

TDMS No. 20107 - 03

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

Date Report Requested: 02/28/2011

Test Type: CHRONIC

N,N-Dimethyl-p-toluidine

Time Report Requested: 11:17:44

Route: GAVAGE

CAS Number: 99-97-8

First Dose M/F: 10/20/04 / 10/21/04

Species/Strain: RATS/F 344/N

Lab: BAT

F1_Rev.1__R2

C Number: C20107
Lock Date: 02/20/2008
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.3.0
PWG Approval Date: 01/25/2011

Test Type: CHRONIC

N,N-Dimethyl-p-toluidine

Time Report Requested: 11:17:44

Route: GAVAGE

CAS Number: 99-97-8

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Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
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Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Dosing Accident		1	1	3
Moribund Sacrifice	11	7	11	7
Natural Death	2	5	7	19
Survivors				
Terminal Sacrifice	37	37	31	21
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Foreign Body			1	
Inflammation				1 [3.0]
Perforation			1	2
Periesophageal Tissue, Inflammation				1 [3.0]
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Parasite Metazoan	1	2	1	
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Parasite Metazoan	3	5	2	3
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Inflammation, Chronic Active			1 [2.0]	
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Parasite Metazoan			1	
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Liver	(50)	(50)	(50)	(50)
Angiectasis	1 [2.0]			
Basophilic Focus	28	6		3
Clear Cell Focus	30	36	26	35
Congestion	1 [2.0]			
Degeneration, Cystic	4 [1.3]	10 [1.4]	9 [1.3]	17 [1.3]
Eosinophilic Focus	11	21	21	29
Fatty Change, Focal	6 [1.3]	2 [1.0]	3 [1.3]	9 [1.2]

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	6 MG/KG	20 MG/KG	60 MG/KG
Fatty Change, Diffuse	1 [2.0]	8 [1.1]	5 [1.6]	5 [2.0]
Hematopoietic Cell Proliferation	1 [1.0]		1 [1.0]	1 [1.0]
Hemorrhage	1 [2.0]			
Hepatodiaphragmatic Nodule	8	1		3
Inflammation	40 [1.1]	46 [1.1]	42 [1.0]	44 [1.0]
Mixed Cell Focus	18	17	17	35
Vacuolization Cytoplasmic		1 [2.0]	3 [1.3]	1 [2.0]
Bile Duct, Cyst		1	3	
Bile Duct, Fibrosis	21 [1.0]	27 [1.0]	41 [1.1]	42 [1.5]
Bile Duct, Hyperplasia	40 [1.2]	42 [1.5]	44 [1.6]	44 [1.8]
Hepatocyte, Hypertrophy			6 [1.5]	31 [1.5]
Hepatocyte, Necrosis	2 [1.0]		2 [2.0]	1 [1.0]
Oval Cell, Hyperplasia			2 [1.5]	2 [1.0]
Mesentery	(7)	(5)	(2)	(1)
Fat, Necrosis	7 [2.9]	5 [3.0]	1 [3.0]	1 [3.0]
Pancreas	(50)	(50)	(50)	(50)
Basophilic Focus	1 [2.0]			
Cyst	2	4	6	2
Hyperplasia		1 [3.0]		
Infiltration Cellular, Mononuclear Cell	16 [1.3]	14 [1.3]	16 [1.2]	20 [1.4]
Lipomatosis			1 [1.0]	
Metaplasia, Hepatocyte				1 [2.0]
Acinus, Atrophy	21 [1.8]	20 [2.0]	17 [1.6]	12 [1.7]
Acinus, Hyperplasia	2 [2.0]	2 [2.5]	1 [3.0]	
Salivary Glands	(50)	(50)	(50)	(50)
Infiltration Cellular		1 [1.0]		
Stomach, Forestomach	(50)	(50)	(50)	(50)
Edema		1 [2.0]		
Erosion	1 [1.0]			
Hyperplasia, Squamous		3 [1.7]	5 [2.2]	11 [2.2]
Inflammation	1 [2.0]	5 [1.6]	5 [2.6]	7 [2.6]
Ulcer		2 [2.0]	5 [2.6]	6 [2.0]
Stomach, Glandular	(50)	(50)	(50)	(50)
Erosion	1 [1.0]			
Inflammation		1 [2.0]	2 [1.5]	1 [2.0]
Mineralization				2 [1.5]

