

**TDMS No.** 20107 - 04  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

**CAS Number:** 99-97-8

**Date Report Requested:** 03/10/2011

**Time Report Requested:** 11:42:39

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

**Lab:** BAT

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

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## SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF N,N-DIMETHYL-P-TOLUIDINE

### MALE MICE

#### Organ

Bone Marrow  
Brain: Olfactory Lobe  
Esophagus: Periesophageal Tissue  
Eye: Cornea  
Heart  
Islets, Pancreatic  
Kidney  
Liver  
  
Liver: Hepatocyte  
Lung: Alveolar Epithelium  
Lung: Alveolus  
Lymph Node, Mesenteric  
Mesentery: Fat  
Nose  
  
Nose: Glands, Respiratory Epithelium  
  
Nose: Nasolacrimal Duct  
Nose: Nerve  
Nose: Olfactory Epithelium  
  
Nose: Olfactory Epithelium, Glands

#### Morphology

Atrophy  
Atrophy  
Inflammation  
Inflammation  
Mineralization  
Hyperplasia  
Infarct  
Angiectasis  
Basophilic Focus  
Clear Cell Focus  
Eosinophilic Focus  
Fatty Change  
Mixed Cell Focus  
Pigmentation  
Hypertrophy  
Hyperplasia  
Infiltration Cellular Histiocyte  
Hyperplasia Lymphoid  
Necrosis  
Inflammation  
Polyp, Inflammatory  
Dilatation  
Hyperplasia  
Metaplasia Respiratory  
Hyperplasia Regenerative  
Atrophy  
Accumulation, Hyaline Droplet  
Metaplasia Respiratory  
Necrosis  
Dilatation  
Hyperplasia  
Metaplasia Respiratory

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## SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF N,N-DIMETHYL-P-TOLUIDINE

Nose: Respiratory Epithelium  
Nose: Vomeronasal Organ  
Spleen

Testes: Germinal Epithelium  
Thymus

Tooth  
Urinary Bladder

### FEMALE MICE

#### Organ

Adrenal Medulla  
Blood Vessel  
Bone Marrow  
Bone  
Brain: Olfactory Lobe  
Eye: Cornea  
Harderian Gland  
Heart  
Kidney

Liver

Liver: Hepatocyte  
Liver: Oval Cell  
Lung: Alveolar Epithelium  
Lung: Alveolus  
Lung: Bronchiole, Epithelium

Hyperplasia  
Necrosis  
Atrophy  
Pigmentation  
Degeneration  
Atrophy  
Necrosis  
Dysplasia  
Calculus Gross Observation

#### Morphology

Hyperplasia  
Inflammation  
Hyperplasia  
Fibro-osseous Lesion  
Atrophy  
Inflammation  
Hyperplasia  
Mineralization  
Infarct  
Mineralization  
Basophilic Focus  
Clear Cell Focus  
Eosinophilic Focus  
Fatty Change  
Inflammation Chronic  
Mixed Cell Focus  
Necrosis  
Pigmentation  
Hypertrophy  
Hyperplasia  
Hyperplasia  
Infiltration Cellular Histiocyte  
Regeneration

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Lung: Bronchus	Necrosis
Lung: Bronchus, Epithelium	Regeneration
Lymph Node, Mandibular	Atrophy
	Hyperplasia Lymphoid
Lymph Node, Mesenteric	Atrophy
	Hyperplasia Lymphoid
Nose	Inflammation
Nose: Glands, Lateral Wall	Dilatation
Nose: Glands, Respiratory Epithelium	Dilatation
	Hyperplasia
	Metaplasia Respiratory
	Hyperplasia Regenerative
Nose: Nasolacrimal Duct	Atrophy
Nose: Nerve	Accumulation, Hyaline Droplet
Nose: Olfactory Epithelium	Metaplasia Respiratory
	Necrosis
Nose: Olfactory Epithelium, Glands	Dilatation
	Hyperplasia
	Metaplasia Respiratory
Nose: Respiratory Epithelium	Hyperplasia
	Hyperplasia Regenerative
	Necrosis
Nose: Transitional Epithelium	Necrosis
Nose: Vomeronasal Organ	Necrosis
Ovary	Atrophy
Spleen	Pigmentation
Spleen: Red Pulp	Atrophy
Stomach, Forestomach	Inflammation
	Ulcer
Stomach, Forestomach: Epithelium	Hyperplasia
Thymus	Hyperplasia Lymphoid
Tooth	Dysplasia
Uterus	Dilatation
Uterus: Endometrium	Hyperplasia Cystic

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Adrenal Cortex Hypertrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/50 (6%)	3/50 (6%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	3/42.79	3/45.25	1/42.68	1/44.58
POLY-3 PERCENT (g)	7%	6.6%	2.3%	2.2%
TERMINAL (d)	3/34 (9%)	3/36 (8%)	1/31 (3%)	1/36 (3%)
FIRST INCIDENCE	730 (T)	730 (T)	730 (T)	730 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.197N	P=0.636N	P=0.306N	P=0.290N
POLY 1.5	P=0.198N	P=0.636N	P=0.298N	P=0.290N
POLY 6	P=0.197N	P=0.638N	P=0.315N	P=0.291N
COCH-ARM / FISHERS	P=0.202N	P=0.661N	P=0.309N	P=0.309N
MAX-ISO-POLY-3	P=0.242N	P=0.471N	P=0.154N	P=0.148N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Adrenal Cortex</b>				
<b>Necrosis</b>				
<hr/>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.79	0/45.25	0/42.68	0/44.58
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Adrenal Medulla Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/43.26	0/45.25	0/42.68	1/44.58
POLY-3 PERCENT (g)	2.3%	0%	0%	2.2%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	1/36 (3%)
FIRST INCIDENCE	591	---	---	730 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

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TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Blood Vessel Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/42.79	0/45.25	1/42.68	0/44.58
POLY-3 PERCENT (g)	0%	0%	2.3%	0%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	1/31 (3%)	0/36 (0%)
FIRST INCIDENCE	---	---	730 (T)	---
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Bone Marrow Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/50 (6%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	3/44.85	0/45.25	1/42.87	0/44.58
POLY-3 PERCENT (g)	6.7%	0%	2.3%	0%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	4	---	681	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.160N	P=0.117N	P=0.321N	P=0.120N
POLY 1.5	P=0.161N	P=0.115N	P=0.310N	P=0.117N
POLY 6	P=0.159N	P=0.120N	P=0.335N	P=0.123N
COCH-ARM / FISHERS	P=0.160N	P=0.121N	P=0.309N	P=0.121N
MAX-ISO-POLY-3	P=0.026N*	P=0.038N*	P=0.171N	P=0.039N*

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Bone Marrow Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	8/50 (16%)	6/50 (12%)	9/50 (18%)	9/50 (18%)
POLY-3 RATE (b)	8/46.06	6/45.99	9/44.89	9/46.68
POLY-3 PERCENT (g)	17.4%	13.1%	20.1%	19.3%
TERMINAL (d)	1/34 (3%)	4/36 (11%)	2/31 (7%)	1/36 (3%)
FIRST INCIDENCE	4	539	512	609
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.360	P=0.387N	P=0.477	P=0.512
POLY 1.5	P=0.353	P=0.380N	P=0.491	P=0.509
POLY 6	P=0.377	P=0.400N	P=0.464	P=0.520
COCH-ARM / FISHERS	P=0.346	P=0.387N	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.462	P=0.283N	P=0.372	P=0.405

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TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Bone</b>				
<b>Fibro-osseous Lesion</b>				
<hr/>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.79	0/45.25	0/42.68	0/44.58
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Brain: Olfactory Lobe Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	5/50 (10%)
POLY-3 RATE (b)	0/42.79	1/45.25	0/42.68	5/45.03
POLY-3 PERCENT (g)	0%	2.2%	0%	11.1%
TERMINAL (d)	0/34 (0%)	1/36 (3%)	0/31 (0%)	3/36 (8%)
FIRST INCIDENCE	---	730 (T)	---	669
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.002**	P=0.511	(e)	P=0.035*
POLY 1.5	P=0.002**	P=0.511	(e)	P=0.035*
POLY 6	P=0.002**	P=0.511	(e)	P=0.035*
COCH-ARM / FISHERS	P=0.003**	P=0.500	(e)	P=0.028*
MAX-ISO-POLY-3	P=0.004**	P=0.173	(e)	P=0.013*

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Epididymis</b>				
<b>Granuloma Sperm</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.79	2/45.36	0/42.68	0/44.58
POLY-3 PERCENT (g)	0%	4.4%	0%	0%
TERMINAL (d)	0/34 (0%)	1/36 (3%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	---	704	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.353N	P=0.250	(e)	(e)
POLY 1.5	P=0.354N	P=0.250	(e)	(e)
POLY 6	P=0.353N	P=0.250	(e)	(e)
COCH-ARM / FISHERS	P=0.369N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.265N	P=0.089	(e)	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Esophagus: Periesophageal Tissue Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/43.79	0/45.25	0/42.68	0/44.58
POLY-3 PERCENT (g)	4.6%	0%	0%	0%
TERMINAL (d)	1/34 (3%)	0/36 (0%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	4	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.245N	P=0.230N	P=0.243N	P=0.233N
POLY 1.5	P=0.246N	P=0.230N	P=0.238N	P=0.233N
POLY 6	P=0.244N	P=0.230N	P=0.249N	P=0.234N
COCH-ARM / FISHERS	P=0.242N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.034N*	P=0.076N	P=0.081N	P=0.076N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG

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Eye: Cornea  
Inflammation

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**LESION RATES**

OVERALL (a)	3/50 (6%)	1/50 (2%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	3/42.99	1/45.36	4/44.28	0/44.58
POLY-3 PERCENT (g)	7%	2.2%	9%	0%
TERMINAL (d)	2/34 (6%)	0/36 (0%)	2/31 (7%)	0/36 (0%)
FIRST INCIDENCE	678	702	402	---

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**STATISTICAL TESTS**

POLY 3	P=0.151N	P=0.286N	P=0.516	P=0.112N
POLY 1.5	P=0.151N	P=0.286N	P=0.522	P=0.112N
POLY 6	P=0.153N	P=0.287N	P=0.506	P=0.113N
COCH-ARM / FISHERS	P=0.154N	P=0.309N	P=0.500	P=0.121N
MAX-ISO-POLY-3	P=0.099N	P=0.147N	P=0.364	P=0.038N*

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TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Harderian Gland Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	4/50 (8%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/42.79	4/45.25	1/43.10	1/44.77
POLY-3 PERCENT (g)	2.3%	8.8%	2.3%	2.2%
TERMINAL (d)	1/34 (3%)	4/36 (11%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	730 (T)	730 (T)	609	682
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.314N	P=0.196	P=0.759N	P=0.751N
POLY 1.5	P=0.315N	P=0.196	P=0.755N	P=0.750N
POLY 6	P=0.313N	P=0.195	P=0.758	P=0.751N
COCH-ARM / FISHERS	P=0.331N	P=0.181	P=0.753N	P=0.753N
MAX-ISO-POLY-3	P=0.343N	P=0.100	P=0.497N	P=0.487N



TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Heart</b>				
<b>Cardiomyopathy</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	8/50 (16%)	7/50 (14%)	10/50 (20%)	13/50 (26%)
<b>POLY-3 RATE (b)</b>	8/43.33	7/45.50	10/43.45	13/45.74
<b>POLY-3 PERCENT (g)</b>	18.5%	15.4%	23%	28.4%
<b>TERMINAL (d)</b>	7/34 (21%)	5/36 (14%)	5/31 (16%)	10/36 (28%)
<b>FIRST INCIDENCE</b>	561	694	655	562
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.087	P=0.459N	P=0.398	P=0.195
<b>POLY 1.5</b>	P=0.086	P=0.457N	P=0.416	P=0.194
<b>POLY 6</b>	P=0.090	P=0.462N	P=0.383	P=0.198
<b>COCH-ARM / FISHERS</b>	P=0.077	P=0.500N	P=0.398	P=0.163
<b>MAX-ISO-POLY-3</b>	P=0.141	P=0.352N	P=0.301	P=0.140

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Heart Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/44.26	0/45.25	0/42.68	1/44.73
POLY-3 PERCENT (g)	4.5%	0%	0%	2.2%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	4	---	---	693
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.653N	P=0.232N	P=0.245N	P=0.496N
POLY 1.5	P=0.654N	P=0.231N	P=0.239N	P=0.494N
POLY 6	P=0.651N	P=0.234N	P=0.253N	P=0.499N
COCH-ARM / FISHERS	P=0.650N	P=0.247N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.137N	P=0.076N	P=0.084N	P=0.278N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Heart Mineralization</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	5/50 (10%)
POLY-3 RATE (b)	0/42.79	1/45.81	2/43.03	5/45.38
POLY-3 PERCENT (g)	0%	2.2%	4.7%	11%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	2/36 (6%)
FIRST INCIDENCE	---	555	681	609
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.009**	P=0.514	P=0.238	P=0.036*
POLY 1.5	P=0.009**	P=0.513	P=0.242	P=0.035*
POLY 6	P=0.009**	P=0.514	P=0.234	P=0.036*
COCH-ARM / FISHERS	P=0.009**	P=0.500	P=0.247	P=0.028*
MAX-ISO-POLY-3	P=0.012*	P=0.175	P=0.077	P=0.014*

TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Heart Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.79	0/45.25	0/42.68	0/44.58
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

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TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Islets, Pancreatic Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	12/50 (24%)	5/50 (10%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	12/43.46	5/45.25	2/43.91	1/44.58
POLY-3 PERCENT (g)	27.6%	11.1%	4.6%	2.2%
TERMINAL (d)	10/34 (29%)	5/36 (14%)	0/31 (0%)	1/36 (3%)
FIRST INCIDENCE	561	730 (T)	512	730 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.002N**	P=0.041N*	P=0.003N**	P<0.001N**
POLY 1.5	P=0.002N**	P=0.041N*	P=0.003N**	P<0.001N**
POLY 6	P=0.002N**	P=0.042N*	P=0.003N**	P<0.001N**
COCH-ARM / FISHERS	P=0.002N**	P=0.054N	P=0.004N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.024N*	P<0.001N**	P<0.001N**

TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS

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DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG

---

Kidney  
Accumulation, Hyaline Droplet

---

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/42.79	0/45.25	0/42.68	0/44.58
POLY-3 PERCENT (g)	2.3%	0%	0%	0%
TERMINAL (d)	1/34 (3%)	0/36 (0%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	730 (T)	---	---	---

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**STATISTICAL TESTS**

POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

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TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Kidney Infarct</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/50 (6%)	2/50 (4%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	3/42.79	2/45.25	0/42.68	2/44.92
POLY-3 PERCENT (g)	7%	4.4%	0%	4.5%
TERMINAL (d)	3/34 (9%)	2/36 (6%)	0/31 (0%)	1/36 (3%)
FIRST INCIDENCE	730 (T)	730 (T)	---	638
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.506N	P=0.474N	P=0.119N	P=0.478N
POLY 1.5	P=0.507N	P=0.474N	P=0.115N	P=0.479N
POLY 6	P=0.503N	P=0.475N	P=0.123N	P=0.477N
COCH-ARM / FISHERS	P=0.510N	P=0.500N	P=0.121N	P=0.500N
MAX-ISO-POLY-3	P=0.220N	P=0.306N	P=0.038N*	P=0.308N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Kidney Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/43.26	1/45.78	0/42.68	0/44.58
POLY-3 PERCENT (g)	4.6%	2.2%	0%	0%
TERMINAL (d)	1/34 (3%)	0/36 (0%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	588	568	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.171N	P=0.480N	P=0.240N	P=0.230N
POLY 1.5	P=0.171N	P=0.480N	P=0.234N	P=0.229N
POLY 6	P=0.171N	P=0.481N	P=0.247N	P=0.232N
COCH-ARM / FISHERS	P=0.169N	P=0.500N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.080N	P=0.270N	P=0.079N	P=0.076N



TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Kidney Mineralization</b>				
<b>LESION RATES</b>				
OVERALL (a)	5/50 (10%)	7/50 (14%)	9/50 (18%)	6/50 (12%)
POLY-3 RATE (b)	5/43.89	7/46.26	9/44.51	6/46.39
POLY-3 PERCENT (g)	11.4%	15.1%	20.2%	12.9%
TERMINAL (d)	1/34 (3%)	5/36 (14%)	2/31 (7%)	0/36 (0%)
FIRST INCIDENCE	584	555	598	562
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.540N	P=0.416	P=0.199	P=0.539
POLY 1.5	P=0.546N	P=0.419	P=0.208	P=0.535
POLY 6	P=0.530N	P=0.410	P=0.191	P=0.543
COCH-ARM / FISHERS	P=0.565	P=0.380	P=0.194	P=0.500
MAX-ISO-POLY-3	P=0.412	P=0.306	P=0.129	P=0.412

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Kidney</b>				
<b>Nephropathy</b>				
<b>LESION RATES</b>				
OVERALL (a)	39/50 (78%)	41/50 (82%)	43/50 (86%)	37/50 (74%)
POLY-3 RATE (b)	39/46.03	41/48.70	43/47.80	37/47.74
POLY-3 PERCENT (g)	84.7%	84.2%	90%	77.5%
TERMINAL (d)	29/34 (85%)	31/36 (86%)	28/31 (90%)	29/36 (81%)
FIRST INCIDENCE	548	539	442	449
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.160N	P=0.587N	P=0.318	P=0.259N
POLY 1.5	P=0.156N	P=0.581N	P=0.353	P=0.250N
POLY 6	P=0.173N	P=0.609N	P=0.283	P=0.282N
COCH-ARM / FISHERS	P=0.239N	P=0.402	P=0.218	P=0.408N
MAX-ISO-POLY-3	P=0.192N	P=0.471N	P=0.217	P=0.184N

TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG

---

Kidney  
Pigmentation

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/42.79	0/45.25	2/43.90	0/44.58
POLY-3 PERCENT (g)	0%	0%	4.6%	0%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	512	---

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**STATISTICAL TESTS**

POLY 3	P=0.693N	(e)	P=0.243	(e)
POLY 1.5	P=0.692N	(e)	P=0.245	(e)
POLY 6	P=0.694N	(e)	P=0.240	(e)
COCH-ARM / FISHERS	P=0.697N	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.267	(e)	P=0.081	(e)

