

Experiment Number: 20107-02
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Mouse/B6C3F1

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

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

Date Report Requested: 10/21/2014
Time Report Requested: 09:11:48
First Dose M/F: NA / NA
Lab: BAT

C Number:	C20107
Lock Date:	07/14/2004
Cage Range:	All
Date Range:	All
Reasons For Removal:	All
Removal Date Range:	All
Treatment Groups:	All
Study Gender:	Both
PWG Approval Date	NONE

Experiment Number: 20107-02

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Mouse/B6C3F1

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

Test Compound: N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 10/21/2014

Time Report Requested: 09:11:48

First Dose M/F: NA / NA

Lab: BAT

B6C3F1 Mouse MALE	0	MG/KG	15	MG/KG	30	MG/KG	60	MG/KG	125	MG/KG	250	MG/KG
Disposition Summary												
Animals Initially In Study	10		10		10		10		10		10	
Early Deaths												
Moribund Sacrifice									1			
Natural Death									2		9	
Survivors												
Terminal Sacrifice	10		10		10		10		7		1	
Animals Examined Microscopically	10		10		10		10		10		10	
ALIMENTARY SYSTEM												
Esophagus	(10)		(0)		(0)		(0)		(10)		(10)	
Epithelium, Degeneration									1 [2.0]			
Gallbladder	(10)		(0)		(0)		(0)		(10)		(10)	
Intestine Large, Cecum	(10)		(0)		(0)		(0)		(10)		(10)	
Intestine Large, Colon	(10)		(0)		(0)		(0)		(10)		(10)	
Intestine Large, Rectum	(10)		(0)		(0)		(0)		(10)		(10)	
Intestine Small, Duodenum	(10)		(0)		(0)		(0)		(10)		(10)	
Intestine Small, Ileum	(10)		(0)		(0)		(0)		(10)		(10)	
Intestine Small, Jejunum	(10)		(0)		(0)		(0)		(10)		(10)	
Liver	(10)		(10)		(10)		(10)		(10)		(10)	
Hematopoietic Cell Proliferation					1 [2.0]		1 [2.0]					
Hepatocyte, Fatty Change											8 [2.3]	
Hepatocyte, Necrosis											4 [2.0]	
Hepatocyte, Vacuolization Cytoplasmic	9 [2.0]		10 [3.0]		9 [2.6]		10 [2.6]		7 [2.6]		1 [3.0]	
Inflammation, Chronic Active	9 [1.0]		10 [1.1]		10 [1.2]		10 [1.1]		7 [1.3]		1 [1.0]	
Tension Lipidosis											1 [2.0]	
Mesentery	(0)		(0)		(0)		(0)		(1)		(0)	
Artery, Fat, Thrombosis									1 [4.0]			
Fat, Inflammation, Chronic Active									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)

Experiment Number: 20107-02

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Mouse/B6C3F1

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

Test Compound: N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 10/21/2014

Time Report Requested: 09:11:48

First Dose M/F: NA / NA

Lab: BAT

B6C3F1 Mouse MALE	0	MG/KG	15	MG/KG	30	MG/KG	60	MG/KG	125	MG/KG	250	MG/KG
Fat, Necrosis									1 [4.0]			
Pancreas	(10)		(0)		(0)		(0)		(10)		(10)	
Salivary Glands	(10)		(0)		(0)		(0)		(10)		(10)	
Stomach, Forestomach	(10)		(0)		(0)		(0)		(10)		(10)	
Stomach, Glandular	(10)		(0)		(0)		(0)		(10)		(10)	
Inflammation, Chronic Active	1 [1.0]											
Tooth	(1)		(0)		(0)		(0)		(0)		(0)	
Malformation	1 [2.0]											
CARDIOVASCULAR SYSTEM												
Blood Vessel	(10)		(0)		(0)		(0)		(10)		(10)	
Heart	(10)		(0)		(0)		(0)		(10)		(10)	
Mineralization									1 [1.0]		2 [1.0]	
ENDOCRINE SYSTEM												
Adrenal Cortex	(10)		(0)		(0)		(0)		(10)		(9)	
Accessory Adrenal Cortical Nodule									1 [1.0]		1 [2.0]	
Subcapsular, Hyperplasia	2 [1.0]								2 [1.0]			
Adrenal Medulla	(10)		(0)		(0)		(0)		(10)		(9)	
Islets, Pancreatic	(10)		(0)		(0)		(0)		(10)		(10)	
Parathyroid Gland	(10)		(0)		(0)		(0)		(7)		(9)	
Pituitary Gland	(10)		(0)		(0)		(0)		(10)		(9)	
Thyroid Gland	(10)		(0)		(0)		(0)		(10)		(10)	
GENERAL BODY SYSTEM												
None												
GENITAL SYSTEM												
Coagulating Gland	(0)		(0)		(0)		(0)		(1)		(0)	
Inflammation, Chronic Active									1 [2.0]			
Epididymis	(10)		(0)		(0)		(0)		(10)		(10)	

