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

N,N-Dimethyl-p-toluidine **CAS Number:** 99-97-8

Species/Strain: RATS/F 344/N

Test Type: 90-DAY

Route: GAVAGE

Date Report Requested: 09/07/2016 Time Report Requested: 11:43:16 First Dose M/F: 10/20/03 / 10/21/03

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

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

Test Type: 90-DAY **Route:** GAVAGE

Species/Strain: RATS/F 344/N

Experiment Number: 20107 - 01

N,N-Dimethyl-p-toluidine **CAS Number:** 99-97-8

Date Report Requested: 09/07/2016 Time Report Requested: 11:43:16 First Dose M/F: 10/20/03 / 10/21/03

FISCHER 344 RATS 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 (10%)					
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Basophilic Focus					2 (20%)	
Fatty Change, Focal	1 (10%)					
Hematopoietic Cell Proliferation	4 (40%)	8 (80%)	10 (100%)	8 (80%)	7 (70%)	
Hepatodiaphragmatic Nodule			1 (10%)	1 (10%)	1 (10%)	
Inflammation, Chronic Active	7 (70%)	10 (100%)	9 (90%)	6 (60%)	7 (70%)	2 (20%)
Pigmentation		4 (40%)	7 (70%)	9 (90%)	9 (90%)	
Bile Duct, Hyperplasia				3 (30%)	1 (10%)	
Centrilobular, Fatty Change					1 (10%)	2 (20%)
Centrilobular, Hepatocyte, Necrosis					1 (10%)	10 (100%)
Hepatocyte, Hypertrophy		2 (20%)	9 (90%)	10 (100%)	10 (100%)	10 (100%)
Hepatocyte, Necrosis	3 (30%)	3 (30%)	5 (50%)	3 (30%)	5 (50%)	
Pancreas	(10)	(0)	(0)	(0)	(10)	(10)
Infiltration Cellular, Lymphocyte	9 (90%)				6 (60%)	
Salivary Glands	(10)	(0)	(0)	(0)	(10)	(10)
Fibrosis					1 (10%)	

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

Test Type: 90-DAY **Route:** GAVAGE

Species/Strain: RATS/F 344/N

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

N,N-Dimethyl-p-toluidine **CAS Number:** 99-97-8

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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
Stomach, Forestomach	(10)	(10)	(10)	(10)	(10)	(10)
Hemorrhage						1 (10%)
Hyperplasia, Squamous				2 (20%)	2 (20%)	
Inflammation			1 (10%)		5 (50%)	9 (90%)
Mineralization					1 (10%)	1 (10%)
Ulcer			1 (10%)		1 (10%)	7 (70%)
Stomach, Glandular	(10)	(0)	(0)	(0)	(10)	(10)
Inflammation					1 (10%)	
Ulcer						1 (10%)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(0)	(0)	(10)	(10)
Heart	(10)	(0)	(0)	(0)	(10)	(10)
Cardiomyopathy	10 (100%)				6 (60%)	1 (10%)
ENDOCRINE SYSTEM						-
Adrenal Cortex	(10)	(0)	(0)	(0)	(10)	(10)
Mineralization					1 (10%)	
Vacuolization Cytoplasmic	10 (100%)				1 (10%)	
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

