Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

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

Time Report Requested: 11:17:44
First Dose M/F: 10/20/04 / 10/21/04
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

FISCHER 344 RATS MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
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)

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]

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)

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	
Peridontal 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]			

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)

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)
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]

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)

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)

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)

FISCHER 344 RATS MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Atrophy	44 [2.8]	46 [2.7]	44 [2.5]	44 [2.5]
Hyperplasia, Lymphoid				1 [3.0]
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(49)	(50)
Cyst				1
Hyperplasia			2 [1.0]	
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion				1
Inflammation				1 [3.0]
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Demyelination	1 [2.0]			
Hemorrhage	1 [2.0]			
Spinal Cord	(0)	(1)	(0)	(0)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Congestion			1 [3.0]	3 [2.7]
Foreign Body		1		
Inflammation	2 [1.5]	5 [1.6]	6 [1.7]	1 [1.0]
Mineralization				1 [1.0]
Alveolar Epithelium, Hyperplasia	8 [2.8]	9 [2.3]	6 [2.3]	6 [2.8]
Alveolus, Foreign Body			1	
Alveolus, Infiltration Cellular, Histiocyte	14 [1.1]	2 [1.0]	5 [1.0]	11 [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)

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]		

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

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)

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

Disposition Summary

Animals Initially In Study	**50**	**50**	**50**	**50**
Early Deaths				
Accidently 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

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)

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)

FISCHER 344 RATS FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
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)

FISCHER 344 RATS FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
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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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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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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FISCHER 344 RATS FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
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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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)