

TDMS No. 91005-07
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
METHYLENE BLUE TRIHYDRATE
CAS Number: 7220-79-3
Pathologist: GILES, H.
RF1_R2

Date Report Reqsted: 04/06/2006
Time Report Reqsted: 10:49:49
First Dose M/F: 06/26/00 / 06/26/00
Lab: SRI

C Number:	C91005C		
Lock Date:	09/05/2003		
Cage Range:	1 - 9999		
Date Range:	1-JAN-1940 to 17-SEP-2040		
Reasons For Removal:	25021 Terminal Sacrifice	25020 Natural Death	25019 Moribund Sacrifice
	25018 Dosing Accident		
Removal Date Range:	JAN /1 /1940 - SEP /17 /2040		
Treatment Groups:	Include 1 0 MG/KG	Include 2 0 MG/KG	Include 3 5 MG/KG
	Include 4 5 MG/KG	Include 5 25 MG/KG	Include 6 25 MG/KG
	Include 7 50 MG/KG	Include 8 50 MG/KG	

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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
Brain
Clitoral/Preputial Gland
Heart
Islets, Pancreatic
Kidney
Liver
Lung
Nose
Ovary
Pancreas
Pituitary Gland
Prostate
Salivary Glands
Spleen
Testes
Thymus
Thyroid Gland
Urinary Bladder

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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF METHYLENE BLUE TRIHYDRATE

MALE RATS

<u>Organ</u>	<u>Morphology</u>
Adrenal Medulla	Pheochromocytoma Benign Pheochromocytoma: Benign, Complex, Malignant, NOS
Islets, Pancreatic	Adenoma Carcinoma or Adenoma
Lung	Alveolar/Bronchiolar Carcinoma Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma
Skin	Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma Fibroma Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma Fibrosarcoma Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma Squamous Cell Papilloma, Papilloma, or Keratoacanthoma
All Organs	Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated Benign Tumors Malignant Tumors

FEMALE RATS

<u>Organ</u>	<u>Morphology</u>
Mammary Gland	Fibroadenoma Fibroma, Fibroadenoma or Adenoma Fibroma, Fibroadenoma, Carcinoma, or Adenoma
Skin	Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma Fibrosarcoma

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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF METHYLENE BLUE TRIHYDRATE

Uterus
All Organs

Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma
Sarcoma Stromal or Polyp Stromal
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated
Benign Tumors
Malignant Tumors
Malignant and Benign Tumors

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Adrenal Cortex
 Adenoma**

TUMOR RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/43.81	0/44.21	1/47.35	2/41.96
POLY-3 PERCENT (g)	2.3%	0%	2.1%	4.8%
TERMINAL (d)	1/31 (3%)	0/33 (0%)	0/39 (0%)	2/31 (7%)
FIRST INCIDENCE	729 (T)	---	619	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.196	P=0.488N	P=0.725N	P=0.500
POLY 3	P=0.193	P=0.498N	P=0.743N	P=0.485
POLY 1.5	P=0.195	P=0.499N	P=0.751N	P=0.488
POLY 6	P=0.193	P=0.495N	P=0.731N	P=0.486
LOGISTIC REGRESSION	P=0.195	(e)	P=0.733	P=0.500
COCH-ARM / FISHERS	P=0.202	P=0.500N	P=0.753N	P=0.500
ORDER RESTRICTED	P=0.210	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.228	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Adrenal Medulla
 Pheochromocytoma Benign**

TUMOR RATES

OVERALL (a)	9/50 (18%)	13/50 (26%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	9/43.98	13/44.76	2/46.96	3/41.96
POLY-3 PERCENT (g)	20.5%	29.1%	4.3%	7.2%
TERMINAL (d)	7/31 (23%)	11/33 (33%)	2/39 (5%)	3/31 (10%)
FIRST INCIDENCE	702	576	729 (T)	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.002N**	P=0.293	P=0.010N**	P=0.060N
POLY 3	P=0.002N**	P=0.244	P=0.018N*	P=0.069N
POLY 1.5	P=0.002N**	P=0.238	P=0.021N*	P=0.067N
POLY 6	P=0.002N**	P=0.257	P=0.015N*	P=0.067N
LOGISTIC REGRESSION	P=0.002N**	P=0.263	P=0.010N**	P=0.057N
COCH-ARM / FISHERS	P=0.003N**	P=0.235	P=0.026N*	P=0.061N
ORDER RESTRICTED	P=0.008N**	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.004N**	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Adrenal Medulla
 Pheochromocytoma: Benign, Complex, Malignant, NOS**

TUMOR RATES

OVERALL (a)	11/50 (22%)	13/50 (26%)	2/50 (4%)	4/50 (8%)
POLY-3 RATE (b)	11/44.29	13/44.76	2/46.96	4/41.96
POLY-3 PERCENT (g)	24.8%	29.1%	4.3%	9.5%
TERMINAL (d)	8/31 (26%)	11/33 (33%)	2/39 (5%)	4/31 (13%)
FIRST INCIDENCE	645	576	729 (T)	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.002N**	P=0.480	P=0.003N**	P=0.047N*
POLY 3	P=0.002N**	P=0.417	P=0.005N**	P=0.053N
POLY 1.5	P=0.003N**	P=0.412	P=0.006N**	P=0.051N
POLY 6	P=0.002N**	P=0.431	P=0.004N**	P=0.053N
LOGISTIC REGRESSION	P=0.003N**	P=0.439	P=0.004N**	P=0.047N*
COCH-ARM / FISHERS	P=0.003N**	P=0.408	P=0.007N**	P=0.045N*
ORDER RESTRICTED	P=0.007N**	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.004N**	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Clitoral/Preputial Gland
 Adenoma**

TUMOR RATES

OVERALL (a)	1/50 (2%)	4/50 (8%)	6/50 (12%)	0/50 (0%)
POLY-3 RATE (b)	1/43.81	4/44.76	6/46.96	0/41.96
POLY-3 PERCENT (g)	2.3%	8.9%	12.8%	0%
TERMINAL (d)	1/31 (3%)	2/33 (6%)	6/39 (15%)	0/31 (0%)
FIRST INCIDENCE	729 (T)	576	729 (T)	---

STATISTICAL TESTS

LIFE TABLE	P=0.272N	P=0.201	P=0.101	P=0.500N
POLY 3	P=0.307N	P=0.185	P=0.068	P=0.509N
POLY 1.5	P=0.300N	P=0.182	P=0.063	P=0.507N
POLY 6	P=0.307N	P=0.192	P=0.077	P=0.508N
LOGISTIC REGRESSION	P=0.286N	P=0.180	P=0.101	(e)
COCH-ARM / FISHERS	P=0.277N	P=0.181	P=0.056	P=0.500N
ORDER RESTRICTED	P=0.092N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.106N	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Clitoral/Preputial Gland
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	1/50 (2%)	4/50 (8%)	6/50 (12%)	0/50 (0%)
POLY-3 RATE (b)	1/43.81	4/44.76	6/46.96	0/41.96
POLY-3 PERCENT (g)	2.3%	8.9%	12.8%	0%
TERMINAL (d)	1/31 (3%)	2/33 (6%)	6/39 (15%)	0/31 (0%)
FIRST INCIDENCE	729 (T)	576	729 (T)	---

STATISTICAL TESTS

LIFE TABLE	P=0.272N	P=0.201	P=0.101	P=0.500N
POLY 3	P=0.307N	P=0.185	P=0.068	P=0.509N
POLY 1.5	P=0.300N	P=0.182	P=0.063	P=0.507N
POLY 6	P=0.307N	P=0.192	P=0.077	P=0.508N
LOGISTIC REGRESSION	P=0.286N	P=0.180	P=0.101	(e)
COCH-ARM / FISHERS	P=0.277N	P=0.181	P=0.056	P=0.500N
ORDER RESTRICTED	P=0.092N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.106N	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Islets, Pancreatic
 Adenoma**

TUMOR RATES

OVERALL (a)	4/50 (8%)	9/50 (18%)	12/50 (24%)	8/50 (16%)
POLY-3 RATE (b)	4/44.44	9/45.32	12/47.97	8/42.64
POLY-3 PERCENT (g)	9%	19.9%	25%	18.8%
TERMINAL (d)	1/31 (3%)	5/33 (15%)	9/39 (23%)	4/31 (13%)
FIRST INCIDENCE	620	561	619	652

STATISTICAL TESTS

LIFE TABLE	P=0.244	P=0.153	P=0.075	P=0.191
POLY 3	P=0.201	P=0.121	P=0.037*	P=0.155
POLY 1.5	P=0.209	P=0.119	P=0.032*	P=0.160
POLY 6	P=0.204	P=0.129	P=0.047*	P=0.157
LOGISTIC REGRESSION	P=0.225	P=0.117	P=0.025*	P=0.161
COCH-ARM / FISHERS	P=0.241	P=0.117	P=0.027*	P=0.178
ORDER RESTRICTED	P=0.090	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.104	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Islets, Pancreatic
 Carcinoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/43.81	0/44.21	2/47.11	0/41.96
POLY-3 PERCENT (g)	0%	0%	4.3%	0%
TERMINAL (d)	0/31 (0%)	0/33 (0%)	1/39 (3%)	0/31 (0%)
FIRST INCIDENCE	---	---	690	---

STATISTICAL TESTS

LIFE TABLE	P=0.539	(e)	P=0.291	(e)
POLY 3	P=0.498	(e)	P=0.254	(e)
POLY 1.5	P=0.509	(e)	P=0.246	(e)
POLY 6	P=0.491	(e)	P=0.265	(e)
LOGISTIC REGRESSION	P=0.530	(e)	P=0.246	(e)
COCH-ARM / FISHERS	P=0.536	(e)	P=0.247	(e)
ORDER RESTRICTED	P=0.261	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.280	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG
Islets, Pancreatic Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	4/50 (8%)	9/50 (18%)	14/50 (28%)	8/50 (16%)
POLY-3 RATE (b)	4/44.44	9/45.32	14/48.13	8/42.64
POLY-3 PERCENT (g)	9%	19.9%	29.1%	18.8%
TERMINAL (d)	1/31 (3%)	5/33 (15%)	10/39 (26%)	4/31 (13%)
FIRST INCIDENCE	620	561	619	652
STATISTICAL TESTS				
LIFE TABLE	P=0.222	P=0.153	P=0.036*	P=0.191
POLY 3	P=0.174	P=0.121	P=0.013*	P=0.155
POLY 1.5	P=0.182	P=0.119	P=0.010**	P=0.160
POLY 6	P=0.176	P=0.129	P=0.017*	P=0.157
LOGISTIC REGRESSION	P=0.201	P=0.117	P=0.009**	P=0.161
COCH-ARM / FISHERS	P=0.218	P=0.117	P=0.009**	P=0.178
ORDER RESTRICTED	P=0.052	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.066	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

Lung
 Alveolar/Bronchiolar Adenoma

TUMOR RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/44.06	0/44.21	1/46.96	2/42.02
POLY-3 PERCENT (g)	2.3%	0%	2.1%	4.8%
TERMINAL (d)	0/31 (0%)	0/33 (0%)	1/39 (3%)	1/31 (3%)
FIRST INCIDENCE	662	---	729 (T)	715

