

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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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
	Dilatation
Nose: Olfactory Epithelium, Glands	Hyperplasia
	Metaplasia Respiratory
	Hyperplasia
	Hyperplasia Regenerative
	Necrosis
Nose: Transitional Epithelium	Necrosis
Nose: Vomeronasal Organ	Necrosis
Ovary	Atrophy
Spleen	Pigmentation
Spleen: Red Pulp	Atrophy
Stomach, Forestomach	Inflammation
	Ulcer
	Hyperplasia
Stomach, Forestomach: Epithelium	Hyperplasia Lymphoid
Thymus	Dysplasia
Tooth	Dilatation
Uterus	Hyperplasia Cystic
Uterus: Endometrium	

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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
Adrenal Cortex Hypertrophy				
LESION RATES				
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)
STATISTICAL TESTS				
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**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Adrenal Cortex Necrosis				
LESION RATES				
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	---	---	---	---
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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**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
Adrenal Medulla Hyperplasia				
LESION RATES				
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)
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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TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Blood Vessel Inflammation				
LESION RATES				
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)	---
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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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Bone Marrow Atrophy				
LESION RATES				
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	---
STATISTICAL TESTS				
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
Bone Marrow Hyperplasia				
LESION RATES				
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
STATISTICAL TESTS				
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**

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

Bone
Fibro-osseous Lesion

LESION RATES

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	---	---	---	---

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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**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
Brain: Olfactory Lobe Atrophy				
LESION RATES				
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
STATISTICAL TESTS				
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
Epididymis				
Granuloma Sperm				
LESION RATES				
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	---	---
STATISTICAL TESTS				
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
Esophagus: Periesophageal Tissue Inflammation				
LESION RATES				
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	---	---	---
STATISTICAL TESTS				
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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 TERMINAL SACRIFICE AT 105 WEEKS**

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

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Heart Necrosis				
LESION RATES				
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	---	---	---	---
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)

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
Islets, Pancreatic Hyperplasia				
LESION RATES				
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)
STATISTICAL TESTS				
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**

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)	---	---	---
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)

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
Kidney Infarct				
LESION RATES				
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
STATISTICAL TESTS				
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
Kidney Inflammation				
LESION RATES				
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	---	---
STATISTICAL TESTS				
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
Kidney Mineralization				
LESION RATES				
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
STATISTICAL TESTS				
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
 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
Kidney Nephropathy				
LESION RATES				
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
STATISTICAL TESTS				
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**

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	---
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)

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

**Kidney: Cortex
Cyst**

LESION RATES				
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)

STATISTICAL TESTS				
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
Kidney: Pelvis Dilatation				
LESION RATES				
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
STATISTICAL TESTS				
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**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Kidney: Renal Tubule Necrosis				
LESION RATES				
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
STATISTICAL TESTS				
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

