

Experiment Number: 20107 - 01

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

Date Report Requested: 09/07/2016

Test Type: 90-DAY

N,N-Dimethyl-p-toluidine

Time Report Requested: 11:43:16

Route: GAVAGE

CAS Number: 99-97-8

First Dose M/F: 10/20/03 / 10/21/03

Species/Strain: RATS/F 344/N

Lab: BAT

NTP Study Number: C20107
Lock Date: 07/14/2004
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 3.0.2.3_002
PWG Approval Date: NONE

Test Type: 90-DAY

N,N-Dimethyl-p-toluidine

Time Report Requested: 11:43:16

Route: GAVAGE

CAS Number: 99-97-8

First Dose M/F: 10/20/03 / 10/21/03

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	62.5 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
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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	
Fatty Change, Focal	1 [1.0]					
Hematopoietic Cell Proliferation	4 [1.0]	8 [1.0]	10 [1.0]	8 [1.0]	7 [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]
Pigmentation		4 [1.0]	7 [1.0]	9 [1.0]	9 [1.0]	
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]
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]	
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]	

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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Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	62.5 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
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						
None						
GENITAL 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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Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	62.5 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
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)
Inflammation, Chronic Active					1 [1.0]	
Epithelium, Hyperplasia	2 [1.5]				2 [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)
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]
Pigmentation	10 [1.0]	10 [2.1]	10 [2.2]	10 [2.0]	9 [2.0]	
Capsule, Fibrosis	1 [1.0]	5 [1.0]	10 [1.4]	10 [2.7]	9 [2.8]	
Lymphoid Follicle, 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]	
Red Pulp, Atrophy					1 [2.0]	10 [2.7]
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)
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Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	62.5 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
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)
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]
Alveolus, Infiltration Cellular, Histiocyte	1 [1.0]				1 [1.0]	
Alveolus, Metaplasia, Squamous, Focal			1 [2.0]			
Nose	(10)	(10)	(10)	(10)	(10)	(10)
Glands, Hyperplasia			10 [1.8]	10 [2.1]	9 [2.1]	
Olfactory Epithelium, Degeneration		5 [1.0]	10 [2.5]	10 [3.0]	10 [3.1]	10 [4.0]
Olfactory Epithelium, Metaplasia				9 [1.9]	9 [2.9]	
Respiratory Epithelium, Hyperplasia	1 [1.0]	2 [1.0]	7 [1.4]	10 [1.5]	9 [1.8]	7 [1.9]
Respiratory Epithelium, 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)
Cataract					1 [3.0]	
Anterior Chamber, Inflammation, Suppurative					1 [4.0]	
Ciliary Body, Inflammation, Suppurative					1 [4.0]	

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FISCHER 344 RATS MALE	0 MG/KG	62.5 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Cornea, Ulcer					1 [4.0]	
Retina, Degeneration					1 [3.0]	
Harderian Gland	(10)	(0)	(0)	(0)	(10)	(10)
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]
Epithelium, Hyperplasia					1 [3.0]	
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]
Pigmentation		10 [1.0]	10 [1.0]	10 [1.6]	9 [1.9]	
Papilla, Necrosis			7 [1.3]	7 [1.7]	9 [2.4]	2 [1.5]
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 ***

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FISCHER 344 RATS FEMALE	0 MG/KG	62.5 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
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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	
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]		
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]
Hepatodiaphragmatic Nodule				1	1	
Inflammation, Chronic Active	8 [1.0]	10 [1.0]	10 [1.0]	4 [1.3]	5 [1.2]	
Pigmentation		10 [1.0]	10 [1.0]	10 [1.8]	10 [1.9]	
Bile Duct, Hyperplasia					1 [2.0]	
Centrilobular, Fatty Change						9 [1.1]
Centrilobular, Hepatocyte, Necrosis					1 [2.0]	7 [1.9]
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]
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)

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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Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	62.5 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
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

None

GENITAL SYSTEM

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FISCHER 344 RATS FEMALE	0 MG/KG	62.5 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
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)
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]
Pigmentation	10 [1.0]	10 [2.0]	10 [2.0]	10 [1.9]	10 [2.0]	
Capsule, Fibrosis		3 [1.0]	7 [1.3]	10 [2.2]	10 [2.7]	
Lymphoid Follicle, Atrophy					10 [1.3]	10 [1.8]
Mesothelium, Hypertrophy		1 [1.0]	2 [1.5]	9 [1.1]	9 [1.1]	1 [1.0]
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)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(10)	(10)

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NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(10)	(10)
RESPIRATORY SYSTEM						
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Hemorrhage						1 [2.0]
Inflammation, Chronic Active	8 [1.0]	5 [1.0]	8 [1.0]	8 [1.0]	8 [1.0]	2 [1.0]
Alveolus, Infiltration Cellular, Histiocyte						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 Epithelium, Degeneration		7 [1.3]	10 [2.1]	10 [3.0]	10 [3.0]	10 [4.0]
Olfactory Epithelium, Metaplasia				7 [1.6]	10 [2.9]	
Respiratory Epithelium, Hyperplasia		1 [1.0]	7 [1.1]	10 [1.7]	10 [1.7]	1 [1.0]
Respiratory Epithelium, 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)
URINARY SYSTEM						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)

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Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	62.5 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
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]
Pigmentation		10 [1.0]	10 [1.0]	10 [1.0]	10 [1.6]	
Papilla, Necrosis				6 [1.5]	2 [2.5]	1 [2.0]
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)