [1.0]			
Seminal Vesicle	(10)		(0)		(0)		(0)		(10)		(8)	
Testes	(10)		(0)		(0)		(0)		(10)		(10)	
Atrophy									1 [1.0]			
HEMATOPOIETIC SYSTEM												
Bone Marrow	(10)		(10)		(10)		(10)		(10)		(10)	
Hyperplasia			10 [2.0]		10 [2.9]		10 [3.0]		10 [2.9]		10 [1.8]	
Lymph Node	(1)		(0)		(0)		(0)		(1)		(0)	
Mediastinal, Hyperplasia, Lymphoid	1 [2.0]								1 [2.0]			
Lymph Node, Mesenteric	(10)		(10)		(10)		(10)		(10)		(10)	
Atrophy									3 [1.7]		6 [2.2]	
Necrosis, Lymphoid											2 [2.0]	
Spleen	(10)		(10)		(10)		(10)		(10)		(10)	
Capsule, Fibrosis	1 [1.0]		5 [1.0]		10 [1.4]		10 [2.7]		9 [2.8]			
Congestion			10 [1.2]		10 [1.8]		10 [2.4]		9 [3.0]			
Hematopoietic Cell Proliferation	9 [1.0]		10 [2.0]		10 [2.0]		10 [1.9]		9 [1.8]		9 [1.0]	
Lymph Follic, Atrophy							8 [1.5]		10 [2.7]		10 [3.7]	
Mesothelium, Hypertrophy	3 [1.3]		5 [1.2]		8 [1.5]		10 [1.5]		9 [1.8]			
Pigmentation	10 [1.0]		10 [2.1]		10 [2.2]		10 [2.0]		9 [2.0]			
Red Pulp, Atrophy									1 [2.0]		10 [2.7]	

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First Dose M/F: NA / NA

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F 344/N Rat MALE	0	MG/KG	62.5	MG/KG	125	MG/KG	250	MG/KG	500	MG/KG	1000	MG/KG
Thymus	(10)		(10)		(10)		(10)		(10)		(10)	
Hemorrhage	1 [2.0]										7 [2.3]	
Thymocyte, Necrosis									1 [3.0]		10 [3.1]	
INTEGUMENTARY SYSTEM												
Mammary Gland	(10)		(0)		(0)		(0)		(5)		(10)	
Skin	(10)		(0)		(0)		(0)		(10)		(10)	
MUSCULOSKELETAL SYSTEM												
Bone	(10)		(0)		(0)		(0)		(10)		(10)	
NERVOUS SYSTEM												
Brain	(10)		(0)		(0)		(0)		(10)		(10)	
RESPIRATORY SYSTEM												
Lung	(10)		(10)		(10)		(10)		(10)		(10)	
Alveolus, Infiltration Cellular, Histiocyte	1 [1.0]								1 [1.0]			
Alveolus, Metaplasia, Squamous, Focal					1 [2.0]							
Hemorrhage			1 [2.0]									
Inflammation, Chronic Active	10 [1.3]		8 [1.0]		9 [1.0]		10 [1.2]		10 [1.0]		10 [1.0]	
Thrombosis											2 [1.5]	
Nose	(10)		(10)		(10)		(10)		(10)		(10)	
Glands, Hyperplasia					10 [1.8]		10 [2.1]		9 [2.1]			
Olfactory Epi, Degeneration			5 [1.0]		10 [2.5]		10 [3.0]		10 [3.1]		10 [4.0]	
Olfactory Epi, Metaplasia							9 [1.9]		9 [2.9]			
Respirat Epith, Hyperplasia	1 [1.0]		2 [1.0]		7 [1.4]		10 [1.5]		9 [1.8]		7 [1.9]	
Respirat Epith, Metaplasia, Squamous			8 [1.5]		10 [2.5]		10 [2.8]		9 [3.0]		1 [2.0]	
Trachea	(10)		(10)		(10)		(10)		(10)		(10)	
Inflammation, Chronic Active	2 [1.5]				2 [1.0]		3 [1.0]		3 [1.7]			
SPECIAL SENSES SYSTEM												
Eye	(10)		(0)		(0)		(0)		(10)		(10)	

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Lab: BAT

F 344/N Rat MALE	0 MG/KG	62.5 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Antr Chamber, Inflammation, Suppurative					1 [4.0]	
Cataract					1 [3.0]	
Ciliary Body, Inflammation, Suppurative					1 [4.0]	
Cornea, Ulcer					1 [4.0]	
Retina, Degeneration					1 [3.0]	
Harderian Gland	(10)	(0)	(0)	(0)	(10)	(10)
Epithelium, Hyperplasia					1 [3.0]	
Hemorrhage					1 [3.0]	
Infiltration Cellular, Lymphocyte					1 [3.0]	
Inflammation, Chronic Active					1 [3.0]	
Pigmentation	2 [1.5]				1 [2.0]	9 [2.0]
URINARY SYSTEM						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Hemorrhage						2 [2.0]
Mineralization	1 [1.0]	4 [1.0]	10 [1.3]	10 [1.8]	8 [2.1]	
Nephropathy	9 [1.0]	10 [1.0]	10 [1.0]	10 [1.1]	9 [1.6]	3 [1.0]
Papilla, Necrosis			7 [1.3]	7 [1.7]	9 [2.4]	2 [1.5]
Pigmentation		10 [1.0]	10 [1.0]	10 [1.6]	9 [1.9]	
Renal Tubule, Dilatation			2 [2.0]	1 [2.0]	3 [2.0]	3 [1.3]
Urinary Bladder	(10)	(0)	(0)	(0)	(10)	(9)
Hemorrhage						2 [2.0]