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TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Kidney: Cortex Cyst</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/50 (6%)	2/50 (4%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	3/42.79	2/45.49	1/42.68	2/44.58
POLY-3 PERCENT (g)	7%	4.4%	2.3%	4.5%
TERMINAL (d)	3/34 (9%)	1/36 (3%)	1/31 (3%)	2/36 (6%)
FIRST INCIDENCE	730 (T)	666	730 (T)	730 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.497N	P=0.472N	P=0.306N	P=0.481N
POLY 1.5	P=0.497N	P=0.473N	P=0.298N	P=0.480N
POLY 6	P=0.498N	P=0.471N	P=0.315N	P=0.483N
COCH-ARM / FISHERS	P=0.500N	P=0.500N	P=0.309N	P=0.500N
MAX-ISO-POLY-3	P=0.355N	P=0.304N	P=0.154N	P=0.311N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Kidney: Pelvis Dilatation</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/43.23	0/45.25	1/42.68	1/44.92
POLY-3 PERCENT (g)	4.6%	0%	2.3%	2.2%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	1/31 (3%)	0/36 (0%)
FIRST INCIDENCE	643	---	730 (T)	638
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.620N	P=0.227N	P=0.504N	P=0.487N
POLY 1.5	P=0.621N	P=0.226N	P=0.495N	P=0.485N
POLY 6	P=0.619N	P=0.229N	P=0.516N	P=0.489N
COCH-ARM / FISHERS	P=0.619N	P=0.247N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.274N	P=0.076N	P=0.285N	P=0.273N

TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

Date Report Requested: 03/10/2011  
Time Report Requested: 11:42:39  
First Dose M/F: 10/26/04 / 10/25/04  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS

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DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Kidney: Renal Tubule Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/42.79	0/45.25	2/43.25	1/44.73
POLY-3 PERCENT (g)	0%	0%	4.6%	2.2%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	1/31 (3%)	0/36 (0%)
FIRST INCIDENCE	---	---	554	693
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.358	(e)	P=0.239	P=0.509
POLY 1.5	P=0.359	(e)	P=0.243	P=0.509
POLY 6	P=0.358	(e)	P=0.235	P=0.509
COCH-ARM / FISHERS	P=0.350	(e)	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.186	(e)	P=0.078	P=0.170

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TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver</b>				
<b>Angiectasis</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	3/50 (6%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
<b>POLY-3 RATE (b)</b>	3/42.79	1/45.25	0/42.68	0/44.58
<b>POLY-3 PERCENT (g)</b>	7%	2.2%	0%	0%
<b>TERMINAL (d)</b>	3/34 (9%)	1/36 (3%)	0/31 (0%)	0/36 (0%)
<b>FIRST INCIDENCE</b>	730 (T)	730 (T)	---	---
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.098N	P=0.285N	P=0.119N	P=0.111N
<b>POLY 1.5</b>	P=0.098N	P=0.285N	P=0.115N	P=0.111N
<b>POLY 6</b>	P=0.097N	P=0.286N	P=0.123N	P=0.112N
<b>COCH-ARM / FISHERS</b>	P=0.097N	P=0.309N	P=0.121N	P=0.121N
<b>MAX-ISO-POLY-3</b>	P=0.025N*	P=0.146N	P=0.038N*	P=0.038N*

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver</b>				
<b>Basophilic Focus</b>				
<b>LESION RATES</b>				
OVERALL (a)	5/50 (10%)	11/50 (22%)	8/50 (16%)	2/50 (4%)
POLY-3 RATE (b)	5/43.50	11/46.36	8/43.55	2/44.58
POLY-3 PERCENT (g)	11.5%	23.7%	18.4%	4.5%
TERMINAL (d)	3/34 (9%)	8/36 (22%)	5/31 (16%)	2/36 (6%)
FIRST INCIDENCE	562	568	597	730 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.036N*	P=0.106	P=0.275	P=0.206N
POLY 1.5	P=0.034N*	P=0.106	P=0.289	P=0.203N
POLY 6	P=0.038N*	P=0.106	P=0.261	P=0.211N
COCH-ARM / FISHERS	P=0.041N*	P=0.086	P=0.277	P=0.218N
MAX-ISO-POLY-3	P=0.057N	P=0.070	P=0.185	P=0.115N



TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver</b>				
<b>Clear Cell Focus</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	15/50 (30%)	22/50 (44%)	15/50 (30%)	7/50 (14%)
<b>POLY-3 RATE (b)</b>	15/42.99	22/45.67	15/43.35	7/44.58
<b>POLY-3 PERCENT (g)</b>	34.9%	48.2%	34.6%	15.7%
<b>TERMINAL (d)</b>	14/34 (41%)	19/36 (53%)	13/31 (42%)	7/36 (19%)
<b>FIRST INCIDENCE</b>	678	666	598	730 (T)
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.002N**	P=0.143	P=0.579N	P=0.031N*
<b>POLY 1.5</b>	P=0.002N**	P=0.145	P=0.555N	P=0.032N*
<b>POLY 6</b>	P=0.002N**	P=0.140	P=0.578	P=0.031N*
<b>COCH-ARM / FISHERS</b>	P=0.004N**	P=0.107	P=0.586N	P=0.045N*
<b>MAX-ISO-POLY-3</b>	P=0.003N**	P=0.105	P=0.488N	P=0.019N*

TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
N,N-Dimethyl-p-toluidine  
CAS Number: 99-97-8

Date Report Requested: 03/10/2011  
Time Report Requested: 11:42:39  
First Dose M/F: 10/26/04 / 10/25/04  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver</b>				
<b>Eosinophilic Focus</b>				
<b>LESION RATES</b>				
OVERALL (a)	25/50 (50%)	30/50 (60%)	39/50 (78%)	43/50 (86%)
POLY-3 RATE (b)	25/44.61	30/46.64	39/46.42	43/47.57
POLY-3 PERCENT (g)	56.1%	64.3%	84%	90.4%
TERMINAL (d)	20/34 (59%)	25/36 (69%)	28/31 (90%)	33/36 (92%)
FIRST INCIDENCE	548	539	449	562
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.272	P=0.002**	P<0.001**
POLY 1.5	P<0.001**	P=0.287	P=0.003**	P<0.001**
POLY 6	P<0.001**	P=0.253	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.211	P=0.003**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.210	P<0.001**	P<0.001**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver</b>				
<b>Fatty Change</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	0/50 (0%)	3/50 (6%)	1/50 (2%)	2/50 (4%)
<b>POLY-3 RATE (b)</b>	0/42.79	3/45.78	1/42.68	2/44.96
<b>POLY-3 PERCENT (g)</b>	0%	6.6%	2.3%	4.5%
<b>TERMINAL (d)</b>	0/34 (0%)	2/36 (6%)	1/31 (3%)	0/36 (0%)
<b>FIRST INCIDENCE</b>	---	568	730 (T)	669
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.459	P=0.131	P=0.500	P=0.248
<b>POLY 1.5</b>	P=0.458	P=0.130	P=0.504	P=0.248
<b>POLY 6</b>	P=0.461	P=0.132	P=0.494	P=0.249
<b>COCH-ARM / FISHERS</b>	P=0.437	P=0.121	P=0.500	P=0.247
<b>MAX-ISO-POLY-3</b>	P=0.210	P=0.049*	P=0.158	P=0.087

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver</b>				
<b>Hematopoietic Cell Proliferation</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	4/50 (8%)	1/50 (2%)	4/50 (8%)	1/50 (2%)
<b>POLY-3 RATE (b)</b>	4/44.25	1/45.49	4/43.99	1/44.58
<b>POLY-3 PERCENT (g)</b>	9%	2.2%	9.1%	2.2%
<b>TERMINAL (d)</b>	1/34 (3%)	0/36 (0%)	1/31 (3%)	1/36 (3%)
<b>FIRST INCIDENCE</b>	156	666	512	730 (T)
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.252N	P=0.170N	P=0.640	P=0.176N
<b>POLY 1.5</b>	P=0.250N	P=0.169N	P=0.637N	P=0.173N
<b>POLY 6</b>	P=0.256N	P=0.172N	P=0.631	P=0.180N
<b>COCH-ARM / FISHERS</b>	P=0.248N	P=0.181N	P=0.643N	P=0.181N
<b>MAX-ISO-POLY-3</b>	P=0.134N	P=0.081N	P=0.496	P=0.083N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver</b>				
<b>Inflammation Chronic</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	23/50 (46%)	22/50 (44%)	18/50 (36%)	19/50 (38%)
<b>POLY-3 RATE (b)</b>	23/44.27	22/45.93	18/44.73	19/45.65
<b>POLY-3 PERCENT (g)</b>	52%	47.9%	40.2%	41.6%
<b>TERMINAL (d)</b>	19/34 (56%)	19/36 (53%)	12/31 (39%)	15/36 (42%)
<b>FIRST INCIDENCE</b>	156	578	449	609
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.214N	P=0.430N	P=0.181N	P=0.217N
<b>POLY 1.5</b>	P=0.222N	P=0.428N	P=0.175N	P=0.223N
<b>POLY 6</b>	P=0.201N	P=0.434N	P=0.186N	P=0.207N
<b>COCH-ARM / FISHERS</b>	P=0.247N	P=0.500N	P=0.208N	P=0.272N
<b>MAX-ISO-POLY-3</b>	P=0.240N	P=0.349N	P=0.131N	P=0.164N

TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

Date Report Requested: 03/10/2011  
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First Dose M/F: 10/26/04 / 10/25/04  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver</b>				
<b>Mitotic Alteration</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/42.79	1/45.25	2/42.68	1/44.58
POLY-3 PERCENT (g)	2.3%	2.2%	4.7%	2.2%
TERMINAL (d)	1/34 (3%)	1/36 (3%)	2/31 (7%)	1/36 (3%)
FIRST INCIDENCE	730 (T)	730 (T)	730 (T)	730 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.633N	P=0.748N	P=0.499	P=0.752N
POLY 1.5	P=0.632N	P=0.748N	P=0.507	P=0.751N
POLY 6	P=0.634N	P=0.749N	P=0.490	P=0.752N
COCH-ARM / FISHERS	P=0.640N	P=0.753N	P=0.500	P=0.753N
MAX-ISO-POLY-3	P=0.589	P=0.484N	P=0.280	P=0.488N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver</b>				
<b>Mixed Cell Focus</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	21/50 (42%)	25/50 (50%)	17/50 (34%)	12/50 (24%)
<b>POLY-3 RATE (b)</b>	21/43.86	25/46.65	17/45.29	12/45.14
<b>POLY-3 PERCENT (g)</b>	47.9%	53.6%	37.5%	26.6%
<b>TERMINAL (d)</b>	17/34 (50%)	20/36 (56%)	11/31 (36%)	9/36 (25%)
<b>FIRST INCIDENCE</b>	561	568	402	669
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.005N**	P=0.368	P=0.217N	P=0.028N*
<b>POLY 1.5</b>	P=0.005N**	P=0.366	P=0.211N	P=0.028N*
<b>POLY 6</b>	P=0.005N**	P=0.369	P=0.227N	P=0.029N*
<b>COCH-ARM / FISHERS</b>	P=0.008N**	P=0.274	P=0.268N	P=0.044N*
<b>MAX-ISO-POLY-3</b>	P=0.009N**	P=0.297	P=0.163N	P=0.018N*

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver</b>				
<b>Necrosis</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	9/50 (18%)	8/50 (16%)	7/50 (14%)	10/50 (20%)
<b>POLY-3 RATE (b)</b>	9/44.87	8/46.88	7/43.91	10/46.90
<b>POLY-3 PERCENT (g)</b>	20.1%	17.1%	15.9%	21.3%
<b>TERMINAL (d)</b>	5/34 (15%)	3/36 (8%)	2/31 (7%)	2/36 (6%)
<b>FIRST INCIDENCE</b>	548	555	554	580
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.408	P=0.460N	P=0.410N	P=0.543
<b>POLY 1.5</b>	P=0.403	P=0.456N	P=0.386N	P=0.542
<b>POLY 6</b>	P=0.420	P=0.465N	P=0.435N	P=0.551
<b>COCH-ARM / FISHERS</b>	P=0.383	P=0.500N	P=0.393N	P=0.500
<b>MAX-ISO-POLY-3</b>	P=0.527	P=0.359N	P=0.309N	P=0.441



TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver Pigmentation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	3/50 (6%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	0/42.79	3/45.25	2/42.68	2/44.58
POLY-3 PERCENT (g)	0%	6.6%	4.7%	4.5%
TERMINAL (d)	0/34 (0%)	3/36 (8%)	2/31 (7%)	2/36 (6%)
FIRST INCIDENCE	---	730 (T)	730 (T)	730 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.470	P=0.129	P=0.236	P=0.246
POLY 1.5	P=0.471	P=0.129	P=0.241	P=0.247
POLY 6	P=0.469	P=0.128	P=0.230	P=0.245
COCH-ARM / FISHERS	P=0.451	P=0.121	P=0.247	P=0.247
MAX-ISO-POLY-3	P=0.177	P=0.046*	P=0.076	P=0.085

TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS

---

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG

---

Liver: Bile Duct  
Cyst

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/42.79	1/45.25	1/42.68	0/44.58
POLY-3 PERCENT (g)	0%	2.2%	2.3%	0%
TERMINAL (d)	0/34 (0%)	1/36 (3%)	1/31 (3%)	0/36 (0%)
FIRST INCIDENCE	---	730 (T)	730 (T)	---

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**STATISTICAL TESTS**

POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

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TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver: Bile Duct Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/42.79	1/45.25	2/43.10	0/44.58
POLY-3 PERCENT (g)	2.3%	2.2%	4.6%	0%
TERMINAL (d)	1/34 (3%)	1/36 (3%)	1/31 (3%)	0/36 (0%)
FIRST INCIDENCE	730 (T)	730 (T)	609	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.327N	P=0.748N	P=0.503	P=0.492N
POLY 1.5	P=0.327N	P=0.748N	P=0.509	P=0.491N
POLY 6	P=0.328N	P=0.749N	P=0.496	P=0.492N
COCH-ARM / FISHERS	P=0.333N	P=0.753N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.287N	P=0.484N	P=0.283	P=0.158N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver: Hepatocyte Hypertrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	9/50 (18%)	11/50 (22%)	16/50 (32%)
POLY-3 RATE (b)	1/43.06	9/45.36	11/44.06	16/46.31
POLY-3 PERCENT (g)	2.3%	19.8%	25%	34.6%
TERMINAL (d)	0/34 (0%)	8/36 (22%)	8/31 (26%)	11/36 (31%)
FIRST INCIDENCE	655	702	449	562
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.010**	P=0.002**	P<0.001**
POLY 1.5	P<0.001**	P=0.010**	P=0.002**	P<0.001**
POLY 6	P<0.001**	P=0.009**	P=0.002**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.008**	P=0.002**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.004**	P<0.001**	P<0.001**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver: Oval Cell Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/42.99	0/45.25	1/43.34	2/44.83
POLY-3 PERCENT (g)	2.3%	0%	2.3%	4.5%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	1/36 (3%)
FIRST INCIDENCE	678	---	512	665
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.234	P=0.490N	P=0.759N	P=0.515
POLY 1.5	P=0.234	P=0.489N	P=0.755N	P=0.515
POLY 6	P=0.235	P=0.491N	P=0.758	P=0.514
COCH-ARM / FISHERS	P=0.231	P=0.500N	P=0.753N	P=0.500
MAX-ISO-POLY-3	P=0.251	P=0.158N	P=0.497N	P=0.296

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Lung Foreign Body				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.79	0/45.25	0/42.68	0/44.58
POLY-3 PERCENT (g)	2.3%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	4	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lung Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.79	0/45.25	0/42.68	0/44.58
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lung: Alveolar Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/50 (6%)	8/50 (16%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	3/43.10	8/45.38	3/42.90	0/44.58
POLY-3 PERCENT (g)	7%	17.6%	7%	0%
TERMINAL (d)	2/34 (6%)	7/36 (19%)	2/31 (7%)	0/36 (0%)
FIRST INCIDENCE	643	697	672	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.016N*	P=0.114	P=0.661	P=0.113N
POLY 1.5	P=0.016N*	P=0.116	P=0.654N	P=0.112N
POLY 6	P=0.016N*	P=0.112	P=0.649	P=0.114N
COCH-ARM / FISHERS	P=0.020N*	P=0.100	P=0.661N	P=0.121N
MAX-ISO-POLY-3	P=0.025N*	P=0.068	P=0.497	P=0.038N*



TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 N,N-Dimethyl-p-toluidine  
 CAS Number: 99-97-8

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lung: Alveolus Infiltration Cellular Histiocyte</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	2/50 (4%)	2/50 (4%)	10/50 (20%)
POLY-3 RATE (b)	1/42.79	2/45.96	2/42.86	10/44.58
POLY-3 PERCENT (g)	2.3%	4.4%	4.7%	22.4%
TERMINAL (d)	1/34 (3%)	0/36 (0%)	0/31 (0%)	10/36 (28%)
FIRST INCIDENCE	730 (T)	539	693	730 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.525	P=0.501	P=0.005**
POLY 1.5	P<0.001**	P=0.523	P=0.507	P=0.005**
POLY 6	P<0.001**	P=0.527	P=0.493	P=0.004**
COCH-ARM / FISHERS	P<0.001**	P=0.500	P=0.500	P=0.004**
MAX-ISO-POLY-3	P<0.001**	P=0.307	P=0.281	P=0.002**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lung: Bronchiole, Epithelium Regeneration</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/42.79	0/45.25	1/42.71	1/44.96
POLY-3 PERCENT (g)	0%	0%	2.3%	2.2%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	723	623
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lung: Bronchus Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/42.79	0/45.25	1/42.71	0/44.58
POLY-3 PERCENT (g)	0%	0%	2.3%	0%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	723	---
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lung: Bronchus, Epithelium Regeneration</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.79	0/45.25	0/42.68	1/44.96
POLY-3 PERCENT (g)	0%	0%	0%	2.2%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	623
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lymph Node, Mandibular Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	5/50 (10%)	4/50 (8%)	6/49 (12%)	3/50 (6%)
POLY-3 RATE (b)	5/43.45	4/47.12	6/42.23	3/44.77
POLY-3 PERCENT (g)	11.5%	8.5%	14.2%	6.7%
TERMINAL (d)	3/34 (9%)	0/36 (0%)	3/30 (10%)	2/36 (6%)
FIRST INCIDENCE	584	550	674	682
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.330N	P=0.449N	P=0.480	P=0.340N
POLY 1.5	P=0.323N	P=0.456N	P=0.497	P=0.336N
POLY 6	P=0.341N	P=0.443N	P=0.462	P=0.345N
COCH-ARM / FISHERS	P=0.325N	P=0.500N	P=0.486	P=0.357N
MAX-ISO-POLY-3	P=0.378N	P=0.323N	P=0.355	P=0.221N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lymph Node, Mandibular Hyperplasia Lymphoid</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	1/50 (2%)	1/49 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/42.99	1/45.36	1/41.68	0/44.58
POLY-3 PERCENT (g)	4.7%	2.2%	2.4%	0%
TERMINAL (d)	1/34 (3%)	0/36 (0%)	1/30 (3%)	0/36 (0%)
FIRST INCIDENCE	678	702	730 (T)	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.195N	P=0.481N	P=0.511N	P=0.229N
POLY 1.5	P=0.195N	P=0.481N	P=0.502N	P=0.228N
POLY 6	P=0.195N	P=0.483N	P=0.522N	P=0.230N
COCH-ARM / FISHERS	P=0.194N	P=0.500N	P=0.508N	P=0.247N
MAX-ISO-POLY-3	P=0.125N	P=0.270N	P=0.291N	P=0.076N

TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

Date Report Requested: 03/10/2011  
Time Report Requested: 11:42:39  
First Dose M/F: 10/26/04 / 10/25/04  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lymph Node, Mesenteric Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	13/50 (26%)	9/50 (18%)	14/49 (29%)	15/50 (30%)
POLY-3 RATE (b)	13/45.10	9/47.78	14/43.55	15/46.55
POLY-3 PERCENT (g)	28.8%	18.8%	32.2%	32.2%
TERMINAL (d)	7/34 (21%)	4/36 (11%)	6/30 (20%)	9/36 (25%)
FIRST INCIDENCE	548	539	554	562
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.207	P=0.187N	P=0.457	P=0.450
POLY 1.5	P=0.214	P=0.188N	P=0.489	P=0.457
POLY 6	P=0.203	P=0.190N	P=0.423	P=0.442
COCH-ARM / FISHERS	P=0.209	P=0.235N	P=0.475	P=0.412
MAX-ISO-POLY-3	P=0.300	P=0.135N	P=0.367	P=0.364

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lymph Node, Mesenteric Hyperplasia Lymphoid</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/42.79	0/45.25	0/41.68	2/44.73
POLY-3 PERCENT (g)	0%	0%	0%	4.5%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/30 (0%)	1/36 (3%)
FIRST INCIDENCE	---	---	---	693
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.042*	(e)	(e)	P=0.247
POLY 1.5	P=0.042*	(e)	(e)	P=0.247
POLY 6	P=0.042*	(e)	(e)	P=0.247
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.043*	(e)	(e)	P=0.086



TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

Date Report Requested: 03/10/2011  
Time Report Requested: 11:42:39  
First Dose M/F: 10/26/04 / 10/25/04  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS

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DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lymph Node: Renal Ectasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/2 (0%)	0/3 (0%)	0/4 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/1.50	0/2.94	0/2.54	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/0 (0%)	0/2 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

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TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
N,N-Dimethyl-p-toluidine  
CAS Number: 99-97-8

Date Report Requested: 03/10/2011  
Time Report Requested: 11:42:39  
First Dose M/F: 10/26/04 / 10/25/04  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Mesentery: Fat Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/4 (50%)	3/3 (100%)	5/5 (100%)	2/2 (100%)
POLY-3 RATE (b)	2/3.83	3/3.00	5/5.00	2/2.00
POLY-3 PERCENT (g)	52.3%	100%	100%	100%
TERMINAL (d)	2/3 (67%)	2/2 (100%)	2/2 (100%)	0/0 (0%)
FIRST INCIDENCE	730 (T)	666	554	672
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.311	P=0.291	P=0.155	P=0.408
POLY 1.5	P=0.290	P=0.281	P=0.147	P=0.397
POLY 6	P=0.352	P=0.314	P=0.175	P=0.430
COCH-ARM / FISHERS	P=0.291	P=0.286	P=0.167	P=0.400
MAX-ISO-POLY-3	P=0.084	P=0.082	P=0.034*	P=0.156

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	13/49 (27%)	12/50 (24%)	10/50 (20%)	20/50 (40%)
POLY-3 RATE (b)	13/42.81	12/46.69	10/45.06	20/45.84
POLY-3 PERCENT (g)	30.4%	25.7%	22.2%	43.6%
TERMINAL (d)	12/34 (35%)	7/36 (19%)	4/31 (13%)	15/36 (42%)
FIRST INCIDENCE	561	568	442	609
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.036*	P=0.399N	P=0.264N	P=0.140
POLY 1.5	P=0.038*	P=0.405N	P=0.259N	P=0.141
POLY 6	P=0.036*	P=0.391N	P=0.269N	P=0.142
COCH-ARM / FISHERS	P=0.037*	P=0.477N	P=0.298N	P=0.113
MAX-ISO-POLY-3	P=0.059	P=0.318N	P=0.196N	P=0.102

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose</b>				
<b>Polyp, Inflammatory</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	3/49 (6%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
<b>POLY-3 RATE (b)</b>	3/42.26	2/45.25	0/42.68	0/44.58
<b>POLY-3 PERCENT (g)</b>	7.1%	4.4%	0%	0%
<b>TERMINAL (d)</b>	3/34 (9%)	2/36 (6%)	0/31 (0%)	0/36 (0%)
<b>FIRST INCIDENCE</b>	730 (T)	730 (T)	---	---
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.069N	P=0.469N	P=0.116N	P=0.109N
<b>POLY 1.5</b>	P=0.069N	P=0.467N	P=0.112N	P=0.108N
<b>POLY 6</b>	P=0.069N	P=0.472N	P=0.122N	P=0.110N
<b>COCH-ARM / FISHERS</b>	P=0.070N	P=0.490N	P=0.117N	P=0.117N
<b>MAX-ISO-POLY-3</b>	P=0.041N*	P=0.302N	P=0.037N*	P=0.037N*

TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

Date Report Requested: 03/10/2011  
Time Report Requested: 11:42:39  
First Dose M/F: 10/26/04 / 10/25/04  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS

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DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG

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Nose: Glands, Lateral Wall  
Dilatation

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**LESION RATES**

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.26	0/45.25	0/42.68	0/44.58
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---

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**STATISTICAL TESTS**

POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

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TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

Date Report Requested: 03/10/2011  
Time Report Requested: 11:42:39  
First Dose M/F: 10/26/04 / 10/25/04  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Glands, Respiratory Epithelium Dilatation</b>				
<b>LESION RATES</b>				
OVERALL (a)	17/49 (35%)	19/50 (38%)	13/50 (26%)	41/50 (82%)
POLY-3 RATE (b)	17/43.30	19/47.55	13/44.45	41/47.48
POLY-3 PERCENT (g)	39.3%	40%	29.3%	86.4%
TERMINAL (d)	15/34 (44%)	11/36 (31%)	9/31 (29%)	32/36 (89%)
FIRST INCIDENCE	561	539	442	562
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.558	P=0.221N	P<0.001**
POLY 1.5	P<0.001**	P=0.546	P=0.205N	P<0.001**
POLY 6	P<0.001**	P=0.576	P=0.242N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.447	P=0.235N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.473	P=0.162N	P<0.001**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 N,N-Dimethyl-p-toluidine  
 CAS Number: 99-97-8

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Glands, Respiratory Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	4/49 (8%)	2/50 (4%)	2/50 (4%)	11/50 (22%)
POLY-3 RATE (b)	4/42.81	2/45.78	2/43.26	11/44.95
POLY-3 PERCENT (g)	9.3%	4.4%	4.6%	24.5%
TERMINAL (d)	3/34 (9%)	1/36 (3%)	1/31 (3%)	9/36 (25%)
FIRST INCIDENCE	561	568	548	672
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.307N	P=0.332N	P=0.053
POLY 1.5	P<0.001**	P=0.305N	P=0.321N	P=0.055
POLY 6	P<0.001**	P=0.310N	P=0.346N	P=0.050*
COCH-ARM / FISHERS	P=0.002**	P=0.329N	P=0.329N	P=0.049*
MAX-ISO-POLY-3	P=0.002**	P=0.184N	P=0.196N	P=0.031*

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Glands, Respiratory Epithelium Metaplasia Respiratory</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/49 (4%)	2/50 (4%)	2/50 (4%)	10/50 (20%)
POLY-3 RATE (b)	2/42.26	2/45.78	2/43.26	10/45.56
POLY-3 PERCENT (g)	4.7%	4.4%	4.6%	22%
TERMINAL (d)	2/34 (6%)	1/36 (3%)	1/31 (3%)	6/36 (17%)
FIRST INCIDENCE	730 (T)	568	548	623
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.665N	P=0.686N	P=0.019*
POLY 1.5	P<0.001**	P=0.665N	P=0.678N	P=0.019*
POLY 6	P<0.001**	P=0.666N	P=0.694	P=0.019*
COCH-ARM / FISHERS	P<0.001**	P=0.684N	P=0.684N	P=0.015*
MAX-ISO-POLY-3	P<0.001**	P=0.468N	P=0.490N	P=0.010**



TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Nasolacrimal Duct Hyperplasia Regenerative</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	4/50 (8%)
POLY-3 RATE (b)	0/42.26	0/45.25	0/42.68	4/45.60
POLY-3 PERCENT (g)	0%	0%	0%	8.8%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	638
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.002**	(e)	(e)	P=0.070
POLY 1.5	P=0.002**	(e)	(e)	P=0.070
POLY 6	P=0.002**	(e)	(e)	P=0.072
COCH-ARM / FISHERS	P=0.002**	(e)	(e)	P=0.061
MAX-ISO-POLY-3	P=0.003**	(e)	(e)	P=0.027*

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Nerve Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/49 (4%)	7/50 (14%)	4/50 (8%)	42/50 (84%)
POLY-3 RATE (b)	2/42.44	7/46.33	4/42.90	42/48.46
POLY-3 PERCENT (g)	4.7%	15.1%	9.3%	86.7%
TERMINAL (d)	1/34 (3%)	5/36 (14%)	3/31 (10%)	31/36 (86%)
FIRST INCIDENCE	685	539	672	256
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.101	P=0.342	P<0.001**
POLY 1.5	P<0.001**	P=0.101	P=0.354	P<0.001**
POLY 6	P<0.001**	P=0.101	P=0.327	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.085	P=0.349	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.058	P=0.204	P<0.001**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Olfactory Epithelium Accumulation, Hyaline Droplet</b>				
<b>LESION RATES</b>				
OVERALL (a)	12/49 (24%)	14/50 (28%)	10/50 (20%)	4/50 (8%)
POLY-3 RATE (b)	12/44.40	14/47.35	10/43.28	4/45.25
POLY-3 PERCENT (g)	27%	29.6%	23.1%	8.8%
TERMINAL (d)	8/34 (24%)	9/36 (25%)	8/31 (26%)	2/36 (6%)
FIRST INCIDENCE	548	539	598	609
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.007N**	P=0.485	P=0.430N	P=0.022N*
POLY 1.5	P=0.007N**	P=0.492	P=0.389N	P=0.020N*
POLY 6	P=0.008N**	P=0.475	P=0.480N	P=0.025N*
COCH-ARM / FISHERS	P=0.008N**	P=0.433	P=0.384N	P=0.024N*
MAX-ISO-POLY-3	P=0.012N*	P=0.395	P=0.338N	P=0.011N*

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Olfactory Epithelium Metaplasia Respiratory</b>				
<b>LESION RATES</b>				
OVERALL (a)	10/49 (20%)	10/50 (20%)	5/50 (10%)	49/50 (98%)
POLY-3 RATE (b)	10/42.98	10/45.83	5/43.79	49/49.72
POLY-3 PERCENT (g)	23.3%	21.8%	11.4%	98.6%
TERMINAL (d)	8/34 (24%)	8/36 (22%)	2/31 (7%)	36/36 (100%)
FIRST INCIDENCE	561	599	548	256
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.536N	P=0.118N	P<0.001**
POLY 1.5	P<0.001**	P=0.530N	P=0.111N	P<0.001**
POLY 6	P<0.001**	P=0.546N	P=0.128N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.579N	P=0.122N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.435N	P=0.072N	P<0.001**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Olfactory Epithelium Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/49 (2%)	3/50 (6%)	3/50 (6%)	8/50 (16%)
POLY-3 RATE (b)	1/42.58	3/46.84	3/44.11	8/47.61
POLY-3 PERCENT (g)	2.4%	6.4%	6.8%	16.8%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	2/36 (6%)
FIRST INCIDENCE	643	539	449	256
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.009**	P=0.340	P=0.318	P=0.025*
POLY 1.5	P=0.008**	P=0.338	P=0.324	P=0.024*
POLY 6	P=0.009**	P=0.342	P=0.309	P=0.025*
COCH-ARM / FISHERS	P=0.007**	P=0.316	P=0.316	P=0.017*
MAX-ISO-POLY-3	P=0.014*	P=0.188	P=0.166	P=0.013*

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 N,N-Dimethyl-p-toluidine  
 CAS Number: 99-97-8

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Olfactory Epithelium, Glands Dilatation</b>				
<b>LESION RATES</b>				
OVERALL (a)	4/49 (8%)	11/50 (22%)	7/50 (14%)	48/50 (96%)
POLY-3 RATE (b)	4/42.81	11/46.05	7/43.04	48/49.72
POLY-3 PERCENT (g)	9.3%	23.9%	16.3%	96.5%
TERMINAL (d)	3/34 (9%)	8/36 (22%)	5/31 (16%)	35/36 (97%)
FIRST INCIDENCE	561	539	655	256
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.059	P=0.263	P<0.001**
POLY 1.5	P<0.001**	P=0.061	P=0.279	P<0.001**
POLY 6	P<0.001**	P=0.057	P=0.244	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.049*	P=0.274	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.036*	P=0.170	P<0.001**

TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

Date Report Requested: 03/10/2011  
Time Report Requested: 11:42:39  
First Dose M/F: 10/26/04 / 10/25/04  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Olfactory Epithelium, Glands Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	4/49 (8%)	9/50 (18%)	7/50 (14%)	49/50 (98%)
POLY-3 RATE (b)	4/42.26	9/45.65	7/43.18	49/49.72
POLY-3 PERCENT (g)	9.5%	19.7%	16.2%	98.6%
TERMINAL (d)	4/34 (12%)	7/36 (19%)	5/31 (16%)	36/36 (100%)
FIRST INCIDENCE	730 (T)	659	655	256
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.146	P=0.272	P<0.001**
POLY 1.5	P<0.001**	P=0.147	P=0.285	P<0.001**
POLY 6	P<0.001**	P=0.144	P=0.259	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.125	P=0.274	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.095	P=0.178	P<0.001**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Olfactory Epithelium, Glands Metaplasia Respiratory</b>				
<b>LESION RATES</b>				
OVERALL (a)	5/49 (10%)	5/50 (10%)	6/50 (12%)	48/50 (96%)
POLY-3 RATE (b)	5/42.81	5/45.38	6/42.98	48/48.96
POLY-3 PERCENT (g)	11.7%	11%	14%	98.1%
TERMINAL (d)	4/34 (12%)	4/36 (11%)	4/31 (13%)	36/36 (100%)
FIRST INCIDENCE	561	697	672	256
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.593N	P=0.503	P<0.001**
POLY 1.5	P<0.001**	P=0.588N	P=0.522	P<0.001**
POLY 6	P<0.001**	P=0.601N	P=0.481	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.617N	P=0.514	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.461N	P=0.376	P<0.001**



TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Respiratory Epithelium Accumulation, Hyaline Droplet</b>				
<b>LESION RATES</b>				
OVERALL (a)	24/49 (49%)	25/50 (50%)	24/50 (48%)	25/50 (50%)
POLY-3 RATE (b)	24/43.59	25/48.33	24/46.00	25/47.81
POLY-3 PERCENT (g)	55.1%	51.7%	52.2%	52.3%
TERMINAL (d)	19/34 (56%)	18/36 (50%)	16/31 (52%)	17/36 (47%)
FIRST INCIDENCE	548	539	402	256
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.499N	P=0.456N	P=0.475N	P=0.478N
POLY 1.5	P=0.506N	P=0.478N	P=0.457N	P=0.493N
POLY 6	P=0.485N	P=0.431N	P=0.501N	P=0.456N
COCH-ARM / FISHERS	P=0.518	P=0.540	P=0.541N	P=0.540
MAX-ISO-POLY-3	P=0.612N	P=0.378N	P=0.391N	P=0.397N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 N,N-Dimethyl-p-toluidine  
 CAS Number: 99-97-8

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Respiratory Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	37/49 (76%)	35/50 (70%)	32/50 (64%)	30/50 (60%)
POLY-3 RATE (b)	37/44.06	35/48.01	32/45.41	30/46.51
POLY-3 PERCENT (g)	84%	72.9%	70.5%	64.5%
TERMINAL (d)	31/34 (91%)	26/36 (72%)	22/31 (71%)	25/36 (69%)
FIRST INCIDENCE	561	539	402	256
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.043N*	P=0.141N	P=0.088N	P=0.023N*
POLY 1.5	P=0.041N*	P=0.159N	P=0.077N	P=0.024N*
POLY 6	P=0.051N	P=0.123N	P=0.105N	P=0.024N*
COCH-ARM / FISHERS	P=0.073N	P=0.349N	P=0.152N	P=0.075N
MAX-ISO-POLY-3	P=0.027N*	P=0.098N	P=0.054N	P=0.014N*

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Respiratory Epithelium Hyperplasia Regenerative</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.26	0/45.25	0/42.68	0/44.58
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Respiratory Epithelium Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/42.26	1/45.74	1/42.76	1/45.00
POLY-3 PERCENT (g)	0%	2.2%	2.3%	2.2%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	---	586	710	609
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

