

TDMS No. 20008 - 04
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Milk thistle extract
CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
Time Report Requested: 13:13:48
First Dose M/F: 03/25/03 / 03/25/03
Lab: SRI

F1_M3

C Number: C20008
Lock Date: 06/29/2006
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.0.0

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HISTORICAL CONTROL STUDIES From October 2007 Report

SAME ROUTE

88138-04 -- Benzophenone (ORAL FEED)
99027-04 -- Chromium picolinate monohydrate (ORAL FEED)
05174-06 -- Cresols (ORAL FEED)
92012-06 -- 2-Methylimidazole (ORAL FEED)
92013-06 -- 4-Methylimidazole (ORAL FEED)

ALL ROUTES

88138-04 -- Benzophenone (ORAL FEED)
99027-04 -- Chromium picolinate monohydrate (ORAL FEED)
05174-06 -- Cresols (ORAL FEED)
96011-06 -- Cumene (INHALATION AIR)
97003-08 -- 1,2-Dibromo-2,4-dicyanobutane (SKIN ETHANOL)
93020-08 -- Diisopropylcarbodiimide (SKIN ETHANOL)
88004-06 -- Divinylbenzene (INHALATION AIR)
88123-07 -- Formamide (GAVAGE WATER)
95011-06 -- 5-(Hydroxymethyl)-2-furfural (GAVAGE WATER)
88105-04 -- Isoeugenol (GAVAGE CORN OIL)
97006-02 -- Methyl isobutyl ketone (INHALATION AIR)
91005-08 -- Methylene blue trihydrate (GAVAGE METHYLCELLULOSE)
92012-06 -- 2-Methylimidazole (ORAL FEED)
92013-06 -- 4-Methylimidazole (ORAL FEED)
88006-04 -- alpha-Methylstyrene (INHALATION AIR)
99023-04 -- beta-Myrcene (GAVAGE CORN OIL)
97008-06 -- Propargyl alcohol (INHALATION AIR)
20114-06 -- Sodium dichromate dihydrate (VI) (ORAL WATER)
96001-06 -- Stoddard solvent (type IIC) (INHALATION AIR)
05109-14 -- Triethanolamine (SKIN ACETONE)

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HISTORICAL CONTROL STUDIES
From October 2007 Report

96019-06 -- Water disinfection byproducts (Bromochloroacetic acid) (ORAL WATER)
96018-04 -- Water disinfection byproducts (Bromodichloromethane) (ORAL WATER)
96017-06 -- Water disinfection byproducts (Dibromoacetic acid) (ORAL WATER)
96015-06 -- Water disinfection byproducts (Dibromoacetonitrile) (ORAL WATER)
96010-04 -- Water disinfection byproducts (Sodium chlorate) (ORAL WATER)

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

Adrenal Cortex
Adrenal Medulla
Bone Marrow
Clitoral/Preputial Gland
Islets, Pancreatic
Liver
Lung
Ovary
Parathyroid Gland
Pituitary Gland
Spleen
Testes
Thyroid Gland
Urinary Bladder

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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF Milk thistle extract

MALE MICE

Organ

Adrenal Cortex
Liver

Skin
All Organs

Morphology

Adenoma
Hepatocellular Adenoma
Hepatocellular Carcinoma
Hepatocellular Carcinoma or Hepatoblastoma
Hepatocellular Carcinoma or Hepatocellular Adenoma
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma
Hemangiosarcoma
Hemangioma
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type
Benign Tumors
Malignant Tumors
Malignant and Benign Tumors

FEMALE MICE

Organ

Liver

Skin

Spleen

Morphology

Hepatocellular Adenoma
Hepatocellular Carcinoma
Hepatocellular Carcinoma or Hepatoblastoma
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma
Fibrosarcoma
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma
Hemangiosarcoma

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Adrenal Cortex
 Adenoma**

TUMOR RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	5/50 (10%)	3/50 (6%)
POLY-3 RATE (b)	1/47.69	1/48.5	5/47.94	3/49.86
POLY-3 PERCENT (g)	2.1%	2.1%	10.4%	6%
TERMINAL (d)	1/45 (2%)	1/46 (2%)	5/43 (12%)	3/49 (6%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
HC TUMORS SAME RTE	4/200 (2%)			
HC TUMORS ALL RTES	74/1142 (7%)			

STATISTICAL TESTS

POLY 3	P=0.179	P=0.757N	P=0.103	P=0.322
POLY 1.5	P=0.173	P=0.758N	P=0.104	P=0.316
POLY 6	P=0.185	P=0.756N	P=0.101	P=0.326
COCH-ARM / FISHERS	P=0.162	P=0.753N	P=0.102	P=0.309
MAX-ISO-POLY-3	P=0.143	P=0.494N	P=0.046*	P=0.172
HISTCONT SAME RTE	P=0.175	P=1.000	P=0.055	P=0.222
HISTCONT ALL RTES	P=0.164	P=1.000	P=0.050*	P=0.205

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Bone Marrow
 Hemangiosarcoma**

TUMOR RATES

OVERALL (a)	1/49 (2%)	1/49 (2%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/46.81	1/47.82	0/47.18	0/49.86
POLY-3 PERCENT (g)	2.1%	2.1%	0%	0%
TERMINAL (d)	1/45 (2%)	1/46 (2%)	0/43 (0%)	0/49 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---	---
HC TUMORS SAME RTE	2/199 (1%)			
HC TUMORS ALL RTES	8/1142 (1%)			

STATISTICAL TESTS

POLY 3	P=0.232N	P=0.756N	P=0.498N	P=0.487N
POLY 1.5	P=0.233N	P=0.757N	P=0.498N	P=0.490N
POLY 6	P=0.232N	P=0.755N	P=0.500N	P=0.485N
COCH-ARM / FISHERS	P=0.233N	P=0.753N	P=0.500N	P=0.495N
MAX-ISO-POLY-3	P=0.254N	P=0.493N	P=0.159N	P=0.157N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM
Harderian Gland Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	5/50 (10%)	4/50 (8%)	7/50 (14%)	5/50 (10%)
POLY-3 RATE (b)	5/47.69	4/48.5	7/48.2	5/49.86
POLY-3 PERCENT (g)	10.5%	8.3%	14.5%	10%
TERMINAL (d)	5/45 (11%)	4/46 (9%)	6/43 (14%)	5/49 (10%)
FIRST INCIDENCE	729 (T)	729 (T)	659	729 (T)
HC TUMORS SAME RTE	24/200 (12%)			
HC TUMORS ALL RTES	152/1149 (13%)			

STATISTICAL TESTS

POLY 3	P=0.518	P=0.490N	P=0.387	P=0.601N
POLY 1.5	P=0.506	P=0.492N	P=0.387	P=0.611N
POLY 6	P=0.528	P=0.489N	P=0.383	P=0.593N
COCH-ARM / FISHERS	P=0.484	P=0.500N	P=0.380	P=0.630N
MAX-ISO-POLY-3	P=0.521	P=0.354N	P=0.278	P=0.470N
HISTCONT SAME RTE	P=0.635	P=1.000	P=0.367	P=1.000
HISTCONT ALL RTES	P=0.612	P=1.000	P=0.347	P=1.000

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Harderian Gland
 Carcinoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/47.69	2/48.5	0/47.94	1/49.86
POLY-3 PERCENT (g)	0%	4.1%	0%	2%
TERMINAL (d)	0/45 (0%)	2/46 (4%)	0/43 (0%)	1/49 (2%)
FIRST INCIDENCE	---	729 (T)	---	729 (T)
HC TUMORS SAME RTE	4/200 (2%)			
HC TUMORS ALL RTES	30/1149 (3%)			

STATISTICAL TESTS

POLY 3	P=0.555	P=0.241	(e)	P=0.509
POLY 1.5	P=0.550	P=0.240	(e)	P=0.506
POLY 6	P=0.559	P=0.241	(e)	P=0.511
COCH-ARM / FISHERS	P=0.539	P=0.247	(e)	P=0.500
MAX-ISO-POLY-3	P=0.341	P=0.080	(e)	P=0.170
HISTCONT SAME RTE	P=0.420	P=0.100	(e)	P=0.220
HISTCONT ALL RTES	P=0.396	P=0.091	(e)	P=0.203