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)

Experiment Number: 20107-02

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Mouse/B6C3F1

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

Test Compound: N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 10/21/2014

Time Report Requested: 09:11:48

First Dose M/F: NA / NA

Lab: BAT

B6C3F1 Mouse MALE	0	MG/KG	15	MG/KG	30	MG/KG	60	MG/KG	125	MG/KG	250	MG/KG
Inflammation, Chronic Active Necrosis									1 [3.0]			
Preputial Gland	(10)		(0)		(0)		(0)		(10)		(10)	
Inflammation, Chronic Active Necrosis									1 [2.0]			
Prostate	(10)		(0)		(0)		(0)		(10)		(10)	
Inflammation, Chronic Active Necrosis									1 [2.0]			
Seminal Vesicle	(10)		(0)		(0)		(0)		(10)		(10)	
Inflammation, Chronic Active									1 [2.0]			
Testes	(10)		(0)		(0)		(0)		(10)		(10)	
Germinal Epith, Degeneration									1 [2.0]			
HEMATOPOIETIC SYSTEM												
Bone Marrow	(10)		(10)		(10)		(10)		(10)		(10)	
Lymph Node	(0)		(0)		(0)		(0)		(0)		(2)	
Bronchial, Atrophy											1 [2.0]	
Inguinal, Necrosis, Lymphoid											1 [2.0]	
Lymph Node, Mandibular	(10)		(10)		(10)		(10)		(10)		(9)	
Atrophy									2 [2.0]		2 [2.0]	
Necrosis, Lymphoid											5 [2.0]	
Lymph Node, Mesenteric	(10)		(10)		(10)		(10)		(10)		(9)	
Atrophy									2 [3.0]		2 [2.0]	
Necrosis, Lymphoid											5 [1.8]	
Spleen	(10)		(10)		(10)		(10)		(10)		(10)	
Atrophy									3 [3.3]		8 [3.0]	
Hematopoietic Cell Proliferation									1 [2.0]			
Lymph Follic, Necrosis											6 [2.2]	
Thymus	(10)		(10)		(10)		(10)		(10)		(10)	
Atrophy									3 [3.3]		3 [3.3]	

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)

Experiment Number: 20107-02

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Mouse/B6C3F1

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

Test Compound: N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 10/21/2014

Time Report Requested: 09:11:48

First Dose M/F: NA / NA

Lab: BAT

B6C3F1 Mouse MALE	0	MG/KG	15	MG/KG	30	MG/KG	60	MG/KG	125	MG/KG	250	MG/KG
Thymocyte, Necrosis									8 [2.0]		7 [3.7]	
INTEGUMENTARY SYSTEM												
Skin	(10)		(0)		(0)		(0)		(10)		(10)	
Subcut Tiss, Inflammation, Chronic Active									1 [2.0]			
Subcut Tiss, Necrosis									1 [4.0]			
MUSCULOSKELETAL SYSTEM												
Bone	(10)		(0)		(0)		(0)		(10)		(10)	
NERVOUS SYSTEM												
Brain	(10)		(0)		(0)		(0)		(10)		(10)	
RESPIRATORY SYSTEM												
Lung	(10)		(10)		(10)		(10)		(10)		(10)	
Alveolus, Infiltration Cellular, Histiocyte									2 [2.0]			
Bronchiole, Epithelium, Degeneration							1 [2.0]		10 [2.8]		8 [3.0]	
Bronchiole, Epithelium, Regeneration							1 [2.0]		9 [2.7]		3 [3.3]	
Bronchus, Epithelium, Regeneration									1 [3.0]			
Peribronchiolr, Inflammation, Chronic Active									9 [2.2]		6 [1.7]	
Nose	(10)		(10)		(10)		(10)		(10)		(10)	
Foreign Body											1	
Glands, Hyperplasia									7 [2.0]		1 [2.0]	
Inflammation, Chronic Active									1 [1.0]		8 [2.3]	
Olfactory Epi, Degeneration									9 [2.9]		2 [2.0]	
Olfactory Epi, Metaplasia									6 [2.3]		1 [4.0]	
Olfactory Epi, Necrosis											1 [4.0]	
Respirat Epith, Degeneration									1 [2.0]		1 [2.0]	
Respirat Epith, Necrosis											1 [4.0]	
Trachea	(10)		(10)		(10)		(10)		(10)		(10)	
Epithelium, Degeneration									2 [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)