STATISTICAL TESTS

LIFE TABLE	P=0.198	P=0.495N	P=0.721N	P=0.501
POLY 3	P=0.193	P=0.499N	P=0.746N	P=0.483
POLY 1.5	P=0.195	P=0.500N	P=0.753N	P=0.487
POLY 6	P=0.192	P=0.497N	P=0.737N	P=0.484
LOGISTIC REGRESSION	P=0.192	P=0.499N	P=0.757	P=0.487
COCH-ARM / FISHERS	P=0.202	P=0.500N	P=0.753N	P=0.500
ORDER RESTRICTED	P=0.209	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.228	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

Lung
 Alveolar/Bronchiolar Carcinoma

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/43.81	0/44.21	0/46.96	2/41.96
POLY-3 PERCENT (g)	0%	0%	0%	4.8%
TERMINAL (d)	0/31 (0%)	0/33 (0%)	0/39 (0%)	2/31 (7%)
FIRST INCIDENCE	---	---	---	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.039*	(e)	(e)	P=0.238
POLY 3	P=0.041*	(e)	(e)	P=0.227
POLY 1.5	P=0.041*	(e)	(e)	P=0.229
POLY 6	P=0.041*	(e)	(e)	P=0.228
LOGISTIC REGRESSION	(e)	(e)	(e)	P=0.238
COCH-ARM / FISHERS	P=0.043*	(e)	(e)	P=0.247
ORDER RESTRICTED	P=0.026*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.035*	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

Lung
 Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma

TUMOR RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	1/44.06	0/44.21	1/46.96	4/42.02
POLY-3 PERCENT (g)	2.3%	0%	2.1%	9.5%
TERMINAL (d)	0/31 (0%)	0/33 (0%)	1/39 (3%)	3/31 (10%)
FIRST INCIDENCE	662	---	729 (T)	715

STATISTICAL TESTS

LIFE TABLE	P=0.023*	P=0.495N	P=0.721N	P=0.184
POLY 3	P=0.023*	P=0.499N	P=0.746N	P=0.164
POLY 1.5	P=0.024*	P=0.500N	P=0.753N	P=0.167
POLY 6	P=0.023*	P=0.497N	P=0.737N	P=0.163
LOGISTIC REGRESSION	P=0.022*	P=0.499N	P=0.757	P=0.167
COCH-ARM / FISHERS	P=0.026*	P=0.500N	P=0.753N	P=0.181
ORDER RESTRICTED	P=0.022*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.030*	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Mammary Gland
 Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.81	0/44.21	0/46.96	0/41.96
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/33 (0%)	0/39 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG
Mammary Gland Carcinoma or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.81	0/44.21	0/46.96	0/41.96
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/33 (0%)	0/39 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Mammary Gland
 Fibroadenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	3/50 (6%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/43.81	3/44.21	1/46.96	1/41.96
POLY-3 PERCENT (g)	4.6%	6.8%	2.1%	2.4%
TERMINAL (d)	2/31 (7%)	3/33 (9%)	1/39 (3%)	1/31 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.220N	P=0.529	P=0.420N	P=0.500N
POLY 3	P=0.235N	P=0.504	P=0.476N	P=0.515N
POLY 1.5	P=0.237N	P=0.502	P=0.487N	P=0.512N
POLY 6	P=0.230N	P=0.511	P=0.460N	P=0.514N
LOGISTIC REGRESSION	P=0.220N	P=0.529	P=0.420N	P=0.500N
COCH-ARM / FISHERS	P=0.232N	P=0.500	P=0.500N	P=0.500N
ORDER RESTRICTED	P=0.337N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.354N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Mammary Gland
 Fibroma, Fibroadenoma or Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	3/50 (6%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/43.81	3/44.21	1/46.96	1/41.96
POLY-3 PERCENT (g)	4.6%	6.8%	2.1%	2.4%
TERMINAL (d)	2/31 (7%)	3/33 (9%)	1/39 (3%)	1/31 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.220N	P=0.529	P=0.420N	P=0.500N
POLY 3	P=0.235N	P=0.504	P=0.476N	P=0.515N
POLY 1.5	P=0.237N	P=0.502	P=0.487N	P=0.512N
POLY 6	P=0.230N	P=0.511	P=0.460N	P=0.514N
LOGISTIC REGRESSION	P=0.220N	P=0.529	P=0.420N	P=0.500N
COCH-ARM / FISHERS	P=0.232N	P=0.500	P=0.500N	P=0.500N
ORDER RESTRICTED	P=0.337N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.354N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Mammary Gland
 Fibroma, Fibroadenoma, Carcinoma, or Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	3/50 (6%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/43.81	3/44.21	1/46.96	1/41.96
POLY-3 PERCENT (g)	4.6%	6.8%	2.1%	2.4%
TERMINAL (d)	2/31 (7%)	3/33 (9%)	1/39 (3%)	1/31 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.220N	P=0.529	P=0.420N	P=0.500N
POLY 3	P=0.235N	P=0.504	P=0.476N	P=0.515N
POLY 1.5	P=0.237N	P=0.502	P=0.487N	P=0.512N
POLY 6	P=0.230N	P=0.511	P=0.460N	P=0.514N
LOGISTIC REGRESSION	P=0.220N	P=0.529	P=0.420N	P=0.500N
COCH-ARM / FISHERS	P=0.232N	P=0.500	P=0.500N	P=0.500N
ORDER RESTRICTED	P=0.337N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.354N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Pancreas
 Adenoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	4/50 (8%)	3/50 (6%)
POLY-3 RATE (b)	0/43.81	2/44.21	4/46.96	3/41.96
POLY-3 PERCENT (g)	0%	4.5%	8.5%	7.2%
TERMINAL (d)	0/31 (0%)	2/33 (6%)	4/39 (10%)	3/31 (10%)
FIRST INCIDENCE	---	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.114	P=0.252	P=0.095	P=0.120
POLY 3	P=0.106	P=0.239	P=0.070	P=0.111
POLY 1.5	P=0.109	P=0.238	P=0.065	P=0.112
POLY 6	P=0.106	P=0.242	P=0.076	P=0.111
LOGISTIC REGRESSION (e)		P=0.252	P=0.095	P=0.120
COCH-ARM / FISHERS	P=0.121	P=0.247	P=0.059	P=0.121
ORDER RESTRICTED	P=0.076	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.090	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Pituitary Gland: Pars Distalis or Unspecified Site
 Adenoma**

TUMOR RATES

OVERALL (a)	25/50 (50%)	32/50 (64%)	26/50 (52%)	21/50 (42%)
POLY-3 RATE (b)	25/45.99	32/48.74	26/48.61	21/45.54
POLY-3 PERCENT (g)	54.4%	65.7%	53.5%	46.1%
TERMINAL (d)	16/31 (52%)	20/33 (61%)	19/39 (49%)	12/31 (39%)
FIRST INCIDENCE	641	473	586	504

STATISTICAL TESTS

LIFE TABLE	P=0.103N	P=0.228	P=0.293N	P=0.323N
POLY 3	P=0.078N	P=0.176	P=0.549N	P=0.278N
POLY 1.5	P=0.079N	P=0.146	P=0.566	P=0.288N
POLY 6	P=0.074N	P=0.221	P=0.485N	P=0.260N
LOGISTIC REGRESSION	P=0.072N	P=0.113	P=0.575N	P=0.307N
COCH-ARM / FISHERS	P=0.068N	P=0.113	P=0.500	P=0.274N
ORDER RESTRICTED	P=0.136N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.128N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Pituitary Gland: Pars Distalis or Unspecified Site
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	25/50 (50%)	32/50 (64%)	27/50 (54%)	21/50 (42%)
POLY-3 RATE (b)	25/45.99	32/48.74	27/48.62	21/45.54
POLY-3 PERCENT (g)	54.4%	65.7%	55.5%	46.1%
TERMINAL (d)	16/31 (52%)	20/33 (61%)	19/39 (49%)	12/31 (39%)
FIRST INCIDENCE	641	473	586	504

STATISTICAL TESTS

LIFE TABLE	P=0.111N	P=0.228	P=0.349N	P=0.323N
POLY 3	P=0.084N	P=0.176	P=0.537	P=0.278N
POLY 1.5	P=0.085N	P=0.146	P=0.487	P=0.288N
POLY 6	P=0.080N	P=0.221	P=0.565N	P=0.260N
LOGISTIC REGRESSION	P=0.078N	P=0.113	P=0.512	P=0.307N
COCH-ARM / FISHERS	P=0.073N	P=0.113	P=0.421	P=0.274N
ORDER RESTRICTED	P=0.136N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.139N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

Skin
 Basal Cell Adenoma

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/43.81	2/44.21	1/46.96	0/41.96
POLY-3 PERCENT (g)	0%	4.5%	2.1%	0%
TERMINAL (d)	0/31 (0%)	2/33 (6%)	1/39 (3%)	0/31 (0%)
FIRST INCIDENCE	---	729 (T)	729 (T)	---

STATISTICAL TESTS

LIFE TABLE	P=0.349N	P=0.252	P=0.546	(e)
POLY 3	P=0.361N	P=0.239	P=0.514	(e)
POLY 1.5	P=0.362N	P=0.238	P=0.508	(e)
POLY 6	P=0.356N	P=0.242	P=0.523	(e)
LOGISTIC REGRESSION	(e)	P=0.252	P=0.546	(e)
COCH-ARM / FISHERS	P=0.356N	P=0.247	P=0.500	(e)
ORDER RESTRICTED	P=0.335N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.352N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Skin
 Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/43.81	2/44.21	1/46.96	0/41.96
POLY-3 PERCENT (g)	0%	4.5%	2.1%	0%
TERMINAL (d)	0/31 (0%)	2/33 (6%)	1/39 (3%)	0/31 (0%)
FIRST INCIDENCE	---	729 (T)	729 (T)	---

STATISTICAL TESTS

LIFE TABLE	P=0.349N	P=0.252	P=0.546	(e)
POLY 3	P=0.361N	P=0.239	P=0.514	(e)
POLY 1.5	P=0.362N	P=0.238	P=0.508	(e)
POLY 6	P=0.356N	P=0.242	P=0.523	(e)
LOGISTIC REGRESSION	(e)	P=0.252	P=0.546	(e)
COCH-ARM / FISHERS	P=0.356N	P=0.247	P=0.500	(e)
ORDER RESTRICTED	P=0.335N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.352N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

Skin
 Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/43.81	2/44.21	1/46.96	0/41.96
POLY-3 PERCENT (g)	0%	4.5%	2.1%	0%
TERMINAL (d)	0/31 (0%)	2/33 (6%)	1/39 (3%)	0/31 (0%)
FIRST INCIDENCE	---	729 (T)	729 (T)	---

