TDMS No. 20107 - 03 Test Type: CHRONIC 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: 02/28/2011 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

Route: GAVAGE

Test Type: CHRONIC

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: 02/28/2011 Time Report Requested: 11:17:44 First Dose M/F: 10/20/04 / 10/21/04 Lab: BAT

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 (2%)	. ,	
Inflammation				1 (2%)	
Perforation			1 (2%)	2 (4%)	
Periesophageal Tissue, Inflammation				1 (2%)	
Intestine Large, Cecum	(50)	(50)	(50)	(50)	
Intestine Large, Colon	(50)	(50)	(50)	(50)	
Parasite Metazoan	1 (2%)	2 (4%)	1 (2%)	()	
Intestine Large, Rectum	(50)	(50)	(50)	(50)	
Parasite Metazoan	3 (6%)	5 (10%)	2 (4%)	3 (6%)	
Intestine Small, Duodenum	(50)	(50)	(50)	(50)	
Inflammation, Chronic Active	· /		1 (2%)	· · /	
Intestine Small, Ileum	(50)	(50)	(50)	(50)	
Parasite Metazoan		· · /	1 (2%)		
Intestine Small, Jejunum	(50)	(50)	(50)	(50)	
Liver	(50)	(50)	(50)	(50)	
Angiectasis	1 (2%)	· · /	. ,	· ·	
Basophilic Focus	28 (56%)	6 (12%)		3 (6%)	
Clear Cell Focus	30 (60%)	36 (72%)	26 (52%)	35 (70%)	
Congestion	1 (2%)	· · ·		. ,	
Degeneration, Cystic	4 (8%)	10 (20%)	9 (18%)	17 (34%)	
Eosinophilic Focus	11 (22%)	21 (42%)	21 (42%)	29 (58%)	
Fatty Change, Focal	6 (12%)	2 (4%)	3 (6%)	9 (18%)	

Test Type: CHRONIC

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: 02/28/2011 Time Report Requested: 11:17:44 First Dose M/F: 10/20/04 / 10/21/04 Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	
Fatty Change, Diffuse	1 (2%)	8 (16%)	5 (10%)	5 (10%)	
Hematopoietic Cell Proliferation	1 (2%)		1 (2%)	1 (2%)	
Hemorrhage	1 (2%)				
Hepatodiaphragmatic Nodule	8 (16%)	1 (2%)		3 (6%)	
Inflammation	40 (80%)	46 (92%)	42 (84%)	44 (88%)	
Mixed Cell Focus	18 (36%)	17 (34%)	17 (34%)	35 (70%)	
Vacuolization Cytoplasmic		1 (2%)	3 (6%)	1 (2%)	
Bile Duct, Cyst		1 (2%)	3 (6%)		
Bile Duct, Fibrosis	21 (42%)	27 (54%)	41 (82%)	42 (84%)	
Bile Duct, Hyperplasia	40 (80%)	42 (84%)	44 (88%)	44 (88%)	
Hepatocyte, Hypertrophy			6 (12%)	31 (62%)	
Hepatocyte, Necrosis	2 (4%)		2 (4%)	1 (2%)	
Oval Cell, Hyperplasia			2 (4%)	2 (4%)	
Mesentery	(7)	(5)	(2)	(1)	
Fat, Necrosis	7 (100%)	5 (100%)	1 (50%)	1 (100%)	
Pancreas	(50)	(50)	(50)	(50)	
Basophilic Focus	1 (2%)				
Cyst	2 (4%)	4 (8%)	6 (12%)	2 (4%)	
Hyperplasia		1 (2%)	()		
Infiltration Cellular, Mononuclear Cell	16 (32%)	14 (28%)	16 (32%)	20 (40%)	
Lipomatosis		()	1 (2%)		
Metaplasia, Hepatocyte			. (_,,	1 (2%)	
Acinus, Atrophy	21 (42%)	20 (40%)	17 (34%)	12 (24%)	
Acinus, Hyperplasia	2 (4%)	2 (4%)	1 (2%)	(2170)	
Salivary Glands	(50)	(50)	(50)	(50)	
Infiltration Cellular	(00)	1 (2%)	(00)	(00)	
Stomach, Forestomach	(50)	(50)	(50)	(50)	
Edema	(00)	1 (2%)	(00)	(55)	
Erosion	1 (2%)	1 (270)			
Hyperplasia, Squamous	1 (270)	3 (6%)	5 (10%)	11 (22%)	
Inflammation	1 (20/)	5 (10%)	· · ·	. ,	
Ulcer	1 (2%)		5 (10%)	7 (14%)	
		2 (4%)	5 (10%)	6 (12%)	
Stomach, Glandular	(50)	(50)	(50)	(50)	
Erosion	1 (2%)	4 (00)	0 (40()	4 (00()	
Inflammation		1 (2%)	2 (4%)	1 (2%)	
Mineralization				2 (4%)	