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Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Necrosis				1 [3.0]
Ulcer		1 [2.0]	2 [2.0]	
Tongue	(0)	(1)	(0)	(1)
Tooth	(1)	(2)	(2)	(0)
Dysplasia			1	
Peridental Tissue, Inflammation	1 [3.0]	2 [2.0]	1 [2.0]	

CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
Aorta, Mineralization				1 [2.0]
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	46 [1.4]	50 [1.3]	49 [1.4]	48 [1.4]
Mineralization				3 [1.3]
Pigmentation	1 [1.0]			
Thrombosis			1 [3.0]	2 [3.0]
Artery, Inflammation		1 [2.0]		
Pericardium, Inflammation				1 [1.0]

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Angiectasis	13 [1.4]	9 [1.2]	7 [1.1]	4 [1.0]
Hyperplasia	17 [1.4]	21 [1.6]	10 [1.4]	8 [1.5]
Hypertrophy	9 [1.4]	6 [1.5]	6 [1.7]	7 [1.3]
Necrosis				1 [2.0]
Vacuolization Cytoplasmic	31 [1.5]	31 [1.2]	26 [1.3]	28 [1.5]
Adrenal Medulla	(50)	(50)	(50)	(50)
Hyperplasia	18 [1.5]	15 [1.9]	12 [1.7]	18 [1.6]
Infiltration Cellular, Lymphocyte		1 [3.0]		
Islets, Pancreatic	(50)	(50)	(50)	(50)
Hyperplasia	1 [1.0]	2 [2.0]	1 [1.0]	
Parathyroid Gland	(49)	(49)	(45)	(48)
Cyst		1		
Hyperplasia, Focal	2 [2.0]			

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FISCHER 344 RATS MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Hyperplasia, Diffuse	1 [2.0]		2 [2.5]	5 [2.0]
Pituitary Gland	(50)	(50)	(50)	(50)
Angiectasis		1 [2.0]		
Cyst	1	2	2	1
Pars Distalis, Cyst			1	
Pars Distalis, Hemorrhage	1 [3.0]			
Pars Distalis, Hyperplasia	15 [2.3]	18 [2.2]	15 [2.3]	18 [1.9]
Thyroid Gland	(50)	(49)	(50)	(49)
C-cell, Hyperplasia	14 [1.7]	20 [1.5]	14 [1.3]	5 [1.8]
Follicle, Cyst		1		
Follicular Cell, Hyperplasia			1 [1.0]	

GENERAL BODY SYSTEM

Tissue NOS	(0)	(0)	(2)	(0)
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GENITAL SYSTEM

Coagulating Gland	(1)	(2)	(1)	(0)
Inflammation	1 [4.0]	2 [3.0]		
Epithelium, Hyperplasia	1 [3.0]	1 [3.0]		
Epididymis	(50)	(50)	(50)	(50)
Atypia Cellular		1 [4.0]		
Inflammation		1 [1.0]	2 [1.5]	2 [1.5]
Preputial Gland	(50)	(50)	(50)	(50)
Cyst				1
Hyperplasia	1 [3.0]			1 [3.0]
Inflammation	49 [1.5]	49 [1.6]	43 [1.4]	45 [1.3]
Prostate	(50)	(50)	(50)	(50)
Inflammation	23 [1.8]	28 [2.0]	18 [1.6]	16 [1.9]
Pigmentation				1 [2.0]
Epithelium, Hyperplasia	2 [1.0]	6 [1.3]	2 [2.0]	3 [1.7]
Seminal Vesicle	(50)	(50)	(50)	(50)
Inflammation	1 [3.0]	1 [3.0]		1 [3.0]
Epithelium, Hyperplasia		1 [4.0]		1 [3.0]

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Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Testes	(50)	(50)	(50)	(50)
Cyst		1		
Mineralization	1 [1.0]		1 [2.0]	1 [2.0]
Interstitial Cell, Hyperplasia	16 [1.2]	16 [1.4]	6 [1.8]	12 [1.4]

