Test Type: CHRONIC

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 03/10/2011 AVERAGE SEVERITY GRADES[b]

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

Time Report Requested: 11:42:39 First Dose M/F: 10/26/04 / 10/25/04

Lab: BAT

Species/Strain: MICE/B6C3F1

F1_M3

C Number: C20107

Lock Date: 02/26/2008

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: NONE

Species/Strain: MICE/B6C3F1

Hematopoietic Cell Proliferation

Inflammation, Chronic Active

Mineralization

Mitotic Alteration

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 03/10/2011 **AVERAGE SEVERITY GRADES[b]**

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

Time Report Requested: 11:42:39 First Dose M/F: 10/26/04 / 10/25/04

Lab: BAT

B6C3F1 MICE 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	•	00	00	•	
Dosing Accident	2				
Moribund Sacrifice	_ 5	4	11	14	
Natural Death	9	10	8	• •	
Survivors	•		·		
Natural Death	1				
Terminal Sacrifice	33	36	31	36	
Animals Examined Microscopically	50	50	50	50	
ALIMENTARY SYSTEM					
Esophagus	(50)	(50)	(50)	(50)	
Necrosis	1 [4.0]	,	,	,	
Perforation	1				
Periesophageal Tissue, Inflammation	2 [1.5]				
Gallbladder	(49)	(50)	(47)	(49)	
Intestine Large, Cecum	(50)	(50)	(50)	(50)	
Intestine Large, Colon	(50)	(50)	(50)	(50)	
Intestine Large, Rectum	(50)	(50)	(50)	(50)	
Intestine Small, Duodenum	(50)	(50)	(50)	(50)	
Intestine Small, Ileum	(50)	(50)	(50)	(50)	
Intestine Small, Jejunum	(50)	(50)	(50)	(50)	
Peyer's Patch, Hyperplasia		1 [3.0]			
Liver	(50)	(50)	(50)	(50)	
Angiectasis	3 [1.0]	1 [1.0]			
Basophilic Focus	5	11	8	2	
Clear Cell Focus	15	22	15	7	
Eosinophilic Focus	25	30	39	43	
Fatty Change		3 [2.7]	1 [2.0]	2 [2.0]	

4 [1.3]

23 [1.0]

1 [1.0]

4 [1.8]

18 [1.2]

1 [1.0]

2 [1.0]

1 [2.0]

19 [1.1]

1 [2.0]

1 [2.0]

1 [1.0]

22 [1.0]

1 [1.0]

1 [1.0]

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)

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 03/10/2011 AVERAGE SEVERITY GRADES[b]

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

Time Report Requested: 11:42:39 First Dose M/F: 10/26/04 / 10/25/04

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	
Mixed Cell Focus	21	25	17	12	
Necrosis	9 [1.6]	8 [2.5]	7 [1.9]	10 [2.0]	
Pigmentation	9 [1.0]	3 [1.0]	2 [2.0]	2 [1.5]	
•				2 [1.5]	
Bile Duct, Cyst	4 [4 0]	1 [1.0]	1 [2.0]		
Bile Duct, Hyperplasia	1 [1.0]	1 [1.0]	2 [1.0]		
Centrilobular, Degeneration	1 [2.0]	0.14.01	1 [3.0]	40 (0.41	
Hepatocyte, Hypertrophy	1 [1.0]	9 [1.2]	11 [1.9]	16 [2.1]	
Hepatocyte, Karyomegaly	1 [1.0]				
Kupffer Cell, Hyperplasia				1 [2.0]	
Oval Cell, Hyperplasia	1 [1.0]		1 [2.0]	2 [1.0]	
Mesentery	(4)	(3)	(5)	(2)	
Inflammation, Suppurative	1 [4.0]				
Fat, Necrosis	2 [2.0]	3 [1.7]	5 [2.0]	2 [3.0]	
Vein, Thrombosis	1 [3.0]				
Pancreas	(50)	(50)	(50)	(50)	
Atrophy		1 [1.0]	1 [4.0]	1 [4.0]	
Basophilic Focus			1 [1.0]		
Inflammation			1 [1.0]		
Acinus, Hyperplasia				1 [1.0]	
Duct, Cyst			1 [4.0]	2 [3.0]	
Salivary Glands	(50)	(50)	(50)	(50)	
Fibrosis	1 [1.0]				
Stomach, Forestomach	(50)	(50)	(50)	(50)	
Erosion	2 [1.0]	1 [2.0]	,	,	
Hemorrhage				1 [3.0]	
Inflammation	13 [1.8]	12 [2.4]	13 [2.6]	8 [2.1]	
Necrosis	- 1		- 1 - 1	1 [1.0]	
Ulcer	5 [1.4]	4 [2.0]	5 [2.0]	5 [2.2]	
Epithelium, Hyperplasia	14 [2.3]	14 [2.7]	17 [2.5]	11 [2.5]	
Stomach, Glandular	(50)	(50)	(50)	(50)	
Inflammation	(00)	1 [3.0]	1 [1.0]	(66)	
Mineralization		1 [0.0]	1 [2.0]		
Epithelium, Necrosis	1 [1.0]	1 [2.0]	1 [2.0]		
	(2)			(0)	
Tongue Angiectasis		(0)	(0)	(0)	
•	1 [3.0]				
Cyst	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)