Experiment Number: 20107-02
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
 AVERAGE SEVERITY GRADES[b]**
 Test Compound: N,N-Dimethyl-p-toluidine
 CAS Number: 99-97-8

Date Report Requested: 10/21/2014
 Time Report Requested: 09:11:48
 First Dose M/F: NA / NA
 Lab: BAT

B6C3F1 Mouse MALE	0 MG/KG	15 MG/KG	30 MG/KG	60 MG/KG	125 MG/KG	250 MG/KG
Epithelium, Hyperplasia					1 [4.0]	
Epithelium, Necrosis					2 [4.0]	8 [4.0]
Inflammation, Chronic						1 [2.0]
SPECIAL SENSES SYSTEM						
Eye	(10)	(0)	(0)	(0)	(10)	(10)
Harderian Gland	(10)	(0)	(0)	(0)	(10)	(10)
URINARY SYSTEM						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic Active	1 [1.0]				1 [1.0]	1 [2.0]
Mineralization	1 [1.0]				1 [1.0]	1 [1.0]
Nephropathy	1 [1.0]				1 [1.0]	2 [1.0]
Urinary Bladder	(10)	(0)	(0)	(0)	(10)	(10)

END OF MALE DATA

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)

Experiment Number: 20107-02

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Mouse/B6C3F1

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

Test Compound: N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 10/21/2014

Time Report Requested: 09:11:49

First Dose M/F: NA / NA

Lab: BAT

B6C3F1 Mouse FEMALE	0	MG/KG	15	MG/KG	30	MG/KG	60	MG/KG	125	MG/KG	250	MG/KG
Disposition Summary												
Animals Initially In Study	10		10		10		10		10		10	
Early Deaths												
Moribund Sacrifice												1
Natural Death									2			9
Survivors												
Terminal Sacrifice	10		10		10		10		8			
Animals Examined Microscopically	10		10		10		10		10			10
ALIMENTARY SYSTEM												
Esophagus	(10)		(0)		(0)		(0)		(10)		(10)	
Gallbladder	(10)		(0)		(0)		(0)		(10)		(10)	
Intestine Large, Cecum	(10)		(0)		(0)		(0)		(10)		(10)	
Intestine Large, Colon	(10)		(0)		(0)		(0)		(10)		(10)	
Intestine Large, Rectum	(10)		(0)		(0)		(0)		(10)		(10)	
Intestine Small, Duodenum	(10)		(0)		(0)		(0)		(10)		(10)	
Intestine Small, Ileum	(10)		(0)		(0)		(0)		(10)		(10)	
Intestine Small, Jejunum	(10)		(0)		(0)		(0)		(10)		(10)	
Liver	(10)		(10)		(10)		(10)		(10)		(10)	
Hepatocyte, Fatty Change												9 [2.7]
Hepatocyte, Necrosis	3 [1.3]		1 [1.0]						1 [2.0]		4 [2.3]	
Hepatocyte, Vacuolization Cytoplasmic	10 [1.0]		10 [2.2]		9 [2.1]		9 [2.3]		8 [2.6]			
Inflammation, Chronic Active	10 [1.1]		10 [1.0]		10 [1.0]		10 [1.0]		7 [1.0]		1 [1.0]	
Tension Lipidosis											1 [3.0]	
Pancreas	(10)		(0)		(0)		(0)		(10)		(10)	
Salivary Glands	(10)		(0)		(0)		(0)		(10)		(10)	
Stomach, Forestomach	(10)		(0)		(0)		(0)		(10)		(10)	
Stomach, Glandular	(10)		(0)		(0)		(0)		(10)		(10)	
CARDIOVASCULAR 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)