Test Type: 90-DAY **Route:** GAVAGE

Species/Strain: RATS/F 344/N

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

N,N-Dimethyl-p-toluidine **CAS Number:** 99-97-8

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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/K
Epididymis	(10)	(0)	(0)	(0)	(10)	(10)
Inflammation	2 (20%)					
Preputial Gland	(10)	(0)	(0)	(0)	(10)	(10)
Duct, Ectasia	1 (10%)					
Prostate	(10)	(0)	(0)	(0)	(10)	(10)
Inflammation, Chronic Active					1 (10%)	
Epithelium, Hyperplasia	2 (20%)				2 (20%)	
Seminal Vesicle	(10)	(0)	(0)	(0)	(10)	(8)
Testes	(10)	(0)	(0)	(0)	(10)	(10)
Atrophy					1 (10%)	
HEMATOPOIETIC SYSTEM						,
Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Hyperplasia		10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%
Lymph Node	(1)	(0)	(0)	(0)	(1)	(0)
Mediastinal, Hyperplasia, Lymphoid	1 (100%)				1 (100%)	
Lymph Node, Mesenteric	(10)	(10)	(10)	(10)	(10)	(10)
Atrophy					3 (30%)	6 (60%)
Necrosis, Lymphoid						2 (20%)
Spleen	(10)	(10)	(10)	(10)	(10)	(10)
Congestion		10 (100%)	10 (100%)	10 (100%)	9 (90%)	
Hematopoietic Cell Proliferation	9 (90%)	10 (100%)	10 (100%)	10 (100%)	9 (90%)	9 (90%)
Pigmentation	10 (100%)	10 (100%)	10 (100%)	10 (100%)	9 (90%)	
Capsule, Fibrosis	1 (10%)	5 (50%)	10 (100%)	10 (100%)	9 (90%)	
Lymphoid Follicle, Atrophy				8 (80%)	10 (100%)	10 (100%
Mesothelium, Hypertrophy	3 (30%)	5 (50%)	8 (80%)	10 (100%)	9 (90%)	
Red Pulp, Atrophy					1 (10%)	10 (100%
Thymus	(10)	(10)	(10)	(10)	(10)	(10)
Hemorrhage	1 (10%)					7 (70%)
Thymocyte, Necrosis					1 (10%)	10 (100%
NTEGUMENTARY SYSTEM						
Mammary Gland	(10)	(0)	(0)	(0)	(5)	(10)

Test Type: 90-DAY **Route:** GAVAGE

Species/Strain: RATS/F 344/N

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

N,N-Dimethyl-p-toluidine **CAS Number:** 99-97-8

Date Report Requested: 09/07/2016 Time Report Requested: 11:43:16 First Dose M/F: 10/20/03 / 10/21/03

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 Hemorrhage	(10)	(10) 1 (10%)	(10)	(10)	(10)	(10)
Inflammation, Chronic Active Thrombosis	10 (100%)	8 (80%)	9 (90%)	10 (100%)	10 (100%)	10 (100%) 2 (20%)
Alveolus, Infiltration Cellular, Histiocyte Alveolus, Metaplasia, Squamous, Focal	1 (10%)		1 (10%)		1 (10%)	
Nose Glands, Hyperplasia	(10)	(10)	(10) 10 (100%)	(10) 10 (100%)	(10) 9 (90%)	(10)
Olfactory Epithelium, Degeneration Olfactory Epithelium, Metaplasia		5 (50%)	10 (100%)	10 (100%) 9 (90%)	10 (100%) 9 (90%)	10 (100%)
Respiratory Epithelium, Hyperplasia Respiratory Epithelium, Metaplasia, Squamous	1 (10%)	2 (20%) 8 (80%)	7 (70%) 10 (100%)	10 (100%) 10 (100%)	9 (90%) 9 (90%)	7 (70%) 1 (10%)
Trachea Inflammation, Chronic Active	(10) 2 (20%)	(10)	(10) 2 (20%)	(10) 3 (30%)	(10) 3 (30%)	(10)
SPECIAL SENSES SYSTEM						
Eye Cataract Anterior Chamber, Inflammation, Suppurative Ciliary Body, Inflammation, Suppurative	(10)	(0)	(0)	(0)	(10) 1 (10%) 1 (10%) 1 (10%)	(10)

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

Test Type: 90-DAY **Route:** GAVAGE

Species/Strain: RATS/F 344/N

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

N,N-Dimethyl-p-toluidine **CAS Number:** 99-97-8

Date Report Requested: 09/07/2016 Time Report Requested: 11:43:16 First Dose M/F: 10/20/03 / 10/21/03

