

**TDMS No.** 99007 - 06  
**Test Type:** CHRONIC  
**Route:** DOSED FEED  
**Species/Strain:** MICE/B6C3F1

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Goldenseal root powder  
**CAS Number:** GOLDENSEALRT

**Date Report Requested:** 06/25/2008  
**Time Report Requested:** 13:40:20  
**First Dose M/F:** 05/12/03 / 05/12/03  
**Lab:** SRI

**C Number:** C99007B  
**Lock Date:** 08/29/2006  
**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  
Islets, Pancreatic  
Liver  
Lung  
Ovary  
Pancreas  
Pituitary Gland  
Spleen  
Testes  
Thyroid Gland

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**SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF Goldenseal root powder**

**MALE MICE**

**Organ**

Liver

Lung

All Organs

**FEMALE MICE**

**Organ**

Harderian Gland

Ovary

All Organs

**Morphology**

Hepatoblastoma

Hepatocellular Adenoma

Alveolar/Bronchiolar Carcinoma

Benign Tumors

**Morphology**

Adenoma

Carcinoma or Adenoma

Cystadenoma

Histiocytic Sarcoma

Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or

Undifferentiated Cell Type

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

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DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

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**Adrenal Cortex  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	2/50 (4%)	2/50 (4%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/47.87	2/46.42	1/47.71	2/48.96
POLY-3 PERCENT (g)	4.2%	4.3%	2.1%	4.1%
TERMINAL (d)	1/43 (2%)	2/38 (5%)	1/45 (2%)	2/45 (4%)
FIRST INCIDENCE	677	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=0.617N	P=0.683	P=0.501N	P=0.685N
POLY 1.5	P=0.621N	P=0.688	P=0.501N	P=0.688N
POLY 6	P=0.611N	P=0.674	P=0.502N	P=0.682N
COCH-ARM / FISHERS	P=0.621	P=0.691N	P=0.500N	P=0.691N
MAX-ISO-POLY-3	P=0.601N	P=0.487	P=0.282N	P=0.490N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>Harderian Gland Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	7/50 (14%)	11/50 (22%)	3/50 (6%)	6/50 (12%)
POLY-3 RATE (b)	7/47.67	11/47.68	3/47.71	6/48.99
POLY-3 PERCENT (g)	14.7%	23.1%	6.3%	12.3%
TERMINAL (d)	7/43 (16%)	8/38 (21%)	3/45 (7%)	5/45 (11%)
FIRST INCIDENCE	729 (T)	557	729 (T)	722
HC TUMORS SAME RTE	24/200 (12%)			
HC TUMORS ALL RTEs	152/1149 (13%)			

**STATISTICAL TESTS**

POLY 3	P=0.230N	P=0.217	P=0.158N	P=0.479N
POLY 1.5	P=0.237N	P=0.218	P=0.158N	P=0.488N
POLY 6	P=0.221N	P=0.213	P=0.156N	P=0.469N
COCH-ARM / FISHERS	P=0.248N	P=0.218	P=0.159N	P=0.500N
MAX-ISO-POLY-3	P=0.143N	P=0.147	P=0.091N	P=0.364N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>Harderian Gland Carcinoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	2/50 (4%)	3/50 (6%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	2/47.67	3/46.79	2/47.71	2/48.96
POLY-3 PERCENT (g)	4.2%	6.4%	4.2%	4.1%
TERMINAL (d)	2/43 (5%)	2/38 (5%)	2/45 (4%)	2/45 (4%)
FIRST INCIDENCE	729 (T)	625	729 (T)	729 (T)
HC TUMORS SAME RTE	4/200 (2%)			
HC TUMORS ALL RTES	30/1149 (3%)			

**STATISTICAL TESTS**

POLY 3	P=0.510N	P=0.492	P=0.693N	P=0.684N
POLY 1.5	P=0.516N	P=0.496	P=0.693N	P=0.688N
POLY 6	P=0.502N	P=0.485	P=0.692N	P=0.679N
COCH-ARM / FISHERS	P=0.525N	P=0.500	P=0.691N	P=0.691N
MAX-ISO-POLY-3	P=0.611N	P=0.318	P=0.499N	P=0.488N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)