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM
Harderian Gland Carcinoma or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	5/50 (10%)	6/50 (12%)	7/50 (14%)	6/50 (12%)
POLY-3 RATE (b)	5/47.69	6/48.5	7/48.2	6/49.86
POLY-3 PERCENT (g)	10.5%	12.4%	14.5%	12%
TERMINAL (d)	5/45 (11%)	6/46 (13%)	6/43 (14%)	6/49 (12%)
FIRST INCIDENCE	729 (T)	729 (T)	659	729 (T)
HC TUMORS SAME RTE	27/200 (14%)			
HC TUMORS ALL RTES	176/1149 (15%)			

STATISTICAL TESTS

POLY 3	P=0.478	P=0.512	P=0.387	P=0.531
POLY 1.5	P=0.466	P=0.509	P=0.387	P=0.521
POLY 6	P=0.488	P=0.513	P=0.383	P=0.540
COCH-ARM / FISHERS	P=0.442	P=0.500	P=0.380	P=0.500
MAX-ISO-POLY-3	P=0.543	P=0.386	P=0.278	P=0.405
HISTCONT SAME RTE	P=0.660	P=0.509	P=0.367	P=0.533
HISTCONT ALL RTES	P=0.639	P=0.491	P=0.347	P=0.515

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Islets, Pancreatic
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	0/49 (0%)	1/49 (2%)	1/49 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/46.81	1/47.82	1/47.18	2/49.86
POLY-3 PERCENT (g)	0%	2.1%	2.1%	4%
TERMINAL (d)	0/45 (0%)	1/46 (2%)	1/43 (2%)	2/49 (4%)
FIRST INCIDENCE	---	729 (T)	729 (T)	729 (T)
HC TUMORS SAME RTE	1/199 (1%)			
HC TUMORS ALL RTES	12/1136 (1%)			

STATISTICAL TESTS

POLY 3	P=0.168	P=0.504	P=0.502	P=0.252
POLY 1.5	P=0.165	P=0.503	P=0.502	P=0.249
POLY 6	P=0.170	P=0.505	P=0.500	P=0.254
COCH-ARM / FISHERS	P=0.157	P=0.500	P=0.500	P=0.253
MAX-ISO-POLY-3	P=0.143	P=0.164	P=0.161	P=0.089
HISTCONT SAME RTE	P=0.072	P=0.196	P=0.196	P=0.083
HISTCONT ALL RTES	P=0.083	P=0.196	P=0.192	P=0.102

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Hepatocellular Adenoma

TUMOR RATES

OVERALL (a)	12/50 (24%)	13/50 (26%)	5/50 (10%)	1/50 (2%)
POLY-3 RATE (b)	12/47.69	13/48.5	5/47.94	1/49.86
POLY-3 PERCENT (g)	25.2%	26.8%	10.4%	2%
TERMINAL (d)	12/45 (27%)	13/46 (28%)	5/43 (12%)	1/49 (2%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
HC TUMORS SAME RTE	56/200 (28%)			
HC TUMORS ALL RTEs	544/1146 (48%)			

STATISTICAL TESTS

POLY 3	P<0.001N**	P=0.519	P=0.051N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.514	P=0.051N	P<0.001N**
POLY 6	P<0.001N**	P=0.521	P=0.053N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.500	P=0.054N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.426	P=0.029N*	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM
Liver				
Hepatocellular Carcinoma				
TUMOR RATES				
OVERALL (a)	17/50 (34%)	15/50 (30%)	14/50 (28%)	7/50 (14%)
POLY-3 RATE (b)	17/49.03	15/48.9	14/49.19	7/49.86
POLY-3 PERCENT (g)	34.7%	30.7%	28.5%	14%
TERMINAL (d)	14/45 (31%)	13/46 (28%)	11/43 (26%)	7/49 (14%)
FIRST INCIDENCE	427	633	460	729 (T)
HC TUMORS SAME RTE	37/200 (19%)			
HC TUMORS ALL RTEs	317/1146 (28%)			

STATISTICAL TESTS

POLY 3	P=0.010N**	P=0.419N	P=0.329N	P=0.014N*
POLY 1.5	P=0.010N**	P=0.417N	P=0.327N	P=0.014N*
POLY 6	P=0.010N**	P=0.423N	P=0.338N	P=0.014N*
COCH-ARM / FISHERS	P=0.012N*	P=0.415N	P=0.333N	P=0.017N*
MAX-ISO-POLY-3	P=0.015N*	P=0.337N	P=0.256N	P=0.008N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Liver
 Hepatocellular Carcinoma or Hepatoblastoma**

TUMOR RATES

OVERALL (a)	17/50 (34%)	15/50 (30%)	14/50 (28%)	7/50 (14%)
POLY-3 RATE (b)	17/49.03	15/48.9	14/49.19	7/49.86
POLY-3 PERCENT (g)	34.7%	30.7%	28.5%	14%
TERMINAL (d)	14/45 (31%)	13/46 (28%)	11/43 (26%)	7/49 (14%)
FIRST INCIDENCE	427	633	460	729 (T)
HC TUMORS SAME RTE	37/200 (19%)			
HC TUMORS ALL RTEs	346/1146 (30%)			

STATISTICAL TESTS

POLY 3	P=0.010N**	P=0.419N	P=0.329N	P=0.014N*
POLY 1.5	P=0.010N**	P=0.417N	P=0.327N	P=0.014N*
POLY 6	P=0.010N**	P=0.423N	P=0.338N	P=0.014N*
COCH-ARM / FISHERS	P=0.012N*	P=0.415N	P=0.333N	P=0.017N*
MAX-ISO-POLY-3	P=0.015N*	P=0.337N	P=0.256N	P=0.008N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Liver
 Hepatocellular Carcinoma or Hepatocellular Adenoma**

TUMOR RATES

OVERALL (a)	26/50 (52%)	22/50 (44%)	16/50 (32%)	8/50 (16%)
POLY-3 RATE (b)	26/49.03	22/48.9	16/49.19	8/49.86
POLY-3 PERCENT (g)	53%	45%	32.5%	16.1%
TERMINAL (d)	23/45 (51%)	20/46 (44%)	13/43 (30%)	8/49 (16%)
FIRST INCIDENCE	427	633	460	729 (T)
HC TUMORS SAME RTE	83/200 (42%)			
HC TUMORS ALL RTEs	729/1146 (64%)			

STATISTICAL TESTS

POLY 3	P<0.001N**	P=0.277N	P=0.030N*	P<0.001N**
POLY 1.5	P<0.001N**	P=0.275N	P=0.030N*	P<0.001N**
POLY 6	P<0.001N**	P=0.282N	P=0.032N*	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.274N	P=0.034N*	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.215N	P=0.019N*	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma

TUMOR RATES

OVERALL (a)	26/50 (52%)	22/50 (44%)	16/50 (32%)	8/50 (16%)
POLY-3 RATE (b)	26/49.03	22/48.9	16/49.19	8/49.86
POLY-3 PERCENT (g)	53%	45%	32.5%	16.1%
TERMINAL (d)	23/45 (51%)	20/46 (44%)	13/43 (30%)	8/49 (16%)
FIRST INCIDENCE	427	633	460	729 (T)
HC TUMORS SAME RTE	83/200 (42%)			
HC TUMORS ALL RTEs	740/1146 (65%)			

STATISTICAL TESTS

POLY 3	P<0.001N**	P=0.277N	P=0.030N*	P<0.001N**
POLY 1.5	P<0.001N**	P=0.275N	P=0.030N*	P<0.001N**
POLY 6	P<0.001N**	P=0.282N	P=0.032N*	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.274N	P=0.034N*	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.215N	P=0.019N*	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
 Alveolar/Bronchiolar Adenoma**

TUMOR RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	1/47.69	2/48.5	4/47.94	2/49.86
POLY-3 PERCENT (g)	2.1%	4.1%	8.3%	4%
TERMINAL (d)	1/45 (2%)	2/46 (4%)	4/43 (9%)	2/49 (4%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
HC TUMORS SAME RTE	46/200 (23%)			
HC TUMORS ALL RTES	209/1148 (18%)			