Test Type: CHRONIC

Species/Strain: MICE/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 03/10/2011 AVERAGE SEVERITY GRADES[b]

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

Time Report Requested: 11:42:39 First Dose M/F: 10/26/04 / 10/25/04

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	
Tooth Dysplasia	(37) 34	(38) 36	(34) 34	(30) 26	
CARDIOVASCULAR SYSTEM					
Blood Vessel	(50)	(50)	(50)	(50)	
Inflammation	, ,	, ,	1 [2.0]		
Mineralization				1 [3.0]	
Heart	(50)	(50)	(50)	(50)	
Cardiomyopathy	8 [1.0]	7 [1.1]	10 [1.3]	13 [1.1]	
Inflammation	2 [2.0]			1 [1.0]	
Mineralization		1 [1.0]	2 [2.5]	5 [1.4]	
Atrium, Thrombosis		1 [2.0]		• •	
Valve, Thrombosis	1 [3.0]				
ENDOCRINE SYSTEM					
Adrenal Cortex	(50)	(50)	(50)	(50)	
Hypertrophy	3 [1.0]	3 [1.3]	1 [1.0]	1 [1.0]	
Adrenal Medulla	(50)	(50)	(50)	(50)	
Hyperplasia	1 [1.0]	()	()	1 [1.0]	
Islets, Pancreatic	(50)	(50)	(50)	(50)	
Hyperplasia	12 [1.5]	5 [1.2]	2 [1.0]	1 [1.0]	
Parathyroid Gland	(40)	(43)	(45)	(42)	
Amyloid Deposition	` '	, ,	1 [2.0]	,	
Pituitary Gland	(50)	(50)	(49)	(50)	
Pars Distalis, Hyperplasia	1 [1.0]	1 [1.0]	, ,	,	
Thyroid Gland	(50)	(50)	(50)	(50)	

GENERAL BODY SYSTEM

None

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)

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 03/10/2011 AVERAGE SEVERITY GRADES[b]

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

Time Report Requested: 11:42:39

First Dose M/F: 10/26/04 / 10/25/04 **Lab:** BAT

B6C3F1 MICE MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	
GENITAL SYSTEM					
Coagulating Gland	(0)	(1)	(0)	(0)	
Inflammation		1 [2.0]			
Epididymis	(50)	(50)	(50)	(50)	
Angiectasis				1 [2.0]	
Granuloma Sperm		2 [2.5]			
Inflammation				1 [2.0]	
Preputial Gland	(50)	(50)	(50)	(50)	
Atrophy	1 [4.0]		, ,	• •	
Ectasia	7 [2.0]	6 [2.0]	7 [2.0]	8 [2.1]	
Inflammation		1 [3.0]	1 [3.0]	1 [3.0]	
Prostate	(50)	(50)	(50)	(50)	
Inflammation	1 [1.0]	1 [2.0]	1 [1.0]	1 [2.0]	
Epithelium, Hyperplasia	1 [1.0]				
Seminal Vesicle	(50)	(50)	(50)	(50)	
Inflammation	1 [4.0]	1 [1.0]			
Mineralization	1 [1.0]				
Testes	(50)	(50)	(50)	(50)	
Hyperplasia, Oncocytic		1 [1.0]			
Germinal Epithelium, Degeneration		2 [1.5]	3 [1.3]		
Germinal Epithelium, Mineralization			1 [1.0]		
Interstitial Cell, Hyperplasia	1 [1.0]			1 [1.0]	
HEMATOPOIETIC SYSTEM					
Bone Marrow	(50)	(50)	(50)	(50)	
Atrophy	3 [1.7]	,	1 [1.0]	, ,	
Hyperplasia	8 [2.0]	6 [1.3]	9 [2.0]	9 [2.0]	
Necrosis	• •	• •	1 [2.0]		
Thrombosis		1 [2.0]	- •		
Lymph Node	(2)	(3)	(4)	(0)	
Lymph Node, Mandibular	(50)	(50)	(49)	(50)	
Atrophy	5 [1.8]	4 [1.5]	6 [1.3]	3 [2.0]	
Hyperplasia, Lymphoid	2 [2.5]	1 [3.0]	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)

