

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

F1_Rev.1__R2

C Number: C20107
Lock Date: 02/20/2008
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.3.0
PWG Approval Date: 01/25/2011

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

MALE RATS

Organ

Adrenal Cortex

Bone Marrow

Eye: Retina
Harderian Gland
Heart

Kidney

Kidney: Pelvis

Kidney: Pelvis, Transitional Epithelium
Liver

Liver: Bile Duct

Liver: Hepatocyte
Lung

Lung: Alveolus
Lymph Node, Mesenteric

Lymph Node: Mediastinal

Morphology

Angiectasis
Hyperplasia
Hemorrhage
Hyperplasia
Atrophy
Inflammation
Cardiomyopathy
Mineralization
Mineralization
Pigmentation
Dilatation
Inflammation
Hyperplasia
Basophilic Focus
Clear Cell Focus
Degeneration Cystic
Eosinophilic Focus
Fatty Change Diffuse
Fatty Change Focal
Hepatodiaphragmatic Nodule
Inflammation
Mixed Cell Focus
Vacuolization Cytoplasmic
Cyst
Fibrosis
Hyperplasia
Hypertrophy
Congestion
Infiltration Cellular Histiocyte
Ectasia
Infiltration Cellular Histiocyte
Ectasia

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Mesentery: Fat	Necrosis
Nose	Inflammation
Nose: Glands, Respiratory Epithelium	Dilatation
	Hyperplasia
	Metaplasia Respiratory
Nose: Nerve	Atrophy
Nose: Olfactory Epithelium	Accumulation, Hyaline Droplet
	Degeneration
	Hyperplasia Basal Cell
	Metaplasia Respiratory
Nose: Olfactory Epithelium, Glands	Dilatation
	Hyperplasia
	Metaplasia
	Necrosis
Nose: Respiratory Epithelium	Accumulation, Hyaline Droplet
	Hyperplasia
Nose: Transitional Epithelium	Hyperplasia
Nose: Transitional Epithelium, Glands	Dilatation
	Hyperplasia
Pancreas: Acinus	Atrophy
Parathyroid Gland	Hyperplasia Diffuse
Preputial Gland	Inflammation
Prostate	Inflammation
Spleen	Congestion
	Hematopoietic Cell Proliferation
	Inflammation
	Pigmentation
Spleen: Capsule	Fibrosis
	Hypertrophy Mesothelium
Spleen: Lymphoid Follicle	Atrophy
Spleen: Red Pulp	Atrophy
Stomach, Forestomach	Hyperplasia
	Inflammation
	Ulcer
Stomach, Glandular	Mineralization
Testes: Interstitial Cell	Hyperplasia

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Thymus
Thyroid Gland: C-Cell
Trachea: Peritracheal Tissue

Atrophy
Hyperplasia
Inflammation

FEMALE RATS

Organ

Adrenal Cortex

Bone Marrow
Clitoral Gland
Harderian Gland
Heart
Kidney

Kidney: Pelvis
Kidney: Pelvis, Transitional Epithelium
Liver

Liver: Bile Duct

Liver: Hepatocyte

Lung

Lung: Alveolus
Mammary Gland

Morphology

Hyperplasia
Vacuolization Cytoplasmic
Hyperplasia
Inflammation
Inflammation
Cardiomyopathy
Accumulation, Hyaline Droplet
Infarct
Nephropathy
Pigmentation
Inflammation
Hyperplasia
Angiectasis
Basophilic Focus
Clear Cell Focus
Degeneration Cystic
Eosinophilic Focus
Fatty Change Diffuse
Fatty Change Focal
Inflammation
Mixed Cell Focus
Fibrosis
Hyperplasia
Hypertrophy
Necrosis
Congestion
Inflammation
Infiltration Cellular Histiocyte
Cyst

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Nose	Hyperplasia
Nose: Glands, Respiratory Epithelium	Inflammation
	Dilatation
	Hyperplasia
	Metaplasia Respiratory
Nose: Nerve	Atrophy
Nose: Olfactory Epithelium	Accumulation, Hyaline Droplet
	Degeneration
	Hyperplasia Basal Cell
	Metaplasia
	Metaplasia Respiratory
Nose: Olfactory Epithelium, Glands	Dilatation
	Hyperplasia
	Metaplasia
	Necrosis
Nose: Respiratory Epithelium	Accumulation, Hyaline Droplet
	Hyperplasia
Nose: Transitional Epithelium	Hyperplasia
Nose: Transitional Epithelium, Glands	Dilatation
	Hyperplasia
Ovary	Cyst
Pancreas: Acinus	Atrophy
Parathyroid Gland	Hyperplasia Diffuse
Pituitary Gland	Cyst
Pituitary Gland: Pars Distalis	Cyst
Spleen	Congestion
	Hematopoietic Cell Proliferation
	Pigmentation
	Fibrosis
Spleen: Capsule	Hypertrophy Mesothelium
	Atrophy
Spleen: Lymphoid Follicle	Hyperplasia
Stomach, Forestomach	Inflammation
	Ulcer
Thyroid Gland: C-Cell	Hyperplasia
Trachea	Inflammation

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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF N,N-DIMETHYL-P-TOLUIDINE

Uterus
Uterus: Endometrium

Hemorrhage
Hyperplasia Cystic

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Adrenal Cortex				
Angiectasis				
LESION RATES				
OVERALL (a)	13/50 (26%)	9/50 (18%)	7/50 (14%)	4/50 (8%)
POLY-3 RATE (b)	13/46.23	9/44.99	7/41.44	4/39.05
POLY-3 PERCENT (g)	28.1%	20%	16.9%	10.2%
TERMINAL (d)	12/37 (32%)	9/37 (24%)	7/31 (23%)	3/21 (14%)
FIRST INCIDENCE	664	727 (T)	727 (T)	724
STATISTICAL TESTS				
POLY 3	P=0.038N*	P=0.254N	P=0.159N	P=0.035N*
POLY 1.5	P=0.028N*	P=0.255N	P=0.145N	P=0.025N*
POLY 6	P=0.056N	P=0.248N	P=0.174N	P=0.051N
COCH-ARM / FISHERS	P=0.019N*	P=0.235N	P=0.105N	P=0.016N*
MAX-ISO-POLY-3	P=0.043N*	P=0.186N	P=0.116N	P=0.027N*

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TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Adrenal Cortex Degeneration Cystic				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.00	0/44.99	0/41.44	0/39.04
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	0/21 (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 RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Adrenal Cortex Hyperplasia				
LESION RATES				
OVERALL (a)	17/50 (34%)	21/50 (42%)	10/50 (20%)	8/50 (16%)
POLY-3 RATE (b)	17/46.41	21/45.61	10/41.66	8/40.00
POLY-3 PERCENT (g)	36.6%	46%	24%	20%
TERMINAL (d)	16/37 (43%)	18/37 (49%)	8/31 (26%)	6/21 (29%)
FIRST INCIDENCE	610	588	686	496
STATISTICAL TESTS				
POLY 3	P=0.014N*	P=0.239	P=0.145N	P=0.069N
POLY 1.5	P=0.009N**	P=0.238	P=0.131N	P=0.051N
POLY 6	P=0.024N*	P=0.252	P=0.158N	P=0.098N
COCH-ARM / FISHERS	P=0.005N**	P=0.268	P=0.088N	P=0.032N*
MAX-ISO-POLY-3	P=0.022N*	P=0.180	P=0.109N	P=0.053N

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Adrenal Cortex Hypertrophy				
LESION RATES				
OVERALL (a)	9/50 (18%)	6/50 (12%)	6/50 (12%)	7/50 (14%)
POLY-3 RATE (b)	9/46.47	6/44.99	6/41.60	7/39.71
POLY-3 PERCENT (g)	19.4%	13.3%	14.4%	17.6%
TERMINAL (d)	7/37 (19%)	6/37 (16%)	5/31 (16%)	5/21 (24%)
FIRST INCIDENCE	610	727 (T)	686	614
STATISTICAL TESTS				
POLY 3	P=0.538	P=0.310N	P=0.371N	P=0.528N
POLY 1.5	P=0.549N	P=0.308N	P=0.351N	P=0.477N
POLY 6	P=0.476	P=0.308N	P=0.391N	P=0.589N
COCH-ARM / FISHERS	P=0.479N	P=0.288N	P=0.288N	P=0.393N
MAX-ISO-POLY-3	P=0.493N	P=0.223N	P=0.281N	P=0.422N

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Adrenal Cortex				
Vacuolization Cytoplasmic				
LESION RATES				
OVERALL (a)	31/50 (62%)	31/50 (62%)	26/50 (52%)	28/50 (56%)
POLY-3 RATE (b)	31/49.60	31/46.36	26/45.99	28/44.05
POLY-3 PERCENT (g)	62.5%	66.9%	56.5%	63.6%
TERMINAL (d)	19/37 (51%)	23/37 (62%)	15/31 (48%)	13/21 (62%)
FIRST INCIDENCE	337	601	129	348
STATISTICAL TESTS				
POLY 3	P=0.522N	P=0.408	P=0.349N	P=0.544
POLY 1.5	P=0.422N	P=0.449	P=0.294N	P=0.519N
POLY 6	P=0.442	P=0.375	P=0.419N	P=0.405
COCH-ARM / FISHERS	P=0.295N	P=0.582N	P=0.210N	P=0.342N
MAX-ISO-POLY-3	P=0.522N	P=0.332	P=0.283N	P=0.458

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Adrenal Medulla Hyperplasia				
LESION RATES				
OVERALL (a)	18/50 (36%)	15/50 (30%)	12/50 (24%)	18/50 (36%)
POLY-3 RATE (b)	18/47.45	15/45.24	12/42.37	18/41.13
POLY-3 PERCENT (g)	37.9%	33.2%	28.3%	43.8%
TERMINAL (d)	11/37 (30%)	13/37 (35%)	7/31 (23%)	9/21 (43%)
FIRST INCIDENCE	612	695	626	614
STATISTICAL TESTS				
POLY 3	P=0.245	P=0.396N	P=0.229N	P=0.366
POLY 1.5	P=0.304	P=0.382N	P=0.205N	P=0.444
POLY 6	P=0.185	P=0.410N	P=0.257N	P=0.284
COCH-ARM / FISHERS	P=0.409	P=0.335N	P=0.138N	P=0.582N
MAX-ISO-POLY-3	P=0.272	P=0.319N	P=0.180N	P=0.300

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Bone Marrow Hemorrhage				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	0/46.00	0/44.99	1/41.84	4/39.55
POLY-3 PERCENT (g)	0%	0%	2.4%	10.1%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	2/21 (10%)
FIRST INCIDENCE	---	---	612	614
STATISTICAL TESTS				
POLY 3	P=0.003**	(e)	P=0.481	P=0.043*
POLY 1.5	P=0.004**	(e)	P=0.485	P=0.049*
POLY 6	P=0.002**	(e)	P=0.478	P=0.037*
COCH-ARM / FISHERS	P=0.005**	(e)	P=0.500	P=0.059
MAX-ISO-POLY-3	P=0.005**	(e)	P=0.158	P=0.019*

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Bone Marrow Hyperplasia				
LESION RATES				
OVERALL (a)	17/50 (34%)	13/50 (26%)	28/50 (56%)	50/50 (100%)
POLY-3 RATE (b)	17/47.68	13/47.13	28/45.94	50/50.00
POLY-3 PERCENT (g)	35.7%	27.6%	61%	100%
TERMINAL (d)	10/37 (27%)	7/37 (19%)	17/31 (55%)	21/21 (100%)
FIRST INCIDENCE	609	324	233	192
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.267N	P=0.010**	P<0.001**
POLY 1.5	P<0.001**	P=0.268N	P=0.012*	P<0.001**
POLY 6	P<0.001**	P=0.265N	P=0.009**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.257N	P=0.022*	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.201N	P=0.006**	P<0.001**

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Coagulating Gland Inflammation				
LESION RATES				
OVERALL (a)	1/1 (100%)	2/2 (100%)	0/1 (0%)	0/0 (0%)
POLY-3 RATE (b)	1/1.00	2/2.00	0/0.64	0/0.00
POLY-3 PERCENT (g)	100%	100%	0%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	645	713	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.896N	(e)	P=0.500N	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Epididymis Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	0/46.00	1/44.99	2/41.44	2/39.27
POLY-3 PERCENT (g)	0%	2.2%	4.8%	5.1%
TERMINAL (d)	0/37 (0%)	1/37 (3%)	2/31 (7%)	1/21 (5%)
FIRST INCIDENCE	---	727 (T)	727 (T)	668
STATISTICAL TESTS				
POLY 3	P=0.176	P=0.496	P=0.215	P=0.204
POLY 1.5	P=0.195	P=0.495	P=0.220	P=0.216
POLY 6	P=0.154	P=0.497	P=0.210	P=0.190
COCH-ARM / FISHERS	P=0.228	P=0.500	P=0.247	P=0.247
MAX-ISO-POLY-3	P=0.162	P=0.159	P=0.076	P=0.075

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Esophagus Perforation				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/46.00	0/44.99	1/42.43	2/40.51
POLY-3 PERCENT (g)	0%	0%	2.4%	4.9%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	---	---	147	192
STATISTICAL TESTS				
POLY 3	P=0.068	(e)	P=0.484	P=0.210
POLY 1.5	P=0.075	(e)	P=0.488	P=0.221
POLY 6	P=0.060	(e)	P=0.480	P=0.197
COCH-ARM / FISHERS	P=0.084	(e)	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.080	(e)	P=0.158	P=0.075

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Eye				
Cataract				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.00	0/44.99	0/41.44	0/39.04
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	0/21 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Eye: Retina				
Atrophy				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	0/46.00	1/44.99	1/41.44	3/39.07
POLY-3 PERCENT (g)	0%	2.2%	2.4%	7.7%
TERMINAL (d)	0/37 (0%)	1/37 (3%)	1/31 (3%)	1/21 (5%)
FIRST INCIDENCE	---	727 (T)	727 (T)	723
STATISTICAL TESTS				
POLY 3	P=0.046*	P=0.496	P=0.479	P=0.092
POLY 1.5	P=0.053	P=0.495	P=0.484	P=0.102
POLY 6	P=0.039*	P=0.497	P=0.475	P=0.081
COCH-ARM / FISHERS	P=0.064	P=0.500	P=0.500	P=0.121
MAX-ISO-POLY-3	P=0.043*	P=0.159	P=0.158	P=0.037*

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Harderian Gland Inflammation				
LESION RATES				
OVERALL (a)	3/50 (6%)	6/50 (12%)	0/50 (0%)	10/50 (20%)
POLY-3 RATE (b)	3/46.41	6/44.99	0/41.44	10/41.45
POLY-3 PERCENT (g)	6.5%	13.3%	0%	24.1%
TERMINAL (d)	2/37 (5%)	6/37 (16%)	0/31 (0%)	6/21 (29%)
FIRST INCIDENCE	610	727 (T)	---	348
STATISTICAL TESTS				
POLY 3	P=0.009**	P=0.227	P=0.140N	P=0.019*
POLY 1.5	P=0.011*	P=0.229	P=0.135N	P=0.025*
POLY 6	P=0.007**	P=0.228	P=0.146N	P=0.014*
COCH-ARM / FISHERS	P=0.016*	P=0.243	P=0.121N	P=0.036*
MAX-ISO-POLY-3	P=0.008**	P=0.139	P=0.056N	P=0.012*

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Heart				
Cardiomyopathy				
LESION RATES				
OVERALL (a)	46/50 (92%)	50/50 (100%)	49/50 (98%)	48/50 (96%)
POLY-3 RATE (b)	46/49.01	50/50.00	49/50.00	48/49.32
POLY-3 PERCENT (g)	93.9%	100%	98%	97.3%
TERMINAL (d)	37/37 (100%)	37/37 (100%)	30/31 (97%)	20/21 (95%)
FIRST INCIDENCE	337	62	129	192
STATISTICAL TESTS				
POLY 3	P=0.543	P=0.088	P=0.282	P=0.352
POLY 1.5	P=0.538	P=0.072	P=0.227	P=0.332
POLY 6	P=0.597	P=0.133	P=0.398	P=0.430
COCH-ARM / FISHERS	P=0.562	P=0.059	P=0.181	P=0.339
MAX-ISO-POLY-3	P=0.103	P=0.023*	P=0.131	P=0.178

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Heart Mineralization				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	0/46.00	0/44.99	0/41.44	3/40.47
POLY-3 PERCENT (g)	0%	0%	0%	7.4%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	---	---	---	412
STATISTICAL TESTS				
POLY 3	P=0.006**	(e)	(e)	P=0.097
POLY 1.5	P=0.007**	(e)	(e)	P=0.105
POLY 6	P=0.006**	(e)	(e)	P=0.089
COCH-ARM / FISHERS	P=0.009**	(e)	(e)	P=0.121
MAX-ISO-POLY-3	P=0.010**	(e)	(e)	P=0.037*

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Heart Thrombosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/46.00	0/44.99	1/41.80	2/39.54
POLY-3 PERCENT (g)	0%	0%	2.4%	5.1%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	---	---	626	616
STATISTICAL TESTS				
POLY 3	P=0.065	(e)	P=0.481	P=0.205
POLY 1.5	P=0.072	(e)	P=0.485	P=0.217
POLY 6	P=0.058	(e)	P=0.478	P=0.192
COCH-ARM / FISHERS	P=0.084	(e)	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.080	(e)	P=0.158	P=0.075

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Intestine Large, Colon				
Parasite Metazoan				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/46.23	2/46.34	1/42.43	0/39.04
POLY-3 PERCENT (g)	2.2%	4.3%	2.4%	0%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	665	324	129	---
STATISTICAL TESTS				
POLY 3	P=0.271N	P=0.501	P=0.741	P=0.533N
POLY 1.5	P=0.256N	P=0.498	P=0.746	P=0.521N
POLY 6	P=0.292N	P=0.506	P=0.736	P=0.549N
COCH-ARM / FISHERS	P=0.231N	P=0.500	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.299N	P=0.282	P=0.476	P=0.199N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Intestine Large, Rectum Parasite Metazoan				
LESION RATES				
OVERALL (a)	3/50 (6%)	5/50 (10%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	3/46.00	5/45.64	2/41.84	3/40.30
POLY-3 PERCENT (g)	6.5%	11%	4.8%	7.4%
TERMINAL (d)	3/37 (8%)	4/37 (11%)	1/31 (3%)	1/21 (5%)
FIRST INCIDENCE	727 (T)	512	612	192
STATISTICAL TESTS				
POLY 3	P=0.521N	P=0.352	P=0.543N	P=0.600
POLY 1.5	P=0.492N	P=0.349	P=0.535N	P=0.626
POLY 6	P=0.557N	P=0.360	P=0.550N	P=0.567
COCH-ARM / FISHERS	P=0.454N	P=0.357	P=0.500N	P=0.661N
MAX-ISO-POLY-3	P=0.528N	P=0.229	P=0.368N	P=0.436

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Islets, Pancreatic Hyperplasia				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/46.00	2/44.99	1/41.44	0/39.04
POLY-3 PERCENT (g)	2.2%	4.5%	2.4%	0%
TERMINAL (d)	1/37 (3%)	2/37 (5%)	1/31 (3%)	0/21 (0%)
FIRST INCIDENCE	727 (T)	727 (T)	727 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.270N	P=0.492	P=0.737	P=0.533N
POLY 1.5	P=0.255N	P=0.492	P=0.742	P=0.520N
POLY 6	P=0.289N	P=0.496	P=0.732	P=0.548N
COCH-ARM / FISHERS	P=0.231N	P=0.500	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.292N	P=0.276	P=0.471	P=0.198N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Kidney				
Accumulation, Hyaline Droplet				
LESION RATES				
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/46.45	1/45.64	0/41.44	0/39.04
POLY-3 PERCENT (g)	4.3%	2.2%	0%	0%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	645	512	---	---
STATISTICAL TESTS				
POLY 3	P=0.181N	P=0.506N	P=0.264N	P=0.278N
POLY 1.5	P=0.175N	P=0.507N	P=0.257N	P=0.262N
POLY 6	P=0.188N	P=0.504N	P=0.271N	P=0.299N
COCH-ARM / FISHERS	P=0.169N	P=0.500N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.135N	P=0.288N	P=0.101N	P=0.114N