STATISTICAL TESTS

POLY 3	P=0.414	P=0.506	P=0.181	P=0.515
POLY 1.5	P=0.405	P=0.504	P=0.181	P=0.510
POLY 6	P=0.422	P=0.506	P=0.178	P=0.520
COCH-ARM / FISHERS	P=0.387	P=0.500	P=0.181	P=0.500
MAX-ISO-POLY-3	P=0.286	P=0.287	P=0.086	P=0.298
HISTCONT SAME RTE	P=0.353	P=0.379	P=0.108	P=0.394
HISTCONT ALL RTES	P=0.332	P=0.359	P=0.098	P=0.373

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
 Alveolar/Bronchiolar Carcinoma**

TUMOR RATES

OVERALL (a)	10/50 (20%)	6/50 (12%)	5/50 (10%)	7/50 (14%)
POLY-3 RATE (b)	10/47.81	6/48.5	5/48.47	7/49.86
POLY-3 PERCENT (g)	20.9%	12.4%	10.3%	14%
TERMINAL (d)	9/45 (20%)	6/46 (13%)	3/43 (7%)	7/49 (14%)
FIRST INCIDENCE	699	729 (T)	657	729 (T)
HC TUMORS SAME RTE	13/200 (7%)			
HC TUMORS ALL RTES	115/1148 (10%)			

STATISTICAL TESTS

POLY 3	P=0.269N	P=0.197N	P=0.124N	P=0.266N
POLY 1.5	P=0.277N	P=0.200N	P=0.125N	P=0.276N
POLY 6	P=0.263N	P=0.198N	P=0.125N	P=0.258N
COCH-ARM / FISHERS	P=0.291N	P=0.207N	P=0.131N	P=0.298N
MAX-ISO-POLY-3	P=0.183N	P=0.132N	P=0.077N	P=0.191N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
 Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma**

TUMOR RATES

OVERALL (a)	11/50 (22%)	8/50 (16%)	9/50 (18%)	9/50 (18%)
POLY-3 RATE (b)	11/47.81	8/48.5	9/48.47	9/49.86
POLY-3 PERCENT (g)	23%	16.5%	18.6%	18.1%
TERMINAL (d)	10/45 (22%)	8/46 (17%)	7/43 (16%)	9/49 (18%)
FIRST INCIDENCE	699	729 (T)	657	729 (T)
HC TUMORS SAME RTE	55/200 (28%)			
HC TUMORS ALL RTES	309/1148 (27%)			

STATISTICAL TESTS

POLY 3	P=0.380N	P=0.293N	P=0.388N	P=0.362N
POLY 1.5	P=0.392N	P=0.296N	P=0.391N	P=0.375N
POLY 6	P=0.371N	P=0.294N	P=0.392N	P=0.352N
COCH-ARM / FISHERS	P=0.415N	P=0.306N	P=0.402N	P=0.402N
MAX-ISO-POLY-3	P=0.415N	P=0.214N	P=0.298N	P=0.278N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM
Mammary Gland Carcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.69	0/48.5	0/47.94	0/49.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/45 (0%)	0/46 (0%)	0/43 (0%)	0/49 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/200 (0%)			
HC TUMORS ALL RTES	1/1149 (0%)			

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

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

TUMOR RATES

OVERALL (a)	0/48 (0%)	0/48 (0%)	0/47 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/47.34	0/45.25	0/49.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/44 (0%)	0/46 (0%)	0/42 (0%)	0/49 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/194 (0%)			
HC TUMORS ALL RTES	3/1119 (0%)			

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

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

TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	3/47.69	2/48.5	1/47.94	1/49.86
POLY-3 PERCENT (g)	6.3%	4.1%	2.1%	2%
TERMINAL (d)	3/45 (7%)	2/46 (4%)	1/43 (2%)	1/49 (2%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
HC TUMORS SAME RTE	2/200 (1%)			
HC TUMORS ALL RTES	14/1149 (1%)			

STATISTICAL TESTS

POLY 3	P=0.193N	P=0.492N	P=0.304N	P=0.290N
POLY 1.5	P=0.195N	P=0.494N	P=0.303N	P=0.295N
POLY 6	P=0.191N	P=0.492N	P=0.307N	P=0.286N
COCH-ARM / FISHERS	P=0.199N	P=0.500N	P=0.309N	P=0.309N
MAX-ISO-POLY-3	P=0.216N	P=0.319N	P=0.154N	P=0.149N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM
Skin				
Fibrosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/47.69	0/48.5	0/47.94	1/49.86
POLY-3 PERCENT (g)	0%	0%	0%	2%
TERMINAL (d)	0/45 (0%)	0/46 (0%)	0/43 (0%)	1/49 (2%)
FIRST INCIDENCE	---	---	---	729 (T)
HC TUMORS SAME RTE	0/200 (0%)			
HC TUMORS ALL RTES	0/1149 (0%)			

STATISTICAL TESTS

POLY 3	P=0.204	(e)	(e)	P=0.509
POLY 1.5	P=0.202	(e)	(e)	P=0.506
POLY 6	P=0.206	(e)	(e)	P=0.511
COCH-ARM / FISHERS	P=0.198	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.139	(e)	(e)	P=0.170
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

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

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/47.69	2/48.5	1/47.94	1/49.86
POLY-3 PERCENT (g)	4.2%	4.1%	2.1%	2%
TERMINAL (d)	2/45 (4%)	2/46 (4%)	1/43 (2%)	1/49 (2%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
HC TUMORS SAME RTE	2/200 (1%)			
HC TUMORS ALL RTES	11/1149 (1%)			

STATISTICAL TESTS

POLY 3	P=0.328N	P=0.687N	P=0.498N	P=0.485N
POLY 1.5	P=0.331N	P=0.689N	P=0.498N	P=0.490N
POLY 6	P=0.325N	P=0.687N	P=0.502N	P=0.480N
COCH-ARM / FISHERS	P=0.337N	P=0.691N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.437N	P=0.492N	P=0.280N	P=0.272N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

	Males			
DOSE	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Skin
 Fibrous Histiocytoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/47.69	2/48.5	1/47.94	0/49.86
POLY-3 PERCENT (g)	4.2%	4.1%	2.1%	0%
TERMINAL (d)	2/45 (4%)	2/46 (4%)	1/43 (2%)	0/49 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	---
HC TUMORS SAME RTE	1/200 (1%)			
HC TUMORS ALL RTES	5/1149 (0%)			

STATISTICAL TESTS

POLY 3	P=0.120N	P=0.687N	P=0.498N	P=0.228N
POLY 1.5	P=0.122N	P=0.689N	P=0.498N	P=0.231N
POLY 6	P=0.119N	P=0.687N	P=0.502N	P=0.225N
COCH-ARM / FISHERS	P=0.125N	P=0.691N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.160N	P=0.492N	P=0.280N	P=0.076N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Skin
 Hemangiosarcoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/47.81	0/48.5	0/47.94	0/49.86
POLY-3 PERCENT (g)	4.2%	0%	0%	0%
TERMINAL (d)	1/45 (2%)	0/46 (0%)	0/43 (0%)	0/49 (0%)
FIRST INCIDENCE	699	---	---	---
HC TUMORS SAME RTE	1/200 (1%)			
HC TUMORS ALL RTES	7/1149 (1%)			

STATISTICAL TESTS

POLY 3	P=0.116N	P=0.234N	P=0.237N	P=0.228N
POLY 1.5	P=0.115N	P=0.235N	P=0.236N	P=0.231N
POLY 6	P=0.116N	P=0.234N	P=0.239N	P=0.226N
COCH-ARM / FISHERS	P=0.115N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.033N*	P=0.076N	P=0.076N	P=0.076N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Skin
 Liposarcoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.69	0/48.5	0/47.94	0/49.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/45 (0%)	0/46 (0%)	0/43 (0%)	0/49 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/200 (0%)			
HC TUMORS ALL RTES	0/1149 (0%)			

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Spleen
 Hemangiosarcoma**

TUMOR RATES

OVERALL (a)	2/50 (4%)	3/50 (6%)	1/49 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/47.81	3/48.5	1/47.18	1/49.86
POLY-3 PERCENT (g)	4.2%	6.2%	2.1%	2%
TERMINAL (d)	1/45 (2%)	3/46 (7%)	1/43 (2%)	1/49 (2%)
FIRST INCIDENCE	699	729 (T)	729 (T)	729 (T)
HC TUMORS SAME RTE	2/199 (1%)			
HC TUMORS ALL RTES	21/1136 (2%)			