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				
Angiectasis				
LESION RATES				
OVERALL (a)	3/50 (6%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/42.79	1/45.25	0/42.68	0/44.58
POLY-3 PERCENT (g)	7%	2.2%	0%	0%
TERMINAL (d)	3/34 (9%)	1/36 (3%)	0/31 (0%)	0/36 (0%)
FIRST INCIDENCE	730 (T)	730 (T)	---	---
STATISTICAL TESTS				
POLY 3	P=0.098N	P=0.285N	P=0.119N	P=0.111N
POLY 1.5	P=0.098N	P=0.285N	P=0.115N	P=0.111N
POLY 6	P=0.097N	P=0.286N	P=0.123N	P=0.112N
COCH-ARM / FISHERS	P=0.097N	P=0.309N	P=0.121N	P=0.121N
MAX-ISO-POLY-3	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
Liver				
Basophilic Focus				
LESION RATES				
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)
STATISTICAL TESTS				
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
Liver				
Clear Cell Focus				
LESION RATES				
OVERALL (a)	15/50 (30%)	22/50 (44%)	15/50 (30%)	7/50 (14%)
POLY-3 RATE (b)	15/42.99	22/45.67	15/43.35	7/44.58
POLY-3 PERCENT (g)	34.9%	48.2%	34.6%	15.7%
TERMINAL (d)	14/34 (41%)	19/36 (53%)	13/31 (42%)	7/36 (19%)
FIRST INCIDENCE	678	666	598	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.002N**	P=0.143	P=0.579N	P=0.031N*
POLY 1.5	P=0.002N**	P=0.145	P=0.555N	P=0.032N*
POLY 6	P=0.002N**	P=0.140	P=0.578	P=0.031N*
COCH-ARM / FISHERS	P=0.004N**	P=0.107	P=0.586N	P=0.045N*
MAX-ISO-POLY-3	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
Liver				
Eosinophilic Focus				
LESION RATES				
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
STATISTICAL TESTS				
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
Liver				
Fatty Change				
LESION RATES				
OVERALL (a)	0/50 (0%)	3/50 (6%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/42.79	3/45.78	1/42.68	2/44.96
POLY-3 PERCENT (g)	0%	6.6%	2.3%	4.5%
TERMINAL (d)	0/34 (0%)	2/36 (6%)	1/31 (3%)	0/36 (0%)
FIRST INCIDENCE	---	568	730 (T)	669
STATISTICAL TESTS				
POLY 3	P=0.459	P=0.131	P=0.500	P=0.248
POLY 1.5	P=0.458	P=0.130	P=0.504	P=0.248
POLY 6	P=0.461	P=0.132	P=0.494	P=0.249
COCH-ARM / FISHERS	P=0.437	P=0.121	P=0.500	P=0.247
MAX-ISO-POLY-3	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
Liver				
Hematopoietic Cell Proliferation				
LESION RATES				
OVERALL (a)	4/50 (8%)	1/50 (2%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	4/44.25	1/45.49	4/43.99	1/44.58
POLY-3 PERCENT (g)	9%	2.2%	9.1%	2.2%
TERMINAL (d)	1/34 (3%)	0/36 (0%)	1/31 (3%)	1/36 (3%)
FIRST INCIDENCE	156	666	512	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.252N	P=0.170N	P=0.640	P=0.176N
POLY 1.5	P=0.250N	P=0.169N	P=0.637N	P=0.173N
POLY 6	P=0.256N	P=0.172N	P=0.631	P=0.180N
COCH-ARM / FISHERS	P=0.248N	P=0.181N	P=0.643N	P=0.181N
MAX-ISO-POLY-3	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
Liver				
Inflammation Chronic				
LESION RATES				
OVERALL (a)	23/50 (46%)	22/50 (44%)	18/50 (36%)	19/50 (38%)
POLY-3 RATE (b)	23/44.27	22/45.93	18/44.73	19/45.65
POLY-3 PERCENT (g)	52%	47.9%	40.2%	41.6%
TERMINAL (d)	19/34 (56%)	19/36 (53%)	12/31 (39%)	15/36 (42%)
FIRST INCIDENCE	156	578	449	609
STATISTICAL TESTS				
POLY 3	P=0.214N	P=0.430N	P=0.181N	P=0.217N
POLY 1.5	P=0.222N	P=0.428N	P=0.175N	P=0.223N
POLY 6	P=0.201N	P=0.434N	P=0.186N	P=0.207N
COCH-ARM / FISHERS	P=0.247N	P=0.500N	P=0.208N	P=0.272N
MAX-ISO-POLY-3	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

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

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

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				
Pigmentation				
LESION RATES				
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)
STATISTICAL TESTS				
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)	---
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)

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 Hyperplasia				
LESION RATES				
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	---
STATISTICAL TESTS				
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
Liver: Hepatocyte Hypertrophy				
LESION RATES				
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
STATISTICAL TESTS				
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
Liver: Oval Cell Hyperplasia				
LESION RATES				
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
STATISTICAL TESTS				
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				
LESION RATES				
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	---	---	---
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)

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 Inflammation				
LESION RATES				
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	---	---	---	---
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)

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: Alveolar Epithelium Hyperplasia				
LESION RATES				
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	---
STATISTICAL TESTS				
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
Lung: Alveolus Infiltration Cellular Histiocyte				
LESION RATES				
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)
STATISTICAL TESTS				
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
Lung: Bronchiole, Epithelium Regeneration				
LESION RATES				
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
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)

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: Bronchus Necrosis				
LESION RATES				
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	---
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)

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: Bronchus, Epithelium Regeneration				
LESION RATES				
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
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)

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
Lymph Node, Mandibular Atrophy				
LESION RATES				
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
STATISTICAL TESTS				
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
Lymph Node, Mandibular Hyperplasia Lymphoid				
LESION RATES				
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)	---
STATISTICAL TESTS				
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