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Hemorrhage			1 [2.0]	4 [2.3]
Hyperplasia	17 [2.5]	13 [2.5]	28 [2.1]	50 [2.7]
Myelofibrosis			1 [2.0]	
Necrosis	1 [2.0]			
Lymph Node	(4)	(3)	(3)	(7)
Deep Cervical, Hyperplasia, Plasma Cell	1 [2.0]			
Mediastinal, Ectasia		2 [2.0]	2 [2.5]	3 [2.7]
Mediastinal, Hemorrhage		1 [3.0]		
Mediastinal, Hyperplasia, Lymphoid			1 [2.0]	3 [2.3]
Mediastinal, Hyperplasia, Plasma Cell		1 [2.0]		1 [3.0]
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Atrophy		1 [2.0]		
Ectasia				2 [2.5]
Hyperplasia, Lymphoid	2 [2.0]	1 [4.0]		1 [2.0]
Hyperplasia, Plasma Cell				1 [2.0]
Infiltration Cellular, Histiocyte	21 [1.1]	23 [1.4]	30 [1.3]	34 [1.5]
Spleen	(50)	(50)	(50)	(50)
Congestion	1 [2.0]			39 [1.9]
Hematopoietic Cell Proliferation	34 [1.0]	44 [1.1]	42 [1.5]	44 [1.3]
Inflammation, Suppurative				2 [1.5]
Pigmentation	36 [1.1]	48 [1.7]	47 [2.1]	48 [2.0]
Capsule, Fibrosis	1 [2.0]		2 [1.5]	46 [1.8]
Capsule, Hemorrhage		1 [3.0]		
Capsule, Hypertrophy, Mesothelium		1 [1.0]	3 [1.0]	39 [1.1]
Lymphoid Follicle, Atrophy		5 [2.2]	2 [1.5]	19 [2.0]
Red Pulp, Atrophy			1 [3.0]	8 [2.6]
Thymus	(50)	(48)	(48)	(47)

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Lab: BAT

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Atrophy Hyperplasia, Lymphoid	44 [2.8]	46 [2.7]	44 [2.5]	44 [2.5] 1 [3.0]
INTEGUMENTARY SYSTEM				
Mammary Gland Cyst Hyperplasia	(50)	(50)	(49)	(50) 1 2 [1.0]
Skin Cyst Epithelial Inclusion Inflammation	(50)	(50)	(50)	(50) 1 1 [3.0]
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
NERVOUS SYSTEM				
Brain Demyelination Hemorrhage	(50) 1 [2.0] 1 [2.0]	(50)	(50)	(50)
Spinal Cord	(0)	(1)	(0)	(0)
RESPIRATORY SYSTEM				
Lung Congestion Foreign Body Inflammation Mineralization Alveolar Epithelium, Hyperplasia Alveolus, Foreign Body Alveolus, Infiltration Cellular, Histiocyte	(50) 2 [1.5] 8 [2.8] 14 [1.1]	(50) 1 5 [1.6] 9 [2.3] 2 [1.0]	(50) 1 [3.0] 6 [1.7] 6 [2.3] 1 5 [1.0]	(50) 3 [2.7] 1 [1.0] 1 [1.0] 6 [2.8] 11 [1.1]

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Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Alveolus, Inflammation, Suppurative				1 [2.0]
Nose	(50)	(49)	(50)	(49)
Foreign Body	13	17	11	9
Inflammation	35 [1.4]	40 [1.6]	38 [1.2]	48 [1.9]
Glands, Olfactory Epithelium, Dilatation			3 [1.0]	49 [2.4]
Glands, Olfactory Epithelium, Hyperplasia		2 [1.0]		48 [1.9]
Glands, Olfactory Epithelium, Metaplasia				38 [1.5]
Glands, Olfactory Epithelium, Necrosis				22 [2.7]
Glands, Respiratory Epithelium, Dilatation	13 [1.0]	15 [1.0]	19 [1.0]	48 [1.6]
Glands, Respiratory Epithelium, Hyperplasia		8 [1.1]	8 [1.5]	41 [1.7]
Glands, Respiratory Epithelium, Metaplasia, Respiratory	29 [1.0]	39 [1.0]	39 [1.0]	47 [2.6]
Glands, Transitional Epithelium, Dilatation			5 [1.2]	3 [1.7]
Glands, Transitional Epithelium, Hyperplasia		1 [1.0]	24 [1.1]	40 [1.6]
Nerve, Atrophy				15 [1.3]
Olfactory Epithelium, Accumulation, Hyaline Droplet	49 [2.1]	44 [2.0]	40 [1.7]	
Olfactory Epithelium, Degeneration			1 [2.0]	47 [2.1]
Olfactory Epithelium, Hyperplasia, Basal Cell		1 [1.0]	2 [1.0]	38 [1.3]
Olfactory Epithelium, Metaplasia, Respiratory	4 [1.0]	9 [1.4]	9 [1.3]	40 [1.3]
Respiratory Epithelium, Accumulation, Hyaline Droplet	42 [1.5]	35 [1.2]	30 [1.4]	8 [1.0]
Respiratory Epithelium, Hyperplasia	15 [1.2]	29 [1.5]	32 [1.3]	49 [1.6]
Respiratory Epithelium, Ulcer				1 [2.0]
Squamous Epithelium, Cyst		1		
Transitional Epithelium, Hyperplasia	1 [2.0]	1 [1.0]	11 [1.1]	46 [1.7]
Trachea	(50)	(50)	(50)	(50)
Inflammation	3 [1.3]	1 [2.0]	1 [1.0]	3 [1.7]
Perforation				1
Peritracheal Tissue, Inflammation				2 [3.0]