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 (10%)	
Retina, Degeneration					1 (10%)	
Harderian Gland	(10)	(0)	(0)	(0)	(10)	(10)
Hemorrhage					1 (10%)	
Infiltration Cellular, Lymphocyte					1 (10%)	
Inflammation, Chronic Active					1 (10%)	
Pigmentation	2 (20%)				1 (10%)	9 (90%)
Epithelium, Hyperplasia					1 (10%)	
JRINARY SYSTEM						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Hemorrhage						2 (20%)
Mineralization	1 (10%)	4 (40%)	10 (100%)	10 (100%)	8 (80%)	
Nephropathy	9 (90%)	10 (100%)	10 (100%)	10 (100%)	9 (90%)	3 (30%)
Pigmentation		10 (100%)	10 (100%)	10 (100%)	9 (90%)	
Papilla, Necrosis		, ,	7 (70%)	7 (70%)	9 (90%)	2 (20%)
Renal Tubule, Dilatation			2 (20%)	1 (10%)	3 (30%)	3 (30%)
	(10)	(0)	(0)	(0)	(10)	(9)
Urinary Bladder	(10)					

^{***} END OF MALE ***

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

Test Type: 90-DAY **Route:** GAVAGE

Species/Strain: RATS/F 344/N

Experiment Number: 20107 - 01

N,N-Dimethyl-p-toluidine **CAS Number:** 99-97-8

Date Report Requested: 09/07/2016 Time Report Requested: 11:43:16 First Dose M/F: 10/20/03 / 10/21/03

FISCHER 344 RATS 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 Survivors						10
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 (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)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Angiectasis				1 (10%)		
Clear Cell Focus					2 (20%)	
Fatty Change, Focal					1 (10%)	
Hematopoietic Cell Proliferation	5 (50%)	6 (60%)	8 (80%)	6 (60%)	9 (90%)	1 (10%)
Hepatodiaphragmatic Nodule				1 (10%)	1 (10%)	
Inflammation, Chronic Active	8 (80%)	10 (100%)	10 (100%)	4 (40%)	5 (50%)	
Pigmentation	, ,	10 (100%)	10 (100%)	10 (100%)	10 (100%)	
Bile Duct, Hyperplasia		, ,	,	,	1 (10%)	
Centrilobular, Fatty Change						9 (90%)
Centrilobular, Hepatocyte, Necrosis					1 (10%)	7 (70%)
Hepatocyte, Hypertrophy		1 (10%)	7 (70%)	9 (90%)	10 (100%)	10 (100%)
Hepatocyte, Necrosis	1 (10%)	6 (60%)	5 (50%)	7 (70%)	6 (60%)	2 (20%)
Pancreas	(10)	(0)	(0)	(0)	(10)	(10)
Infiltration Cellular, Lymphocyte	7 (70%)		. ,	, ,	4 (40%)	1 (10%)
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

Test Type: 90-DAY **Route:** GAVAGE

Species/Strain: RATS/F 344/N

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

N,N-Dimethyl-p-toluidine **CAS Number:** 99-97-8

Date Report Requested: 09/07/2016 Time Report Requested: 11:43:16 First Dose M/F: 10/20/03 / 10/21/03

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 (10%)		
Inflammation				3 (30%)	2 (20%)	10 (100%)
Mineralization					1 (10%)	4 (40%)
Ulcer					1 (10%)	8 (80%)
Stomach, Glandular	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation						1 (10%)
Inflammation, Granulomatous					1 (10%)	
Ulcer						2 (20%)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(0)	(0)	(10)	(10)
Heart	(10)	(10)	(10)	(10)	(10)	(10)
Cardiomyopathy	7 (70%)	4 (40%)	7 (70%)	7 (70%)	6 (60%)	2 (20%)
Inflammation	1 (10%)					
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(0)	(10)	(10)
Hemorrhage						1 (10%)
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 (10%)	

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

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

Test Type: 90-DAY **Route:** GAVAGE

Species/Strain: RATS/F 344/N

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

N,N-Dimethyl-p-toluidine **CAS Number:** 99-97-8

Date Report Requested: 09/07/2016 Time Report Requested: 11:43:16 First Dose M/F: 10/20/03 / 10/21/03