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<hr/>				
Kidney Infarct				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.00	0/44.99	0/41.44	0/39.04
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	0/21 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Kidney Mineralization				
LESION RATES				
OVERALL (a)	44/50 (88%)	37/50 (74%)	38/50 (76%)	49/50 (98%)
POLY-3 RATE (b)	44/48.21	37/48.55	38/47.27	49/49.11
POLY-3 PERCENT (g)	91.3%	76.2%	80.4%	99.8%
TERMINAL (d)	35/37 (95%)	28/37 (76%)	25/31 (81%)	21/21 (100%)
FIRST INCIDENCE	610	324	129	192
STATISTICAL TESTS				
POLY 3	P=0.005**	P=0.036N*	P=0.097N	P=0.043*
POLY 1.5	P=0.005**	P=0.049N*	P=0.099N	P=0.040*
POLY 6	P=0.006**	P=0.026N*	P=0.097N	P=0.060
COCH-ARM / FISHERS	P=0.008**	P=0.062N	P=0.096N	P=0.056
MAX-ISO-POLY-3	P=0.006**	P=0.019N*	P=0.055N	P=0.012*

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Kidney				
Nephropathy				
LESION RATES				
OVERALL (a)	49/50 (98%)	49/50 (98%)	48/50 (96%)	49/50 (98%)
POLY-3 RATE (b)	49/49.59	49/49.00	48/48.04	49/49.15
POLY-3 PERCENT (g)	98.8%	100%	99.9%	99.7%
TERMINAL (d)	37/37 (100%)	37/37 (100%)	31/31 (100%)	21/21 (100%)
FIRST INCIDENCE	337	324	129	192
STATISTICAL TESTS				
POLY 3	P=0.817	P=0.760	P=0.783	P=0.822
POLY 1.5	P=0.799	P=0.634	P=0.743	P=0.764
POLY 6	P=0.950	P=0.970	P=0.971	P=0.974
COCH-ARM / FISHERS	P=0.640	P=0.753N	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.185	P=0.163	P=0.186	P=0.239

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Kidney Pigmentation				
LESION RATES				
OVERALL (a)	24/50 (48%)	46/50 (92%)	37/50 (74%)	44/50 (88%)
POLY-3 RATE (b)	24/49.00	46/48.87	37/44.56	44/46.68
POLY-3 PERCENT (g)	49%	94.1%	83%	94.3%
TERMINAL (d)	14/37 (38%)	35/37 (95%)	29/31 (94%)	21/21 (100%)
FIRST INCIDENCE	337	324	519	384
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=0.003**	P<0.001**	P=0.007**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Kidney: Papilla Necrosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.00	2/45.07	0/41.44	0/39.04
POLY-3 PERCENT (g)	0%	4.4%	0%	0%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	---	713	---	---
STATISTICAL TESTS				
POLY 3	P=0.393N	P=0.233	(e)	(e)
POLY 1.5	P=0.385N	P=0.232	(e)	(e)
POLY 6	P=0.402N	P=0.235	(e)	(e)
COCH-ARM / FISHERS	P=0.369N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.313N	P=0.076	(e)	(e)

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	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%)	3/50 (6%)
POLY-3 RATE (b)	0/46.00	0/44.99	0/41.44	3/40.22
POLY-3 PERCENT (g)	0%	0%	0%	7.5%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	1/21 (5%)
FIRST INCIDENCE	---	---	---	412
STATISTICAL TESTS				
POLY 3	P=0.006**	(e)	(e)	P=0.096
POLY 1.5	P=0.007**	(e)	(e)	P=0.104
POLY 6	P=0.006**	(e)	(e)	P=0.087
COCH-ARM / FISHERS	P=0.009**	(e)	(e)	P=0.121
MAX-ISO-POLY-3	P=0.010**	(e)	(e)	P=0.037*

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Kidney: Pelvis Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	3/50 (6%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/46.00	3/45.07	1/41.44	0/39.04
POLY-3 PERCENT (g)	0%	6.7%	2.4%	0%
TERMINAL (d)	0/37 (0%)	1/37 (3%)	1/31 (3%)	0/21 (0%)
FIRST INCIDENCE	---	713	727 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.320N	P=0.115	P=0.479	(e)
POLY 1.5	P=0.302N	P=0.115	P=0.484	(e)
POLY 6	P=0.343N	P=0.117	P=0.475	(e)
COCH-ARM / FISHERS	P=0.273N	P=0.121	P=0.500	(e)
MAX-ISO-POLY-3	P=0.289N	P=0.038*	P=0.158	(e)

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Kidney: Pelvis, Transitional Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	6/50 (12%)	5/50 (10%)
POLY-3 RATE (b)	1/46.41	2/44.99	6/41.68	5/39.58
POLY-3 PERCENT (g)	2.2%	4.5%	14.4%	12.6%
TERMINAL (d)	0/37 (0%)	2/37 (5%)	4/31 (13%)	2/21 (10%)
FIRST INCIDENCE	609	727 (T)	680	616
STATISTICAL TESTS				
POLY 3	P=0.051	P=0.489	P=0.040*	P=0.069
POLY 1.5	P=0.065	P=0.490	P=0.044*	P=0.080
POLY 6	P=0.037*	P=0.490	P=0.037*	P=0.057
COCH-ARM / FISHERS	P=0.094	P=0.500	P=0.056	P=0.102
MAX-ISO-POLY-3	P=0.059	P=0.274	P=0.021*	P=0.038*

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	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)	1/46.00	0/44.99	0/41.44	0/39.04
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	1/37 (3%)	0/37 (0%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	727 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver				
Basophilic Focus				
LESION RATES				
OVERALL (a)	28/50 (56%)	6/50 (12%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	28/46.42	6/44.99	0/41.44	3/39.46
POLY-3 PERCENT (g)	60.3%	13.3%	0%	7.6%
TERMINAL (d)	26/37 (70%)	6/37 (16%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	664	727 (T)	---	616
STATISTICAL TESTS				
POLY 3	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver				
Clear Cell Focus				
LESION RATES				
OVERALL (a)	30/50 (60%)	36/50 (72%)	26/50 (52%)	35/50 (70%)
POLY-3 RATE (b)	30/46.23	36/45.02	26/42.09	35/44.40
POLY-3 PERCENT (g)	64.9%	80%	61.8%	78.8%
TERMINAL (d)	29/37 (78%)	35/37 (95%)	24/31 (77%)	20/21 (95%)
FIRST INCIDENCE	665	721	612	348
STATISTICAL TESTS				
POLY 3	P=0.184	P=0.072	P=0.466N	P=0.093
POLY 1.5	P=0.221	P=0.085	P=0.424N	P=0.123
POLY 6	P=0.147	P=0.063	P=0.503N	P=0.068
COCH-ARM / FISHERS	P=0.296	P=0.146	P=0.273N	P=0.201
MAX-ISO-POLY-3	P=0.096	P=0.045*	P=0.380N	P=0.061

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver				
Degeneration Cystic				
LESION RATES				
OVERALL (a)	4/50 (8%)	10/50 (20%)	9/50 (18%)	17/50 (34%)
POLY-3 RATE (b)	4/46.18	10/44.99	9/42.23	17/40.51
POLY-3 PERCENT (g)	8.7%	22.2%	21.3%	42%
TERMINAL (d)	3/37 (8%)	10/37 (27%)	7/31 (23%)	9/21 (43%)
FIRST INCIDENCE	680	727 (T)	612	582
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.064	P=0.083	P<0.001**
POLY 1.5	P<0.001**	P=0.065	P=0.089	P<0.001**
POLY 6	P<0.001**	P=0.065	P=0.078	P<0.001**
COCH-ARM / FISHERS	P=0.002**	P=0.074	P=0.117	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.037*	P=0.052	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver				
Eosinophilic Focus				
LESION RATES				
OVERALL (a)	11/50 (22%)	21/50 (42%)	21/50 (42%)	29/50 (58%)
POLY-3 RATE (b)	11/46.00	21/45.02	21/43.19	29/43.32
POLY-3 PERCENT (g)	23.9%	46.7%	48.6%	67%
TERMINAL (d)	11/37 (30%)	20/37 (54%)	15/31 (48%)	15/21 (71%)
FIRST INCIDENCE	727 (T)	721	519	431
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.017*	P=0.011*	P<0.001**
POLY 1.5	P<0.001**	P=0.018*	P=0.013*	P<0.001**
POLY 6	P<0.001**	P=0.018*	P=0.011*	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.026*	P=0.026*	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.010**	P=0.007**	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver				
Fatty Change Diffuse				
LESION RATES				
OVERALL (a)	1/50 (2%)	8/50 (16%)	5/50 (10%)	5/50 (10%)
POLY-3 RATE (b)	1/46.06	8/46.12	5/42.01	5/40.06
POLY-3 PERCENT (g)	2.2%	17.4%	11.9%	12.5%
TERMINAL (d)	0/37 (0%)	3/37 (8%)	3/31 (10%)	1/21 (5%)
FIRST INCIDENCE	710	512	581	612
STATISTICAL TESTS				
POLY 3	P=0.309	P=0.016*	P=0.081	P=0.072
POLY 1.5	P=0.348	P=0.015*	P=0.085	P=0.082
POLY 6	P=0.265	P=0.017*	P=0.078	P=0.062
COCH-ARM / FISHERS	P=0.420	P=0.015*	P=0.102	P=0.102
MAX-ISO-POLY-3	P=0.080	P=0.006**	P=0.040*	P=0.038*

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver				
Fatty Change Focal				
LESION RATES				
OVERALL (a)	6/50 (12%)	2/50 (4%)	3/50 (6%)	9/50 (18%)
POLY-3 RATE (b)	6/46.00	2/44.99	3/42.08	9/41.81
POLY-3 PERCENT (g)	13%	4.5%	7.1%	21.5%
TERMINAL (d)	6/37 (16%)	2/37 (5%)	2/31 (7%)	1/21 (5%)
FIRST INCIDENCE	727 (T)	727 (T)	519	431
STATISTICAL TESTS				
POLY 3	P=0.036*	P=0.140N	P=0.288N	P=0.220
POLY 1.5	P=0.041*	P=0.141N	P=0.279N	P=0.242
POLY 6	P=0.031*	P=0.136N	P=0.295N	P=0.199
COCH-ARM / FISHERS	P=0.051	P=0.134N	P=0.243N	P=0.288
MAX-ISO-POLY-3	P=0.048*	P=0.075N	P=0.191N	P=0.157

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver				
Hematopoietic Cell Proliferation				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/46.06	0/44.99	1/41.80	1/39.43
POLY-3 PERCENT (g)	2.2%	0%	2.4%	2.5%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	710	---	626	616
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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver				
Hepatodiaphragmatic Nodule				
LESION RATES				
OVERALL (a)	8/50 (16%)	1/50 (2%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	8/46.74	1/44.99	0/41.44	3/39.54
POLY-3 PERCENT (g)	17.1%	2.2%	0%	7.6%
TERMINAL (d)	5/37 (14%)	1/37 (3%)	0/31 (0%)	1/21 (5%)
FIRST INCIDENCE	610	727 (T)	---	582
STATISTICAL TESTS				
POLY 3	P=0.275N	P=0.018N*	P=0.006N**	P=0.160N
POLY 1.5	P=0.261N	P=0.018N*	P=0.006N**	P=0.134N
POLY 6	P=0.293N	P=0.018N*	P=0.007N**	P=0.197N
COCH-ARM / FISHERS	P=0.254N	P=0.015N*	P=0.003N**	P=0.100N
MAX-ISO-POLY-3	P=0.013N*	P=0.008N**	P=0.003N**	P=0.111N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver Inflammation				
LESION RATES				
OVERALL (a)	40/50 (80%)	46/50 (92%)	42/50 (84%)	44/50 (88%)
POLY-3 RATE (b)	40/47.23	46/47.89	42/46.63	44/46.21
POLY-3 PERCENT (g)	84.7%	96.1%	90.1%	95.2%
TERMINAL (d)	36/37 (97%)	37/37 (100%)	28/31 (90%)	21/21 (100%)
FIRST INCIDENCE	610	324	233	348
STATISTICAL TESTS				
POLY 3	P=0.149	P=0.042*	P=0.305	P=0.061
POLY 1.5	P=0.209	P=0.041*	P=0.286	P=0.092
POLY 6	P=0.118	P=0.045*	P=0.378	P=0.043*
COCH-ARM / FISHERS	P=0.370	P=0.074	P=0.398	P=0.207
MAX-ISO-POLY-3	P=0.034*	P=0.018*	P=0.201	P=0.027*

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver				
Mixed Cell Focus				
LESION RATES				
OVERALL (a)	18/50 (36%)	17/50 (34%)	17/50 (34%)	35/50 (70%)
POLY-3 RATE (b)	18/46.64	17/44.99	17/42.36	35/44.30
POLY-3 PERCENT (g)	38.6%	37.8%	40.1%	79%
TERMINAL (d)	16/37 (43%)	17/37 (46%)	14/31 (45%)	19/21 (91%)
FIRST INCIDENCE	610	727 (T)	612	431
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.554N	P=0.528	P<0.001**
POLY 1.5	P<0.001**	P=0.546N	P=0.555	P<0.001**
POLY 6	P<0.001**	P=0.556N	P=0.505	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500N	P=0.500N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.468N	P=0.442	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver				
Vacuolization Cytoplasmic				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	0/46.00	1/44.99	3/41.44	1/39.04
POLY-3 PERCENT (g)	0%	2.2%	7.2%	2.6%
TERMINAL (d)	0/37 (0%)	1/37 (3%)	3/31 (10%)	1/21 (5%)
FIRST INCIDENCE	---	727 (T)	727 (T)	727 (T)
STATISTICAL TESTS				
POLY 3	P=0.420	P=0.496	P=0.101	P=0.467
POLY 1.5	P=0.456	P=0.495	P=0.105	P=0.480
POLY 6	P=0.375	P=0.497	P=0.097	P=0.452
COCH-ARM / FISHERS	P=0.512	P=0.500	P=0.121	P=0.500
MAX-ISO-POLY-3	P=0.172	P=0.159	P=0.038*	P=0.158

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 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%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	0/46.00	1/44.99	3/41.44	0/39.04
POLY-3 PERCENT (g)	0%	2.2%	7.2%	0%
TERMINAL (d)	0/37 (0%)	1/37 (3%)	3/31 (10%)	0/21 (0%)
FIRST INCIDENCE	---	727 (T)	727 (T)	---

STATISTICAL TESTS				
POLY 3	P=0.578N	P=0.496	P=0.101	(e)
POLY 1.5	P=0.548N	P=0.495	P=0.105	(e)
POLY 6	P=0.616N	P=0.497	P=0.097	(e)
COCH-ARM / FISHERS	P=0.500N	P=0.500	P=0.121	(e)
MAX-ISO-POLY-3	P=0.239	P=0.159	P=0.038*	(e)

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver: Bile Duct Fibrosis				
LESION RATES				
OVERALL (a)	21/50 (42%)	27/50 (54%)	41/50 (82%)	42/50 (84%)
POLY-3 RATE (b)	21/46.23	27/45.07	41/45.01	42/44.72
POLY-3 PERCENT (g)	45.4%	59.9%	91.1%	93.9%
TERMINAL (d)	20/37 (54%)	25/37 (68%)	30/31 (97%)	21/21 (100%)
FIRST INCIDENCE	664	713	519	496
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.114	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.120	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.115	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.158	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.081	P<0.001**	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver: Bile Duct Hyperplasia				
LESION RATES				
OVERALL (a)	40/50 (80%)	42/50 (84%)	44/50 (88%)	44/50 (88%)
POLY-3 RATE (b)	40/47.73	42/47.08	44/45.41	44/46.40
POLY-3 PERCENT (g)	83.8%	89.2%	96.9%	94.8%
TERMINAL (d)	33/37 (89%)	35/37 (95%)	31/31 (100%)	21/21 (100%)
FIRST INCIDENCE	610	324	519	348
STATISTICAL TESTS				
POLY 3	P=0.053	P=0.309	P=0.026*	P=0.062
POLY 1.5	P=0.085	P=0.318	P=0.035*	P=0.091
POLY 6	P=0.035*	P=0.303	P=0.029*	P=0.043*
COCH-ARM / FISHERS	P=0.206	P=0.398	P=0.207	P=0.207
MAX-ISO-POLY-3	P=0.019*	P=0.208	P=0.012*	P=0.030*

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver: Hepatocyte Hypertrophy				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	6/50 (12%)	31/50 (62%)
POLY-3 RATE (b)	0/46.00	0/44.99	6/42.47	31/41.77
POLY-3 PERCENT (g)	0%	0%	14.1%	74.2%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	3/31 (10%)	19/21 (91%)
FIRST INCIDENCE	---	---	581	576
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P=0.011*	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.012*	P<0.001**
POLY 6	P<0.001**	(e)	P=0.011*	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.013*	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.004**	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver: Hepatocyte Necrosis				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/46.25	0/44.99	2/41.86	1/39.29
POLY-3 PERCENT (g)	4.3%	0%	4.8%	2.6%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	680	---	626	661
STATISTICAL TESTS				
POLY 3	P=0.642N	P=0.243N	P=0.658	P=0.556N
POLY 1.5	P=0.623N	P=0.243N	P=0.665	P=0.535N
POLY 6	P=0.613	P=0.242N	P=0.651	P=0.582N
COCH-ARM / FISHERS	P=0.596N	P=0.247N	P=0.691N	P=0.500N
MAX-ISO-POLY-3	P=0.499N	P=0.082N	P=0.461	P=0.341N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	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%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	0/46.00	0/44.99	2/41.93	2/39.29
POLY-3 PERCENT (g)	0%	0%	4.8%	5.1%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	1/31 (3%)	1/21 (5%)
FIRST INCIDENCE	---	---	581	661
STATISTICAL TESTS				
POLY 3	P=0.089	(e)	P=0.217	P=0.204
POLY 1.5	P=0.101	(e)	P=0.221	P=0.216
POLY 6	P=0.076	(e)	P=0.214	P=0.190
COCH-ARM / FISHERS	P=0.122	(e)	P=0.247	P=0.247
MAX-ISO-POLY-3	P=0.122	(e)	P=0.076	P=0.075

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Lung Congestion				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	0/46.00	0/44.99	1/42.43	3/41.56
POLY-3 PERCENT (g)	0%	0%	2.4%	7.2%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	---	---	129	192
STATISTICAL TESTS				
POLY 3	P=0.016*	(e)	P=0.484	P=0.101
POLY 1.5	P=0.018*	(e)	P=0.488	P=0.109
POLY 6	P=0.014*	(e)	P=0.480	P=0.092
COCH-ARM / FISHERS	P=0.021*	(e)	P=0.500	P=0.121
MAX-ISO-POLY-3	P=0.024*	(e)	P=0.158	P=0.038*