Test Type: CHRONIC

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 03/10/2011 AVERAGE SEVERITY GRADES[b]

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

Time Report Requested: 11:42:39

First Dose M/F: 10/26/04 / 10/25/04

Lab: BAT

Route: GAVAGE Species/Strain: MICE/B6C3F1

B6C3F1 MICE MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	
Necrosis	1 [2.0]				
Lymph Node, Mesenteric	(50)	(50)	(49)	(50)	
Atrophy	13 [2.2]	9 [2.4]	14 [2.5]	15 [2.3]	
Hyperplasia, Lymphoid				2 [2.5]	
Spleen	(48)	(50)	(49)	(50)	
Atrophy	4 [2.5]	11 [2.2]	11 [2.4]	6 [1.8]	
Hematopoietic Cell Proliferation	15 [2.3]	18 [2.2]	23 [2.4]	22 [2.5]	
Hyperplasia, Lymphoid	5 [2.2]	9 [1.9]	6 [2.0]	9 [2.0]	
Necrosis, Lymphoid	1 [2.0]				
Pigmentation	38 [1.0]	34 [1.1]	25 [1.0]	44 [1.6]	
Red Pulp, Atrophy	4 [2.0]	1 [1.0]	2 [1.5]	2 [1.5]	
Thymus	(48)	(48)	(48)	(49)	
Atrophy	41 [3.1]	47 [3.2]	47 [3.1]	48 [3.0]	
Hyperplasia, Lymphoid	1 [3.0]			1 [2.0]	
Infiltration Cellular, Mast Cell				1 [2.0]	
Necrosis	2 [3.5]				
INTEGUMENTARY SYSTEM					
Skin	(50)	(50)	(50)	(50)	
Inflammation	3 [3.0]	1 [3.0]	1 [3.0]	1 [2.0]	
Ulcer	4 [3.5]	1 [3.0]	1 [4.0]	2 [3.0]	
Dermis, Fibrosis	2 [2.0]	• •		1 [4.0]	
Epidermis, Hyperplasia	1 [2.0]		1 [2.0]	1 [2.0]	
Hair Follicle, Hyperkeratosis				1 [2.0]	
MUSCULOSKELETAL SYSTEM					
Bone	(50)	(50)	(50)	(50)	
Fibrosis	1 [1.0]	(00)	(00)	(55)	
Fracture	. []	1			
Osteopetrosis		1 [2.0]			
Skeletal Muscle	(0)	(1)	(2)	(2)	
Inflammation	(0)	(1)	(-)	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)

Test Type: CHRONIC

Respiratory

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 03/10/2011 AVERAGE SEVERITY GRADES[b]

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

Time Report Requested: 11:42:39 First Dose M/F: 10/26/04 / 10/25/04

Species/Strain: MICE/B6C3F1		3.13.1.1.		Lab: BAT	
B6C3F1 MICE MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	
NERVOUS SYSTEM					
Brain	(50)	(50)	(50)	(50)	
Hemorrhage			1 [2.0]		
Hydrocephalus			1 [2.0]	1 [1.0]	
Necrosis			1 [2.0]		
Olfactory Lobe, Atrophy		1 [3.0]		5 [1.2]	
RESPIRATORY SYSTEM					
Lung	(50)	(50)	(50)	(50)	
Foreign Body	1				
Hemorrhage				1 [2.0]	
Inflammation, Chronic Active				1 [3.0]	
Alveolar Epithelium, Hyperplasia	3 [1.0]	8 [1.9]	3 [1.3]		
Alveolar Epithelium, Metaplasia	1 [1.0]		1 [2.0]		
Alveolus, Infiltration Cellular, Histiocyte	1 [2.0]	2 [1.5]	2 [2.5]	10 [1.2]	
Artery, Inflammation		1 [3.0]			
Bronchiole, Epithelium, Hyperplasia		1 [2.0]			
Bronchiole, Epithelium, Regeneration			1 [1.0]	1 [1.0]	
Bronchus, Necrosis			1 [1.0]	,	
Bronchus, Epithelium, Regeneration			1	1 [1.0]	
Mediastinum, Inflammation	1 [3.0]			,	
Perivascular, Infiltration Cellular, Lymphoid	. []		1 [2.0]		
Serosa, Inflammation	1 [3.0]		. [=.0]		
Nose	(49)	(50)	(50)	(50)	
Foreign Body	(- /	1	(/	()	
Hyperplasia		1 [1.0]			
Inflammation	13 [1.1]	12 [1.0]	10 [1.0]	20 [1.1]	
Polyp, Inflammatory	3	2	[]	[]	
Glands, Olfactory Epithelium, Dilatation	4 [1.0]	_ 11 [1.0]	7 [1.0]	48 [1.8]	
Glands, Olfactory Epithelium, Hyperplasia	4 [1.0]	9 [1.1]	7 [1.3]	49 [2.1]	
Glands, Olfactory Epithelium, Metaplasia,	5 [1.0]	5 [1.0]	6 [1.0]	48 [1.7]	