STATISTICAL TESTS

POLY 3	P=0.270N	P=0.507	P=0.505N	P=0.485N
POLY 1.5	P=0.273N	P=0.505	P=0.504N	P=0.490N
POLY 6	P=0.267N	P=0.506	P=0.508N	P=0.482N
COCH-ARM / FISHERS	P=0.280N	P=0.500	P=0.508N	P=0.500N
MAX-ISO-POLY-3	P=0.332N	P=0.331	P=0.285N	P=0.273N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**All Organs
 Hemangioma**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/47.76	0/48.5	0/47.94	0/49.86
POLY-3 PERCENT (g)	4.2%	0%	0%	0%
TERMINAL (d)	1/45 (2%)	0/46 (0%)	0/43 (0%)	0/49 (0%)
FIRST INCIDENCE	712	---	---	---
HC TUMORS SAME RTE	0/200 (0%)			
HC TUMORS ALL RTES	9/1149 (1%)			

STATISTICAL TESTS

POLY 3	P=0.116N	P=0.234N	P=0.237N	P=0.228N
POLY 1.5	P=0.115N	P=0.235N	P=0.236N	P=0.231N
POLY 6	P=0.116N	P=0.234N	P=0.239N	P=0.226N
COCH-ARM / FISHERS	P=0.115N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.033N*	P=0.076N	P=0.076N	P=0.076N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM
All Organs				
Hemangiosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	3/50 (6%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	3/47.88	3/48.5	2/47.94	3/49.86
POLY-3 PERCENT (g)	6.3%	6.2%	4.2%	6%
TERMINAL (d)	1/45 (2%)	3/46 (7%)	2/43 (5%)	3/49 (6%)
FIRST INCIDENCE	699	729 (T)	729 (T)	729 (T)
HC TUMORS SAME RTE	8/200 (4%)			
HC TUMORS ALL RTES	67/1149 (6%)			

STATISTICAL TESTS

POLY 3	P=0.547N	P=0.656N	P=0.499N	P=0.643N
POLY 1.5	P=0.552N	P=0.657N	P=0.498N	P=0.649N
POLY 6	P=0.544N	P=0.657N	P=0.506N	P=0.639N
COCH-ARM / FISHERS	P=0.562N	P=0.661N	P=0.500N	P=0.661N
MAX-ISO-POLY-3	P=0.630N	P=0.493N	P=0.324N	P=0.479N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
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 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**All Organs
 Hemangiosarcoma or Hemangioma**

TUMOR RATES	#	#	#	#
OVERALL (a)	4/50 (8%)	3/50 (6%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	4/47.88	3/48.5	2/47.94	3/49.86
POLY-3 PERCENT (g)	8.4%	6.2%	4.2%	6%
TERMINAL (d)	2/45 (4%)	3/46 (7%)	2/43 (5%)	3/49 (6%)
FIRST INCIDENCE	699	729 (T)	729 (T)	729 (T)
HC TUMORS SAME RTE	8/200 (4%)			
HC TUMORS ALL RTES	76/1149 (7%)			

STATISTICAL TESTS

POLY 3	P=0.407N	P=0.493N	P=0.337N	P=0.478N
POLY 1.5	P=0.411N	P=0.494N	P=0.335N	P=0.485N
POLY 6	P=0.403N	P=0.494N	P=0.343N	P=0.473N
COCH-ARM / FISHERS	P=0.420N	P=0.500N	P=0.339N	P=0.500N
MAX-ISO-POLY-3	P=0.416N	P=0.342N	P=0.201N	P=0.331N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**All Organs
 Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type**

TUMOR RATES	#	#	#	#
OVERALL (a)	6/50 (12%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	6/47.69	0/48.5	1/47.94	2/49.86
POLY-3 PERCENT (g)	12.6%	0%	2.1%	4%
TERMINAL (d)	6/45 (13%)	0/46 (0%)	1/43 (2%)	2/49 (4%)
FIRST INCIDENCE	729 (T)	---	729 (T)	729 (T)
HC TUMORS SAME RTE	9/200 (5%)			
HC TUMORS ALL RTES	34/1149 (3%)			

STATISTICAL TESTS

POLY 3	P=0.132N	P=0.015N*	P=0.055N	P=0.120N
POLY 1.5	P=0.132N	P=0.015N*	P=0.055N	P=0.125N
POLY 6	P=0.131N	P=0.014N*	P=0.057N	P=0.116N
COCH-ARM / FISHERS	P=0.137N	P=0.013N*	P=0.056N	P=0.134N
MAX-ISO-POLY-3	P=0.011N*	P=0.005N**	P=0.024N*	P=0.065N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM
All Organs				
Benign Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	21/50 (42%)	19/50 (38%)	16/50 (32%)	11/50 (22%)
POLY-3 RATE (b)	21/47.76	19/48.5	16/48.2	11/49.86
POLY-3 PERCENT (g)	44%	39.2%	33.2%	22.1%
TERMINAL (d)	20/45 (44%)	19/46 (41%)	15/43 (35%)	11/49 (22%)
FIRST INCIDENCE	712	729 (T)	659	729 (T)
HC TUMORS SAME RTE	104/200 (52%)			
HC TUMORS ALL RTEs	753/1149 (66%)			

STATISTICAL TESTS

POLY 3	P=0.010N**	P=0.394N	P=0.191N	P=0.017N*
POLY 1.5	P=0.011N*	P=0.400N	P=0.192N	P=0.019N*
POLY 6	P=0.008N**	P=0.394N	P=0.197N	P=0.015N*
COCH-ARM / FISHERS	P=0.016N*	P=0.419N	P=0.204N	P=0.026N*
MAX-ISO-POLY-3	P=0.014N*	P=0.318N	P=0.140N	P=0.011N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM
All Organs				
Malignant Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	29/50 (58%)	24/50 (48%)	24/50 (48%)	19/50 (38%)
POLY-3 RATE (b)	29/49.15	24/49.22	24/49.86	19/49.86
POLY-3 PERCENT (g)	59%	48.8%	48.1%	38.1%
TERMINAL (d)	25/45 (56%)	21/46 (46%)	18/43 (42%)	19/49 (39%)
FIRST INCIDENCE	427	633	460	729 (T)
HC TUMORS SAME RTE	76/200 (38%)			
HC TUMORS ALL RTES	582/1149 (51%)			

STATISTICAL TESTS

POLY 3	P=0.028N*	P=0.208N	P=0.189N	P=0.028N*
POLY 1.5	P=0.030N*	P=0.208N	P=0.195N	P=0.030N*
POLY 6	P=0.028N*	P=0.209N	P=0.189N	P=0.028N*
COCH-ARM / FISHERS	P=0.035N*	P=0.212N	P=0.212N	P=0.036N*
MAX-ISO-POLY-3	P=0.029N*	P=0.155N	P=0.141N	P=0.018N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**All Organs
 Malignant and Benign Tumors**

TUMOR RATES	#	#	#	#
OVERALL (a)	39/50 (78%)	33/50 (66%)	31/50 (62%)	26/50 (52%)
POLY-3 RATE (b)	39/49.15	33/49.22	31/49.86	26/49.86
POLY-3 PERCENT (g)	79.4%	67.1%	62.2%	52.2%
TERMINAL (d)	35/45 (78%)	30/46 (65%)	25/43 (58%)	26/49 (53%)
FIRST INCIDENCE	427	633	460	729 (T)
HC TUMORS SAME RTE	144/200 (72%)			
HC TUMORS ALL RTES	976/1149 (85%)			

STATISTICAL TESTS

POLY 3	P=0.003N**	P=0.124N	P=0.047N*	P=0.003N**
POLY 1.5	P=0.003N**	P=0.125N	P=0.050N*	P=0.003N**
POLY 6	P=0.003N**	P=0.126N	P=0.046N*	P=0.003N**
COCH-ARM / FISHERS	P=0.005N**	P=0.133N	P=0.063N	P=0.006N**
MAX-ISO-POLY-3	P=0.003N**	P=0.084N	P=0.030N*	P=0.002N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Adrenal Cortex
 Adenoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.01	0/46.78	0/47.98	0/48.22
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/40 (0%)	0/43 (0%)	0/42 (0%)	0/45 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	1/249 (0%)			
HC TUMORS ALL RTES	5/1244 (0%)			