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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
Lymph Node, Mesenteric Atrophy				
LESION RATES				
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
STATISTICAL TESTS				
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

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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
Lymph Node, Mesenteric Hyperplasia Lymphoid				
LESION RATES				
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
STATISTICAL TESTS				
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

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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
Lymph Node: Renal Ectasia				
LESION RATES				
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	---	---	---	---
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)

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
Mesentery: Fat Necrosis				
LESION RATES				
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
STATISTICAL TESTS				
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

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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
Nose Inflammation				
LESION RATES				
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
STATISTICAL TESTS				
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

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

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Glands, Lateral Wall Dilatation				
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	---	---	---	---
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)

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
Nose: Glands, Respiratory Epithelium Dilatation				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose: Glands, Respiratory Epithelium Hyperplasia				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose: Glands, Respiratory Epithelium Metaplasia Respiratory				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose: Nasolacrimal Duct Hyperplasia Regenerative				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose: Nerve Atrophy				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose: Olfactory Epithelium Accumulation, Hyaline Droplet				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose: Olfactory Epithelium Metaplasia Respiratory				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose: Olfactory Epithelium Necrosis				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose: Olfactory Epithelium, Glands Dilatation				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose: Olfactory Epithelium, Glands Hyperplasia				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose: Olfactory Epithelium, Glands				
Metaplasia Respiratory				
LESION RATES				
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
STATISTICAL TESTS				
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

Nose: Respiratory Epithelium
Accumulation, Hyaline Droplet

LESION RATES

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

STATISTICAL TESTS

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
Nose: Respiratory Epithelium Hyperplasia				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose: Respiratory Epithelium Hyperplasia Regenerative				
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	---	---	---	---
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)

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
Nose: Respiratory Epithelium Necrosis				
LESION RATES				
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
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)

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
Nose: Transitional Epithelium Necrosis				
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
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)

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
Nose: Vomeronasal Organ Necrosis				
LESION RATES				
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
STATISTICAL TESTS				
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**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Pancreas				
Atrophy				
<hr/>				
LESION RATES				
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/>				
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)

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
Pancreas: Duct Cyst				
LESION RATES				
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
STATISTICAL TESTS				
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
Pituitary Gland: Pars Distalis Hyperplasia				
LESION RATES				
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)	---	---
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)

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

Pituitary Gland: Pars Intermedia
Hyperplasia

LESION RATES

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	---	---	---	---

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)

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
Preputial Gland Ectasia				
LESION RATES				
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
STATISTICAL TESTS				
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
Skin Inflammation				
LESION RATES				
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
STATISTICAL TESTS				
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

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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
Skin				
Ulcer				
LESION RATES				
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
STATISTICAL TESTS				
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

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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
Skin: Dermis				
Fibrosis				
LESION RATES				
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)
STATISTICAL TESTS				
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
Skin: Epidermis Hyperplasia				
LESION RATES				
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)
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)

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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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
Spleen Atrophy				
LESION RATES				
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
STATISTICAL TESTS				
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

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

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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
Spleen Pigmentation				
LESION RATES				
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
STATISTICAL TESTS				
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
Spleen: Red Pulp Atrophy				
LESION RATES				
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)
STATISTICAL TESTS				
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
 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
Stomach, Forestomach Erosion				
LESION RATES				
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)	---	---
STATISTICAL TESTS				
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

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
Stomach, Forestomach Inflammation				
LESION RATES				
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
STATISTICAL TESTS				
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

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
Stomach, Forestomach Ulcer				
LESION RATES				
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
STATISTICAL TESTS				
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

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

Stomach, Forestomach: Epithelium
Hyperplasia

LESION RATES

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

STATISTICAL TESTS

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

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
Testes: Germinal Epithelium Degeneration				
LESION RATES				
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	---
STATISTICAL TESTS				
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

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
Thymus Atrophy				
LESION RATES				
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
STATISTICAL TESTS				
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
Thymus				
Hyperplasia Lymphoid				
LESION RATES				
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)
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)

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
Thymus Necrosis				
LESION RATES				
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	---	---	---
STATISTICAL TESTS				
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

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
Thyroid Gland Atrophy				
LESION RATES				
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	---	---	---	---
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)

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
Tooth Dysplasia				
LESION RATES				
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
STATISTICAL TESTS				
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