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

Species/Strain: MICE/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 03/10/2011 AVERAGE SEVERITY GRADES[b]

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

Time Report Requested: 11:42:39 First Dose M/F: 10/26/04 / 10/25/04

B6C3F1 MICE MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	<u> </u>
Glands, Respiratory Epithelium, Dilatation	17 [1.0]	19 [1.0]	13 [1.0]	41 [1.8]	
Glands, Respiratory Epithelium, Hyperplasia	4 [1.0]	2 [1.0]	2 [1.0]	11 [1.1]	
Glands, Respiratory Epithelium, Metaplasia, Respiratory	2 [1.5]	2 [1.0]	2 [1.0]	10 [1.1]	
Nasolacrimal Duct, Hyperplasia, Regenerative				4 [1.0]	
Nerve, Atrophy	2 [1.0]	7 [1.1]	4 [1.3]	42 [2.0]	
Olfactory Epithelium, Accumulation, Hyaline Droplet	12 [1.2]	14 [1.3]	10 [1.0]	4 [1.0]	
Olfactory Epithelium, Metaplasia, Respiratory	10 [1.3]	10 [1.3]	5 [1.2]	49 [2.3]	
Olfactory Epithelium, Necrosis	1 [1.0]	3 [1.3]	3 [1.0]	8 [1.5]	
Respiratory Epithelium, Accumulation, Hyaline Droplet	24 [1.1]	25 [1.2]	24 [1.2]	25 [1.2]	
Respiratory Epithelium, Hyperplasia	37 [1.2]	35 [1.4]	32 [1.1]	30 [1.3]	
Respiratory Epithelium, Necrosis		1 [1.0]	1 [1.0]	1 [2.0]	
Transitional Epithelium, Hyperplasia				1 [1.0]	
Transitional Epithelium, Necrosis				1 [2.0]	
Vomeronasal Organ, Necrosis		1 [2.0]	2 [1.0]	3 [1.0]	
Trachea	(50)	(50)	(50)	(50)	
Necrosis				1 [2.0]	
SPECIAL SENSES SYSTEM					
Ear	(1)	(0)	(0)	(0)	
External Ear, Inflammation	1 [2.0]				
External Ear, Necrosis	1 [2.0]				
Eye	(50)	(50)	(50)	(50)	
Cornea, Inflammation	3 [2.0]	1 [2.0]	4 [2.3]		
Lens, Cataract			1 [2.0]		
Optic Nerve, Atrophy		1 [2.0]			
Harderian Gland	(50)	(50)	(50)	(50)	
Atrophy			1 [2.0]		
Hyperplasia	1 [1.0]	4 [2.5]	1 [1.0]	1 [2.0]	
Zymbal's Gland	(1)	(0)	(0)	(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)

Test Type: CHRONIC

Species/Strain: MICE/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 03/10/2011 AVERAGE SEVERITY GRADES[b]

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

Time Report Requested: 11:42:39 First Dose M/F: 10/26/04 / 10/25/04

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	
URINARY SYSTEM					
Kidney	(50)	(50)	(50)	(50)	
Accumulation, Hyaline Droplet	1 [2.0]	, ,	, ,	, ,	
Infarct	3 [1.7]	2 [1.5]		2 [1.5]	
Inflammation	2 [2.5]	1 [3.0]			
Mineralization	5 [1.2]	7 [1.0]	9 [1.0]	6 [1.2]	
Nephropathy	39 [1.6]	41 [1.6]	43 [1.5]	37 [1.3]	
Pigmentation			2 [2.5]		
Cortex, Cyst	3 [1.0]	2 [1.5]	1 [1.0]	2 [1.5]	
Papilla, Necrosis	1 [3.0]	1 [2.0]			
Pelvis, Dilatation	2 [1.5]		1 [2.0]	1 [2.0]	
Renal Tubule, Dilatation				1 [4.0]	
Renal Tubule, Hyperplasia				1 [1.0]	
Renal Tubule, Necrosis			2 [2.0]	1 [1.0]	
Ureter	(1)	(0)	(0)	(0)	
Inflammation	1 [2.0]				
Necrosis	1 [2.0]				
Urethra	(0)	(1)	(0)	(0)	
Inflammation		1 [3.0]			
Necrosis		1 [1.0]			
Urinary Bladder	(50)	(50)	(50)	(50)	
Calculus Gross Observation				2	
Inflammation				1 [4.0]	
Transitional Epithelium, Hyperplasia				1 [3.0]	