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
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 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Bone Marrow
 Hemangiosarcoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/47.01	2/47.02	0/47.98	1/48.57
POLY-3 PERCENT (g)	0%	4.3%	0%	2.1%
TERMINAL (d)	0/40 (0%)	1/43 (2%)	0/42 (0%)	0/45 (0%)
FIRST INCIDENCE	---	664	---	632
HC TUMORS SAME RTE	1/250 (0%)			
HC TUMORS ALL RTES	7/1243 (1%)			

STATISTICAL TESTS

POLY 3	P=0.551	P=0.237	(e)	P=0.506
POLY 1.5	P=0.543	P=0.236	(e)	P=0.503
POLY 6	P=0.561	P=0.242	(e)	P=0.512
COCH-ARM / FISHERS	P=0.539	P=0.247	(e)	P=0.500
MAX-ISO-POLY-3	P=0.339	P=0.076	(e)	P=0.167
HISTCONT SAME RTE	P=0.412	P=0.061	(e)	P=0.156
HISTCONT ALL RTES	P=0.393	P=0.037*	(e)	P=0.199

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
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 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Harderian Gland
 Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	6/50 (12%)	3/50 (6%)	5/50 (10%)	7/50 (14%)
POLY-3 RATE (b)	6/47.01	3/46.78	5/48.23	7/48.57
POLY-3 PERCENT (g)	12.8%	6.4%	10.4%	14.4%
TERMINAL (d)	6/40 (15%)	3/43 (7%)	4/42 (10%)	6/45 (13%)
FIRST INCIDENCE	729 (T)	729 (T)	661	632
HC TUMORS SAME RTE	23/250 (9%)			
HC TUMORS ALL RTES	128/1249 (10%)			

STATISTICAL TESTS

POLY 3	P=0.329	P=0.245N	P=0.482N	P=0.525
POLY 1.5	P=0.318	P=0.247N	P=0.489N	P=0.510
POLY 6	P=0.344	P=0.237N	P=0.475N	P=0.547
COCH-ARM / FISHERS	P=0.306	P=0.243N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.372	P=0.149N	P=0.359N	P=0.407
HISTCONT SAME RTE	P=0.384	P=1.000	P=0.597	P=0.311
HISTCONT ALL RTES	P=0.433	P=1.000	P=1.000	P=0.409

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
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 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM
Harderian Gland Carcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	2/50 (4%)	5/50 (10%)	0/50 (0%)
POLY-3 RATE (b)	2/47.01	2/46.78	5/48.14	0/48.22
POLY-3 PERCENT (g)	4.3%	4.3%	10.4%	0%
TERMINAL (d)	2/40 (5%)	2/43 (5%)	4/42 (10%)	0/45 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	688	---
HC TUMORS SAME RTE	5/250 (2%)			
HC TUMORS ALL RTES	33/1249 (3%)			

STATISTICAL TESTS

POLY 3	P=0.247N	P=0.692	P=0.226	P=0.232N
POLY 1.5	P=0.256N	P=0.690	P=0.223	P=0.235N
POLY 6	P=0.236N	P=0.690N	P=0.230	P=0.226N
COCH-ARM / FISHERS	P=0.263N	P=0.691N	P=0.218	P=0.247N
MAX-ISO-POLY-3	P=0.116N	P=0.497	P=0.129	P=0.076N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
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 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM
Harderian Gland Carcinoma or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	8/50 (16%)	5/50 (10%)	10/50 (20%)	7/50 (14%)
POLY-3 RATE (b)	8/47.01	5/46.78	10/48.39	7/48.57
POLY-3 PERCENT (g)	17%	10.7%	20.7%	14.4%
TERMINAL (d)	8/40 (20%)	5/43 (12%)	8/42 (19%)	6/45 (13%)
FIRST INCIDENCE	729 (T)	729 (T)	661	632
HC TUMORS SAME RTE	28/250 (11%)			
HC TUMORS ALL RTES	160/1249 (13%)			

STATISTICAL TESTS

POLY 3	P=0.545N	P=0.279N	P=0.424	P=0.473N
POLY 1.5	P=0.544	P=0.282N	P=0.413	P=0.490N
POLY 6	P=0.522N	P=0.269N	P=0.436	P=0.449N
COCH-ARM / FISHERS	P=0.527	P=0.277N	P=0.398	P=0.500N
MAX-ISO-POLY-3	P=0.501	P=0.189N	P=0.327	P=0.365N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
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 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Islets, Pancreatic
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	0/49 (0%)	1/48 (2%)	1/49 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/46.32	1/45.61	1/47.66	1/48.22
POLY-3 PERCENT (g)	0%	2.2%	2.1%	2.1%
TERMINAL (d)	0/40 (0%)	1/42 (2%)	0/42 (0%)	1/45 (2%)
FIRST INCIDENCE	---	729 (T)	602	729 (T)
HC TUMORS SAME RTE	3/249 (1%)			
HC TUMORS ALL RTES	16/1228 (1%)			

STATISTICAL TESTS

POLY 3	P=0.400	P=0.497	P=0.506	P=0.508
POLY 1.5	P=0.395	P=0.496	P=0.503	P=0.505
POLY 6	P=0.408	P=0.500	P=0.508	P=0.512
COCH-ARM / FISHERS	P=0.391	P=0.495	P=0.500	P=0.505
MAX-ISO-POLY-3	P=0.342	P=0.157	P=0.166	P=0.168
HISTCONT SAME RTE	P=0.416	P=0.200	P=0.211	P=0.213
HISTCONT ALL RTES	P=0.397	P=0.187	P=0.197	P=0.200

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Hepatocellular Adenoma

TUMOR RATES

OVERALL (a)	3/50 (6%)	1/50 (2%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	3/47.18	1/46.78	4/47.98	0/48.22
POLY-3 PERCENT (g)	6.4%	2.1%	8.3%	0%
TERMINAL (d)	2/40 (5%)	1/43 (2%)	4/42 (10%)	0/45 (0%)
FIRST INCIDENCE	685	729 (T)	729 (T)	---
HC TUMORS SAME RTE	17/250 (7%)			
HC TUMORS ALL RTES	345/1245 (28%)			

STATISTICAL TESTS

POLY 3	P=0.155N	P=0.309N	P=0.509	P=0.115N
POLY 1.5	P=0.160N	P=0.309N	P=0.506	P=0.118N
POLY 6	P=0.150N	P=0.304N	P=0.511	P=0.111N
COCH-ARM / FISHERS	P=0.165N	P=0.309N	P=0.500	P=0.121N
MAX-ISO-POLY-3	P=0.097N	P=0.158N	P=0.357	P=0.038N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Liver
 Hepatocellular Carcinoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	4/50 (8%)
POLY-3 RATE (b)	0/47.01	1/46.78	0/47.98	4/48.25
POLY-3 PERCENT (g)	0%	2.1%	0%	8.3%
TERMINAL (d)	0/40 (0%)	1/43 (2%)	0/42 (0%)	3/45 (7%)
FIRST INCIDENCE	---	729 (T)	---	721
HC TUMORS SAME RTE	7/250 (3%)			
HC TUMORS ALL RTES	131/1245 (11%)			

STATISTICAL TESTS

POLY 3	P=0.013*	P=0.499	(e)	P=0.064
POLY 1.5	P=0.013*	P=0.498	(e)	P=0.062
POLY 6	P=0.013*	P=0.502	(e)	P=0.067
COCH-ARM / FISHERS	P=0.013*	P=0.500	(e)	P=0.059
MAX-ISO-POLY-3	P=0.008**	P=0.159	(e)	P=0.022*
HISTCONT SAME RTE	P=0.009**	P=0.201	(e)	P=0.024*
HISTCONT ALL RTES	P=0.009**	P=0.189	(e)	P=0.023*

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Liver
 Hepatocellular Carcinoma or Hepatoblastoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	4/50 (8%)
POLY-3 RATE (b)	0/47.01	1/46.78	0/47.98	4/48.25
POLY-3 PERCENT (g)	0%	2.1%	0%	8.3%
TERMINAL (d)	0/40 (0%)	1/43 (2%)	0/42 (0%)	3/45 (7%)
FIRST INCIDENCE	---	729 (T)	---	721
HC TUMORS SAME RTE	7/250 (3%)			
HC TUMORS ALL RTES	136/1245 (11%)			