TDMS No. 20107 - 03 Test Type: CHRONIC Route: GAVAGE Species/Strain: RATS/F 344/N	P03: INCIDENCE F		LASTIC LESIONS BY yl-p-toluidine per: 99-97-8	ANATOMIC SITE(a)	Date Report Requested: 02/28/2011 Time Report Requested: 11:17:44 First Dose M/F: 10/20/04 / 10/21/04 Lab: BAT
FISCHER 344 RATS MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	
Necrosis				1 (2%)	
Ulcer		1 (2%)	2 (4%)	(/	
Tongue	(0)	(1)	(0)	(1)	
Tooth	(1)	(2)	(2)	(0)	
Dysplasia	(-)	(-)	1 (50%)	(0)	
Peridontal Tissue, Inflammation	1 (100%)	2 (100%)	1 (50%)		
CARDIOVASCULAR SYSTEM					
Blood Vessel	(50)	(50)	(50)	(50)	
Aorta, Mineralization	()	()	()	1 (2%)	
Heart	(50)	(50)	(50)	(50)	
Cardiomyopathy	46 (92%)	50 (100%)	49 (98%)	48 (96%)	
Mineralization				3 (6%)	
Pigmentation	1 (2%)			0 (070)	
Thrombosis	1 (270)		1 (2%)	2 (4%)	
Artery, Inflammation		1 (2%)	1 (270)	2 (470)	
Pericardium, Inflammation		1 (270)		1 (2%)	
ENDOCRINE SYSTEM					
Adrenal Cortex	(50)	(50)	(50)	(50)	
Angiectasis	13 (26%)	9 (18%)	7 (14%)	4 (8%)	
Hyperplasia	17 (34%)	21 (42%)	10 (20%)	8 (16%)	
Hypertrophy	9 (18%)	6 (12%)	6 (12%)	7 (14%)	
Necrosis	· · ·	. ,	. ,	1 (2%)	
Vacuolization Cytoplasmic	31 (62%)	31 (62%)	26 (52%)	28 (56%)	
Adrenal Medulla	(50)	(50)	(50)	(50)	
Hyperplasia	18 (36%)	15 (30%)	12 (24%)	18 (36%)	
Infiltration Cellular, Lymphocyte		1 (2%)			
Islets, Pancreatic	(50)	(50)	(50)	(50)	
Hyperplasia	1 (2%)	2 (4%)	1 (2%)	· ·	
Parathyroid Gland	(49)	(49)	(45)	(48)	
Cyst	× 7	1 (2%)	. ,	. ,	
Hyperplasia, Focal	2 (4%)	. ,			

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

Test Type: CHRONIC

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: 02/28/2011 Time Report Requested: 11:17:44 First Dose M/F: 10/20/04 / 10/21/04 Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	
Hyperplasia, Diffuse	1 (2%)		2 (4%)	5 (10%)	
Pituitary Gland	(50)	(50)	(50)	(50)	
Angiectasis		1 (2%)			
Cyst	1 (2%)	2 (4%)	2 (4%)	1 (2%)	
Pars Distalis, Cyst		(),	1 (2%)		
Pars Distalis, Hemorrhage	1 (2%)		(
Pars Distalis, Hyperplasia	15 (30%)	18 (36%)	15 (30%)	18 (36%)	
Thyroid Gland	(50)	(49)	(50)	(49)	
C-cell, Hyperplasia	14 (28%)	20 (41%)	14 (28%)	5 (10%)	
Follicle, Cyst	, , , , , , , , , , , , , , , , , , ,	1 (2%)		· · · ·	
Follicular Cell, Hyperplasia		()	1 (2%)		
GENERAL BODY SYSTEM				· · · · · · · · · · · · · · · · · · ·	
Tissue NOS	(0)	(0)	(2)	(0)	
GENITAL SYSTEM					
Coagulating Gland	(1)	(2)	(1)	(0)	
Inflammation	1 (100%)	2 (100%)	(1)	(0)	
Epithelium, Hyperplasia	1 (100%)	1 (50%)			
Epididymis	(50)	(50)	(50)	(50)	
Atypia Cellular	(88)	1 (2%)	(00)	(00)	
Inflammation		1 (2%)	2 (4%)	2 (4%)	
Preputial Gland	(50)	(50)	(50)	(50)	
Cyst	(86)	(00)	(00)	1 (2%)	
Hyperplasia	1 (2%)			1 (2%)	
Inflammation	49 (98%)	49 (98%)	43 (86%)	45 (90%)	
Prostate	(50)	(50)	(50)	(50)	
Inflammation	23 (46%)	28 (56%)	18 (36%)	16 (32%)	
Pigmentation	20 (10,0)	20 (0070)	10 (0070)	1 (2%)	
Epithelium, Hyperplasia	2 (4%)	6 (12%)	2 (4%)	3 (6%)	
Seminal Vesicle	(50)	(50)	(50)	(50)	
Inflammation	1 (2%)	1 (2%)	(00)	1 (2%)	
Epithelium, Hyperplasia	. (_ /0)	1 (2%)		1 (2%)	