*** 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)

Species/Strain: MICE/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 03/10/2011 AVERAGE SEVERITY GRADES[b]

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

Time Report Requested: 11:42:39 First Dose M/F: 10/26/04 / 10/25/04

Species/Strain. MICE/DOCSF1					Lab. DAT	
B6C3F1 MICE FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG		
Disposition Summary						
•	50	50	50	50		
Animals Initially In Study Early Deaths	50	50	50	50		
Dosing Accident		1	1	2		
Moribund Sacrifice	3	1	7	10		
Natural Death	4	8	3	6		
Survivors	7	· ·	J	· ·		
Terminal Sacrifice	43	40	39	32		
Animals Examined Microscopically	50	50	50	50		
ALIMENTARY SYSTEM						
Esophagus	(50)	(50)	(50)	(50)		
Foreign Body				1		
Perforation			1	1		
Epithelium, Inflammation				1 [1.0]		
Muscularis, Degeneration			1 [1.0]	1 [1.0]		
Muscularis, Inflammation	1 [1.0]					
Periesophageal Tissue, Hemorrhage			1 [4.0]			
Gallbladder	(50)	(50)	(49)	(49)		
Intestine Large, Cecum	(50)	(50)	(50)	(50)		
Fibrosis		1 [3.0]				
Lymphoid Tissue, Hyperplasia, Lymphoid	1 [3.0]					
Intestine Large, Colon	(50)	(50)	(50)	(50)		
Fibrosis		1 [3.0]				
Intestine Large, Rectum	(50)	(50)	(50)	(50)		
Intestine Small, Duodenum	(50)	(50)	(50)	(50)		
Intestine Small, Ileum	(50)	(50)	(50)	(50)		
Fibrosis		1 [3.0]				
Intestine Small, Jejunum	(50)	(50)	(50)	(50)		
Fibrosis		1 [3.0]				
Peyer's Patch, Hyperplasia, Lymphoid		1 [4.0]				
Liver	(50)	(50)	(50)	(50)		
Angiectasis	1 [2.0]					
Basophilic Focus	7	5	9	11		

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)

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 03/10/2011 AVERAGE SEVERITY GRADES[b]

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

Time Report Requested: 11:42:39 First Dose M/F: 10/26/04 / 10/25/04

Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	
Clear Call Facus		2	2	2	
Clear Cell Focus	20	2	2	3	
Eosinophilic Focus	20	18	45	38	
Fatty Change	1 [4.0]	4 [4 0]	0 [4 0]	8 [2.5]	
Hematopoietic Cell Proliferation	2 [1.0]	4 [1.3]	2 [1.0]	3 [2.0]	
Inflammation, Chronic Active	39 [1.1]	27 [1.0]	33 [1.1]	35 [1.0]	
Mineralization	•	•	7	1 [1.0]	
Mixed Cell Focus	3	9	7	7	
Necrosis	1 [2.0]	8 [1.5]	4 [2.0]	10 [1.8]	
Pigmentation	1 [3.0]	1 [1.0]	1 [1.0]	4 [1.0]	
Bile Duct, Cyst	2 [2.0]	1 [2.0]	1 [3.0]	3 [3.0]	
Hepatocyte, Hypertrophy		11 [1.6]	10 [1.6]	17 [1.9]	
Kupffer Cell, Hyperplasia		1 [2.0]		1 [2.0]	
Oval Cell, Hyperplasia				2 [1.5]	
Serosa, Fibrosis		1 [3.0]			
Serosa, Inflammation, Chronic Active		1 [2.0]			
Mesentery	(3)	(8)	(9)	(6)	
Inflammation, Chronic		1 [4.0]			
Fat, Necrosis	3 [2.0]	5 [2.4]	9 [2.8]	6 [2.0]	
Pancreas	(50)	(50)	(50)	(50)	
Atrophy	1 [3.0]		2 [2.0]		
Acinus, Hyperplasia				1 [1.0]	
Acinus, Necrosis				1 [2.0]	
Duct, Cyst			2 [3.5]		
Salivary Glands	(50)	(50)	(50)	(48)	
Atrophy				1 [1.0]	
Fibrosis				1 [2.0]	
Stomach, Forestomach	(50)	(50)	(50)	(50)	
Erosion		1 [1.0]		2 [1.5]	
Fibrosis		1 [3.0]			
Inflammation	3 [3.0]	4 [2.0]	7 [2.3]	16 [2.3]	
Necrosis	1 [1.0]				
Ulcer	2 [2.0]	2 [2.0]	4 [1.3]	7 [1.6]	
Epithelium, Cyst	,	1 [1.0]	,	1 [2.0]	
Epithelium, Hyperplasia	3 [2.7]	5 [2.8]	12 [2.2]	17 [2.6]	
Stomach, Glandular	(50)	(50)	(50)	(50)	
Mineralization	1 [1.0]	(55)	(55)	(00)	

