

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

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

Date Report Requested: 01/24/2011
Time Report Requested: 10:59:00
First Dose M/F: 10/20/04 / 10/21/04
Lab: BAT

F1_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: NONE

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HISTORICAL CONTROL STUDIES

From March 2010 report

SAME ROUTE

88105-03 -- Isoeugenol (GAVAGE CORN OIL)
20007-05 -- Kava kava extract (GAVAGE CORN OIL)
99023-03 -- beta-Myrcene (GAVAGE CORN OIL)
99020-05 -- Pulegone (GAVAGE CORN OIL)

ALL ROUTES

99024-07 -- Androstenedione (GAVAGE METHYLCELLULOSE)
99037-05 -- alpha/beta Thujone mixture (GAVAGE METHYLCELLULOSE)
99028-05 -- bis(2-Chloroethoxy)methane (SKIN ETHANOL)
20011-05 -- 1-Bromopropane (INHALATION AIR)
99027-03 -- Chromium picolinate monohydrate (ORAL FEED)
05174-05 -- Cresols (ORAL FEED)
96011-05 -- Cumene (INHALATION AIR)
97003-07 -- 1,2-Dibromo-2,4-dicyanobutane (SKIN ETHANOL)
99017-05 -- Diethylamine (INHALATION AIR)
88123-05 -- Formamide (GAVAGE WATER)
20005-05 -- Ginseng (GAVAGE WATER)
99007-05 -- Goldenseal root powder (ORAL FEED)
95011-07 -- 5-(Hydroxymethyl)-2-furfural (GAVAGE WATER)
88105-03 -- Isoeugenol (GAVAGE CORN OIL)
20007-05 -- Kava kava extract (GAVAGE CORN OIL)
88006-03 -- alpha-Methylstyrene (INHALATION AIR)
20008-03 -- Milk thistle extract (ORAL FEED)
99023-03 -- beta-Myrcene (GAVAGE CORN OIL)
97008-05 -- Propargyl alcohol (INHALATION AIR)
99020-05 -- Pulegone (GAVAGE CORN OIL)
99032-03 -- Pyrogallol (SKIN ETHANOL)
20114-07 -- Sodium dichromate dihydrate (VI) (ORAL WATER)
93025-07 -- Tetralin (INHALATION AIR)

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HISTORICAL CONTROL STUDIES

From March 2010 report

- 88133-07 -- Trimethylolpropane triacrylate (SKIN ACETONE)
- 96019-05 -- Water disinfection byproducts (Bromochloroacetic acid) (ORAL WATER)
- 96015-05 -- Water disinfection byproducts (Dibromoacetonitrile) (ORAL WATER)

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**FOR ALL DOSES THE TUMOR RATES IN THE FOLLOWING TISSUES/ORGANS ARE BASED ON NUMBER OF TISSUES EXAMINED.
IN OTHER TISSUES/ORGANS RATES ARE BASED ON THE NUMBER OF ANIMALS NECROPSIED.**

Adrenal Cortex
Adrenal Medulla
Clitoral/Preputial Gland
Islets, Pancreatic
Liver
Nose
Ovary
Pituitary Gland
Testes
Thyroid Gland

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

MALE RATS

Organ

Liver

Nose

Pituitary Gland: Pars Distalis or Unspecified Site

Skin

Testes

Thyroid Gland: C-Cell

All Organs

Morphology

Hepatocellular Carcinoma
Hepatocellular Carcinoma or Hepatocellular Adenoma
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma
Adenoma
Carcinoma
Adenoma
Carcinoma or Adenoma
Basal Cell Carcinoma
Adenoma
Adenoma
Carcinoma or Adenoma
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated
Malignant and Benign Tumors

FEMALE RATS

Organ

Bone

Liver

Mammary Gland

Ovary

Pituitary Gland: Pars Distalis or Unspecified Site

Skin

Thyroid Gland: C-Cell

Uterus

Morphology

Osteosarcoma
Hepatocellular Adenoma
Hepatocellular Carcinoma
Hepatocellular Carcinoma or Hepatocellular Adenoma
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma
Fibroadenoma
Fibroma, Fibroadenoma, Carcinoma, or Adenoma
Granulosa Cell Tumor: Benign, Malignant, NOS
Adenoma
Carcinoma or Adenoma
Fibrosarcoma
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma
Adenoma
Carcinoma or Adenoma
Polyp Stromal
Sarcoma Stromal or Polyp Stromal

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

All Organs

Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated
Osteosarcoma
Osteosarcoma or Osteoma
Benign Tumors
Malignant Tumors
Malignant and Benign Tumors

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Adenoma				
TUMOR RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/46.00	0/44.99	0/41.44	1/39.04
POLY-3 PERCENT (g)	2.2%	0%	0%	2.6%
TERMINAL (d)	1/37 (3%)	0/37 (0%)	0/31 (0%)	1/21 (5%)
FIRST INCIDENCE	727 (T)	---	---	727 (T)
HC TUMORS SAME ROUTE	3/199 (2%)			
HC TUMORS ALL ROUTES	15/1298 (1%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Medulla				
Pheochromocytoma Benign				
TUMOR RATES				
OVERALL (a)	6/50 (12%)	2/50 (4%)	8/50 (16%)	4/50 (8%)
POLY-3 RATE (b)	6/46.00	2/44.99	8/41.71	4/39.56
POLY-3 PERCENT (g)	13%	4.5%	19.2%	10.1%
TERMINAL (d)	6/37 (16%)	2/37 (5%)	7/31 (23%)	1/21 (5%)
FIRST INCIDENCE	727 (T)	727 (T)	654	616
HC TUMORS SAME ROUTE	29/199 (15%)			
HC TUMORS ALL ROUTES	183/1295 (14%)			
STATISTICAL TESTS				
POLY 3	P=0.531	P=0.140N	P=0.312	P=0.467N
POLY 1.5	P=0.577N	P=0.141N	P=0.328	P=0.431N
POLY 6	P=0.468	P=0.136N	P=0.299	P=0.511N
COCH-ARM / FISHERS	P=0.508N	P=0.134N	P=0.387	P=0.370N
MAX-ISO-POLY-3	P=0.345	P=0.075N	P=0.229	P=0.348N
HISTCONT SAME RTE	P=0.727	P=1.000	P=0.394	P=1.000
HISTCONT ALL RTEs	P=1.000	P=1.000	P=0.340	P=1.000
CURR VS HC SAME RTE	P=0.609			
CURR VS HC ALL RTEs	P=0.534			

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Medulla				
Pheochromocytoma Malignant				
TUMOR RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	1/46.15	0/44.99	3/42.34	1/39.48
POLY-3 PERCENT (g)	2.2%	0%	7.1%	2.5%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	1/31 (3%)	0/21 (0%)
FIRST INCIDENCE	688	---	538	601
HC TUMORS SAME ROUTE	5/199 (3%)			
HC TUMORS ALL ROUTES	24/1295 (2%)			
STATISTICAL TESTS				
POLY 3	P=0.479	P=0.505N	P=0.275	P=0.725
POLY 1.5	P=0.511	P=0.505N	P=0.280	P=0.738
POLY 6	P=0.438	P=0.504N	P=0.271	P=0.707
COCH-ARM / FISHERS	P=0.558	P=0.500N	P=0.309	P=0.753N
MAX-ISO-POLY-3	P=0.273	P=0.165N	P=0.144	P=0.458
HISTCONT SAME RTE	P=0.434	P=1.000	P=0.187	P=1.000
HISTCONT ALL RTES	P=0.338	P=1.000	P=0.041*	P=1.000
CURR VS HC SAME RTE	P=0.836			
CURR VS HC ALL RTES	P=0.999			

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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				
Pheochromocytoma: Benign, Complex, Malignant, NOS				
TUMOR RATES				
OVERALL (a)	8/50 (16%)	3/50 (6%)	11/50 (22%)	5/50 (10%)
POLY-3 RATE (b)	8/46.15	3/45.02	11/42.61	5/39.99
POLY-3 PERCENT (g)	17.3%	6.7%	25.8%	12.5%
TERMINAL (d)	7/37 (19%)	2/37 (5%)	8/31 (26%)	1/21 (5%)
FIRST INCIDENCE	688	721	538	601
HC TUMORS SAME ROUTE	33/199 (17%)			
HC TUMORS ALL ROUTES	208/1295 (16%)			
STATISTICAL TESTS				
POLY 3	P=0.552N	P=0.106N	P=0.238	P=0.374N
POLY 1.5	P=0.499N	P=0.107N	P=0.248	P=0.337N
POLY 6	P=0.518	P=0.103N	P=0.230	P=0.419N
COCH-ARM / FISHERS	P=0.421N	P=0.100N	P=0.306	P=0.277N
MAX-ISO-POLY-3	P=0.310	P=0.060N	P=0.175	P=0.281N
HISTCONT SAME RTE	P=0.614	P=1.000	P=0.197	P=1.000
HISTCONT ALL RTES	P=0.699	P=1.000	P=0.093	P=1.000
CURR VS HC SAME RTE	P=0.873			
CURR VS HC ALL RTES	P=0.833			

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Bone				
Osteosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/46.00	1/45.02	0/41.44	0/39.04
POLY-3 PERCENT (g)	2.2%	2.2%	0%	0%
TERMINAL (d)	1/37 (3%)	0/37 (0%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	727 (T)	721	---	---
HC TUMORS SAME ROUTE	4/199 (2%)			
HC TUMORS ALL ROUTES	16/1298 (1%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Clitoral/Preputial Gland Adenoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/46.00	1/44.99	1/41.44	0/39.04
POLY-3 PERCENT (g)	0%	2.2%	2.4%	0%
TERMINAL (d)	0/37 (0%)	1/37 (3%)	1/31 (3%)	0/21 (0%)
FIRST INCIDENCE	---	727 (T)	727 (T)	---
HC TUMORS SAME ROUTE	10/199 (5%)			
HC TUMORS ALL ROUTES	51/1295 (4%)			
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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TERMINAL SACRIFICE AT 104 WEEKS

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Clitoral/Preputial Gland Carcinoma				
TUMOR 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	---	---	---	---
HC TUMORS SAME ROUTE	4/199 (2%)			
HC TUMORS ALL ROUTES	19/1295 (2%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Clitoral/Preputial Gland Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/46.00	1/44.99	1/41.44	0/39.04
POLY-3 PERCENT (g)	0%	2.2%	2.4%	0%
TERMINAL (d)	0/37 (0%)	1/37 (3%)	1/31 (3%)	0/21 (0%)
FIRST INCIDENCE	---	727 (T)	727 (T)	---
HC TUMORS SAME ROUTE	14/199 (7%)			
HC TUMORS ALL ROUTES	68/1295 (5%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Islets, Pancreatic Adenoma				
TUMOR RATES				
OVERALL (a)	2/50 (4%)	6/50 (12%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	2/46.00	6/45.48	4/41.50	1/39.04
POLY-3 PERCENT (g)	4.4%	13.2%	9.6%	2.6%
TERMINAL (d)	2/37 (5%)	4/37 (11%)	3/31 (10%)	1/21 (5%)
FIRST INCIDENCE	727 (T)	601	712	727 (T)
HC TUMORS SAME ROUTE	12/199 (6%)			
HC TUMORS ALL ROUTES	92/1296 (7%)			
STATISTICAL TESTS				
POLY 3	P=0.222N	P=0.129	P=0.291	P=0.557N
POLY 1.5	P=0.193N	P=0.128	P=0.301	P=0.535N
POLY 6	P=0.263N	P=0.134	P=0.282	P=0.583N
COCH-ARM / FISHERS	P=0.153N	P=0.134	P=0.339	P=0.500N
MAX-ISO-POLY-3	P=0.245N	P=0.067	P=0.177	P=0.341N
HISTCONT SAME RTE	P=0.562	P=0.057	P=0.277	P=1.000
HISTCONT ALL RTEs	P=0.762	P=0.238	P=0.489	P=1.000
CURR VS HC SAME RTE	P=0.534			
CURR VS HC ALL RTEs	P=0.341			