TDMS	No.	20107	- 03	

Test Type: CHRONIC

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: 02/28/2011 Time Report Requested: 11:17:44 First Dose M/F: 10/20/04 / 10/21/04 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 (2%)			
Mineralization	1 (2%)		1 (2%)	1 (2%)	
Interstitial Cell, Hyperplasia	16 (32%)	16 (32%)	6 (12%)	12 (24%)	
HEMATOPOIETIC SYSTEM	· · · · · · · · · · · · · · · · · · ·				
Bone Marrow	(50)	(50)	(50)	(50)	
Hemorrhage			1 (2%)	4 (8%)	
Hyperplasia	17 (34%)	13 (26%)	28 (56%)	50 (100%)	
Myelofibrosis			1 (2%)		
Necrosis	1 (2%)				
Lymph Node	(4)	(3)	(3)	(7)	
Deep Cervical, Hyperplasia, Plasma Cell	1 (25%)				
Mediastinal, Ectasia		2 (67%)	2 (67%)	3 (43%)	
Mediastinal, Hemorrhage		1 (33%)			
Mediastinal, Hyperplasia, Lymphoid			1 (33%)	3 (43%)	
Mediastinal, Hyperplasia, Plasma Cell		1 (33%)		1 (14%)	
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)	
Atrophy		1 (2%)			
Ectasia				2 (4%)	
Hyperplasia, Lymphoid	2 (4%)	1 (2%)		1 (2%)	
Hyperplasia, Plasma Cell				1 (2%)	
Infiltration Cellular, Histiocyte	21 (42%)	23 (46%)	30 (60%)	34 (68%)	
Spleen	(50)	(50)	(50)	(50)	
Congestion	1 (2%)			39 (78%)	
Hematopoietic Cell Proliferation	34 (68%)	44 (88%)	42 (84%)	44 (88%)	
Inflammation, Suppurative				2 (4%)	
Pigmentation	36 (72%)	48 (96%)	47 (94%)	48 (96%)	
Capsule, Fibrosis	1 (2%)		2 (4%)	46 (92%)	
Capsule, Hemorrhage		1 (2%)			
Capsule, Hypertrophy, Mesothelium		1 (2%)	3 (6%)	39 (78%)	
Lymphoid Follicle, Atrophy		5 (10%)	2 (4%)	19 (38%)	
Red Pulp, Atrophy			1 (2%)	8 (16%)	
Thymus	(50)	(48)	(48)	(47)	

TDMS No. 20107 - 03 Test Type: CHRONIC Route: GAVAGE Species/Strain: RATS/F 344/N	P03: INCIDENCE R.	N,N-Dimeth	PLASTIC LESIONS BY yl-p-toluidine ber: 99-97-8	ANATOMIC SITE(a)	Date Report Requested: 02/28/2011 Time Report Requested: 11:17:44 First Dose M/F: 10/20/04 / 10/21/04 Lab: BAT
FISCHER 344 RATS MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	
Atrophy Hyperplasia, Lymphoid	44 (88%)	46 (96%)	44 (92%)	44 (94%) 1 (2%)	
INTEGUMENTARY SYSTEM					
Mammary Gland Cyst Hyperplasia	(50)	(50)	(49) 2 (4%)	(50) 1 (2%)	
Skin Cyst Epithelial Inclusion Inflammation	(50)	(50)	(50)	(50) 1 (2%) 1 (2%)	
MUSCULOSKELETAL SYSTEM					
Bone	(50)	(50)	(50)	(50)	
NERVOUS SYSTEM					
Brain Demyelination Hemorrhage	(50) 1 (2%) 1 (2%)	(50)	(50)	(50)	
Spinal Cord	(0)	(1)	(0)	(0)	
RESPIRATORY SYSTEM					
Lung Congestion	(50)	(50)	(50) 1 (2%)	(50) 3 (6%)	
Foreign Body Inflammation Mineralization	2 (4%)	1 (2%) 5 (10%)	6 (12%)	1 (2%) 1 (2%)	
Alveolar Epithelium, Hyperplasia Alveolus, Foreign Body Alveolus, Infiltration Collular, Histionato	8 (16%)	9 (18%)	6 (12%) 1 (2%) 5 (10%)	6 (12%)	
Alveolus, Infiltration Cellular, Histiocyte	14 (28%)	2 (4%)	5 (10%)	11 (22%)	