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

Species/Strain: MICE/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 03/10/2011 AVERAGE SEVERITY GRADES[b]

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

Time Report Requested: 11:42:39

First Dose M/F: 10/26/04 / 10/25/04

B6C3F1 MICE FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	
Epithelium, Necrosis	1 [1.0]				
Glands, Dysplasia	1 [1.0]			1 [1.0]	
	(0)	(0)	(0)	(1)	
Tongue Cyst	(0)	(0)	(0)	1 [3.0]	
Tooth	(42)	(10)	(7)		
	(13) 13	(10)	(7)	(4)	
Dysplasia		10	4	4	
Peridontal Tissue, Pulp, Inflammation	1 [2.0]				
CARDIOVASCULAR SYSTEM					
Blood Vessel	(50)	(49)	(50)	(50)	
Embolus Bacterial		1 [2.0]			
Inflammation				3 [1.7]	
Media, Pulmonary Artery, Hyperplasia		1 [2.0]			
Heart	(50)	(50)	(50)	(50)	
Cardiomyopathy	5 [1.2]	2 [1.0]	4 [1.3]	2 [1.0]	
Inflammation				1 [3.0]	
Mineralization	1 [1.0]	2 [1.0]	1 [3.0]	5 [2.8]	
Necrosis			2 [2.5]		
Epicardium, Fibrosis				1 [2.0]	
Valve, Thrombosis		1 [1.0]	1 [2.0]		
Ventricle, Thrombosis			1 [3.0]		
ENDOCRINE SYSTEM					
Adrenal Cortex	(50)	(50)	(50)	(50)	
Angiectasis		1 [2.0]			
Necrosis			2 [1.5]		
Vacuolization Cytoplasmic			1 [4.0]		
Adrenal Medulla	(50)	(50)	(50)	(50)	
Hyperplasia	3 [2.3]	. ,	, ,	` ,	
Necrosis			1 [2.0]		
Islets, Pancreatic	(50)	(50)	(50)	(50)	
Hyperplasia	, ,	1 [1.0]	, ,	2 [1.0]	
Parathyroid Gland	(48)	(38)	(38)	(34)	

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

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 03/10/2011 AVERAGE SEVERITY GRADES[b]

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

Time Report Requested: 11:42:39 First Dose M/F: 10/26/04 / 10/25/04

Lab: BAT

Route: GAVAGE
Species/Strain: MICE/B6C3F1

B6C3F1 MICE FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	
Pituitary Gland	(48)	(50)	(50)	(49)	
Pars Distalis, Angiectasis				1 [1.0]	
Pars Distalis, Hyperplasia	5 [2.2]	3 [1.3]	3 [2.0]	3 [1.7]	
Pars Intermedia, Hyperplasia	1 [1.0]	1 [2.0]	1 [3.0]	2 [2.0]	
Thyroid Gland	(50)	(50)	(50)	(50)	
Atrophy		2 [2.0]			
Inflammation		1 [2.0]	1 [1.0]		
Follicle, Degeneration			1 [1.0]		
Follicular Cell, Hyperplasia		1 [3.0]			
Follicular Cell, Hypertrophy			1 [3.0]		

GENERAL BODY SYSTEM

None

GENI	TAL	SYS	TEM

Clitoral Gland	(50)	(50)	(50)	(49)
Ovary	(50)	(49)	(50)	(50)
Angiectasis	2 [4.0]		1 [2.0]	1 [3.0]
Atrophy	40 [3.6]	43 [3.3]	40 [3.6]	45 [3.7]
Cyst	4 [2.0]	6 [2.0]	4 [3.5]	2 [4.0]
Hemorrhage	2 [3.5]		1 [4.0]	
Inflammation		2 [4.0]		
Thrombosis	2 [4.0]			3 [3.3]
Oviduct	(0)	(1)	(0)	(0)
Uterus	(50)	(50)	(50)	(50)
Angiectasis	2 [2.5]	2 [3.0]	1 [3.0]	
Atrophy				1 [3.0]
Dilatation	13 [2.5]	13 [3.2]	6 [3.3]	10 [2.6]
Inflammation	1 [2.0]	3 [2.7]	2 [3.0]	
Thrombosis		1 [4.0]	1 [1.0]	
Endometrium, Hyperplasia, Cystic	25 [1.8]	17 [2.0]	11 [2.0]	9 [1.7]

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

Species/Strain: MICE/B6C3F1

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 03/10/2011 AVERAGE SEVERITY GRADES[b]