END OF MALE DATA

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Lab: BAT

F 344/N Rat FEMALE	0	MG/KG	62.5	MG/KG	125	MG/KG	250	MG/KG	500	MG/KG	1000	MG/KG
Disposition Summary												
Animals Initially In Study	10		10		10		10		10		10	
Early Deaths												
Moribund Sacrifice											10	
Survivors												
Terminal Sacrifice	10		10		10		10		10		10	
Animals Examined Microscopically	10		10		10		10		10		10	
ALIMENTARY SYSTEM												
Esophagus	(10)		(0)		(0)		(0)		(10)		(10)	
Muscularis, Inflammation	1 [1.0]											
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)	
Angiectasis							1 [1.0]					
Bile Duct, Hyperplasia									1 [2.0]			
Centrilobular, Fatty Change											9 [1.1]	
Centrilobular, Hepatocyte, Necrosis									1 [2.0]		7 [1.9]	
Clear Cell Focus									2			
Fatty Change, Focal									1 [2.0]			
Hematopoietic Cell Proliferation	5 [1.0]		6 [1.0]		8 [1.0]		6 [1.2]		9 [1.0]		1 [1.0]	
Hepatocyte, Hypertrophy			1 [1.0]		7 [1.0]		9 [1.1]		10 [2.7]		10 [1.4]	
Hepatocyte, Necrosis	1 [1.0]		6 [1.5]		5 [1.4]		7 [1.3]		6 [1.2]		2 [2.0]	
Hepatodiaphragmatic Nodule							1		1			
Inflammation, Chronic Active	8 [1.0]		10 [1.0]		10 [1.0]		4 [1.3]		5 [1.2]			

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F 344/N Rat FEMALE	0	MG/KG	62.5	MG/KG	125	MG/KG	250	MG/KG	500	MG/KG	1000	MG/KG
Pigmentation			10	[1.0]	10	[1.0]	10	[1.8]	10	[1.9]		
Pancreas	(10)		(0)		(0)		(0)		(10)		(10)	
Infiltration Cellular, Lymphocyte	7	[1.7]							4	[1.3]	1	[1.0]
Salivary Glands	(10)		(0)		(0)		(0)		(10)		(10)	
Stomach, Forestomach	(10)		(10)		(10)		(10)		(10)		(10)	
Erosion							1	[2.0]				
Inflammation							3	[1.7]	2	[2.0]	10	[2.3]
Mineralization									1	[1.0]	4	[1.5]
Ulcer									1	[2.0]	8	[2.1]
Stomach, Glandular	(10)		(10)		(10)		(10)		(10)		(10)	
Inflammation											1	[2.0]
Inflammation, Granulomatous									1	[3.0]		
Ulcer											2	[2.0]
CARDIOVASCULAR SYSTEM												
Blood Vessel	(10)		(0)		(0)		(0)		(10)		(10)	
Heart	(10)		(10)		(10)		(10)		(10)		(10)	
Cardiomyopathy	7	[1.1]	4	[1.0]	7	[1.0]	7	[1.0]	6	[1.0]	2	[1.0]
Inflammation	1	[2.0]										
ENDOCRINE SYSTEM												
Adrenal Cortex	(10)		(0)		(0)		(0)		(10)		(10)	
Hemorrhage											1	[3.0]
Adrenal Medulla	(10)		(0)		(0)		(0)		(10)		(10)	
Islets, Pancreatic	(10)		(0)		(0)		(0)		(10)		(10)	
Parathyroid Gland	(9)		(0)		(0)		(0)		(9)		(8)	
Pituitary Gland	(10)		(0)		(0)		(0)		(10)		(10)	
Thyroid Gland	(10)		(0)		(0)		(0)		(10)		(10)	
Infiltration Cellular, Lymphocyte									1	[2.0]		
GENERAL BODY SYSTEM												