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Lung Inflammation				
LESION RATES				
OVERALL (a)	2/50 (4%)	5/50 (10%)	6/50 (12%)	1/50 (2%)
POLY-3 RATE (b)	2/46.90	5/45.97	6/42.41	1/39.43
POLY-3 PERCENT (g)	4.3%	10.9%	14.2%	2.5%
TERMINAL (d)	1/37 (3%)	3/37 (8%)	5/31 (16%)	0/21 (0%)
FIRST INCIDENCE	337	530	233	616
STATISTICAL TESTS				
POLY 3	P=0.300N	P=0.208	P=0.103	P=0.560N
POLY 1.5	P=0.259N	P=0.207	P=0.110	P=0.539N
POLY 6	P=0.353N	P=0.215	P=0.096	P=0.584N
COCH-ARM / FISHERS	P=0.200N	P=0.218	P=0.134	P=0.500N
MAX-ISO-POLY-3	P=0.219N	P=0.116	P=0.059	P=0.345N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Lung Metaplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.00	0/44.99	0/41.44	0/39.04
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	0/21 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Lung: Alveolar Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	8/50 (16%)	9/50 (18%)	6/50 (12%)	6/50 (12%)
POLY-3 RATE (b)	8/46.90	9/45.76	6/41.60	6/39.59
POLY-3 PERCENT (g)	17.1%	19.7%	14.4%	15.2%
TERMINAL (d)	7/37 (19%)	6/37 (16%)	5/31 (16%)	4/21 (19%)
FIRST INCIDENCE	337	601	686	645
STATISTICAL TESTS				
POLY 3	P=0.401N	P=0.478	P=0.481N	P=0.521N
POLY 1.5	P=0.351N	P=0.474	P=0.460N	P=0.473N
POLY 6	P=0.464N	P=0.495	P=0.499N	P=0.575N
COCH-ARM / FISHERS	P=0.275N	P=0.500	P=0.387N	P=0.387N
MAX-ISO-POLY-3	P=0.543N	P=0.373	P=0.374N	P=0.411N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Lung: Alveolus Infiltration Cellular Histiocyte				
LESION RATES				
OVERALL (a)	14/50 (28%)	2/50 (4%)	5/50 (10%)	11/50 (22%)
POLY-3 RATE (b)	14/46.52	2/44.99	5/44.86	11/41.44
POLY-3 PERCENT (g)	30.1%	4.5%	11.2%	26.6%
TERMINAL (d)	12/37 (32%)	2/37 (5%)	1/31 (3%)	5/21 (24%)
FIRST INCIDENCE	610	727 (T)	129	412
STATISTICAL TESTS				
POLY 3	P=0.231	P<0.001N**	P=0.022N*	P=0.448N
POLY 1.5	P=0.257	P<0.001N**	P=0.021N*	P=0.401N
POLY 6	P=0.201	P<0.001N**	P=0.023N*	P=0.504N
COCH-ARM / FISHERS	P=0.299	P<0.001N**	P=0.020N*	P=0.322N
MAX-ISO-POLY-3	P=0.042N*	P<0.001N**	P=0.012N*	P=0.363N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Lymph Node, Mesenteric Ectasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/46.00	0/44.99	0/41.44	2/39.34
POLY-3 PERCENT (g)	0%	0%	0%	5.1%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	1/21 (5%)
FIRST INCIDENCE	---	---	---	645
STATISTICAL TESTS				
POLY 3	P=0.034*	(e)	(e)	P=0.204
POLY 1.5	P=0.037*	(e)	(e)	P=0.216
POLY 6	P=0.031*	(e)	(e)	P=0.190
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.034*	(e)	(e)	P=0.075

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Lymph Node, Mesenteric Hyperplasia Lymphoid				
LESION RATES				
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/46.00	1/44.99	0/41.44	1/39.15
POLY-3 PERCENT (g)	4.4%	2.2%	0%	2.6%
TERMINAL (d)	2/37 (5%)	1/37 (3%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	727 (T)	727 (T)	---	699
STATISTICAL TESTS				
POLY 3	P=0.521N	P=0.508N	P=0.261N	P=0.556N
POLY 1.5	P=0.512N	P=0.508N	P=0.256N	P=0.535N
POLY 6	P=0.532N	P=0.504N	P=0.266N	P=0.581N
COCH-ARM / FISHERS	P=0.500N	P=0.500N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.314N	P=0.289N	P=0.099N	P=0.340N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Lymph Node, Mesenteric Infiltration Cellular Histiocyte				
LESION RATES				
OVERALL (a)	21/50 (42%)	23/50 (46%)	30/50 (60%)	34/50 (68%)
POLY-3 RATE (b)	21/47.29	23/47.06	30/45.84	34/46.11
POLY-3 PERCENT (g)	44.4%	48.9%	65.4%	73.7%
TERMINAL (d)	17/37 (46%)	18/37 (49%)	20/31 (65%)	18/21 (86%)
FIRST INCIDENCE	610	324	233	192
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.410	P=0.030*	P=0.002**
POLY 1.5	P=0.002**	P=0.402	P=0.033*	P=0.004**
POLY 6	P<0.001**	P=0.424	P=0.028*	P<0.001**
COCH-ARM / FISHERS	P=0.004**	P=0.420	P=0.055	P=0.008**
MAX-ISO-POLY-3	P=0.002**	P=0.332	P=0.020*	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Lymph Node: Mediastinal Ectasia				
LESION RATES				
OVERALL (a)	0/4 (0%)	2/3 (67%)	2/3 (67%)	3/7 (43%)
POLY-3 RATE (b)	0/3.11	2/3.00	2/3.00	3/6.51
POLY-3 PERCENT (g)	0%	66.7%	66.7%	46.1%
TERMINAL (d)	0/0 (0%)	1/2 (50%)	0/1 (0%)	2/4 (50%)
FIRST INCIDENCE	---	601	581	661
STATISTICAL TESTS				
POLY 3	P=0.557	P=0.143	P=0.143	P=0.244
POLY 1.5	P=0.507	P=0.114	P=0.114	P=0.220
POLY 6	P=0.630	P=0.208	P=0.208	P=0.290
COCH-ARM / FISHERS	P=0.449	P=0.143	P=0.143	P=0.212
MAX-ISO-POLY-3	P=0.156	P=0.023*	P=0.023*	P=0.115

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Lymph Node: Mediastinal Hyperplasia Lymphoid				
LESION RATES				
OVERALL (a)	0/4 (0%)	0/3 (0%)	1/3 (33%)	3/7 (43%)
POLY-3 RATE (b)	0/3.11	0/2.57	1/2.69	3/6.75
POLY-3 PERCENT (g)	0%	0%	37.2%	44.4%
TERMINAL (d)	0/0 (0%)	0/2 (0%)	0/1 (0%)	1/4 (25%)
FIRST INCIDENCE	---	---	581	656
STATISTICAL TESTS				
POLY 3	P=0.129	(e)	P=0.470	P=0.259
POLY 1.5	P=0.108	(e)	P=0.455	P=0.228
POLY 6	P=0.170	(e)	P=0.499	P=0.319
COCH-ARM / FISHERS	P=0.087	(e)	P=0.429	P=0.212
MAX-ISO-POLY-3	P=0.199	(e)	P=0.127	P=0.128

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Mammary Gland Cyst				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/46.00	0/44.99	0/40.44	1/39.04
POLY-3 PERCENT (g)	0%	0%	0%	2.6%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/30 (0%)	1/21 (5%)
FIRST INCIDENCE	---	---	---	727 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Mammary Gland Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/49 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/46.00	0/44.99	2/40.62	0/39.04
POLY-3 PERCENT (g)	0%	0%	4.9%	0%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	1/30 (3%)	0/21 (0%)
FIRST INCIDENCE	---	---	680	---
STATISTICAL TESTS				
POLY 3	P=0.691	(e)	P=0.210	(e)
POLY 1.5	P=0.719	(e)	P=0.215	(e)
POLY 6	P=0.653	(e)	P=0.206	(e)
COCH-ARM / FISHERS	P=0.697N	(e)	P=0.242	(e)
MAX-ISO-POLY-3	P=0.262	(e)	P=0.074	(e)

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Mesentery: Fat Necrosis				
LESION RATES				
OVERALL (a)	7/7 (100%)	5/5 (100%)	1/2 (50%)	1/1 (100%)
POLY-3 RATE (b)	7/7.00	5/5.00	1/1.64	1/1.00
POLY-3 PERCENT (g)	100%	100%	61%	100%
TERMINAL (d)	5/5 (100%)	3/3 (100%)	0/0 (0%)	1/1 (100%)
FIRST INCIDENCE	609	624	688	727 (T)
STATISTICAL TESTS				
POLY 3	P=0.967N	(e)	P=0.469N	(e)
POLY 1.5	P=0.888N	(e)	P=0.309N	(e)
POLY 6	P=1.000N	(e)	P=0.863N	(e)
COCH-ARM / FISHERS	P=0.723N	(e)	P=0.222N	(e)
MAX-ISO-POLY-3	P=0.178N	(e)	P=0.036N*	(e)

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

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

Nose
Foreign Body

LESION RATES

OVERALL (a)	13/50 (26%)	17/49 (35%)	11/50 (22%)	9/49 (18%)
POLY-3 RATE (b)	13/46.36	17/45.84	11/43.56	9/41.63
POLY-3 PERCENT (g)	28%	37.1%	25.3%	21.6%
TERMINAL (d)	11/37 (30%)	13/37 (35%)	6/31 (19%)	2/21 (10%)
FIRST INCIDENCE	680	588	129	412

STATISTICAL TESTS

POLY 3	P=0.146N	P=0.240	P=0.476N	P=0.327N
POLY 1.5	P=0.123N	P=0.227	P=0.463N	P=0.299N
POLY 6	P=0.181N	P=0.266	P=0.486N	P=0.364N
COCH-ARM / FISHERS	P=0.095N	P=0.235	P=0.408N	P=0.251N
MAX-ISO-POLY-3	P=0.225N	P=0.177	P=0.385N	P=0.254N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose Inflammation				
LESION RATES				
OVERALL (a)	35/50 (70%)	40/49 (82%)	38/50 (76%)	48/49 (98%)
POLY-3 RATE (b)	35/47.77	40/46.44	38/46.49	48/48.02
POLY-3 PERCENT (g)	73.3%	86.1%	81.7%	100%
TERMINAL (d)	27/37 (73%)	31/37 (84%)	24/31 (77%)	21/21 (100%)
FIRST INCIDENCE	609	588	237	348
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.092	P=0.226	P<0.001**
POLY 1.5	P<0.001**	P=0.087	P=0.219	P<0.001**
POLY 6	P<0.001**	P=0.109	P=0.248	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.132	P=0.326	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.057	P=0.161	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Glands, Respiratory Epithelium Dilatation				
LESION RATES				
OVERALL (a)	13/50 (26%)	15/49 (31%)	19/50 (38%)	48/49 (98%)
POLY-3 RATE (b)	13/47.40	15/46.91	19/43.87	48/48.02
POLY-3 PERCENT (g)	27.4%	32%	43.3%	100%
TERMINAL (d)	7/37 (19%)	8/37 (22%)	12/31 (39%)	21/21 (100%)
FIRST INCIDENCE	610	324	519	348
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.399	P=0.083	P<0.001**
POLY 1.5	P<0.001**	P=0.387	P=0.092	P<0.001**
POLY 6	P<0.001**	P=0.411	P=0.077	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.387	P=0.142	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.315	P=0.061	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Glands, Respiratory Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	8/49 (16%)	8/50 (16%)	41/49 (84%)
POLY-3 RATE (b)	0/46.00	8/45.09	8/42.36	41/45.98
POLY-3 PERCENT (g)	0%	17.7%	18.9%	89.2%
TERMINAL (d)	0/37 (0%)	5/37 (14%)	3/31 (10%)	18/21 (86%)
FIRST INCIDENCE	---	601	645	348
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.003**	P=0.002**	P<0.001**
POLY 1.5	P<0.001**	P=0.003**	P=0.003**	P<0.001**
POLY 6	P<0.001**	P=0.004**	P=0.002**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.003**	P=0.003**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 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)	29/50 (58%)	39/49 (80%)	39/50 (78%)	47/49 (96%)
POLY-3 RATE (b)	29/47.88	39/47.63	39/46.08	47/47.13
POLY-3 PERCENT (g)	60.6%	81.9%	84.6%	99.7%
TERMINAL (d)	20/37 (54%)	29/37 (78%)	29/31 (94%)	21/21 (100%)
FIRST INCIDENCE	610	324	233	412
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.016*	P=0.006**	P<0.001**
POLY 1.5	P<0.001**	P=0.014*	P=0.008**	P<0.001**
POLY 6	P<0.001**	P=0.019*	P=0.005**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.017*	P=0.026*	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.009**	P=0.003**	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	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%)	15/49 (31%)
POLY-3 RATE (b)	0/46.00	0/44.60	0/41.44	15/40.81
POLY-3 PERCENT (g)	0%	0%	0%	36.8%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	9/21 (43%)
FIRST INCIDENCE	---	---	---	412
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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 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)	49/50 (98%)	44/49 (90%)	40/50 (80%)	0/49 (0%)
POLY-3 RATE (b)	49/49.10	44/46.38	40/46.09	0/38.89
POLY-3 PERCENT (g)	99.8%	94.9%	86.8%	0%
TERMINAL (d)	37/37 (100%)	36/37 (97%)	27/31 (87%)	0/21 (0%)
FIRST INCIDENCE	609	588	237	---
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.168N	P=0.010N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.143N	P=0.008N**	P<0.001N**
POLY 6	P<0.001N**	P=0.210N	P=0.013N*	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.098N	P=0.004N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.050N*	P=0.003N**	P<0.001N**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Olfactory Epithelium Degeneration				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/49 (0%)	1/50 (2%)	47/49 (96%)
POLY-3 RATE (b)	0/46.00	0/44.60	1/41.44	47/47.13
POLY-3 PERCENT (g)	0%	0%	2.4%	99.7%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	1/31 (3%)	21/21 (100%)
FIRST INCIDENCE	---	---	727 (T)	412
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P=0.479	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.484	P<0.001**
POLY 6	P<0.001**	(e)	P=0.475	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.500	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.158	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Olfactory Epithelium Hyperplasia Basal Cell				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/49 (2%)	2/50 (4%)	38/49 (78%)
POLY-3 RATE (b)	0/46.00	1/44.66	2/41.86	38/47.32
POLY-3 PERCENT (g)	0%	2.2%	4.8%	80.3%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	14/21 (67%)
FIRST INCIDENCE	---	713	654	192
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.494	P=0.217	P<0.001**
POLY 1.5	P<0.001**	P=0.493	P=0.221	P<0.001**
POLY 6	P<0.001**	P=0.497	P=0.214	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.495	P=0.247	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.157	P=0.076	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Olfactory Epithelium Metaplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/46.00	0/44.60	0/41.44	0/38.89
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	0/21 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Olfactory Epithelium Metaplasia Respiratory				
LESION RATES				
OVERALL (a)	4/50 (8%)	9/49 (18%)	9/50 (18%)	40/49 (82%)
POLY-3 RATE (b)	4/46.00	9/44.93	9/43.14	40/45.02
POLY-3 PERCENT (g)	8.7%	20%	20.9%	88.9%
TERMINAL (d)	4/37 (11%)	7/37 (19%)	5/31 (16%)	18/21 (86%)
FIRST INCIDENCE	727 (T)	674	519	412
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.106	P=0.091	P<0.001**
POLY 1.5	P<0.001**	P=0.103	P=0.094	P<0.001**
POLY 6	P<0.001**	P=0.113	P=0.090	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.109	P=0.117	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.061	P=0.056	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Olfactory Epithelium, Glands Dilatation				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/49 (0%)	3/50 (6%)	49/49 (100%)
POLY-3 RATE (b)	0/46.00	0/44.60	3/41.44	49/49.00
POLY-3 PERCENT (g)	0%	0%	7.2%	100%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	3/31 (10%)	21/21 (100%)
FIRST INCIDENCE	---	---	727 (T)	192
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P=0.101	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.105	P<0.001**
POLY 6	P<0.001**	(e)	P=0.097	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.121	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.038*	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Olfactory Epithelium, Glands Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/49 (4%)	0/50 (0%)	48/49 (98%)
POLY-3 RATE (b)	0/46.00	2/44.60	0/41.44	48/49.00
POLY-3 PERCENT (g)	0%	4.5%	0%	98%
TERMINAL (d)	0/37 (0%)	2/37 (5%)	0/31 (0%)	20/21 (95%)
FIRST INCIDENCE	---	727 (T)	---	192
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.230	(e)	P<0.001**
POLY 1.5	P<0.001**	P=0.229	(e)	P<0.001**
POLY 6	P<0.001**	P=0.233	(e)	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.242	(e)	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.075	(e)	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Olfactory Epithelium, Glands Metaplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	38/49 (78%)
POLY-3 RATE (b)	0/46.00	0/44.60	0/41.44	38/44.15
POLY-3 PERCENT (g)	0%	0%	0%	86.1%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	20/21 (95%)
FIRST INCIDENCE	---	---	---	412
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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Olfactory Epithelium, Glands				
Necrosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	22/49 (45%)
POLY-3 RATE (b)	0/46.00	0/44.60	0/41.44	22/46.74
POLY-3 PERCENT (g)	0%	0%	0%	47.1%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	---	---	---	348
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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 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)	42/50 (84%)	35/49 (71%)	30/50 (60%)	8/49 (16%)
POLY-3 RATE (b)	42/48.46	35/45.47	30/44.95	8/39.82
POLY-3 PERCENT (g)	86.7%	77%	66.8%	20.1%
TERMINAL (d)	32/37 (87%)	32/37 (87%)	22/31 (71%)	6/21 (29%)
FIRST INCIDENCE	609	588	237	582
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.162N	P=0.016N*	P<0.001N**
POLY 1.5	P<0.001N**	P=0.147N	P=0.013N*	P<0.001N**
POLY 6	P<0.001N**	P=0.185N	P=0.021N*	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.103N	P=0.007N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.108N	P=0.010N**	P<0.001N**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Respiratory Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	15/50 (30%)	29/49 (59%)	32/50 (64%)	49/49 (100%)
POLY-3 RATE (b)	15/46.83	29/46.11	32/44.91	49/49.00
POLY-3 PERCENT (g)	32%	62.9%	71.3%	100%
TERMINAL (d)	11/37 (30%)	24/37 (65%)	23/31 (74%)	21/21 (100%)
FIRST INCIDENCE	664	512	233	192
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.002**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.002**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.002**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.003**	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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Transitional Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/49 (2%)	11/50 (22%)	46/49 (94%)
POLY-3 RATE (b)	1/46.00	1/44.60	11/42.10	46/49.00
POLY-3 PERCENT (g)	2.2%	2.2%	26.1%	93.9%
TERMINAL (d)	1/37 (3%)	1/37 (3%)	9/31 (29%)	18/21 (86%)
FIRST INCIDENCE	727 (T)	727 (T)	538	192
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.754	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.752	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.757	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.747	P=0.002**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.491	P<0.001**	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Transitional Epithelium, Glands Dilatation				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/49 (0%)	5/50 (10%)	3/49 (6%)
POLY-3 RATE (b)	0/46.00	0/44.60	5/42.14	3/38.89
POLY-3 PERCENT (g)	0%	0%	11.9%	7.7%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	3/31 (10%)	3/21 (14%)
FIRST INCIDENCE	---	---	616	727 (T)
STATISTICAL TESTS				
POLY 3	P=0.048*	(e)	P=0.024*	P=0.091
POLY 1.5	P=0.060	(e)	P=0.025*	P=0.100
POLY 6	P=0.035*	(e)	P=0.023*	P=0.081
COCH-ARM / FISHERS	P=0.084	(e)	P=0.028*	P=0.117
MAX-ISO-POLY-3	P=0.036*	(e)	P=0.009**	P=0.037*

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Transitional Epithelium, Glands Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/49 (2%)	24/50 (48%)	40/49 (82%)
POLY-3 RATE (b)	0/46.00	1/44.60	24/49.11	40/48.87
POLY-3 PERCENT (g)	0%	2.2%	48.9%	81.8%
TERMINAL (d)	0/37 (0%)	1/37 (3%)	8/31 (26%)	13/21 (62%)
FIRST INCIDENCE	---	727 (T)	129	192
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.494	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.493	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.497	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.495	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.157	P<0.001**	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Pancreas Cyst				
LESION RATES				
OVERALL (a)	2/50 (4%)	4/50 (8%)	6/50 (12%)	2/50 (4%)
POLY-3 RATE (b)	2/46.00	4/44.99	6/41.62	2/39.30
POLY-3 PERCENT (g)	4.4%	8.9%	14.4%	5.1%
TERMINAL (d)	2/37 (5%)	4/37 (11%)	5/31 (16%)	0/21 (0%)
FIRST INCIDENCE	727 (T)	727 (T)	680	661
STATISTICAL TESTS				
POLY 3	P=0.533N	P=0.327	P=0.103	P=0.636
POLY 1.5	P=0.489N	P=0.327	P=0.109	P=0.658
POLY 6	P=0.588N	P=0.331	P=0.097	P=0.609
COCH-ARM / FISHERS	P=0.420N	P=0.339	P=0.134	P=0.691N
MAX-ISO-POLY-3	P=0.317	P=0.195	P=0.059	P=0.440