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Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	3/50 (6%)	6/50 (12%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	3/46.00	6/45.48	4/41.50	1/39.04
POLY-3 PERCENT (g)	6.5%	13.2%	9.6%	2.6%
TERMINAL (d)	3/37 (8%)	4/37 (11%)	3/31 (10%)	1/21 (5%)
FIRST INCIDENCE	727 (T)	601	712	727 (T)
HC TUMORS SAME ROUTE	13/199 (7%)			
HC TUMORS ALL ROUTES	117/1296 (9%)			
STATISTICAL TESTS				
POLY 3	P=0.162N	P=0.236	P=0.444	P=0.366N
POLY 1.5	P=0.138N	P=0.234	P=0.456	P=0.343N
POLY 6	P=0.196N	P=0.244	P=0.433	P=0.396N
COCH-ARM / FISHERS	P=0.107N	P=0.243	P=0.500	P=0.309N
MAX-ISO-POLY-3	P=0.213N	P=0.144	P=0.306	P=0.216N
HISTCONT SAME RTE	P=0.615	P=0.058	P=0.334	P=1.000
HISTCONT ALL RTES	P=1.000	P=0.380	P=1.000	P=1.000
CURR VS HC SAME RTE	P=0.853			
CURR VS HC ALL RTES	P=0.381			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Hepatocellular Adenoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/46.00	0/44.99	1/41.59	1/39.25
POLY-3 PERCENT (g)	0%	0%	2.4%	2.6%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	---	---	688	671
HC TUMORS SAME ROUTE	3/199 (2%)			
HC TUMORS ALL ROUTES	15/1298 (1%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Hepatocellular Carcinoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	6/50 (12%)
POLY-3 RATE (b)	0/46.00	0/44.99	1/41.44	6/40.35
POLY-3 PERCENT (g)	0%	0%	2.4%	14.9%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	1/31 (3%)	2/21 (10%)
FIRST INCIDENCE	---	---	727 (T)	612
HC TUMORS SAME ROUTE	0/199 (0%)			
HC TUMORS ALL ROUTES	6/1298 (1%)			
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P=0.479	P=0.009**
POLY 1.5	P<0.001**	(e)	P=0.484	P=0.011*
POLY 6	P<0.001**	(e)	P=0.475	P=0.008**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.500	P=0.013*
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.158	P=0.004**
HISTCONT SAME RTE	P=0.007**	(e)	P=0.173	P=0.010**
HISTCONT ALL RTES	P<0.001**	(e)	P=0.254	P<0.001**
CURR VS HC SAME RTE	P=1.000			
CURR VS HC ALL RTES	P=0.434			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Hepatocellular Carcinoma or Hepatocellular Adenoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	6/50 (12%)
POLY-3 RATE (b)	0/46.00	0/44.99	2/41.59	6/40.35
POLY-3 PERCENT (g)	0%	0%	4.8%	14.9%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	1/31 (3%)	2/21 (10%)
FIRST INCIDENCE	---	---	688	612
HC TUMORS SAME ROUTE	3/199 (2%)			
HC TUMORS ALL ROUTES	21/1298 (2%)			
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P=0.215	P=0.009**
POLY 1.5	P<0.001**	(e)	P=0.220	P=0.011*
POLY 6	P<0.001**	(e)	P=0.211	P=0.008**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.247	P=0.013*
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.076	P=0.004**
HISTCONT SAME RTE	P=0.011*	(e)	P=0.145	P=0.015*
HISTCONT ALL RTES	P<0.001**	(e)	P=0.135	P<0.001**
CURR VS HC SAME RTE	P=0.312			
CURR VS HC ALL RTES	P=0.259			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	6/50 (12%)
POLY-3 RATE (b)	0/46.00	0/44.99	2/41.59	6/40.35
POLY-3 PERCENT (g)	0%	0%	4.8%	14.9%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	1/31 (3%)	2/21 (10%)
FIRST INCIDENCE	---	---	688	612
HC TUMORS SAME ROUTE	3/199 (2%)			
HC TUMORS ALL ROUTES	21/1298 (2%)			
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P=0.215	P=0.009**
POLY 1.5	P<0.001**	(e)	P=0.220	P=0.011*
POLY 6	P<0.001**	(e)	P=0.211	P=0.008**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.247	P=0.013*
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.076	P=0.004**
HISTCONT SAME RTE	P=0.011*	(e)	P=0.145	P=0.015*
HISTCONT ALL RTES	P<0.001**	(e)	P=0.135	P<0.001**
CURR VS HC SAME RTE	P=0.312			
CURR VS HC ALL RTES	P=0.259			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Carcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.00	1/44.99	0/41.44	0/39.04
POLY-3 PERCENT (g)	0%	2.2%	0%	0%
TERMINAL (d)	0/37 (0%)	1/37 (3%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	---	727 (T)	---	---
HC TUMORS SAME ROUTE	0/199 (0%)			
HC TUMORS ALL ROUTES	5/1298 (0%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTEs	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTEs	(n)			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Fibroadenoma				
TUMOR 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	---	---	---	---
HC TUMORS SAME ROUTE	5/199 (3%)			
HC TUMORS ALL ROUTES	41/1298 (3%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Fibroma, Fibroadenoma, Carcinoma, or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.00	1/44.99	0/41.44	0/39.04
POLY-3 PERCENT (g)	0%	2.2%	0%	0%
TERMINAL (d)	0/37 (0%)	1/37 (3%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	---	727 (T)	---	---
HC TUMORS SAME ROUTE	5/199 (3%)			
HC TUMORS ALL ROUTES	51/1298 (4%)			
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Adenoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	3/49 (6%)	2/50 (4%)	11/49 (22%)
POLY-3 RATE (b)	0/46.00	3/44.66	2/41.59	11/40.07
POLY-3 PERCENT (g)	0%	6.7%	4.8%	27.5%
TERMINAL (d)	0/37 (0%)	2/37 (5%)	1/31 (3%)	7/21 (33%)
FIRST INCIDENCE	---	713	688	582
HC TUMORS SAME ROUTE	0/199 (0%)			
HC TUMORS ALL ROUTES	0/1297 (0%)			
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.113	P=0.215	P<0.001**
POLY 1.5	P<0.001**	P=0.112	P=0.220	P<0.001**
POLY 6	P<0.001**	P=0.116	P=0.211	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.117	P=0.247	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.037*	P=0.076	P<0.001**
HISTCONT SAME RTE	P=0.005**	P=0.020*	P=0.042*	P=0.005**
HISTCONT ALL RTES	P<0.001**	P<0.001**	P<0.001**	P<0.001**
CURR VS HC SAME RTE	P=1.000			
CURR VS HC ALL RTES	P=1.000			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Carcinoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	2/49 (4%)
POLY-3 RATE (b)	0/46.00	0/44.60	0/41.44	2/39.13
POLY-3 PERCENT (g)	0%	0%	0%	5.1%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	---	---	---	669
HC TUMORS SAME ROUTE	0/199 (0%)			
HC TUMORS ALL ROUTES	0/1297 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.033*	(e)	(e)	P=0.203
POLY 1.5	P=0.036*	(e)	(e)	P=0.214
POLY 6	P=0.031*	(e)	(e)	P=0.190
COCH-ARM / FISHERS	P=0.041*	(e)	(e)	P=0.242
MAX-ISO-POLY-3	P=0.034*	(e)	(e)	P=0.074
HISTCONT SAME RTE	P=0.030*	(e)	(e)	P=0.043*
HISTCONT ALL RTES	P<0.001**	(e)	(e)	P<0.001**
CURR VS HC SAME RTE	P=1.000			
CURR VS HC ALL RTES	P=1.000			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/46.00	1/44.99	0/41.44	1/39.04
POLY-3 PERCENT (g)	0%	2.2%	0%	2.6%
TERMINAL (d)	0/37 (0%)	1/37 (3%)	0/31 (0%)	1/21 (5%)
FIRST INCIDENCE	---	727 (T)	---	727 (T)
HC TUMORS SAME ROUTE	3/199 (2%)			
HC TUMORS ALL ROUTES	11/1298 (1%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 or Unspecified Site Adenoma				
TUMOR RATES				
OVERALL (a)	23/50 (46%)	27/50 (54%)	18/50 (36%)	15/50 (30%)
POLY-3 RATE (b)	23/47.37	27/46.93	18/42.54	15/40.85
POLY-3 PERCENT (g)	48.6%	57.5%	42.3%	36.7%
TERMINAL (d)	18/37 (49%)	20/37 (54%)	14/31 (45%)	7/21 (33%)
FIRST INCIDENCE	610	512	581	496
HC TUMORS SAME ROUTE	57/199 (29%)			
HC TUMORS ALL ROUTES	604/1293 (47%)			
STATISTICAL TESTS				
POLY 3	P=0.062N	P=0.251	P=0.351N	P=0.180N
POLY 1.5	P=0.037N*	P=0.244	P=0.315N	P=0.131N
POLY 6	P=0.111N	P=0.270	P=0.389N	P=0.253N
COCH-ARM / FISHERS	P=0.018N*	P=0.274	P=0.208N	P=0.074N
MAX-ISO-POLY-3	P=0.100N	P=0.191	P=0.286N	P=0.145N
HISTCONT SAME RTE	P=0.342	P=0.039*	P=0.212	P=0.367
HISTCONT ALL RTES	P=1.000	P=0.345	P=1.000	P=1.000
CURR VS HC SAME RTE	P=0.075			
CURR VS HC ALL RTES	P=0.740			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 or Unspecified Site Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	24/50 (48%)	28/50 (56%)	18/50 (36%)	15/50 (30%)
POLY-3 RATE (b)	24/47.37	28/47.29	18/42.54	15/40.85
POLY-3 PERCENT (g)	50.7%	59.2%	42.3%	36.7%
TERMINAL (d)	19/37 (51%)	20/37 (54%)	14/31 (45%)	7/21 (33%)
FIRST INCIDENCE	610	512	581	496
HC TUMORS SAME ROUTE	57/199 (29%)			
HC TUMORS ALL ROUTES	605/1293 (47%)			
STATISTICAL TESTS				
POLY 3	P=0.040N*	P=0.264	P=0.279N	P=0.132N
POLY 1.5	P=0.022N*	P=0.250	P=0.247N	P=0.093N
POLY 6	P=0.077N	P=0.294	P=0.314N	P=0.194N
COCH-ARM / FISHERS	P=0.010N**	P=0.274	P=0.156N	P=0.050N*
MAX-ISO-POLY-3	P=0.064N	P=0.201	P=0.224N	P=0.105N
HISTCONT SAME RTE	P=0.337	P=0.033*	P=0.212	P=0.367
HISTCONT ALL RTES	P=1.000	P=0.302	P=1.000	P=1.000
CURR VS HC SAME RTE	P=0.045*			
CURR VS HC ALL RTES	P=0.949			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin				
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/46.00	0/44.99	1/41.44	2/39.43
POLY-3 PERCENT (g)	2.2%	0%	2.4%	5.1%
TERMINAL (d)	1/37 (3%)	0/37 (0%)	1/31 (3%)	1/21 (5%)
FIRST INCIDENCE	727 (T)	---	727 (T)	616
HC TUMORS SAME ROUTE	2/199 (1%)			
HC TUMORS ALL ROUTES	21/1298 (2%)			
STATISTICAL TESTS				
POLY 3	P=0.196	P=0.504N	P=0.737	P=0.447
POLY 1.5	P=0.210	P=0.505N	P=0.742	P=0.466
POLY 6	P=0.179	P=0.503N	P=0.732	P=0.423
COCH-ARM / FISHERS	P=0.231	P=0.500N	P=0.753N	P=0.500
MAX-ISO-POLY-3	P=0.215	P=0.164N	P=0.471	P=0.253
HISTCONT SAME RTE	P=0.135	P=1.000	P=1.000	P=0.169
HISTCONT ALL RTES	P=0.183	P=1.000	P=1.000	P=0.146
CURR VS HC SAME RTE	P=0.740			
CURR VS HC ALL RTES	P=0.889			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin				
Basal Cell Carcinoma				
TUMOR 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)	---
HC TUMORS SAME ROUTE	2/199 (1%)			
HC TUMORS ALL ROUTES	11/1298 (1%)			
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)
HISTCONT SAME RTE	P=0.361	P=1.000	P=0.042*	(e)
HISTCONT ALL RTES	P=0.229	P=0.474	P<0.001**	(e)
CURR VS HC SAME RTE	P=0.377			
CURR VS HC ALL RTES	P=0.450			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin				
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	1/46.00	1/44.99	4/41.44	2/39.43
POLY-3 PERCENT (g)	2.2%	2.2%	9.7%	5.1%
TERMINAL (d)	1/37 (3%)	1/37 (3%)	4/31 (13%)	1/21 (5%)
FIRST INCIDENCE	727 (T)	727 (T)	727 (T)	616
HC TUMORS SAME ROUTE	4/199 (2%)			
HC TUMORS ALL ROUTES	32/1298 (3%)			
STATISTICAL TESTS				
POLY 3	P=0.326	P=0.756	P=0.148	P=0.447
POLY 1.5	P=0.360	P=0.755	P=0.155	P=0.466
POLY 6	P=0.285	P=0.758	P=0.142	P=0.423
COCH-ARM / FISHERS	P=0.414	P=0.753N	P=0.181	P=0.500
MAX-ISO-POLY-3	P=0.235	P=0.493	P=0.076	P=0.253
HISTCONT SAME RTE	P=0.168	P=1.000	P=0.038*	P=0.257
HISTCONT ALL RTEs	P=0.177	P=1.000	P=0.010**	P=0.350
CURR VS HC SAME RTE	P=0.947			
CURR VS HC ALL RTEs	P=0.773			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin				
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma				
TUMOR RATES	#	#	#	#
OVERALL (a)	4/50 (8%)	4/50 (8%)	6/50 (12%)	4/50 (8%)
POLY-3 RATE (b)	4/46.00	4/44.99	6/41.52	4/39.68
POLY-3 PERCENT (g)	8.7%	8.9%	14.5%	10.1%
TERMINAL (d)	4/37 (11%)	4/37 (11%)	5/31 (16%)	2/21 (10%)
FIRST INCIDENCE	727 (T)	727 (T)	707	616
HC TUMORS SAME ROUTE	16/199 (8%)			
HC TUMORS ALL ROUTES	112/1298 (9%)			
STATISTICAL TESTS				
POLY 3	P=0.484	P=0.631	P=0.307	P=0.560
POLY 1.5	P=0.528	P=0.630	P=0.320	P=0.591
POLY 6	P=0.431	P=0.637	P=0.294	P=0.523
COCH-ARM / FISHERS	P=0.571N	P=0.643N	P=0.370	P=0.643N
MAX-ISO-POLY-3	P=0.491	P=0.486	P=0.212	P=0.418
HISTCONT SAME RTE	P=0.475	P=1.000	P=0.217	P=1.000
HISTCONT ALL RTES	P=0.612	P=1.000	P=0.251	P=1.000
CURR VS HC SAME RTE	P=0.966			
CURR VS HC ALL RTES	P=0.767			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin				