STATISTICAL TESTS

LIFE TABLE	P=0.349N	P=0.252	P=0.546	(e)
POLY 3	P=0.361N	P=0.239	P=0.514	(e)
POLY 1.5	P=0.362N	P=0.238	P=0.508	(e)
POLY 6	P=0.356N	P=0.242	P=0.523	(e)
LOGISTIC REGRESSION	(e)	P=0.252	P=0.546	(e)
COCH-ARM / FISHERS	P=0.356N	P=0.247	P=0.500	(e)
ORDER RESTRICTED	P=0.335N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.352N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 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)	7/50 (14%)	5/50 (10%)	10/50 (20%)	1/50 (2%)
POLY-3 RATE (b)	7/44.19	5/44.39	10/47.4	1/41.96
POLY-3 PERCENT (g)	15.8%	11.3%	21.1%	2.4%
TERMINAL (d)	5/31 (16%)	4/33 (12%)	8/39 (21%)	1/31 (3%)
FIRST INCIDENCE	662	682	649	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.078N	P=0.341N	P=0.480	P=0.035N*
POLY 3	P=0.101N	P=0.375N	P=0.353	P=0.035N*
POLY 1.5	P=0.096N	P=0.378N	P=0.328	P=0.034N*
POLY 6	P=0.103N	P=0.366N	P=0.393	P=0.035N*
LOGISTIC REGRESSION	P=0.086N	P=0.356N	P=0.378	P=0.035N*
COCH-ARM / FISHERS	P=0.084N	P=0.380N	P=0.298	P=0.030N*
ORDER RESTRICTED	P=0.039N*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.052N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG
Skin Fibroma				
TUMOR RATES	#	#	#	#
OVERALL (a)	6/50 (12%)	4/50 (8%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	6/44.08	4/44.21	1/46.96	1/41.96
POLY-3 PERCENT (g)	13.6%	9.1%	2.1%	2.4%
TERMINAL (d)	4/31 (13%)	4/33 (12%)	1/39 (3%)	1/31 (3%)
FIRST INCIDENCE	685	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS				
LIFE TABLE	P=0.019N*	P=0.331N	P=0.031N*	P=0.060N
POLY 3	P=0.022N*	P=0.367N	P=0.046N*	P=0.063N
POLY 1.5	P=0.022N*	P=0.369N	P=0.051N	P=0.062N
POLY 6	P=0.021N*	P=0.360N	P=0.040N*	P=0.063N
LOGISTIC REGRESSION	P=0.020N*	P=0.334N	P=0.038N*	P=0.061N
COCH-ARM / FISHERS	P=0.023N*	P=0.370N	P=0.056N	P=0.056N
ORDER RESTRICTED	P=0.025N*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.034N*	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

Skin
 Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma

TUMOR RATES	#	#	#	#
OVERALL (a)	8/50 (16%)	6/50 (12%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	8/44.15	6/44.74	1/46.96	2/42.13
POLY-3 PERCENT (g)	18.1%	13.4%	2.1%	4.8%
TERMINAL (d)	5/31 (16%)	5/33 (15%)	1/39 (3%)	1/31 (3%)
FIRST INCIDENCE	685	568	729 (T)	687

STATISTICAL TESTS

LIFE TABLE	P=0.012N*	P=0.342N	P=0.008N**	P=0.051N
POLY 3	P=0.012N*	P=0.375N	P=0.012N*	P=0.052N
POLY 1.5	P=0.013N*	P=0.382N	P=0.014N*	P=0.051N
POLY 6	P=0.012N*	P=0.363N	P=0.010N**	P=0.051N
LOGISTIC REGRESSION	P=0.013N*	P=0.373N	P=0.010N**	P=0.052N
COCH-ARM / FISHERS	P=0.013N*	P=0.387N	P=0.015N*	P=0.046N*
ORDER RESTRICTED	P=0.013N*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.018N*	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Skin
 Fibrosarcoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/43.98	2/44.74	0/46.96	0/41.96
POLY-3 PERCENT (g)	6.8%	4.5%	0%	0%
TERMINAL (d)	1/31 (3%)	1/33 (3%)	0/39 (0%)	0/31 (0%)
FIRST INCIDENCE	702	568	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.035N*	P=0.468N	P=0.085N	P=0.121N
POLY 3	P=0.036N*	P=0.492N	P=0.107N	P=0.127N
POLY 1.5	P=0.037N*	P=0.496N	P=0.112N	P=0.125N
POLY 6	P=0.035N*	P=0.484N	P=0.100N	P=0.127N
LOGISTIC REGRESSION	P=0.036N*	P=0.501N	P=0.103N	P=0.126N
COCH-ARM / FISHERS	P=0.037N*	P=0.500N	P=0.121N	P=0.121N
ORDER RESTRICTED	P=0.041N*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.053N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Skin
 Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	3/43.98	2/44.74	0/46.96	1/42.13
POLY-3 PERCENT (g)	6.8%	4.5%	0%	2.4%
TERMINAL (d)	1/31 (3%)	1/33 (3%)	0/39 (0%)	0/31 (0%)
FIRST INCIDENCE	702	568	---	687

STATISTICAL TESTS

LIFE TABLE	P=0.155N	P=0.468N	P=0.085N	P=0.301N
POLY 3	P=0.157N	P=0.492N	P=0.107N	P=0.321N
POLY 1.5	P=0.159N	P=0.496N	P=0.112N	P=0.318N
POLY 6	P=0.154N	P=0.484N	P=0.100N	P=0.319N
LOGISTIC REGRESSION	P=0.155N	P=0.501N	P=0.103N	P=0.319N
COCH-ARM / FISHERS	P=0.159N	P=0.500N	P=0.121N	P=0.309N
ORDER RESTRICTED	P=0.114N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.130N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG
Skin				
Keratoacanthoma				
TUMOR RATES				
	#	#	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	3/43.94	1/44.21	3/47.11	0/41.96
POLY-3 PERCENT (g)	6.8%	2.3%	6.4%	0%
TERMINAL (d)	2/31 (7%)	1/33 (3%)	2/39 (5%)	0/31 (0%)
FIRST INCIDENCE	694	729 (T)	690	---
STATISTICAL TESTS				
LIFE TABLE	P=0.169N	P=0.285N	P=0.556N	P=0.125N
POLY 3	P=0.190N	P=0.303N	P=0.630N	P=0.127N
POLY 1.5	P=0.187N	P=0.305N	P=0.644N	P=0.125N
POLY 6	P=0.191N	P=0.298N	P=0.608N	P=0.126N
LOGISTIC REGRESSION	P=0.177N	P=0.287N	P=0.614N	P=0.125N
COCH-ARM / FISHERS	P=0.177N	P=0.309N	P=0.661N	P=0.121N
ORDER RESTRICTED	P=0.082N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.097N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

Skin
 Squamous Cell Carcinoma

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/43.81	0/44.21	2/46.96	0/41.96
POLY-3 PERCENT (g)	0%	0%	4.3%	0%
TERMINAL (d)	0/31 (0%)	0/33 (0%)	2/39 (5%)	0/31 (0%)
FIRST INCIDENCE	---	---	729 (T)	---

STATISTICAL TESTS

LIFE TABLE	P=0.539	(e)	P=0.290	(e)
POLY 3	P=0.498	(e)	P=0.253	(e)
POLY 1.5	P=0.509	(e)	P=0.246	(e)
POLY 6	P=0.492	(e)	P=0.264	(e)
LOGISTIC REGRESSION	(e)	(e)	P=0.290	(e)
COCH-ARM / FISHERS	P=0.536	(e)	P=0.247	(e)
ORDER RESTRICTED	P=0.261	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.279	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

Skin
 Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/43.81	0/44.21	2/46.96	0/41.96
POLY-3 PERCENT (g)	0%	0%	4.3%	0%
TERMINAL (d)	0/31 (0%)	0/33 (0%)	2/39 (5%)	0/31 (0%)
FIRST INCIDENCE	---	---	729 (T)	---

STATISTICAL TESTS

LIFE TABLE	P=0.539	(e)	P=0.290	(e)
POLY 3	P=0.498	(e)	P=0.253	(e)
POLY 1.5	P=0.509	(e)	P=0.246	(e)
POLY 6	P=0.492	(e)	P=0.264	(e)
LOGISTIC REGRESSION	(e)	(e)	P=0.290	(e)
COCH-ARM / FISHERS	P=0.536	(e)	P=0.247	(e)
ORDER RESTRICTED	P=0.261	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.279	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
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 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Skin
 Squamous Cell Papilloma**

TUMOR RATES	#	#	#	#
OVERALL (a)	4/50 (8%)	2/50 (4%)	5/50 (10%)	1/50 (2%)
POLY-3 RATE (b)	4/44.06	2/44.39	5/47.25	1/41.96
POLY-3 PERCENT (g)	9.1%	4.5%	10.6%	2.4%
TERMINAL (d)	3/31 (10%)	1/33 (3%)	4/39 (10%)	1/31 (3%)
FIRST INCIDENCE	662	682	649	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.254N	P=0.314N	P=0.625	P=0.184N
POLY 3	P=0.285N	P=0.333N	P=0.544	P=0.193N
POLY 1.5	P=0.280N	P=0.336N	P=0.524	P=0.190N
POLY 6	P=0.287N	P=0.326N	P=0.573	P=0.193N
LOGISTIC REGRESSION	P=0.270N	P=0.329N	P=0.547	P=0.189N
COCH-ARM / FISHERS	P=0.260N	P=0.339N	P=0.500	P=0.181N
ORDER RESTRICTED	P=0.172N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.193N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
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 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Skin
 Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	7/50 (14%)	3/50 (6%)	9/50 (18%)	1/50 (2%)
POLY-3 RATE (b)	7/44.19	3/44.39	9/47.4	1/41.96
POLY-3 PERCENT (g)	15.8%	6.8%	19%	2.4%
TERMINAL (d)	5/31 (16%)	2/33 (6%)	7/39 (18%)	1/31 (3%)
FIRST INCIDENCE	662	682	649	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.116N	P=0.141N	P=0.574	P=0.035N*
POLY 3	P=0.142N	P=0.154N	P=0.452	P=0.035N*
POLY 1.5	P=0.136N	P=0.157N	P=0.425	P=0.034N*
POLY 6	P=0.146N	P=0.148N	P=0.492	P=0.035N*
LOGISTIC REGRESSION	P=0.126N	P=0.147N	P=0.472	P=0.035N*
COCH-ARM / FISHERS	P=0.122N	P=0.159N	P=0.393	P=0.030N*
ORDER RESTRICTED	P=0.033N*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.044N*	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Skin
 Squamous Cell Papilloma, Papilloma, or Keratoacanthoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	7/50 (14%)	3/50 (6%)	8/50 (16%)	1/50 (2%)
POLY-3 RATE (b)	7/44.19	3/44.39	8/47.4	1/41.96
POLY-3 PERCENT (g)	15.8%	6.8%	16.9%	2.4%
TERMINAL (d)	5/31 (16%)	2/33 (6%)	6/39 (15%)	1/31 (3%)
FIRST INCIDENCE	662	682	649	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.099N	P=0.141N	P=0.546N	P=0.035N*
POLY 3	P=0.122N	P=0.154N	P=0.559	P=0.035N*
POLY 1.5	P=0.117N	P=0.157N	P=0.532	P=0.034N*
POLY 6	P=0.124N	P=0.148N	P=0.597	P=0.035N*
LOGISTIC REGRESSION	P=0.109N	P=0.147N	P=0.573	P=0.035N*
COCH-ARM / FISHERS	P=0.105N	P=0.159N	P=0.500	P=0.030N*
ORDER RESTRICTED	P=0.030N*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.041N*	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
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 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

Testes
 Adenoma

TUMOR RATES

OVERALL (a)	41/50 (82%)	39/50 (78%)	45/50 (90%)	34/50 (68%)
POLY-3 RATE (b)	41/47.46	39/46.9	45/49.37	34/44.7
POLY-3 PERCENT (g)	86.4%	83.2%	91.2%	76.1%
TERMINAL (d)	29/31 (94%)	30/33 (91%)	36/39 (92%)	26/31 (84%)
FIRST INCIDENCE	563	540	489	401