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Lab: BAT

F 344/N Rat FEMALE	0	MG/KG	62.5	MG/KG	125	MG/KG	250	MG/KG	500	MG/KG	1000	MG/KG
None												
GENITAL SYSTEM												
Clitoral Gland	(10)		(0)		(0)		(0)		(10)		(10)	
Inflammation	2 [1.0]								1 [3.0]			
Ovary	(10)		(0)		(0)		(0)		(10)		(10)	
Uterus	(10)		(0)		(0)		(0)		(10)		(10)	
Endometrium, Hyperplasia, Cystic	1 [3.0]											
HEMATOPOIETIC SYSTEM												
Bone Marrow	(10)		(10)		(10)		(10)		(10)		(10)	
Hyperplasia			10 [1.9]		10 [2.7]		10 [3.0]		10 [3.0]		10 [2.6]	
Lymph Node, Mesenteric	(10)		(10)		(10)		(10)		(10)		(10)	
Atrophy							1 [2.0]		6 [2.2]		5 [2.2]	
Necrosis, Lymphoid											1 [1.0]	
Spleen	(10)		(10)		(10)		(10)		(10)		(10)	
Capsule, Fibrosis			3 [1.0]		7 [1.3]		10 [2.2]		10 [2.7]			
Congestion			2 [1.0]		10 [1.4]		10 [2.4]		10 [3.0]			
Hematopoietic Cell Proliferation	10 [1.0]		10 [1.9]		10 [1.9]		10 [2.3]		10 [2.0]		9 [1.0]	
Lymph Follic, Atrophy									10 [1.3]		10 [1.8]	
Mesothelium, Hypertrophy			1 [1.0]		2 [1.5]		9 [1.1]		9 [1.1]		1 [1.0]	
Pigmentation	10 [1.0]		10 [2.0]		10 [2.0]		10 [1.9]		10 [2.0]			
Red Pulp, Atrophy											10 [3.0]	
Thymus	(10)		(10)		(10)		(10)		(10)		(10)	
Hemorrhage											2 [1.5]	
Thymocyte, Necrosis											10 [3.1]	
INTEGUMENTARY SYSTEM												
Mammary Gland	(10)		(0)		(0)		(0)		(10)		(10)	
Skin	(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)

Experiment Number: 20107-01

Test Type: 90-DAY

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: N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 10/22/2014

Time Report Requested: 11:56:53

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat FEMALE	0	MG/KG	62.5	MG/KG	125	MG/KG	250	MG/KG	500	MG/KG	1000	MG/KG
MUSCULOSKELETAL SYSTEM												
Bone	(10)		(0)		(0)		(0)		(10)		(10)	
NERVOUS SYSTEM												
Brain	(10)		(0)		(0)		(0)		(10)		(10)	
RESPIRATORY SYSTEM												
Lung	(10)		(10)		(10)		(10)		(10)		(10)	
Alveolus, Infiltration Cellular, Histiocyte Hemorrhage											2 [1.0]	
Inflammation, Chronic Active	8 [1.0]		5 [1.0]		8 [1.0]		8 [1.0]		8 [1.0]		2 [1.0]	
Nose	(10)		(10)		(10)		(10)		(10)		(10)	
Glands, Hyperplasia			3 [1.0]		9 [1.7]		10 [1.9]		10 [2.0]			
Olfactory Epi, Degeneration			7 [1.3]		10 [2.1]		10 [3.0]		10 [3.0]		10 [4.0]	
Olfactory Epi, Metaplasia							7 [1.6]		10 [2.9]			
Respirat Epith, Hyperplasia			1 [1.0]		7 [1.1]		10 [1.7]		10 [1.7]		1 [1.0]	
Respirat Epith, Metaplasia, Squamous					6 [1.5]		10 [2.2]		10 [2.6]		7 [1.1]	
Trachea	(10)		(10)		(10)		(10)		(10)		(10)	
SPECIAL SENSES SYSTEM												
Eye	(10)		(0)		(0)		(0)		(10)		(10)	
Ciliary Body, Inflammation	1 [2.0]											
Cornea, Inflammation	1 [2.0]											
Retina, Atrophy	1 [2.0]											
Retina, Degeneration	1 [4.0]											
Harderian Gland	(10)		(0)		(0)		(0)		(10)		(10)	
Inflammation	3 [3.0]								2 [2.0]			
Mineralization	1 [1.0]											
Pigmentation	10 [2.1]								8 [1.4]		9 [2.3]	
Lacrimal Gland	(1)		(0)		(0)		(0)		(0)		(0)	

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Experiment Number: 20107-01

Test Type: 90-DAY

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: N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 10/22/2014

Time Report Requested: 11:56:53

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat FEMALE	0	MG/KG	62.5	MG/KG	125	MG/KG	250	MG/KG	500	MG/KG	1000	MG/KG
URINARY SYSTEM												
Kidney	(10)		(10)		(10)		(10)		(10)		(10)	
Mineralization	9 [1.0]		6 [1.0]		6 [1.3]		8 [1.1]		8 [1.1]			
Nephropathy	2 [1.0]		2 [1.0]		9 [1.0]		10 [1.0]		10 [1.3]		1 [1.0]	
Papilla, Necrosis							6 [1.5]		2 [2.5]		1 [2.0]	
Pigmentation			10 [1.0]		10 [1.0]		10 [1.0]		10 [1.6]			
Renal Tubule, Dilatation									1 [3.0]		10 [1.3]	
Urinary Bladder	(10)		(0)		(0)		(0)		(10)		(10)	
Inflammation	1 [1.0]								1 [1.0]			

** 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)