Fibroma				
TUMOR RATES	#	#	#	#
OVERALL (a)	6/50 (12%)	4/50 (8%)	5/50 (10%)	3/50 (6%)
POLY-3 RATE (b)	6/46.30	4/44.99	5/41.84	3/39.45
POLY-3 PERCENT (g)	13%	8.9%	12%	7.6%
TERMINAL (d)	5/37 (14%)	4/37 (11%)	4/31 (13%)	1/21 (5%)
FIRST INCIDENCE	645	727 (T)	612	645
HC TUMORS SAME ROUTE	18/199 (9%)			
HC TUMORS ALL ROUTES	113/1298 (9%)			
STATISTICAL TESTS				
POLY 3	P=0.339N	P=0.388N	P=0.571N	P=0.327N
POLY 1.5	P=0.303N	P=0.387N	P=0.555N	P=0.294N
POLY 6	P=0.386N	P=0.384N	P=0.585N	P=0.368N
COCH-ARM / FISHERS	P=0.253N	P=0.370N	P=0.500N	P=0.243N
MAX-ISO-POLY-3	P=0.373N	P=0.271N	P=0.444N	P=0.229N
HISTCONT SAME RTE	P=1.000	P=1.000	P=0.457	P=1.000
HISTCONT ALL RTES	P=1.000	P=1.000	P=0.442	P=1.000
CURR VS HC SAME RTE	P=0.581			
CURR VS HC ALL RTES	P=0.521			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin				
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	6/50 (12%)	5/50 (10%)	6/50 (12%)	3/50 (6%)
POLY-3 RATE (b)	6/46.30	5/45.12	6/42.15	3/39.45
POLY-3 PERCENT (g)	13%	11.1%	14.2%	7.6%
TERMINAL (d)	5/37 (14%)	4/37 (11%)	4/31 (13%)	1/21 (5%)
FIRST INCIDENCE	645	695	612	645
HC TUMORS SAME ROUTE	21/199 (11%)			
HC TUMORS ALL ROUTES	143/1298 (11%)			
STATISTICAL TESTS				
POLY 3	P=0.301N	P=0.518N	P=0.554	P=0.327N
POLY 1.5	P=0.263N	P=0.518N	P=0.567	P=0.294N
POLY 6	P=0.351N	P=0.513N	P=0.543	P=0.368N
COCH-ARM / FISHERS	P=0.210N	P=0.500N	P=0.620N	P=0.243N
MAX-ISO-POLY-3	P=0.389N	P=0.391N	P=0.432	P=0.229N
HISTCONT SAME RTE	P=1.000	P=1.000	P=0.393	P=1.000
HISTCONT ALL RTES	P=1.000	P=1.000	P=0.477	P=1.000
CURR VS HC SAME RTE	P=0.826			
CURR VS HC ALL RTES	P=0.961			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin				
Fibrosarcoma				
TUMOR 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	---	---	---	---
HC TUMORS SAME ROUTE	1/199 (1%)			
HC TUMORS ALL ROUTES	17/1298 (1%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin				
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/46.00	1/45.12	1/41.75	0/39.04
POLY-3 PERCENT (g)	0%	2.2%	2.4%	0%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	---	695	643	---
HC TUMORS SAME ROUTE	3/199 (2%)			
HC TUMORS ALL ROUTES	31/1298 (2%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin				
Keratoacanthoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	3/50 (6%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	3/46.00	3/44.99	2/41.52	2/39.29
POLY-3 PERCENT (g)	6.5%	6.7%	4.8%	5.1%
TERMINAL (d)	3/37 (8%)	3/37 (8%)	1/31 (3%)	1/21 (5%)
FIRST INCIDENCE	727 (T)	727 (T)	707	661
HC TUMORS SAME ROUTE	12/199 (6%)			
HC TUMORS ALL ROUTES	67/1298 (5%)			
STATISTICAL TESTS				
POLY 3	P=0.473N	P=0.652	P=0.546N	P=0.571N
POLY 1.5	P=0.447N	P=0.651	P=0.536N	P=0.545N
POLY 6	P=0.506N	P=0.657	P=0.556N	P=0.603N
COCH-ARM / FISHERS	P=0.407N	P=0.661N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.601N	P=0.488	P=0.372N	P=0.396N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	P=1.000	P=1.000	P=1.000	P=1.000
CURR VS HC SAME RTE	P=0.960			
CURR VS HC ALL RTEs	P=0.884			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin				
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	3/50 (6%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	3/46.00	3/44.99	2/41.52	3/39.29
POLY-3 PERCENT (g)	6.5%	6.7%	4.8%	7.6%
TERMINAL (d)	3/37 (8%)	3/37 (8%)	1/31 (3%)	2/21 (10%)
FIRST INCIDENCE	727 (T)	727 (T)	707	661
HC TUMORS SAME ROUTE	12/199 (6%)			
HC TUMORS ALL ROUTES	83/1298 (6%)			
STATISTICAL TESTS				
POLY 3	P=0.519	P=0.652	P=0.546N	P=0.588
POLY 1.5	P=0.550	P=0.651	P=0.536N	P=0.616
POLY 6	P=0.481	P=0.657	P=0.556N	P=0.553
COCH-ARM / FISHERS	P=0.597	P=0.661N	P=0.500N	P=0.661N
MAX-ISO-POLY-3	P=0.612	P=0.488	P=0.372N	P=0.425
HISTCONT SAME RTE	P=0.675	P=1.000	P=1.000	P=1.000
HISTCONT ALL RTES	P=0.761	P=1.000	P=1.000	P=1.000
CURR VS HC SAME RTE	P=0.960			
CURR VS HC ALL RTES	P=0.814			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin				
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	3/50 (6%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	3/46.00	3/44.99	2/41.52	3/39.29
POLY-3 PERCENT (g)	6.5%	6.7%	4.8%	7.6%
TERMINAL (d)	3/37 (8%)	3/37 (8%)	1/31 (3%)	2/21 (10%)
FIRST INCIDENCE	727 (T)	727 (T)	707	661
HC TUMORS SAME ROUTE	12/199 (6%)			
HC TUMORS ALL ROUTES	77/1298 (6%)			
STATISTICAL TESTS				
POLY 3	P=0.519	P=0.652	P=0.546N	P=0.588
POLY 1.5	P=0.550	P=0.651	P=0.536N	P=0.616
POLY 6	P=0.481	P=0.657	P=0.556N	P=0.553
COCH-ARM / FISHERS	P=0.597	P=0.661N	P=0.500N	P=0.661N
MAX-ISO-POLY-3	P=0.612	P=0.488	P=0.372N	P=0.425
HISTCONT SAME RTE	P=0.675	P=1.000	P=1.000	P=1.000
HISTCONT ALL RTEs	P=0.721	P=1.000	P=1.000	P=1.000
CURR VS HC SAME RTE	P=0.960			
CURR VS HC ALL RTEs	P=0.918			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin: Sebaceous Gland Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/46.00	0/44.99	2/41.52	1/39.04
POLY-3 PERCENT (g)	2.2%	0%	4.8%	2.6%
TERMINAL (d)	1/37 (3%)	0/37 (0%)	1/31 (3%)	1/21 (5%)
FIRST INCIDENCE	727 (T)	---	707	727 (T)
HC TUMORS SAME ROUTE	2/199 (1%)			
HC TUMORS ALL ROUTES	7/1298 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.483	P=0.504N	P=0.464	P=0.723
POLY 1.5	P=0.511	P=0.505N	P=0.472	P=0.737
POLY 6	P=0.446	P=0.503N	P=0.457	P=0.704
COCH-ARM / FISHERS	P=0.552	P=0.500N	P=0.500	P=0.753N
MAX-ISO-POLY-3	P=0.378	P=0.164N	P=0.261	P=0.456
HISTCONT SAME RTE	P=0.198	P=1.000	P=0.114	P=1.000
HISTCONT ALL RTES	P=0.067	P=1.000	P=0.004**	P=0.278
CURR VS HC SAME RTE	P=0.650			
CURR VS HC ALL RTES	P=0.207			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Adenoma				
TUMOR RATES				
OVERALL (a)	40/50 (80%)	36/50 (72%)	43/50 (86%)	37/50 (74%)
POLY-3 RATE (b)	40/47.49	36/45.33	43/45.45	37/43.62
POLY-3 PERCENT (g)	84.2%	79.4%	94.6%	84.8%
TERMINAL (d)	34/37 (92%)	32/37 (87%)	29/31 (94%)	19/21 (91%)
FIRST INCIDENCE	609	695	538	384
HC TUMORS SAME ROUTE	176/199 (88%)			
HC TUMORS ALL ROUTES	1053/1298 (81%)			
STATISTICAL TESTS				
POLY 3	P=0.418	P=0.363N	P=0.083	P=0.591
POLY 1.5	P=0.547	P=0.334N	P=0.088	P=0.530N
POLY 6	P=0.294	P=0.386N	P=0.114	P=0.482
COCH-ARM / FISHERS	P=0.391N	P=0.241N	P=0.298	P=0.318N
MAX-ISO-POLY-3	P=0.206	P=0.267N	P=0.043*	P=0.466
HISTCONT SAME RTE	P=1.000	P=1.000	P=0.453	P=1.000
HISTCONT ALL RTES	P=0.621	P=1.000	P=0.175	P=1.000
CURR VS HC SAME RTE	P=0.131			
CURR VS HC ALL RTES	P=0.604			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Adenoma				
TUMOR RATES				
OVERALL (a)	11/50 (22%)	7/49 (14%)	8/50 (16%)	3/49 (6%)
POLY-3 RATE (b)	11/46.69	7/44.60	8/42.17	3/39.11
POLY-3 PERCENT (g)	23.6%	15.7%	19%	7.7%
TERMINAL (d)	8/37 (22%)	7/37 (19%)	5/31 (16%)	2/21 (10%)
FIRST INCIDENCE	612	727 (T)	616	669
HC TUMORS SAME ROUTE	37/199 (19%)			
HC TUMORS ALL ROUTES	169/1290 (13%)			
STATISTICAL TESTS				
POLY 3	P=0.057N	P=0.248N	P=0.395N	P=0.044N*
POLY 1.5	P=0.043N*	P=0.248N	P=0.376N	P=0.034N*
POLY 6	P=0.081N	P=0.245N	P=0.413N	P=0.061N
COCH-ARM / FISHERS	P=0.030N*	P=0.232N	P=0.306N	P=0.022N*
MAX-ISO-POLY-3	P=0.057N	P=0.177N	P=0.309N	P=0.032N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	P=1.000	P=1.000	P=0.291	P=1.000
CURR VS HC SAME RTE	P=0.639			
CURR VS HC ALL RTEs	P=0.103			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	11/50 (22%)	8/49 (16%)	8/50 (16%)	3/49 (6%)
POLY-3 RATE (b)	11/46.69	8/44.60	8/42.17	3/39.11
POLY-3 PERCENT (g)	23.6%	17.9%	19%	7.7%
TERMINAL (d)	8/37 (22%)	8/37 (22%)	5/31 (16%)	2/21 (10%)
FIRST INCIDENCE	612	727 (T)	616	669
HC TUMORS SAME ROUTE	43/199 (22%)			
HC TUMORS ALL ROUTES	198/1290 (15%)			
STATISTICAL TESTS				
POLY 3	P=0.047N*	P=0.344N	P=0.395N	P=0.044N*
POLY 1.5	P=0.035N*	P=0.343N	P=0.376N	P=0.034N*
POLY 6	P=0.067N	P=0.340N	P=0.413N	P=0.061N
COCH-ARM / FISHERS	P=0.024N*	P=0.323N	P=0.306N	P=0.022N*
MAX-ISO-POLY-3	P=0.060N	P=0.259N	P=0.309N	P=0.032N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	P=1.000	P=1.000	P=0.496	P=1.000
CURR VS HC SAME RTE	P=0.977			
CURR VS HC ALL RTES	P=0.294			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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: Follicular Cell Adenoma				
TUMOR RATES				
OVERALL (a)	1/50 (2%)	0/49 (0%)	1/50 (2%)	3/49 (6%)
POLY-3 RATE (b)	1/46.00	0/44.60	1/41.62	3/38.89
POLY-3 PERCENT (g)	2.2%	0%	2.4%	7.7%
TERMINAL (d)	1/37 (3%)	0/37 (0%)	0/31 (0%)	3/21 (14%)
FIRST INCIDENCE	727 (T)	---	680	727 (T)
HC TUMORS SAME ROUTE	3/199 (2%)			
HC TUMORS ALL ROUTES	12/1290 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.060	P=0.506N	P=0.738	P=0.248
POLY 1.5	P=0.067	P=0.507N	P=0.743	P=0.267
POLY 6	P=0.052	P=0.503N	P=0.734	P=0.225
COCH-ARM / FISHERS	P=0.078	P=0.505N	P=0.753N	P=0.301
MAX-ISO-POLY-3	P=0.078	P=0.165N	P=0.472	P=0.134
HISTCONT SAME RTE	P=0.037*	P=1.000	P=1.000	P=0.046*
HISTCONT ALL RTES	P=0.004**	P=1.000	P=0.479	P<0.001**
CURR VS HC SAME RTE	P=0.845			
CURR VS HC ALL RTES	P=0.487			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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: Follicular Cell Carcinoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	2/49 (4%)	1/50 (2%)	2/49 (4%)
POLY-3 RATE (b)	0/46.00	2/44.60	1/41.44	2/38.89
POLY-3 PERCENT (g)	0%	4.5%	2.4%	5.1%
TERMINAL (d)	0/37 (0%)	2/37 (5%)	1/31 (3%)	2/21 (10%)
FIRST INCIDENCE	---	727 (T)	727 (T)	727 (T)
HC TUMORS SAME ROUTE	3/199 (2%)			
HC TUMORS ALL ROUTES	11/1290 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.261	P=0.230	P=0.479	P=0.202
POLY 1.5	P=0.281	P=0.229	P=0.484	P=0.213
POLY 6	P=0.237	P=0.233	P=0.475	P=0.187
COCH-ARM / FISHERS	P=0.313	P=0.242	P=0.500	P=0.242
MAX-ISO-POLY-3	P=0.160	P=0.075	P=0.158	P=0.074
HISTCONT SAME RTE	P=0.186	P=0.242	P=1.000	P=0.208
HISTCONT ALL RTES	P=0.022*	P=0.029*	P=0.446	P=0.024*
CURR VS HC SAME RTE	P=0.382			
CURR VS HC ALL RTES	P=0.445			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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: Follicular Cell Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	1/50 (2%)	2/49 (4%)	2/50 (4%)	4/49 (8%)
POLY-3 RATE (b)	1/46.00	2/44.60	2/41.62	4/38.89
POLY-3 PERCENT (g)	2.2%	4.5%	4.8%	10.3%
TERMINAL (d)	1/37 (3%)	2/37 (5%)	1/31 (3%)	4/21 (19%)
FIRST INCIDENCE	727 (T)	727 (T)	680	727 (T)
HC TUMORS SAME ROUTE	6/199 (3%)			
HC TUMORS ALL ROUTES	23/1290 (2%)			
STATISTICAL TESTS				
POLY 3	P=0.088	P=0.489	P=0.465	P=0.132
POLY 1.5	P=0.101	P=0.487	P=0.472	P=0.147
POLY 6	P=0.073	P=0.494	P=0.459	P=0.114
COCH-ARM / FISHERS	P=0.122	P=0.492	P=0.500	P=0.175
MAX-ISO-POLY-3	P=0.100	P=0.273	P=0.262	P=0.071
HISTCONT SAME RTE	P=0.063	P=1.000	P=1.000	P=0.077
HISTCONT ALL RTES	P=0.004**	P=0.253	P=0.230	P=0.002**
CURR VS HC SAME RTE	P=0.690			
CURR VS HC ALL RTES	P=0.966			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Tongue				
Squamous Cell Carcinoma or Papilloma Squamous				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/46.00	1/44.99	0/41.44	1/39.04
POLY-3 PERCENT (g)	0%	2.2%	0%	2.6%
TERMINAL (d)	0/37 (0%)	1/37 (3%)	0/31 (0%)	1/21 (5%)
FIRST INCIDENCE	---	727 (T)	---	727 (T)
HC TUMORS SAME ROUTE	0/199 (0%)			
HC TUMORS ALL ROUTES	6/1298 (1%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Zymbal's Gland Carcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/46.00	0/44.99	2/41.69	1/39.31
POLY-3 PERCENT (g)	0%	0%	4.8%	2.5%
TERMINAL (d)	0/37 (0%)	0/37 (0%)	1/31 (3%)	0/21 (0%)