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

Time Report Requested: 11:42:39

First Dose M/F: 10/26/04 / 10/25/04

Species/Strain. MIGE/BOGSF1				Lab. DAT		
B6C3F1 MICE FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG		
HEMATOPOIETIC SYSTEM						
Bone Marrow	(50)	(50)	(50)	(49)		
Atrophy	1 [1.0]	2 [1.5]	2 [2.0]	3 [1.3]		
Hyperplasia	5 [2.2]	14 [1.9]	15 [2.1]	14 [2.1]		
Lymph Node	(7)	(3)	(5)	(4)		
Lumbar, Hemorrhage				1 [3.0]		
Mediastinal, Hyperplasia, Lymphoid			1 [3.0]			
Renal, Ectasia	2 [4.0]					
Renal, Hemorrhage		1 [4.0]				
Lymph Node, Mandibular	(50)	(50)	(50)	(48)		
Atrophy	1 [3.0]	4 [3.0]	5 [2.0]	5 [2.4]		
Hyperplasia, Lymphoid	3 [2.3]	5 [2.0]		3 [2.0]		
Hyperplasia, Plasma Cell		1 [3.0]				
Lymph Node, Mesenteric	(49)	(49)	(49)	(50)		
Angiectasis	1 [2.0]	, ,		, ,		
Atrophy	1 [2.0]	5 [2.0]	5 [2.2]	12 [2.9]		
Hyperplasia, Lymphoid	7 [2.3]	3 [3.7]	1 [2.0]			
Infiltration Cellular, Plasma Cell			1 [3.0]			
Inflammation, Granulomatous				1 [4.0]		
Necrosis				1 [1.0]		
Spleen	(49)	(49)	(49)	(50)		
Atrophy	3 [1.7]	8 [1.8]	1 [1.0]	6 [2.5]		
Hematopoietic Cell Proliferation	18 [2.1]	23 [2.1]	24 [2.3]	21 [2.1]		
Hyperplasia, Lymphoid	14 [2.1]	15 [1.7]	12 [2.0]	15 [1.8]		
Infarct		1 [2.0]				
Infiltration Cellular, Plasma Cell	1 [3.0]					
Pigmentation	37 [1.1]	39 [1.0]	33 [1.2]	43 [1.1]		
Capsule, Fibrosis		1 [3.0]				
Red Pulp, Atrophy				5 [3.2]		
Thymus	(50)	(50)	(48)	(48)		
Atrophy	46 [2.4]	46 [2.5]	39 [2.6]	43 [2.7]		
Hyperplasia, Histiocytic		1 [2.0]				
Hyperplasia, Lymphoid	3 [1.7]	1				
21 1 2 1	- L J					

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

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 03/10/2011 AVERAGE SEVERITY GRADES[b]

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

Time Report Requested: 11:42:39

First Dose M/F: 10/26/04 / 10/25/04

Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	
INTEGUMENTARY SYSTEM					
Mammary Gland	(50)	(50)	(50)	(50)	
Skin	(50)	(50)	(50)	(50)	
Hemorrhage			1 [4.0]		
Inflammation	1 [2.0]	2 [3.0]		1 [3.0]	
Ulcer		2 [3.5]	2 [2.0]	1 [3.0]	
Dermis, Fibrosis		1 [2.0]	1 [2.0]		
Epidermis, Hyperplasia	1 [2.0]		2 [2.5]		
Sebaceous Gland, Hyperplasia			1 [2.0]		
MUSCULOSKELETAL SYSTEM					
Bone	(50)	(50)	(50)	(50)	
Fibro-Osseous Lesion	3 [1.7]	5 [1.6]	6 [1.5]	11 [1.5]	
Fracture				1	
Osteopetrosis	1 [1.0]	1 [2.0]		1 [1.0]	
Skeletal Muscle	(0)	(2)	(1)	(2)	
Inflammation	, ,	1 [3.0]	. ,	`,	
NERVOUS SYSTEM					
Brain	(50)	(50)	(50)	(49)	
Necrosis	1 [3.0]	()	1 [1.0]	(- /	
Olfactory Lobe, Atrophy			• •	8 [1.6]	
Peripheral Nerve	(0)	(0)	(1)	(0)	
Spinal Cord	(0)	(0)	(1)	(0)	
RESPIRATORY SYSTEM					
Lung	(50)	(50)	(50)	(50)	
Foreign Body	()	1	(/	2	
Hemorrhage		•	1 [1.0]	-	
Inflammation		2 [2.5]	. []	2 [4.0]	

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)

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 03/10/2011 AVERAGE SEVERITY GRADES[b]