STATISTICAL TESTS

LIFE TABLE	P=0.135N	P=0.273N	P=0.225N	P=0.136N
POLY 3	P=0.161N	P=0.435N	P=0.326	P=0.138N
POLY 1.5	P=0.142N	P=0.419N	P=0.262	P=0.118N
POLY 6	P=0.169N	P=0.456N	P=0.434	P=0.156N
LOGISTIC REGRESSION	P=0.175N	P=0.406N	P=0.334	P=0.151N
COCH-ARM / FISHERS	P=0.095N	P=0.402N	P=0.194	P=0.083N
ORDER RESTRICTED	P=0.093N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.110N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
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 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Thyroid Gland: C-Cell
 Adenoma**

TUMOR RATES

OVERALL (a)	6/50 (12%)	3/50 (6%)	7/50 (14%)	4/50 (8%)
POLY-3 RATE (b)	6/44.19	3/44.21	7/46.96	4/42.02
POLY-3 PERCENT (g)	13.6%	6.8%	14.9%	9.5%
TERMINAL (d)	4/31 (13%)	3/33 (9%)	7/39 (18%)	3/31 (10%)
FIRST INCIDENCE	662	729 (T)	729 (T)	715

STATISTICAL TESTS

LIFE TABLE	P=0.507N	P=0.217N	P=0.570N	P=0.373N
POLY 3	P=0.545N	P=0.241N	P=0.547	P=0.401N
POLY 1.5	P=0.538N	P=0.242N	P=0.526	P=0.394N
POLY 6	P=0.546N	P=0.236N	P=0.576	P=0.402N
LOGISTIC REGRESSION	P=0.524N	P=0.223N	P=0.615	P=0.388N
COCH-ARM / FISHERS	P=0.512N	P=0.243N	P=0.500	P=0.370N
ORDER RESTRICTED	P=0.442N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.456N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

Thyroid Gland: C-Cell
 Carcinoma

TUMOR RATES

OVERALL (a)	2/50 (4%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/43.81	2/44.21	0/46.96	0/41.96
POLY-3 PERCENT (g)	4.6%	4.5%	0%	0%
TERMINAL (d)	2/31 (7%)	2/33 (6%)	0/39 (0%)	0/31 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.063N	P=0.673N	P=0.189N	P=0.238N
POLY 3	P=0.068N	P=0.691N	P=0.222N	P=0.247N
POLY 1.5	P=0.069N	P=0.693N	P=0.229N	P=0.245N
POLY 6	P=0.066N	P=0.686N	P=0.212N	P=0.245N
LOGISTIC REGRESSION	P=0.063N	P=0.673N	(e)	(e)
COCH-ARM / FISHERS	P=0.070N	P=0.691N	P=0.247N	P=0.247N
ORDER RESTRICTED	P=0.124N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.112N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

Thyroid Gland: C-Cell
 Carcinoma or Adenoma

TUMOR RATES

OVERALL (a)	8/50 (16%)	5/50 (10%)	7/50 (14%)	4/50 (8%)
POLY-3 RATE (b)	8/44.19	5/44.21	7/46.96	4/42.02
POLY-3 PERCENT (g)	18.1%	11.3%	14.9%	9.5%
TERMINAL (d)	6/31 (19%)	5/33 (15%)	7/39 (18%)	3/31 (10%)
FIRST INCIDENCE	662	729 (T)	729 (T)	715

STATISTICAL TESTS

LIFE TABLE	P=0.215N	P=0.239N	P=0.322N	P=0.182N
POLY 3	P=0.251N	P=0.274N	P=0.449N	P=0.200N
POLY 1.5	P=0.247N	P=0.276N	P=0.472N	P=0.195N
POLY 6	P=0.249N	P=0.267N	P=0.417N	P=0.200N
LOGISTIC REGRESSION	P=0.225N	P=0.241N	P=0.366N	P=0.187N
COCH-ARM / FISHERS	P=0.228N	P=0.277N	P=0.500N	P=0.178N
ORDER RESTRICTED	P=0.196N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.217N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Thyroid Gland: Follicular Cell
 Adenoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	0/43.81	0/44.21	2/46.96	2/42.48
POLY-3 PERCENT (g)	0%	0%	4.3%	4.7%
TERMINAL (d)	0/31 (0%)	0/33 (0%)	2/39 (5%)	0/31 (0%)
FIRST INCIDENCE	---	---	729 (T)	626

STATISTICAL TESTS

LIFE TABLE	P=0.067	(e)	P=0.290	P=0.235
POLY 3	P=0.064	(e)	P=0.253	P=0.230
POLY 1.5	P=0.065	(e)	P=0.246	P=0.231
POLY 6	P=0.065	(e)	P=0.264	P=0.233
LOGISTIC REGRESSION	P=0.069	(e)	P=0.290	P=0.249
COCH-ARM / FISHERS	P=0.070	(e)	P=0.247	P=0.247
ORDER RESTRICTED	P=0.111	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.105	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

Thyroid Gland: Follicular Cell
 Carcinoma or Adenoma

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	0/43.81	0/44.21	2/46.96	2/42.48
POLY-3 PERCENT (g)	0%	0%	4.3%	4.7%
TERMINAL (d)	0/31 (0%)	0/33 (0%)	2/39 (5%)	0/31 (0%)
FIRST INCIDENCE	---	---	729 (T)	626

STATISTICAL TESTS

LIFE TABLE	P=0.067	(e)	P=0.290	P=0.235
POLY 3	P=0.064	(e)	P=0.253	P=0.230
POLY 1.5	P=0.065	(e)	P=0.246	P=0.231
POLY 6	P=0.065	(e)	P=0.264	P=0.233
LOGISTIC REGRESSION	P=0.069	(e)	P=0.290	P=0.249
COCH-ARM / FISHERS	P=0.070	(e)	P=0.247	P=0.247
ORDER RESTRICTED	P=0.111	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.105	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**All Organs
 Hemangiosarcoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/44.11	1/44.43	2/46.96	0/41.96
POLY-3 PERCENT (g)	2.3%	2.3%	4.3%	0%
TERMINAL (d)	0/31 (0%)	0/33 (0%)	2/39 (5%)	0/31 (0%)
FIRST INCIDENCE	645	673	729 (T)	---

STATISTICAL TESTS

LIFE TABLE	P=0.376N	P=0.749N	P=0.564	P=0.510N
POLY 3	P=0.392N	P=0.759N	P=0.522	P=0.510N
POLY 1.5	P=0.388N	P=0.760N	P=0.512	P=0.508N
POLY 6	P=0.393N	P=0.756N	P=0.536	P=0.510N
LOGISTIC REGRESSION	P=0.375N	P=0.762N	P=0.498	P=0.475N
COCH-ARM / FISHERS	P=0.374N	P=0.753N	P=0.500	P=0.500N
ORDER RESTRICTED	P=0.291N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.310N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**All Organs
 Hemangiosarcoma or Hemangioma**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/44.11	1/44.43	2/46.96	0/41.96
POLY-3 PERCENT (g)	4.5%	2.3%	4.3%	0%
TERMINAL (d)	1/31 (3%)	0/33 (0%)	2/39 (5%)	0/31 (0%)
FIRST INCIDENCE	645	673	729 (T)	---

STATISTICAL TESTS

LIFE TABLE	P=0.225N	P=0.481N	P=0.622N	P=0.245N
POLY 3	P=0.241N	P=0.498N	P=0.671N	P=0.248N
POLY 1.5	P=0.238N	P=0.499N	P=0.681N	P=0.246N
POLY 6	P=0.242N	P=0.493N	P=0.656N	P=0.248N
LOGISTIC REGRESSION	P=0.231N	P=0.500N	P=0.683N	P=0.239N
COCH-ARM / FISHERS	P=0.227N	P=0.500N	P=0.691N	P=0.247N
ORDER RESTRICTED	P=0.165N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.184N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

All Organs
 Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated

TUMOR RATES	#	#	#	#
OVERALL (a)	23/50 (46%)	10/50 (20%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	23/47.22	10/44.52	2/47.11	2/41.96
POLY-3 PERCENT (g)	48.7%	22.5%	4.3%	4.8%
TERMINAL (d)	12/31 (39%)	7/33 (21%)	1/39 (3%)	2/31 (7%)
FIRST INCIDENCE	544	673	690	729 (T)

STATISTICAL TESTS

LIFE TABLE	P<0.001N**	P=0.008N**	P<0.001N**	P<0.001N**
POLY 3	P<0.001N**	P=0.006N**	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.005N**	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P=0.008N**	P<0.001N**	P<0.001N**
LOGISTIC REGRESSION	P<0.001N**	P=0.005N**	P<0.001N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.005N**	P<0.001N**	P<0.001N**
ORDER RESTRICTED	P<0.001N**	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001N**	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

All Organs
 Mesothelioma: Benign, Malignant, NOS

TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	5/50 (10%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	3/43.94	5/45.18	2/47.41	3/42.23
POLY-3 PERCENT (g)	6.8%	11.1%	4.2%	7.1%
TERMINAL (d)	2/31 (7%)	2/33 (6%)	0/39 (0%)	2/31 (7%)
FIRST INCIDENCE	694	590	619	658

STATISTICAL TESTS

LIFE TABLE	P=0.375N	P=0.388	P=0.413N	P=0.657
POLY 3	P=0.379N	P=0.371	P=0.465N	P=0.644
POLY 1.5	P=0.381N	P=0.364	P=0.481N	P=0.647
POLY 6	P=0.372N	P=0.387	P=0.443N	P=0.648
LOGISTIC REGRESSION	P=0.367N	P=0.356	P=0.515N	P=0.646
COCH-ARM / FISHERS	P=0.372N	P=0.357	P=0.500N	P=0.661N
ORDER RESTRICTED	P=0.437N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.450N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**All Organs
 Mesothelioma: Malignant**

TUMOR RATES

	#	#	#	#
OVERALL (a)	3/50 (6%)	5/50 (10%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	3/43.94	5/45.18	2/47.41	3/42.23
POLY-3 PERCENT (g)	6.8%	11.1%	4.2%	7.1%
TERMINAL (d)	2/31 (7%)	2/33 (6%)	0/39 (0%)	2/31 (7%)
FIRST INCIDENCE	694	590	619	658