Date Report Requested: 03/10/2011  
Time Report Requested: 11:42:39  
First Dose M/F: 10/26/04 / 10/25/04  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS

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DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG

---

Nose: Transitional Epithelium  
Necrosis

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**LESION RATES**

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.26	0/45.25	0/42.68	1/45.35
POLY-3 PERCENT (g)	0%	0%	0%	2.2%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	449

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**STATISTICAL TESTS**

POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

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TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Vomeronasal Organ Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	1/50 (2%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	0/42.26	1/45.74	2/43.27	3/45.46
POLY-3 PERCENT (g)	0%	2.2%	4.6%	6.6%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	1/36 (3%)
FIRST INCIDENCE	---	586	554	580
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.095	P=0.516	P=0.242	P=0.132
POLY 1.5	P=0.094	P=0.516	P=0.247	P=0.132
POLY 6	P=0.095	P=0.515	P=0.237	P=0.133
COCH-ARM / FISHERS	P=0.088	P=0.505	P=0.253	P=0.125
MAX-ISO-POLY-3	P=0.080	P=0.177	P=0.080	P=0.049*

TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Pancreas</b>				
<b>Atrophy</b>				
<hr/>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/42.79	1/45.25	1/42.85	1/44.77
POLY-3 PERCENT (g)	0%	2.2%	2.3%	2.2%
TERMINAL (d)	0/34 (0%)	1/36 (3%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	---	730 (T)	688	682
<hr/>				
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

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TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Pancreas: Duct Cyst</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/42.79	0/45.25	1/43.13	2/45.53
POLY-3 PERCENT (g)	0%	0%	2.3%	4.4%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	598	449
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.089	(e)	P=0.502	P=0.251
POLY 1.5	P=0.088	(e)	P=0.505	P=0.250
POLY 6	P=0.090	(e)	P=0.498	P=0.252
COCH-ARM / FISHERS	P=0.084	(e)	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.098	(e)	P=0.161	P=0.090



TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Pituitary Gland: Pars Distalis Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/42.79	1/45.25	0/41.68	0/44.58
POLY-3 PERCENT (g)	2.3%	2.2%	0%	0%
TERMINAL (d)	1/34 (3%)	1/36 (3%)	0/30 (0%)	0/36 (0%)
FIRST INCIDENCE	730 (T)	730 (T)	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Pituitary Gland: Pars Intermedia Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.79	0/45.25	0/41.68	0/44.58
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/30 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Preputial Gland Ectasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	7/50 (14%)	6/50 (12%)	7/50 (14%)	8/50 (16%)
POLY-3 RATE (b)	7/42.79	6/45.25	7/42.96	8/45.37
POLY-3 PERCENT (g)	16.4%	13.3%	16.3%	17.6%
TERMINAL (d)	7/34 (21%)	6/36 (17%)	6/31 (19%)	5/36 (14%)
FIRST INCIDENCE	730 (T)	730 (T)	655	623
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.413	P=0.457N	P=0.611N	P=0.549
POLY 1.5	P=0.407	P=0.457N	P=0.596N	P=0.544
POLY 6	P=0.425	P=0.458N	P=0.603	P=0.558
COCH-ARM / FISHERS	P=0.383	P=0.500N	P=0.613N	P=0.500
MAX-ISO-POLY-3	P=0.569	P=0.345N	P=0.496N	P=0.437

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Skin Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/50 (6%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	3/43.78	1/45.25	1/42.91	1/44.86
POLY-3 PERCENT (g)	6.9%	2.2%	2.3%	2.2%
TERMINAL (d)	2/34 (6%)	1/36 (3%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	156	730 (T)	669	655
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.342N	P=0.293N	P=0.312N	P=0.296N
POLY 1.5	P=0.343N	P=0.292N	P=0.304N	P=0.296N
POLY 6	P=0.340N	P=0.294N	P=0.320N	P=0.296N
COCH-ARM / FISHERS	P=0.342N	P=0.309N	P=0.309N	P=0.309N
MAX-ISO-POLY-3	P=0.191N	P=0.149N	P=0.161N	P=0.150N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Skin</b>				
<b>Ulcer</b>				
<b>LESION RATES</b>				
OVERALL (a)	4/50 (8%)	1/50 (2%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	4/43.78	1/45.25	1/42.91	2/44.86
POLY-3 PERCENT (g)	9.1%	2.2%	2.3%	4.5%
TERMINAL (d)	3/34 (9%)	1/36 (3%)	0/31 (0%)	1/36 (3%)
FIRST INCIDENCE	156	730 (T)	669	655
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.464N	P=0.168N	P=0.184N	P=0.326N
POLY 1.5	P=0.465N	P=0.168N	P=0.178N	P=0.325N
POLY 6	P=0.462N	P=0.169N	P=0.191N	P=0.325N
COCH-ARM / FISHERS	P=0.463N	P=0.181N	P=0.181N	P=0.339N
MAX-ISO-POLY-3	P=0.137N	P=0.081N	P=0.089N	P=0.194N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Skin: Dermis</b>				
<b>Fibrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/43.78	0/45.25	0/42.68	1/44.58
POLY-3 PERCENT (g)	4.6%	0%	0%	2.2%
TERMINAL (d)	1/34 (3%)	0/36 (0%)	0/31 (0%)	1/36 (3%)
FIRST INCIDENCE	156	---	---	730 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.654N	P=0.230N	P=0.243N	P=0.494N
POLY 1.5	P=0.655N	P=0.229N	P=0.237N	P=0.492N
POLY 6	P=0.654N	P=0.230N	P=0.249N	P=0.495N
COCH-ARM / FISHERS	P=0.650N	P=0.247N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.137N	P=0.076N	P=0.081N	P=0.277N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Skin: Epidermis Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/42.79	0/45.25	1/42.91	1/44.58
POLY-3 PERCENT (g)	2.3%	0%	2.3%	2.2%
TERMINAL (d)	1/34 (3%)	0/36 (0%)	0/31 (0%)	1/36 (3%)
FIRST INCIDENCE	730 (T)	---	669	730 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Spleen Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	4/48 (8%)	11/50 (22%)	11/49 (22%)	6/50 (12%)
POLY-3 RATE (b)	4/42.61	11/47.65	11/43.89	6/45.56
POLY-3 PERCENT (g)	9.4%	23.1%	25.1%	13.2%
TERMINAL (d)	1/34 (3%)	5/36 (14%)	4/31 (13%)	2/36 (6%)
FIRST INCIDENCE	562	555	609	623
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.395N	P=0.071	P=0.048*	P=0.412
POLY 1.5	P=0.385N	P=0.070	P=0.053	P=0.418
POLY 6	P=0.407N	P=0.072	P=0.044*	P=0.406
COCH-ARM / FISHERS	P=0.405N	P=0.054	P=0.049*	P=0.397
MAX-ISO-POLY-3	P=0.151	P=0.046*	P=0.027*	P=0.294



TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Spleen</b>				
<b>Hematopoietic Cell Proliferation</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	15/48 (31%)	18/50 (36%)	23/49 (47%)	22/50 (44%)
<b>POLY-3 RATE (b)</b>	15/43.77	18/48.05	23/45.45	22/47.55
<b>POLY-3 PERCENT (g)</b>	34.3%	37.5%	50.6%	46.3%
<b>TERMINAL (d)</b>	10/34 (29%)	10/36 (28%)	12/31 (39%)	12/36 (33%)
<b>FIRST INCIDENCE</b>	156	539	512	580
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.157	P=0.460	P=0.086	P=0.170
<b>POLY 1.5</b>	P=0.154	P=0.454	P=0.094	P=0.165
<b>POLY 6</b>	P=0.173	P=0.469	P=0.082	P=0.184
<b>COCH-ARM / FISHERS</b>	P=0.141	P=0.389	P=0.084	P=0.137
<b>MAX-ISO-POLY-3</b>	P=0.150	P=0.378	P=0.059	P=0.128

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 N,N-Dimethyl-p-toluidine  
 CAS Number: 99-97-8

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Spleen</b>				
<b>Hyperplasia Lymphoid</b>				
<b>LESION RATES</b>				
OVERALL (a)	5/48 (10%)	9/50 (18%)	6/49 (12%)	9/50 (18%)
POLY-3 RATE (b)	5/42.02	9/45.61	6/43.23	9/46.85
POLY-3 PERCENT (g)	11.9%	19.7%	13.9%	19.2%
TERMINAL (d)	3/34 (9%)	7/36 (19%)	5/31 (16%)	6/36 (17%)
FIRST INCIDENCE	561	666	449	256
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.339	P=0.240	P=0.520	P=0.258
POLY 1.5	P=0.334	P=0.246	P=0.535	P=0.257
POLY 6	P=0.338	P=0.232	P=0.498	P=0.253
COCH-ARM / FISHERS	P=0.292	P=0.217	P=0.515	P=0.217
MAX-ISO-POLY-3	P=0.302	P=0.167	P=0.392	P=0.184

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Spleen Pigmentation</b>				
<b>LESION RATES</b>				
OVERALL (a)	38/48 (79%)	34/50 (68%)	25/49 (51%)	44/50 (88%)
POLY-3 RATE (b)	38/43.65	34/46.99	25/44.11	44/49.21
POLY-3 PERCENT (g)	87.1%	72.4%	56.7%	89.4%
TERMINAL (d)	31/34 (91%)	27/36 (75%)	21/31 (68%)	33/36 (92%)
FIRST INCIDENCE	561	555	402	256
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.075	P=0.060N	P<0.001N**	P=0.487
POLY 1.5	P=0.063	P=0.057N	P<0.001N**	P=0.448
POLY 6	P=0.093	P=0.072N	P<0.001N**	P=0.519
COCH-ARM / FISHERS	P=0.040*	P=0.153N	P=0.003N**	P=0.182
MAX-ISO-POLY-3	P=0.030*	P=0.037N*	P<0.001N**	P=0.361

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Spleen: Red Pulp Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	4/48 (8%)	1/50 (2%)	2/49 (4%)	2/50 (4%)
POLY-3 RATE (b)	4/41.28	1/45.25	2/42.46	2/44.58
POLY-3 PERCENT (g)	9.7%	2.2%	4.7%	4.5%
TERMINAL (d)	4/34 (12%)	1/36 (3%)	2/31 (7%)	2/36 (6%)
FIRST INCIDENCE	730 (T)	730 (T)	730 (T)	730 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.447N	P=0.151N	P=0.324N	P=0.302N
POLY 1.5	P=0.447N	P=0.151N	P=0.315N	P=0.300N
POLY 6	P=0.447N	P=0.153N	P=0.335N	P=0.305N
COCH-ARM / FISHERS	P=0.445N	P=0.168N	P=0.329N	P=0.319N
MAX-ISO-POLY-3	P=0.188N	P=0.074N	P=0.192N	P=0.180N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Stomach, Forestomach Erosion</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/42.79	1/45.25	0/42.68	0/44.58
POLY-3 PERCENT (g)	4.7%	2.2%	0%	0%
TERMINAL (d)	2/34 (6%)	1/36 (3%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	730 (T)	730 (T)	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.170N	P=0.480N	P=0.237N	P=0.228N
POLY 1.5	P=0.170N	P=0.480N	P=0.233N	P=0.228N
POLY 6	P=0.169N	P=0.481N	P=0.243N	P=0.229N
COCH-ARM / FISHERS	P=0.169N	P=0.500N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.080N	P=0.270N	P=0.076N	P=0.076N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Stomach, Forestomach Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	13/50 (26%)	12/50 (24%)	13/50 (26%)	8/50 (16%)
POLY-3 RATE (b)	13/45.08	12/47.21	13/43.50	8/46.08
POLY-3 PERCENT (g)	28.8%	25.4%	29.9%	17.4%
TERMINAL (d)	6/34 (18%)	7/36 (19%)	9/31 (29%)	3/36 (8%)
FIRST INCIDENCE	561	550	597	609
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.123N	P=0.447N	P=0.550	P=0.146N
POLY 1.5	P=0.121N	P=0.441N	P=0.591N	P=0.141N
POLY 6	P=0.126N	P=0.457N	P=0.498	P=0.151N
COCH-ARM / FISHERS	P=0.130N	P=0.500N	P=0.590N	P=0.163N
MAX-ISO-POLY-3	P=0.171N	P=0.359N	P=0.457	P=0.098N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Stomach, Forestomach Ulcer</b>				
<b>LESION RATES</b>				
OVERALL (a)	5/50 (10%)	4/50 (8%)	5/50 (10%)	5/50 (10%)
POLY-3 RATE (b)	5/43.59	4/45.89	5/43.50	5/45.70
POLY-3 PERCENT (g)	11.5%	8.7%	11.5%	10.9%
TERMINAL (d)	2/34 (6%)	2/36 (6%)	1/31 (3%)	1/36 (3%)
FIRST INCIDENCE	591	568	597	609
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.537	P=0.468N	P=0.629	P=0.600N
POLY 1.5	P=0.534	P=0.466N	P=0.618N	P=0.601N
POLY 6	P=0.542	P=0.472N	P=0.615	P=0.599N
COCH-ARM / FISHERS	P=0.519	P=0.500N	P=0.630N	P=0.630N
MAX-ISO-POLY-3	P=0.665	P=0.337N	P=0.498	P=0.468N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 N,N-Dimethyl-p-toluidine  
 CAS Number: 99-97-8

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Stomach, Forestomach: Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	14/50 (28%)	14/50 (28%)	17/50 (34%)	11/50 (22%)
POLY-3 RATE (b)	14/45.07	14/47.21	17/44.59	11/46.05
POLY-3 PERCENT (g)	31.1%	29.7%	38.1%	23.9%
TERMINAL (d)	8/34 (24%)	9/36 (25%)	10/31 (32%)	6/36 (17%)
FIRST INCIDENCE	561	550	512	609
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.243N	P=0.532N	P=0.315	P=0.297N
POLY 1.5	P=0.236N	P=0.525N	P=0.348	P=0.289N
POLY 6	P=0.248N	P=0.543N	P=0.280	P=0.308N
COCH-ARM / FISHERS	P=0.250N	P=0.588N	P=0.333	P=0.322N
MAX-ISO-POLY-3	P=0.290N	P=0.441N	P=0.242	P=0.224N



TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Testes: Germinal Epithelium Degeneration</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	2/50 (4%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	0/42.79	2/45.25	3/43.06	0/44.58
POLY-3 PERCENT (g)	0%	4.4%	7%	0%
TERMINAL (d)	0/34 (0%)	2/36 (6%)	1/31 (3%)	0/36 (0%)
FIRST INCIDENCE	---	730 (T)	674	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.365N	P=0.250	P=0.119	(e)
POLY 1.5	P=0.365N	P=0.250	P=0.123	(e)
POLY 6	P=0.367N	P=0.249	P=0.116	(e)
COCH-ARM / FISHERS	P=0.382N	P=0.247	P=0.121	(e)
MAX-ISO-POLY-3	P=0.238N	P=0.088	P=0.039*	(e)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine  
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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Thymus Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	41/48 (85%)	47/48 (98%)	47/48 (98%)	48/49 (98%)
POLY-3 RATE (b)	41/45.45	47/48.00	47/47.55	48/49.00
POLY-3 PERCENT (g)	90.2%	97.9%	98.9%	98%
TERMINAL (d)	30/33 (91%)	34/35 (97%)	30/30 (100%)	34/35 (97%)
FIRST INCIDENCE	4	539	402	256
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.176	P=0.119	P=0.070	P=0.114
POLY 1.5	P=0.154	P=0.099	P=0.072	P=0.094
POLY 6	P=0.199	P=0.141	P=0.063	P=0.135
COCH-ARM / FISHERS	P=0.062	P=0.029*	P=0.029*	P=0.028*
MAX-ISO-POLY-3	P=0.027*	P=0.055	P=0.027*	P=0.054

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Thymus</b>				
<b>Hyperplasia Lymphoid</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/48 (2%)	0/48 (0%)	0/48 (0%)	1/49 (2%)
POLY-3 RATE (b)	1/40.96	0/43.38	0/41.34	1/43.58
POLY-3 PERCENT (g)	2.4%	0%	0%	2.3%
TERMINAL (d)	1/33 (3%)	0/35 (0%)	0/30 (0%)	1/35 (3%)
FIRST INCIDENCE	730 (T)	---	---	730 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Thymus Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/48 (4%)	0/48 (0%)	0/48 (0%)	0/49 (0%)
POLY-3 RATE (b)	2/42.50	0/43.38	0/41.34	0/43.58
POLY-3 PERCENT (g)	4.7%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/35 (0%)	0/30 (0%)	0/35 (0%)
FIRST INCIDENCE	4	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.241N	P=0.232N	P=0.243N	P=0.231N
POLY 1.5	P=0.242N	P=0.231N	P=0.238N	P=0.229N
POLY 6	P=0.239N	P=0.235N	P=0.250N	P=0.234N
COCH-ARM / FISHERS	P=0.239N	P=0.247N	P=0.247N	P=0.242N
MAX-ISO-POLY-3	P=0.034N*	P=0.076N	P=0.082N	P=0.075N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Thyroid Gland Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.79	0/45.25	0/42.68	0/44.58
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Tooth Dysplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	34/37 (92%)	36/38 (95%)	34/34 (100%)	26/30 (87%)
POLY-3 RATE (b)	34/37.00	36/37.43	34/34.00	26/28.46
POLY-3 PERCENT (g)	91.9%	96.2%	100%	91.4%
TERMINAL (d)	25/28 (89%)	29/30 (97%)	23/23 (100%)	20/20 (100%)
FIRST INCIDENCE	561	599	548	449
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.472N	P=0.383	P=0.133	P=0.655N
POLY 1.5	P=0.319N	P=0.426	P=0.133	P=0.525N
POLY 6	P=0.578	P=0.337	P=0.133	P=0.545
COCH-ARM / FISHERS	P=0.192N	P=0.487	P=0.136	P=0.382N
MAX-ISO-POLY-3	P=0.325N	P=0.213	P=0.047*	P=0.468N

TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

Date Report Requested: 03/10/2011  
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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Urinary Bladder</b>				
<b>Calculus Gross Observation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/42.79	0/45.25	0/42.68	2/44.58
POLY-3 PERCENT (g)	0%	0%	0%	4.5%
TERMINAL (d)	0/34 (0%)	0/36 (0%)	0/31 (0%)	2/36 (6%)
FIRST INCIDENCE	---	---	---	730 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.041*	(e)	(e)	P=0.246
POLY 1.5	P=0.041*	(e)	(e)	P=0.247
POLY 6	P=0.041*	(e)	(e)	P=0.245
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.042*	(e)	(e)	P=0.085

TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Adrenal Cortex Hypertrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.76	0/46.14	0/45.50	0/40.98
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

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TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Adrenal Cortex Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/47.76	0/46.14	2/46.18	0/40.98
POLY-3 PERCENT (g)	0%	0%	4.3%	0%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	1/39 (3%)	0/32 (0%)
FIRST INCIDENCE	---	---	501	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.698	(e)	P=0.230	(e)
POLY 1.5	P=0.717	(e)	P=0.230	(e)
POLY 6	P=0.674	(e)	P=0.229	(e)
COCH-ARM / FISHERS	P=0.697N	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.278	(e)	P=0.076	(e)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Adrenal Medulla Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/50 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/47.76	0/46.14	0/45.50	0/40.98
POLY-3 PERCENT (g)	6.3%	0%	0%	0%
TERMINAL (d)	3/43 (7%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	729 (T)	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.131N	P=0.125N	P=0.128N	P=0.149N
POLY 1.5	P=0.130N	P=0.124N	P=0.126N	P=0.140N
POLY 6	P=0.132N	P=0.125N	P=0.129N	P=0.159N
COCH-ARM / FISHERS	P=0.134N	P=0.121N	P=0.121N	P=0.121N
MAX-ISO-POLY-3	P=0.025N*	P=0.043N*	P=0.046N*	P=0.064N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Blood Vessel Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	0/47.76	0/45.14	0/45.50	3/41.06
POLY-3 PERCENT (g)	0%	0%	0%	7.3%
TERMINAL (d)	0/43 (0%)	0/39 (0%)	0/39 (0%)	2/32 (6%)
FIRST INCIDENCE	---	---	---	708
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.006**	(e)	(e)	P=0.094
POLY 1.5	P=0.007**	(e)	(e)	P=0.101
POLY 6	P=0.006**	(e)	(e)	P=0.088
COCH-ARM / FISHERS	P=0.009**	(e)	(e)	P=0.121
MAX-ISO-POLY-3	P=0.010**	(e)	(e)	P=0.038*

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 N,N-Dimethyl-p-toluidine  
 CAS Number: 99-97-8

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Bone Marrow Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	2/50 (4%)	2/50 (4%)	3/49 (6%)
POLY-3 RATE (b)	1/47.76	2/47.70	2/45.50	3/41.65
POLY-3 PERCENT (g)	2.1%	4.2%	4.4%	7.2%
TERMINAL (d)	1/43 (2%)	0/40 (0%)	2/39 (5%)	0/31 (0%)
FIRST INCIDENCE	729 (T)	8	729 (T)	512
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.215	P=0.500	P=0.483	P=0.258
POLY 1.5	P=0.226	P=0.499	P=0.486	P=0.268
POLY 6	P=0.205	P=0.501	P=0.481	P=0.249
COCH-ARM / FISHERS	P=0.260	P=0.500	P=0.500	P=0.301
MAX-ISO-POLY-3	P=0.224	P=0.280	P=0.271	P=0.137

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Bone Marrow Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	5/50 (10%)	14/50 (28%)	15/50 (30%)	14/49 (29%)
POLY-3 RATE (b)	5/48.06	14/47.02	15/47.42	14/43.63
POLY-3 PERCENT (g)	10.4%	29.8%	31.6%	32.1%
TERMINAL (d)	4/43 (9%)	8/40 (20%)	8/39 (21%)	6/31 (19%)
FIRST INCIDENCE	645	621	501	43
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.056	P=0.016*	P=0.009**	P=0.009**
POLY 1.5	P=0.070	P=0.016*	P=0.009**	P=0.011*
POLY 6	P=0.045*	P=0.016*	P=0.010**	P=0.007**
COCH-ARM / FISHERS	P=0.098	P=0.020*	P=0.011*	P=0.017*
MAX-ISO-POLY-3	P=0.018*	P=0.009**	P=0.005**	P=0.006**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 N,N-Dimethyl-p-toluidine  
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Date Report Requested: 03/10/2011  
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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Bone</b>				
<b>Fibro-osseous Lesion</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/50 (6%)	5/50 (10%)	6/50 (12%)	11/50 (22%)
POLY-3 RATE (b)	3/47.76	5/46.52	6/45.56	11/41.42
POLY-3 PERCENT (g)	6.3%	10.8%	13.2%	26.6%
TERMINAL (d)	3/43 (7%)	4/40 (10%)	5/39 (13%)	10/32 (31%)
FIRST INCIDENCE	729 (T)	621	715	602
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.004**	P=0.342	P=0.219	P=0.008**
POLY 1.5	P=0.005**	P=0.343	P=0.223	P=0.011*
POLY 6	P=0.003**	P=0.344	P=0.216	P=0.006**
COCH-ARM / FISHERS	P=0.010**	P=0.357	P=0.243	P=0.020*
MAX-ISO-POLY-3	P=0.007**	P=0.223	P=0.136	P=0.006**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 N,N-Dimethyl-p-toluidine  
 CAS Number: 99-97-8

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Brain: Olfactory Lobe Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	8/49 (16%)
POLY-3 RATE (b)	0/47.76	0/46.14	0/45.50	8/41.70
POLY-3 PERCENT (g)	0%	0%	0%	19.2%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	4/32 (13%)
FIRST INCIDENCE	---	---	---	570
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	(e)	(e)	P=0.002**
POLY 1.5	P<0.001**	(e)	(e)	P=0.002**
POLY 6	P<0.001**	(e)	(e)	P=0.002**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.003**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P<0.001**

TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS

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DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG

---

Esophagus: Periesophageal Tissue  
Inflammation

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.76	0/46.14	0/45.50	0/40.98
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	---	---

---

**STATISTICAL TESTS**

POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

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TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Eye: Cornea Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	3/49 (6%)
POLY-3 RATE (b)	0/47.76	1/46.14	1/45.73	3/41.61
POLY-3 PERCENT (g)	0%	2.2%	2.2%	7.2%
TERMINAL (d)	0/43 (0%)	1/40 (3%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	729 (T)	669	573
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.049*	P=0.493	P=0.491	P=0.096
POLY 1.5	P=0.052	P=0.494	P=0.492	P=0.100
POLY 6	P=0.046*	P=0.493	P=0.491	P=0.092
COCH-ARM / FISHERS	P=0.061	P=0.500	P=0.500	P=0.117
MAX-ISO-POLY-3	P=0.042*	P=0.159	P=0.159	P=0.037*

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Harderian Gland Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	4/50 (8%)	2/50 (4%)	0/50 (0%)	2/49 (4%)
POLY-3 RATE (b)	4/47.76	2/46.14	0/45.50	2/40.21
POLY-3 PERCENT (g)	8.4%	4.3%	0%	5%
TERMINAL (d)	4/43 (9%)	2/40 (5%)	0/39 (0%)	1/32 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	---	701
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.415N	P=0.353N	P=0.067N	P=0.419N
POLY 1.5	P=0.407N	P=0.351N	P=0.066N	P=0.399N
POLY 6	P=0.424N	P=0.354N	P=0.068N	P=0.441N
COCH-ARM / FISHERS	P=0.387N	P=0.339N	P=0.059N	P=0.349N
MAX-ISO-POLY-3	P=0.170N	P=0.218N	P=0.025N*	P=0.282N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Heart</b>				
<b>Cardiomyopathy</b>				
<b>LESION RATES</b>				
OVERALL (a)	5/50 (10%)	2/50 (4%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	5/48.06	2/46.14	4/46.28	2/40.98
POLY-3 PERCENT (g)	10.4%	4.3%	8.6%	4.9%
TERMINAL (d)	4/43 (9%)	2/40 (5%)	2/39 (5%)	2/32 (6%)
FIRST INCIDENCE	645	729 (T)	501	729 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.348N	P=0.234N	P=0.524N	P=0.286N
POLY 1.5	P=0.327N	P=0.230N	P=0.521N	P=0.265N
POLY 6	P=0.373N	P=0.236N	P=0.527N	P=0.311N
COCH-ARM / FISHERS	P=0.280N	P=0.218N	P=0.500N	P=0.218N
MAX-ISO-POLY-3	P=0.292N	P=0.136N	P=0.387N	P=0.187N

TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

Date Report Requested: 03/10/2011  
Time Report Requested: 11:42:39  
First Dose M/F: 10/26/04 / 10/25/04  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Heart Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/47.76	0/46.14	0/45.50	1/41.48
POLY-3 PERCENT (g)	0%	0%	0%	2.4%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	---	578
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

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TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Heart Mineralization</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	5/50 (10%)
POLY-3 RATE (b)	1/47.99	2/47.00	1/45.86	5/43.67
POLY-3 PERCENT (g)	2.1%	4.3%	2.2%	11.5%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	666	449	627	512
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.033*	P=0.493	P=0.750	P=0.081
POLY 1.5	P=0.035*	P=0.493	P=0.752	P=0.085
POLY 6	P=0.031*	P=0.493	P=0.749	P=0.078
COCH-ARM / FISHERS	P=0.042*	P=0.500	P=0.753N	P=0.102
MAX-ISO-POLY-3	P=0.038*	P=0.277	P=0.487	P=0.040*

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Heart Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/47.76	0/46.14	2/46.66	0/40.98
POLY-3 PERCENT (g)	0%	0%	4.3%	0%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	501	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.697	(e)	P=0.232	(e)
POLY 1.5	P=0.717	(e)	P=0.232	(e)
POLY 6	P=0.674	(e)	P=0.233	(e)
COCH-ARM / FISHERS	P=0.697N	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.280	(e)	P=0.076	(e)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Islets, Pancreatic Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/47.76	1/46.14	0/45.50	2/40.98
POLY-3 PERCENT (g)	0%	2.2%	0%	4.9%
TERMINAL (d)	0/43 (0%)	1/40 (3%)	0/39 (0%)	2/32 (6%)
FIRST INCIDENCE	---	729 (T)	---	729 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.129	P=0.493	(e)	P=0.205
POLY 1.5	P=0.135	P=0.494	(e)	P=0.214
POLY 6	P=0.123	P=0.493	(e)	P=0.196
COCH-ARM / FISHERS	P=0.151	P=0.500	(e)	P=0.247
MAX-ISO-POLY-3	P=0.080	P=0.159	(e)	P=0.075

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Kidney</b>				
Accumulation, Hyaline Droplet				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/47.76	2/46.29	1/45.98	0/40.98
POLY-3 PERCENT (g)	0%	4.3%	2.2%	0%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	700	585	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.422N	P=0.230	P=0.492	(e)
POLY 1.5	P=0.410N	P=0.231	P=0.493	(e)
POLY 6	P=0.435N	P=0.231	P=0.492	(e)
COCH-ARM / FISHERS	P=0.378N	P=0.247	P=0.500	(e)
MAX-ISO-POLY-3	P=0.364	P=0.076	P=0.159	(e)



TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Kidney Infarct</b>				
<b>LESION RATES</b>				
OVERALL (a)	4/50 (8%)	3/50 (6%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	4/47.76	3/46.14	4/45.50	0/40.98
POLY-3 PERCENT (g)	8.4%	6.5%	8.8%	0%
TERMINAL (d)	4/43 (9%)	3/40 (8%)	4/39 (10%)	0/32 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.085N	P=0.519N	P=0.616	P=0.083N
POLY 1.5	P=0.076N	P=0.516N	P=0.620	P=0.076N
POLY 6	P=0.095N	P=0.520N	P=0.612	P=0.091N
COCH-ARM / FISHERS	P=0.058N	P=0.500N	P=0.643N	P=0.059N
MAX-ISO-POLY-3	P=0.105N	P=0.367N	P=0.471	P=0.038N*

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Kidney Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/47.76	0/46.14	1/46.18	2/41.48
POLY-3 PERCENT (g)	0%	0%	2.2%	4.8%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	1/32 (3%)
FIRST INCIDENCE	---	---	501	578
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.067	(e)	P=0.493	P=0.207
POLY 1.5	P=0.072	(e)	P=0.494	P=0.215
POLY 6	P=0.063	(e)	P=0.493	P=0.199
COCH-ARM / FISHERS	P=0.084	(e)	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.080	(e)	P=0.159	P=0.076

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Kidney Mineralization</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	0/47.76	1/46.24	0/45.50	3/42.10
POLY-3 PERCENT (g)	0%	2.2%	0%	7.1%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	704	---	578
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.034*	P=0.494	(e)	P=0.098
POLY 1.5	P=0.036*	P=0.494	(e)	P=0.103
POLY 6	P=0.032*	P=0.494	(e)	P=0.093
COCH-ARM / FISHERS	P=0.042*	P=0.500	(e)	P=0.121
MAX-ISO-POLY-3	P=0.025*	P=0.159	(e)	P=0.038*

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Kidney</b>				
<b>Nephropathy</b>				
<b>LESION RATES</b>				
OVERALL (a)	13/50 (26%)	15/50 (30%)	15/50 (30%)	17/50 (34%)
POLY-3 RATE (b)	13/47.76	15/46.40	15/46.53	17/43.74
POLY-3 PERCENT (g)	27.2%	32.3%	32.2%	38.9%
TERMINAL (d)	13/43 (30%)	13/40 (33%)	11/39 (28%)	11/32 (34%)
FIRST INCIDENCE	729 (T)	671	585	387
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.166	P=0.376	P=0.380	P=0.167
POLY 1.5	P=0.186	P=0.379	P=0.378	P=0.186
POLY 6	P=0.145	P=0.379	P=0.388	P=0.148
COCH-ARM / FISHERS	P=0.255	P=0.412	P=0.412	P=0.257
MAX-ISO-POLY-3	P=0.209	P=0.297	P=0.300	P=0.127

TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Kidney Pigmentation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.76	0/46.14	0/45.50	0/40.98
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Kidney: Cortex Cyst</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/47.76	0/46.14	0/45.50	1/41.06
POLY-3 PERCENT (g)	0%	0%	0%	2.4%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	---	708
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Kidney: Pelvis Dilatation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.76	0/46.14	0/45.50	0/40.98
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Kidney: Renal Tubule Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	1/47.99	0/46.14	2/46.66	2/41.50
POLY-3 PERCENT (g)	2.1%	0%	4.3%	4.8%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	1/32 (3%)
FIRST INCIDENCE	666	---	501	570
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.221	P=0.508N	P=0.490	P=0.450
POLY 1.5	P=0.234	P=0.506N	P=0.490	P=0.464
POLY 6	P=0.207	P=0.509N	P=0.490	P=0.434
COCH-ARM / FISHERS	P=0.265	P=0.500N	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.259	P=0.168N	P=0.275	P=0.254



TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver</b>				
<b>Angiectasis</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>POLY-3 RATE (b)</b>	1/47.76	0/46.14	0/45.50	0/40.98
<b>POLY-3 PERCENT (g)</b>	2.1%	0%	0%	0%
<b>TERMINAL (d)</b>	1/43 (2%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
<b>FIRST INCIDENCE</b>	729 (T)	---	---	---
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	(n)	(n)	(n)	(n)
<b>POLY 1.5</b>	(n)	(n)	(n)	(n)
<b>POLY 6</b>	(n)	(n)	(n)	(n)
<b>COCH-ARM / FISHERS</b>	(n)	(n)	(n)	(n)
<b>MAX-ISO-POLY-3</b>	(n)	(n)	(n)	(n)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 N,N-Dimethyl-p-toluidine  
 CAS Number: 99-97-8

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver</b>				
<b>Basophilic Focus</b>				
<b>LESION RATES</b>				
OVERALL (a)	7/50 (14%)	5/50 (10%)	9/50 (18%)	11/50 (22%)
POLY-3 RATE (b)	7/47.76	5/46.95	9/45.90	11/42.00
POLY-3 PERCENT (g)	14.7%	10.7%	19.6%	26.2%
TERMINAL (d)	7/43 (16%)	2/40 (5%)	7/39 (18%)	8/32 (25%)
FIRST INCIDENCE	729 (T)	509	649	570
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.048*	P=0.391N	P=0.360	P=0.136
POLY 1.5	P=0.058	P=0.393N	P=0.363	P=0.155
POLY 6	P=0.039*	P=0.387N	P=0.359	P=0.119
COCH-ARM / FISHERS	P=0.091	P=0.380N	P=0.393	P=0.218
MAX-ISO-POLY-3	P=0.077	P=0.282N	P=0.268	P=0.100

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver</b>				
<b>Clear Cell Focus</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	0/50 (0%)	2/50 (4%)	2/50 (4%)	3/50 (6%)
<b>POLY-3 RATE (b)</b>	0/47.76	2/46.14	2/45.73	3/40.98
<b>POLY-3 PERCENT (g)</b>	0%	4.3%	4.4%	7.3%
<b>TERMINAL (d)</b>	0/43 (0%)	2/40 (5%)	1/39 (3%)	3/32 (9%)
<b>FIRST INCIDENCE</b>	---	729 (T)	669	729 (T)
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.115	P=0.230	P=0.228	P=0.094
<b>POLY 1.5</b>	P=0.126	P=0.231	P=0.229	P=0.101
<b>POLY 6</b>	P=0.104	P=0.229	P=0.227	P=0.087
<b>COCH-ARM / FISHERS</b>	P=0.156	P=0.247	P=0.247	P=0.121
<b>MAX-ISO-POLY-3</b>	P=0.082	P=0.076	P=0.076	P=0.038*