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 (20%)				1 (10%)	
Ovary	(10)	(0)	(0)	(0)	(10)	(10)
Uterus	(10)	(0)	(0)	(0)	(10)	(10)
Endometrium, Hyperplasia, Cystic	1 (10%)					
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Hyperplasia		10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)
Lymph Node, Mesenteric	(10)	(10)	(10)	(10)	(10)	(10)
Atrophy				1 (10%)	6 (60%)	5 (50%)
Necrosis, Lymphoid						1 (10%)
Spleen	(10)	(10)	(10)	(10)	(10)	(10)
Congestion		2 (20%)	10 (100%)	10 (100%)	10 (100%)	
Hematopoietic Cell Proliferation	10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)	9 (90%)
Pigmentation	10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)	
Capsule, Fibrosis		3 (30%)	7 (70%)	10 (100%)	10 (100%)	
Lymphoid Follicle, Atrophy					10 (100%)	10 (100%)
Mesothelium, Hypertrophy		1 (10%)	2 (20%)	9 (90%)	9 (90%)	1 (10%)
Red Pulp, Atrophy						10 (100%)
Thymus	(10)	(10)	(10)	(10)	(10)	(10)
Hemorrhage						2 (20%)
Thymocyte, Necrosis						10 (100%)
NTEGUMENTARY 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)

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

Test Type: 90-DAY
Route: GAVAGE

Species/Strain: RATS/F 344/N

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

N,N-Dimethyl-p-toluidine **CAS Number:** 99-97-8

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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/K0
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(10)	(10)
RESPIRATORY SYSTEM						
Lung Hemorrhage	(10)	(10)	(10)	(10)	(10)	(10) 1 (10%)
Inflammation, Chronic Active Alveolus, Infiltration Cellular, Histiocyte	8 (80%)	5 (50%)	8 (80%)	8 (80%)	8 (80%)	2 (20%) 2 (20%)
Nose Glands, Hyperplasia	(10)	(10) 3 (30%)	(10) 9 (90%)	(10) 10 (100%)	(10) 10 (100%)	(10)
Olfactory Epithelium, Degeneration Olfactory Epithelium, Metaplasia		7 (70%)	10 (100%)	10 (100%) 7 (70%)	10 (100%) 10 (100%)	10 (100%)
Respiratory Epithelium, Hyperplasia Respiratory Epithelium, Metaplasia, Squamous		1 (10%)	7 (70%) 6 (60%)	10 (100%) 10 (100%)	10 (100%) 10 (100%)	1 (10%) 7 (70%)
Trachea	(10)	(10)	(10)	(10)	(10)	(10)
SPECIAL SENSES SYSTEM						
Eye	(10)	(0)	(0)	(0)	(10)	(10)
Ciliary Body, Inflammation	1 (10%)					
Cornea, Inflammation Retina, Atrophy	1 (10%) 1 (10%)					
Retina, Attopriy Retina, Degeneration	1 (10%)					
Harderian Gland	(10)	(0)	(0)	(0)	(10)	(10)
Inflammation	3 (30%)	(=)	(=)	(=)	2 (20%)	(.3)
Mineralization	1 (10%)				(/	
Pigmentation	10 (100%)				8 (80%)	9 (90%)
Lacrimal Gland	(1)	(0)	(0)	(0)	(0)	(0)
URINARY SYSTEM						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)

Test Type: 90-DAY **Route:** GAVAGE

Species/Strain: RATS/F 344/N

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

N,N-Dimethyl-p-toluidine **CAS Number:** 99-97-8

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ISCHER 344 RATS FEMALE	0 MG/KG	62.5 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Mineralization	9 (90%)	6 (60%)	6 (60%)	8 (80%)	8 (80%)	
Nephropathy	2 (20%)	2 (20%)	9 (90%)	10 (100%)	10 (100%)	1 (10%)
Pigmentation		10 (100%)	10 (100%)	10 (100%)	10 (100%)	
Papilla, Necrosis				6 (60%)	2 (20%)	1 (10%)
Renal Tubule, Dilatation					1 (10%)	10 (100%)
Urinary Bladder	(10)	(0)	(0)	(0)	(10)	(10)
Inflammation	1 (10%)				1 (10%)	

^{***} END OF REPORT ***