STATISTICAL TESTS

LIFE TABLE	P=0.375N	P=0.388	P=0.413N	P=0.657
POLY 3	P=0.379N	P=0.371	P=0.465N	P=0.644
POLY 1.5	P=0.381N	P=0.364	P=0.481N	P=0.647
POLY 6	P=0.372N	P=0.387	P=0.443N	P=0.648
LOGISTIC REGRESSION	P=0.367N	P=0.356	P=0.515N	P=0.646
COCH-ARM / FISHERS	P=0.372N	P=0.357	P=0.500N	P=0.661N
ORDER RESTRICTED	P=0.437N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.450N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG
All Organs				
Benign Tumors				
TUMOR RATES				
	#	#	#	#
OVERALL (a)	47/50 (94%)	50/50 (100%)	50/50 (100%)	48/50 (96%)
POLY-3 RATE (b)	47/48.66	50/50	50/50	48/48.28
POLY-3 PERCENT (g)	96.6%	100%	100%	99.4%
TERMINAL (d)	30/31 (97%)	33/33 (100%)	39/39 (100%)	31/31 (100%)
FIRST INCIDENCE	563	473	489	401
STATISTICAL TESTS				
LIFE TABLE	P=0.523	P=0.528	P=0.143N	P=0.458
POLY 3	P=0.294	P=0.269	P=0.269	P=0.372
POLY 1.5	P=0.347	P=0.182	P=0.182	P=0.365
POLY 6	P=0.310	P=0.402	P=0.402	P=0.437
LOGISTIC REGRESSION	P=0.166	P=0.091	P=0.199	P=0.122
COCH-ARM / FISHERS	P=0.613	P=0.121	P=0.121	P=0.500
ORDER RESTRICTED	P=0.035*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.043*	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG
All Organs				
Malignant Tumors				
TUMOR RATES				
	#	#	#	#
OVERALL (a)	30/50 (60%)	19/50 (38%)	12/50 (24%)	12/50 (24%)
POLY-3 RATE (b)	30/47.94	19/46.61	12/48.43	12/43.64
POLY-3 PERCENT (g)	62.6%	40.8%	24.8%	27.5%
TERMINAL (d)	16/31 (52%)	11/33 (33%)	6/39 (15%)	6/31 (19%)
FIRST INCIDENCE	544	540	489	563
STATISTICAL TESTS				
LIFE TABLE	P<0.001N**	P=0.035N*	P<0.001N**	P=0.002N**
POLY 3	P<0.001N**	P=0.024N*	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.023N*	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P=0.027N*	P<0.001N**	P<0.001N**
LOGISTIC REGRESSION	P<0.001N**	P=0.023N*	P<0.001N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.022N*	P<0.001N**	P<0.001N**
ORDER RESTRICTED	P<0.001N**	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001N**	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**All Organs
 Malignant and Benign Tumors**

TUMOR RATES

	#	#	#	#
OVERALL (a)	49/50 (98%)	50/50 (100%)	50/50 (100%)	48/50 (96%)
POLY-3 RATE (b)	49/49.24	50/50	50/50	48/48.28
POLY-3 PERCENT (g)	99.5%	100%	100%	99.4%
TERMINAL (d)	31/31 (100%)	33/33 (100%)	39/39 (100%)	31/31 (100%)
FIRST INCIDENCE	544	473	489	401

STATISTICAL TESTS

LIFE TABLE	P=0.439N	P=0.472N	P=0.072N	P=0.546N
POLY 3	P=0.892N	P=0.999	P=0.999	P=0.996N
POLY 1.5	P=0.576N	P=0.849	P=0.849	P=0.875N
POLY 6	P=1.000N	P=1.000	P=1.000	P=1.000N
LOGISTIC REGRESSION	P=0.476	(e)	(e)	P=0.527
COCH-ARM / FISHERS	P=0.208N	P=0.500	P=0.500	P=0.500N
ORDER RESTRICTED	P=0.336N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.349N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Adrenal Cortex
 Adenoma**

TUMOR RATES

OVERALL (a)	1/50 (2%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.71	0/43.83	0/44.18	0/41.11
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	1/35 (3%)	0/32 (0%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	729 (T)	---	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.345N	P=0.518N	P=0.494N	P=0.500N
POLY 3	P=0.344N	P=0.504N	P=0.502N	P=0.517N
POLY 1.5	P=0.345N	P=0.504N	P=0.501N	P=0.514N
POLY 6	P=0.344N	P=0.505N	P=0.503N	P=0.515N
LOGISTIC REGRESSION	P=0.345N	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.350N	P=0.505N	P=0.500N	P=0.500N
ORDER RESTRICTED	P=0.136N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.160N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Adrenal Medulla
 Pheochromocytoma Benign**

TUMOR RATES

OVERALL (a)	2/50 (4%)	0/49 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/44.71	0/43.83	1/44.18	1/41.31
POLY-3 PERCENT (g)	4.5%	0%	2.3%	2.4%
TERMINAL (d)	2/35 (6%)	0/32 (0%)	1/36 (3%)	0/35 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	677

STATISTICAL TESTS

LIFE TABLE	P=0.562N	P=0.258N	P=0.490N	P=0.494N
POLY 3	P=0.588N	P=0.241N	P=0.504N	P=0.528N
POLY 1.5	P=0.586N	P=0.241N	P=0.502N	P=0.524N
POLY 6	P=0.585N	P=0.242N	P=0.505N	P=0.522N
LOGISTIC REGRESSION	P=0.596N	(e)	P=0.490N	P=0.526N
COCH-ARM / FISHERS	P=0.573N	P=0.253N	P=0.500N	P=0.500N
ORDER RESTRICTED	P=0.294N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.319N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

Adrenal Medulla
Pheochromocytoma: Benign, Complex, Malignant, NOS

TUMOR RATES

OVERALL (a)	2/50 (4%)	1/49 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/44.71	1/44.21	1/44.18	1/41.31
POLY-3 PERCENT (g)	4.5%	2.3%	2.3%	2.4%
TERMINAL (d)	2/35 (6%)	0/32 (0%)	1/36 (3%)	0/35 (0%)
FIRST INCIDENCE	729 (T)	621	729 (T)	677

STATISTICAL TESTS

LIFE TABLE	P=0.431N	P=0.523N	P=0.490N	P=0.494N
POLY 3	P=0.449N	P=0.504N	P=0.504N	P=0.528N
POLY 1.5	P=0.445N	P=0.505N	P=0.502N	P=0.524N
POLY 6	P=0.446N	P=0.503N	P=0.505N	P=0.522N
LOGISTIC REGRESSION	P=0.443N	P=0.508N	P=0.490N	P=0.526N
COCH-ARM / FISHERS	P=0.428N	P=0.508N	P=0.500N	P=0.500N
ORDER RESTRICTED	P=0.440N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.458N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Clitoral/Preputial Gland
 Adenoma**

TUMOR RATES

OVERALL (a)	7/50 (14%)	10/48 (21%)	8/50 (16%)	9/50 (18%)
POLY-3 RATE (b)	7/44.94	10/43.49	8/45.99	9/41.13
POLY-3 PERCENT (g)	15.6%	23%	17.4%	21.9%
TERMINAL (d)	6/35 (17%)	8/32 (25%)	3/36 (8%)	8/35 (23%)
FIRST INCIDENCE	668	663	492	725

STATISTICAL TESTS

LIFE TABLE	P=0.503	P=0.244	P=0.519	P=0.394
POLY 3	P=0.408	P=0.269	P=0.519	P=0.318
POLY 1.5	P=0.422	P=0.269	P=0.512	P=0.332
POLY 6	P=0.416	P=0.269	P=0.532	P=0.322
LOGISTIC REGRESSION	P=0.416	P=0.265	P=0.503	P=0.360
COCH-ARM / FISHERS	P=0.491	P=0.266	P=0.500	P=0.393
ORDER RESTRICTED	P=0.369	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.393	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Clitoral/Preputial Gland
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	8/50 (16%)	11/48 (23%)	9/50 (18%)	10/50 (20%)
POLY-3 RATE (b)	8/44.94	11/43.49	9/45.99	10/41.13
POLY-3 PERCENT (g)	17.8%	25.3%	19.6%	24.3%
TERMINAL (d)	7/35 (20%)	9/32 (28%)	4/36 (11%)	9/35 (26%)
FIRST INCIDENCE	668	663	492	725

STATISTICAL TESTS

LIFE TABLE	P=0.508	P=0.245	P=0.521	P=0.398
POLY 3	P=0.405	P=0.274	P=0.521	P=0.317
POLY 1.5	P=0.420	P=0.274	P=0.513	P=0.332
POLY 6	P=0.414	P=0.274	P=0.535	P=0.321
LOGISTIC REGRESSION	P=0.409	P=0.269	P=0.501	P=0.366
COCH-ARM / FISHERS	P=0.494	P=0.271	P=0.500	P=0.398
ORDER RESTRICTED	P=0.372	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.396	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

Islets, Pancreatic
 Adenoma

TUMOR RATES

OVERALL (a)	2/49 (4%)	0/48 (0%)	1/48 (2%)	1/49 (2%)
POLY-3 RATE (b)	2/44.36	0/43.14	1/43.32	1/40.27
POLY-3 PERCENT (g)	4.5%	0%	2.3%	2.5%
TERMINAL (d)	2/35 (6%)	0/32 (0%)	1/36 (3%)	1/35 (3%)
FIRST INCIDENCE	729 (T)	---	729 (T)	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.562N	P=0.258N	P=0.490N	P=0.500N
POLY 3	P=0.589N	P=0.243N	P=0.508N	P=0.534N
POLY 1.5	P=0.587N	P=0.243N	P=0.508N	P=0.527N
POLY 6	P=0.586N	P=0.244N	P=0.507N	P=0.531N
LOGISTIC REGRESSION	P=0.562N	(e)	P=0.490N	P=0.500N
COCH-ARM / FISHERS	P=0.574N	P=0.253N	P=0.508N	P=0.500N
ORDER RESTRICTED	P=0.299N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.329N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Islets, Pancreatic
 Carcinoma**

TUMOR RATES

OVERALL (a)	0/49 (0%)	0/48 (0%)	0/48 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/44.36	0/43.14	0/43.32	0/40.27
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/32 (0%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Islets, Pancreatic
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	2/49 (4%)	0/48 (0%)	1/48 (2%)	1/49 (2%)
POLY-3 RATE (b)	2/44.36	0/43.14	1/43.32	1/40.27
POLY-3 PERCENT (g)	4.5%	0%	2.3%	2.5%
TERMINAL (d)	2/35 (6%)	0/32 (0%)	1/36 (3%)	1/35 (3%)
FIRST INCIDENCE	729 (T)	---	729 (T)	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.562N	P=0.258N	P=0.490N	P=0.500N
POLY 3	P=0.589N	P=0.243N	P=0.508N	P=0.534N
POLY 1.5	P=0.587N	P=0.243N	P=0.508N	P=0.527N
POLY 6	P=0.586N	P=0.244N	P=0.507N	P=0.531N
LOGISTIC REGRESSION	P=0.562N	(e)	P=0.490N	P=0.500N
COCH-ARM / FISHERS	P=0.574N	P=0.253N	P=0.508N	P=0.500N
ORDER RESTRICTED	P=0.299N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.329N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

Lung
 Alveolar/Bronchiolar Adenoma

TUMOR RATES

OVERALL (a)	0/50 (0%)	1/49 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.71	1/44.21	1/44.18	0/41.11
POLY-3 PERCENT (g)	0%	2.3%	2.3%	0%
TERMINAL (d)	0/35 (0%)	0/32 (0%)	1/36 (3%)	0/35 (0%)
FIRST INCIDENCE	---	621	729 (T)	---

STATISTICAL TESTS

LIFE TABLE	P=0.549N	P=0.496	P=0.506	(e)
POLY 3	P=0.553N	P=0.498	P=0.498	(e)
POLY 1.5	P=0.550N	P=0.497	P=0.499	(e)
POLY 6	P=0.551N	P=0.498	P=0.497	(e)
LOGISTIC REGRESSION	P=0.522N	P=0.480	P=0.506	(e)
COCH-ARM / FISHERS	P=0.534N	P=0.495	P=0.500	(e)
ORDER RESTRICTED	P=0.402	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.423	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

Lung
 Alveolar/Bronchiolar Carcinoma

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.71	0/43.83	0/44.18	0/41.11
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/32 (0%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

Lung
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma

TUMOR RATES

OVERALL (a)	0/50 (0%)	1/49 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.71	1/44.21	1/44.18	0/41.11
POLY-3 PERCENT (g)	0%	2.3%	2.3%	0%
TERMINAL (d)	0/35 (0%)	0/32 (0%)	1/36 (3%)	0/35 (0%)
FIRST INCIDENCE	---	621	729 (T)	---