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Pancreas				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	16/50 (32%)	14/50 (28%)	16/50 (32%)	20/50 (40%)
POLY-3 RATE (b)	16/47.76	14/46.08	16/43.20	20/43.33
POLY-3 PERCENT (g)	33.5%	30.4%	37%	46.2%
TERMINAL (d)	12/37 (32%)	12/37 (32%)	12/31 (39%)	8/21 (38%)
FIRST INCIDENCE	337	512	237	348
STATISTICAL TESTS				
POLY 3	P=0.076	P=0.459N	P=0.447	P=0.151
POLY 1.5	P=0.099	P=0.456N	P=0.479	P=0.187
POLY 6	P=0.054	P=0.453N	P=0.417	P=0.117
COCH-ARM / FISHERS	P=0.144	P=0.414N	P=0.585N	P=0.266
MAX-ISO-POLY-3	P=0.122	P=0.374N	P=0.367	P=0.116

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Pancreas: Acinus Atrophy				
LESION RATES				
OVERALL (a)	21/50 (42%)	20/50 (40%)	17/50 (34%)	12/50 (24%)
POLY-3 RATE (b)	21/48.51	20/45.68	17/45.24	12/40.29
POLY-3 PERCENT (g)	43.3%	43.8%	37.6%	29.8%
TERMINAL (d)	15/37 (41%)	16/37 (43%)	10/31 (32%)	7/21 (33%)
FIRST INCIDENCE	337	601	129	616
STATISTICAL TESTS				
POLY 3	P=0.091N	P=0.563	P=0.362N	P=0.136N
POLY 1.5	P=0.058N	P=0.580N	P=0.337N	P=0.092N
POLY 6	P=0.145N	P=0.554	P=0.388N	P=0.201N
COCH-ARM / FISHERS	P=0.027N*	P=0.500N	P=0.268N	P=0.044N*
MAX-ISO-POLY-3	P=0.147N	P=0.480	P=0.293N	P=0.112N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Pancreas: Acinus Hyperplasia				
LESION RATES				
OVERALL (a)	2/50 (4%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/46.00	2/44.99	1/41.44	0/39.04
POLY-3 PERCENT (g)	4.4%	4.5%	2.4%	0%
TERMINAL (d)	2/37 (5%)	2/37 (5%)	1/31 (3%)	0/21 (0%)
FIRST INCIDENCE	727 (T)	727 (T)	727 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.169N	P=0.686	P=0.536N	P=0.275N
POLY 1.5	P=0.158N	P=0.685	P=0.528N	P=0.261N
POLY 6	P=0.185N	P=0.690	P=0.544N	P=0.295N
COCH-ARM / FISHERS	P=0.141N	P=0.691N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.221N	P=0.490	P=0.320N	P=0.112N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Parathyroid Gland Hyperplasia Diffuse				
LESION RATES				
OVERALL (a)	1/49 (2%)	0/49 (0%)	2/45 (4%)	5/48 (10%)
POLY-3 RATE (b)	1/45.70	0/44.99	2/37.95	5/38.09
POLY-3 PERCENT (g)	2.2%	0%	5.3%	13.1%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/28 (0%)	0/20 (0%)
FIRST INCIDENCE	645	---	680	645
STATISTICAL TESTS				
POLY 3	P=0.006**	P=0.503N	P=0.436	P=0.065
POLY 1.5	P=0.007**	P=0.502N	P=0.444	P=0.075
POLY 6	P=0.005**	P=0.503N	P=0.427	P=0.054
COCH-ARM / FISHERS	P=0.011*	P=0.500N	P=0.468	P=0.097
MAX-ISO-POLY-3	P=0.010**	P=0.163N	P=0.243	P=0.036*

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Parathyroid Gland Hyperplasia Focal				
LESION RATES				
OVERALL (a)	2/49 (4%)	0/49 (0%)	0/45 (0%)	0/48 (0%)
POLY-3 RATE (b)	2/45.40	0/44.99	0/37.71	0/37.15
POLY-3 PERCENT (g)	4.4%	0%	0%	0%
TERMINAL (d)	2/37 (5%)	0/37 (0%)	0/28 (0%)	0/20 (0%)
FIRST INCIDENCE	727 (T)	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.249N	P=0.239N	P=0.280N	P=0.284N
POLY 1.5	P=0.248N	P=0.239N	P=0.274N	P=0.268N
POLY 6	P=0.252N	P=0.238N	P=0.287N	P=0.306N
COCH-ARM / FISHERS	P=0.247N	P=0.247N	P=0.269N	P=0.253N
MAX-ISO-POLY-3	P=0.080N	P=0.078N	P=0.112N	P=0.120N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Pituitary Gland Cyst				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/46.00	2/44.99	2/41.83	1/39.04
POLY-3 PERCENT (g)	2.2%	4.5%	4.8%	2.6%
TERMINAL (d)	1/37 (3%)	2/37 (5%)	1/31 (3%)	1/21 (5%)
FIRST INCIDENCE	727 (T)	727 (T)	616	727 (T)
STATISTICAL TESTS				
POLY 3	P=0.585N	P=0.492	P=0.467	P=0.723
POLY 1.5	P=0.560N	P=0.492	P=0.473	P=0.737
POLY 6	P=0.616N	P=0.496	P=0.462	P=0.704
COCH-ARM / FISHERS	P=0.521N	P=0.500	P=0.500	P=0.753N
MAX-ISO-POLY-3	P=0.540	P=0.276	P=0.263	P=0.456

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Pituitary Gland: Pars Distalis Cyst				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/46.00	0/44.99	1/41.44	0/39.04
POLY-3 PERCENT (g)	0%	0%	2.4%	0%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	1/31 (3%)	0/21 (0%)
FIRST INCIDENCE	---	---	727 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Pituitary Gland: Pars Distalis Hyperplasia				
LESION RATES				
OVERALL (a)	15/50 (30%)	18/50 (36%)	15/50 (30%)	18/50 (36%)
POLY-3 RATE (b)	15/46.92	18/45.17	15/42.66	18/43.08
POLY-3 PERCENT (g)	32%	39.9%	35.2%	41.8%
TERMINAL (d)	12/37 (32%)	16/37 (43%)	10/31 (32%)	8/21 (38%)
FIRST INCIDENCE	609	695	612	192
STATISTICAL TESTS				
POLY 3	P=0.267	P=0.284	P=0.462	P=0.226
POLY 1.5	P=0.314	P=0.293	P=0.486	P=0.267
POLY 6	P=0.216	P=0.281	P=0.445	P=0.183
COCH-ARM / FISHERS	P=0.376	P=0.335	P=0.586N	P=0.335
MAX-ISO-POLY-3	P=0.285	P=0.219	P=0.379	P=0.175

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Preputial Gland Inflammation				
LESION RATES				
OVERALL (a)	49/50 (98%)	49/50 (98%)	43/50 (86%)	45/50 (90%)
POLY-3 RATE (b)	49/50.00	49/49.00	43/45.68	45/47.54
POLY-3 PERCENT (g)	98%	100%	94.1%	94.7%
TERMINAL (d)	36/37 (97%)	37/37 (100%)	29/31 (94%)	20/21 (95%)
FIRST INCIDENCE	337	324	519	348
STATISTICAL TESTS				
POLY 3	P=0.149N	P=0.504	P=0.321N	P=0.356N
POLY 1.5	P=0.084N	P=0.514	P=0.218N	P=0.246N
POLY 6	P=0.254N	P=0.504	P=0.383N	P=0.494N
COCH-ARM / FISHERS	P=0.069N	P=0.753N	P=0.030N*	P=0.102N
MAX-ISO-POLY-3	P=0.141N	P=0.164	P=0.165N	P=0.175N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Prostate Inflammation				
LESION RATES				
OVERALL (a)	23/50 (46%)	28/50 (56%)	18/50 (36%)	16/50 (32%)
POLY-3 RATE (b)	23/47.98	28/46.36	18/42.68	16/41.94
POLY-3 PERCENT (g)	47.9%	60.4%	42.2%	38.2%
TERMINAL (d)	16/37 (43%)	20/37 (54%)	14/31 (45%)	6/21 (29%)
FIRST INCIDENCE	609	601	581	412
STATISTICAL TESTS				
POLY 3	P=0.071N	P=0.155	P=0.367N	P=0.234N
POLY 1.5	P=0.046N*	P=0.163	P=0.324N	P=0.179N
POLY 6	P=0.116N	P=0.154	P=0.416N	P=0.312N
COCH-ARM / FISHERS	P=0.025N*	P=0.212	P=0.208N	P=0.109N
MAX-ISO-POLY-3	P=0.114N	P=0.114	P=0.301N	P=0.189N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Prostate: Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	2/50 (4%)	6/50 (12%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	2/46.41	6/45.04	2/41.44	3/39.58
POLY-3 PERCENT (g)	4.3%	13.3%	4.8%	7.6%
TERMINAL (d)	1/37 (3%)	4/37 (11%)	2/31 (7%)	1/21 (5%)
FIRST INCIDENCE	609	721	727 (T)	653
STATISTICAL TESTS				
POLY 3	P=0.567N	P=0.123	P=0.652	P=0.428
POLY 1.5	P=0.535N	P=0.124	P=0.662	P=0.455
POLY 6	P=0.578	P=0.124	P=0.642	P=0.397
COCH-ARM / FISHERS	P=0.483N	P=0.134	P=0.691N	P=0.500
MAX-ISO-POLY-3	P=0.386	P=0.066	P=0.456	P=0.277

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Spleen Congestion				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	39/50 (78%)
POLY-3 RATE (b)	1/46.00	0/44.99	0/41.44	39/45.54
POLY-3 PERCENT (g)	2.2%	0%	0%	85.6%
TERMINAL (d)	1/37 (3%)	0/37 (0%)	0/31 (0%)	20/21 (95%)
FIRST INCIDENCE	727 (T)	---	---	348
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.504N	P=0.521N	P<0.001**
POLY 1.5	P<0.001**	P=0.505N	P=0.516N	P<0.001**
POLY 6	P<0.001**	P=0.503N	P=0.525N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500N	P=0.500N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.164N	P=0.184N	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Spleen				
Hematopoietic Cell Proliferation				
LESION RATES				
OVERALL (a)	34/50 (68%)	44/50 (88%)	42/50 (84%)	44/50 (88%)
POLY-3 RATE (b)	34/47.05	44/48.49	42/46.69	44/47.96
POLY-3 PERCENT (g)	72.3%	90.7%	90%	91.7%
TERMINAL (d)	31/37 (84%)	35/37 (95%)	29/31 (94%)	21/21 (100%)
FIRST INCIDENCE	610	62	147	192
STATISTICAL TESTS				
POLY 3	P=0.035*	P=0.013*	P=0.019*	P=0.008**
POLY 1.5	P=0.041*	P=0.013*	P=0.021*	P=0.009**
POLY 6	P=0.031*	P=0.014*	P=0.021*	P=0.007**
COCH-ARM / FISHERS	P=0.060	P=0.014*	P=0.050*	P=0.014*
MAX-ISO-POLY-3	P=0.002**	P=0.006**	P=0.010**	P=0.003**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Spleen Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/46.00	0/44.99	0/41.44	2/39.34
POLY-3 PERCENT (g)	0%	0%	0%	5.1%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	1/21 (5%)
FIRST INCIDENCE	---	---	---	645
STATISTICAL TESTS				
POLY 3	P=0.034*	(e)	(e)	P=0.204
POLY 1.5	P=0.037*	(e)	(e)	P=0.216
POLY 6	P=0.031*	(e)	(e)	P=0.190
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.034*	(e)	(e)	P=0.075

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Spleen Necrosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.00	0/44.99	0/41.44	0/39.04
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	0/21 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Spleen Pigmentation				
LESION RATES				
OVERALL (a)	36/50 (72%)	48/50 (96%)	47/50 (94%)	48/50 (96%)
POLY-3 RATE (b)	36/47.23	48/49.63	47/49.39	48/49.40
POLY-3 PERCENT (g)	76.2%	96.7%	95.2%	97.2%
TERMINAL (d)	32/37 (87%)	36/37 (97%)	30/31 (97%)	21/21 (100%)
FIRST INCIDENCE	610	62	129	192
STATISTICAL TESTS				
POLY 3	P=0.008**	P=0.002**	P=0.004**	P<0.001**
POLY 1.5	P=0.008**	P<0.001**	P=0.004**	P<0.001**
POLY 6	P=0.008**	P=0.002**	P=0.006**	P<0.001**
COCH-ARM / FISHERS	P=0.009**	P<0.001**	P=0.003**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P=0.002**	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Spleen: Capsule Fibrosis				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	46/50 (92%)
POLY-3 RATE (b)	1/46.30	0/44.99	2/41.44	46/48.03
POLY-3 PERCENT (g)	2.2%	0%	4.8%	95.8%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	2/31 (7%)	20/21 (95%)
FIRST INCIDENCE	645	---	727 (T)	192
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.506N	P=0.461	P<0.001**
POLY 1.5	P<0.001**	P=0.505N	P=0.471	P<0.001**
POLY 6	P<0.001**	P=0.505N	P=0.452	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500N	P=0.500	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.166N	P=0.260	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Spleen: Capsule Hypertrophy Mesothelium				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	3/50 (6%)	39/50 (78%)
POLY-3 RATE (b)	0/46.00	1/45.12	3/41.44	39/44.78
POLY-3 PERCENT (g)	0%	2.2%	7.2%	87.1%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	3/31 (10%)	19/21 (91%)
FIRST INCIDENCE	---	695	727 (T)	192
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.496	P=0.101	P<0.001**
POLY 1.5	P<0.001**	P=0.496	P=0.105	P<0.001**
POLY 6	P<0.001**	P=0.499	P=0.097	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500	P=0.121	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.159	P=0.038*	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Spleen: Lymphoid Follicle Atrophy				
LESION RATES				
OVERALL (a)	0/50 (0%)	5/50 (10%)	2/50 (4%)	19/50 (38%)
POLY-3 RATE (b)	0/46.00	5/45.98	2/42.10	19/44.14
POLY-3 PERCENT (g)	0%	10.9%	4.8%	43%
TERMINAL (d)	0/37 (0%)	2/37 (5%)	0/31 (0%)	6/21 (29%)
FIRST INCIDENCE	---	324	538	192
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.030*	P=0.218	P<0.001**
POLY 1.5	P<0.001**	P=0.030*	P=0.221	P<0.001**
POLY 6	P<0.001**	P=0.031*	P=0.215	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.028*	P=0.247	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.010**	P=0.076	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Spleen: Red Pulp Atrophy				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	8/50 (16%)
POLY-3 RATE (b)	0/46.00	0/44.99	1/41.44	8/39.65
POLY-3 PERCENT (g)	0%	0%	2.4%	20.2%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	1/31 (3%)	4/21 (19%)
FIRST INCIDENCE	---	---	727 (T)	661
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P=0.479	P=0.002**
POLY 1.5	P<0.001**	(e)	P=0.484	P=0.002**
POLY 6	P<0.001**	(e)	P=0.475	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.500	P=0.003**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.158	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Stomach, Forestomach Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	3/50 (6%)	5/50 (10%)	11/50 (22%)
POLY-3 RATE (b)	0/46.00	3/45.85	5/41.92	11/40.28
POLY-3 PERCENT (g)	0%	6.5%	11.9%	27.3%
TERMINAL (d)	0/37 (0%)	1/37 (3%)	1/31 (3%)	4/21 (19%)
FIRST INCIDENCE	---	512	680	612
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.118	P=0.023*	P<0.001**
POLY 1.5	P<0.001**	P=0.117	P=0.025*	P<0.001**
POLY 6	P<0.001**	P=0.121	P=0.022*	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.121	P=0.028*	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.038*	P=0.009**	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Stomach, Forestomach Inflammation				
LESION RATES				
OVERALL (a)	1/50 (2%)	5/50 (10%)	5/50 (10%)	7/50 (14%)
POLY-3 RATE (b)	1/46.23	5/45.78	5/41.92	7/40.06
POLY-3 PERCENT (g)	2.2%	10.9%	11.9%	17.5%
TERMINAL (d)	0/37 (0%)	1/37 (3%)	1/31 (3%)	1/21 (5%)
FIRST INCIDENCE	664	601	680	612
STATISTICAL TESTS				
POLY 3	P=0.035*	P=0.099	P=0.080	P=0.017*
POLY 1.5	P=0.044*	P=0.098	P=0.085	P=0.021*
POLY 6	P=0.026*	P=0.103	P=0.077	P=0.013*
COCH-ARM / FISHERS	P=0.065	P=0.102	P=0.102	P=0.030*
MAX-ISO-POLY-3	P=0.024*	P=0.044*	P=0.040*	P=0.010**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Stomach, Forestomach Ulcer				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	5/50 (10%)	6/50 (12%)
POLY-3 RATE (b)	0/46.00	2/45.55	5/41.92	6/40.06
POLY-3 PERCENT (g)	0%	4.4%	11.9%	15%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	1/31 (3%)	0/21 (0%)
FIRST INCIDENCE	---	601	680	612
STATISTICAL TESTS				
POLY 3	P=0.008**	P=0.235	P=0.023*	P=0.009**
POLY 1.5	P=0.010**	P=0.234	P=0.025*	P=0.011*
POLY 6	P=0.006**	P=0.239	P=0.022*	P=0.007**
COCH-ARM / FISHERS	P=0.017*	P=0.247	P=0.028*	P=0.013*
MAX-ISO-POLY-3	P=0.011*	P=0.076	P=0.009**	P=0.004**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Stomach, Glandular Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/46.00	1/45.02	2/41.52	1/39.05
POLY-3 PERCENT (g)	0%	2.2%	4.8%	2.6%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	1/31 (3%)	0/21 (0%)
FIRST INCIDENCE	---	721	707	724
STATISTICAL TESTS				
POLY 3	P=0.423	P=0.496	P=0.215	P=0.468
POLY 1.5	P=0.453	P=0.495	P=0.220	P=0.480
POLY 6	P=0.385	P=0.498	P=0.211	P=0.452
COCH-ARM / FISHERS	P=0.500	P=0.500	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.244	P=0.159	P=0.076	P=0.158

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Stomach, Glandular Mineralization				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/46.00	0/44.99	0/41.44	2/40.22
POLY-3 PERCENT (g)	0%	0%	0%	5%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	---	---	---	412
STATISTICAL TESTS				
POLY 3	P=0.035*	(e)	(e)	P=0.209
POLY 1.5	P=0.037*	(e)	(e)	P=0.219
POLY 6	P=0.032*	(e)	(e)	P=0.196
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.034*	(e)	(e)	P=0.075

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Stomach, Glandular Ulcer				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/46.00	1/45.02	2/41.52	0/39.04
POLY-3 PERCENT (g)	0%	2.2%	4.8%	0%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	1/31 (3%)	0/21 (0%)
FIRST INCIDENCE	---	721	707	---
STATISTICAL TESTS				
POLY 3	P=0.577N	P=0.496	P=0.215	(e)
POLY 1.5	P=0.553N	P=0.495	P=0.220	(e)
POLY 6	P=0.606N	P=0.498	P=0.211	(e)
COCH-ARM / FISHERS	P=0.515N	P=0.500	P=0.247	(e)
MAX-ISO-POLY-3	P=0.346	P=0.159	P=0.076	(e)