Test Type: CHRONIC

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: 02/28/2011 Time Report Requested: 11:17:44 First Dose M/F: 10/20/04 / 10/21/04 Lab: BAT

ISCHER 344 RATS MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	
Alveolus, Inflammation, Suppurative				1 (2%)	
Nose	(50)	(49)	(50)	(49)	
Foreign Body	13 (26%)	17 (35%)	11 (22%)	9 (18%)	
Inflammation	35 (70%)	40 (82%)	38 (76%)	48 (98%)	
Glands, Olfactory Epithelium, Dilatation			3 (6%)	49 (100%)	
Glands, Olfactory Epithelium, Hyperplasia		2 (4%)	· · ·	48 (98%)	
Glands, Olfactory Epithelium, Metaplasia		· · /		38 (78%)	
Glands, Olfactory Epithelium, Necrosis				22 (45%)	
Glands, Respiratory Epithelium, Dilatation	13 (26%)	15 (31%)	19 (38%)	48 (98%)	
Glands, Respiratory Epithelium, Hyperplasia		8 (16%)	8 (16%)	41 (84%)	
Glands, Respiratory Epithelium, Metaplasia, Respiratory	29 (58%)	39 (80%)	39 (78%)	47 (96%)	
Glands, Transitional Epithelium, Dilatation			5 (10%)	3 (6%)	
Glands, Transitional Epithelium, Hyperplasia		1 (2%)	24 (48%)	40 (82%)	
Nerve, Atrophy				15 (31%)	
Olfactory Epithelium, Accumulation, Hyaline Droplet	49 (98%)	44 (90%)	40 (80%)		
Olfactory Epithelium, Degeneration			1 (2%)	47 (96%)	
Olfactory Epithelium, Hyperplasia, Basal Cell		1 (2%)	2 (4%)	38 (78%)	
Olfactory Epithelium, Metaplasia, Respiratory	4 (8%)	9 (18%)	9 (18%)	40 (82%)	
Respiratory Epithelium, Accumulation, Hyaline Droplet	42 (84%)	35 (71%)	30 (60%)	8 (16%)	
Respiratory Epithelium, Hyperplasia	15 (30%)	29 (59%)	32 (64%)	49 (100%)	
Respiratory Epithelium, Ulcer				1 (2%)	
Squamous Epithelium, Cyst		1 (2%)			
Transitional Epithelium, Hyperplasia	1 (2%)	1 (2%)	11 (22%)	46 (94%)	
Trachea	(50)	(50)	(50)	(50)	
Inflammation	3 (6%)	1 (2%)	1 (2%)	3 (6%)	
Perforation				1 (2%)	
Peritracheal Tissue, Inflammation				2 (4%)	
SPECIAL SENSES SYSTEM				·	
Eye	(50)	(50)	(50)	(50)	
Dysplasia		1 (2%)			
Inflammation		1 (2%)			