SPECIAL SENSES SYSTEM

Eye	(50)	(50)	(50)	(50)
Dysplasia		1		
Inflammation		1 [2.0]		

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Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Cornea, Hyperplasia		1 [2.0]		
Cornea, Inflammation	1 [2.0]	1 [3.0]		
Lens, Degeneration		1 [3.0]		1 [3.0]
Retina, Atrophy		1 [3.0]	1 [3.0]	3 [2.3]
Harderian Gland	(50)	(50)	(50)	(50)
Infiltration Cellular, Lymphoid		1 [3.0]		
Inflammation	3 [1.3]	6 [1.5]		10 [1.3]
Zymbal's Gland	(49)	(50)	(50)	(50)
Hyperplasia	1 [4.0]		1 [1.0]	

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Accumulation, Hyaline Droplet	2 [2.0]	1 [1.0]		
Cyst			1	1
Mineralization	44 [1.0]	37 [1.0]	38 [1.0]	49 [1.1]
Nephropathy	49 [1.4]	49 [2.0]	48 [2.5]	49 [2.7]
Pigmentation	24 [1.2]	46 [1.0]	37 [1.2]	44 [1.6]
Papilla, Necrosis		2 [4.0]		
Pelvis, Dilatation				3 [2.3]
Pelvis, Inflammation		3 [2.3]	1 [2.0]	
Pelvis, Transitional Epithelium, Hyperplasia	1 [2.0]	2 [1.0]	6 [1.7]	5 [1.0]
Ureter	(0)	(0)	(0)	(1)
Inflammation				1 [2.0]
Urinary Bladder	(50)	(50)	(50)	(50)
Hemorrhage		1 [3.0]		2 [3.0]
Inflammation		2 [3.0]	2 [1.5]	2 [3.0]
Ulcer		1 [4.0]		
Transitional Epithelium, Necrosis				1 [4.0]

*** END OF MALE ***

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FISCHER 344 RATS FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
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Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Accidentally Killed		1		
Dosing Accident				1
Moribund Sacrifice	14	3	8	8
Natural Death	3	4	9	18
Survivors				
Terminal Sacrifice	33	42	33	23
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Parasite Metazoan		1		
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Parasite Metazoan	4	4	3	3
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Hyperplasia, Lymphoid		1 [3.0]		
Liver	(50)	(50)	(50)	(49)
Angiectasis	1 [1.0]	4 [1.8]	10 [1.1]	5 [1.4]
Basophilic Focus	46	45	5	6
Clear Cell Focus	7	17	24	29
Degeneration, Cystic			2 [1.0]	10 [1.2]
Eosinophilic Focus	18	24	29	32
Fatty Change, Focal	8 [1.4]	13 [1.2]	3 [1.3]	4 [1.3]
Fatty Change, Diffuse	9 [1.6]	1 [1.0]	3 [2.7]	1 [3.0]
Hematopoietic Cell Proliferation			2 [1.0]	2 [1.0]
Hepatodiaphragmatic Nodule	3	6	5	3
Inflammation	38 [1.1]	46 [1.0]	42 [1.0]	39 [1.1]
Mixed Cell Focus	14	20	17	26