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Testes: Interstitial Cell Hyperplasia				
LESION RATES				
OVERALL (a)	16/50 (32%)	16/50 (32%)	6/50 (12%)	12/50 (24%)
POLY-3 RATE (b)	16/47.35	16/45.48	6/41.89	12/40.80
POLY-3 PERCENT (g)	33.8%	35.2%	14.3%	29.4%
TERMINAL (d)	10/37 (27%)	13/37 (35%)	4/31 (13%)	4/21 (19%)
FIRST INCIDENCE	610	601	645	612
STATISTICAL TESTS				
POLY 3	P=0.313N	P=0.531	P=0.028N*	P=0.417N
POLY 1.5	P=0.265N	P=0.541	P=0.023N*	P=0.352N
POLY 6	P=0.374N	P=0.522	P=0.034N*	P=0.495N
COCH-ARM / FISHERS	P=0.203N	P=0.585N	P=0.014N*	P=0.252N
MAX-ISO-POLY-3	P=0.173N	P=0.443	P=0.021N*	P=0.340N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Thymus Atrophy				
LESION RATES				
OVERALL (a)	44/50 (88%)	46/48 (96%)	44/48 (92%)	44/47 (94%)
POLY-3 RATE (b)	44/49.30	46/46.39	44/46.38	44/46.61
POLY-3 PERCENT (g)	89.3%	99.2%	94.9%	94.4%
TERMINAL (d)	34/37 (92%)	35/35 (100%)	30/31 (97%)	18/20 (90%)
FIRST INCIDENCE	337	324	129	192
STATISTICAL TESTS				
POLY 3	P=0.497	P=0.040*	P=0.251	P=0.286
POLY 1.5	P=0.474	P=0.049*	P=0.272	P=0.279
POLY 6	P=0.530	P=0.038*	P=0.236	P=0.304
COCH-ARM / FISHERS	P=0.390	P=0.148	P=0.397	P=0.275
MAX-ISO-POLY-3	P=0.097	P=0.015*	P=0.147	P=0.174

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Thyroid Gland: C-Cell Hyperplasia				
LESION RATES				
OVERALL (a)	14/50 (28%)	20/49 (41%)	14/50 (28%)	5/49 (10%)
POLY-3 RATE (b)	14/47.59	20/46.04	14/42.89	5/38.89
POLY-3 PERCENT (g)	29.4%	43.4%	32.6%	12.9%
TERMINAL (d)	9/37 (24%)	15/37 (41%)	9/31 (29%)	5/21 (24%)
FIRST INCIDENCE	609	512	581	727 (T)
STATISTICAL TESTS				
POLY 3	P=0.010N**	P=0.115	P=0.459	P=0.055N
POLY 1.5	P=0.005N**	P=0.113	P=0.488	P=0.038N*
POLY 6	P=0.024N*	P=0.119	P=0.432	P=0.087N
COCH-ARM / FISHERS	P=0.002N**	P=0.129	P=0.588N	P=0.022N*
MAX-ISO-POLY-3	P=0.016N*	P=0.080	P=0.375	P=0.043N*

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Tooth: Peridental Tissue Inflammation				
LESION RATES				
OVERALL (a)	1/1 (100%)	2/2 (100%)	1/2 (50%)	0/0 (0%)
POLY-3 RATE (b)	1/1.00	2/2.00	1/2.00	0/0.00
POLY-3 PERCENT (g)	100%	100%	50%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)
FIRST INCIDENCE	665	695	612	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	P=0.614N	(e)
POLY 1.5	(e)	(e)	P=0.614N	(e)
POLY 6	(e)	(e)	P=0.614N	(e)
COCH-ARM / FISHERS	P=0.923N	(e)	P=0.667N	(e)
MAX-ISO-POLY-3	(e)	(e)	P=0.308N	(e)

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Trachea Inflammation				
LESION RATES				
OVERALL (a)	3/50 (6%)	1/50 (2%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	3/46.41	1/45.60	1/41.44	3/39.27
POLY-3 PERCENT (g)	6.5%	2.2%	2.4%	7.6%
TERMINAL (d)	2/37 (5%)	0/37 (0%)	1/31 (3%)	2/21 (10%)
FIRST INCIDENCE	609	530	727 (T)	668
STATISTICAL TESTS				
POLY 3	P=0.356	P=0.312N	P=0.347N	P=0.583
POLY 1.5	P=0.380	P=0.313N	P=0.337N	P=0.613
POLY 6	P=0.326	P=0.308N	P=0.357N	P=0.545
COCH-ARM / FISHERS	P=0.414	P=0.309N	P=0.309N	P=0.661N
MAX-ISO-POLY-3	P=0.354	P=0.161N	P=0.196N	P=0.421

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Trachea: Peritracheal Tissue Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/46.00	0/44.99	0/41.44	2/40.51
POLY-3 PERCENT (g)	0%	0%	0%	4.9%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	---	---	---	192
STATISTICAL TESTS				
POLY 3	P=0.035*	(e)	(e)	P=0.210
POLY 1.5	P=0.038*	(e)	(e)	P=0.221
POLY 6	P=0.032*	(e)	(e)	P=0.197
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.034*	(e)	(e)	P=0.075

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Urinary Bladder Hemorrhage				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/46.00	1/45.05	0/41.44	2/40.22
POLY-3 PERCENT (g)	0%	2.2%	0%	5%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	---	713	---	412
STATISTICAL TESTS				
POLY 3	P=0.131	P=0.496	(e)	P=0.209
POLY 1.5	P=0.138	P=0.495	(e)	P=0.219
POLY 6	P=0.122	P=0.498	(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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Urinary Bladder Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	0/46.00	2/45.07	2/42.41	2/40.22
POLY-3 PERCENT (g)	0%	4.4%	4.7%	5%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	1/31 (3%)	0/21 (0%)
FIRST INCIDENCE	---	713	233	412
STATISTICAL TESTS				
POLY 3	P=0.283	P=0.233	P=0.219	P=0.209
POLY 1.5	P=0.305	P=0.232	P=0.223	P=0.219
POLY 6	P=0.256	P=0.235	P=0.215	P=0.196
COCH-ARM / FISHERS	P=0.342	P=0.247	P=0.247	P=0.247
MAX-ISO-POLY-3	P=0.196	P=0.076	P=0.076	P=0.075

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Adrenal Cortex				
Angiectasis				
LESION RATES				
OVERALL (a)	39/50 (78%)	42/50 (84%)	43/50 (86%)	34/49 (69%)
POLY-3 RATE (b)	39/48.27	42/47.42	43/48.53	34/43.53
POLY-3 PERCENT (g)	80.8%	88.6%	88.6%	78.1%
TERMINAL (d)	27/33 (82%)	39/42 (93%)	32/33 (97%)	20/23 (87%)
FIRST INCIDENCE	625	611	604	381
STATISTICAL TESTS				
POLY 3	P=0.233N	P=0.209	P=0.204	P=0.474N
POLY 1.5	P=0.167N	P=0.217	P=0.213	P=0.396N
POLY 6	P=0.314N	P=0.209	P=0.179	P=0.556N
COCH-ARM / FISHERS	P=0.072N	P=0.306	P=0.218	P=0.228N
MAX-ISO-POLY-3	P=0.242N	P=0.136	P=0.131	P=0.372N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Adrenal Cortex Degeneration Cystic				
LESION RATES				
OVERALL (a)	8/50 (16%)	5/50 (10%)	5/50 (10%)	3/49 (6%)
POLY-3 RATE (b)	8/46.18	5/46.74	5/46.20	3/38.55
POLY-3 PERCENT (g)	17.3%	10.7%	10.8%	7.8%
TERMINAL (d)	6/33 (18%)	5/42 (12%)	4/33 (12%)	3/23 (13%)
FIRST INCIDENCE	642	728 (T)	714	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.189N	P=0.268N	P=0.275N	P=0.165N
POLY 1.5	P=0.164N	P=0.278N	P=0.275N	P=0.144N
POLY 6	P=0.219N	P=0.248N	P=0.275N	P=0.188N
COCH-ARM / FISHERS	P=0.122N	P=0.277N	P=0.277N	P=0.106N
MAX-ISO-POLY-3	P=0.181N	P=0.181N	P=0.185N	P=0.115N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Adrenal Cortex Hyperplasia				
LESION RATES				
OVERALL (a)	26/50 (52%)	24/50 (48%)	28/50 (56%)	12/49 (24%)
POLY-3 RATE (b)	26/47.25	24/46.89	28/47.99	12/38.99
POLY-3 PERCENT (g)	55%	51.2%	58.4%	30.8%
TERMINAL (d)	20/33 (61%)	22/42 (52%)	17/33 (52%)	9/23 (39%)
FIRST INCIDENCE	574	701	604	625
STATISTICAL TESTS				
POLY 3	P=0.016N*	P=0.433N	P=0.452	P=0.017N*
POLY 1.5	P=0.007N**	P=0.448N	P=0.437	P=0.010N**
POLY 6	P=0.032N*	P=0.400N	P=0.477	P=0.028N*
COCH-ARM / FISHERS	P=0.002N**	P=0.421N	P=0.421	P=0.004N**
MAX-ISO-POLY-3	P=0.025N*	P=0.352N	P=0.370	P=0.016N*

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Adrenal Cortex Hypertrophy				
LESION RATES				
OVERALL (a)	11/50 (22%)	10/50 (20%)	12/50 (24%)	8/49 (16%)
POLY-3 RATE (b)	11/46.44	10/47.13	12/47.03	8/38.89
POLY-3 PERCENT (g)	23.7%	21.2%	25.5%	20.6%
TERMINAL (d)	8/33 (24%)	9/42 (21%)	7/33 (21%)	5/23 (22%)
FIRST INCIDENCE	642	617	613	682
STATISTICAL TESTS				
POLY 3	P=0.466N	P=0.485N	P=0.514	P=0.467N
POLY 1.5	P=0.403N	P=0.502N	P=0.508	P=0.419N
POLY 6	P=0.531N	P=0.454N	P=0.521	P=0.513N
COCH-ARM / FISHERS	P=0.290N	P=0.500N	P=0.500	P=0.323N
MAX-ISO-POLY-3	P=0.595N	P=0.387N	P=0.417	P=0.374N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Adrenal Cortex				
Vacuolization Cytoplasmic				
LESION RATES				
OVERALL (a)	26/50 (52%)	26/50 (52%)	26/50 (52%)	18/49 (37%)
POLY-3 RATE (b)	26/47.43	26/47.75	26/48.17	18/39.48
POLY-3 PERCENT (g)	54.8%	54.5%	54%	45.6%
TERMINAL (d)	17/33 (52%)	23/42 (55%)	15/33 (46%)	11/23 (48%)
FIRST INCIDENCE	645	574	611	625
STATISTICAL TESTS				
POLY 3	P=0.214N	P=0.568N	P=0.549N	P=0.258N
POLY 1.5	P=0.138N	P=0.570	P=0.562N	P=0.189N
POLY 6	P=0.311N	P=0.528N	P=0.533N	P=0.340N
COCH-ARM / FISHERS	P=0.050N*	P=0.579N	P=0.579N	P=0.092N
MAX-ISO-POLY-3	P=0.348N	P=0.485N	P=0.466N	P=0.211N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Adrenal Medulla Hyperplasia				
LESION RATES				
OVERALL (a)	4/50 (8%)	3/50 (6%)	1/50 (2%)	5/49 (10%)
POLY-3 RATE (b)	4/45.96	3/46.74	1/46.55	5/39.06
POLY-3 PERCENT (g)	8.7%	6.4%	2.2%	12.8%
TERMINAL (d)	3/33 (9%)	3/42 (7%)	0/33 (0%)	2/23 (9%)
FIRST INCIDENCE	673	728 (T)	613	625
STATISTICAL TESTS				
POLY 3	P=0.248	P=0.491N	P=0.175N	P=0.399
POLY 1.5	P=0.267	P=0.501N	P=0.177N	P=0.426
POLY 6	P=0.231	P=0.473N	P=0.173N	P=0.377
COCH-ARM / FISHERS	P=0.307	P=0.500N	P=0.181N	P=0.487
MAX-ISO-POLY-3	P=0.209	P=0.340N	P=0.082N	P=0.287

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<hr/>				
Bone Marrow Hemorrhage				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.75	0/46.74	0/46.14	0/39.33
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Bone Marrow Hyperplasia				
LESION RATES				
OVERALL (a)	18/50 (36%)	13/50 (26%)	18/50 (36%)	49/50 (98%)
POLY-3 RATE (b)	18/47.68	13/47.74	18/47.54	49/49.00
POLY-3 PERCENT (g)	37.8%	27.2%	37.9%	100%
TERMINAL (d)	12/33 (36%)	12/42 (29%)	11/33 (33%)	23/23 (100%)
FIRST INCIDENCE	547	37	611	381
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.189N	P=0.579	P<0.001**
POLY 1.5	P<0.001**	P=0.193N	P=0.580	P<0.001**
POLY 6	P<0.001**	P=0.179N	P=0.579	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.194N	P=0.582N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.135N	P=0.495	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Clitoral Gland Cyst				
LESION RATES				
OVERALL (a)	11/50 (22%)	8/49 (16%)	7/50 (14%)	5/50 (10%)
POLY-3 RATE (b)	11/46.02	8/45.78	7/46.14	5/40.54
POLY-3 PERCENT (g)	23.9%	17.5%	15.2%	12.3%
TERMINAL (d)	9/33 (27%)	7/41 (17%)	7/33 (21%)	2/23 (9%)
FIRST INCIDENCE	673	718	728 (T)	533
STATISTICAL TESTS				
POLY 3	P=0.145N	P=0.308N	P=0.213N	P=0.134N
POLY 1.5	P=0.125N	P=0.324N	P=0.215N	P=0.118N
POLY 6	P=0.168N	P=0.280N	P=0.212N	P=0.148N
COCH-ARM / FISHERS	P=0.090N	P=0.323N	P=0.218N	P=0.086N
MAX-ISO-POLY-3	P=0.154N	P=0.225N	P=0.145N	P=0.095N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Clitoral Gland Hyperplasia				
LESION RATES				
OVERALL (a)	9/50 (18%)	9/49 (18%)	6/50 (12%)	4/50 (8%)
POLY-3 RATE (b)	9/46.18	9/45.74	6/46.14	4/39.57
POLY-3 PERCENT (g)	19.5%	19.7%	13%	10.1%
TERMINAL (d)	7/33 (21%)	9/41 (22%)	6/33 (18%)	2/23 (9%)
FIRST INCIDENCE	642	728 (T)	728 (T)	682
STATISTICAL TESTS				
POLY 3	P=0.122N	P=0.595	P=0.287N	P=0.183N
POLY 1.5	P=0.102N	P=0.580	P=0.287N	P=0.159N
POLY 6	P=0.146N	P=0.586N	P=0.288N	P=0.208N
COCH-ARM / FISHERS	P=0.069N	P=0.584	P=0.288N	P=0.117N
MAX-ISO-POLY-3	P=0.199N	P=0.490	P=0.200N	P=0.131N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Clitoral Gland Inflammation				
LESION RATES				
OVERALL (a)	22/50 (44%)	26/49 (53%)	20/50 (40%)	15/50 (30%)
POLY-3 RATE (b)	22/46.79	26/46.30	20/46.92	15/41.22
POLY-3 PERCENT (g)	47%	56.2%	42.6%	36.4%
TERMINAL (d)	16/33 (49%)	23/41 (56%)	17/33 (52%)	10/23 (44%)
FIRST INCIDENCE	646	611	604	533
STATISTICAL TESTS				
POLY 3	P=0.081N	P=0.248	P=0.412N	P=0.211N
POLY 1.5	P=0.057N	P=0.229	P=0.414N	P=0.174N
POLY 6	P=0.115N	P=0.286	P=0.417N	P=0.255N
COCH-ARM / FISHERS	P=0.027N*	P=0.242	P=0.420N	P=0.107N
MAX-ISO-POLY-3	P=0.130N	P=0.187	P=0.333N	P=0.168N

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Coagulating Gland Inflammation				
LESION RATES				
OVERALL (a)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/0.00	0/0.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/0 (0%)	0/0 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Esophagus				
Perforation				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.75	0/46.74	0/46.14	0/39.33
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Eye Cataract				
LESION RATES				
OVERALL (a)	3/50 (6%)	2/50 (4%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	3/46.24	2/46.74	3/46.14	0/39.33
POLY-3 PERCENT (g)	6.5%	4.3%	6.5%	0%
TERMINAL (d)	1/33 (3%)	2/42 (5%)	3/33 (9%)	0/23 (0%)
FIRST INCIDENCE	625	728 (T)	728 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.151N	P=0.495N	P=0.661	P=0.150N
POLY 1.5	P=0.135N	P=0.502N	P=0.662	P=0.139N
POLY 6	P=0.170N	P=0.482N	P=0.660	P=0.162N
COCH-ARM / FISHERS	P=0.108N	P=0.500N	P=0.661N	P=0.121N
MAX-ISO-POLY-3	P=0.156N	P=0.320N	P=0.498	P=0.066N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Eye: Retina				
Atrophy				
LESION RATES				
OVERALL (a)	2/50 (4%)	3/50 (6%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	2/45.87	3/46.74	3/46.14	1/39.33
POLY-3 PERCENT (g)	4.4%	6.4%	6.5%	2.5%
TERMINAL (d)	1/33 (3%)	3/42 (7%)	3/33 (9%)	1/23 (4%)
FIRST INCIDENCE	698	728 (T)	728 (T)	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.377N	P=0.509	P=0.503	P=0.553N
POLY 1.5	P=0.352N	P=0.500	P=0.502	P=0.536N
POLY 6	P=0.405N	P=0.524	P=0.503	P=0.570N
COCH-ARM / FISHERS	P=0.302N	P=0.500	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.437N	P=0.333	P=0.327	P=0.338N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Harderian Gland Inflammation				
LESION RATES				
OVERALL (a)	6/50 (12%)	4/50 (8%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	6/45.75	4/47.13	2/46.33	1/40.19
POLY-3 PERCENT (g)	13.1%	8.5%	4.3%	2.5%
TERMINAL (d)	6/33 (18%)	3/42 (7%)	1/33 (3%)	0/23 (0%)
FIRST INCIDENCE	728 (T)	617	680	381
STATISTICAL TESTS				
POLY 3	P=0.066N	P=0.351N	P=0.129N	P=0.079N
POLY 1.5	P=0.059N	P=0.366N	P=0.131N	P=0.071N
POLY 6	P=0.075N	P=0.325N	P=0.125N	P=0.087N
COCH-ARM / FISHERS	P=0.048N*	P=0.370N	P=0.134N	P=0.056N
MAX-ISO-POLY-3	P=0.065N	P=0.241N	P=0.067N	P=0.044N*

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Heart				
Cardiomyopathy				
LESION RATES				
OVERALL (a)	36/50 (72%)	42/50 (84%)	40/50 (80%)	42/50 (84%)
POLY-3 RATE (b)	36/48.10	42/48.55	40/49.08	42/45.92
POLY-3 PERCENT (g)	74.9%	86.5%	81.5%	91.5%
TERMINAL (d)	26/33 (79%)	37/42 (88%)	27/33 (82%)	22/23 (96%)
FIRST INCIDENCE	574	516	604	381
STATISTICAL TESTS				
POLY 3	P=0.049*	P=0.108	P=0.286	P=0.021*
POLY 1.5	P=0.078	P=0.092	P=0.266	P=0.035*
POLY 6	P=0.030*	P=0.141	P=0.318	P=0.013*
COCH-ARM / FISHERS	P=0.199	P=0.114	P=0.241	P=0.114
MAX-ISO-POLY-3	P=0.022*	P=0.067	P=0.209	P=0.011*

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Heart Mineralization				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.75	0/46.74	0/46.14	0/39.33
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (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 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<hr/>				
Heart Thrombosis				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/45.75	0/46.74	0/46.14	1/39.39
POLY-3 PERCENT (g)	0%	0%	0%	2.5%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	---	---	---	714
<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 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<hr/>				
Intestine Large, Colon Parasite Metazoan				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.75	1/46.74	0/46.14	0/39.33
POLY-3 PERCENT (g)	0%	2.1%	0%	0%
TERMINAL (d)	0/33 (0%)	1/42 (2%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	---	728 (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 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Intestine Large, Rectum Parasite Metazoan				
LESION RATES				
OVERALL (a)	4/50 (8%)	4/50 (8%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	4/45.86	4/46.74	3/46.14	3/39.74
POLY-3 PERCENT (g)	8.7%	8.6%	6.5%	7.6%
TERMINAL (d)	3/33 (9%)	4/42 (10%)	3/33 (9%)	2/23 (9%)
FIRST INCIDENCE	701	728 (T)	728 (T)	612
STATISTICAL TESTS				
POLY 3	P=0.502N	P=0.633N	P=0.497N	P=0.578N
POLY 1.5	P=0.475N	P=0.643	P=0.498N	P=0.553N
POLY 6	P=0.530N	P=0.614N	P=0.496N	P=0.599N
COCH-ARM / FISHERS	P=0.420N	P=0.643N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.614N	P=0.488N	P=0.345N	P=0.426N