Test Type: CHRONIC

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: 02/28/2011 Time Report Requested: 11:17:44 First Dose M/F: 10/20/04 / 10/21/04 Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	
Cornea, Hyperplasia		1 (2%)			
Cornea, Inflammation	1 (2%)	1 (2%)			
Lens, Degeneration		1 (2%)		1 (2%)	
Retina, Atrophy		1 (2%)	1 (2%)	3 (6%)	
Harderian Gland	(50)	(50)	(50)	(50)	
Infiltration Cellular, Lymphoid		1 (2%)		()	
Inflammation	3 (6%)	6 (12%)		10 (20%)	
Zymbal's Gland	(49)	(50)	(50)	(50)	
Hyperplasia	1 (2%)		1 (2%)		
JRINARY SYSTEM					· · · · · · · · · · · · · · · · · · ·
Kidney	(50)	(50)	(50)	(50)	
Accumulation, Hyaline Droplet	2 (4%)	1 (2%)			
Cyst			1 (2%)	1 (2%)	
Mineralization	44 (88%)	37 (74%)	38 (76%)	49 (98%)	
Nephropathy	49 (98%)	49 (98%)	48 (96%)	49 (98%)	
Pigmentation	24 (48%)	46 (92%)	37 (74%)	44 (88%)	
Papilla, Necrosis		2 (4%)			
Pelvis, Dilatation				3 (6%)	
Pelvis, Inflammation		3 (6%)	1 (2%)		
Pelvis, Transitional Epithelium, Hyperplasia	1 (2%)	2 (4%)	6 (12%)	5 (10%)	
Ureter	(0)	(0)	(0)	(1)	
Inflammation				1 (100%)	
Urinary Bladder	(50)	(50)	(50)	(50)	
Hemorrhage		1 (2%)		2 (4%)	
Inflammation		2 (4%)	2 (4%)	2 (4%)	
Ulcer		1 (2%)			
Transitional Epithelium, Necrosis				1 (2%)	

*** END OF MALE ***

TDMS	No.	20107	- (03
10110		20101		00

Test Type: CHRONIC

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: 02/28/2011 Time Report Requested: 11:17:44 First Dose M/F: 10/20/04 / 10/21/04 Lab: BAT

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 (2%)	x - /	× /	
Intestine Large, Rectum	(50)	(50)	(50)	(50)	
Parasite Metazoan	4 (8%)	4 (8%)	3 (6%)	3 (6%)	
Intestine Small, Duodenum	(50)	(50)	(50)	(50)	
Intestine Small, Ileum	(50)	(50)	(50)	(50)	
Intestine Small, Jejunum	(50)	(50)	(50)	(50)	
Hyperplasia, Lymphoid		1 (2%)			
Liver	(50)	(50)	(50)	(49)	
Angiectasis	1 (2%)	4 (8%)	10 (20%)	5 (10%)	
Basophilic Focus	46 (92%)	45 (90%)	5 (10%)	6 (12%)	
Clear Cell Focus	7 (14%)	17 (34%)	24 (48%)	29 (59%)	
Degeneration, Cystic			2 (4%)	10 (20%)	
Eosinophilic Focus	18 (36%)	24 (48%)	29 (58%)	32 (65%)	
Fatty Change, Focal	8 (16%)	13 (26%)	3 (6%)	4 (8%)	
Fatty Change, Diffuse	9 (18%)	1 (2%)	3 (6%)	1 (2%)	
Hematopoietic Cell Proliferation			2 (4%)	2 (4%)	
Hepatodiaphragmatic Nodule	3 (6%)	6 (12%)	5 (10%)	3 (6%)	
Inflammation	38 (76%)	46 (92%)	42 (84%)	39 (80%)	
Mixed Cell Focus	14 (28%)	20 (40%)	17 (34%)	26 (53%)	

Test Type: CHRONIC

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: 02/28/2011 Time Report Requested: 11:17:44 First Dose M/F: 10/20/04 / 10/21/04 Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	
Bile Duct, Cyst		1 (2%)		1 (2%)	
Bile Duct, Fibrosis	6 (12%)	11 (22%)	23 (46%)	27 (55%)	
Bile Duct, Hyperplasia	10 (20%)	21 (42%)	27 (54%)	43 (88%)	
Centrilobular, Degeneration	10 (2076)	21 (4270)	1 (2%)	1 (2%)	
Hepatocyte, Hypertrophy			6 (12%)	22 (45%)	
Hepatocyte, Necrosis			1 (2%)	5 (10%)	
Oval Cell, Hyperplasia	2 (4%)			1 (2%)	
Mesentery		(0)	2 (4%)		
	(8)	(9)	(9)	(3)	
Fat, Necrosis	8 (100%)	9 (100%)	9 (100%)	3 (100%)	
Pancreas	(50)	(50)	(50)	(50)	
Cyst	5 (10%)	4 (8%)	5 (10%)	5 (10%)	
Fibrosis	1 (2%)				
Infiltration Cellular, Mononuclear Cell	13 (26%)	11 (22%)	9 (18%)	9 (18%)	
Acinus, Atrophy	14 (28%)	7 (14%)	9 (18%)	7 (14%)	
Acinus, Hyperplasia				1 (2%)	
Duct, Fibrosis	1 (2%)				
Duct, Inflammation, Chronic Active		1 (2%)			
Salivary Glands	(50)	(50)	(50)	(48)	
Stomach, Forestomach	(50)	(50)	(50)	(50)	
Hyperplasia, Squamous	5 (10%)	1 (2%)	4 (8%)	4 (8%)	
Inflammation	5 (10%)		4 (8%)	2 (4%)	
Ulcer	5 (10%)		3 (6%)	2 (4%)	
Stomach, Glandular	(50)	(50)	(50)	(50)	
Inflammation			1 (2%)		
Mineralization	1 (2%)				
Ulcer			1 (2%)		
Tongue	(1)	(0)	(0)	(2)	
Tooth	(0)	(1)	(0)	(0)	
Peridontal Tissue, Inflammation	.,	1 (100%)			
CARDIOVASCULAR SYSTEM					
Blood Vessel	(50)	(50)	(50)	(50)	
Heart	(50)	(50)	(50)	(50)	
Cardiomyopathy	36 (72%)	42 (84%)	40 (80%)	42 (84%)	
Cardiomyopamy	50 (12/0)	42 (0470)	+0 (00 /0)	42 (0470)	