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver</b>				
<b>Eosinophilic Focus</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	20/50 (40%)	18/50 (36%)	45/50 (90%)	38/50 (76%)
<b>POLY-3 RATE (b)</b>	20/48.12	18/46.16	45/47.30	38/44.13
<b>POLY-3 PERCENT (g)</b>	41.6%	39%	95.1%	86.1%
<b>TERMINAL (d)</b>	18/43 (42%)	17/40 (43%)	38/39 (97%)	29/32 (91%)
<b>FIRST INCIDENCE</b>	666	723	501	481
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P<0.001**	P=0.482N	P<0.001**	P<0.001**
<b>POLY 1.5</b>	P<0.001**	P=0.470N	P<0.001**	P<0.001**
<b>POLY 6</b>	P<0.001**	P=0.495N	P<0.001**	P<0.001**
<b>COCH-ARM / FISHERS</b>	P<0.001**	P=0.418N	P<0.001**	P<0.001**
<b>MAX-ISO-POLY-3</b>	P<0.001**	P=0.399N	P<0.001**	P<0.001**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver</b>				
<b>Fatty Change</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	8/50 (16%)
POLY-3 RATE (b)	1/48.07	0/46.14	0/45.50	8/43.74
POLY-3 PERCENT (g)	2.1%	0%	0%	18.3%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	2/32 (6%)
FIRST INCIDENCE	642	---	---	512
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.508N	P=0.511N	P=0.010**
POLY 1.5	P<0.001**	P=0.507N	P=0.509N	P=0.011*
POLY 6	P<0.001**	P=0.510N	P=0.513N	P=0.009**
COCH-ARM / FISHERS	P<0.001**	P=0.500N	P=0.500N	P=0.015*
MAX-ISO-POLY-3	P<0.001**	P=0.169N	P=0.172N	P=0.005**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver</b>				
<b>Hematopoietic Cell Proliferation</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	4/50 (8%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	2/48.06	4/46.14	2/45.50	3/42.69
POLY-3 PERCENT (g)	4.2%	8.7%	4.4%	7%
TERMINAL (d)	1/43 (2%)	4/40 (10%)	2/39 (5%)	1/32 (3%)
FIRST INCIDENCE	645	729 (T)	729 (T)	43
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.506	P=0.319	P=0.674	P=0.446
POLY 1.5	P=0.526	P=0.322	P=0.678	P=0.464
POLY 6	P=0.483	P=0.316	P=0.669	P=0.426
COCH-ARM / FISHERS	P=0.566	P=0.339	P=0.691N	P=0.500
MAX-ISO-POLY-3	P=0.475	P=0.191	P=0.477	P=0.289

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 N,N-Dimethyl-p-toluidine  
 CAS Number: 99-97-8

Date Report Requested: 03/10/2011  
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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver</b>				
<b>Inflammation Chronic</b>				
<b>LESION RATES</b>				
OVERALL (a)	39/50 (78%)	27/50 (54%)	33/50 (66%)	35/50 (70%)
POLY-3 RATE (b)	39/48.75	27/46.54	33/47.72	35/43.72
POLY-3 PERCENT (g)	80%	58%	69.2%	80.1%
TERMINAL (d)	35/43 (81%)	25/40 (63%)	28/39 (72%)	28/32 (88%)
FIRST INCIDENCE	642	621	11	387
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.178	P=0.015N*	P=0.156N	P=0.604
POLY 1.5	P=0.243	P=0.013N*	P=0.150N	P=0.499N
POLY 6	P=0.116	P=0.016N*	P=0.167N	P=0.474
COCH-ARM / FISHERS	P=0.446	P=0.010N**	P=0.133N	P=0.247N
MAX-ISO-POLY-3	P=0.197N	P=0.009N**	P=0.108N	P=0.496

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver</b>				
<b>Mitotic Alteration</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.76	0/46.14	0/45.50	0/40.98
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)



TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver</b>				
<b>Mixed Cell Focus</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/50 (6%)	9/50 (18%)	7/50 (14%)	7/50 (14%)
POLY-3 RATE (b)	3/47.76	9/46.38	7/46.11	7/43.36
POLY-3 PERCENT (g)	6.3%	19.4%	15.2%	16.1%
TERMINAL (d)	3/43 (7%)	7/40 (18%)	4/39 (10%)	3/32 (9%)
FIRST INCIDENCE	729 (T)	671	649	481
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.296	P=0.053	P=0.144	P=0.121
POLY 1.5	P=0.313	P=0.054	P=0.145	P=0.129
POLY 6	P=0.277	P=0.053	P=0.144	P=0.113
COCH-ARM / FISHERS	P=0.376	P=0.061	P=0.159	P=0.159
MAX-ISO-POLY-3	P=0.134	P=0.029*	P=0.085	P=0.075

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver</b>				
<b>Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	8/50 (16%)	4/50 (8%)	10/50 (20%)
POLY-3 RATE (b)	1/47.99	8/46.94	4/46.28	10/43.79
POLY-3 PERCENT (g)	2.1%	17%	8.6%	22.8%
TERMINAL (d)	0/43 (0%)	6/40 (15%)	2/39 (5%)	3/32 (9%)
FIRST INCIDENCE	666	449	585	512
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.012*	P=0.014*	P=0.168	P=0.002**
POLY 1.5	P=0.013*	P=0.015*	P=0.169	P=0.003**
POLY 6	P=0.011*	P=0.014*	P=0.168	P=0.002**
COCH-ARM / FISHERS	P=0.021*	P=0.015*	P=0.181	P=0.004**
MAX-ISO-POLY-3	P=0.003**	P=0.006**	P=0.081	P<0.001**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver Pigmentation</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	1/50 (2%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	1/47.76	1/46.14	1/45.50	4/41.06
POLY-3 PERCENT (g)	2.1%	2.2%	2.2%	9.7%
TERMINAL (d)	1/43 (2%)	1/40 (3%)	1/39 (3%)	3/32 (9%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	708
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.043*	P=0.753	P=0.750	P=0.137
POLY 1.5	P=0.047*	P=0.754	P=0.751	P=0.148
POLY 6	P=0.039*	P=0.752	P=0.748	P=0.125
COCH-ARM / FISHERS	P=0.058	P=0.753N	P=0.753N	P=0.181
MAX-ISO-POLY-3	P=0.070	P=0.490	P=0.486	P=0.073

TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver: Bile Duct Cyst</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	1/50 (2%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	2/47.99	1/46.14	1/45.50	3/40.98
POLY-3 PERCENT (g)	4.2%	2.2%	2.2%	7.3%
TERMINAL (d)	1/43 (2%)	1/40 (3%)	1/39 (3%)	3/32 (9%)
FIRST INCIDENCE	666	729 (T)	729 (T)	729 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.238	P=0.514N	P=0.519N	P=0.429
POLY 1.5	P=0.250	P=0.511N	P=0.515N	P=0.450
POLY 6	P=0.224	P=0.516N	P=0.523N	P=0.406
COCH-ARM / FISHERS	P=0.280	P=0.500N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.261	P=0.296N	P=0.301N	P=0.278

TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine  
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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS

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DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<hr/>				
Liver: Bile Duct Hyperplasia				
<hr/>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.76	0/46.14	0/45.50	0/40.98
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

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TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 N,N-Dimethyl-p-toluidine  
 CAS Number: 99-97-8

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver: Hepatocyte Hypertrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	11/50 (22%)	10/50 (20%)	17/50 (34%)
POLY-3 RATE (b)	0/47.76	11/46.64	10/45.60	17/42.17
POLY-3 PERCENT (g)	0%	23.6%	21.9%	40.3%
TERMINAL (d)	0/43 (0%)	8/40 (20%)	9/39 (23%)	14/32 (44%)
FIRST INCIDENCE	---	621	703	53
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	P<0.001**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 N,N-Dimethyl-p-toluidine  
 CAS Number: 99-97-8

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Liver: Oval Cell Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/47.76	0/46.14	0/45.50	2/41.59
POLY-3 PERCENT (g)	0%	0%	0%	4.8%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	---	570
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.035*	(e)	(e)	P=0.208
POLY 1.5	P=0.037*	(e)	(e)	P=0.216
POLY 6	P=0.034*	(e)	(e)	P=0.200
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.034*	(e)	(e)	P=0.076

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 N,N-Dimethyl-p-toluidine  
 CAS Number: 99-97-8

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lung</b>				
<b>Foreign Body</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/47.76	1/47.14	0/45.50	2/42.98
POLY-3 PERCENT (g)	0%	2.1%	0%	4.7%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	8	---	43
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.135	P=0.497	(e)	P=0.215
POLY 1.5	P=0.141	P=0.498	(e)	P=0.223
POLY 6	P=0.129	P=0.497	(e)	P=0.205
COCH-ARM / FISHERS	P=0.151	P=0.500	(e)	P=0.247
MAX-ISO-POLY-3	P=0.080	P=0.159	(e)	P=0.076



TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lung Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/47.76	2/47.14	0/45.50	2/42.98
POLY-3 PERCENT (g)	0%	4.2%	0%	4.7%
TERMINAL (d)	0/43 (0%)	1/40 (3%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	8	---	43
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.260	P=0.234	(e)	P=0.215
POLY 1.5	P=0.270	P=0.235	(e)	P=0.223
POLY 6	P=0.249	P=0.234	(e)	P=0.205
COCH-ARM / FISHERS	P=0.287	P=0.247	(e)	P=0.247
MAX-ISO-POLY-3	P=0.123	P=0.076	(e)	P=0.076

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lung: Alveolar Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	3/50 (6%)	8/50 (16%)	2/50 (4%)
POLY-3 RATE (b)	2/47.76	3/46.16	8/45.98	2/41.49
POLY-3 PERCENT (g)	4.2%	6.5%	17.4%	4.8%
TERMINAL (d)	2/43 (5%)	2/40 (5%)	7/39 (18%)	1/32 (3%)
FIRST INCIDENCE	729 (T)	723	585	573
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.587	P=0.485	P=0.039*	P=0.642
POLY 1.5	P=0.558N	P=0.487	P=0.040*	P=0.657
POLY 6	P=0.550	P=0.484	P=0.039*	P=0.626
COCH-ARM / FISHERS	P=0.479N	P=0.500	P=0.046*	P=0.691N
MAX-ISO-POLY-3	P=0.201	P=0.313	P=0.020*	P=0.445

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lung: Alveolus Infiltration Cellular Histiocyte</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	7/50 (14%)
POLY-3 RATE (b)	1/47.76	0/46.14	0/45.50	7/43.65
POLY-3 PERCENT (g)	2.1%	0%	0%	16%
TERMINAL (d)	1/43 (2%)	0/40 (0%)	0/39 (0%)	2/32 (6%)
FIRST INCIDENCE	729 (T)	---	---	43
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.507N	P=0.510N	P=0.022*
POLY 1.5	P<0.001**	P=0.506N	P=0.508N	P=0.025*
POLY 6	P<0.001**	P=0.507N	P=0.511N	P=0.019*
COCH-ARM / FISHERS	P<0.001**	P=0.500N	P=0.500N	P=0.030*
MAX-ISO-POLY-3	P<0.001**	P=0.167N	P=0.171N	P=0.011*

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lung: Bronchiole, Epithelium Regeneration</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	5/50 (10%)
POLY-3 RATE (b)	0/47.76	0/46.14	0/45.50	5/43.87
POLY-3 PERCENT (g)	0%	0%	0%	11.4%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	---	387
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	(e)	(e)	P=0.024*
POLY 1.5	P<0.001**	(e)	(e)	P=0.025*
POLY 6	P<0.001**	(e)	(e)	P=0.023*
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.028*
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P=0.010**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lung: Bronchus Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	5/50 (10%)
POLY-3 RATE (b)	0/47.76	0/46.14	0/45.50	5/43.73
POLY-3 PERCENT (g)	0%	0%	0%	11.4%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	---	481
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	(e)	(e)	P=0.024*
POLY 1.5	P<0.001**	(e)	(e)	P=0.025*
POLY 6	P<0.001**	(e)	(e)	P=0.023*
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.028*
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P=0.010**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lung: Bronchus, Epithelium Regeneration</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	5/50 (10%)
POLY-3 RATE (b)	0/47.76	0/46.14	0/45.50	5/43.87
POLY-3 PERCENT (g)	0%	0%	0%	11.4%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	---	387
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	(e)	(e)	P=0.024*
POLY 1.5	P<0.001**	(e)	(e)	P=0.025*
POLY 6	P<0.001**	(e)	(e)	P=0.023*
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.028*
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P=0.010**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lymph Node, Mandibular Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	4/50 (8%)	5/50 (10%)	5/48 (10%)
POLY-3 RATE (b)	1/48.07	4/47.18	5/47.24	5/40.12
POLY-3 PERCENT (g)	2.1%	8.5%	10.6%	12.5%
TERMINAL (d)	0/43 (0%)	2/40 (5%)	2/39 (5%)	4/32 (13%)
FIRST INCIDENCE	642	8	253	627
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.102	P=0.173	P=0.098	P=0.066
POLY 1.5	P=0.115	P=0.176	P=0.098	P=0.072
POLY 6	P=0.090	P=0.172	P=0.097	P=0.059
COCH-ARM / FISHERS	P=0.156	P=0.181	P=0.102	P=0.093
MAX-ISO-POLY-3	P=0.085	P=0.082	P=0.044*	P=0.036*

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lymph Node, Mandibular Hyperplasia Lymphoid</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/50 (6%)	5/50 (10%)	0/50 (0%)	3/48 (6%)
POLY-3 RATE (b)	3/48.53	5/46.14	0/45.50	3/40.46
POLY-3 PERCENT (g)	6.2%	10.8%	0%	7.4%
TERMINAL (d)	2/43 (5%)	5/40 (13%)	0/39 (0%)	2/32 (6%)
FIRST INCIDENCE	444	729 (T)	---	481
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.535N	P=0.329	P=0.131N	P=0.576
POLY 1.5	P=0.523N	P=0.335	P=0.128N	P=0.594
POLY 6	P=0.548N	P=0.326	P=0.133N	P=0.556
COCH-ARM / FISHERS	P=0.488N	P=0.357	P=0.121N	P=0.641
MAX-ISO-POLY-3	P=0.299N	P=0.215	P=0.048N*	P=0.414



TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lymph Node, Mesenteric Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/49 (2%)	5/49 (10%)	5/49 (10%)	12/50 (24%)
POLY-3 RATE (b)	1/47.31	5/47.08	5/45.94	12/44.11
POLY-3 PERCENT (g)	2.1%	10.6%	10.9%	27.2%
TERMINAL (d)	0/43 (0%)	3/40 (8%)	4/39 (10%)	6/32 (19%)
FIRST INCIDENCE	642	555	585	512
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.101	P=0.095	P<0.001**
POLY 1.5	P<0.001**	P=0.101	P=0.096	P<0.001**
POLY 6	P<0.001**	P=0.101	P=0.093	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.102	P=0.102	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.044*	P=0.043*	P<0.001**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lymph Node, Mesenteric Hyperplasia Lymphoid</b>				
<b>LESION RATES</b>				
OVERALL (a)	7/49 (14%)	3/49 (6%)	1/49 (2%)	0/50 (0%)
POLY-3 RATE (b)	7/47.12	3/46.14	1/45.46	0/40.98
POLY-3 PERCENT (g)	14.9%	6.5%	2.2%	0%
TERMINAL (d)	6/43 (14%)	3/40 (8%)	1/39 (3%)	0/32 (0%)
FIRST INCIDENCE	698	729 (T)	729 (T)	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.011N*	P=0.166N	P=0.034N*	P=0.013N*
POLY 1.5	P=0.010N**	P=0.163N	P=0.033N*	P=0.011N*
POLY 6	P=0.012N*	P=0.169N	P=0.035N*	P=0.016N*
COCH-ARM / FISHERS	P=0.008N**	P=0.159N	P=0.030N*	P=0.006N**
MAX-ISO-POLY-3	P=0.006N**	P=0.098N	P=0.015N*	P=0.007N**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Lymph Node: Renal Ectasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/7 (29%)	0/3 (0%)	0/5 (0%)	0/4 (0%)
POLY-3 RATE (b)	2/7.00	0/2.78	0/4.35	0/2.65
POLY-3 PERCENT (g)	28.6%	0%	0%	0%
TERMINAL (d)	2/7 (29%)	0/2 (0%)	0/2 (0%)	0/1 (0%)
FIRST INCIDENCE	729 (T)	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.276N	P=0.456N	P=0.340N	P=0.470N
POLY 1.5	P=0.280N	P=0.446N	P=0.322N	P=0.429N
POLY 6	P=0.276N	P=0.472N	P=0.371N	P=0.511N
COCH-ARM / FISHERS	P=0.280N	P=0.467N	P=0.318N	P=0.382N
MAX-ISO-POLY-3	P=0.314N	P=0.222N	P=0.149N	P=0.252N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Mesentery: Fat Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/3 (100%)	5/8 (63%)	9/9 (100%)	6/6 (100%)
POLY-3 RATE (b)	3/3.00	5/7.13	9/9.00	6/6.00
POLY-3 PERCENT (g)	100%	70.2%	100%	100%
TERMINAL (d)	3/3 (100%)	4/4 (100%)	8/8 (100%)	5/5 (100%)
FIRST INCIDENCE	729 (T)	720	660	573
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.293	P=0.406N	(e)	(e)
POLY 1.5	P=0.234	P=0.363N	(e)	(e)
POLY 6	P=0.389	P=0.477N	(e)	(e)
COCH-ARM / FISHERS	P=0.199	P=0.339N	(e)	(e)
MAX-ISO-POLY-3	P=0.217	P=0.162N	(e)	(e)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/50 (6%)	7/49 (14%)	3/50 (6%)	32/50 (64%)
POLY-3 RATE (b)	3/47.99	7/45.91	3/45.50	32/45.44
POLY-3 PERCENT (g)	6.3%	15.3%	6.6%	70.4%
TERMINAL (d)	2/43 (5%)	6/40 (15%)	3/39 (8%)	22/32 (69%)
FIRST INCIDENCE	666	700	729 (T)	43
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.140	P=0.637	P<0.001**
POLY 1.5	P<0.001**	P=0.141	P=0.642	P<0.001**
POLY 6	P<0.001**	P=0.140	P=0.632	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.151	P=0.661N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.082	P=0.473	P<0.001**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose</b>				
<b>Polyp, Inflammatory</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.76	0/45.80	0/45.50	0/40.98
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Glands, Lateral Wall Dilatation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/47.76	0/45.80	0/45.50	2/41.99
POLY-3 PERCENT (g)	0%	0%	0%	4.8%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	---	573
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.036*	(e)	(e)	P=0.210
POLY 1.5	P=0.037*	(e)	(e)	P=0.217
POLY 6	P=0.034*	(e)	(e)	P=0.203
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.035*	(e)	(e)	P=0.076