Experiment Number: 20107-02

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Mouse/B6C3F1

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

Test Compound: N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 10/21/2014

Time Report Requested: 09:11:49

First Dose M/F: NA / NA

Lab: BAT

B6C3F1 Mouse FEMALE	0	MG/KG	15	MG/KG	30	MG/KG	60	MG/KG	125	MG/KG	250	MG/KG
Blood Vessel	(10)		(0)		(0)		(0)		(10)		(10)	
Heart	(10)		(0)		(0)		(0)		(10)		(10)	
Mineralization											2 [1.0]	
ENDOCRINE SYSTEM												
Adrenal Cortex	(10)		(0)		(0)		(0)		(10)		(10)	
Accessory Adrenal Cortical Nodule	1											
Subcapsular, Hyperplasia	10 [1.4]								8 [1.8]			
Adrenal Medulla	(10)		(0)		(0)		(0)		(10)		(10)	
Islets, Pancreatic	(10)		(0)		(0)		(0)		(10)		(10)	
Parathyroid Gland	(9)		(0)		(0)		(0)		(7)		(6)	
Pituitary Gland	(10)		(0)		(0)		(0)		(10)		(9)	
Thyroid Gland	(10)		(0)		(0)		(0)		(10)		(10)	
GENERAL BODY SYSTEM												
None												
GENITAL SYSTEM												
Clitoral Gland	(10)		(0)		(0)		(0)		(10)		(10)	
Ovary	(10)		(0)		(0)		(0)		(10)		(10)	
Cyst	1											
Uterus	(10)		(0)		(0)		(0)		(10)		(10)	
HEMATOPOIETIC SYSTEM												
Bone Marrow	(10)		(10)		(10)		(10)		(10)		(10)	
Lymph Node	(0)		(0)		(0)		(0)		(0)		(3)	
Inguinal, Necrosis, Lymphoid											2 [2.5]	
Renal, Necrosis, Lymphoid											1 [2.0]	
Lymph Node, Mandibular	(10)		(10)		(10)		(10)		(10)		(8)	
Atrophy											3 [2.7]	
Necrosis, Lymphoid									3 [1.7]		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)

Experiment Number: 20107-02

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Mouse/B6C3F1

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

Test Compound: N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 10/21/2014

Time Report Requested: 09:11:49

First Dose M/F: NA / NA

Lab: BAT

B6C3F1 Mouse FEMALE	0	MG/KG	15	MG/KG	30	MG/KG	60	MG/KG	125	MG/KG	250	MG/KG
Lymph Node, Mesenteric Atrophy	(10)		(10)		(10)		(10)		(10)		(9)	
Necrosis, Lymphoid									2 [2.0]		4 [2.3]	
Spleen Atrophy	(10)		(10)		(10)		(10)		(10)		(10)	
Hematopoietic Cell Proliferation							1 [2.0]		1 [2.0]		7 [2.6]	
Lymph Follic, Necrosis									2 [2.0]		6 [2.0]	
Thymus Atrophy	(10)		(10)		(10)		(10)		(10)		(10)	
Inflammation, Chronic Active	1 [1.0]								2 [3.0]		6 [3.0]	
Thymocyte, Necrosis					1 [1.0]				10 [2.0]		8 [3.1]	
INTEGUMENTARY SYSTEM												
Mammary Gland	(10)		(0)		(0)		(0)		(10)		(10)	
Skin	(10)		(0)		(0)		(0)		(10)		(10)	
MUSCULOSKELETAL SYSTEM												
Bone	(10)		(0)		(0)		(0)		(10)		(10)	
Skeletal Muscle	(0)		(0)		(0)		(0)		(0)		(1)	
Inflammation, Chronic Active											1 [1.0]	
NERVOUS SYSTEM												
Brain	(10)		(0)		(0)		(0)		(10)		(10)	
RESPIRATORY SYSTEM												
Lung	(10)		(10)		(10)		(10)		(10)		(10)	
Alveolus, Infiltration Cellular, Histiocyte									7 [2.0]			
Bronchiole, Epithelium, Degeneration									6 [2.5]		9 [2.6]	
Bronchiole, Epithelium, Regeneration					1 [2.0]		1 [1.0]		7 [3.1]			
Bronchus, Epithelium, Degeneration											1 [2.0]	
Peribronchiolr, Inflammation, Chronic Active			1 [2.0]		1 [2.0]		1 [2.0]		10 [2.3]		10 [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)

Experiment Number: 20107-02

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Mouse/B6C3F1

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

Test Compound: N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 10/21/2014

Time Report Requested: 09:11:49

First Dose M/F: NA / NA

Lab: BAT

B6C3F1 Mouse FEMALE	0	MG/KG	15	MG/KG	30	MG/KG	60	MG/KG	125	MG/KG	250	MG/KG
Nose	(10)		(10)		(10)		(10)		(10)		(10)	
Glands, Dilatation	2 [2.0]											
Glands, Hyperplasia									7 [2.1]			
Inflammation, Chronic Active									1 [2.0]		8 [2.0]	
Olfactory Epi, Degeneration							5 [1.8]		8 [2.5]			
Olfactory Epi, Metaplasia									4 [2.5]			
Trachea	(10)		(10)		(10)		(10)		(10)		(10)	
Epithelium, Necrosis									2 [4.0]		10 [4.0]	
SPECIAL SENSES SYSTEM												
Eye	(10)		(0)		(0)		(0)		(10)		(10)	
Cornea, Inflammation, Chronic Active											2 [2.0]	
Harderian Gland	(9)		(0)		(0)		(0)		(10)		(10)	
URINARY SYSTEM												
Kidney	(10)		(10)		(10)		(10)		(10)		(10)	
Inflammation, Chronic Active	2 [1.0]											
Urinary Bladder	(10)		(0)		(0)		(0)		(10)		(9)	

**** 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)