TDMS No. 20107 - 03	P03: INCIDENCE R	Date Report Requested: 02/28/2011			
Test Type: CHRONIC		Time Report Requested: 11:17:44			
Route: GAVAGE		First Dose M/F: 10/20/04 / 10/21/04 Lab: BAT			
Species/Strain: RATS/F 344/N FISCHER 344 RATS FEMALE					
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	
Pigmentation			1 (2%)		
Thrombosis			- (- / -)	1 (2%)	
Endocardium, Hyperplasia		1 (2%)		()	
ENDOCRINE SYSTEM					
Adrenal Cortex	(50)	(50)	(50)	(49)	
Angiectasis	39 (78%)	42 (84%)	43 (86%)	34 (69%)	
Degeneration, Cystic	8 (16%)	5 (10%)	5 (10%)	3 (6%)	
Hyperplasia	26 (52%)	24 (48%)	28 (56%)	12 (24%)	
Hypertrophy	11 (22%)	10 (20%)	12 (24%)	8 (16%)	
Necrosis	1 (2%)			1 (2%)	
Pigmentation		1 (2%)			
Vacuolization Cytoplasmic	26 (52%)	26 (52%)	26 (52%)	18 (37%)	
Adrenal Medulla	(50)	(50)	(50)	(49)	
Atrophy		1 (2%)			
Hyperplasia	4 (8%)	3 (6%)	1 (2%)	5 (10%)	
Islets, Pancreatic	(50)	(50)	(50)	(50)	
Parathyroid Gland	(50)	(50)	(50)	(46)	
Hyperplasia, Focal			1 (2%)		
Hyperplasia, Diffuse	1 (2%)	2 (4%)	2 (4%)	5 (11%)	
Pituitary Gland	(50)	(50)	(50)	(50)	
Cyst	11 (22%)	20 (40%)	15 (30%)	4 (8%)	
Fibrosis		1 (2%)		·	
Pigmentation		1 (2%)			
Pars Distalis, Angiectasis	1 (2%)			1 (2%)	
Pars Distalis, Cyst	4 (8%)		2 (4%)	1 (2%)	
Pars Distalis, Hyperplasia	14 (28%)	17 (34%)	15 (30%)	17 (34%)	
Thyroid Gland	(49)	(47)	(47)	(45)	
C-cell, Hyperplasia	29 (59%)	33 (70%)	15 (32%)	4 (9%)	
Follicle, Cyst	1 (2%)				
Follicular Cell, Hyperplasia	1 (2%)	1 (2%)			