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Glands, Respiratory Epithelium Dilatation</b>				
<b>LESION RATES</b>				
OVERALL (a)	10/50 (20%)	17/49 (35%)	15/50 (30%)	33/50 (66%)
POLY-3 RATE (b)	10/47.76	17/46.72	15/46.93	33/44.54
POLY-3 PERCENT (g)	20.9%	36.4%	32%	74.1%
TERMINAL (d)	10/43 (23%)	14/40 (35%)	12/39 (31%)	24/32 (75%)
FIRST INCIDENCE	729 (T)	449	253	386
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.074	P=0.162	P<0.001**
POLY 1.5	P<0.001**	P=0.072	P=0.163	P<0.001**
POLY 6	P<0.001**	P=0.078	P=0.162	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.078	P=0.178	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.047*	P=0.113	P<0.001**



TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 N,N-Dimethyl-p-toluidine  
 CAS Number: 99-97-8

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Glands, Respiratory Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	2/49 (4%)	12/50 (24%)	13/50 (26%)
POLY-3 RATE (b)	0/47.76	2/45.80	12/46.02	13/42.77
POLY-3 PERCENT (g)	0%	4.4%	26.1%	30.4%
TERMINAL (d)	0/43 (0%)	2/40 (5%)	9/39 (23%)	9/32 (28%)
FIRST INCIDENCE	---	729 (T)	627	578
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.228	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.228	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.229	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.242	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.075	P<0.001**	P<0.001**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Glands, Respiratory Epithelium</b>				
<b>Metaplasia Respiratory</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/49 (0%)	10/50 (20%)	10/50 (20%)
POLY-3 RATE (b)	0/47.76	0/45.80	10/45.97	10/41.40
POLY-3 PERCENT (g)	0%	0%	21.8%	24.2%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	8/39 (21%)	9/32 (28%)
FIRST INCIDENCE	---	---	627	607
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	(e)	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	(e)	P<0.001**	P<0.001**
POLY 6	P<0.001**	(e)	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P<0.001**	P<0.001**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Nasolacrimal Duct Hyperplasia Regenerative</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	4/50 (8%)
POLY-3 RATE (b)	0/47.76	0/45.80	0/45.50	4/43.02
POLY-3 PERCENT (g)	0%	0%	0%	9.3%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	---	570
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	(e)	(e)	P=0.048*
POLY 1.5	P<0.001**	(e)	(e)	P=0.051
POLY 6	P<0.001**	(e)	(e)	P=0.046*
COCH-ARM / FISHERS	P=0.002**	(e)	(e)	P=0.059
MAX-ISO-POLY-3	P=0.002**	(e)	(e)	P=0.019*

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Nerve Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	41/50 (82%)
POLY-3 RATE (b)	0/47.76	0/45.80	0/45.50	41/47.03
POLY-3 PERCENT (g)	0%	0%	0%	87.2%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	27/32 (84%)
FIRST INCIDENCE	---	---	---	387
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	(e)	(e)	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	P<0.001**
POLY 6	P<0.001**	(e)	(e)	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P<0.001**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Olfactory Epithelium Accumulation, Hyaline Droplet</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	5/49 (10%)	8/50 (16%)	15/50 (30%)
POLY-3 RATE (b)	2/47.76	5/46.06	8/46.81	15/43.42
POLY-3 PERCENT (g)	4.2%	10.9%	17.1%	34.5%
TERMINAL (d)	2/43 (5%)	3/40 (8%)	5/39 (13%)	10/32 (31%)
FIRST INCIDENCE	729 (T)	671	253	386
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.202	P=0.042*	P<0.001**
POLY 1.5	P<0.001**	P=0.201	P=0.042*	P<0.001**
POLY 6	P<0.001**	P=0.205	P=0.042*	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.210	P=0.046*	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.113	P=0.020*	P<0.001**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Olfactory Epithelium Metaplasia Respiratory</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	6/49 (12%)	14/50 (28%)	46/50 (92%)
POLY-3 RATE (b)	1/48.07	6/46.02	14/45.66	46/47.49
POLY-3 PERCENT (g)	2.1%	13%	30.7%	96.9%
TERMINAL (d)	0/43 (0%)	5/40 (13%)	12/39 (31%)	32/32 (100%)
FIRST INCIDENCE	642	671	703	43
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.049*	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.050*	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.049*	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.053	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.022*	P<0.001**	P<0.001**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Olfactory Epithelium Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/49 (0%)	3/50 (6%)	6/50 (12%)
POLY-3 RATE (b)	0/47.76	0/45.80	3/47.28	6/44.87
POLY-3 PERCENT (g)	0%	0%	6.4%	13.4%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	11	43
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	(e)	P=0.117	P=0.012*
POLY 1.5	P<0.001**	(e)	P=0.117	P=0.013*
POLY 6	P<0.001**	(e)	P=0.117	P=0.012*
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.121	P=0.013*
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.038*	P=0.005**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Olfactory Epithelium, Glands Dilatation</b>				
<b>LESION RATES</b>				
OVERALL (a)	13/50 (26%)	14/49 (29%)	20/50 (40%)	46/50 (92%)
POLY-3 RATE (b)	13/47.99	14/46.78	20/45.78	46/47.00
POLY-3 PERCENT (g)	27.1%	29.9%	43.7%	97.9%
TERMINAL (d)	12/43 (28%)	12/40 (30%)	18/39 (46%)	32/32 (100%)
FIRST INCIDENCE	666	449	669	386
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.469	P=0.069	P<0.001**
POLY 1.5	P<0.001**	P=0.462	P=0.074	P<0.001**
POLY 6	P<0.001**	P=0.477	P=0.065	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.475	P=0.101	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.380	P=0.048*	P<0.001**



TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Olfactory Epithelium, Glands Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	14/49 (29%)	14/50 (28%)	50/50 (100%)
POLY-3 RATE (b)	2/47.76	14/46.92	14/46.04	50/50.00
POLY-3 PERCENT (g)	4.2%	29.8%	30.4%	100%
TERMINAL (d)	2/43 (5%)	10/40 (25%)	12/39 (31%)	32/32 (100%)
FIRST INCIDENCE	729 (T)	449	585	43
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	P<0.001**

TDMS No. 20107 - 04  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
N,N-Dimethyl-p-toluidine  
CAS Number: 99-97-8

Date Report Requested: 03/10/2011  
Time Report Requested: 11:42:39  
First Dose M/F: 10/26/04 / 10/25/04  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Olfactory Epithelium, Glands Metaplasia Respiratory</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	5/49 (10%)	7/50 (14%)	44/50 (88%)
POLY-3 RATE (b)	2/47.76	5/46.02	7/45.56	44/45.63
POLY-3 PERCENT (g)	4.2%	10.9%	15.4%	96.4%
TERMINAL (d)	2/43 (5%)	4/40 (10%)	6/39 (15%)	32/32 (100%)
FIRST INCIDENCE	729 (T)	671	715	387
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.202	P=0.068	P<0.001**
POLY 1.5	P<0.001**	P=0.201	P=0.070	P<0.001**
POLY 6	P<0.001**	P=0.204	P=0.066	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.210	P=0.080	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.112	P=0.036*	P<0.001**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 N,N-Dimethyl-p-toluidine  
 CAS Number: 99-97-8

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Respiratory Epithelium Accumulation, Hyaline Droplet</b>				
<b>LESION RATES</b>				
OVERALL (a)	33/50 (66%)	34/49 (69%)	39/50 (78%)	36/50 (72%)
POLY-3 RATE (b)	33/48.67	34/47.52	39/48.74	36/44.91
POLY-3 PERCENT (g)	67.8%	71.6%	80%	80.2%
TERMINAL (d)	29/43 (67%)	28/40 (70%)	30/39 (77%)	28/32 (88%)
FIRST INCIDENCE	642	449	253	386
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.109	P=0.429	P=0.124	P=0.123
POLY 1.5	P=0.159	P=0.414	P=0.114	P=0.168
POLY 6	P=0.062	P=0.443	P=0.136	P=0.076
COCH-ARM / FISHERS	P=0.344	P=0.442	P=0.133	P=0.333
MAX-ISO-POLY-3	P=0.147	P=0.345	P=0.083	P=0.089

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 N,N-Dimethyl-p-toluidine  
 CAS Number: 99-97-8

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Respiratory Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	11/50 (22%)	15/49 (31%)	11/50 (22%)	30/50 (60%)
POLY-3 RATE (b)	11/48.23	15/46.60	11/45.99	30/43.13
POLY-3 PERCENT (g)	22.8%	32.2%	23.9%	69.6%
TERMINAL (d)	9/43 (21%)	13/40 (33%)	9/39 (23%)	23/32 (72%)
FIRST INCIDENCE	666	449	660	481
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.214	P=0.546	P<0.001**
POLY 1.5	P<0.001**	P=0.214	P=0.553	P<0.001**
POLY 6	P<0.001**	P=0.213	P=0.539	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.228	P=0.595N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.156	P=0.449	P<0.001**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 N,N-Dimethyl-p-toluidine  
 CAS Number: 99-97-8

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Respiratory Epithelium Hyperplasia Regenerative</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	0/47.76	0/45.80	0/45.50	3/42.49
POLY-3 PERCENT (g)	0%	0%	0%	7.1%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	---	573
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.007**	(e)	(e)	P=0.099
POLY 1.5	P=0.007**	(e)	(e)	P=0.104
POLY 6	P=0.006**	(e)	(e)	P=0.095
COCH-ARM / FISHERS	P=0.009**	(e)	(e)	P=0.121
MAX-ISO-POLY-3	P=0.010**	(e)	(e)	P=0.038*

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Respiratory Epithelium Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	5/50 (10%)
POLY-3 RATE (b)	0/47.76	0/45.80	0/45.50	5/43.73
POLY-3 PERCENT (g)	0%	0%	0%	11.4%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	---	481
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	(e)	(e)	P=0.024*
POLY 1.5	P<0.001**	(e)	(e)	P=0.025*
POLY 6	P<0.001**	(e)	(e)	P=0.023*
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.028*
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P=0.010**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Transitional Epithelium Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/47.76	0/45.80	0/45.50	2/42.00
POLY-3 PERCENT (g)	0%	0%	0%	4.8%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	---	570
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.036*	(e)	(e)	P=0.210
POLY 1.5	P=0.037*	(e)	(e)	P=0.217
POLY 6	P=0.034*	(e)	(e)	P=0.203
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.035*	(e)	(e)	P=0.076

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Nose: Vomeronasal Organ</b>				
<b>Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	4/50 (8%)
POLY-3 RATE (b)	0/47.76	0/45.80	0/45.50	4/43.34
POLY-3 PERCENT (g)	0%	0%	0%	9.2%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	---	387
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	(e)	(e)	P=0.049*
POLY 1.5	P<0.001**	(e)	(e)	P=0.052
POLY 6	P<0.001**	(e)	(e)	P=0.047*
COCH-ARM / FISHERS	P=0.002**	(e)	(e)	P=0.059
MAX-ISO-POLY-3	P=0.002**	(e)	(e)	P=0.019*



TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Ovary</b>				
<b>Angiectasis</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	0/49 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/47.76	0/45.24	1/45.50	1/40.98
POLY-3 PERCENT (g)	4.2%	0%	2.2%	2.4%
TERMINAL (d)	2/43 (5%)	0/40 (0%)	1/39 (3%)	1/32 (3%)
FIRST INCIDENCE	729 (T)	---	729 (T)	729 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.641N	P=0.250N	P=0.517N	P=0.553N
POLY 1.5	P=0.633N	P=0.249N	P=0.514N	P=0.538N
POLY 6	P=0.650N	P=0.250N	P=0.519N	P=0.569N
COCH-ARM / FISHERS	P=0.616N	P=0.253N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.356N	P=0.087N	P=0.299N	P=0.337N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Ovary Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	40/50 (80%)	43/49 (88%)	40/50 (80%)	45/50 (90%)
POLY-3 RATE (b)	40/49.23	43/46.55	40/45.97	45/46.44
POLY-3 PERCENT (g)	81.3%	92.4%	87%	96.9%
TERMINAL (d)	34/43 (79%)	38/40 (95%)	36/39 (92%)	31/32 (97%)
FIRST INCIDENCE	642	555	669	386
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.026*	P=0.092	P=0.308	P=0.014*
POLY 1.5	P=0.037*	P=0.110	P=0.385	P=0.020*
POLY 6	P=0.021*	P=0.078	P=0.218	P=0.012*
COCH-ARM / FISHERS	P=0.173	P=0.220	P=0.598N	P=0.131
MAX-ISO-POLY-3	P=0.009**	P=0.054	P=0.223	P=0.007**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 N,N-Dimethyl-p-toluidine  
 CAS Number: 99-97-8

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Ovary Cyst				
<b>LESION RATES</b>				
OVERALL (a)	4/50 (8%)	6/49 (12%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	4/47.76	6/45.24	4/45.80	2/40.98
POLY-3 PERCENT (g)	8.4%	13.3%	8.7%	4.9%
TERMINAL (d)	4/43 (9%)	6/40 (15%)	3/39 (8%)	2/32 (6%)
FIRST INCIDENCE	729 (T)	729 (T)	649	729 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.224N	P=0.336	P=0.620	P=0.410N
POLY 1.5	P=0.204N	P=0.339	P=0.622	P=0.389N
POLY 6	P=0.247N	P=0.336	P=0.618	P=0.434N
COCH-ARM / FISHERS	P=0.160N	P=0.357	P=0.643N	P=0.339N
MAX-ISO-POLY-3	P=0.305N	P=0.230	P=0.475	P=0.274N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Ovary Hemorrhage</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	0/49 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/48.77	0/45.24	1/45.50	0/40.98
POLY-3 PERCENT (g)	4.1%	0%	2.2%	0%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	1/39 (3%)	0/32 (0%)
FIRST INCIDENCE	444	---	729 (T)	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.288N	P=0.254N	P=0.524N	P=0.278N
POLY 1.5	P=0.282N	P=0.252N	P=0.519N	P=0.266N
POLY 6	P=0.296N	P=0.256N	P=0.530N	P=0.292N
COCH-ARM / FISHERS	P=0.269N	P=0.253N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.136N	P=0.091N	P=0.307N	P=0.115N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Ovary Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	2/49 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.76	2/45.38	0/45.50	0/40.98
POLY-3 PERCENT (g)	0%	4.4%	0%	0%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	700	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.391N	P=0.226	(e)	(e)
POLY 1.5	P=0.385N	P=0.227	(e)	(e)
POLY 6	P=0.396N	P=0.226	(e)	(e)
COCH-ARM / FISHERS	P=0.367N	P=0.242	(e)	(e)
MAX-ISO-POLY-3	P=0.305N	P=0.075	(e)	(e)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 N,N-Dimethyl-p-toluidine  
 CAS Number: 99-97-8

Date Report Requested: 03/10/2011  
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 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Ovary Thrombosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	0/49 (0%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	2/47.76	0/45.24	0/45.50	3/41.40
POLY-3 PERCENT (g)	4.2%	0%	0%	7.3%
TERMINAL (d)	2/43 (5%)	0/40 (0%)	0/39 (0%)	2/32 (6%)
FIRST INCIDENCE	729 (T)	---	---	607
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.139	P=0.250N	P=0.248N	P=0.435
POLY 1.5	P=0.144	P=0.249N	P=0.246N	P=0.453
POLY 6	P=0.134	P=0.250N	P=0.250N	P=0.417
COCH-ARM / FISHERS	P=0.157	P=0.253N	P=0.247N	P=0.500
MAX-ISO-POLY-3	P=0.098	P=0.087N	P=0.087N	P=0.282

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Pancreas Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/47.76	0/46.14	2/45.50	0/40.98
POLY-3 PERCENT (g)	2.1%	0%	4.4%	0%
TERMINAL (d)	1/43 (2%)	0/40 (0%)	2/39 (5%)	0/32 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.501N	P=0.507N	P=0.483	P=0.530N
POLY 1.5	P=0.486N	P=0.506N	P=0.486	P=0.522N
POLY 6	P=0.516N	P=0.507N	P=0.481	P=0.540N
COCH-ARM / FISHERS	P=0.455N	P=0.500N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.380N	P=0.167N	P=0.271	P=0.196N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Pancreas: Duct Cyst</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/47.76	0/46.14	2/45.50	0/40.98
POLY-3 PERCENT (g)	0%	0%	4.4%	0%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	2/39 (5%)	0/32 (0%)
FIRST INCIDENCE	---	---	729 (T)	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.698	(e)	P=0.227	(e)
POLY 1.5	P=0.717	(e)	P=0.228	(e)
POLY 6	P=0.675	(e)	P=0.225	(e)
COCH-ARM / FISHERS	P=0.697N	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.275	(e)	P=0.076	(e)



TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Pituitary Gland: Pars Distalis Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	5/48 (10%)	3/50 (6%)	3/50 (6%)	3/49 (6%)
POLY-3 RATE (b)	5/45.76	3/46.14	3/45.50	3/40.10
POLY-3 PERCENT (g)	10.9%	6.5%	6.6%	7.5%
TERMINAL (d)	5/41 (12%)	3/40 (8%)	3/39 (8%)	3/32 (9%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.460N	P=0.352N	P=0.360N	P=0.431N
POLY 1.5	P=0.439N	P=0.350N	P=0.356N	P=0.406N
POLY 6	P=0.483N	P=0.352N	P=0.363N	P=0.458N
COCH-ARM / FISHERS	P=0.391N	P=0.335N	P=0.335N	P=0.346N
MAX-ISO-POLY-3	P=0.419N	P=0.229N	P=0.237N	P=0.306N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Pituitary Gland: Pars Intermedia Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/48 (2%)	1/50 (2%)	1/50 (2%)	2/49 (4%)
POLY-3 RATE (b)	1/45.76	1/46.14	1/45.50	2/40.10
POLY-3 PERCENT (g)	2.2%	2.2%	2.2%	5%
TERMINAL (d)	1/41 (2%)	1/40 (3%)	1/39 (3%)	2/32 (6%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.314	P=0.759N	P=0.759	P=0.454
POLY 1.5	P=0.328	P=0.758N	P=0.760N	P=0.469
POLY 6	P=0.299	P=0.759N	P=0.758	P=0.438
COCH-ARM / FISHERS	P=0.360	P=0.742N	P=0.742N	P=0.508
MAX-ISO-POLY-3	P=0.383	P=0.497N	P=0.498	P=0.257