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Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Bile Duct, Cyst		1		1
Bile Duct, Fibrosis	6 [1.2]	11 [1.0]	23 [1.0]	27 [1.1]
Bile Duct, Hyperplasia	10 [1.6]	21 [1.0]	27 [1.0]	43 [1.5]
Centrilobular, Degeneration			1 [2.0]	1 [2.0]
Hepatocyte, Hypertrophy			6 [1.3]	22 [1.3]
Hepatocyte, Necrosis			1 [2.0]	5 [1.8]
Oval Cell, Hyperplasia	2 [2.0]		2 [1.5]	1 [1.0]
Mesentery	(8)	(9)	(9)	(3)
Fat, Necrosis	8 [3.0]	9 [3.0]	9 [3.0]	3 [3.0]
Pancreas	(50)	(50)	(50)	(50)
Cyst	5	4	5	5
Fibrosis	1 [2.0]			
Infiltration Cellular, Mononuclear Cell	13 [1.5]	11 [1.1]	9 [1.6]	9 [1.2]
Acinus, Atrophy	14 [1.4]	7 [1.7]	9 [1.2]	7 [1.6]
Acinus, Hyperplasia				1 [1.0]
Duct, Fibrosis	1 [2.0]			
Duct, Inflammation, Chronic Active		1 [3.0]		
Salivary Glands	(50)	(50)	(50)	(48)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Hyperplasia, Squamous	5 [1.8]	1 [1.0]	4 [1.8]	4 [2.3]
Inflammation	5 [2.2]		4 [2.0]	2 [2.5]
Ulcer	5 [2.4]		3 [2.0]	2 [2.5]
Stomach, Glandular	(50)	(50)	(50)	(50)
Inflammation			1 [1.0]	
Mineralization	1 [1.0]			
Ulcer			1 [3.0]	
Tongue	(1)	(0)	(0)	(2)
Tooth	(0)	(1)	(0)	(0)
Peridontal Tissue, Inflammation		1 [1.0]		

CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	36 [1.1]	42 [1.1]	40 [1.1]	42 [1.1]

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)

Test Type: CHRONIC

N,N-Dimethyl-p-toluidine

Time Report Requested: 11:17:44

Route: GAVAGE

CAS Number: 99-97-8

First Dose M/F: 10/20/04 / 10/21/04

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
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Pigmentation			1 [1.0]	
Thrombosis				1 [3.0]
Endocardium, Hyperplasia		1 [2.0]		

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(49)
Angiectasis	39 [1.8]	42 [1.7]	43 [1.6]	34 [1.5]
Degeneration, Cystic	8 [2.0]	5 [1.0]	5 [1.0]	3 [2.0]
Hyperplasia	26 [1.7]	24 [1.5]	28 [1.5]	12 [1.4]
Hypertrophy	11 [1.7]	10 [1.2]	12 [1.9]	8 [1.4]
Necrosis	1 [1.0]			1 [2.0]
Pigmentation		1 [3.0]		
Vacuolization Cytoplasmic	26 [1.5]	26 [1.3]	26 [1.3]	18 [1.4]
Adrenal Medulla	(50)	(50)	(50)	(49)
Atrophy		1 [3.0]		
Hyperplasia	4 [1.5]	3 [1.7]	1 [3.0]	5 [1.8]
Islets, Pancreatic	(50)	(50)	(50)	(50)
Parathyroid Gland	(50)	(50)	(50)	(46)
Hyperplasia, Focal			1 [2.0]	
Hyperplasia, Diffuse	1 [1.0]	2 [1.0]	2 [1.0]	5 [1.4]
Pituitary Gland	(50)	(50)	(50)	(50)
Cyst	11	20	15	4
Fibrosis		1 [2.0]		
Pigmentation		1 [2.0]		
Pars Distalis, Angiectasis	1 [3.0]			1 [3.0]
Pars Distalis, Cyst	4		2	1
Pars Distalis, Hyperplasia	14 [2.5]	17 [2.6]	15 [2.5]	17 [2.6]
Thyroid Gland	(49)	(47)	(47)	(45)
C-cell, Hyperplasia	29 [1.5]	33 [1.4]	15 [1.0]	4 [1.5]
Follicle, Cyst	1			
Follicular Cell, Hyperplasia	1 [1.0]	1 [1.0]		

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)

Test Type: CHRONIC

N,N-Dimethyl-p-toluidine

Time Report Requested: 11:17:44

Route: GAVAGE

CAS Number: 99-97-8

First Dose M/F: 10/20/04 / 10/21/04

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
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None