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.75	0/46.74	0/46.14	0/39.33
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Kidney				
Accumulation, Hyaline Droplet				
LESION RATES				
OVERALL (a)	25/50 (50%)	23/50 (46%)	5/50 (10%)	1/50 (2%)
POLY-3 RATE (b)	25/48.01	23/47.77	5/47.18	1/40.06
POLY-3 PERCENT (g)	52.1%	48.2%	10.6%	2.5%
TERMINAL (d)	16/33 (49%)	20/42 (48%)	2/33 (6%)	0/23 (0%)
FIRST INCIDENCE	574	574	604	471
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.429N	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.444N	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P=0.400N	P<0.001N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.421N	P<0.001N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.350N	P<0.001N**	P<0.001N**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Kidney Infarct				
LESION RATES				
OVERALL (a)	4/50 (8%)	0/50 (0%)	5/50 (10%)	2/50 (4%)
POLY-3 RATE (b)	4/45.75	0/46.74	5/46.35	2/39.50
POLY-3 PERCENT (g)	8.7%	0%	10.8%	5.1%
TERMINAL (d)	4/33 (12%)	0/42 (0%)	4/33 (12%)	0/23 (0%)
FIRST INCIDENCE	728 (T)	---	673	701
STATISTICAL TESTS				
POLY 3	P=0.585	P=0.058N	P=0.508	P=0.407N
POLY 1.5	P=0.580N	P=0.060N	P=0.505	P=0.385N
POLY 6	P=0.542	P=0.053N	P=0.513	P=0.427N
COCH-ARM / FISHERS	P=0.519N	P=0.059N	P=0.500	P=0.339N
MAX-ISO-POLY-3	P=0.407	P=0.019N*	P=0.371	P=0.270N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Kidney Mineralization				
LESION RATES				
OVERALL (a)	33/50 (66%)	35/50 (70%)	35/50 (70%)	37/50 (74%)
POLY-3 RATE (b)	33/48.13	35/49.80	35/48.84	37/46.89
POLY-3 PERCENT (g)	68.6%	70.3%	71.7%	78.9%
TERMINAL (d)	21/33 (64%)	29/42 (69%)	24/33 (73%)	17/23 (74%)
FIRST INCIDENCE	600	37	604	381
STATISTICAL TESTS				
POLY 3	P=0.142	P=0.514	P=0.455	P=0.174
POLY 1.5	P=0.164	P=0.471	P=0.440	P=0.186
POLY 6	P=0.118	P=0.571	P=0.471	P=0.165
COCH-ARM / FISHERS	P=0.255	P=0.415	P=0.415	P=0.257
MAX-ISO-POLY-3	P=0.215	P=0.426	P=0.368	P=0.123

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Kidney				
Nephropathy				
LESION RATES				
OVERALL (a)	28/50 (56%)	38/50 (76%)	38/50 (76%)	41/50 (82%)
POLY-3 RATE (b)	28/48.12	38/47.92	38/48.19	41/43.92
POLY-3 PERCENT (g)	58.2%	79.3%	78.9%	93.4%
TERMINAL (d)	18/33 (55%)	34/42 (81%)	28/33 (85%)	23/23 (100%)
FIRST INCIDENCE	574	574	613	468
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.018*	P=0.020*	P<0.001**
POLY 1.5	P<0.001**	P=0.018*	P=0.023*	P<0.001**
POLY 6	P<0.001**	P=0.022*	P=0.016*	P<0.001**
COCH-ARM / FISHERS	P=0.018*	P=0.028*	P=0.028*	P=0.004**
MAX-ISO-POLY-3	P<0.001**	P=0.010**	P=0.011*	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Kidney Pigmentation				
LESION RATES				
OVERALL (a)	41/50 (82%)	45/50 (90%)	43/50 (86%)	49/50 (98%)
POLY-3 RATE (b)	41/49.03	45/48.36	43/49.20	49/49.00
POLY-3 PERCENT (g)	83.6%	93.1%	87.4%	100%
TERMINAL (d)	27/33 (82%)	39/42 (93%)	31/33 (94%)	23/23 (100%)
FIRST INCIDENCE	547	574	604	381
STATISTICAL TESTS				
POLY 3	P=0.008**	P=0.120	P=0.401	P=0.003**
POLY 1.5	P=0.007**	P=0.119	P=0.399	P=0.002**
POLY 6	P=0.009**	P=0.136	P=0.394	P=0.004**
COCH-ARM / FISHERS	P=0.016*	P=0.194	P=0.393	P=0.008**
MAX-ISO-POLY-3	P=0.002**	P=0.068	P=0.293	P<0.001**

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Kidney: Papilla Necrosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/45.75	0/46.74	0/46.14	1/39.44
POLY-3 PERCENT (g)	0%	0%	0%	2.5%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	---	---	---	701
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 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 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%)	1/50 (2%)
POLY-3 RATE (b)	0/45.75	0/46.74	0/46.14	1/39.51
POLY-3 PERCENT (g)	0%	0%	0%	2.5%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	---	---	---	682
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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Kidney: Pelvis Inflammation				
LESION RATES				
OVERALL (a)	3/50 (6%)	3/50 (6%)	9/50 (18%)	5/50 (10%)
POLY-3 RATE (b)	3/46.57	3/46.74	9/46.59	5/39.50
POLY-3 PERCENT (g)	6.4%	6.4%	19.3%	12.7%
TERMINAL (d)	1/33 (3%)	3/42 (7%)	6/33 (18%)	3/23 (13%)
FIRST INCIDENCE	574	728 (T)	673	701
STATISTICAL TESTS				
POLY 3	P=0.185	P=0.660N	P=0.059	P=0.270
POLY 1.5	P=0.227	P=0.658	P=0.060	P=0.298
POLY 6	P=0.147	P=0.649N	P=0.058	P=0.244
COCH-ARM / FISHERS	P=0.314	P=0.661N	P=0.061	P=0.357
MAX-ISO-POLY-3	P=0.153	P=0.497N	P=0.030*	P=0.182

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Kidney: Pelvis, Transitional Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	2/50 (4%)	3/50 (6%)	8/50 (16%)	6/50 (12%)
POLY-3 RATE (b)	2/46.06	3/46.74	8/46.59	6/39.50
POLY-3 PERCENT (g)	4.3%	6.4%	17.2%	15.2%
TERMINAL (d)	1/33 (3%)	3/42 (7%)	5/33 (15%)	4/23 (17%)
FIRST INCIDENCE	645	728 (T)	673	701
STATISTICAL TESTS				
POLY 3	P=0.065	P=0.507	P=0.047*	P=0.089
POLY 1.5	P=0.084	P=0.499	P=0.046*	P=0.102
POLY 6	P=0.049*	P=0.521	P=0.047*	P=0.077
COCH-ARM / FISHERS	P=0.129	P=0.500	P=0.046*	P=0.134
MAX-ISO-POLY-3	P=0.083	P=0.331	P=0.023*	P=0.054

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver				
Angiectasis				
LESION RATES				
OVERALL (a)	1/50 (2%)	4/50 (8%)	10/50 (20%)	5/49 (10%)
POLY-3 RATE (b)	1/45.75	4/46.74	10/46.14	5/38.55
POLY-3 PERCENT (g)	2.2%	8.6%	21.7%	13%
TERMINAL (d)	1/33 (3%)	4/42 (10%)	10/33 (30%)	5/23 (22%)
FIRST INCIDENCE	728 (T)	728 (T)	728 (T)	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.110	P=0.185	P=0.004**	P=0.067
POLY 1.5	P=0.140	P=0.179	P=0.004**	P=0.076
POLY 6	P=0.084	P=0.197	P=0.004**	P=0.059
COCH-ARM / FISHERS	P=0.215	P=0.181	P=0.004**	P=0.098
MAX-ISO-POLY-3	P=0.032*	P=0.090	P<0.001**	P=0.037*

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver				
Basophilic Focus				
LESION RATES				
OVERALL (a)	46/50 (92%)	45/50 (90%)	5/50 (10%)	6/49 (12%)
POLY-3 RATE (b)	46/49.61	45/48.36	5/46.63	6/39.77
POLY-3 PERCENT (g)	92.7%	93.1%	10.7%	15.1%
TERMINAL (d)	32/33 (97%)	39/42 (93%)	3/33 (9%)	3/23 (13%)
FIRST INCIDENCE	547	574	646	384
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.632	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.637	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P=0.652	P<0.001N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.500N	P<0.001N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.472	P<0.001N**	P<0.001N**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver				
Clear Cell Focus				
LESION RATES				
OVERALL (a)	7/50 (14%)	17/50 (34%)	24/50 (48%)	29/49 (59%)
POLY-3 RATE (b)	7/46.12	17/46.74	24/46.14	29/41.64
POLY-3 PERCENT (g)	15.2%	36.4%	52%	69.6%
TERMINAL (d)	6/33 (18%)	17/42 (41%)	24/33 (73%)	20/23 (87%)
FIRST INCIDENCE	625	728 (T)	728 (T)	537
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.016*	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.015*	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.019*	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.017*	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.009**	P<0.001**	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver				
Degeneration Cystic				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	10/49 (20%)
POLY-3 RATE (b)	0/45.75	0/46.74	2/46.14	10/39.16
POLY-3 PERCENT (g)	0%	0%	4.3%	25.5%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	2/33 (6%)	6/23 (26%)
FIRST INCIDENCE	---	---	728 (T)	625
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P=0.239	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.238	P<0.001**
POLY 6	P<0.001**	(e)	P=0.240	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.247	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.078	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver				
Eosinophilic Focus				
LESION RATES				
OVERALL (a)	18/50 (36%)	24/50 (48%)	29/50 (58%)	32/49 (65%)
POLY-3 RATE (b)	18/46.77	24/46.89	29/46.82	32/42.19
POLY-3 PERCENT (g)	38.5%	51.2%	61.9%	75.9%
TERMINAL (d)	15/33 (46%)	22/42 (52%)	25/33 (76%)	19/23 (83%)
FIRST INCIDENCE	600	701	611	471
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.149	P=0.016*	P<0.001**
POLY 1.5	P<0.001**	P=0.141	P=0.018*	P<0.001**
POLY 6	P<0.001**	P=0.171	P=0.013*	P<0.001**
COCH-ARM / FISHERS	P=0.004**	P=0.156	P=0.022*	P=0.003**
MAX-ISO-POLY-3	P<0.001**	P=0.105	P=0.009**	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver				
Fatty Change Diffuse				
LESION RATES				
OVERALL (a)	9/50 (18%)	1/50 (2%)	3/50 (6%)	1/49 (2%)
POLY-3 RATE (b)	9/46.82	1/46.74	3/46.70	1/38.55
POLY-3 PERCENT (g)	19.2%	2.1%	6.4%	2.6%
TERMINAL (d)	2/33 (6%)	1/42 (2%)	0/33 (0%)	1/23 (4%)
FIRST INCIDENCE	645	728 (T)	659	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.048N*	P=0.008N**	P=0.060N	P=0.019N*
POLY 1.5	P=0.041N*	P=0.008N**	P=0.060N	P=0.015N*
POLY 6	P=0.057N	P=0.007N**	P=0.060N	P=0.025N*
COCH-ARM / FISHERS	P=0.035N*	P=0.008N**	P=0.061N	P=0.009N**
MAX-ISO-POLY-3	P=0.008N**	P=0.003N**	P=0.031N*	P=0.013N*

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver				
Fatty Change Focal				
LESION RATES				
OVERALL (a)	8/50 (16%)	13/50 (26%)	3/50 (6%)	4/49 (8%)
POLY-3 RATE (b)	8/46.20	13/47.01	3/46.14	4/39.14
POLY-3 PERCENT (g)	17.3%	27.7%	6.5%	10.2%
TERMINAL (d)	6/33 (18%)	11/42 (26%)	3/33 (9%)	3/23 (13%)
FIRST INCIDENCE	646	688	728 (T)	542
STATISTICAL TESTS				
POLY 3	P=0.066N	P=0.171	P=0.098N	P=0.266N
POLY 1.5	P=0.056N	P=0.161	P=0.099N	P=0.240N
POLY 6	P=0.077N	P=0.193	P=0.098N	P=0.293N
COCH-ARM / FISHERS	P=0.041N*	P=0.163	P=0.100N	P=0.188N
MAX-ISO-POLY-3	P=0.075N	P=0.117	P=0.053N	P=0.192N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver				
Hematopoietic Cell Proliferation				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	2/49 (4%)
POLY-3 RATE (b)	0/45.75	0/46.74	2/46.55	2/39.10
POLY-3 PERCENT (g)	0%	0%	4.3%	5.1%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	1/33 (3%)	0/23 (0%)
FIRST INCIDENCE	---	---	611	583
STATISTICAL TESTS				
POLY 3	P=0.086	(e)	P=0.241	P=0.204
POLY 1.5	P=0.096	(e)	P=0.240	P=0.212
POLY 6	P=0.077	(e)	P=0.243	P=0.197
COCH-ARM / FISHERS	P=0.117	(e)	P=0.247	P=0.242
MAX-ISO-POLY-3	P=0.120	(e)	P=0.080	P=0.074

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver				
Hepatodiaphragmatic Nodule				
LESION RATES				
OVERALL (a)	3/50 (6%)	6/50 (12%)	5/50 (10%)	3/49 (6%)
POLY-3 RATE (b)	3/45.75	6/46.74	5/46.64	3/38.98
POLY-3 PERCENT (g)	6.6%	12.8%	10.7%	7.7%
TERMINAL (d)	3/33 (9%)	6/42 (14%)	3/33 (9%)	2/23 (9%)
FIRST INCIDENCE	728 (T)	728 (T)	611	607
STATISTICAL TESTS				
POLY 3	P=0.489N	P=0.253	P=0.367	P=0.586
POLY 1.5	P=0.457N	P=0.243	P=0.363	P=0.607
POLY 6	P=0.520N	P=0.271	P=0.373	P=0.569
COCH-ARM / FISHERS	P=0.388N	P=0.243	P=0.357	P=0.651
MAX-ISO-POLY-3	P=0.459	P=0.157	P=0.242	P=0.423

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver Inflammation				
LESION RATES				
OVERALL (a)	38/50 (76%)	46/50 (92%)	42/50 (84%)	39/49 (80%)
POLY-3 RATE (b)	38/47.96	46/48.32	42/49.30	39/44.07
POLY-3 PERCENT (g)	79.2%	95.2%	85.2%	88.5%
TERMINAL (d)	30/33 (91%)	41/42 (98%)	29/33 (88%)	22/23 (96%)
FIRST INCIDENCE	574	574	604	381
STATISTICAL TESTS				
POLY 3	P=0.399	P=0.013*	P=0.300	P=0.159
POLY 1.5	P=0.510	P=0.012*	P=0.264	P=0.222
POLY 6	P=0.305	P=0.020*	P=0.369	P=0.116
COCH-ARM / FISHERS	P=0.374N	P=0.027*	P=0.227	P=0.426
MAX-ISO-POLY-3	P=0.103	P=0.005**	P=0.216	P=0.104

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver				
Mixed Cell Focus				
LESION RATES				
OVERALL (a)	14/50 (28%)	20/50 (40%)	17/50 (34%)	26/49 (53%)
POLY-3 RATE (b)	14/47.01	20/46.74	17/46.22	26/40.47
POLY-3 PERCENT (g)	29.8%	42.8%	36.8%	64.2%
TERMINAL (d)	10/33 (30%)	20/42 (48%)	16/33 (49%)	17/23 (74%)
FIRST INCIDENCE	600	728 (T)	709	542
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.135	P=0.309	P<0.001**
POLY 1.5	P=0.003**	P=0.131	P=0.321	P=0.002**
POLY 6	P<0.001**	P=0.146	P=0.288	P<0.001**
COCH-ARM / FISHERS	P=0.012*	P=0.146	P=0.333	P=0.010**
MAX-ISO-POLY-3	P=0.002**	P=0.094	P=0.238	P<0.001**

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
<hr/>				
Liver				
Vacuolization Cytoplasmic				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/45.75	0/46.74	0/46.14	0/38.55
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	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%)	0/50 (0%)	1/49 (2%)
POLY-3 RATE (b)	0/45.75	1/46.74	0/46.14	1/38.55
POLY-3 PERCENT (g)	0%	2.1%	0%	2.6%
TERMINAL (d)	0/33 (0%)	1/42 (2%)	0/33 (0%)	1/23 (4%)
FIRST INCIDENCE	---	728 (T)	---	728 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver: Bile Duct Fibrosis				
LESION RATES				
OVERALL (a)	6/50 (12%)	11/50 (22%)	23/50 (46%)	27/49 (55%)
POLY-3 RATE (b)	6/45.75	11/47.25	23/47.30	27/40.43
POLY-3 PERCENT (g)	13.1%	23.3%	48.6%	66.8%
TERMINAL (d)	6/33 (18%)	10/42 (24%)	18/33 (55%)	18/23 (78%)
FIRST INCIDENCE	728 (T)	574	604	471
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.158	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.146	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.182	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.143	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.105	P<0.001**	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver: Bile Duct Hyperplasia				
LESION RATES				
OVERALL (a)	10/50 (20%)	21/50 (42%)	27/50 (54%)	43/49 (88%)
POLY-3 RATE (b)	10/46.33	21/47.80	27/47.49	43/46.24
POLY-3 PERCENT (g)	21.6%	43.9%	56.9%	93%
TERMINAL (d)	8/33 (24%)	18/42 (43%)	21/33 (64%)	21/23 (91%)
FIRST INCIDENCE	625	574	613	381
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.016*	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.014*	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.022*	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.015*	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.010**	P<0.001**	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 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%)	0/50 (0%)	6/50 (12%)	22/49 (45%)
POLY-3 RATE (b)	0/45.75	0/46.74	6/46.48	22/42.64
POLY-3 PERCENT (g)	0%	0%	12.9%	51.6%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	4/33 (12%)	10/23 (44%)
FIRST INCIDENCE	---	---	659	381
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P=0.016*	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.016*	P<0.001**
POLY 6	P<0.001**	(e)	P=0.016*	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.013*	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.005**	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver: Hepatocyte Necrosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	5/49 (10%)
POLY-3 RATE (b)	0/45.75	0/46.74	1/46.23	5/38.89
POLY-3 PERCENT (g)	0%	0%	2.2%	12.9%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	2/23 (9%)
FIRST INCIDENCE	---	---	705	685
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P=0.502	P=0.019*
POLY 1.5	P<0.001**	(e)	P=0.501	P=0.022*
POLY 6	P<0.001**	(e)	P=0.503	P=0.017*
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.500	P=0.027*
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.161	P=0.009**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Liver: Oval Cell Hyperplasia				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	2/50 (4%)	1/49 (2%)
POLY-3 RATE (b)	2/45.96	0/46.74	2/46.23	1/38.61
POLY-3 PERCENT (g)	4.4%	0%	4.3%	2.6%
TERMINAL (d)	1/33 (3%)	0/42 (0%)	1/33 (3%)	0/23 (0%)
FIRST INCIDENCE	673	---	705	714
STATISTICAL TESTS				
POLY 3	P=0.630	P=0.233N	P=0.692N	P=0.560N
POLY 1.5	P=0.637N	P=0.238N	P=0.692N	P=0.543N
POLY 6	P=0.602	P=0.226N	P=0.691N	P=0.576N
COCH-ARM / FISHERS	P=0.603N	P=0.247N	P=0.691N	P=0.508N
MAX-ISO-POLY-3	P=0.485N	P=0.076N	P=0.497N	P=0.344N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Lung Congestion				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.75	0/46.74	0/46.14	2/40.12
POLY-3 PERCENT (g)	0%	0%	0%	5%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	---	---	---	533
STATISTICAL TESTS				
POLY 3	P=0.034*	(e)	(e)	P=0.209
POLY 1.5	P=0.036*	(e)	(e)	P=0.217
POLY 6	P=0.032*	(e)	(e)	P=0.202
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.034*	(e)	(e)	P=0.075