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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
Urinary Bladder				
Calculus Gross Observation				
LESION RATES				
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)
STATISTICAL TESTS				
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**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Adrenal Cortex Hypertrophy				
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)

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
Adrenal Cortex Necrosis				
LESION RATES				
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	---
STATISTICAL TESTS				
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

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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
Adrenal Medulla Hyperplasia				
LESION RATES				
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)	---	---	---
STATISTICAL TESTS				
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
Blood Vessel Inflammation				
LESION RATES				
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
STATISTICAL TESTS				
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
Bone Marrow Atrophy				
LESION RATES				
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
STATISTICAL TESTS				
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

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
Bone Marrow Hyperplasia				
LESION RATES				
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
STATISTICAL TESTS				
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

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
Bone				
Fibro-osseous Lesion				
LESION RATES				
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
STATISTICAL TESTS				
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

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
Brain: Olfactory Lobe Atrophy				
LESION RATES				
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
STATISTICAL TESTS				
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

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
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)

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
Eye: Cornea Inflammation				
LESION RATES				
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
STATISTICAL TESTS				
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

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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
Harderian Gland Hyperplasia				
LESION RATES				
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
STATISTICAL TESTS				
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
Heart				
Cardiomyopathy				
LESION RATES				
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)
STATISTICAL TESTS				
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

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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
Heart Inflammation				
LESION RATES				
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
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)

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
Heart Mineralization				
LESION RATES				
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
STATISTICAL TESTS				
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

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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
Heart Necrosis				
LESION RATES				
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	---
STATISTICAL TESTS				
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

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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
Islets, Pancreatic Hyperplasia				
LESION RATES				
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)
STATISTICAL TESTS				
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

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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
Kidney				
Accumulation, Hyaline Droplet				
LESION RATES				
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	---
STATISTICAL TESTS				
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

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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
Kidney Infarct				
LESION RATES				
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)	---
STATISTICAL TESTS				
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
Kidney Inflammation				
LESION RATES				
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
STATISTICAL TESTS				
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
Kidney Mineralization				
LESION RATES				
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
STATISTICAL TESTS				
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
Kidney				
Nephropathy				
LESION RATES				
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
STATISTICAL TESTS				
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
Kidney Pigmentation				
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)

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
Kidney: Cortex Cyst				
LESION RATES				
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
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)

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
Kidney: Pelvis Dilatation				
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)

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
Kidney: Renal Tubule Necrosis				
LESION RATES				
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
STATISTICAL TESTS				
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
<hr/>				
Liver				
Angiectasis				
<hr/>				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/47.76	0/46.14	0/45.50	0/40.98
POLY-3 PERCENT (g)	2.1%	0%	0%	0%
TERMINAL (d)	1/43 (2%)	0/40 (0%)	0/39 (0%)	0/32 (0%)
FIRST INCIDENCE	729 (T)	---	---	---
<hr/>				
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)

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

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

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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
Liver				
Fatty Change				
LESION RATES				
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
STATISTICAL TESTS				
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

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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
Liver				
Hematopoietic Cell Proliferation				
LESION RATES				
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
STATISTICAL TESTS				
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

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
Liver				
Inflammation Chronic				
LESION RATES				
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
STATISTICAL TESTS				
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
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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
Liver				
Mitotic Alteration				
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)

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
Liver				
Mixed Cell Focus				
LESION RATES				
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
STATISTICAL TESTS				
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

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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
Liver				
Necrosis				
LESION RATES				
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
STATISTICAL TESTS				
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

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
Liver				
Pigmentation				
LESION RATES				
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
STATISTICAL TESTS				
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

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
Liver: Bile Duct Cyst				
LESION RATES				
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)
STATISTICAL TESTS				
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

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

Liver: Bile Duct
Hyperplasia

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)

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
Liver: Hepatocyte Hypertrophy				
LESION RATES				
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
STATISTICAL TESTS				
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
Liver: Oval Cell Hyperplasia				
LESION RATES				
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
STATISTICAL TESTS				
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
Lung				
Foreign Body				
LESION RATES				
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
STATISTICAL TESTS				
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

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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
Lung Inflammation				
LESION RATES				
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
STATISTICAL TESTS				
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

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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
Lung: Alveolar Epithelium Hyperplasia				
LESION RATES				
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
STATISTICAL TESTS				
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