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Skin Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/47.76	2/46.18	0/45.50	1/40.98
POLY-3 PERCENT (g)	2.1%	4.3%	0%	2.4%
TERMINAL (d)	1/43 (2%)	1/40 (3%)	0/39 (0%)	1/32 (3%)
FIRST INCIDENCE	729 (T)	720	---	729 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.578N	P=0.488	P=0.510N	P=0.725
POLY 1.5	P=0.571N	P=0.490	P=0.508N	P=0.736
POLY 6	P=0.585N	P=0.488	P=0.511N	P=0.714
COCH-ARM / FISHERS	P=0.552N	P=0.500	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.445N	P=0.274	P=0.171N	P=0.459

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Skin</b>				
<b>Ulcer</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/47.76	2/46.18	2/45.60	1/40.98
POLY-3 PERCENT (g)	0%	4.3%	4.4%	2.4%
TERMINAL (d)	0/43 (0%)	1/40 (3%)	1/39 (3%)	1/32 (3%)
FIRST INCIDENCE	---	720	703	729 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.544	P=0.230	P=0.227	P=0.470
POLY 1.5	P=0.566	P=0.231	P=0.229	P=0.478
POLY 6	P=0.519	P=0.230	P=0.226	P=0.460
COCH-ARM / FISHERS	P=0.618	P=0.247	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.263	P=0.076	P=0.076	P=0.158

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Skin: Dermis</b>				
<b>Fibrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/47.76	1/46.14	1/45.50	0/40.98
POLY-3 PERCENT (g)	0%	2.2%	2.2%	0%
TERMINAL (d)	0/43 (0%)	1/40 (3%)	1/39 (3%)	0/32 (0%)
FIRST INCIDENCE	---	729 (T)	729 (T)	---
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Skin: Epidermis Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/47.76	0/46.14	2/45.60	0/40.98
POLY-3 PERCENT (g)	2.1%	0%	4.4%	0%
TERMINAL (d)	1/43 (2%)	0/40 (0%)	1/39 (3%)	0/32 (0%)
FIRST INCIDENCE	729 (T)	---	703	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.501N	P=0.507N	P=0.484	P=0.530N
POLY 1.5	P=0.486N	P=0.506N	P=0.486	P=0.522N
POLY 6	P=0.516N	P=0.507N	P=0.482	P=0.540N
COCH-ARM / FISHERS	P=0.455N	P=0.500N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.380N	P=0.167N	P=0.272	P=0.196N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Spleen Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/49 (6%)	8/49 (16%)	1/49 (2%)	6/50 (12%)
POLY-3 RATE (b)	3/47.23	8/46.86	1/45.46	6/43.95
POLY-3 PERCENT (g)	6.4%	17.1%	2.2%	13.7%
TERMINAL (d)	2/43 (5%)	4/40 (10%)	1/39 (3%)	0/32 (0%)
FIRST INCIDENCE	666	555	729 (T)	512
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.372	P=0.096	P=0.319N	P=0.208
POLY 1.5	P=0.382	P=0.097	P=0.316N	P=0.217
POLY 6	P=0.363	P=0.096	P=0.324N	P=0.201
COCH-ARM / FISHERS	P=0.427	P=0.100	P=0.309N	P=0.254
MAX-ISO-POLY-3	P=0.211	P=0.052	P=0.169N	P=0.132

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Spleen</b>				
<b>Hematopoietic Cell Proliferation</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	18/49 (37%)	23/49 (47%)	24/49 (49%)	21/50 (42%)
<b>POLY-3 RATE (b)</b>	18/48.44	23/48.34	24/47.64	21/44.18
<b>POLY-3 PERCENT (g)</b>	37.2%	47.6%	50.4%	47.5%
<b>TERMINAL (d)</b>	14/43 (33%)	16/40 (40%)	16/39 (41%)	14/32 (44%)
<b>FIRST INCIDENCE</b>	444	449	501	43
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.292	P=0.203	P=0.135	P=0.212
<b>POLY 1.5</b>	P=0.358	P=0.204	P=0.134	P=0.257
<b>POLY 6</b>	P=0.233	P=0.204	P=0.138	P=0.171
<b>COCH-ARM / FISHERS</b>	P=0.519	P=0.206	P=0.154	P=0.371
<b>MAX-ISO-POLY-3</b>	P=0.229	P=0.150	P=0.097	P=0.168



TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Spleen</b>				
<b>Hyperplasia Lymphoid</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	14/49 (29%)	15/49 (31%)	12/49 (24%)	15/50 (30%)
<b>POLY-3 RATE (b)</b>	14/47.12	15/46.14	12/45.69	15/40.98
<b>POLY-3 PERCENT (g)</b>	29.7%	32.5%	26.3%	36.6%
<b>TERMINAL (d)</b>	13/43 (30%)	15/40 (38%)	11/39 (28%)	15/32 (47%)
<b>FIRST INCIDENCE</b>	698	729 (T)	669	729 (T)
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.312	P=0.473	P=0.445N	P=0.323
<b>POLY 1.5</b>	P=0.368	P=0.483	P=0.439N	P=0.383
<b>POLY 6</b>	P=0.254	P=0.463	P=0.455N	P=0.260
<b>COCH-ARM / FISHERS</b>	P=0.513	P=0.500	P=0.410N	P=0.526
<b>MAX-ISO-POLY-3</b>	P=0.413	P=0.385	P=0.357N	P=0.262

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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N,N-Dimethyl-p-toluidine

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Spleen Pigmentation</b>				
<b>LESION RATES</b>				
OVERALL (a)	37/49 (76%)	39/49 (80%)	33/49 (67%)	43/50 (86%)
POLY-3 RATE (b)	37/47.48	39/46.98	33/45.74	43/47.06
POLY-3 PERCENT (g)	77.9%	83%	72.1%	91.4%
TERMINAL (d)	35/43 (81%)	35/40 (88%)	31/39 (80%)	29/32 (91%)
FIRST INCIDENCE	663	555	669	386
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.057	P=0.354	P=0.339N	P=0.055
POLY 1.5	P=0.057	P=0.373	P=0.319N	P=0.057
POLY 6	P=0.058	P=0.338	P=0.376N	P=0.054
COCH-ARM / FISHERS	P=0.129	P=0.405	P=0.251N	P=0.142
MAX-ISO-POLY-3	P=0.063	P=0.262	P=0.258N	P=0.030*

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Spleen: Red Pulp Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	0/49 (0%)	0/49 (0%)	5/50 (10%)
POLY-3 RATE (b)	0/46.99	0/46.14	0/45.46	5/43.08
POLY-3 PERCENT (g)	0%	0%	0%	11.6%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	1/32 (3%)
FIRST INCIDENCE	---	---	---	512
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	(e)	(e)	P=0.024*
POLY 1.5	P<0.001**	(e)	(e)	P=0.026*
POLY 6	P<0.001**	(e)	(e)	P=0.022*
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.030*
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P=0.010**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Stomach, Forestomach Erosion</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/47.76	1/47.14	0/45.50	2/41.42
POLY-3 PERCENT (g)	0%	2.1%	0%	4.8%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	1/32 (3%)
FIRST INCIDENCE	---	8	---	602
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.130	P=0.497	(e)	P=0.207
POLY 1.5	P=0.135	P=0.498	(e)	P=0.215
POLY 6	P=0.125	P=0.497	(e)	P=0.199
COCH-ARM / FISHERS	P=0.151	P=0.500	(e)	P=0.247
MAX-ISO-POLY-3	P=0.080	P=0.159	(e)	P=0.076

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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N,N-Dimethyl-p-toluidine

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Stomach, Forestomach Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/50 (6%)	4/50 (8%)	7/50 (14%)	16/50 (32%)
POLY-3 RATE (b)	3/48.63	4/46.54	7/47.32	16/43.07
POLY-3 PERCENT (g)	6.2%	8.6%	14.8%	37.2%
TERMINAL (d)	0/43 (0%)	2/40 (5%)	3/39 (8%)	9/32 (28%)
FIRST INCIDENCE	642	621	501	481
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.476	P=0.147	P<0.001**
POLY 1.5	P<0.001**	P=0.481	P=0.147	P<0.001**
POLY 6	P<0.001**	P=0.471	P=0.147	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500	P=0.159	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.330	P=0.086	P<0.001**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Stomach, Forestomach Ulcer</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	2/50 (4%)	4/50 (8%)	7/50 (14%)
POLY-3 RATE (b)	2/48.38	2/46.52	4/47.32	7/41.88
POLY-3 PERCENT (g)	4.1%	4.3%	8.5%	16.7%
TERMINAL (d)	0/43 (0%)	1/40 (3%)	0/39 (0%)	4/32 (13%)
FIRST INCIDENCE	642	621	501	481
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.015*	P=0.679	P=0.327	P=0.050*
POLY 1.5	P=0.017*	P=0.682	P=0.326	P=0.057
POLY 6	P=0.012*	P=0.677	P=0.329	P=0.042*
COCH-ARM / FISHERS	P=0.026*	P=0.691N	P=0.339	P=0.080
MAX-ISO-POLY-3	P=0.023*	P=0.484	P=0.196	P=0.030*

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 N,N-Dimethyl-p-toluidine  
 CAS Number: 99-97-8

Date Report Requested: 03/10/2011  
 Time Report Requested: 11:42:39  
 First Dose M/F: 10/26/04 / 10/25/04  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Stomach, Forestomach: Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/50 (6%)	5/50 (10%)	12/50 (24%)	17/50 (34%)
POLY-3 RATE (b)	3/48.63	5/46.77	12/46.75	17/44.07
POLY-3 PERCENT (g)	6.2%	10.7%	25.7%	38.6%
TERMINAL (d)	0/43 (0%)	2/40 (5%)	8/39 (21%)	9/32 (28%)
FIRST INCIDENCE	642	621	585	43
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.336	P=0.008**	P<0.001**
POLY 1.5	P<0.001**	P=0.339	P=0.009**	P<0.001**
POLY 6	P<0.001**	P=0.333	P=0.008**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.357	P=0.011*	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.219	P=0.004**	P<0.001**

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 N,N-Dimethyl-p-toluidine  
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Date Report Requested: 03/10/2011  
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Thymus Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	46/50 (92%)	46/50 (92%)	39/48 (81%)	43/48 (90%)
POLY-3 RATE (b)	46/50.00	46/49.85	39/45.19	43/45.51
POLY-3 PERCENT (g)	92%	92.3%	86.3%	94.5%
TERMINAL (d)	39/43 (91%)	38/40 (95%)	34/38 (90%)	31/32 (97%)
FIRST INCIDENCE	444	8	501	386
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.396	P=0.625	P=0.281N	P=0.469
POLY 1.5	P=0.433	P=0.634	P=0.232N	P=0.509
POLY 6	P=0.351	P=0.609	P=0.349N	P=0.417
COCH-ARM / FISHERS	P=0.426N	P=0.643N	P=0.102N	P=0.474N
MAX-ISO-POLY-3	P=0.384	P=0.478	P=0.189N	P=0.318



TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Thymus</b>				
<b>Hyperplasia Lymphoid</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/50 (6%)	0/50 (0%)	0/48 (0%)	0/48 (0%)
POLY-3 RATE (b)	3/47.76	0/46.14	0/43.60	0/39.86
POLY-3 PERCENT (g)	6.3%	0%	0%	0%
TERMINAL (d)	3/43 (7%)	0/40 (0%)	0/38 (0%)	0/32 (0%)
FIRST INCIDENCE	729 (T)	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.136N	P=0.125N	P=0.136N	P=0.154N
POLY 1.5	P=0.136N	P=0.124N	P=0.134N	P=0.147N
POLY 6	P=0.137N	P=0.125N	P=0.137N	P=0.163N
COCH-ARM / FISHERS	P=0.139N	P=0.121N	P=0.129N	P=0.129N
MAX-ISO-POLY-3	P=0.028N*	P=0.043N*	P=0.051N	P=0.068N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Thymus Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/48 (0%)	0/48 (0%)
POLY-3 RATE (b)	0/47.76	0/46.14	0/43.60	0/39.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/38 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Thyroid Gland Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.76	2/46.14	0/45.50	0/40.98
POLY-3 PERCENT (g)	0%	4.3%	0%	0%
TERMINAL (d)	0/43 (0%)	2/40 (5%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	729 (T)	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.393N	P=0.230	(e)	(e)
POLY 1.5	P=0.387N	P=0.231	(e)	(e)
POLY 6	P=0.398N	P=0.229	(e)	(e)
COCH-ARM / FISHERS	P=0.369N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.307N	P=0.076	(e)	(e)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

Time Report Requested: 11:42:39

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Tooth Dysplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	13/13 (100%)	10/10 (100%)	4/7 (57%)	4/4 (100%)
POLY-3 RATE (b)	13/13.00	10/10.00	4/6.26	4/4.00
POLY-3 PERCENT (g)	100%	100%	63.9%	100%
TERMINAL (d)	12/12 (100%)	10/10 (100%)	3/4 (75%)	3/3 (100%)
FIRST INCIDENCE	642	729 (T)	627	627
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.604N	(e)	P=0.028N*	(e)
POLY 1.5	P=0.546N	(e)	P=0.019N*	(e)
POLY 6	P=0.687N	(e)	P=0.061N	(e)
COCH-ARM / FISHERS	P=0.485N	(e)	P=0.031N*	(e)
MAX-ISO-POLY-3	P=0.085N	(e)	P=0.008N**	(e)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 03/10/2011

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

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Urinary Bladder</b>				
<b>Calculus Gross Observation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.76	0/46.14	0/45.50	0/40.98
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/43 (0%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Uterus</b>				
<b>Angiectasis</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	2/50 (4%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
<b>POLY-3 RATE (b)</b>	2/47.76	2/46.14	1/45.50	0/40.98
<b>POLY-3 PERCENT (g)</b>	4.2%	4.3%	2.2%	0%
<b>TERMINAL (d)</b>	2/43 (5%)	2/40 (5%)	1/39 (3%)	0/32 (0%)
<b>FIRST INCIDENCE</b>	729 (T)	729 (T)	729 (T)	---
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.166N	P=0.681	P=0.517N	P=0.273N
<b>POLY 1.5</b>	P=0.159N	P=0.683	P=0.514N	P=0.262N
<b>POLY 6</b>	P=0.175N	P=0.681	P=0.519N	P=0.285N
<b>COCH-ARM / FISHERS</b>	P=0.141N	P=0.691N	P=0.500N	P=0.247N
<b>MAX-ISO-POLY-3</b>	P=0.216N	P=0.486	P=0.299N	P=0.109N

TDMS No. 20107 - 04  
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 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Uterus Dilatation</b>				
<b>LESION RATES</b>				
OVERALL (a)	13/50 (26%)	13/50 (26%)	6/50 (12%)	10/50 (20%)
POLY-3 RATE (b)	13/47.99	13/46.52	6/45.50	10/41.69
POLY-3 PERCENT (g)	27.1%	27.9%	13.2%	24%
TERMINAL (d)	12/43 (28%)	12/40 (30%)	6/39 (15%)	9/32 (28%)
FIRST INCIDENCE	666	621	729 (T)	481
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.374N	P=0.554	P=0.077N	P=0.463N
POLY 1.5	P=0.339N	P=0.558	P=0.075N	P=0.420N
POLY 6	P=0.415N	P=0.554	P=0.081N	P=0.513N
COCH-ARM / FISHERS	P=0.264N	P=0.590N	P=0.062N	P=0.318N
MAX-ISO-POLY-3	P=0.276N	P=0.463	P=0.050N*	P=0.376N

TDMS No. 20107 - 04  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine  
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Uterus Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	3/50 (6%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/47.76	3/46.16	2/45.50	0/40.98
POLY-3 PERCENT (g)	2.1%	6.5%	4.4%	0%
TERMINAL (d)	1/43 (2%)	2/40 (5%)	2/39 (5%)	0/32 (0%)
FIRST INCIDENCE	729 (T)	723	729 (T)	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.229N	P=0.293	P=0.483	P=0.530N
POLY 1.5	P=0.215N	P=0.295	P=0.486	P=0.522N
POLY 6	P=0.244N	P=0.293	P=0.481	P=0.540N
COCH-ARM / FISHERS	P=0.183N	P=0.309	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.245N	P=0.150	P=0.271	P=0.196N



TDMS No. 20107 - 04  
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<b>Uterus: Endometrium Hyperplasia Cystic</b>				
<b>LESION RATES</b>				
OVERALL (a)	25/50 (50%)	17/50 (34%)	11/50 (22%)	9/50 (18%)
POLY-3 RATE (b)	25/48.44	17/46.40	11/45.73	9/42.42
POLY-3 PERCENT (g)	51.6%	36.6%	24.1%	21.2%
TERMINAL (d)	22/43 (51%)	15/40 (38%)	10/39 (26%)	5/32 (16%)
FIRST INCIDENCE	642	671	669	573
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.003N**	P=0.102N	P=0.004N**	P=0.002N**
POLY 1.5	P=0.003N**	P=0.097N	P=0.004N**	P<0.001N**
POLY 6	P=0.004N**	P=0.107N	P=0.005N**	P=0.003N**
COCH-ARM / FISHERS	P=0.002N**	P=0.078N	P=0.003N**	P<0.001N**
MAX-ISO-POLY-3	P=0.003N**	P=0.073N	P=0.003N**	P=0.002N**

TDMS No. 20107 - 04  
Test Type: CHRONIC  
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Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

N,N-Dimethyl-p-toluidine  
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**LEGEND**

- (a) Number of tumor-bearing animals/number of animals examined at site.
  - (b) Number of tumor-bearing animals/Poly-3 number
  - (d) Observed incidence at terminal kill.
  - (e) Value of statistic cannot be computed.
  - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
  - (g) Poly-3 adjusted lifetime tumor incidence.
  - (n) No statistics are calculated if all dose groups have fewer than two tumors.
  - (I) Interim sacrifice
  - (T) Terminal sacrifice
  - # Tumor rates based on numbers of animals necropsied.
  - \* To the right of any statistical result, indicates significance at ( $P \leq 0.05$ ).
  - \*\* To the right of any statistical result, indicates significance at ( $P \leq 0.01$ ).
  - N Indicates a negative trend for all tests
- The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

\*\*\* END OF REPORT \*\*\*