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

Time Report Requested: 11:42:39 First Dose M/F: 10/26/04 / 10/25/04

Lab: BAT

Route: GAVAGE Species/Strain: MICE/B6C3F1

B6C3F1 MICE FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	
Alveolar Epithelium, Hyperplasia	2 [3.0]	3 [2.3]	8 [1.5]	2 [1.0]	
Alveolus, Infiltration Cellular, Histiocyte	2 [3.0] 1 [1.0]	3 [2.3]	0 [1.0]	7 [1.4]	
Bronchiole, Epithelium, Necrosis	1 [1.0]			7 [1. 4] 1 [1.0]	
Bronchiole, Epithelium, Regeneration				5 [1.8]	
Bronchus, Necrosis				5 [1.6] 5 [1.6]	
Bronchus, Epithelium, Regeneration				5 [1.0] 5 [2.0]	
Nose	(50)	(49)	(50)	(50)	
Inflammation	3 [1.0]	7 [1.0]	3 [1.0]	32 [1.3]	
	3 [1.0]	7 [1.0]	3 [1.0]		
Glands, Lateral Wall, Dilatation	12 [1 0]	4.4.[4.4]	10.11.00	2 [1.5]	
Glands, Olfactory Epithelium, Dilatation	13 [1.0]	14 [1.1]	20 [1.0]	46 [2.3]	
Glands, Olfactory Epithelium, Hyperplasia	2 [1.0]	14 [1.0]	14 [1.1]	50 [2.2]	
Glands, Olfactory Epithelium, Metaplasia, Respiratory	2 [1.0]	5 [1.0]	7 [1.0]	44 [2.3]	
Glands, Respiratory Epithelium, Dilatation	10 [1.0]	17 [1.0]	15 [1.1]	33 [1.4]	
Glands, Respiratory Epithelium, Hyperplasia		2 [1.0]	12 [1.2]	13 [1.2]	
Glands, Respiratory Epithelium, Metaplasia, Respiratory			10 [1.0]	10 [1.4]	
Nasolacrimal Duct, Hyperplasia, Regenerative				4 [2.5]	
Nerve, Atrophy				41 [2.3]	
Olfactory Epithelium, Accumulation, Hyaline Droplet	2 [1.0]	5 [1.0]	8 [1.0]	15 [1.1]	
Olfactory Epithelium, Degeneration				1 [1.0]	
Olfactory Epithelium, Metaplasia, Respiratory	1 [1.0]	6 [1.0]	14 [1.1]	46 [2.9]	
Olfactory Epithelium, Necrosis			3 [1.3]	6 [2.3]	
Respiratory Epithelium, Accumulation, Hyaline Droplet	33 [1.2]	34 [1.1]	39 [1.2]	36 [1.1]	
Respiratory Epithelium, Hyperplasia	11 [1.0]	15 [1.0]	11 [1.0]	30 [1.2]	
Respiratory Epithelium, Hyperplasia, Regenerative				3 [1.3]	
Respiratory Epithelium, Necrosis				5 [2.0]	
Transitional Epithelium, Hyperplasia, Regenerative				1 [2.0]	
Transitional Epithelium, Necrosis				2 [2.0]	
Vomeronasal Organ, Necrosis				4 [1.5]	
Trachea	(50)	(50)	(50)	(50)	
Inflammation	· · /	\·-/	V - /	1 [2.0]	
Glands, Hyperplasia				1 [2.0]	

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Test Type: CHRONIC

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 03/10/2011 AVERAGE SEVERITY GRADES[b]

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

Time Report Requested: 11:42:39

First Dose M/F: 10/26/04 / 10/25/04

Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG	
SPECIAL SENSES SYSTEM					
Eye	(50)	(50)	(50)	(49)	
Fibrosis			1 [2.0]		
Cornea, Inflammation		1 [2.0]	1 [3.0]	3 [1.7]	
Lens, Cataract			1 [4.0]		
Optic Nerve, Atrophy			1 [2.0]		
Harderian Gland	(50)	(50)	(50)	(49)	
Fibrosis		1 [2.0]			
Hyperplasia	4 [2.8]	2 [2.5]		2 [2.5]	
Inflammation	1 [3.0]				
URINARY SYSTEM					
Kidney	(50)	(50)	(50)	(50)	
Accumulation, Hyaline Droplet	,	2 [2.5]	1 [4.0]	, ,	
Infarct	4 [1.8]	3 [1.3]	4 [1.5]		
Inflammation			1 [2.0]	2 [2.5]	
Mineralization		1 [1.0]		3 [1.0]	
Nephropathy	13 [1.0]	15 [1.2]	15 [1.1]	17 [1.2]	
Cortex, Cyst				1 [1.0]	
Papilla, Necrosis				1 [3.0]	
Renal Tubule, Necrosis	1 [4.0]		2 [3.0]	2 [1.5]	
Urinary Bladder	(50)	(50)	(50)	(50)	

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

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