GENITAL SYSTEM

Clitoral Gland	(50)	(49)	(50)	(50)
Cyst	11	8	7	5
Hyperplasia	9 [1.6]	9 [2.0]	6 [2.2]	4 [2.0]
Inflammation	22 [1.4]	26 [1.5]	20 [1.5]	15 [1.1]
Ovary	(50)	(50)	(50)	(50)
Atrophy		2 [2.0]		
Cyst	4	3	5	
Uterus	(50)	(50)	(50)	(50)
Cyst	1			
Decidual Reaction			1 [3.0]	
Hemorrhage				2 [3.0]
Inflammation	1 [1.0]		1 [2.0]	
Cervix, Cyst				1
Endometrium, Hyperplasia, Cystic				2 [3.0]
Myometrium, Fibrosis		1 [3.0]		
Vagina	(1)	(1)	(0)	(0)

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Hyperplasia	18 [2.8]	13 [2.5]	18 [2.7]	49 [2.6]
Myelofibrosis	1 [2.0]			1 [3.0]
Lymph Node	(2)	(1)	(2)	(1)
Mediastinal, Ectasia	1 [2.0]	1 [2.0]	1 [2.0]	1 [3.0]
Lymph Node, Mesenteric	(50)	(49)	(50)	(49)
Hyperplasia, Lymphoid	1 [3.0]			
Infiltration Cellular, Histiocyte	30 [1.3]	29 [1.2]	35 [1.2]	33 [1.5]
Spleen	(50)	(50)	(50)	(50)
Congestion		9 [1.1]	26 [1.3]	28 [1.8]
Hematopoietic Cell Proliferation	32 [1.6]	45 [1.8]	47 [1.9]	42 [1.7]
Necrosis	2 [3.0]			

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Test Type: CHRONIC

N,N-Dimethyl-p-toluidine

Time Report Requested: 11:17:44

Route: GAVAGE

CAS Number: 99-97-8

First Dose M/F: 10/20/04 / 10/21/04

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Pigmentation	44 [2.0]	47 [2.1]	47 [2.5]	49 [2.2]
Capsule, Fibrosis	8 [1.1]		8 [1.1]	41 [1.3]
Capsule, Hemorrhage		1 [3.0]		
Capsule, Hypertrophy, Mesothelium	1 [1.0]	14 [1.0]	10 [1.0]	16 [1.1]
Lymphoid Follicle, Atrophy	1 [2.0]	2 [3.0]		28 [2.4]
Red Pulp, Hyperplasia		1 [3.0]		
Thymus	(47)	(50)	(50)	(48)
Atrophy	45 [2.6]	45 [2.2]	45 [2.3]	44 [2.4]

INTEGUMENTARY SYSTEM

Mammary Gland	(50)	(50)	(50)	(50)
Cyst	4		3	
Hyperplasia	9 [1.2]	9 [1.1]	2 [1.0]	
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion		1 [3.0]		

MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Hyperostosis			1 [2.0]	

NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
Hemorrhage		1 [2.0]	1 [3.0]	
Hydrocephalus		1 [2.0]		
Peripheral Nerve	(0)	(0)	(1)	(0)
Spinal Cord	(0)	(0)	(1)	(0)

RESPIRATORY SYSTEM

Lung	(50)	(50)	(50)	(50)
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Test Type: CHRONIC