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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
Lung: Alveolus Infiltration Cellular Histiocyte				
LESION RATES				
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
STATISTICAL TESTS				
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
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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
Lung: Bronchiole, Epithelium Regeneration				
LESION RATES				
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
STATISTICAL TESTS				
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
Lung: Bronchus Necrosis				
LESION RATES				
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
STATISTICAL TESTS				
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
Lung: Bronchus, Epithelium Regeneration				
LESION RATES				
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
STATISTICAL TESTS				
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
Lymph Node, Mandibular Atrophy				
LESION RATES				
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
STATISTICAL TESTS				
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
Lymph Node, Mandibular Hyperplasia Lymphoid				
LESION RATES				
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
STATISTICAL TESTS				
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
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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
Lymph Node, Mesenteric Atrophy				
LESION RATES				
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
STATISTICAL TESTS				
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

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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
Lymph Node, Mesenteric Hyperplasia Lymphoid				
LESION RATES				
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)	---
STATISTICAL TESTS				
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
 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
Lymph Node: Renal Ectasia				
LESION RATES				
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)	---	---	---
STATISTICAL TESTS				
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
Mesentery: Fat Necrosis				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose Inflammation				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose				
Polyp, Inflammatory				
LESION RATES				
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	---	---	---	---
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)

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
Nose: Glands, Lateral Wall Dilatation				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose: Glands, Respiratory Epithelium Dilatation				
LESION RATES				
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
STATISTICAL TESTS				
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

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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
Nose: Glands, Respiratory Epithelium Hyperplasia				
LESION RATES				
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
STATISTICAL TESTS				
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
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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
Nose: Glands, Respiratory Epithelium Metaplasia Respiratory				
LESION RATES				
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
STATISTICAL TESTS				
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

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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
Nose: Nasolacrimal Duct Hyperplasia Regenerative				
LESION RATES				
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
STATISTICAL TESTS				
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

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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
Nose: Nerve Atrophy				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose: Olfactory Epithelium Accumulation, Hyaline Droplet				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose: Olfactory Epithelium Metaplasia Respiratory				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose: Olfactory Epithelium Necrosis				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose: Olfactory Epithelium, Glands Dilatation				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose: Olfactory Epithelium, Glands Hyperplasia				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose: Olfactory Epithelium, Glands Metaplasia Respiratory				
LESION RATES				
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
STATISTICAL TESTS				
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

Nose: Respiratory Epithelium
Accumulation, Hyaline Droplet

LESION RATES				
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

STATISTICAL TESTS				
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
Nose: Respiratory Epithelium Hyperplasia				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose: Respiratory Epithelium Hyperplasia Regenerative				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose: Respiratory Epithelium Necrosis				
LESION RATES				
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
STATISTICAL TESTS				
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

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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
Nose: Transitional Epithelium Necrosis				
LESION RATES				
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
STATISTICAL TESTS				
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
Nose: Vomeronasal Organ				
Necrosis				
LESION RATES				
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
STATISTICAL TESTS				
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
Ovary				
Angiectasis				
LESION RATES				
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)
STATISTICAL TESTS				
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
Ovary Atrophy				
LESION RATES				
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
STATISTICAL TESTS				
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				
LESION RATES				
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)
STATISTICAL TESTS				
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
Ovary Hemorrhage				
LESION RATES				
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)	---
STATISTICAL TESTS				
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
Ovary Inflammation				
LESION RATES				
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	---	---
STATISTICAL TESTS				
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

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 Thrombosis				
LESION RATES				
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
STATISTICAL TESTS				
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
Pancreas Atrophy				
LESION RATES				
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)	---
STATISTICAL TESTS				
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
Pancreas: Duct Cyst				
LESION RATES				
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)	---
STATISTICAL TESTS				
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
Pituitary Gland: Pars Distalis Hyperplasia				
LESION RATES				
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)
STATISTICAL TESTS				
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

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
Pituitary Gland: Pars Intermedia Hyperplasia				
LESION RATES				
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)
STATISTICAL TESTS				
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

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
Skin Inflammation				
LESION RATES				
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)
STATISTICAL TESTS				
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

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
Skin				
Ulcer				
LESION RATES				
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)
STATISTICAL TESTS				
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
 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
Skin: Dermis				
Fibrosis				
LESION RATES				
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)	---
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)

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
Skin: Epidermis Hyperplasia				
LESION RATES				
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	---
STATISTICAL TESTS				
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