FIRST INCIDENCE	---	---	661	656
HC TUMORS SAME ROUTE	2/199 (1%)			
HC TUMORS ALL ROUTES	6/1298 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.286	(e)	P=0.216	P=0.469
POLY 1.5	P=0.310	(e)	P=0.220	P=0.480
POLY 6	P=0.256	(e)	P=0.212	P=0.455
COCH-ARM / FISHERS	P=0.350	(e)	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.186	(e)	P=0.076	P=0.158
HISTCONT SAME RTE	P=0.277	(e)	P=0.170	P=1.000
HISTCONT ALL RTES	P=0.048*	(e)	P=0.002**	P=0.236
CURR VS HC SAME RTE	P=0.481			
CURR VS HC ALL RTES	P=0.440			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Zymbal's Gland Carcinoma or Adenoma				
TUMOR 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	2/41.69	2/39.31
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	---	---	661	656
HC TUMORS SAME ROUTE	2/199 (1%)			
HC TUMORS ALL ROUTES	10/1298 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.089	(e)	P=0.216	P=0.204
POLY 1.5	P=0.101	(e)	P=0.220	P=0.216
POLY 6	P=0.076	(e)	P=0.212	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
HISTCONT SAME RTE	P=0.120	(e)	P=0.170	P=0.163
HISTCONT ALL RTES	P=0.006**	(e)	P=0.015*	P=0.014*
CURR VS HC SAME RTE	P=0.481			
CURR VS HC ALL RTES	P=0.465			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
All Organs				
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated				
TUMOR RATES	#	#	#	#
OVERALL (a)	14/50 (28%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	14/48.76	1/45.36	2/41.80	0/39.04
POLY-3 PERCENT (g)	28.7%	2.2%	4.8%	0%
TERMINAL (d)	5/37 (14%)	0/37 (0%)	1/31 (3%)	0/21 (0%)
FIRST INCIDENCE	337	624	626	---
HC TUMORS SAME ROUTE	30/199 (15%)			
HC TUMORS ALL ROUTES	502/1298 (39%)			
STATISTICAL TESTS				
POLY 3	P<0.001N**	P<0.001N**	P=0.003N**	P<0.001N**
POLY 1.5	P<0.001N**	P<0.001N**	P=0.002N**	P<0.001N**
POLY 6	P<0.001N**	P<0.001N**	P=0.004N**	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=0.002N**	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.052			
CURR VS HC ALL RTES	P=0.054			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
All Organs				
Mesothelioma: Benign, Malignant, NOS				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	1/46.00	2/44.99	3/42.07	1/39.04
POLY-3 PERCENT (g)	2.2%	4.5%	7.1%	2.6%
TERMINAL (d)	1/37 (3%)	2/37 (5%)	1/31 (3%)	1/21 (5%)
FIRST INCIDENCE	727 (T)	727 (T)	626	727 (T)
HC TUMORS SAME ROUTE	10/199 (5%)			
HC TUMORS ALL ROUTES	32/1298 (3%)			
STATISTICAL TESTS				
POLY 3	P=0.588N	P=0.492	P=0.274	P=0.723
POLY 1.5	P=0.557N	P=0.492	P=0.280	P=0.737
POLY 6	P=0.613	P=0.496	P=0.270	P=0.704
COCH-ARM / FISHERS	P=0.510N	P=0.500	P=0.309	P=0.753N
MAX-ISO-POLY-3	P=0.450	P=0.276	P=0.143	P=0.456
HISTCONT SAME RTE	P=1.000	P=1.000	P=0.475	P=1.000
HISTCONT ALL RTES	P=0.412	P=0.403	P=0.057	P=1.000
CURR VS HC SAME RTE	P=0.304			
CURR VS HC ALL RTES	P=0.774			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
All Organs				
Mesothelioma: Malignant				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	1/46.00	2/44.99	3/42.07	1/39.04
POLY-3 PERCENT (g)	2.2%	4.5%	7.1%	2.6%
TERMINAL (d)	1/37 (3%)	2/37 (5%)	1/31 (3%)	1/21 (5%)
FIRST INCIDENCE	727 (T)	727 (T)	626	727 (T)
HC TUMORS SAME ROUTE	10/199 (5%)			
HC TUMORS ALL ROUTES	31/1298 (2%)			
STATISTICAL TESTS				
POLY 3	P=0.588N	P=0.492	P=0.274	P=0.723
POLY 1.5	P=0.557N	P=0.492	P=0.280	P=0.737
POLY 6	P=0.613	P=0.496	P=0.270	P=0.704
COCH-ARM / FISHERS	P=0.510N	P=0.500	P=0.309	P=0.753N
MAX-ISO-POLY-3	P=0.450	P=0.276	P=0.143	P=0.456
HISTCONT SAME RTE	P=1.000	P=1.000	P=0.475	P=1.000
HISTCONT ALL RTES	P=0.405	P=0.385	P=0.056	P=1.000
CURR VS HC SAME RTE	P=0.304			
CURR VS HC ALL RTES	P=0.800			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
All Organs				
Osteosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/46.00	1/45.02	0/41.44	0/39.04
POLY-3 PERCENT (g)	2.2%	2.2%	0%	0%
TERMINAL (d)	1/37 (3%)	0/37 (0%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	727 (T)	721	---	---
HC TUMORS SAME ROUTE	4/199 (2%)			
HC TUMORS ALL ROUTES	17/1298 (1%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
All Organs				
Osteosarcoma or Osteoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/46.00	1/45.02	0/41.44	0/39.04
POLY-3 PERCENT (g)	2.2%	2.2%	0%	0%
TERMINAL (d)	1/37 (3%)	0/37 (0%)	0/31 (0%)	0/21 (0%)
FIRST INCIDENCE	727 (T)	721	---	---
HC TUMORS SAME ROUTE	4/199 (2%)			
HC TUMORS ALL ROUTES	18/1298 (1%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
All Organs				
Benign Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	48/50 (96%)	46/50 (92%)	46/50 (92%)	43/50 (86%)
POLY-3 RATE (b)	48/48.86	46/47.11	46/46.08	43/45.25
POLY-3 PERCENT (g)	98.2%	97.7%	99.8%	95%
TERMINAL (d)	37/37 (100%)	37/37 (100%)	31/31 (100%)	21/21 (100%)
FIRST INCIDENCE	609	512	519	384
HC TUMORS SAME ROUTE	194/199 (98%)			
HC TUMORS ALL ROUTES	1248/1298 (96%)			
STATISTICAL TESTS				
POLY 3	P=0.173N	P=0.747N	P=0.626	P=0.348N
POLY 1.5	P=0.076N	P=0.613N	P=0.656	P=0.184N
POLY 6	P=0.453N	P=0.913	P=0.769	P=0.686N
COCH-ARM / FISHERS	P=0.067N	P=0.339N	P=0.339N	P=0.080N
MAX-ISO-POLY-3	P=0.105N	P=0.396N	P=0.172	P=0.132N
HISTCONT SAME RTE	P=1.000	P=1.000	P=1.000	P=1.000
HISTCONT ALL RTES	P=1.000	P=1.000	P=0.390	P=1.000
CURR VS HC SAME RTE	P=0.089			
CURR VS HC ALL RTES	P=0.903			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
All Organs				
Malignant Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	20/50 (40%)	13/50 (26%)	16/50 (32%)	15/50 (30%)
POLY-3 RATE (b)	20/48.94	13/46.45	16/44.07	15/41.28
POLY-3 PERCENT (g)	40.9%	28%	36.3%	36.3%
TERMINAL (d)	10/37 (27%)	8/37 (22%)	8/31 (26%)	7/21 (33%)
FIRST INCIDENCE	337	324	538	601
HC TUMORS SAME ROUTE	79/199 (40%)			
HC TUMORS ALL ROUTES	721/1298 (56%)			
STATISTICAL TESTS				
POLY 3	P=0.535	P=0.134N	P=0.407N	P=0.412N
POLY 1.5	P=0.486N	P=0.125N	P=0.379N	P=0.329N
POLY 6	P=0.444	P=0.144N	P=0.427N	P=0.511N
COCH-ARM / FISHERS	P=0.353N	P=0.101N	P=0.266N	P=0.201N
MAX-ISO-POLY-3	P=0.401N	P=0.098N	P=0.334N	P=0.342N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.950			
CURR VS HC ALL RTES	P=0.014*			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
All Organs				
Malignant and Benign Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	49/50 (98%)	48/50 (96%)	46/50 (92%)	44/50 (88%)
POLY-3 RATE (b)	49/49.76	48/48.39	46/46.08	44/45.65
POLY-3 PERCENT (g)	98.5%	99.2%	99.8%	96.4%
TERMINAL (d)	37/37 (100%)	37/37 (100%)	31/31 (100%)	21/21 (100%)
FIRST INCIDENCE	337	324	519	384
HC TUMORS SAME ROUTE	196/199 (99%)			
HC TUMORS ALL ROUTES	1286/1298 (99%)			
STATISTICAL TESTS				
POLY 3	P=0.210N	P=0.772	P=0.677	P=0.501N
POLY 1.5	P=0.057N	P=0.769	P=0.778	P=0.238N
POLY 6	P=0.608N	P=0.832	P=0.776	P=0.843N
COCH-ARM / FISHERS	P=0.031N*	P=0.500N	P=0.181N	P=0.056N
MAX-ISO-POLY-3	P=0.114N	P=0.340	P=0.208	P=0.205N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.119			
CURR VS HC ALL RTES	P<0.001**			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Adenoma				
TUMOR RATES				
OVERALL (a)	3/50 (6%)	3/50 (6%)	1/50 (2%)	2/49 (4%)
POLY-3 RATE (b)	3/45.75	3/46.74	1/46.55	2/38.73
POLY-3 PERCENT (g)	6.6%	6.4%	2.2%	5.2%
TERMINAL (d)	3/33 (9%)	3/42 (7%)	0/33 (0%)	1/23 (4%)
FIRST INCIDENCE	728 (T)	728 (T)	613	682
HC TUMORS SAME ROUTE	0/200 (0%)			
HC TUMORS ALL ROUTES	24/1245 (2%)			
STATISTICAL TESTS				
POLY 3	P=0.473N	P=0.652N	P=0.299N	P=0.575N
POLY 1.5	P=0.456N	P=0.661N	P=0.302N	P=0.555N
POLY 6	P=0.489N	P=0.635N	P=0.295N	P=0.593N
COCH-ARM / FISHERS	P=0.420N	P=0.661N	P=0.309N	P=0.510N
MAX-ISO-POLY-3	P=0.457N	P=0.488N	P=0.152N	P=0.400N
HISTCONT SAME RTE	P=0.130	P=0.019*	P=0.173	P=0.043*
HISTCONT ALL RTES	P=0.433	P=0.134	P=1.000	P=0.309
CURR VS HC SAME RTE	P=0.002**			
CURR VS HC ALL RTES	P=0.057			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Pheochromocytoma Benign				
TUMOR RATES				
OVERALL (a)	2/50 (4%)	2/50 (4%)	1/50 (2%)	1/49 (2%)
POLY-3 RATE (b)	2/46.19	2/46.74	1/46.23	1/38.55
POLY-3 PERCENT (g)	4.3%	4.3%	2.2%	2.6%
TERMINAL (d)	1/33 (3%)	2/42 (5%)	0/33 (0%)	1/23 (4%)
FIRST INCIDENCE	600	728 (T)	705	728 (T)
HC TUMORS SAME ROUTE	9/200 (5%)			
HC TUMORS ALL ROUTES	32/1238 (3%)			
STATISTICAL TESTS				
POLY 3	P=0.437N	P=0.690N	P=0.500N	P=0.562N
POLY 1.5	P=0.421N	P=0.692	P=0.500N	P=0.545N
POLY 6	P=0.453N	P=0.679N	P=0.500N	P=0.579N
COCH-ARM / FISHERS	P=0.389N	P=0.691N	P=0.500N	P=0.508N
MAX-ISO-POLY-3	P=0.521N	P=0.494N	P=0.280N	P=0.346N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	P=0.772	P=0.443	P=1.000	P=1.000
CURR VS HC SAME RTE	P=0.801			
CURR VS HC ALL RTEs	P=0.588			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Pheochromocytoma Malignant				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/49 (0%)
POLY-3 RATE (b)	0/45.75	0/46.74	1/46.33	0/38.55
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	---	---	680	---
HC TUMORS SAME ROUTE	0/200 (0%)			
HC TUMORS ALL ROUTES	7/1238 (1%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Pheochromocytoma: Benign, Complex, Malignant, NOS				
TUMOR RATES				
OVERALL (a)	2/50 (4%)	2/50 (4%)	2/50 (4%)	1/49 (2%)
POLY-3 RATE (b)	2/46.19	2/46.74	2/46.42	1/38.55
POLY-3 PERCENT (g)	4.3%	4.3%	4.3%	2.6%
TERMINAL (d)	1/33 (3%)	2/42 (5%)	0/33 (0%)	1/23 (4%)
FIRST INCIDENCE	600	728 (T)	680	728 (T)
HC TUMORS SAME ROUTE	9/200 (5%)			
HC TUMORS ALL ROUTES	44/1238 (4%)			
STATISTICAL TESTS				
POLY 3	P=0.453N	P=0.690N	P=0.692N	P=0.562N
POLY 1.5	P=0.431N	P=0.692	P=0.693N	P=0.545N
POLY 6	P=0.475N	P=0.679N	P=0.691N	P=0.579N
COCH-ARM / FISHERS	P=0.388N	P=0.691N	P=0.691N	P=0.508N
MAX-ISO-POLY-3	P=0.564N	P=0.494N	P=0.497N	P=0.346N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	P=1.000	P=1.000	P=1.000	P=1.000
CURR VS HC SAME RTE	P=0.801			
CURR VS HC ALL RTES	P=0.931			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Osteosarcoma				
TUMOR 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	2/40.24
POLY-3 PERCENT (g)	0%	0%	0%	5%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	---	---	---	468
HC TUMORS SAME ROUTE	0/200 (0%)			
HC TUMORS ALL ROUTES	4/1250 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.034*	(e)	(e)	P=0.210
POLY 1.5	P=0.036*	(e)	(e)	P=0.218
POLY 6	P=0.032*	(e)	(e)	P=0.203
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.034*	(e)	(e)	P=0.075
HISTCONT SAME RTE	P=0.029*	(e)	(e)	P=0.042*
HISTCONT ALL RTES	P=0.002**	(e)	(e)	P<0.001**
CURR VS HC SAME RTE	P=1.000			
CURR VS HC ALL RTES	P=0.440			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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/Preputial Gland Adenoma				
TUMOR RATES				
OVERALL (a)	5/50 (10%)	3/49 (6%)	8/50 (16%)	2/50 (4%)
POLY-3 RATE (b)	5/46.20	3/45.74	8/46.52	2/39.39
POLY-3 PERCENT (g)	10.8%	6.6%	17.2%	5.1%
TERMINAL (d)	3/33 (9%)	3/41 (7%)	5/33 (15%)	1/23 (4%)
FIRST INCIDENCE	646	728 (T)	659	714
HC TUMORS SAME ROUTE	15/198 (8%)			
HC TUMORS ALL ROUTES	119/1247 (10%)			
STATISTICAL TESTS				
POLY 3	P=0.344N	P=0.362N	P=0.280	P=0.286N
POLY 1.5	P=0.300N	P=0.371N	P=0.279	P=0.262N
POLY 6	P=0.394N	P=0.346N	P=0.280	P=0.310N
COCH-ARM / FISHERS	P=0.229N	P=0.369N	P=0.277	P=0.218N
MAX-ISO-POLY-3	P=0.300N	P=0.236N	P=0.190	P=0.187N
HISTCONT SAME RTE	P=0.523	P=1.000	P=0.080	P=1.000
HISTCONT ALL RTES	P=0.747	P=1.000	P=0.211	P=1.000
CURR VS HC SAME RTE	P=0.681			
CURR VS HC ALL RTES	P=0.984			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