STATISTICAL TESTS

LIFE TABLE	P=0.549N	P=0.496	P=0.506	(e)
POLY 3	P=0.553N	P=0.498	P=0.498	(e)
POLY 1.5	P=0.550N	P=0.497	P=0.499	(e)
POLY 6	P=0.551N	P=0.498	P=0.497	(e)
LOGISTIC REGRESSION	P=0.522N	P=0.480	P=0.506	(e)
COCH-ARM / FISHERS	P=0.534N	P=0.495	P=0.500	(e)
ORDER RESTRICTED	P=0.402	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.423	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG
Mammary Gland Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	2/49 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.71	2/43.83	0/44.18	0/41.11
POLY-3 PERCENT (g)	2.2%	4.6%	0%	0%
TERMINAL (d)	1/35 (3%)	2/32 (6%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---	---
STATISTICAL TESTS				
LIFE TABLE	P=0.127N	P=0.469	P=0.494N	P=0.500N
POLY 3	P=0.137N	P=0.493	P=0.502N	P=0.517N
POLY 1.5	P=0.136N	P=0.494	P=0.501N	P=0.514N
POLY 6	P=0.137N	P=0.491	P=0.503N	P=0.515N
LOGISTIC REGRESSION	P=0.127N	P=0.469	(e)	(e)
COCH-ARM / FISHERS	P=0.133N	P=0.492	P=0.500N	P=0.500N
ORDER RESTRICTED	P=0.180N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.208N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Mammary Gland
 Carcinoma or Adenoma**

TUMOR RATES

	#	#	#	#
OVERALL (a)	2/50 (4%)	2/49 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.71	2/43.83	0/44.18	0/41.11
POLY-3 PERCENT (g)	4.5%	4.6%	0%	0%
TERMINAL (d)	2/35 (6%)	2/32 (6%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.065N	P=0.663	P=0.232N	P=0.238N
POLY 3	P=0.072N	P=0.687	P=0.240N	P=0.256N
POLY 1.5	P=0.072N	P=0.687	P=0.239N	P=0.253N
POLY 6	P=0.072N	P=0.686	P=0.240N	P=0.254N
LOGISTIC REGRESSION	P=0.065N	P=0.663	(e)	(e)
COCH-ARM / FISHERS	P=0.069N	P=0.684	P=0.247N	P=0.247N
ORDER RESTRICTED	P=0.129N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.119N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG
Mammary Gland Fibroadenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	28/50 (56%)	30/49 (61%)	28/50 (56%)	17/50 (34%)
POLY-3 RATE (b)	28/45.85	30/46.22	28/46.68	17/42.3
POLY-3 PERCENT (g)	61.1%	64.9%	60%	40.2%
TERMINAL (d)	23/35 (66%)	21/32 (66%)	20/36 (56%)	15/35 (43%)
FIRST INCIDENCE	652	568	492	509
STATISTICAL TESTS				
LIFE TABLE	P=0.007N**	P=0.284	P=0.537N	P=0.024N*
POLY 3	P=0.013N*	P=0.432	P=0.543N	P=0.036N*
POLY 1.5	P=0.011N*	P=0.409	P=0.557N	P=0.034N*
POLY 6	P=0.011N*	P=0.462	P=0.515N	P=0.032N*
LOGISTIC REGRESSION	P=0.014N*	P=0.369	P=0.547	P=0.044N*
COCH-ARM / FISHERS	P=0.005N**	P=0.373	P=0.580N	P=0.022N*
ORDER RESTRICTED	P=0.018N*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.021N*	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Mammary Gland
 Fibroma, Fibroadenoma or Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	29/50 (58%)	32/49 (65%)	28/50 (56%)	17/50 (34%)
POLY-3 RATE (b)	29/45.85	32/46.22	28/46.68	17/42.3
POLY-3 PERCENT (g)	63.3%	69.2%	60%	40.2%
TERMINAL (d)	24/35 (69%)	23/32 (72%)	20/36 (56%)	15/35 (43%)
FIRST INCIDENCE	652	568	492	509

STATISTICAL TESTS

LIFE TABLE	P=0.003N**	P=0.213	P=0.463N	P=0.015N*
POLY 3	P=0.004N**	P=0.345	P=0.456N	P=0.021N*
POLY 1.5	P=0.004N**	P=0.324	P=0.473N	P=0.020N*
POLY 6	P=0.003N**	P=0.371	P=0.424N	P=0.018N*
LOGISTIC REGRESSION	P=0.005N**	P=0.285	P=0.538N	P=0.028N*
COCH-ARM / FISHERS	P=0.002N**	P=0.295	P=0.500N	P=0.013N*
ORDER RESTRICTED	P=0.007N**	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.007N**	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Mammary Gland
 Fibroma, Fibroadenoma, Carcinoma, or Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	30/50 (60%)	32/49 (65%)	28/50 (56%)	17/50 (34%)
POLY-3 RATE (b)	30/45.85	32/46.22	28/46.68	17/42.3
POLY-3 PERCENT (g)	65.4%	69.2%	60%	40.2%
TERMINAL (d)	25/35 (71%)	23/32 (72%)	20/36 (56%)	15/35 (43%)
FIRST INCIDENCE	652	568	492	509

STATISTICAL TESTS

LIFE TABLE	P=0.002N**	P=0.267	P=0.390N	P=0.008N**
POLY 3	P=0.002N**	P=0.431	P=0.369N	P=0.012N*
POLY 1.5	P=0.002N**	P=0.405	P=0.389N	P=0.012N*
POLY 6	P=0.002N**	P=0.464	P=0.336N	P=0.010N**
LOGISTIC REGRESSION	P=0.003N**	P=0.360	P=0.457N	P=0.017N*
COCH-ARM / FISHERS	P<0.001N**	P=0.368	P=0.420N	P=0.008N**
ORDER RESTRICTED	P=0.005N**	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.004N**	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Pancreas
 Adenoma**

TUMOR RATES

OVERALL (a)	1/49 (2%)	0/48 (0%)	0/48 (0%)	0/49 (0%)
POLY-3 RATE (b)	1/44.36	0/43.14	0/43.32	0/40.27
POLY-3 PERCENT (g)	2.3%	0%	0%	0%
TERMINAL (d)	1/35 (3%)	0/32 (0%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	729 (T)	---	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.345N	P=0.518N	P=0.494N	P=0.500N
POLY 3	P=0.341N	P=0.506N	P=0.505N	P=0.519N
POLY 1.5	P=0.343N	P=0.505N	P=0.504N	P=0.516N
POLY 6	P=0.341N	P=0.507N	P=0.504N	P=0.518N
LOGISTIC REGRESSION	P=0.345N	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.351N	P=0.505N	P=0.505N	P=0.500N
ORDER RESTRICTED	P=0.138N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.165N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Pituitary Gland: Pars Distalis or Unspecified Site
 Adenoma**

TUMOR RATES

OVERALL (a)	36/50 (72%)	32/49 (65%)	31/50 (62%)	28/50 (56%)
POLY-3 RATE (b)	36/46.6	32/46.1	31/48	28/41.99
POLY-3 PERCENT (g)	77.3%	69.4%	64.6%	66.7%
TERMINAL (d)	28/35 (80%)	24/32 (75%)	21/36 (58%)	25/35 (71%)
FIRST INCIDENCE	638	568	492	573

STATISTICAL TESTS

LIFE TABLE	P=0.075N	P=0.464N	P=0.219N	P=0.086N
POLY 3	P=0.175N	P=0.260N	P=0.122N	P=0.182N
POLY 1.5	P=0.146N	P=0.275N	P=0.147N	P=0.148N
POLY 6	P=0.174N	P=0.252N	P=0.098N	P=0.190N
LOGISTIC REGRESSION	P=0.179N	P=0.293N	P=0.207N	P=0.169N
COCH-ARM / FISHERS	P=0.065N	P=0.308N	P=0.198N	P=0.072N
ORDER RESTRICTED	P=0.175N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.207N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Pituitary Gland: Pars Distalis or Unspecified Site
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	36/50 (72%)	32/49 (65%)	31/50 (62%)	28/50 (56%)
POLY-3 RATE (b)	36/46.6	32/46.1	31/48	28/41.99
POLY-3 PERCENT (g)	77.3%	69.4%	64.6%	66.7%
TERMINAL (d)	28/35 (80%)	24/32 (75%)	21/36 (58%)	25/35 (71%)
FIRST INCIDENCE	638	568	492	573

STATISTICAL TESTS

LIFE TABLE	P=0.075N	P=0.464N	P=0.219N	P=0.086N
POLY 3	P=0.175N	P=0.260N	P=0.122N	P=0.182N
POLY 1.5	P=0.146N	P=0.275N	P=0.147N	P=0.148N
POLY 6	P=0.174N	P=0.252N	P=0.098N	P=0.190N
LOGISTIC REGRESSION	P=0.179N	P=0.293N	P=0.207N	P=0.169N
COCH-ARM / FISHERS	P=0.065N	P=0.308N	P=0.198N	P=0.072N
ORDER RESTRICTED	P=0.175N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.207N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Skin
 Basal Cell Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.71	0/43.83	0/44.18	0/41.11
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/32 (0%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Skin
 Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma**

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/49 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/44.71	0/43.83	1/44.72	0/41.11
POLY-3 PERCENT (g)	2.2%	0%	2.2%	0%
TERMINAL (d)	1/35 (3%)	0/32 (0%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	729 (T)	---	563	---

STATISTICAL TESTS

LIFE TABLE	P=0.476N	P=0.518N	P=0.756	P=0.500N
POLY 3	P=0.478N	P=0.504N	P=0.761N	P=0.517N
POLY 1.5	P=0.476N	P=0.504N	P=0.760N	P=0.514N
POLY 6	P=0.475N	P=0.505N	P=0.760N	P=0.515N
LOGISTIC REGRESSION	P=0.412N	(e)	P=0.760	(e)
COCH-ARM / FISHERS	P=0.462N	P=0.505N	P=0.753N	P=0.500N
ORDER RESTRICTED	P=0.268N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.294N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

Skin
 Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	0/49 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/45.04	0/43.83	1/44.72	0/41.11
POLY-3 PERCENT (g)	4.4%	0%	2.2%	0%
TERMINAL (d)	1/35 (3%)	0/32 (0%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	638	---	563	---

STATISTICAL TESTS

LIFE TABLE	P=0.272N	P=0.257N	P=0.517N	P=0.258N
POLY 3	P=0.264N	P=0.243N	P=0.502N	P=0.258N
POLY 1.5	P=0.262N	P=0.242N	P=0.501N	P=0.254N
POLY 6	P=0.260N	P=0.245N	P=0.503N	P=0.257N
LOGISTIC REGRESSION	P=0.197N	P=0.243N	P=0.507N	P=0.239N
COCH-ARM / FISHERS	P=0.251N	P=0.253N	P=0.500N	P=0.247N
ORDER RESTRICTED	P=0.088N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.110N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 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)	3/50 (6%)	1/49 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	3/45.04	1/43.83	1/44.72	0/41.11
POLY-3 PERCENT (g)	6.7%	2.3%	2.2%	0%
TERMINAL (d)	2/35 (6%)	1/32 (3%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	638	729 (T)	563	---