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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>Harderian Gland Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	9/50 (18%)	13/50 (26%)	4/50 (8%)	8/50 (16%)
POLY-3 RATE (b)	9/47.67	13/48.05	4/47.71	8/48.99
POLY-3 PERCENT (g)	18.9%	27.1%	8.4%	16.3%
TERMINAL (d)	9/43 (21%)	9/38 (24%)	4/45 (9%)	7/45 (16%)
FIRST INCIDENCE	729 (T)	557	729 (T)	722
HC TUMORS SAME RTE	27/200 (14%)			
HC TUMORS ALL RTES	176/1149 (15%)			

**STATISTICAL TESTS**

POLY 3	P=0.249N	P=0.240	P=0.115N	P=0.475N
POLY 1.5	P=0.257N	P=0.239	P=0.116N	P=0.485N
POLY 6	P=0.239N	P=0.240	P=0.114N	P=0.463N
COCH-ARM / FISHERS	P=0.270N	P=0.235	P=0.117N	P=0.500N
MAX-ISO-POLY-3	P=0.140N	P=0.173	P=0.067N	P=0.372N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>Intestine Small: Duodenum Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.67	2/46.42	0/47.71	0/48.96
POLY-3 PERCENT (g)	0%	4.3%	0%	0%
TERMINAL (d)	0/43 (0%)	2/38 (5%)	0/45 (0%)	0/45 (0%)
FIRST INCIDENCE	---	729 (T)	---	---
HC TUMORS SAME RTE	1/200 (1%)			
HC TUMORS ALL RTES	9/1149 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.370N	P=0.231	(e)	(e)
POLY 1.5	P=0.370N	P=0.234	(e)	(e)
POLY 6	P=0.372N	P=0.227	(e)	(e)
COCH-ARM / FISHERS	P=0.370N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.248N	P=0.076	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTES	(h)	(h)	(e)	(e)

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>Intestine Small: Jejunum Carcinoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/48.02	1/46.42	0/47.71	0/48.96
POLY-3 PERCENT (g)	4.2%	2.2%	0%	0%
TERMINAL (d)	1/43 (2%)	1/38 (3%)	0/45 (0%)	0/45 (0%)
FIRST INCIDENCE	632	729 (T)	---	---
HC TUMORS SAME RTE	2/200 (1%)			
HC TUMORS ALL RTES	14/1149 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.153N	P=0.512N	P=0.239N	P=0.233N
POLY 1.5	P=0.154N	P=0.506N	P=0.238N	P=0.235N
POLY 6	P=0.150N	P=0.521N	P=0.239N	P=0.231N
COCH-ARM / FISHERS	P=0.156N	P=0.500N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.080N	P=0.294N	P=0.077N	P=0.076N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Intestine Small: Site Unspecified  
 Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.67	2/46.42	0/47.71	0/48.96
POLY-3 PERCENT (g)	0%	4.3%	0%	0%
TERMINAL (d)	0/43 (0%)	2/38 (5%)	0/45 (0%)	0/45 (0%)
FIRST INCIDENCE	---	729 (T)	---	---
HC TUMORS SAME RTE	1/200 (1%)			
HC TUMORS ALL RTES	10/1149 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.370N	P=0.231	(e)	(e)
POLY 1.5	P=0.370N	P=0.234	(e)	(e)
POLY 6	P=0.372N	P=0.227	(e)	(e)
COCH-ARM / FISHERS	P=0.370N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.248N	P=0.076	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTES	(h)	(h)	(e)	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Intestine Small: Site Unspecified  
 Carcinoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/48.02	1/46.42	0/47.71	0/48.96
POLY-3 PERCENT (g)	4.2%	2.2%	0%	0%
TERMINAL (d)	1/43 (2%)	1/38 (3%)	0/45 (0%)	0/45 (0%)
FIRST INCIDENCE	632	729 (T)	---	---
HC TUMORS SAME RTE	3/200 (2%)			
HC TUMORS ALL RTES	18/1149 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.153N	P=0.512N	P=0.239N	P=0.233N
POLY 1.5	P=0.154N	P=0.506N	P=0.238N	P=0.235N
POLY 6	P=0.150N	P=0.521N	P=0.239N	P=0.231N
COCH-ARM / FISHERS	P=0.156N	P=0.500N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.080N	P=0.294N	P=0.077N	P=0.076N
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	3000 PPM	9000 PPM	25000 PPM