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

Date Report Requested: 01/24/2011
 Time Report Requested: 10:59:00
 First Dose M/F: 10/20/04 / 10/21/04
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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/Preputial Gland Carcinoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	2/49 (4%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/45.75	2/45.74	2/46.55	0/39.33
POLY-3 PERCENT (g)	0%	4.4%	4.3%	0%
TERMINAL (d)	0/33 (0%)	2/41 (5%)	1/33 (3%)	0/23 (0%)
FIRST INCIDENCE	---	728 (T)	611	---
HC TUMORS SAME ROUTE	4/198 (2%)			
HC TUMORS ALL ROUTES	40/1247 (3%)			
STATISTICAL TESTS				
POLY 3	P=0.439N	P=0.237	P=0.241	(e)
POLY 1.5	P=0.420N	P=0.233	P=0.240	(e)
POLY 6	P=0.458N	P=0.245	P=0.243	(e)
COCH-ARM / FISHERS	P=0.379N	P=0.242	P=0.247	(e)
MAX-ISO-POLY-3	P=0.320	P=0.077	P=0.080	(e)
HISTCONT SAME RTE	P=0.659	P=0.375	P=0.384	(e)
HISTCONT ALL RTES	P=1.000	P=1.000	P=1.000	(e)
CURR VS HC SAME RTE	P=0.311			
CURR VS HC ALL RTES	P=0.158			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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/Preputial Gland Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	5/50 (10%)	5/49 (10%)	10/50 (20%)	2/50 (4%)
POLY-3 RATE (b)	5/46.20	5/45.74	10/46.93	2/39.39
POLY-3 PERCENT (g)	10.8%	10.9%	21.3%	5.1%
TERMINAL (d)	3/33 (9%)	5/41 (12%)	6/33 (18%)	1/23 (4%)
FIRST INCIDENCE	646	728 (T)	611	714
HC TUMORS SAME ROUTE	19/198 (10%)			
HC TUMORS ALL ROUTES	158/1247 (13%)			
STATISTICAL TESTS				
POLY 3	P=0.267N	P=0.624	P=0.136	P=0.286N
POLY 1.5	P=0.223N	P=0.614	P=0.134	P=0.262N
POLY 6	P=0.319N	P=0.619N	P=0.138	P=0.310N
COCH-ARM / FISHERS	P=0.156N	P=0.617	P=0.131	P=0.218N
MAX-ISO-POLY-3	P=0.190N	P=0.493	P=0.085	P=0.187N
HISTCONT SAME RTE	P=0.569	P=1.000	P=0.036*	P=1.000
HISTCONT ALL RTES	P=1.000	P=1.000	P=0.194	P=1.000
CURR VS HC SAME RTE	P=0.972			
CURR VS HC ALL RTES	P=0.490			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