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
Spleen Atrophy				
LESION RATES				
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
STATISTICAL TESTS				
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

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
Spleen				
Hematopoietic Cell Proliferation				
LESION RATES				
OVERALL (a)	18/49 (37%)	23/49 (47%)	24/49 (49%)	21/50 (42%)
POLY-3 RATE (b)	18/48.44	23/48.34	24/47.64	21/44.18
POLY-3 PERCENT (g)	37.2%	47.6%	50.4%	47.5%
TERMINAL (d)	14/43 (33%)	16/40 (40%)	16/39 (41%)	14/32 (44%)
FIRST INCIDENCE	444	449	501	43
STATISTICAL TESTS				
POLY 3	P=0.292	P=0.203	P=0.135	P=0.212
POLY 1.5	P=0.358	P=0.204	P=0.134	P=0.257
POLY 6	P=0.233	P=0.204	P=0.138	P=0.171
COCH-ARM / FISHERS	P=0.519	P=0.206	P=0.154	P=0.371
MAX-ISO-POLY-3	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

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
Spleen				
Hyperplasia Lymphoid				
LESION RATES				
OVERALL (a)	14/49 (29%)	15/49 (31%)	12/49 (24%)	15/50 (30%)
POLY-3 RATE (b)	14/47.12	15/46.14	12/45.69	15/40.98
POLY-3 PERCENT (g)	29.7%	32.5%	26.3%	36.6%
TERMINAL (d)	13/43 (30%)	15/40 (38%)	11/39 (28%)	15/32 (47%)
FIRST INCIDENCE	698	729 (T)	669	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.312	P=0.473	P=0.445N	P=0.323
POLY 1.5	P=0.368	P=0.483	P=0.439N	P=0.383
POLY 6	P=0.254	P=0.463	P=0.455N	P=0.260
COCH-ARM / FISHERS	P=0.513	P=0.500	P=0.410N	P=0.526
MAX-ISO-POLY-3	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

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
Spleen Pigmentation				
LESION RATES				
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
STATISTICAL TESTS				
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

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
Spleen: Red Pulp Atrophy				
LESION RATES				
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
STATISTICAL TESTS				
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

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
Stomach, Forestomach Erosion				
LESION RATES				
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
STATISTICAL TESTS				
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

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
Stomach, Forestomach Inflammation				
LESION RATES				
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
STATISTICAL TESTS				
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
Stomach, Forestomach Ulcer				
LESION RATES				
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
STATISTICAL TESTS				
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
Stomach, Forestomach: Epithelium Hyperplasia				
LESION RATES				
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
STATISTICAL TESTS				
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

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
Thymus Atrophy				
LESION RATES				
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
STATISTICAL TESTS				
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
Thymus				
Hyperplasia Lymphoid				
LESION RATES				
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)	---	---	---
STATISTICAL TESTS				
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

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
<hr/>				
Thymus Necrosis				
<hr/>				
LESION RATES				
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	---	---	---	---
<hr/>				
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)

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
Thyroid Gland Atrophy				
LESION RATES				
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)	---	---
STATISTICAL TESTS				
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
Tooth Dysplasia				
LESION RATES				
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
STATISTICAL TESTS				
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

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
Urinary Bladder				
Calculus Gross Observation				
<hr/>				
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	---	---	---	---
<hr/>				
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)

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
Uterus				
Angiectasis				
LESION RATES				
OVERALL (a)	2/50 (4%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/47.76	2/46.14	1/45.50	0/40.98
POLY-3 PERCENT (g)	4.2%	4.3%	2.2%	0%
TERMINAL (d)	2/43 (5%)	2/40 (5%)	1/39 (3%)	0/32 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.166N	P=0.681	P=0.517N	P=0.273N
POLY 1.5	P=0.159N	P=0.683	P=0.514N	P=0.262N
POLY 6	P=0.175N	P=0.681	P=0.519N	P=0.285N
COCH-ARM / FISHERS	P=0.141N	P=0.691N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.216N	P=0.486	P=0.299N	P=0.109N

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
Uterus Dilatation				
LESION RATES				
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
STATISTICAL TESTS				
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

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
Uterus Inflammation				
LESION RATES				
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)	---
STATISTICAL TESTS				
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
 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
Uterus: Endometrium Hyperplasia Cystic				
LESION RATES				
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
STATISTICAL TESTS				
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
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

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 ***