**Intestine Small: Site Unspecified  
 Carcinoma or Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	3/50 (6%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/48.02	3/46.42	0/47.71	0/48.96
POLY-3 PERCENT (g)	4.2%	6.5%	0%	0%
TERMINAL (d)	1/43 (2%)	3/38 (8%)	0/45 (0%)	0/45 (0%)
FIRST INCIDENCE	632	729 (T)	---	---
HC TUMORS SAME RTE	4/200 (2%)			
HC TUMORS ALL RTES	27/1149 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.082N	P=0.485	P=0.239N	P=0.233N
POLY 1.5	P=0.083N	P=0.492	P=0.238N	P=0.235N
POLY 6	P=0.081N	P=0.473	P=0.239N	P=0.231N
COCH-ARM / FISHERS	P=0.085N	P=0.500	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.081N	P=0.313	P=0.077N	P=0.076N
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	3000 PPM	9000 PPM	25000 PPM

**Liver  
 Hemangiosarcoma**

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	0/47.67	2/46.61	2/47.71	2/48.96
POLY-3 PERCENT (g)	0%	4.3%	4.2%	4.1%
TERMINAL (d)	0/43 (0%)	1/38 (3%)	2/45 (4%)	2/45 (4%)
FIRST INCIDENCE	---	680	729 (T)	729 (T)
HC TUMORS SAME RTE	3/200 (2%)			
HC TUMORS ALL RTES	30/1146 (3%)			

**STATISTICAL TESTS**

POLY 3	P=0.341	P=0.232	P=0.238	P=0.243
POLY 1.5	P=0.335	P=0.235	P=0.237	P=0.241
POLY 6	P=0.349	P=0.229	P=0.238	P=0.246
COCH-ARM / FISHERS	P=0.326	P=0.247	P=0.247	P=0.247
MAX-ISO-POLY-3	P=0.197	P=0.076	P=0.076	P=0.082
HISTCONT SAME RTE	P=0.243	P=0.095	P=0.095	P=0.103
HISTCONT ALL RTES	P=0.228	P=0.086	P=0.087	P=0.094

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>Liver</b>				
<b>Hepatoblastoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	6/50 (12%)
POLY-3 RATE (b)	1/47.67	2/46.63	1/47.71	6/48.99
POLY-3 PERCENT (g)	2.1%	4.3%	2.1%	12.3%
TERMINAL (d)	1/43 (2%)	1/38 (3%)	1/45 (2%)	5/45 (11%)
FIRST INCIDENCE	729 (T)	673	729 (T)	722
HC TUMORS SAME RTE	0/200 (0%)			
HC TUMORS ALL RTES	43/1146 (4%)			

**STATISTICAL TESTS**

POLY 3	P=0.016*	P=0.492	P=0.760N	P=0.061
POLY 1.5	P=0.015*	P=0.496	P=0.760N	P=0.059
POLY 6	P=0.017*	P=0.487	P=0.760N	P=0.063
COCH-ARM / FISHERS	P=0.015*	P=0.500	P=0.753N	P=0.056
MAX-ISO-POLY-3	P=0.020*	P=0.276	P=0.499N	P=0.028*
HISTCONT SAME RTE	P=0.014*	P=0.056	P=0.118	P=0.031*
HISTCONT ALL RTES	P=0.022*	P=0.345	P=1.000	P=0.028*



TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Liver  
 Hepatocellular Adenoma