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

Date Report Requested: 01/24/2011
 Time Report Requested: 10:59:00
 First Dose M/F: 10/20/04 / 10/21/04
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Adenoma				
TUMOR 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	1/46.14	0/39.33
POLY-3 PERCENT (g)	0%	0%	2.2%	0%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	1/33 (3%)	0/23 (0%)
FIRST INCIDENCE	---	---	728 (T)	---
HC TUMORS SAME ROUTE	3/200 (2%)			
HC TUMORS ALL ROUTES	27/1244 (2%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/45.75	0/46.74	2/46.14	0/39.33
POLY-3 PERCENT (g)	0%	0%	4.3%	0%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	2/33 (6%)	0/23 (0%)
FIRST INCIDENCE	---	---	728 (T)	---
HC TUMORS SAME ROUTE	3/200 (2%)			
HC TUMORS ALL ROUTES	31/1244 (3%)			
STATISTICAL TESTS				
POLY 3	P=0.687	(e)	P=0.239	(e)
POLY 1.5	P=0.714	(e)	P=0.238	(e)
POLY 6	P=0.656	(e)	P=0.240	(e)
COCH-ARM / FISHERS	P=0.697N	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.286	(e)	P=0.078	(e)
HISTCONT SAME RTE	P=0.544	(e)	P=0.180	(e)
HISTCONT ALL RTES	P=1.000	(e)	P=0.413	(e)
CURR VS HC SAME RTE	P=0.302			
CURR VS HC ALL RTES	P=0.185			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Hepatocellular Adenoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	3/49 (6%)
POLY-3 RATE (b)	0/45.75	1/46.74	1/46.14	3/38.59
POLY-3 PERCENT (g)	0%	2.1%	2.2%	7.8%
TERMINAL (d)	0/33 (0%)	1/42 (2%)	1/33 (3%)	2/23 (9%)
FIRST INCIDENCE	---	728 (T)	728 (T)	720
HC TUMORS SAME ROUTE	1/200 (1%)			
HC TUMORS ALL ROUTES	11/1250 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.044*	P=0.504	P=0.502	P=0.091
POLY 1.5	P=0.049*	P=0.500	P=0.501	P=0.098
POLY 6	P=0.040*	P=0.512	P=0.502	P=0.085
COCH-ARM / FISHERS	P=0.061	P=0.500	P=0.500	P=0.117
MAX-ISO-POLY-3	P=0.042*	P=0.164	P=0.161	P=0.037*
HISTCONT SAME RTE	P=0.023*	P=0.420	P=0.416	P=0.033*
HISTCONT ALL RTEs	P=0.002**	P=0.494	P=0.490	P<0.001**
CURR VS HC SAME RTE	P=0.355			
CURR VS HC ALL RTEs	P=0.471			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Hepatocellular Carcinoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	4/49 (8%)
POLY-3 RATE (b)	0/45.75	0/46.74	0/46.14	4/38.55
POLY-3 PERCENT (g)	0%	0%	0%	10.4%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	4/23 (17%)
FIRST INCIDENCE	---	---	---	728 (T)
HC TUMORS SAME ROUTE	0/200 (0%)			
HC TUMORS ALL ROUTES	1/1250 (0%)			
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	(e)	P=0.041*
POLY 1.5	P<0.001**	(e)	(e)	P=0.046*
POLY 6	P<0.001**	(e)	(e)	P=0.037*
COCH-ARM / FISHERS	P=0.002**	(e)	(e)	P=0.056
MAX-ISO-POLY-3	P=0.002**	(e)	(e)	P=0.018*
HISTCONT SAME RTE	P=0.016*	(e)	(e)	P=0.016*
HISTCONT ALL RTES	P<0.001**	(e)	(e)	P<0.001**
CURR VS HC SAME RTE	P=1.000			
CURR VS HC ALL RTES	P=0.300			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Hepatocellular Carcinoma or Hepatocellular Adenoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	7/49 (14%)
POLY-3 RATE (b)	0/45.75	1/46.74	1/46.14	7/38.59
POLY-3 PERCENT (g)	0%	2.1%	2.2%	18.1%
TERMINAL (d)	0/33 (0%)	1/42 (2%)	1/33 (3%)	6/23 (26%)
FIRST INCIDENCE	---	728 (T)	728 (T)	720
HC TUMORS SAME ROUTE	1/200 (1%)			
HC TUMORS ALL ROUTES	12/1250 (1%)			
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.504	P=0.502	P=0.003**
POLY 1.5	P<0.001**	P=0.500	P=0.501	P=0.004**
POLY 6	P<0.001**	P=0.512	P=0.502	P=0.003**
COCH-ARM / FISHERS	P<0.001**	P=0.500	P=0.500	P=0.006**
MAX-ISO-POLY-3	P<0.001**	P=0.164	P=0.161	P=0.002**
HISTCONT SAME RTE	P=0.010**	P=0.420	P=0.416	P=0.010**
HISTCONT ALL RTES	P<0.001**	P=1.000	P=1.000	P<0.001**
CURR VS HC SAME RTE	P=0.355			
CURR VS HC ALL RTES	P=0.433			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	7/49 (14%)
POLY-3 RATE (b)	0/45.75	1/46.74	1/46.14	7/38.59
POLY-3 PERCENT (g)	0%	2.1%	2.2%	18.1%
TERMINAL (d)	0/33 (0%)	1/42 (2%)	1/33 (3%)	6/23 (26%)
FIRST INCIDENCE	---	728 (T)	728 (T)	720
HC TUMORS SAME ROUTE	1/200 (1%)			
HC TUMORS ALL ROUTES	12/1250 (1%)			
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.504	P=0.502	P=0.003**
POLY 1.5	P<0.001**	P=0.500	P=0.501	P=0.004**
POLY 6	P<0.001**	P=0.512	P=0.502	P=0.003**
COCH-ARM / FISHERS	P<0.001**	P=0.500	P=0.500	P=0.006**
MAX-ISO-POLY-3	P<0.001**	P=0.164	P=0.161	P=0.002**
HISTCONT SAME RTE	P=0.010**	P=0.420	P=0.416	P=0.010**
HISTCONT ALL RTES	P<0.001**	P=1.000	P=1.000	P<0.001**
CURR VS HC SAME RTE	P=0.355			
CURR VS HC ALL RTES	P=0.433			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Carcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/46.26	1/47.15	2/46.40	0/39.33
POLY-3 PERCENT (g)	2.2%	2.1%	4.3%	0%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	1/33 (3%)	0/23 (0%)
FIRST INCIDENCE	574	611	659	---
HC TUMORS SAME ROUTE	5/200 (3%)			
HC TUMORS ALL ROUTES	65/1250 (5%)			
STATISTICAL TESTS				
POLY 3	P=0.392N	P=0.756N	P=0.501	P=0.532N
POLY 1.5	P=0.371N	P=0.760	P=0.501	P=0.522N
POLY 6	P=0.416N	P=0.748N	P=0.502	P=0.542N
COCH-ARM / FISHERS	P=0.333N	P=0.753N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.344N	P=0.494N	P=0.282	P=0.198N
HISTCONT SAME RTE	P=1.000	P=1.000	P=0.489	P=1.000
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.831			
CURR VS HC ALL RTES	P=0.280			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Fibroadenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	29/50 (58%)	26/50 (52%)	26/50 (52%)	11/50 (22%)
POLY-3 RATE (b)	29/47.99	26/46.94	26/47.73	11/39.80
POLY-3 PERCENT (g)	60.4%	55.4%	54.5%	27.6%
TERMINAL (d)	18/33 (55%)	24/42 (57%)	17/33 (52%)	9/23 (39%)
FIRST INCIDENCE	625	688	646	612
HC TUMORS SAME ROUTE	88/200 (44%)			
HC TUMORS ALL ROUTES	655/1250 (52%)			
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.385N	P=0.349N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.386N	P=0.345N	P<0.001N**
POLY 6	P=0.003N**	P=0.380N	P=0.360N	P=0.003N**
COCH-ARM / FISHERS	P<0.001N**	P=0.344N	P=0.344N	P<0.001N**
MAX-ISO-POLY-3	P=0.002N**	P=0.310N	P=0.276N	P<0.001N**
HISTCONT SAME RTE	P=1.000	P=0.200	P=0.241	P=1.000
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.151			
CURR VS HC ALL RTES	P=0.728			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Fibroma, Fibroadenoma, Carcinoma, or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	30/50 (60%)	27/50 (54%)	26/50 (52%)	11/50 (22%)
POLY-3 RATE (b)	30/48.50	27/47.35	26/47.73	11/39.80
POLY-3 PERCENT (g)	61.9%	57%	54.5%	27.6%
TERMINAL (d)	18/33 (55%)	24/42 (57%)	17/33 (52%)	9/23 (39%)
FIRST INCIDENCE	574	611	646	612
HC TUMORS SAME ROUTE	93/200 (47%)			
HC TUMORS ALL ROUTES	702/1250 (56%)			
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.392N	P=0.297N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.390N	P=0.285N	P<0.001N**
POLY 6	P=0.002N**	P=0.387N	P=0.318N	P=0.002N**
COCH-ARM / FISHERS	P<0.001N**	P=0.343N	P=0.273N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.316N	P=0.231N	P<0.001N**
HISTCONT SAME RTE	P=1.000	P=0.288	P=0.430	P=1.000
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.220			
CURR VS HC ALL RTES	P=0.980			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Adenoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	1/49 (2%)	0/50 (0%)	2/49 (4%)
POLY-3 RATE (b)	0/45.75	1/46.39	0/46.14	2/38.98
POLY-3 PERCENT (g)	0%	2.2%	0%	5.1%
TERMINAL (d)	0/33 (0%)	1/42 (2%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	---	728 (T)	---	625
HC TUMORS SAME ROUTE	0/200 (0%)			
HC TUMORS ALL ROUTES	1/1247 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.127	P=0.503	(e)	P=0.203
POLY 1.5	P=0.133	P=0.498	(e)	P=0.212
POLY 6	P=0.123	P=0.511	(e)	P=0.196
COCH-ARM / FISHERS	P=0.148	P=0.495	(e)	P=0.242
MAX-ISO-POLY-3	P=0.078	P=0.163	(e)	P=0.074
HISTCONT SAME RTE	P=0.036*	P=0.172	(e)	P=0.042*
HISTCONT ALL RTES	P<0.001**	P=0.012*	(e)	P<0.001**
CURR VS HC SAME RTE	P=1.000			
CURR VS HC ALL RTES	P=0.307			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Carcinoma				
TUMOR 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	---	---	---	---
HC TUMORS SAME ROUTE	0/200 (0%)			
HC TUMORS ALL ROUTES	0/1247 (0%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/45.87	0/46.74	0/46.14	2/39.39
POLY-3 PERCENT (g)	2.2%	0%	0%	5.1%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	1/23 (4%)
FIRST INCIDENCE	698	---	---	714
HC TUMORS SAME ROUTE	2/200 (1%)			
HC TUMORS ALL ROUTES	9/1250 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.165	P=0.496N	P=0.499N	P=0.447
POLY 1.5	P=0.173	P=0.500N	P=0.499N	P=0.464
POLY 6	P=0.156	P=0.489N	P=0.499N	P=0.431
COCH-ARM / FISHERS	P=0.189	P=0.500N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.127	P=0.159N	P=0.159N	P=0.253
HISTCONT SAME RTE	P=0.135	P=1.000	P=1.000	P=0.174
HISTCONT ALL RTEs	P=0.021*	P=1.000	P=1.000	P=0.009**
CURR VS HC SAME RTE	P=0.796			
CURR VS HC ALL RTEs	P=0.331			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Granulosa Cell Tumor Malignant				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/45.75	2/46.74	0/46.14	1/39.33
POLY-3 PERCENT (g)	0%	4.3%	0%	2.5%
TERMINAL (d)	0/33 (0%)	2/42 (5%)	0/33 (0%)	1/23 (4%)
FIRST INCIDENCE	---	728 (T)	---	728 (T)
HC TUMORS SAME ROUTE	0/200 (0%)			
HC TUMORS ALL ROUTES	6/1248 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.582	P=0.242	(e)	P=0.470
POLY 1.5	P=0.594	P=0.238	(e)	P=0.480
POLY 6	P=0.571	P=0.250	(e)	P=0.461
COCH-ARM / FISHERS	P=0.622	P=0.247	(e)	P=0.500
MAX-ISO-POLY-3	P=0.334	P=0.081	(e)	P=0.158
HISTCONT SAME RTE	P=0.228	P=0.038*	(e)	P=0.172
HISTCONT ALL RTEs	P=0.206	P=0.003**	(e)	P=0.250
CURR VS HC SAME RTE	P=1.000			
CURR VS HC ALL RTEs	P=0.472			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Granulosa Cell Tumor: Benign, Malignant, NOS				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	3/50 (6%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/45.75	3/46.74	0/46.14	1/39.33
POLY-3 PERCENT (g)	0%	6.4%	0%	2.5%
TERMINAL (d)	0/33 (0%)	3/42 (7%)	0/33 (0%)	1/23 (4%)
FIRST INCIDENCE	---	728 (T)	---	728 (T)
HC TUMORS SAME ROUTE	1/200 (1%)			
HC TUMORS ALL ROUTES	8/1248 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.630N	P=0.123	(e)	P=0.470
POLY 1.5	P=0.624N	P=0.119	(e)	P=0.480