N,N-Dimethyl-p-toluidine

Time Report Requested: 11:17:44

Route: GAVAGE

CAS Number: 99-97-8

First Dose M/F: 10/20/04 / 10/21/04

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Congestion				2 [2.0]
Fibrosis	1 [2.0]			
Inflammation	3 [1.3]			1 [1.0]
Metaplasia, Squamous	2 [1.5]			
Alveolar Epithelium, Hyperplasia	5 [1.8]	2 [2.5]	2 [2.0]	2 [1.5]
Alveolus, Infiltration Cellular, Histiocyte	11 [1.0]	10 [1.0]	11 [1.0]	17 [1.0]
Nose	(50)	(49)	(50)	(49)
Foreign Body	3	8	1	4
Inflammation	23 [1.3]	24 [1.4]	22 [1.1]	45 [1.5]
Glands, Hyperplasia				1 [1.0]
Glands, Olfactory Epithelium, Dilatation				48 [2.4]
Glands, Olfactory Epithelium, Hyperplasia			4 [1.0]	47 [1.9]
Glands, Olfactory Epithelium, Metaplasia				42 [1.3]
Glands, Olfactory Epithelium, Necrosis				18 [2.8]
Glands, Respiratory Epithelium, Dilatation	5 [1.0]	12 [1.0]	27 [1.1]	47 [1.2]
Glands, Respiratory Epithelium, Hyperplasia	6 [1.2]	9 [1.0]	22 [1.3]	45 [1.6]
Glands, Respiratory Epithelium, Metaplasia, Respiratory	17 [1.1]	33 [1.1]	44 [1.8]	47 [2.0]
Glands, Transitional Epithelium, Dilatation				9 [1.4]
Glands, Transitional Epithelium, Hyperplasia		4 [1.0]	12 [1.2]	24 [1.4]
Nasolacrimal Duct, Inflammation	1 [3.0]			
Nerve, Atrophy				4 [1.8]
Olfactory Epithelium, Accumulation, Hyaline Droplet	43 [1.7]	42 [2.1]	38 [1.6]	
Olfactory Epithelium, Degeneration			1 [1.0]	46 [2.0]
Olfactory Epithelium, Hyperplasia, Basal Cell				25 [1.2]
Olfactory Epithelium, Metaplasia, Respiratory	4 [1.5]	6 [1.5]	1 [2.0]	21 [1.2]
Olfactory Epithelium, Metaplasia, Squamous				2 [1.5]
Respiratory Epithelium, Accumulation, Hyaline Droplet	35 [1.4]	30 [1.2]	23 [1.1]	2 [1.0]
Respiratory Epithelium, Hyperplasia	10 [1.0]	13 [1.4]	11 [1.1]	41 [1.3]
Transitional Epithelium, Degeneration				1 [1.0]
Transitional Epithelium, Hyperplasia		1 [1.0]	6 [1.0]	33 [1.1]
Trachea	(50)	(50)	(50)	(50)
Inflammation				1 [2.0]
Inflammation, Suppurative				1 [1.0]
Perforation				1

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Test Type: CHRONIC

N,N-Dimethyl-p-toluidine

Time Report Requested: 11:17:44

Route: GAVAGE

CAS Number: 99-97-8

First Dose M/F: 10/20/04 / 10/21/04

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
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SPECIAL SENSES SYSTEM

Ear	(1)	(0)	(0)	(1)
Eye	(50)	(50)	(50)	(50)
Cataract	3 [3.0]	2 [3.5]	3 [3.0]	
Ciliary Body, Cornea, Inflammation	1 [4.0]			
Cornea, Degeneration				1 [2.0]
Retina, Atrophy	2 [3.5]	3 [3.0]	3 [3.0]	1 [3.0]
Harderian Gland	(50)	(50)	(50)	(50)
Inflammation	6 [1.7]	4 [1.5]	2 [1.0]	1 [1.0]
Lacrimal Gland	(0)	(0)	(0)	(1)

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Accumulation, Hyaline Droplet	25 [1.2]	23 [1.1]	5 [1.0]	1 [1.0]
Calculus Micro Observation Only			1	
Cyst		1		1
Infarct	4 [2.3]		5 [2.0]	2 [3.0]
Mineralization	33 [1.1]	35 [1.0]	35 [1.1]	37 [1.1]
Nephropathy	28 [1.1]	38 [1.2]	38 [1.2]	41 [1.8]
Pigmentation	41 [1.0]	45 [1.0]	43 [1.0]	49 [1.4]
Papilla, Fibrosis	1 [2.0]		1 [1.0]	
Papilla, Inflammation	1 [2.0]			
Papilla, Necrosis				1 [3.0]
Pelvis, Dilatation				1 [2.0]
Pelvis, Inflammation	3 [1.7]	3 [2.3]	9 [2.0]	5 [2.6]
Pelvis, Transitional Epithelium, Hyperplasia	2 [2.0]	3 [1.3]	8 [2.0]	6 [2.0]
Renal Tubule, Dilatation	1 [2.0]			
Renal Tubule, Hyperplasia	1 [1.0]			
Urinary Bladder	(50)	(50)	(50)	(50)
Inflammation				1 [1.0]

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TDMS No. 20107 - 03

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

Date Report Requested: 02/28/2011

Test Type: CHRONIC

N,N-Dimethyl-p-toluidine

Time Report Requested: 11:17:44

Route: GAVAGE

CAS Number: 99-97-8

First Dose M/F: 10/20/04 / 10/21/04

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE

0 MG/KG

6 MG/KG

20 MG/KG

60 MG/KG

*** 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)