**TUMOR RATES**

OVERALL (a)	22/50 (44%)	16/50 (32%)	23/50 (46%)	29/50 (58%)
POLY-3 RATE (b)	22/48.15	16/47.38	23/47.95	29/49.85
POLY-3 PERCENT (g)	45.7%	33.8%	48%	58.2%
TERMINAL (d)	19/43 (44%)	13/38 (34%)	22/45 (49%)	26/45 (58%)
FIRST INCIDENCE	677	555	666	596
HC TUMORS SAME RTE	56/200 (28%)			
HC TUMORS ALL RTES	544/1146 (48%)			

**STATISTICAL TESTS**

POLY 3	P=0.030*	P=0.162N	P=0.492	P=0.150
POLY 1.5	P=0.025*	P=0.156N	P=0.496	P=0.135
POLY 6	P=0.039*	P=0.176N	P=0.488	P=0.168
COCH-ARM / FISHERS	P=0.020*	P=0.151N	P=0.500	P=0.115
MAX-ISO-POLY-3	P=0.048*	P=0.117N	P=0.410	P=0.111
HISTCONT SAME RTE	P=0.042*	P=0.517	P=0.204	P=0.103
HISTCONT ALL RTES	P=0.054	P=1.000	P=0.521	P=0.129

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TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Liver  
 Hepatocellular Carcinoma**

**TUMOR RATES**

OVERALL (a)	8/50 (16%)	14/50 (28%)	15/50 (30%)	12/50 (24%)
POLY-3 RATE (b)	8/47.95	14/48.75	15/49.43	12/49.65
POLY-3 PERCENT (g)	16.7%	28.7%	30.3%	24.2%
TERMINAL (d)	6/43 (14%)	8/38 (21%)	11/45 (24%)	8/45 (18%)
FIRST INCIDENCE	681	555	551	596
HC TUMORS SAME RTE	37/200 (19%)			
HC TUMORS ALL RTES	317/1146 (28%)			

**STATISTICAL TESTS**

POLY 3	P=0.436	P=0.120	P=0.088	P=0.254
POLY 1.5	P=0.419	P=0.118	P=0.083	P=0.243
POLY 6	P=0.459	P=0.121	P=0.095	P=0.268
COCH-ARM / FISHERS	P=0.394	P=0.114	P=0.077	P=0.227
MAX-ISO-POLY-3	P=0.175	P=0.080	P=0.058	P=0.185
HISTCONT SAME RTE	P=0.216	P=0.100	P=0.071	P=0.241
HISTCONT ALL RTES	P=0.202	P=0.091	P=0.063	P=0.223

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Liver  
 Hepatocellular Carcinoma or Hepatoblastoma**

**TUMOR RATES**

OVERALL (a)	9/50 (18%)	15/50 (30%)	15/50 (30%)	15/50 (30%)
POLY-3 RATE (b)	9/47.95	15/48.96	15/49.43	15/49.65
POLY-3 PERCENT (g)	18.8%	30.6%	30.3%	30.2%
TERMINAL (d)	7/43 (16%)	8/38 (21%)	11/45 (24%)	11/45 (24%)
FIRST INCIDENCE	681	555	551	596
HC TUMORS SAME RTE	37/200 (19%)			
HC TUMORS ALL RTES	346/1146 (30%)			

**STATISTICAL TESTS**

POLY 3	P=0.248	P=0.131	P=0.138	P=0.141
POLY 1.5	P=0.235	P=0.127	P=0.130	P=0.132
POLY 6	P=0.266	P=0.134	P=0.148	P=0.151
COCH-ARM / FISHERS	P=0.217	P=0.121	P=0.121	P=0.121
MAX-ISO-POLY-3	P=0.168	P=0.090	P=0.096	P=0.098
HISTCONT SAME RTE	P=0.207	P=0.113	P=0.120	P=0.124
HISTCONT ALL RTES	P=0.194	P=0.103	P=0.110	P=0.113

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Liver  
 Hepatocellular Carcinoma or Hepatocellular Adenoma**