STATISTICAL TESTS

POLY 3	P=0.013*	P=0.499	(e)	P=0.064
POLY 1.5	P=0.013*	P=0.498	(e)	P=0.062
POLY 6	P=0.013*	P=0.502	(e)	P=0.067
COCH-ARM / FISHERS	P=0.013*	P=0.500	(e)	P=0.059
MAX-ISO-POLY-3	P=0.008**	P=0.159	(e)	P=0.022*
HISTCONT SAME RTE	P=0.009**	P=0.201	(e)	P=0.024*
HISTCONT ALL RTES	P=0.009**	P=0.189	(e)	P=0.023*

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Liver
 Hepatocellular Carcinoma or Hepatocellular Adenoma**

TUMOR RATES

OVERALL (a)	3/50 (6%)	2/50 (4%)	4/50 (8%)	4/50 (8%)
POLY-3 RATE (b)	3/47.18	2/46.78	4/47.98	4/48.25
POLY-3 PERCENT (g)	6.4%	4.3%	8.3%	8.3%
TERMINAL (d)	2/40 (5%)	2/43 (5%)	4/42 (10%)	3/45 (7%)
FIRST INCIDENCE	685	729 (T)	729 (T)	721
HC TUMORS SAME RTE	22/250 (9%)			
HC TUMORS ALL RTES	419/1245 (34%)			

STATISTICAL TESTS

POLY 3	P=0.347	P=0.504N	P=0.509	P=0.512
POLY 1.5	P=0.339	P=0.505N	P=0.506	P=0.504
POLY 6	P=0.357	P=0.499N	P=0.511	P=0.524
COCH-ARM / FISHERS	P=0.331	P=0.500N	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.457	P=0.328N	P=0.357	P=0.360
HISTCONT SAME RTE	P=0.554	P=1.000	P=0.468	P=0.472
HISTCONT ALL RTES	P=0.535	P=1.000	P=0.452	P=0.456

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma

TUMOR RATES

OVERALL (a)	3/50 (6%)	2/50 (4%)	4/50 (8%)	4/50 (8%)
POLY-3 RATE (b)	3/47.18	2/46.78	4/47.98	4/48.25
POLY-3 PERCENT (g)	6.4%	4.3%	8.3%	8.3%
TERMINAL (d)	2/40 (5%)	2/43 (5%)	4/42 (10%)	3/45 (7%)
FIRST INCIDENCE	685	729 (T)	729 (T)	721
HC TUMORS SAME RTE	22/250 (9%)			
HC TUMORS ALL RTES	421/1245 (34%)			

STATISTICAL TESTS

POLY 3	P=0.347	P=0.504N	P=0.509	P=0.512
POLY 1.5	P=0.339	P=0.505N	P=0.506	P=0.504
POLY 6	P=0.357	P=0.499N	P=0.511	P=0.524
COCH-ARM / FISHERS	P=0.331	P=0.500N	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.457	P=0.328N	P=0.357	P=0.360
HISTCONT SAME RTE	P=0.554	P=1.000	P=0.468	P=0.472
HISTCONT ALL RTES	P=0.535	P=1.000	P=0.452	P=0.456

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
 Alveolar/Bronchiolar Adenoma**

TUMOR RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/47.01	2/46.78	1/47.98	1/48.22
POLY-3 PERCENT (g)	2.1%	4.3%	2.1%	2.1%
TERMINAL (d)	1/40 (3%)	2/43 (5%)	1/42 (2%)	1/45 (2%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
HC TUMORS SAME RTE	10/250 (4%)			
HC TUMORS ALL RTES	65/1248 (5%)			

STATISTICAL TESTS

POLY 3	P=0.522N	P=0.498	P=0.756N	P=0.755N
POLY 1.5	P=0.527N	P=0.497	P=0.758N	P=0.758N
POLY 6	P=0.515N	P=0.504	P=0.755N	P=0.749N
COCH-ARM / FISHERS	P=0.531N	P=0.500	P=0.753N	P=0.753N
MAX-ISO-POLY-3	P=0.579N	P=0.280	P=0.493N	P=0.492N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
 Alveolar/Bronchiolar Carcinoma**

TUMOR RATES

OVERALL (a)	1/50 (2%)	4/50 (8%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/47.01	4/47.54	0/47.98	0/48.22
POLY-3 PERCENT (g)	2.1%	8.4%	0%	0%
TERMINAL (d)	1/40 (3%)	3/43 (7%)	0/42 (0%)	0/45 (0%)
FIRST INCIDENCE	729 (T)	450	---	---
HC TUMORS SAME RTE	7/250 (3%)			
HC TUMORS ALL RTES	47/1248 (4%)			

STATISTICAL TESTS

POLY 3	P=0.117N	P=0.182	P=0.496N	P=0.495N
POLY 1.5	P=0.120N	P=0.180	P=0.497N	P=0.498N
POLY 6	P=0.112N	P=0.188	P=0.495N	P=0.490N
COCH-ARM / FISHERS	P=0.125N	P=0.181	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.083N	P=0.087	P=0.159N	P=0.159N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
 Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma**

TUMOR RATES

OVERALL (a)	2/50 (4%)	5/50 (10%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/47.01	5/47.54	1/47.98	1/48.22
POLY-3 PERCENT (g)	4.3%	10.5%	2.1%	2.1%
TERMINAL (d)	2/40 (5%)	4/43 (9%)	1/42 (2%)	1/45 (2%)
FIRST INCIDENCE	729 (T)	450	729 (T)	729 (T)
HC TUMORS SAME RTE	15/250 (6%)			
HC TUMORS ALL RTES	107/1248 (9%)			

STATISTICAL TESTS

POLY 3	P=0.184N	P=0.221	P=0.493N	P=0.491N
POLY 1.5	P=0.189N	P=0.217	P=0.496N	P=0.497N
POLY 6	P=0.177N	P=0.229	P=0.491N	P=0.483N
COCH-ARM / FISHERS	P=0.194N	P=0.218	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.179N	P=0.125	P=0.277N	P=0.276N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Mammary Gland
 Carcinoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.01	2/47	0/47.98	0/48.22
POLY-3 PERCENT (g)	0%	4.3%	0%	0%
TERMINAL (d)	0/40 (0%)	0/43 (0%)	0/42 (0%)	0/45 (0%)
FIRST INCIDENCE	---	675	---	---
HC TUMORS SAME RTE	4/250 (2%)			
HC TUMORS ALL RTES	16/1249 (1%)			

STATISTICAL TESTS

POLY 3	P=0.399N	P=0.237	(e)	(e)
POLY 1.5	P=0.403N	P=0.236	(e)	(e)
POLY 6	P=0.392N	P=0.241	(e)	(e)
COCH-ARM / FISHERS	P=0.405N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.251N	P=0.076	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTES	(h)	(h)	(e)	(e)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

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

TUMOR RATES

OVERALL (a)	2/49 (4%)	2/49 (4%)	1/48 (2%)	2/48 (4%)
POLY-3 RATE (b)	2/46.76	2/45.78	1/46.43	2/46.22
POLY-3 PERCENT (g)	4.3%	4.4%	2.2%	4.3%
TERMINAL (d)	1/40 (3%)	2/42 (5%)	0/41 (0%)	2/43 (5%)
FIRST INCIDENCE	618	729 (T)	674	729 (T)
HC TUMORS SAME RTE	11/246 (5%)			
HC TUMORS ALL RTES	97/1216 (8%)			

STATISTICAL TESTS

POLY 3	P=0.580N	P=0.686	P=0.502N	P=0.689
POLY 1.5	P=0.583N	P=0.687	P=0.504N	P=0.686
POLY 6	P=0.577N	P=0.688	P=0.501N	P=0.693N
COCH-ARM / FISHERS	P=0.587N	P=0.691N	P=0.508N	P=0.684
MAX-ISO-POLY-3	P=0.613N	P=0.491	P=0.283N	P=0.494
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

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

TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	2/50 (4%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	3/47.16	2/46.78	0/47.98	2/48.25
POLY-3 PERCENT (g)	6.4%	4.3%	0%	4.2%
TERMINAL (d)	1/40 (3%)	2/43 (5%)	0/42 (0%)	1/45 (2%)
FIRST INCIDENCE	705	729 (T)	---	721
HC TUMORS SAME RTE	10/250 (4%)			
HC TUMORS ALL RTES	53/1249 (4%)			