POLY 6	P=0.633N	P=0.129	(e)	P=0.461
COCH-ARM / FISHERS	P=0.602N	P=0.121	(e)	P=0.500
MAX-ISO-POLY-3	P=0.319	P=0.041*	(e)	P=0.158
HISTCONT SAME RTE	P=0.375	P=0.031*	(e)	P=0.373
HISTCONT ALL RTEs	P=0.224	P<0.001**	(e)	P=0.321
CURR VS HC SAME RTE	P=0.359			
CURR VS HC ALL RTEs	P=0.490			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 or Unspecified Site Adenoma				
TUMOR RATES				
OVERALL (a)	31/50 (62%)	29/50 (58%)	30/50 (60%)	20/50 (40%)
POLY-3 RATE (b)	31/48.85	29/47.97	30/48.58	20/41.83
POLY-3 PERCENT (g)	63.5%	60.5%	61.8%	47.8%
TERMINAL (d)	19/33 (58%)	24/42 (57%)	17/33 (52%)	9/23 (39%)
FIRST INCIDENCE	547	574	604	471
HC TUMORS SAME ROUTE	106/200 (53%)			
HC TUMORS ALL ROUTES	682/1247 (55%)			
STATISTICAL TESTS				
POLY 3	P=0.079N	P=0.462N	P=0.514N	P=0.095N
POLY 1.5	P=0.044N*	P=0.467N	P=0.508N	P=0.060N
POLY 6	P=0.133N	P=0.444N	P=0.519N	P=0.142N
COCH-ARM / FISHERS	P=0.012N*	P=0.419N	P=0.500N	P=0.022N*
MAX-ISO-POLY-3	P=0.127N	P=0.380N	P=0.429N	P=0.077N
HISTCONT SAME RTE	P=1.000	P=0.325	P=0.213	P=1.000
HISTCONT ALL RTES	P=1.000	P=0.478	P=0.413	P=1.000
CURR VS HC SAME RTE	P=0.409			
CURR VS HC ALL RTES	P=0.522			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 or Unspecified Site Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	31/50 (62%)	29/50 (58%)	30/50 (60%)	20/50 (40%)
POLY-3 RATE (b)	31/48.85	29/47.97	30/48.58	20/41.83
POLY-3 PERCENT (g)	63.5%	60.5%	61.8%	47.8%
TERMINAL (d)	19/33 (58%)	24/42 (57%)	17/33 (52%)	9/23 (39%)
FIRST INCIDENCE	547	574	604	471
HC TUMORS SAME ROUTE	107/200 (54%)			
HC TUMORS ALL ROUTES	696/1247 (56%)			
STATISTICAL TESTS				
POLY 3	P=0.079N	P=0.462N	P=0.514N	P=0.095N
POLY 1.5	P=0.044N*	P=0.467N	P=0.508N	P=0.060N
POLY 6	P=0.133N	P=0.444N	P=0.519N	P=0.142N
COCH-ARM / FISHERS	P=0.012N*	P=0.419N	P=0.500N	P=0.022N*
MAX-ISO-POLY-3	P=0.127N	P=0.380N	P=0.429N	P=0.077N
HISTCONT SAME RTE	P=1.000	P=0.400	P=0.287	P=1.000
HISTCONT ALL RTES	P=1.000	P=1.000	P=0.466	P=1.000
CURR VS HC SAME RTE	P=0.462			
CURR VS HC ALL RTES	P=0.629			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin				
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.75	2/46.74	0/46.14	0/39.33
POLY-3 PERCENT (g)	0%	4.3%	0%	0%
TERMINAL (d)	0/33 (0%)	2/42 (5%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	---	728 (T)	---	---
HC TUMORS SAME ROUTE	1/200 (1%)			
HC TUMORS ALL ROUTES	8/1250 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.383N	P=0.242	(e)	(e)
POLY 1.5	P=0.381N	P=0.238	(e)	(e)
POLY 6	P=0.382N	P=0.250	(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)
HISTCONT SAME RTE	P=0.561	P=0.080	(e)	(e)
HISTCONT ALL RTES	P=0.536	P=0.007**	(e)	(e)
CURR VS HC SAME RTE	P=0.367			
CURR VS HC ALL RTES	P=0.500			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin				
Basal Cell Carcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/45.86	0/46.74	1/46.14	1/39.33
POLY-3 PERCENT (g)	2.2%	0%	2.2%	2.5%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	1/33 (3%)	1/23 (4%)
FIRST INCIDENCE	701	---	728 (T)	728 (T)
HC TUMORS SAME ROUTE	0/200 (0%)			
HC TUMORS ALL ROUTES	2/1250 (0%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin				
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/45.86	2/46.74	1/46.14	1/39.33
POLY-3 PERCENT (g)	2.2%	4.3%	2.2%	2.5%
TERMINAL (d)	0/33 (0%)	2/42 (5%)	1/33 (3%)	1/23 (4%)
FIRST INCIDENCE	701	728 (T)	728 (T)	728 (T)
HC TUMORS SAME ROUTE	1/200 (1%)			
HC TUMORS ALL ROUTES	10/1250 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.580N	P=0.507	P=0.759N	P=0.725
POLY 1.5	P=0.566N	P=0.500	P=0.760N	P=0.737
POLY 6	P=0.594N	P=0.519	P=0.759N	P=0.714
COCH-ARM / FISHERS	P=0.535N	P=0.500	P=0.753N	P=0.753N
MAX-ISO-POLY-3	P=0.638N	P=0.288	P=0.497N	P=0.459
HISTCONT SAME RTE	P=0.229	P=0.080	P=0.418	P=0.373
HISTCONT ALL RTES	P=0.231	P=0.020*	P=0.453	P=0.398
CURR VS HC SAME RTE	P=0.227			
CURR VS HC ALL RTES	P=0.387			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin				
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma				
TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	3/50 (6%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	2/45.86	3/47.25	1/46.14	3/39.33
POLY-3 PERCENT (g)	4.4%	6.4%	2.2%	7.6%
TERMINAL (d)	1/33 (3%)	2/42 (5%)	1/33 (3%)	3/23 (13%)
FIRST INCIDENCE	701	574	728 (T)	728 (T)
HC TUMORS SAME ROUTE	2/200 (1%)			
HC TUMORS ALL ROUTES	21/1250 (2%)			
STATISTICAL TESTS				
POLY 3	P=0.404	P=0.514	P=0.498N	P=0.431
POLY 1.5	P=0.428	P=0.503	P=0.499N	P=0.453
POLY 6	P=0.381	P=0.532	P=0.497N	P=0.409
COCH-ARM / FISHERS	P=0.474	P=0.500	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.427	P=0.338	P=0.279N	P=0.278
HISTCONT SAME RTE	P=0.078	P=0.042*	P=1.000	P=0.042*
HISTCONT ALL RTES	P=0.025*	P=0.019*	P=1.000	P=0.012*
CURR VS HC SAME RTE	P=0.093			
CURR VS HC ALL RTES	P=0.248			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin				
Fibroma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	4/50 (8%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/45.75	4/47.15	1/46.14	0/39.33
POLY-3 PERCENT (g)	2.2%	8.5%	2.2%	0%
TERMINAL (d)	1/33 (3%)	3/42 (7%)	1/33 (3%)	0/23 (0%)
FIRST INCIDENCE	728 (T)	611	728 (T)	---
HC TUMORS SAME ROUTE	6/200 (3%)			
HC TUMORS ALL ROUTES	25/1250 (2%)			
STATISTICAL TESTS				
POLY 3	P=0.151N	P=0.188	P=0.759N	P=0.530N
POLY 1.5	P=0.143N	P=0.181	P=0.759N	P=0.520N
POLY 6	P=0.160N	P=0.201	P=0.758N	P=0.539N
COCH-ARM / FISHERS	P=0.125N	P=0.181	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.171N	P=0.093	P=0.497N	P=0.195N
HISTCONT SAME RTE	P=0.741	P=0.104	P=1.000	P=1.000
HISTCONT ALL RTES	P=0.506	P<0.001**	P=1.000	P=1.000
CURR VS HC SAME RTE	P=0.684			
CURR VS HC ALL RTES	P=0.957			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin				
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	4/50 (8%)	4/50 (8%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	4/45.75	4/47.15	2/46.40	1/39.82
POLY-3 PERCENT (g)	8.7%	8.5%	4.3%	2.5%
TERMINAL (d)	4/33 (12%)	3/42 (7%)	1/33 (3%)	0/23 (0%)
FIRST INCIDENCE	728 (T)	611	659	583
HC TUMORS SAME ROUTE	7/200 (4%)			
HC TUMORS ALL ROUTES	31/1250 (3%)			
STATISTICAL TESTS				
POLY 3	P=0.145N	P=0.627N	P=0.331N	P=0.224N
POLY 1.5	P=0.133N	P=0.640N	P=0.334N	P=0.209N
POLY 6	P=0.159N	P=0.603N	P=0.326N	P=0.237N
COCH-ARM / FISHERS	P=0.110N	P=0.643N	P=0.339N	P=0.181N
MAX-ISO-POLY-3	P=0.224N	P=0.482N	P=0.197N	P=0.127N
HISTCONT SAME RTE	P=0.621	P=0.158	P=1.000	P=1.000
HISTCONT ALL RTES	P=0.353	P=0.005**	P=0.415	P=1.000
CURR VS HC SAME RTE	P=0.215			
CURR VS HC ALL RTES	P=0.021*			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin				
Fibrosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/45.75	0/46.74	0/46.14	0/39.33
POLY-3 PERCENT (g)	6.6%	0%	0%	0%
TERMINAL (d)	3/33 (9%)	0/42 (0%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	728 (T)	---	---	---
HC TUMORS SAME ROUTE	1/200 (1%)			
HC TUMORS ALL ROUTES	4/1250 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.138N	P=0.115N	P=0.117N	P=0.148N
POLY 1.5	P=0.135N	P=0.119N	P=0.118N	P=0.138N
POLY 6	P=0.144N	P=0.108N	P=0.116N	P=0.158N
COCH-ARM / FISHERS	P=0.134N	P=0.121N	P=0.121N	P=0.121N
MAX-ISO-POLY-3	P=0.025N*	P=0.038N*	P=0.038N*	P=0.064N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.016*			
CURR VS HC ALL RTES	P<0.001**			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin				
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	3/45.75	0/46.74	1/46.40	1/39.82
POLY-3 PERCENT (g)	6.6%	0%	2.2%	2.5%
TERMINAL (d)	3/33 (9%)	0/42 (0%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	728 (T)	---	659	583
HC TUMORS SAME ROUTE	1/200 (1%)			
HC TUMORS ALL ROUTES	7/1250 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.480N	P=0.115N	P=0.300N	P=0.357N
POLY 1.5	P=0.465N	P=0.119N	P=0.303N	P=0.341N
POLY 6	P=0.497N	P=0.108N	P=0.297N	P=0.371N
COCH-ARM / FISHERS	P=0.442N	P=0.121N	P=0.309N	P=0.309N
MAX-ISO-POLY-3	P=0.159N	P=0.038N*	P=0.152N	P=0.206N
HISTCONT SAME RTE	P=0.176	P=1.000	P=0.419	P=0.376
HISTCONT ALL RTES	P=0.146	P=1.000	P=0.326	P=0.286
CURR VS HC SAME RTE	P=0.016*			
CURR VS HC ALL RTES	P<0.001**			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin				
Keratoacanthoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/45.75	1/47.25	0/46.14	1/39.33
POLY-3 PERCENT (g)	2.2%	2.1%	0%	2.5%
TERMINAL (d)	1/33 (3%)	0/42 (0%)	0/33 (0%)	1/23 (4%)
FIRST INCIDENCE	728 (T)	574	---	728 (T)
HC TUMORS SAME ROUTE	0/200 (0%)			
HC TUMORS ALL ROUTES	7/1250 (1%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin				
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/45.75	1/47.25	0/46.14	2/39.33
POLY-3 PERCENT (g)	2.2%	2.1%	0%	5.1%
TERMINAL (d)	1/33 (3%)	0/42 (0%)	0/33 (0%)	2/23 (9%)
FIRST INCIDENCE	728 (T)	574	---	728 (T)
HC TUMORS SAME ROUTE	1/200 (1%)			
HC TUMORS ALL ROUTES	12/1250 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.296	P=0.753N	P=0.498N	P=0.448
POLY 1.5	P=0.308	P=0.759N	P=0.499N	P=0.464
POLY 6	P=0.283	P=0.744N	P=0.498N	P=0.432
COCH-ARM / FISHERS	P=0.333	P=0.753N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.250	P=0.490N	P=0.159N	P=0.253
HISTCONT SAME RTE	P=0.061	P=0.424	P=1.000	P=0.077
HISTCONT ALL RTES	P=0.066	P=1.000	P=1.000	P=0.037*
CURR VS HC SAME RTE	P=0.224			
CURR VS HC ALL RTES	P=0.498			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin				
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/45.75	1/47.25	0/46.14	2/39.33
POLY-3 PERCENT (g)	2.2%	2.1%	0%	5.1%
TERMINAL (d)	1/33 (3%)	0/42 (0%)	0/33 (0%)	2/23 (9%)
FIRST INCIDENCE	728 (T)	574	---	728 (T)
HC TUMORS SAME ROUTE	1/200 (1%)			
HC TUMORS ALL ROUTES	9/1250 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.296	P=0.753N	P=0.498N	P=0.448
POLY 1.5	P=0.308	P=0.759N	P=0.499N	P=0.464
POLY 6	P=0.283	P=0.744N	P=0.498N	P=0.432
COCH-ARM / FISHERS	P=0.333	P=0.753N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.250	P=0.490N	P=0.159N	P=0.253
HISTCONT SAME RTE	P=0.061	P=0.424	P=1.000	P=0.077
HISTCONT ALL RTES	P=0.051	P=0.435	P=1.000	P=0.024*
CURR VS HC SAME RTE	P=0.224			
CURR VS HC ALL RTES	P=0.334			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