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Lung Inflammation				
LESION RATES				
OVERALL (a)	3/50 (6%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	3/46.34	0/46.74	0/46.14	1/39.33
POLY-3 PERCENT (g)	6.5%	0%	0%	2.5%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	1/23 (4%)
FIRST INCIDENCE	673	---	---	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.465N	P=0.117N	P=0.119N	P=0.366N
POLY 1.5	P=0.458N	P=0.120N	P=0.119N	P=0.346N
POLY 6	P=0.474N	P=0.113N	P=0.121N	P=0.389N
COCH-ARM / FISHERS	P=0.448N	P=0.121N	P=0.121N	P=0.309N
MAX-ISO-POLY-3	P=0.085N	P=0.038N*	P=0.039N*	P=0.216N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Lung Metaplasia				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/46.13	0/46.74	0/46.14	0/39.33
POLY-3 PERCENT (g)	4.3%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	673	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.245N	P=0.234N	P=0.237N	P=0.274N
POLY 1.5	P=0.243N	P=0.238N	P=0.237N	P=0.262N
POLY 6	P=0.249N	P=0.228N	P=0.238N	P=0.288N
COCH-ARM / FISHERS	P=0.242N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.068N	P=0.076N	P=0.076N	P=0.111N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Lung: Alveolar Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	5/50 (10%)	2/50 (4%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	5/46.33	2/46.74	2/46.22	2/39.33
POLY-3 PERCENT (g)	10.8%	4.3%	4.3%	5.1%
TERMINAL (d)	3/33 (9%)	2/42 (5%)	1/33 (3%)	2/23 (9%)
FIRST INCIDENCE	625	728 (T)	709	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.339N	P=0.213N	P=0.217N	P=0.288N
POLY 1.5	P=0.316N	P=0.219N	P=0.217N	P=0.263N
POLY 6	P=0.365N	P=0.201N	P=0.218N	P=0.314N
COCH-ARM / FISHERS	P=0.278N	P=0.218N	P=0.218N	P=0.218N
MAX-ISO-POLY-3	P=0.227N	P=0.118N	P=0.121N	P=0.188N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Lung: Alveolus Infiltration Cellular Histiocyte				
LESION RATES				
OVERALL (a)	11/50 (22%)	10/50 (20%)	11/50 (22%)	17/50 (34%)
POLY-3 RATE (b)	11/46.41	10/46.74	11/46.91	17/41.86
POLY-3 PERCENT (g)	23.7%	21.4%	23.5%	40.6%
TERMINAL (d)	9/33 (27%)	10/42 (24%)	8/33 (24%)	12/23 (52%)
FIRST INCIDENCE	574	728 (T)	611	384
STATISTICAL TESTS				
POLY 3	P=0.024*	P=0.493N	P=0.585N	P=0.067
POLY 1.5	P=0.032*	P=0.507N	P=0.589N	P=0.083
POLY 6	P=0.017*	P=0.464N	P=0.579N	P=0.053
COCH-ARM / FISHERS	P=0.056	P=0.500N	P=0.595N	P=0.133
MAX-ISO-POLY-3	P=0.039*	P=0.393N	P=0.488N	P=0.049*

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Lymph Node, Mesenteric Ectasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/45.75	0/46.39	0/46.14	0/38.55
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Lymph Node, Mesenteric Hyperplasia Lymphoid				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/49 (0%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	1/45.75	0/46.39	0/46.14	0/38.55
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	1/33 (3%)	0/42 (0%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	728 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Lymph Node, Mesenteric Infiltration Cellular Histiocyte				
LESION RATES				
OVERALL (a)	30/50 (60%)	29/49 (59%)	35/50 (70%)	33/49 (67%)
POLY-3 RATE (b)	30/48.76	29/47.96	35/48.46	33/45.28
POLY-3 PERCENT (g)	61.5%	60.5%	72.2%	72.9%
TERMINAL (d)	20/33 (61%)	24/42 (57%)	27/33 (82%)	17/23 (74%)
FIRST INCIDENCE	547	574	604	381
STATISTICAL TESTS				
POLY 3	P=0.106	P=0.540N	P=0.178	P=0.166
POLY 1.5	P=0.137	P=0.567N	P=0.189	P=0.193
POLY 6	P=0.079	P=0.493N	P=0.163	P=0.145
COCH-ARM / FISHERS	P=0.226	P=0.548N	P=0.201	P=0.291
MAX-ISO-POLY-3	P=0.172	P=0.457N	P=0.128	P=0.124

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Lymph Node: Mediastinal Ectasia				
LESION RATES				
OVERALL (a)	1/2 (50%)	1/1 (100%)	1/2 (50%)	1/1 (100%)
POLY-3 RATE (b)	1/2.00	1/1.00	1/1.74	1/1.00
POLY-3 PERCENT (g)	50%	100%	57.4%	100%
TERMINAL (d)	0/1 (0%)	1/1 (100%)	1/1 (100%)	1/1 (100%)
FIRST INCIDENCE	687	728 (T)	728 (T)	728 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Lymph Node: Mediastinal Hyperplasia Lymphoid				
LESION RATES				
OVERALL (a)	0/2 (0%)	0/1 (0%)	0/2 (0%)	0/1 (0%)
POLY-3 RATE (b)	0/1.84	0/1.00	0/1.74	0/1.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/1 (0%)	0/1 (0%)	0/1 (0%)	0/1 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Mammary Gland Cyst				
LESION RATES				
OVERALL (a)	4/50 (8%)	0/50 (0%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	4/46.19	0/46.74	3/46.94	0/39.33
POLY-3 PERCENT (g)	8.7%	0%	6.4%	0%
TERMINAL (d)	3/33 (9%)	0/42 (0%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	600	---	613	---
STATISTICAL TESTS				
POLY 3	P=0.162N	P=0.059N	P=0.491N	P=0.084N
POLY 1.5	P=0.145N	P=0.061N	P=0.495N	P=0.075N
POLY 6	P=0.182N	P=0.055N	P=0.486N	P=0.092N
COCH-ARM / FISHERS	P=0.123N	P=0.059N	P=0.500N	P=0.059N
MAX-ISO-POLY-3	P=0.049N*	P=0.019N*	P=0.341N	P=0.039N*

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Mammary Gland Hyperplasia				
LESION RATES				
OVERALL (a)	9/50 (18%)	9/50 (18%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	9/46.56	9/46.90	2/46.33	0/39.33
POLY-3 PERCENT (g)	19.3%	19.2%	4.3%	0%
TERMINAL (d)	6/33 (18%)	8/42 (19%)	1/33 (3%)	0/23 (0%)
FIRST INCIDENCE	600	688	680	---
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.596N	P=0.025N*	P=0.004N**
POLY 1.5	P<0.001N**	P=0.597	P=0.025N*	P=0.003N**
POLY 6	P=0.002N**	P=0.573N	P=0.025N*	P=0.005N**
COCH-ARM / FISHERS	P<0.001N**	P=0.602N	P=0.026N*	P<0.001N**
MAX-ISO-POLY-3	P=0.002N**	P=0.493N	P=0.011N*	P=0.003N**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Mesentery: Fat Necrosis				
LESION RATES				
OVERALL (a)	8/8 (100%)	9/9 (100%)	9/9 (100%)	3/3 (100%)
POLY-3 RATE (b)	8/8.00	9/9.00	9/9.00	3/3.00
POLY-3 PERCENT (g)	100%	100%	100%	100%
TERMINAL (d)	5/5 (100%)	8/8 (100%)	7/7 (100%)	3/3 (100%)
FIRST INCIDENCE	625	617	680	728 (T)
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose				
Foreign Body				
LESION RATES				
OVERALL (a)	3/50 (6%)	8/49 (16%)	1/50 (2%)	4/49 (8%)
POLY-3 RATE (b)	3/45.75	8/47.00	1/46.14	4/39.28
POLY-3 PERCENT (g)	6.6%	17%	2.2%	10.2%
TERMINAL (d)	3/33 (9%)	6/42 (14%)	1/33 (3%)	3/23 (13%)
FIRST INCIDENCE	728 (T)	574	728 (T)	471
STATISTICAL TESTS				
POLY 3	P=0.504N	P=0.107	P=0.302N	P=0.417
POLY 1.5	P=0.484N	P=0.098	P=0.304N	P=0.439
POLY 6	P=0.522N	P=0.124	P=0.300N	P=0.398
COCH-ARM / FISHERS	P=0.437N	P=0.094	P=0.309N	P=0.489
MAX-ISO-POLY-3	P=0.304N	P=0.062	P=0.153N	P=0.288

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose Inflammation				
LESION RATES				
OVERALL (a)	23/50 (46%)	24/49 (49%)	22/50 (44%)	45/49 (92%)
POLY-3 RATE (b)	23/47.09	24/47.40	22/48.17	45/46.41
POLY-3 PERCENT (g)	48.9%	50.6%	45.7%	97%
TERMINAL (d)	19/33 (58%)	21/42 (50%)	15/33 (46%)	22/23 (96%)
FIRST INCIDENCE	600	574	613	381
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.513	P=0.458N	P<0.001**
POLY 1.5	P<0.001**	P=0.472	P=0.477N	P<0.001**
POLY 6	P<0.001**	P=0.579	P=0.429N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.462	P=0.500N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.430	P=0.377N	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Glands, Respiratory Epithelium Dilatation				
LESION RATES				
OVERALL (a)	5/50 (10%)	12/49 (24%)	27/50 (54%)	47/49 (96%)
POLY-3 RATE (b)	5/46.21	12/46.39	27/49.04	47/48.00
POLY-3 PERCENT (g)	10.8%	25.9%	55.1%	97.9%
TERMINAL (d)	3/33 (9%)	12/42 (29%)	15/33 (46%)	22/23 (96%)
FIRST INCIDENCE	645	728 (T)	604	381
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.052	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.048*	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.061	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.049*	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.030*	P<0.001**	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Glands, Respiratory Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	6/50 (12%)	9/49 (18%)	22/50 (44%)	45/49 (92%)
POLY-3 RATE (b)	6/45.75	9/46.69	22/48.89	45/46.66
POLY-3 PERCENT (g)	13.1%	19.3%	45%	96.4%
TERMINAL (d)	6/33 (18%)	6/42 (14%)	10/33 (30%)	22/23 (96%)
FIRST INCIDENCE	728 (T)	688	611	381
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.302	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.282	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.337	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.274	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.216	P<0.001**	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 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)	17/50 (34%)	33/49 (67%)	44/50 (88%)	47/49 (96%)
POLY-3 RATE (b)	17/46.79	33/47.84	44/48.98	47/48.00
POLY-3 PERCENT (g)	36.3%	69%	89.8%	97.9%
TERMINAL (d)	13/33 (39%)	28/42 (67%)	32/33 (97%)	22/23 (96%)
FIRST INCIDENCE	547	574	604	381
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=0.002**	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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 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%)	4/49 (8%)
POLY-3 RATE (b)	0/45.75	0/46.39	0/46.14	4/38.92
POLY-3 PERCENT (g)	0%	0%	0%	10.3%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	3/23 (13%)
FIRST INCIDENCE	---	---	---	625
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	(e)	P=0.042*
POLY 1.5	P<0.001**	(e)	(e)	P=0.047*
POLY 6	P<0.001**	(e)	(e)	P=0.039*
COCH-ARM / FISHERS	P=0.002**	(e)	(e)	P=0.056
MAX-ISO-POLY-3	P=0.002**	(e)	(e)	P=0.018*

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 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)	43/50 (86%)	42/49 (86%)	38/50 (76%)	0/49 (0%)
POLY-3 RATE (b)	43/49.74	42/47.55	38/47.99	0/38.55
POLY-3 PERCENT (g)	86.4%	88.3%	79.2%	0%
TERMINAL (d)	28/33 (85%)	38/42 (91%)	29/33 (88%)	0/23 (0%)
FIRST INCIDENCE	547	574	604	---
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.510	P=0.239N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.520	P=0.196N	P<0.001N**
POLY 6	P<0.001N**	P=0.503	P=0.323N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.597N	P=0.154N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.389	P=0.166N	P<0.001N**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Olfactory Epithelium Degeneration				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/49 (0%)	1/50 (2%)	46/49 (94%)
POLY-3 RATE (b)	0/45.75	0/46.39	1/46.33	46/46.29
POLY-3 PERCENT (g)	0%	0%	2.2%	99.4%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	23/23 (100%)
FIRST INCIDENCE	---	---	680	459
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P=0.502	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.501	P<0.001**
POLY 6	P<0.001**	(e)	P=0.504	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.500	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.162	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Olfactory Epithelium Hyperplasia Basal Cell				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	25/49 (51%)
POLY-3 RATE (b)	0/45.75	0/46.39	0/46.14	25/46.81
POLY-3 PERCENT (g)	0%	0%	0%	53.4%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	5/23 (22%)
FIRST INCIDENCE	---	---	---	381
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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Olfactory Epithelium Metaplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	2/49 (4%)
POLY-3 RATE (b)	0/45.75	0/46.39	0/46.14	2/38.73
POLY-3 PERCENT (g)	0%	0%	0%	5.2%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	1/23 (4%)
FIRST INCIDENCE	---	---	---	682
STATISTICAL TESTS				
POLY 3	P=0.033*	(e)	(e)	P=0.202
POLY 1.5	P=0.035*	(e)	(e)	P=0.211
POLY 6	P=0.030*	(e)	(e)	P=0.194
COCH-ARM / FISHERS	P=0.041*	(e)	(e)	P=0.242
MAX-ISO-POLY-3	P=0.034*	(e)	(e)	P=0.074

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Olfactory Epithelium Metaplasia Respiratory				
LESION RATES				
OVERALL (a)	4/50 (8%)	6/49 (12%)	1/50 (2%)	21/49 (43%)
POLY-3 RATE (b)	4/45.96	6/47.00	1/46.14	21/39.88
POLY-3 PERCENT (g)	8.7%	12.8%	2.2%	52.7%
TERMINAL (d)	3/33 (9%)	4/42 (10%)	1/33 (3%)	13/23 (57%)
FIRST INCIDENCE	673	574	728 (T)	547
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.384	P=0.177N	P<0.001**
POLY 1.5	P<0.001**	P=0.366	P=0.178N	P<0.001**
POLY 6	P<0.001**	P=0.413	P=0.177N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.357	P=0.181N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.269	P=0.083N	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Olfactory Epithelium, Glands Dilatation				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	48/49 (98%)
POLY-3 RATE (b)	0/45.75	0/46.39	0/46.14	48/48.00
POLY-3 PERCENT (g)	0%	0%	0%	100%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	23/23 (100%)
FIRST INCIDENCE	---	---	---	381
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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Olfactory Epithelium, Glands Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/49 (0%)	4/50 (8%)	47/49 (96%)
POLY-3 RATE (b)	0/45.75	0/46.39	4/46.95	47/47.40
POLY-3 PERCENT (g)	0%	0%	8.5%	99.2%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	23/23 (100%)
FIRST INCIDENCE	---	---	630	381
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P=0.064	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.062	P<0.001**
POLY 6	P<0.001**	(e)	P=0.066	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.059	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.022*	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Olfactory Epithelium, Glands Metaplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	42/49 (86%)
POLY-3 RATE (b)	0/45.75	0/46.39	0/46.14	42/45.02
POLY-3 PERCENT (g)	0%	0%	0%	93.3%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	23/23 (100%)
FIRST INCIDENCE	---	---	---	384
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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Olfactory Epithelium, Glands				
Necrosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	18/49 (37%)
POLY-3 RATE (b)	0/45.75	0/46.39	0/46.14	18/44.63
POLY-3 PERCENT (g)	0%	0%	0%	40.3%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	2/23 (9%)
FIRST INCIDENCE	---	---	---	381
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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 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)	35/50 (70%)	30/49 (61%)	23/50 (46%)	2/49 (4%)
POLY-3 RATE (b)	35/48.25	30/47.29	23/47.28	2/39.15
POLY-3 PERCENT (g)	72.5%	63.4%	48.7%	5.1%
TERMINAL (d)	25/33 (76%)	28/42 (67%)	18/33 (55%)	0/23 (0%)
FIRST INCIDENCE	547	574	604	583
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.228N	P=0.011N*	P<0.001N**
POLY 1.5	P<0.001N**	P=0.252N	P=0.011N*	P<0.001N**
POLY 6	P<0.001N**	P=0.196N	P=0.012N*	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.240N	P=0.013N*	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.169N	P=0.007N**	P<0.001N**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Respiratory Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	10/50 (20%)	13/49 (27%)	11/50 (22%)	41/49 (84%)
POLY-3 RATE (b)	10/46.75	13/46.82	11/47.41	41/45.09
POLY-3 PERCENT (g)	21.4%	27.8%	23.2%	90.9%
TERMINAL (d)	7/33 (21%)	11/42 (26%)	5/33 (15%)	21/23 (91%)
FIRST INCIDENCE	547	617	611	381
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.317	P=0.514	P<0.001**
POLY 1.5	P<0.001**	P=0.299	P=0.508	P<0.001**
POLY 6	P<0.001**	P=0.350	P=0.525	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.298	P=0.500	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.239	P=0.415	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Transitional Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/49 (2%)	6/50 (12%)	33/49 (67%)
POLY-3 RATE (b)	0/45.75	1/47.39	6/46.23	33/46.26
POLY-3 PERCENT (g)	0%	2.1%	13%	71.3%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	5/33 (15%)	14/23 (61%)
FIRST INCIDENCE	---	37	705	381
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.507	P=0.016*	P<0.001**
POLY 1.5	P<0.001**	P=0.502	P=0.016*	P<0.001**
POLY 6	P<0.001**	P=0.515	P=0.016*	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.495	P=0.013*	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.169	P=0.005**	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Transitional Epithelium, Glands Dilatation				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	9/49 (18%)
POLY-3 RATE (b)	0/45.75	0/46.39	0/46.14	9/38.64
POLY-3 PERCENT (g)	0%	0%	0%	23.3%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	7/23 (30%)
FIRST INCIDENCE	---	---	---	714
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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose: Transitional Epithelium, Glands Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	4/49 (8%)	12/50 (24%)	24/49 (49%)
POLY-3 RATE (b)	0/45.75	4/47.82	12/48.27	24/46.99
POLY-3 PERCENT (g)	0%	8.4%	24.9%	51.1%
TERMINAL (d)	0/33 (0%)	1/42 (2%)	1/33 (3%)	4/23 (17%)
FIRST INCIDENCE	---	37	613	381
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.066	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.062	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.073	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.056	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.025*	P<0.001**	P<0.001**

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Ovary Atrophy				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.75	2/46.85	0/46.14	0/39.33
POLY-3 PERCENT (g)	0%	4.3%	0%	0%
TERMINAL (d)	0/33 (0%)	1/42 (2%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	---	701	---	---
STATISTICAL TESTS				
POLY 3	P=0.383N	P=0.243	(e)	(e)
POLY 1.5	P=0.381N	P=0.238	(e)	(e)
POLY 6	P=0.381N	P=0.251	(e)	(e)
COCH-ARM / FISHERS	P=0.369N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.317N	P=0.081	(e)	(e)

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Ovary Cyst				
LESION RATES				
OVERALL (a)	4/50 (8%)	3/50 (6%)	5/50 (10%)	0/50 (0%)
POLY-3 RATE (b)	4/45.75	3/46.74	5/46.66	0/39.33
POLY-3 PERCENT (g)	8.7%	6.4%	10.7%	0%
TERMINAL (d)	4/33 (12%)	3/42 (7%)	2/33 (6%)	0/23 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	659	---
STATISTICAL TESTS				
POLY 3	P=0.101N	P=0.488N	P=0.512	P=0.082N
POLY 1.5	P=0.086N	P=0.499N	P=0.507	P=0.075N
POLY 6	P=0.120N	P=0.468N	P=0.521	P=0.089N
COCH-ARM / FISHERS	P=0.063N	P=0.500N	P=0.500	P=0.059N
MAX-ISO-POLY-3	P=0.117N	P=0.338N	P=0.375	P=0.037N*