STATISTICAL TESTS

POLY 3	P=0.367N	P=0.504N	P=0.116N	P=0.490N
POLY 1.5	P=0.369N	P=0.505N	P=0.117N	P=0.497N
POLY 6	P=0.364N	P=0.498N	P=0.115N	P=0.480N
COCH-ARM / FISHERS	P=0.373N	P=0.500N	P=0.121N	P=0.500N
MAX-ISO-POLY-3	P=0.219N	P=0.328N	P=0.038N*	P=0.317N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM
Skin				
Fibrosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	3/47.16	2/46.78	0/47.98	1/48.25
POLY-3 PERCENT (g)	6.4%	4.3%	0%	2.1%
TERMINAL (d)	1/40 (3%)	2/43 (5%)	0/42 (0%)	0/45 (0%)
FIRST INCIDENCE	705	729 (T)	---	721
HC TUMORS SAME RTE	7/250 (3%)			
HC TUMORS ALL RTES	20/1249 (2%)			

STATISTICAL TESTS

POLY 3	P=0.160N	P=0.504N	P=0.116N	P=0.297N
POLY 1.5	P=0.161N	P=0.505N	P=0.117N	P=0.303N
POLY 6	P=0.158N	P=0.498N	P=0.115N	P=0.290N
COCH-ARM / FISHERS	P=0.163N	P=0.500N	P=0.121N	P=0.309N
MAX-ISO-POLY-3	P=0.111N	P=0.328N	P=0.038N*	P=0.151N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

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

TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	2/50 (4%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	3/47.16	2/46.78	0/47.98	2/48.25
POLY-3 PERCENT (g)	6.4%	4.3%	0%	4.2%
TERMINAL (d)	1/40 (3%)	2/43 (5%)	0/42 (0%)	1/45 (2%)
FIRST INCIDENCE	705	729 (T)	---	721
HC TUMORS SAME RTE	10/250 (4%)			
HC TUMORS ALL RTES	53/1249 (4%)			

STATISTICAL TESTS

POLY 3	P=0.367N	P=0.504N	P=0.116N	P=0.490N
POLY 1.5	P=0.369N	P=0.505N	P=0.117N	P=0.497N
POLY 6	P=0.364N	P=0.498N	P=0.115N	P=0.480N
COCH-ARM / FISHERS	P=0.373N	P=0.500N	P=0.121N	P=0.500N
MAX-ISO-POLY-3	P=0.219N	P=0.328N	P=0.038N*	P=0.317N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM
Skin				
Fibrous Histiocytoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/47.01	0/46.78	0/47.98	1/48.22
POLY-3 PERCENT (g)	0%	0%	0%	2.1%
TERMINAL (d)	0/40 (0%)	0/43 (0%)	0/42 (0%)	1/45 (2%)
FIRST INCIDENCE	---	---	---	729 (T)
HC TUMORS SAME RTE	1/250 (0%)			
HC TUMORS ALL RTES	7/1249 (1%)			

STATISTICAL TESTS

POLY 3	P=0.203	(e)	(e)	P=0.505
POLY 1.5	P=0.201	(e)	(e)	P=0.502
POLY 6	P=0.205	(e)	(e)	P=0.510
COCH-ARM / FISHERS	P=0.198	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.133	(e)	(e)	P=0.165
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM
Skin				
Hemangiosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.01	1/47.02	0/47.98	0/48.22
POLY-3 PERCENT (g)	0%	2.1%	0%	0%
TERMINAL (d)	0/40 (0%)	0/43 (0%)	0/42 (0%)	0/45 (0%)
FIRST INCIDENCE	---	664	---	---
HC TUMORS SAME RTE	3/250 (1%)			
HC TUMORS ALL RTES	17/1249 (1%)			

STATISTICAL TESTS

POLY 3	P=0.565N	P=0.500	(e)	(e)
POLY 1.5	P=0.567N	P=0.499	(e)	(e)
POLY 6	P=0.561N	P=0.504	(e)	(e)
COCH-ARM / FISHERS	P=0.567N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.388N	P=0.159	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTES	(h)	(h)	(e)	(e)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM
Skin				
Liposarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/47.01	0/46.78	2/48.14	1/48.48
POLY-3 PERCENT (g)	0%	0%	4.2%	2.1%
TERMINAL (d)	0/40 (0%)	0/43 (0%)	1/42 (2%)	0/45 (0%)
FIRST INCIDENCE	---	---	688	659
HC TUMORS SAME RTE	0/250 (0%)			
HC TUMORS ALL RTES	1/1249 (0%)			

STATISTICAL TESTS

POLY 3	P=0.258	(e)	P=0.243	P=0.506
POLY 1.5	P=0.251	(e)	P=0.241	P=0.502
POLY 6	P=0.268	(e)	P=0.245	P=0.512
COCH-ARM / FISHERS	P=0.246	(e)	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.183	(e)	P=0.081	P=0.166
HISTCONT SAME RTE	P=0.101	(e)	P=0.030*	P=0.031*
HISTCONT ALL RTES	P<0.001**	(e)	P<0.001**	P=0.004**

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Spleen
 Hemangiosarcoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	3/48 (6%)	1/49 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/47.01	3/45.85	1/47.47	1/48.57
POLY-3 PERCENT (g)	0%	6.5%	2.1%	2.1%
TERMINAL (d)	0/40 (0%)	2/42 (5%)	0/42 (0%)	0/45 (0%)
FIRST INCIDENCE	---	664	661	632
HC TUMORS SAME RTE	5/247 (2%)			
HC TUMORS ALL RTES	24/1230 (2%)			

STATISTICAL TESTS

POLY 3	P=0.611	P=0.114	P=0.502	P=0.506
POLY 1.5	P=0.601	P=0.112	P=0.500	P=0.503
POLY 6	P=0.619N	P=0.118	P=0.505	P=0.512
COCH-ARM / FISHERS	P=0.594	P=0.114	P=0.495	P=0.500
MAX-ISO-POLY-3	P=0.235	P=0.037*	P=0.162	P=0.167
HISTCONT SAME RTE	P=0.285	P=0.042*	P=0.206	P=0.212
HISTCONT ALL RTES	P=0.271	P=0.039*	P=0.193	P=0.199

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM
Uterus				
Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	4/50 (8%)	1/50 (2%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	4/47.01	1/46.78	4/47.98	1/48.22
POLY-3 PERCENT (g)	8.5%	2.1%	8.3%	2.1%
TERMINAL (d)	4/40 (10%)	1/43 (2%)	4/42 (10%)	1/45 (2%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
HC TUMORS SAME RTE	6/250 (2%)			
HC TUMORS ALL RTES	33/1249 (3%)			

STATISTICAL TESTS

POLY 3	P=0.210N	P=0.180N	P=0.632N	P=0.171N
POLY 1.5	P=0.216N	P=0.182N	P=0.636N	P=0.177N
POLY 6	P=0.204N	P=0.176N	P=0.628N	P=0.164N
COCH-ARM / FISHERS	P=0.221N	P=0.181N	P=0.643N	P=0.181N
MAX-ISO-POLY-3	P=0.129N	P=0.085N	P=0.487N	P=0.082N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM
Uterus				
Sarcoma Stromal or Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	4/50 (8%)	1/50 (2%)	5/50 (10%)	1/50 (2%)
POLY-3 RATE (b)	4/47.01	1/46.78	5/48.1	1/48.22
POLY-3 PERCENT (g)	8.5%	2.1%	10.4%	2.1%
TERMINAL (d)	4/40 (10%)	1/43 (2%)	4/42 (10%)	1/45 (2%)
FIRST INCIDENCE	729 (T)	729 (T)	697	729 (T)
HC TUMORS SAME RTE	8/250 (3%)			
HC TUMORS ALL RTES	40/1249 (3%)			

STATISTICAL TESTS

POLY 3	P=0.233N	P=0.180N	P=0.514	P=0.171N
POLY 1.5	P=0.241N	P=0.182N	P=0.509	P=0.177N
POLY 6	P=0.225N	P=0.176N	P=0.520	P=0.164N
COCH-ARM / FISHERS	P=0.248N	P=0.181N	P=0.500	P=0.181N
MAX-ISO-POLY-3	P=0.144N	P=0.085N	P=0.378	P=0.082N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM
All Organs				
Hemangioma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/47.01	0/46.78	1/47.98	0/48.22
POLY-3 PERCENT (g)	2.1%	0%	2.1%	0%
TERMINAL (d)	1/40 (3%)	0/43 (0%)	1/42 (2%)	0/45 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	---
HC TUMORS SAME RTE	0/250 (0%)			
HC TUMORS ALL RTES	20/1249 (2%)			