GENERAL BODY SYSTEM

TDMS No. 20107 - 03 Test Type: CHRONIC Route: GAVAGE Species/Strain: RATS/F 344/N	P03: INCIDENCE R	Date Report Requested: 02/28/2011 Time Report Requested: 11:17:44 First Dose M/F: 10/20/04 / 10/21/04 Lab: BAT			
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 (22%)	8 (16%)	7 (14%)	5 (10%)	
Hyperplasia	9 (18%)	9 (18%)	6 (12%)	4 (8%)	
Inflammation	22 (44%)	26 (53%)	20 (40%)	15 (30%)	
Ovary	(50)	(50)	(50)	(50)	
Atrophy		2 (4%)			
Cyst	4 (8%)	3 (6%)	5 (10%)		
Uterus	(50)	(50)	(50)	(50)	
Cyst	1 (2%)				
Decidual Reaction			1 (2%)		
Hemorrhage				2 (4%)	
Inflammation	1 (2%)		1 (2%)		
Cervix, Cyst				1 (2%)	
Endometrium, Hyperplasia, Cystic				2 (4%)	
Myometrium, Fibrosis		1 (2%)			
Vagina	(1)	(1)	(0)	(0)	
HEMATOPOIETIC SYSTEM					
Bone Marrow	(50)	(50)	(50)	(50)	
Hyperplasia	18 (36%)	13 (26%)	18 (36%)	49 (98%)	
Myelofibrosis	1 (2%)			1 (2%)	
Lymph Node	(2)	(1)	(2)	(1)	
Mediastinal, Ectasia	1 (50%)	1 (100%)	1 (50%)	1 (100%)	
Lymph Node, Mesenteric	(50)	(49)	(50)	(49)	
Hyperplasia, Lymphoid	1 (2%)				
Infiltration Cellular, Histiocyte	30 (60%)	29 (59%)	35 (70%)	33 (67%)	
Spleen	(50)	(50)	(50)	(50)	
Congestion		9 (18%)	26 (52%)	28 (56%)	
Hematopoietic Cell Proliferation	32 (64%)	45 (90%)	47 (94%)	42 (84%)	
Necrosis	2 (4%)				

TDMS No. 20107 - 03 Test Type: CHRONIC Route: GAVAGE Species/Strain: RATS/F 344/N	P03: INCIDENCE R	Date Report Requested: 02/28/2011 Time Report Requested: 11:17:44 First Dose M/F: 10/20/04 / 10/21/04 Lab: BAT			
FISCHER 344 RATS FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	
Pigmentation	44 (88%)	47 (94%)	47 (94%)	49 (98%)	
Capsule, Fibrosis Capsule, Hemorrhage	8 (16%)	1 (2%)	8 (16%)	41 (82%)	
Capsule, Hypertrophy, Mesothelium Lymphoid Follicle, Atrophy Red Pulp, Hyperplasia	1 (2%) 1 (2%)	14 (28%) 2 (4%) 1 (2%)	10 (20%)	16 (32%) 28 (56%)	
Thymus Atrophy	(47) 45 (96%)	(50) 45 (90%)	(50) 45 (90%)	(48) 44 (92%)	
INTEGUMENTARY SYSTEM					
Mammary Gland Cyst	(50) 4 (8%)	(50)	(50) 3 (6%)	(50)	
Hyperplasia Skin Cyst Epithelial Inclusion	9 (18%) (50)	9 (18%) (50) 1 (2%)	2 (4%) (50)	(50)	
MUSCULOSKELETAL SYSTEM					
Bone Hyperostosis	(50)	(50)	(50) 1 (2%)	(50)	
NERVOUS SYSTEM					
Brain Hemorrhage Hydrocephalus	(50)	(50) 1 (2%) 1 (2%)	(50) 1 (2%)	(50)	
Peripheral Nerve Spinal Cord	(0) (0)	(0) (0)	(1) (1)	(0) (0)	
RESPIRATORY SYSTEM					· · · · · · · · · · · · · · · · · · ·
Lung	(50)	(50)	(50)	(50)	

Test Type: CHRONIC

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: 02/28/2011 Time Report Requested: 11:17:44 First Dose M/F: 10/20/04 / 10/21/04 Lab: BAT