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

Date Report Requested: 01/24/2011
 Time Report Requested: 10:59:00
 First Dose M/F: 10/20/04 / 10/21/04
 Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Skin: Sebaceous Gland Adenoma				
TUMOR 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	---	---	---	---
HC TUMORS SAME ROUTE	0/200 (0%)			
HC TUMORS ALL ROUTES	1/1250 (0%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Adenoma				
TUMOR RATES				
OVERALL (a)	9/49 (18%)	3/47 (6%)	5/47 (11%)	2/45 (4%)
POLY-3 RATE (b)	9/46.01	3/44.82	5/44.18	2/37.11
POLY-3 PERCENT (g)	19.6%	6.7%	11.3%	5.4%
TERMINAL (d)	6/33 (18%)	3/42 (7%)	3/33 (9%)	0/23 (0%)
FIRST INCIDENCE	547	728 (T)	659	701
HC TUMORS SAME ROUTE	25/200 (13%)			
HC TUMORS ALL ROUTES	126/1233 (10%)			
STATISTICAL TESTS				
POLY 3	P=0.109N	P=0.065N	P=0.215N	P=0.057N
POLY 1.5	P=0.094N	P=0.070N	P=0.216N	P=0.050N*
POLY 6	P=0.127N	P=0.057N	P=0.212N	P=0.065N
COCH-ARM / FISHERS	P=0.074N	P=0.070N	P=0.217N	P=0.035N*
MAX-ISO-POLY-3	P=0.050N*	P=0.034N*	P=0.142N	P=0.039N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.346			
CURR VS HC ALL RTES	P=0.091			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	9/49 (18%)	3/47 (6%)	6/47 (13%)	2/45 (4%)
POLY-3 RATE (b)	9/46.01	3/44.82	6/44.49	2/37.11
POLY-3 PERCENT (g)	19.6%	6.7%	13.5%	5.4%
TERMINAL (d)	6/33 (18%)	3/42 (7%)	3/33 (9%)	0/23 (0%)
FIRST INCIDENCE	547	728 (T)	646	701
HC TUMORS SAME ROUTE	27/200 (14%)			
HC TUMORS ALL ROUTES	141/1233 (11%)			
STATISTICAL TESTS				
POLY 3	P=0.117N	P=0.065N	P=0.311N	P=0.057N
POLY 1.5	P=0.101N	P=0.070N	P=0.315N	P=0.050N*
POLY 6	P=0.138N	P=0.057N	P=0.305N	P=0.065N
COCH-ARM / FISHERS	P=0.077N	P=0.070N	P=0.319N	P=0.035N*
MAX-ISO-POLY-3	P=0.055N	P=0.034N*	P=0.221N	P=0.039N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	P=1.000	P=1.000	P=1.000	P=1.000
CURR VS HC SAME RTE	P=0.482			
CURR VS HC ALL RTEs	P=0.192			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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: Follicular Cell Adenoma				
TUMOR RATES				
OVERALL (a)	1/49 (2%)	1/47 (2%)	2/47 (4%)	0/45 (0%)
POLY-3 RATE (b)	1/45.01	1/44.82	2/43.85	0/36.95
POLY-3 PERCENT (g)	2.2%	2.2%	4.6%	0%
TERMINAL (d)	0/33 (0%)	1/42 (2%)	2/33 (6%)	0/23 (0%)
FIRST INCIDENCE	701	728 (T)	728 (T)	---
HC TUMORS SAME ROUTE	1/200 (1%)			
HC TUMORS ALL ROUTES	5/1233 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.397N	P=0.760	P=0.491	P=0.539N
POLY 1.5	P=0.381N	P=0.754	P=0.489	P=0.533N
POLY 6	P=0.414N	P=0.752N	P=0.494	P=0.545N
COCH-ARM / FISHERS	P=0.352N	P=0.742	P=0.484	P=0.521N
MAX-ISO-POLY-3	P=0.343N	P=0.498	P=0.273	P=0.201N
HISTCONT SAME RTE	P=0.355	P=0.405	P=0.073	P=1.000
HISTCONT ALL RTEs	P=0.164	P=0.195	P<0.001**	P=1.000
CURR VS HC SAME RTE	P=0.209			
CURR VS HC ALL RTEs	P=0.102			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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: Follicular Cell Carcinoma				
TUMOR RATES				
OVERALL (a)	0/49 (0%)	0/47 (0%)	0/47 (0%)	0/45 (0%)
POLY-3 RATE (b)	0/44.90	0/44.82	0/43.85	0/36.95
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	1/200 (1%)			
HC TUMORS ALL ROUTES	5/1233 (0%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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: Follicular Cell Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	1/49 (2%)	1/47 (2%)	2/47 (4%)	0/45 (0%)
POLY-3 RATE (b)	1/45.01	1/44.82	2/43.85	0/36.95
POLY-3 PERCENT (g)	2.2%	2.2%	4.6%	0%
TERMINAL (d)	0/33 (0%)	1/42 (2%)	2/33 (6%)	0/23 (0%)
FIRST INCIDENCE	701	728 (T)	728 (T)	---
HC TUMORS SAME ROUTE	2/200 (1%)			
HC TUMORS ALL ROUTES	9/1233 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.397N	P=0.760	P=0.491	P=0.539N
POLY 1.5	P=0.381N	P=0.754	P=0.489	P=0.533N
POLY 6	P=0.414N	P=0.752N	P=0.494	P=0.545N
COCH-ARM / FISHERS	P=0.352N	P=0.742	P=0.484	P=0.521N
MAX-ISO-POLY-3	P=0.343N	P=0.498	P=0.273	P=0.201N
HISTCONT SAME RTE	P=0.463	P=1.000	P=0.114	P=1.000
HISTCONT ALL RTES	P=0.346	P=0.411	P=0.015*	P=1.000
CURR VS HC SAME RTE	P=0.660			
CURR VS HC ALL RTES	P=0.329			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Tongue				
Squamous Cell Carcinoma or Papilloma Squamous				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/45.87	0/46.74	0/46.14	2/39.39
POLY-3 PERCENT (g)	2.2%	0%	0%	5.1%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	1/23 (4%)
FIRST INCIDENCE	698	---	---	714
HC TUMORS SAME ROUTE	1/200 (1%)			
HC TUMORS ALL ROUTES	5/1250 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.165	P=0.496N	P=0.499N	P=0.447
POLY 1.5	P=0.173	P=0.500N	P=0.499N	P=0.464
POLY 6	P=0.156	P=0.489N	P=0.499N	P=0.431
COCH-ARM / FISHERS	P=0.189	P=0.500N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.127	P=0.159N	P=0.159N	P=0.253
HISTCONT SAME RTE	P=0.053	P=1.000	P=1.000	P=0.078
HISTCONT ALL RTES	P=0.003**	P=1.000	P=1.000	P<0.001**
CURR VS HC SAME RTE	P=0.234			
CURR VS HC ALL RTES	P=0.104			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	9/50 (18%)	4/50 (8%)	8/50 (16%)
POLY-3 RATE (b)	3/45.96	9/46.74	4/46.20	8/39.72
POLY-3 PERCENT (g)	6.5%	19.3%	8.7%	20.1%
TERMINAL (d)	2/33 (6%)	9/42 (21%)	3/33 (9%)	4/23 (17%)
FIRST INCIDENCE	673	728 (T)	714	694
HC TUMORS SAME ROUTE	28/200 (14%)			
HC TUMORS ALL ROUTES	219/1250 (18%)			
STATISTICAL TESTS				
POLY 3	P=0.150	P=0.063	P=0.503	P=0.058
POLY 1.5	P=0.174	P=0.059	P=0.502	P=0.070
POLY 6	P=0.129	P=0.070	P=0.503	P=0.049*
COCH-ARM / FISHERS	P=0.234	P=0.061	P=0.500	P=0.100
MAX-ISO-POLY-3	P=0.073	P=0.034*	P=0.350	P=0.038*
HISTCONT SAME RTE	P=0.324	P=0.220	P=1.000	P=0.188
HISTCONT ALL RTES	P=0.741	P=1.000	P=1.000	P=1.000
CURR VS HC SAME RTE	P=0.080			
CURR VS HC ALL RTES	P=0.022*			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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				
Sarcoma Stromal or Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	9/50 (18%)	5/50 (10%)	8/50 (16%)
POLY-3 RATE (b)	3/45.96	9/46.74	5/46.20	8/39.72
POLY-3 PERCENT (g)	6.5%	19.3%	10.8%	20.1%
TERMINAL (d)	2/33 (6%)	9/42 (21%)	4/33 (12%)	4/23 (17%)
FIRST INCIDENCE	673	728 (T)	714	694
HC TUMORS SAME ROUTE	28/200 (14%)			
HC TUMORS ALL ROUTES	224/1250 (18%)			
STATISTICAL TESTS				
POLY 3	P=0.151	P=0.063	P=0.359	P=0.058
POLY 1.5	P=0.178	P=0.059	P=0.359	P=0.070
POLY 6	P=0.129	P=0.070	P=0.359	P=0.049*
COCH-ARM / FISHERS	P=0.242	P=0.061	P=0.357	P=0.100
MAX-ISO-POLY-3	P=0.078	P=0.034*	P=0.234	P=0.038*
HISTCONT SAME RTE	P=0.296	P=0.220	P=1.000	P=0.188
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.080			
CURR VS HC ALL RTES	P=0.019*			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Zymbal's Gland Carcinoma				
TUMOR 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	---	---	---	---
HC TUMORS SAME ROUTE	1/200 (1%)			
HC TUMORS ALL ROUTES	6/1250 (1%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Zymbal's Gland Carcinoma or Adenoma				
TUMOR 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	---	---	---	---
HC TUMORS SAME ROUTE	1/200 (1%)			
HC TUMORS ALL ROUTES	6/1250 (1%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
All Organs				
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated				
TUMOR RATES	#	#	#	#
OVERALL (a)	15/50 (30%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	15/47.32	2/47.39	1/46.23	1/39.33
POLY-3 PERCENT (g)	31.7%	4.2%	2.2%	2.5%
TERMINAL (d)	8/33 (24%)	1/42 (2%)	0/33 (0%)	1/23 (4%)
FIRST INCIDENCE	547	516	705	728 (T)
HC TUMORS SAME ROUTE	22/200 (11%)			
HC TUMORS ALL ROUTES	263/1250 (21%)			
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**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P<0.001**			
CURR VS HC ALL RTES	P=0.187			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
All Organs				
Mesothelioma: Benign, Malignant, NOS				
TUMOR 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	---	---	---	---
HC TUMORS SAME ROUTE	2/200 (1%)			
HC TUMORS ALL ROUTES	5/1250 (0%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTES	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTES	(n)			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
All Organs				
Mesothelioma: Malignant				
TUMOR 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	---	---	---	---
HC TUMORS SAME ROUTE	2/200 (1%)			
HC TUMORS ALL ROUTES	4/1250 (0%)			
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)
HISTCONT SAME RTE	(n)	(n)	(n)	(n)
HISTCONT ALL RTEs	(n)	(n)	(n)	(n)
CURR VS HC SAME RTE	(n)			
CURR VS HC ALL RTEs	(n)			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
All Organs				
Osteosarcoma				
TUMOR 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	2/40.24
POLY-3 PERCENT (g)	0%	0%	0%	5%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	---	---	---	468
HC TUMORS SAME ROUTE	0/200 (0%)			
HC TUMORS ALL ROUTES	4/1250 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.034*	(e)	(e)	P=0.210
POLY 1.5	P=0.036*	(e)	(e)	P=0.218
POLY 6	P=0.032*	(e)	(e)	P=0.203
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.034*	(e)	(e)	P=0.075
HISTCONT SAME RTE	P=0.029*	(e)	(e)	P=0.042*
HISTCONT ALL RTES	P=0.002**	(e)	(e)	P<0.001**
CURR VS HC SAME RTE	P=1.000			
CURR VS HC ALL RTES	P=0.440			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
All Organs				
Osteosarcoma or Osteoma				
TUMOR 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	2/40.24
POLY-3 PERCENT (g)	0%	0%	0%	5%
TERMINAL (d)	0/33 (0%)	0/42 (0%)	0/33 (0%)	0/23 (0%)
FIRST INCIDENCE	---	---	---	468
HC TUMORS SAME ROUTE	0/200 (0%)			
HC TUMORS ALL ROUTES	5/1250 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.034*	(e)	(e)	P=0.210
POLY 1.5	P=0.036*	(e)	(e)	P=0.218
POLY 6	P=0.032*	(e)	(e)	P=0.203
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.034*	(e)	(e)	P=0.075
HISTCONT SAME RTE	P=0.029*	(e)	(e)	P=0.042*
HISTCONT ALL RTES	P=0.003**	(e)	(e)	P<0.001**
CURR VS HC SAME RTE	P=1.000			
CURR VS HC ALL RTES	P=0.461			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
All Organs				
Benign Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	46/50 (92%)	44/50 (88%)	42/50 (84%)	33/50 (66%)
POLY-3 RATE (b)	46/50.00	44/47.97	42/48.84	33/42.83
POLY-3 PERCENT (g)	92%	91.7%	86%	77.1%
TERMINAL (d)	29/33 (88%)	39/42 (93%)	28/33 (85%)	18/23 (78%)
FIRST INCIDENCE	547	574	604	471
HC TUMORS SAME ROUTE	166/200 (83%)			
HC TUMORS ALL ROUTES	1083/1250 (87%)			
STATISTICAL TESTS				
POLY 3	P=0.011N*	P=0.628N	P=0.258N	P=0.032N*
POLY 1.5	P=0.002N**	P=0.569N	P=0.219N	P=0.010N**
POLY 6	P=0.041N*	P=0.605	P=0.327N	P=0.095N
COCH-ARM / FISHERS	P<0.001N**	P=0.370N	P=0.178N	P<0.001N**
MAX-ISO-POLY-3	P=0.017N*	P=0.480N	P=0.167N	P=0.022N*
HISTCONT SAME RTE	P=1.000	P=0.173	P=1.000	P=1.000
HISTCONT ALL RTES	P=1.000	P=0.467	P=1.000	P=1.000
CURR VS HC SAME RTE	P=0.360			
CURR VS HC ALL RTES	P=0.687			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
All Organs				
Malignant Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	23/50 (46%)	9/50 (18%)	12/50 (24%)	11/50 (22%)
POLY-3 RATE (b)	23/48.13	9/47.80	12/47.65	11/41.35
POLY-3 PERCENT (g)	47.8%	18.8%	25.2%	26.6%
TERMINAL (d)	14/33 (42%)	7/42 (17%)	6/33 (18%)	6/23 (26%)
FIRST INCIDENCE	547	516	611	468
HC TUMORS SAME ROUTE	48/200 (24%)			
HC TUMORS ALL ROUTES	446/1250 (36%)			
STATISTICAL TESTS				
POLY 3	P=0.156N	P=0.002N**	P=0.016N*	P=0.030N*
POLY 1.5	P=0.122N	P=0.002N**	P=0.016N*	P=0.020N*
POLY 6	P=0.200N	P<0.001N**	P=0.016N*	P=0.044N*
COCH-ARM / FISHERS	P=0.079N	P=0.002N**	P=0.018N*	P=0.010N**
MAX-ISO-POLY-3	P=0.015N*	P<0.001N**	P=0.010N**	P=0.025N*
HISTCONT SAME RTE	P=0.660	P=1.000	P=1.000	P=1.000
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.006**			
CURR VS HC ALL RTES	P=0.199			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
All Organs				
Malignant and Benign Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	49/50 (98%)	46/50 (92%)	43/50 (86%)	36/50 (72%)
POLY-3 RATE (b)	49/50.00	46/48.61	43/49.25	36/44.30
POLY-3 PERCENT (g)	98%	94.6%	87.3%	81.3%
TERMINAL (d)	32/33 (97%)	40/42 (95%)	28/33 (85%)	18/23 (78%)
FIRST INCIDENCE	547	516	604	468
HC TUMORS SAME ROUTE	181/200 (91%)			
HC TUMORS ALL ROUTES	1175/1250 (94%)			
STATISTICAL TESTS				
POLY 3	P=0.002N**	P=0.358N	P=0.042N*	P=0.004N**
POLY 1.5	P<0.001N**	P=0.327N	P=0.036N*	P<0.001N**
POLY 6	P=0.008N**	P=0.404N	P=0.054N	P=0.014N*
COCH-ARM / FISHERS	P<0.001N**	P=0.181N	P=0.030N*	P<0.001N**
MAX-ISO-POLY-3	P=0.004N**	P=0.184N	P=0.017N*	P=0.002N**
HISTCONT SAME RTE	P=1.000	P=0.201	P=1.000	P=1.000
HISTCONT ALL RTES	(h)	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.089			
CURR VS HC ALL RTES	P=0.371			

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

N,N-Dimethyl-p-toluidine

CAS Number: 99-97-8

Date Report Requested: 01/24/2011

Time Report Requested: 10:59:00

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

Lab: BAT

LEGEND

- (a) Number of tumor-bearing animals/number of animals examined at site.
- (b) Number of tumor-bearing animals/Poly-3 number
- (d) Observed incidence at terminal kill.
- (e) Value of statistic cannot be computed.
- (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
- (g) Poly-3 adjusted lifetime tumor incidence.
- (h) Historical Controls statistic is not calculated when the HC Poly-3 rate is higher than the Poly-3 rates for all dose groups.
- (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 ***