STATISTICAL TESTS

POLY 3	P=0.400N	P=0.501N	P=0.756N	P=0.495N
POLY 1.5	P=0.403N	P=0.502N	P=0.758N	P=0.498N
POLY 6	P=0.399N	P=0.498N	P=0.755N	P=0.490N
COCH-ARM / FISHERS	P=0.405N	P=0.500N	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.255N	P=0.160N	P=0.493N	P=0.159N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM
All Organs				
Hemangiosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	4/50 (8%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/47.01	4/47.02	2/48.23	1/48.57
POLY-3 PERCENT (g)	4.3%	8.5%	4.2%	2.1%
TERMINAL (d)	2/40 (5%)	3/43 (7%)	1/42 (2%)	0/45 (0%)
FIRST INCIDENCE	729 (T)	664	661	632
HC TUMORS SAME RTE	10/250 (4%)			
HC TUMORS ALL RTES	60/1249 (5%)			

STATISTICAL TESTS

POLY 3	P=0.250N	P=0.338	P=0.684N	P=0.489N
POLY 1.5	P=0.258N	P=0.335	P=0.688N	P=0.496N
POLY 6	P=0.239N	P=0.346	P=0.681N	P=0.479N
COCH-ARM / FISHERS	P=0.263N	P=0.339	P=0.691N	P=0.500N
MAX-ISO-POLY-3	P=0.265N	P=0.201	P=0.489N	P=0.274N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**All Organs
 Hemangiosarcoma or Hemangioma**

TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	4/50 (8%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	3/47.01	4/47.02	3/48.23	1/48.57
POLY-3 PERCENT (g)	6.4%	8.5%	6.2%	2.1%
TERMINAL (d)	3/40 (8%)	3/43 (7%)	2/42 (5%)	0/45 (0%)
FIRST INCIDENCE	729 (T)	664	661	632
HC TUMORS SAME RTE	10/250 (4%)			
HC TUMORS ALL RTES	79/1249 (6%)			

STATISTICAL TESTS

POLY 3	P=0.175N	P=0.500	P=0.650N	P=0.294N
POLY 1.5	P=0.182N	P=0.497	P=0.655N	P=0.301N
POLY 6	P=0.165N	P=0.511	P=0.645N	P=0.284N
COCH-ARM / FISHERS	P=0.186N	P=0.500	P=0.661N	P=0.309N
MAX-ISO-POLY-3	P=0.216N	P=0.348	P=0.487N	P=0.150N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**All Organs
 Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type**

TUMOR RATES	#	#	#	#
OVERALL (a)	11/50 (22%)	13/50 (26%)	16/50 (32%)	15/50 (30%)
POLY-3 RATE (b)	11/48.27	13/48.11	16/48.59	15/48.22
POLY-3 PERCENT (g)	22.8%	27%	32.9%	31.1%
TERMINAL (d)	7/40 (18%)	10/43 (23%)	13/42 (31%)	15/45 (33%)
FIRST INCIDENCE	582	406	665	729 (T)
HC TUMORS SAME RTE	33/250 (13%)			
HC TUMORS ALL RTES	284/1249 (23%)			

STATISTICAL TESTS

POLY 3	P=0.203	P=0.404	P=0.188	P=0.245
POLY 1.5	P=0.200	P=0.401	P=0.187	P=0.241
POLY 6	P=0.206	P=0.413	P=0.186	P=0.251
COCH-ARM / FISHERS	P=0.203	P=0.408	P=0.184	P=0.247
MAX-ISO-POLY-3	P=0.255	P=0.317	P=0.133	P=0.180
HISTCONT SAME RTE	P=0.014*	P=0.066	P=0.041*	P=0.046*
HISTCONT ALL RTES	P=0.296	P=0.398	P=0.158	P=0.216

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM
All Organs				
Benign Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	18/50 (36%)	11/50 (22%)	18/50 (36%)	15/50 (30%)
POLY-3 RATE (b)	18/47.57	11/46.78	18/48.88	15/48.57
POLY-3 PERCENT (g)	37.8%	23.5%	36.8%	30.9%
TERMINAL (d)	16/40 (40%)	11/43 (26%)	15/42 (36%)	14/45 (31%)
FIRST INCIDENCE	618	729 (T)	602	632
HC TUMORS SAME RTE	78/250 (31%)			
HC TUMORS ALL RTES	644/1249 (52%)			

STATISTICAL TESTS

POLY 3	P=0.435N	P=0.098N	P=0.543N	P=0.308N
POLY 1.5	P=0.459N	P=0.098N	P=0.558N	P=0.327N
POLY 6	P=0.408N	P=0.093N	P=0.527N	P=0.282N
COCH-ARM / FISHERS	P=0.479N	P=0.093N	P=0.582N	P=0.335N
MAX-ISO-POLY-3	P=0.361N	P=0.066N	P=0.459N	P=0.240N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM
All Organs				
Malignant Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	19/50 (38%)	26/50 (52%)	26/50 (52%)	22/50 (44%)
POLY-3 RATE (b)	19/48.89	26/49.13	26/49.67	22/49.02
POLY-3 PERCENT (g)	38.9%	52.9%	52.4%	44.9%
TERMINAL (d)	12/40 (30%)	20/43 (47%)	19/42 (45%)	18/45 (40%)
FIRST INCIDENCE	549	406	602	632
HC TUMORS SAME RTE	90/250 (36%)			
HC TUMORS ALL RTES	629/1249 (50%)			

STATISTICAL TESTS

POLY 3	P=0.420	P=0.116	P=0.126	P=0.346
POLY 1.5	P=0.406	P=0.112	P=0.121	P=0.335
POLY 6	P=0.442	P=0.125	P=0.133	P=0.365
COCH-ARM / FISHERS	P=0.415	P=0.114	P=0.114	P=0.342
MAX-ISO-POLY-3	P=0.216	P=0.081	P=0.091	P=0.275
HISTCONT SAME RTE	P=0.230	P=0.099	P=0.111	P=0.306
HISTCONT ALL RTES	P=0.249	P=0.092	P=0.104	P=0.342

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**All Organs
 Malignant and Benign Tumors**

TUMOR RATES	#	#	#	#
OVERALL (a)	32/50 (64%)	33/50 (66%)	34/50 (68%)	31/50 (62%)
POLY-3 RATE (b)	32/49.45	33/49.13	34/49.67	31/49.02
POLY-3 PERCENT (g)	64.7%	67.2%	68.5%	63.2%
TERMINAL (d)	23/40 (58%)	27/43 (63%)	27/42 (64%)	27/45 (60%)
FIRST INCIDENCE	549	406	602	632
HC TUMORS SAME RTE	137/250 (55%)			
HC TUMORS ALL RTES	939/1249 (75%)			

STATISTICAL TESTS

POLY 3	P=0.458N	P=0.482	P=0.428	P=0.523N
POLY 1.5	P=0.465N	P=0.483	P=0.424	P=0.528N
POLY 6	P=0.447N	P=0.489	P=0.429	P=0.511N
COCH-ARM / FISHERS	P=0.440N	P=0.500	P=0.417	P=0.500N
MAX-ISO-POLY-3	P=0.563N	P=0.397	P=0.346	P=0.439N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 20008 - 04
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Milk thistle extract
CAS Number: 84604-20-6

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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.
 - (e) Value of Statistic cannot be computed.
 - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
 - (g) Poly-3 adjusted lifetime tumor incidence.
 - (h) Value of Historical Controls statistic is only calculated when Poly-3 trend is positive and when there is more than one tumor in the treatment groups.
 - (I) Interim sacrifice
 - (T) Terminal sacrifice
 - # Tumor rates based on numbers of animals necropsied.
 - * To the right of any statistical result, indicates significance at ($P \leq 0.05$).
 - ** To the right of any statistical result, indicates significance at ($P \leq 0.01$).
 - N Indicates a negative trend for all tests
- The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

*** END OF REPORT ***