STATISTICAL TESTS

LIFE TABLE	P=0.098N	P=0.337N	P=0.319N	P=0.133N
POLY 3	P=0.100N	P=0.315N	P=0.308N	P=0.136N
POLY 1.5	P=0.099N	P=0.313N	P=0.307N	P=0.133N
POLY 6	P=0.098N	P=0.318N	P=0.308N	P=0.134N
LOGISTIC REGRESSION	P=0.083N	P=0.312N	P=0.304N	P=0.130N
COCH-ARM / FISHERS	P=0.092N	P=0.316N	P=0.309N	P=0.121N
ORDER RESTRICTED	P=0.047N*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.065N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Skin
 Fibroma**

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/49 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/44.71	1/43.83	2/44.29	0/41.11
POLY-3 PERCENT (g)	2.2%	2.3%	4.5%	0%
TERMINAL (d)	1/35 (3%)	1/32 (3%)	1/36 (3%)	0/35 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	702	---

STATISTICAL TESTS

LIFE TABLE	P=0.364N	P=0.742	P=0.513	P=0.500N
POLY 3	P=0.403N	P=0.756	P=0.497	P=0.517N
POLY 1.5	P=0.398N	P=0.756	P=0.498	P=0.514N
POLY 6	P=0.398N	P=0.755	P=0.497	P=0.515N
LOGISTIC REGRESSION	P=0.383N	P=0.742	P=0.497	(e)
COCH-ARM / FISHERS	P=0.371N	P=0.747	P=0.500	P=0.500N
ORDER RESTRICTED	P=0.284N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.311N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

Skin
 Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	4/49 (8%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/45.61	4/44.67	2/44.29	0/41.11
POLY-3 PERCENT (g)	4.4%	9%	4.5%	0%
TERMINAL (d)	1/35 (3%)	3/32 (9%)	1/36 (3%)	0/35 (0%)
FIRST INCIDENCE	344	395	702	---

STATISTICAL TESTS

LIFE TABLE	P=0.077N	P=0.311	P=0.682N	P=0.249N
POLY 3	P=0.094N	P=0.327	P=0.683	P=0.261N
POLY 1.5	P=0.091N	P=0.328	P=0.687	P=0.257N
POLY 6	P=0.092N	P=0.325	P=0.683	P=0.259N
LOGISTIC REGRESSION	P=0.036N*	P=0.286	P=0.689	P=0.108N
COCH-ARM / FISHERS	P=0.076N	P=0.329	P=0.691N	P=0.247N
ORDER RESTRICTED	P=0.107N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.134N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG
Skin				
Fibrosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	3/49 (6%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/45.61	3/44.67	0/44.18	0/41.11
POLY-3 PERCENT (g)	2.2%	6.7%	0%	0%
TERMINAL (d)	0/35 (0%)	2/32 (6%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	344	395	---	---
STATISTICAL TESTS				
LIFE TABLE	P=0.091N	P=0.290	P=0.500N	P=0.517N
POLY 3	P=0.094N	P=0.298	P=0.506N	P=0.521N
POLY 1.5	P=0.092N	P=0.298	P=0.504N	P=0.517N
POLY 6	P=0.094N	P=0.296	P=0.507N	P=0.519N
LOGISTIC REGRESSION	P=0.014N*	P=0.223	(e)	P=0.144N
COCH-ARM / FISHERS	P=0.088N	P=0.301	P=0.500N	P=0.500N
ORDER RESTRICTED	P=0.130N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.155N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Skin
 Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	3/49 (6%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/45.61	3/44.67	0/44.18	0/41.11
POLY-3 PERCENT (g)	2.2%	6.7%	0%	0%
TERMINAL (d)	0/35 (0%)	2/32 (6%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	344	395	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.091N	P=0.290	P=0.500N	P=0.517N
POLY 3	P=0.094N	P=0.298	P=0.506N	P=0.521N
POLY 1.5	P=0.092N	P=0.298	P=0.504N	P=0.517N
POLY 6	P=0.094N	P=0.296	P=0.507N	P=0.519N
LOGISTIC REGRESSION	P=0.014N*	P=0.223	(e)	P=0.144N
COCH-ARM / FISHERS	P=0.088N	P=0.301	P=0.500N	P=0.500N
ORDER RESTRICTED	P=0.130N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.155N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Skin
 Keratoacanthoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.71	0/43.83	0/44.18	0/41.11
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/32 (0%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Skin
 Squamous Cell Carcinoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.71	0/43.83	0/44.18	0/41.11
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/32 (0%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

Skin
 Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/45.04	0/43.83	0/44.18	0/41.11
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/32 (0%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	638	---	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.372N	P=0.513N	P=0.523N	P=0.533N
POLY 3	P=0.343N	P=0.505N	P=0.504N	P=0.518N
POLY 1.5	P=0.344N	P=0.504N	P=0.502N	P=0.515N
POLY 6	P=0.342N	P=0.508N	P=0.505N	P=0.517N
LOGISTIC REGRESSION	P=0.307N	P=0.515N	P=0.507N	P=0.473N
COCH-ARM / FISHERS	P=0.350N	P=0.505N	P=0.500N	P=0.500N
ORDER RESTRICTED	P=0.137N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.162N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Skin
 Squamous Cell Papilloma**

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/49 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.71	1/43.83	0/44.18	0/41.11
POLY-3 PERCENT (g)	2.2%	2.3%	0%	0%
TERMINAL (d)	1/35 (3%)	1/32 (3%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.201N	P=0.742	P=0.494N	P=0.500N
POLY 3	P=0.210N	P=0.756	P=0.502N	P=0.517N
POLY 1.5	P=0.210N	P=0.756	P=0.501N	P=0.514N
POLY 6	P=0.210N	P=0.755	P=0.503N	P=0.515N
LOGISTIC REGRESSION	P=0.201N	P=0.742	(e)	(e)
COCH-ARM / FISHERS	P=0.207N	P=0.747	P=0.500N	P=0.500N
ORDER RESTRICTED	P=0.264N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.290N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Skin
 Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/49 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.71	1/43.83	0/44.18	0/41.11
POLY-3 PERCENT (g)	2.2%	2.3%	0%	0%
TERMINAL (d)	1/35 (3%)	1/32 (3%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.201N	P=0.742	P=0.494N	P=0.500N
POLY 3	P=0.210N	P=0.756	P=0.502N	P=0.517N
POLY 1.5	P=0.210N	P=0.756	P=0.501N	P=0.514N
POLY 6	P=0.210N	P=0.755	P=0.503N	P=0.515N
LOGISTIC REGRESSION	P=0.201N	P=0.742	(e)	(e)
COCH-ARM / FISHERS	P=0.207N	P=0.747	P=0.500N	P=0.500N
ORDER RESTRICTED	P=0.264N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.290N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Skin
 Squamous Cell Papilloma, Papilloma, or Keratoacanthoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/49 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.71	1/43.83	0/44.18	0/41.11
POLY-3 PERCENT (g)	2.2%	2.3%	0%	0%
TERMINAL (d)	1/35 (3%)	1/32 (3%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.201N	P=0.742	P=0.494N	P=0.500N
POLY 3	P=0.210N	P=0.756	P=0.502N	P=0.517N
POLY 1.5	P=0.210N	P=0.756	P=0.501N	P=0.514N
POLY 6	P=0.210N	P=0.755	P=0.503N	P=0.515N
LOGISTIC REGRESSION	P=0.201N	P=0.742	(e)	(e)
COCH-ARM / FISHERS	P=0.207N	P=0.747	P=0.500N	P=0.500N
ORDER RESTRICTED	P=0.264N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.290N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Thyroid Gland: C-Cell
 Adenoma**

TUMOR RATES

OVERALL (a)	7/50 (14%)	5/49 (10%)	8/50 (16%)	3/50 (6%)
POLY-3 RATE (b)	7/45.3	5/43.83	8/44.21	3/41.11
POLY-3 PERCENT (g)	15.5%	11.4%	18.1%	7.3%
TERMINAL (d)	5/35 (14%)	5/32 (16%)	7/36 (19%)	3/35 (9%)
FIRST INCIDENCE	648	729 (T)	723	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.186N	P=0.440N	P=0.512	P=0.169N
POLY 3	P=0.262N	P=0.402N	P=0.480	P=0.199N
POLY 1.5	P=0.251N	P=0.397N	P=0.489	P=0.190N
POLY 6	P=0.256N	P=0.413N	P=0.470	P=0.198N
LOGISTIC REGRESSION	P=0.224N	P=0.396N	P=0.490	P=0.190N
COCH-ARM / FISHERS	P=0.202N	P=0.394N	P=0.500	P=0.159N
ORDER RESTRICTED	P=0.209N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.238N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Thyroid Gland: C-Cell
 Carcinoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	1/49 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.71	1/43.83	0/44.18	0/41.11
POLY-3 PERCENT (g)	0%	2.3%	0%	0%
TERMINAL (d)	0/35 (0%)	1/32 (3%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	---	729 (T)	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.442N	P=0.482	(e)	(e)
POLY 3	P=0.446N	P=0.496	(e)	(e)
POLY 1.5	P=0.446N	P=0.496	(e)	(e)
POLY 6	P=0.447N	P=0.495	(e)	(e)
LOGISTIC REGRESSION	(e)	P=0.482	(e)	(e)
COCH-ARM / FISHERS	P=0.448N	P=0.495	(e)	(e)
ORDER RESTRICTED	P=0.392N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.413N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Thyroid Gland: C-Cell
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	7/50 (14%)	6/49 (12%)	8/50 (16%)	3/50 (6%)
POLY-3 RATE (b)	7/45.3	6/43.83	8/44.21	3/41.11
POLY-3 PERCENT (g)	15.5%	13.7%	18.1%	7.3%
TERMINAL (d)	5/35 (14%)	6/32 (19%)	7/36 (19%)	3/35 (9%)
FIRST INCIDENCE	648	729 (T)	723	729 (T)

STATISTICAL TESTS

LIFE TABLE	P=0.147N	P=0.565N	P=0.512	P=0.169N
POLY 3	P=0.216N	P=0.525N	P=0.480	P=0.199N
POLY 1.5	P=0.206N	P=0.519N	P=0.489	P=0.190N
POLY 6	P=0.211N	P=0.538N	P=0.470	P=0.198N
LOGISTIC REGRESSION	P=0.180N	P=0.520N	P=0.490	P=0.190N
COCH-ARM / FISHERS	P=0.162N	P=0.516N	P=0.500	P=0.159N
ORDER RESTRICTED	P=0.202N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.231N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Thyroid Gland: Follicular Cell
 Adenoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/49 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.71	0/43.83	1/44.47	0/41.11
POLY-3 PERCENT (g)	0%	0%	2.3%	0%
TERMINAL (d)	0/35 (0%)	0/32 (0%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	---	---	651	---

STATISTICAL TESTS

LIFE TABLE	P=0.641	(e)	P=0.490	(e)
POLY 3	P=0.608	(e)	P=0.499	(e)
POLY 1.5	P=0.615	(e)	P=0.499	(e)
POLY 6	P=0.614	(e)	P=0.500	(e)
LOGISTIC REGRESSION	P=0.681	(e)	P=0.497	(e)
COCH-ARM / FISHERS	P=0.650	(e)	P=0.500	(e)
ORDER RESTRICTED	P=0.381	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.402	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**Thyroid Gland: Follicular Cell
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	1/49 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.71	1/43.83	1/44.47	0/41.11
POLY-3 PERCENT (g)	0%	2.3%	2.3%	0%
TERMINAL (d)	0/35 (0%)	1/32 (3%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	---	729 (T)	651	---