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Pancreas Cyst				
LESION RATES				
OVERALL (a)	5/50 (10%)	4/50 (8%)	5/50 (10%)	5/50 (10%)
POLY-3 RATE (b)	5/46.12	4/46.74	5/46.14	5/39.73
POLY-3 PERCENT (g)	10.8%	8.6%	10.8%	12.6%
TERMINAL (d)	2/33 (6%)	4/42 (10%)	5/33 (15%)	3/23 (13%)
FIRST INCIDENCE	687	728 (T)	728 (T)	625
STATISTICAL TESTS				
POLY 3	P=0.404	P=0.492N	P=0.630N	P=0.534
POLY 1.5	P=0.443	P=0.502N	P=0.629N	P=0.565
POLY 6	P=0.363	P=0.473N	P=0.629	P=0.504
COCH-ARM / FISHERS	P=0.519	P=0.500N	P=0.630N	P=0.630N
MAX-ISO-POLY-3	P=0.549	P=0.356N	P=0.499N	P=0.406

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Pancreas				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	13/50 (26%)	11/50 (22%)	9/50 (18%)	9/50 (18%)
POLY-3 RATE (b)	13/46.94	11/47.64	9/46.59	9/41.78
POLY-3 PERCENT (g)	27.7%	23.1%	19.3%	21.5%
TERMINAL (d)	9/33 (27%)	9/42 (21%)	7/33 (21%)	4/23 (17%)
FIRST INCIDENCE	600	574	613	471
STATISTICAL TESTS				
POLY 3	P=0.346N	P=0.391N	P=0.238N	P=0.336N
POLY 1.5	P=0.308N	P=0.409N	P=0.236N	P=0.305N
POLY 6	P=0.389N	P=0.359N	P=0.243N	P=0.366N
COCH-ARM / FISHERS	P=0.236N	P=0.408N	P=0.235N	P=0.235N
MAX-ISO-POLY-3	P=0.363N	P=0.305N	P=0.171N	P=0.263N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Pancreas: Acinus Atrophy				
LESION RATES				
OVERALL (a)	14/50 (28%)	7/50 (14%)	9/50 (18%)	7/50 (14%)
POLY-3 RATE (b)	14/47.50	7/46.90	9/47.88	7/40.13
POLY-3 PERCENT (g)	29.5%	14.9%	18.8%	17.4%
TERMINAL (d)	7/33 (21%)	6/42 (14%)	3/33 (9%)	4/23 (17%)
FIRST INCIDENCE	600	688	611	547
STATISTICAL TESTS				
POLY 3	P=0.255N	P=0.072N	P=0.163N	P=0.144N
POLY 1.5	P=0.213N	P=0.074N	P=0.166N	P=0.114N
POLY 6	P=0.304N	P=0.067N	P=0.159N	P=0.181N
COCH-ARM / FISHERS	P=0.149N	P=0.070N	P=0.171N	P=0.070N
MAX-ISO-POLY-3	P=0.156N	P=0.044N*	P=0.111N	P=0.111N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Pancreas: Acinus Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/45.75	0/46.74	0/46.14	1/39.33
POLY-3 PERCENT (g)	0%	0%	0%	2.5%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	1/23 (4%)
FIRST INCIDENCE	---	---	---	728 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Parathyroid Gland Hyperplasia Diffuse				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	2/50 (4%)	5/46 (11%)
POLY-3 RATE (b)	1/45.75	2/46.74	2/46.14	5/37.89
POLY-3 PERCENT (g)	2.2%	4.3%	4.3%	13.2%
TERMINAL (d)	1/33 (3%)	2/42 (5%)	2/33 (6%)	4/22 (18%)
FIRST INCIDENCE	728 (T)	728 (T)	728 (T)	701
STATISTICAL TESTS				
POLY 3	P=0.027*	P=0.507	P=0.503	P=0.063
POLY 1.5	P=0.031*	P=0.500	P=0.502	P=0.069
POLY 6	P=0.024*	P=0.520	P=0.504	P=0.057
COCH-ARM / FISHERS	P=0.039*	P=0.500	P=0.500	P=0.084
MAX-ISO-POLY-3	P=0.037*	P=0.289	P=0.284	P=0.034*

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Parathyroid Gland Hyperplasia Focal				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/46 (0%)
POLY-3 RATE (b)	0/45.75	0/46.74	1/46.14	0/37.78
POLY-3 PERCENT (g)	0%	0%	2.2%	0%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	1/33 (3%)	0/22 (0%)
FIRST INCIDENCE	---	---	728 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Pituitary Gland Cyst				
LESION RATES				
OVERALL (a)	11/50 (22%)	20/50 (40%)	15/50 (30%)	4/50 (8%)
POLY-3 RATE (b)	11/46.54	20/46.74	15/46.45	4/39.33
POLY-3 PERCENT (g)	23.6%	42.8%	32.3%	10.2%
TERMINAL (d)	8/33 (24%)	20/42 (48%)	13/33 (39%)	4/23 (17%)
FIRST INCIDENCE	625	728 (T)	659	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.011N*	P=0.038*	P=0.241	P=0.087N
POLY 1.5	P=0.007N**	P=0.036*	P=0.245	P=0.070N
POLY 6	P=0.020N*	P=0.043*	P=0.234	P=0.108N
COCH-ARM / FISHERS	P=0.003N**	P=0.041*	P=0.247	P=0.045N*
MAX-ISO-POLY-3	P=0.018N*	P=0.023*	P=0.176	P=0.064N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Pituitary Gland: Pars Distalis Cyst				
LESION RATES				
OVERALL (a)	4/50 (8%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	4/45.75	0/46.74	2/46.14	1/39.33
POLY-3 PERCENT (g)	8.7%	0%	4.3%	2.5%
TERMINAL (d)	4/33 (12%)	0/42 (0%)	2/33 (6%)	1/23 (4%)
FIRST INCIDENCE	728 (T)	---	728 (T)	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.361N	P=0.058N	P=0.333N	P=0.228N
POLY 1.5	P=0.340N	P=0.060N	P=0.335N	P=0.212N
POLY 6	P=0.386N	P=0.053N	P=0.331N	P=0.244N
COCH-ARM / FISHERS	P=0.308N	P=0.059N	P=0.339N	P=0.181N
MAX-ISO-POLY-3	P=0.132N	P=0.019N*	P=0.198N	P=0.131N

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Pituitary Gland: Pars Distalis Hyperplasia				
LESION RATES				
OVERALL (a)	14/50 (28%)	17/50 (34%)	15/50 (30%)	17/50 (34%)
POLY-3 RATE (b)	14/46.60	17/46.74	15/47.16	17/40.94
POLY-3 PERCENT (g)	30%	36.4%	31.8%	41.5%
TERMINAL (d)	10/33 (30%)	17/42 (41%)	12/33 (36%)	11/23 (48%)
FIRST INCIDENCE	625	728 (T)	611	547
STATISTICAL TESTS				
POLY 3	P=0.204	P=0.334	P=0.515	P=0.183
POLY 1.5	P=0.255	P=0.321	P=0.509	P=0.225
POLY 6	P=0.160	P=0.360	P=0.522	P=0.148
COCH-ARM / FISHERS	P=0.379	P=0.333	P=0.500	P=0.333
MAX-ISO-POLY-3	P=0.241	P=0.258	P=0.425	P=0.143

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Spleen Congestion				
LESION RATES				
OVERALL (a)	0/50 (0%)	9/50 (18%)	26/50 (52%)	28/50 (56%)
POLY-3 RATE (b)	0/45.75	9/46.74	26/46.57	28/44.37
POLY-3 PERCENT (g)	0%	19.3%	55.8%	63.1%
TERMINAL (d)	0/33 (0%)	9/42 (21%)	23/33 (70%)	15/23 (65%)
FIRST INCIDENCE	---	728 (T)	680	384
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.002**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.002**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.002**	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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Spleen				
Hematopoietic Cell Proliferation				
LESION RATES				
OVERALL (a)	32/50 (64%)	45/50 (90%)	47/50 (94%)	42/50 (84%)
POLY-3 RATE (b)	32/47.70	45/48.70	47/49.58	42/47.77
POLY-3 PERCENT (g)	67.1%	92.4%	94.8%	87.9%
TERMINAL (d)	25/33 (76%)	41/42 (98%)	33/33 (100%)	21/23 (91%)
FIRST INCIDENCE	600	37	604	381
STATISTICAL TESTS				
POLY 3	P=0.071	P<0.001**	P<0.001**	P=0.010**
POLY 1.5	P=0.067	P<0.001**	P<0.001**	P=0.010**
POLY 6	P=0.085	P<0.001**	P<0.001**	P=0.012*
COCH-ARM / FISHERS	P=0.128	P=0.002**	P<0.001**	P=0.020*
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	P=0.005**

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Spleen Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.75	0/46.74	0/46.14	0/39.33
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Spleen Necrosis				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/46.39	0/46.74	0/46.14	0/39.33
POLY-3 PERCENT (g)	4.3%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	547	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.244N	P=0.236N	P=0.238N	P=0.276N
POLY 1.5	P=0.242N	P=0.239N	P=0.238N	P=0.263N
POLY 6	P=0.248N	P=0.229N	P=0.239N	P=0.289N
COCH-ARM / FISHERS	P=0.242N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.070N	P=0.076N	P=0.077N	P=0.112N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Spleen Pigmentation				
LESION RATES				
OVERALL (a)	44/50 (88%)	47/50 (94%)	47/50 (94%)	49/50 (98%)
POLY-3 RATE (b)	44/48.90	47/48.36	47/49.50	49/49.00
POLY-3 PERCENT (g)	90%	97.2%	95%	100%
TERMINAL (d)	32/33 (97%)	41/42 (98%)	32/33 (97%)	23/23 (100%)
FIRST INCIDENCE	574	574	604	381
STATISTICAL TESTS				
POLY 3	P=0.038*	P=0.132	P=0.278	P=0.024*
POLY 1.5	P=0.031*	P=0.131	P=0.261	P=0.020*
POLY 6	P=0.052	P=0.155	P=0.311	P=0.033*
COCH-ARM / FISHERS	P=0.068	P=0.243	P=0.243	P=0.056
MAX-ISO-POLY-3	P=0.008**	P=0.060	P=0.162	P=0.006**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Spleen: Capsule Fibrosis				
LESION RATES				
OVERALL (a)	8/50 (16%)	0/50 (0%)	8/50 (16%)	41/50 (82%)
POLY-3 RATE (b)	8/46.72	0/46.74	8/46.57	41/46.06
POLY-3 PERCENT (g)	17.1%	0%	17.2%	89%
TERMINAL (d)	4/33 (12%)	0/42 (0%)	5/33 (15%)	20/23 (87%)
FIRST INCIDENCE	547	---	680	459
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.004N**	P=0.605	P<0.001**
POLY 1.5	P<0.001**	P=0.004N**	P=0.606	P<0.001**
POLY 6	P<0.001**	P=0.003N**	P=0.604	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.003N**	P=0.607N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001N**	P=0.496	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Spleen: Capsule Hypertrophy Mesothelium				
LESION RATES				
OVERALL (a)	1/50 (2%)	14/50 (28%)	10/50 (20%)	16/50 (32%)
POLY-3 RATE (b)	1/45.87	14/47.26	10/46.78	16/41.50
POLY-3 PERCENT (g)	2.2%	29.6%	21.4%	38.6%
TERMINAL (d)	0/33 (0%)	12/42 (29%)	8/33 (24%)	10/23 (44%)
FIRST INCIDENCE	698	611	604	468
STATISTICAL TESTS				
POLY 3	P<0.001**	P<0.001**	P=0.004**	P<0.001**
POLY 1.5	P=0.002**	P<0.001**	P=0.004**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P=0.004**	P<0.001**
COCH-ARM / FISHERS	P=0.005**	P<0.001**	P=0.004**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P=0.002**	P<0.001**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Spleen: Lymphoid Follicle Atrophy				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	28/50 (56%)
POLY-3 RATE (b)	1/45.87	2/46.74	0/46.14	28/47.79
POLY-3 PERCENT (g)	2.2%	4.3%	0%	58.6%
TERMINAL (d)	0/33 (0%)	2/42 (5%)	0/33 (0%)	10/23 (44%)
FIRST INCIDENCE	698	728 (T)	---	14
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.507	P=0.499N	P<0.001**
POLY 1.5	P<0.001**	P=0.500	P=0.499N	P<0.001**
POLY 6	P<0.001**	P=0.519	P=0.499N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500	P=0.500N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.288	P=0.159N	P<0.001**

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Spleen: Red Pulp Atrophy				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.75	0/46.74	0/46.14	0/39.33
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Stomach, Forestomach Hyperplasia				
LESION RATES				
OVERALL (a)	5/50 (10%)	1/50 (2%)	4/50 (8%)	4/50 (8%)
POLY-3 RATE (b)	5/46.08	1/46.74	4/46.70	4/39.50
POLY-3 PERCENT (g)	10.9%	2.1%	8.6%	10.1%
TERMINAL (d)	2/33 (6%)	1/42 (2%)	1/33 (3%)	2/23 (9%)
FIRST INCIDENCE	690	728 (T)	659	701
STATISTICAL TESTS				
POLY 3	P=0.377	P=0.098N	P=0.492N	P=0.596N
POLY 1.5	P=0.412	P=0.102N	P=0.495N	P=0.565N
POLY 6	P=0.339	P=0.091N	P=0.487N	P=0.625N
COCH-ARM / FISHERS	P=0.476	P=0.102N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.424N	P=0.044N*	P=0.356N	P=0.459N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Stomach, Forestomach Inflammation				
LESION RATES				
OVERALL (a)	5/50 (10%)	0/50 (0%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	5/46.08	0/46.74	4/46.96	2/39.33
POLY-3 PERCENT (g)	10.9%	0%	8.5%	5.1%
TERMINAL (d)	2/33 (6%)	0/42 (0%)	0/33 (0%)	2/23 (9%)
FIRST INCIDENCE	691	---	659	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.501N	P=0.029N*	P=0.488N	P=0.285N
POLY 1.5	P=0.468N	P=0.031N*	P=0.493N	P=0.262N
POLY 6	P=0.539N	P=0.027N*	P=0.481N	P=0.310N
COCH-ARM / FISHERS	P=0.413N	P=0.028N*	P=0.500N	P=0.218N
MAX-ISO-POLY-3	P=0.219N	P=0.010N**	P=0.353N	P=0.186N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Stomach, Forestomach Ulcer				
LESION RATES				
OVERALL (a)	5/50 (10%)	0/50 (0%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	5/46.08	0/46.74	3/46.70	2/39.33
POLY-3 PERCENT (g)	10.9%	0%	6.4%	5.1%
TERMINAL (d)	2/33 (6%)	0/42 (0%)	0/33 (0%)	2/23 (9%)
FIRST INCIDENCE	691	---	659	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.493N	P=0.029N*	P=0.349N	P=0.285N
POLY 1.5	P=0.464N	P=0.031N*	P=0.352N	P=0.262N
POLY 6	P=0.525N	P=0.027N*	P=0.345N	P=0.310N
COCH-ARM / FISHERS	P=0.418N	P=0.028N*	P=0.357N	P=0.218N
MAX-ISO-POLY-3	P=0.160N	P=0.010N**	P=0.227N	P=0.186N

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Stomach, Glandular Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/45.75	0/46.74	1/46.35	0/39.33
POLY-3 PERCENT (g)	0%	0%	2.2%	0%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	---	---	673	---
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 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Stomach, Glandular Mineralization				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/45.75	0/46.74	0/46.14	0/39.33
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	1/33 (3%)	0/42 (0%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	728 (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 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Stomach, Glandular Ulcer				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/45.75	0/46.74	1/46.35	0/39.33
POLY-3 PERCENT (g)	0%	0%	2.2%	0%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	---	---	673	---
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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Thymus Atrophy				
LESION RATES				
OVERALL (a)	45/47 (96%)	45/50 (90%)	45/50 (90%)	44/48 (92%)
POLY-3 RATE (b)	45/47.00	45/48.32	45/49.54	44/46.18
POLY-3 PERCENT (g)	95.7%	93.1%	90.8%	95.3%
TERMINAL (d)	28/30 (93%)	40/42 (95%)	30/33 (91%)	22/22 (100%)
FIRST INCIDENCE	547	574	604	14
STATISTICAL TESTS				
POLY 3	P=0.536	P=0.456N	P=0.287N	P=0.671N
POLY 1.5	P=0.549N	P=0.413N	P=0.266N	P=0.511N
POLY 6	P=0.362	P=0.502N	P=0.321N	P=0.569
COCH-ARM / FISHERS	P=0.469N	P=0.244N	P=0.244N	P=0.349N
MAX-ISO-POLY-3	P=0.456N	P=0.287N	P=0.168N	P=0.452N

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Thyroid Gland: C-Cell Hyperplasia				
LESION RATES				
OVERALL (a)	29/49 (59%)	33/47 (70%)	15/47 (32%)	4/45 (9%)
POLY-3 RATE (b)	29/46.80	33/46.00	15/43.97	4/37.11
POLY-3 PERCENT (g)	62%	71.7%	34.1%	10.8%
TERMINAL (d)	21/33 (64%)	29/42 (69%)	13/33 (39%)	2/23 (9%)
FIRST INCIDENCE	574	574	709	694
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.216	P=0.005N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.180	P=0.005N**	P<0.001N**
POLY 6	P<0.001N**	P=0.280	P=0.005N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.180	P=0.006N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.157	P=0.003N**	P<0.001N**

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Tooth: Peridental Tissue Inflammation				
LESION RATES				
OVERALL (a)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/0.00	1/1.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	100%	0%	0%
TERMINAL (d)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	728 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Trachea Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.75	0/46.74	0/46.14	2/40.00
POLY-3 PERCENT (g)	0%	0%	0%	5%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	---	---	---	533
STATISTICAL TESTS				
POLY 3	P=0.034*	(e)	(e)	P=0.208
POLY 1.5	P=0.036*	(e)	(e)	P=0.217
POLY 6	P=0.032*	(e)	(e)	P=0.201
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.034*	(e)	(e)	P=0.075

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS

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

Trachea: Peritracheal Tissue
Inflammation

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.75	0/46.74	0/46.14	0/39.33
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Urinary Bladder Hemorrhage				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.75	0/46.74	0/46.14	0/39.33
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Urinary Bladder Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/45.75	0/46.74	0/46.14	1/39.44
POLY-3 PERCENT (g)	0%	0%	0%	2.5%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	---	---	---	701
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 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 02/28/2011

Time Report Requested: 11:17:44

First Dose M/F: 10/20/04 / 10/21/04

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Uterus Hemorrhage				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.75	0/46.74	0/46.14	2/39.52
POLY-3 PERCENT (g)	0%	0%	0%	5.1%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	1/23 (4%)
FIRST INCIDENCE	---	---	---	681
STATISTICAL TESTS				
POLY 3	P=0.034*	(e)	(e)	P=0.206
POLY 1.5	P=0.036*	(e)	(e)	P=0.216
POLY 6	P=0.032*	(e)	(e)	P=0.198
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.034*	(e)	(e)	P=0.075

TDMS No. 20107 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Uterus: Endometrium Hyperplasia Cystic				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.75	0/46.74	0/46.14	2/39.33
POLY-3 PERCENT (g)	0%	0%	0%	5.1%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	2/23 (9%)
FIRST INCIDENCE	---	---	---	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.034*	(e)	(e)	P=0.205
POLY 1.5	P=0.036*	(e)	(e)	P=0.215
POLY 6	P=0.031*	(e)	(e)	P=0.196
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.034*	(e)	(e)	P=0.075

TDMS No. 20107 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

N,N-Dimethyl-p-toluidine

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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 ***