SISCHER 344 RATS FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	
Congestion				2 (4%)	
Fibrosis	1 (2%)				
Inflammation	3 (6%)			1 (2%)	
Metaplasia, Squamous	2 (4%)			, , , , , , , , , , , , , , , , , , ,	
Alveolar Epithelium, Hyperplasia	5 (10%)	2 (4%)	2 (4%)	2 (4%)	
Alveolus, Infiltration Cellular, Histiocyte	11 (22%)	10 (20%)	11 (22%)	17 (34%)	
Nose	(50)	(49)	(50)	(49)	
Foreign Body	3 (6%)	8 (16%)	1 (2%)	4 (8%)	
Inflammation	23 (46%)	24 (49%)	22 (44%)	45 (92%)	
Glands, Hyperplasia		(, , , , , , , , , , , , , , , , , , ,	(, , , , , , , , , , , , , , , , , , ,	1 (2%)	
Glands, Olfactory Epithelium, Dilatation				48 (98%)	
Glands, Olfactory Epithelium, Hyperplasia			4 (8%)	47 (96%)	
Glands, Olfactory Epithelium, Metaplasia			(42 (86%)	
Glands, Olfactory Epithelium, Necrosis				18 (37%)	
Glands, Respiratory Epithelium, Dilatation	5 (10%)	12 (24%)	27 (54%)	47 (96%)	
Glands, Respiratory Epithelium, Hyperplasia	6 (12%)	9 (18%)	22 (44%)	45 (92%)	
Glands, Respiratory Epithelium, Metaplasia, Respiratory	17 (34%)	33 (67%)	44 (88%)	47 (96%)	
Glands, Transitional Epithelium, Dilatation				9 (18%)	
Glands, Transitional Epithelium, Hyperplasia		4 (8%)	12 (24%)	24 (49%)	
Nasolacrimal Duct, Inflammation	1 (2%)	((, , , , , , , , , , , , , , , , , , ,		
Nerve, Atrophy				4 (8%)	
Olfactory Epithelium, Accumulation, Hyaline Droplet	43 (86%)	42 (86%)	38 (76%)		
Olfactory Epithelium, Degeneration			1 (2%)	46 (94%)	
Olfactory Epithelium, Hyperplasia, Basal Cell			(25 (51%)	
Olfactory Epithelium, Metaplasia, Respiratory	4 (8%)	6 (12%)	1 (2%)	21 (43%)	
Olfactory Epithelium, Metaplasia, Squamous		· · ·	· · ·	2 (4%)	
Respiratory Epithelium, Accumulation, Hyaline Droplet	35 (70%)	30 (61%)	23 (46%)	2 (4%)	
Respiratory Epithelium, Hyperplasia	10 (20%)	13 (27%)	11 (22%)	41 (84%)	
Transitional Epithelium, Degeneration				1 (2%)	
Transitional Epithelium, Hyperplasia		1 (2%)	6 (12%)	33 (67%)	
Trachea	(50)	(50)	(50)	(50)	
Inflammation	-			1 (2%)	
Inflammation, Suppurative				1 (2%)	
Perforation				1 (2%)	

Route: GAVAGE

Test Type: CHRONIC

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

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011 Time Report Requested: 11:17:44 First Dose M/F: 10/20/04 / 10/21/04 Lab: BAT

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 (6%)	2 (4%)	3 (6%)		
Ciliary Body, Cornea, Inflammation	1 (2%)				
Cornea, Degeneration				1 (2%)	
Retina, Atrophy	2 (4%)	3 (6%)	3 (6%)	1 (2%)	
Harderian Gland	(50)	(50)	(50)	(50)	
Inflammation	6 (12%)	4 (8%)	2 (4%)	1 (2%)	
Lacrimal Gland	(0)	(0)	(0)	(1)	
URINARY SYSTEM			·		
Kidney	(50)	(50)	(50)	(50)	
Accumulation, Hyaline Droplet	25 (50%)	23 (46%)	5 (10%)	1 (2%)	
Calculus Micro Observation Only	. ,	, , ,	1 (2%)		
Cyst		1 (2%)	· · /	1 (2%)	
Infarct	4 (8%)		5 (10%)	2 (4%)	
Mineralization	33 (66%)	35 (70%)	35 (70%)	37 (74%)	
Nephropathy	28 (56%)	38 (76%)	38 (76%)	41 (82%)	
Pigmentation	41 (82%)	45 (90%)	43 (86%)	49 (98%)	
Papilla, Fibrosis	1 (2%)	, , ,	1 (2%)		
Papilla, Inflammation	1 (2%)		· · /		
Papilla, Necrosis				1 (2%)	
Pelvis, Dilatation				1 (2%)	
Pelvis, Inflammation	3 (6%)	3 (6%)	9 (18%)	5 (10%)	
Pelvis, Transitional Epithelium, Hyperplasia	2 (4%)	3 (6%)	8 (16%)	6 (12%)	
Renal Tubule, Dilatation	1 (2%)		· · · ·		
Renal Tubule, Hyperplasia	1 (2%)				
Urinary Bladder	(50)	(50)	(50)	(50)	
Inflammation				1 (2%)	

TDMS No. 20107 - 03	Date Report Requested: 02/28/2011					
Test Type: CHRONIC	Time Report Requested: 11:17:44					
Route: GAVAGE		First Dose M/F: 10/20/04 / 10/21/04				
Species/Strain: RATS/F 344/N						
FISCHER 344 RATS FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG		

*** END OF REPORT ***