STATISTICAL TESTS

LIFE TABLE	P=0.537N	P=0.482	P=0.490	(e)
POLY 3	P=0.553N	P=0.496	P=0.499	(e)
POLY 1.5	P=0.550N	P=0.496	P=0.499	(e)
POLY 6	P=0.550N	P=0.495	P=0.500	(e)
LOGISTIC REGRESSION	P=0.538N	P=0.482	P=0.497	(e)
COCH-ARM / FISHERS	P=0.534N	P=0.495	P=0.500	(e)
ORDER RESTRICTED	P=0.402	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.423	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG
Uterus				
Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	13/50 (26%)	14/49 (29%)	13/50 (26%)	7/50 (14%)
POLY-3 RATE (b)	13/46.03	14/45.92	13/45.48	7/42.92
POLY-3 PERCENT (g)	28.2%	30.5%	28.6%	16.3%
TERMINAL (d)	9/35 (26%)	6/32 (19%)	10/36 (28%)	5/35 (14%)
FIRST INCIDENCE	591	576	540	312
STATISTICAL TESTS				
LIFE TABLE	P=0.071N	P=0.436	P=0.575N	P=0.129N
POLY 3	P=0.088N	P=0.497	P=0.577	P=0.136N
POLY 1.5	P=0.080N	P=0.489	P=0.584	P=0.129N
POLY 6	P=0.091N	P=0.509	P=0.570	P=0.137N
LOGISTIC REGRESSION	P=0.051N	P=0.474	P=0.587	P=0.093N
COCH-ARM / FISHERS	P=0.058N	P=0.475	P=0.590N	P=0.105N
ORDER RESTRICTED	P=0.125N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.144N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG
Uterus				
Sarcoma Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	0/49 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/45.57	0/43.83	1/44.18	1/41.11
POLY-3 PERCENT (g)	4.4%	0%	2.3%	2.4%
TERMINAL (d)	0/35 (0%)	0/32 (0%)	1/36 (3%)	1/35 (3%)
FIRST INCIDENCE	516	---	729 (T)	729 (T)
STATISTICAL TESTS				
LIFE TABLE	P=0.576N	P=0.239N	P=0.494N	P=0.512N
POLY 3	P=0.589N	P=0.246N	P=0.511N	P=0.536N
POLY 1.5	P=0.587N	P=0.244N	P=0.506N	P=0.528N
POLY 6	P=0.586N	P=0.249N	P=0.515N	P=0.536N
LOGISTIC REGRESSION	P=0.535N	P=0.259N	P=0.508N	P=0.455N
COCH-ARM / FISHERS	P=0.573N	P=0.253N	P=0.500N	P=0.500N
ORDER RESTRICTED	P=0.303N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.332N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG
Uterus				
Sarcoma Stromal or Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	15/50 (30%)	14/49 (29%)	13/50 (26%)	8/50 (16%)
POLY-3 RATE (b)	15/46.89	14/45.92	13/45.48	8/42.92
POLY-3 PERCENT (g)	32%	30.5%	28.6%	18.6%
TERMINAL (d)	9/35 (26%)	6/32 (19%)	10/36 (28%)	6/35 (17%)
FIRST INCIDENCE	516	576	540	312
STATISTICAL TESTS				
LIFE TABLE	P=0.067N	P=0.561N	P=0.406N	P=0.102N
POLY 3	P=0.086N	P=0.527N	P=0.448N	P=0.113N
POLY 1.5	P=0.076N	P=0.526N	P=0.431N	P=0.102N
POLY 6	P=0.093N	P=0.527N	P=0.468N	P=0.119N
LOGISTIC REGRESSION	P=0.042N*	P=0.530N	P=0.410N	P=0.061N
COCH-ARM / FISHERS	P=0.052N	P=0.526N	P=0.412N	P=0.077N
ORDER RESTRICTED	P=0.121N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.142N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**All Organs
 Hemangiosarcoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/45.25	0/43.83	0/44.18	0/41.11
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/32 (0%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	563	---	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.373N	P=0.500N	P=0.513N	P=0.531N
POLY 3	P=0.342N	P=0.506N	P=0.505N	P=0.519N
POLY 1.5	P=0.344N	P=0.505N	P=0.503N	P=0.515N
POLY 6	P=0.342N	P=0.509N	P=0.506N	P=0.518N
LOGISTIC REGRESSION	P=0.231N	P=0.541N	P=0.552N	P=0.409N
COCH-ARM / FISHERS	P=0.350N	P=0.505N	P=0.500N	P=0.500N
ORDER RESTRICTED	P=0.138N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.164N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**All Organs
 Hemangiosarcoma or Hemangioma**

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/45.25	0/43.83	0/44.18	0/41.11
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/32 (0%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	563	---	---	---

STATISTICAL TESTS

LIFE TABLE	P=0.373N	P=0.500N	P=0.513N	P=0.531N
POLY 3	P=0.342N	P=0.506N	P=0.505N	P=0.519N
POLY 1.5	P=0.344N	P=0.505N	P=0.503N	P=0.515N
POLY 6	P=0.342N	P=0.509N	P=0.506N	P=0.518N
LOGISTIC REGRESSION	P=0.231N	P=0.541N	P=0.552N	P=0.409N
COCH-ARM / FISHERS	P=0.350N	P=0.505N	P=0.500N	P=0.500N
ORDER RESTRICTED	P=0.138N	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.164N	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

All Organs
 Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated

TUMOR RATES	#	#	#	#
OVERALL (a)	12/50 (24%)	6/49 (12%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	12/46.44	6/44.82	3/45.41	2/41.13
POLY-3 PERCENT (g)	25.8%	13.4%	6.6%	4.9%
TERMINAL (d)	6/35 (17%)	2/32 (6%)	1/36 (3%)	1/35 (3%)
FIRST INCIDENCE	591	585	521	725

STATISTICAL TESTS

LIFE TABLE	P=0.005N**	P=0.140N	P=0.018N*	P=0.008N**
POLY 3	P=0.004N**	P=0.108N	P=0.012N*	P=0.007N**
POLY 1.5	P=0.004N**	P=0.105N	P=0.011N*	P=0.006N**
POLY 6	P=0.004N**	P=0.114N	P=0.013N*	P=0.008N**
LOGISTIC REGRESSION	P=0.002N**	P=0.106N	P=0.011N*	P=0.006N**
COCH-ARM / FISHERS	P=0.003N**	P=0.104N	P=0.011N*	P=0.004N**
ORDER RESTRICTED	P=0.002N**	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.005N**	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

All Organs
 Mesothelioma: Benign, Malignant, NOS

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.71	0/43.83	0/44.18	0/41.11
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/32 (0%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**All Organs
 Mesothelioma: Malignant**

TUMOR RATES

	#	#	#	#
OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.71	0/43.83	0/44.18	0/41.11
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/32 (0%)	0/36 (0%)	0/35 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

LIFE TABLE	(e)	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**All Organs
 Benign Tumors**

TUMOR RATES

	#	#	#	#
OVERALL (a)	47/50 (94%)	45/49 (92%)	45/50 (90%)	40/50 (80%)
POLY-3 RATE (b)	47/47.92	45/47.57	45/48.9	40/45
POLY-3 PERCENT (g)	98.1%	94.6%	92%	88.9%
TERMINAL (d)	35/35 (100%)	31/32 (97%)	33/36 (92%)	32/35 (91%)
FIRST INCIDENCE	591	568	492	312

STATISTICAL TESTS

LIFE TABLE	P=0.078N	P=0.476	P=0.380N	P=0.133N
POLY 3	P=0.039N*	P=0.335N	P=0.155N	P=0.053N
POLY 1.5	P=0.031N*	P=0.396N	P=0.215N	P=0.048N*
POLY 6	P=0.046N*	P=0.286N	P=0.123N	P=0.059N
LOGISTIC REGRESSION	P=0.160N	P=0.430N	P=0.391N	P=0.205N
COCH-ARM / FISHERS	P=0.014N*	P=0.489N	P=0.357N	P=0.036N*
ORDER RESTRICTED	P=0.033N*	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.046N*	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG
All Organs				
Malignant Tumors				
TUMOR RATES				
	#	#	#	#
OVERALL (a)	19/50 (38%)	16/49 (33%)	8/50 (16%)	5/50 (10%)
POLY-3 RATE (b)	19/49.06	16/46.57	8/46.32	5/41.13
POLY-3 PERCENT (g)	38.7%	34.4%	17.3%	12.2%
TERMINAL (d)	8/35 (23%)	9/32 (28%)	3/36 (8%)	4/35 (11%)
FIRST INCIDENCE	344	395	521	725
STATISTICAL TESTS				
LIFE TABLE	P<0.001N**	P=0.426N	P=0.025N*	P=0.004N**
POLY 3	P<0.001N**	P=0.409N	P=0.016N*	P=0.004N**
POLY 1.5	P<0.001N**	P=0.389N	P=0.014N*	P=0.002N**
POLY 6	P<0.001N**	P=0.441N	P=0.019N*	P=0.005N**
LOGISTIC REGRESSION	P<0.001N**	P=0.353N	P=0.005N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.365N	P=0.012N*	P<0.001N**
ORDER RESTRICTED	P=0.002N**	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001N**	(e)	(e)	(e)

TDMS No. 91005-07
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 METHYLENE BLUE TRIHYDRATE
 CAS Number: 7220-79-3
 Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
 Time Report Reqsted: 10:49:49
 First Dose M/F: 06/26/00 / 06/26/00
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	5 MG/KG	25 MG/KG	50 MG/KG

**All Organs
 Malignant and Benign Tumors**

TUMOR RATES	#	#	#	#
OVERALL (a)	50/50 (100%)	48/49 (98%)	46/50 (92%)	40/50 (80%)
POLY-3 RATE (b)	50/50	48/49	46/48.9	40/45
POLY-3 PERCENT (g)	100%	98%	94.1%	88.9%
TERMINAL (d)	35/35 (100%)	31/32 (97%)	34/36 (94%)	32/35 (91%)
FIRST INCIDENCE	344	395	492	312

STATISTICAL TESTS

LIFE TABLE	P=0.022N*	P=0.477	P=0.254N	P=0.055N
POLY 3	P=0.003N**	P=0.496N	P=0.102N	P=0.013N*
POLY 1.5	P<0.001N**	P=0.496N	P=0.077N	P=0.004N**
POLY 6	P=0.011N*	P=0.496N	P=0.155N	P=0.033N*
LOGISTIC REGRESSION	P<0.001N**	(e)	P=0.059N	P=0.007N**
COCH-ARM / FISHERS	P<0.001N**	P=0.495N	P=0.059N	P<0.001N**
ORDER RESTRICTED	P=0.003N**	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.005N**	(e)	(e)	(e)

TDMS No. 91005-07
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344

P8: STATISTICAL ANALYSIS OF PRIMARY TUMORS
METHYLENE BLUE TRIHYDRATE
CAS Number: 7220-79-3
Pathologist: GILES, H.

Date Report Reqsted: 04/06/2006
Time Report Reqsted: 10:49:49
First Dose M/F: 06/26/00 / 06/26/00
Lab: SRI

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.
- (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. The life table analysis regards tumors in animals dying prior to terminal kill as being (directly or indirectly) the cause of death.
- (e) Value of Statistic cannot be computed.
- (g) Poly-3 adjusted lifetime tumor incidence.
- (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
- Logistic regression is an alternative method for analyzing the incidence of non-fatal tumors.
The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

*** END OF REPORT ***