**TUMOR RATES**

OVERALL (a)	26/50 (52%)	27/50 (54%)	31/50 (62%)	33/50 (66%)
POLY-3 RATE (b)	26/48.15	27/49.15	31/49.43	33/50
POLY-3 PERCENT (g)	54%	54.9%	62.7%	66%
TERMINAL (d)	23/43 (54%)	19/38 (50%)	27/45 (60%)	28/45 (62%)
FIRST INCIDENCE	677	555	551	596
HC TUMORS SAME RTE	83/200 (42%)			
HC TUMORS ALL RTES	729/1146 (64%)			

**STATISTICAL TESTS**

POLY 3	P=0.111	P=0.544	P=0.252	P=0.156
POLY 1.5	P=0.097	P=0.528	P=0.234	P=0.136
POLY 6	P=0.133	P=0.556	P=0.276	P=0.183
COCH-ARM / FISHERS	P=0.079	P=0.500	P=0.210	P=0.111
MAX-ISO-POLY-3	P=0.179	P=0.462	P=0.194	P=0.115
HISTCONT SAME RTE	P=0.144	P=0.371	P=0.240	P=0.147
HISTCONT ALL RTES	P=0.206	P=0.586	P=0.234	P=0.134

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

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DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

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Liver  
 Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma

**TUMOR RATES**

OVERALL (a)	26/50 (52%)	28/50 (56%)	31/50 (62%)	33/50 (66%)
POLY-3 RATE (b)	26/48.15	28/49.36	31/49.43	33/50
POLY-3 PERCENT (g)	54%	56.7%	62.7%	66%
TERMINAL (d)	23/43 (54%)	19/38 (50%)	27/45 (60%)	28/45 (62%)
FIRST INCIDENCE	677	555	551	596
HC TUMORS SAME RTE	83/200 (42%)			
HC TUMORS ALL RTES	740/1146 (65%)			

**STATISTICAL TESTS**

POLY 3	P=0.128	P=0.473	P=0.252	P=0.156
POLY 1.5	P=0.113	P=0.453	P=0.234	P=0.136
POLY 6	P=0.150	P=0.493	P=0.276	P=0.183
COCH-ARM / FISHERS	P=0.094	P=0.421	P=0.210	P=0.111
MAX-ISO-POLY-3	P=0.189	P=0.392	P=0.194	P=0.115
HISTCONT SAME RTE	P=0.150	P=0.336	P=0.240	P=0.147
HISTCONT ALL RTES	P=0.218	P=0.500	P=0.234	P=0.134

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TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lung  
 Alveolar/Bronchiolar Adenoma**

**TUMOR RATES**

OVERALL (a)	4/50 (8%)	5/50 (10%)	9/50 (18%)	8/50 (16%)
POLY-3 RATE (b)	4/47.67	5/46.42	9/47.71	8/49.32
POLY-3 PERCENT (g)	8.4%	10.8%	18.9%	16.2%
TERMINAL (d)	4/43 (9%)	5/38 (13%)	9/45 (20%)	7/45 (16%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	631
HC TUMORS SAME RTE	46/200 (23%)			
HC TUMORS ALL RTES	209/1148 (18%)			

**STATISTICAL TESTS**

POLY 3	P=0.178	P=0.483	P=0.116	P=0.195
POLY 1.5	P=0.166	P=0.491	P=0.116	P=0.188
POLY 6	P=0.195	P=0.471	P=0.116	P=0.204
COCH-ARM / FISHERS	P=0.150	P=0.500	P=0.117	P=0.178
MAX-ISO-POLY-3	P=0.157	P=0.349	P=0.067	P=0.126
HISTCONT SAME RTE	P=0.193	P=0.463	P=0.083	P=0.161
HISTCONT ALL RTES	P=0.180	P=0.443	P=0.075	P=0.147

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lung  
 Alveolar/Bronchiolar Carcinoma**

**TUMOR RATES**

OVERALL (a)	6/50 (12%)	4/50 (8%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	6/47.92	4/46.5	4/47.71	0/48.96
POLY-3 PERCENT (g)	12.5%	8.6%	8.4%	0%
TERMINAL (d)	5/43 (12%)	3/38 (8%)	4/45 (9%)	0/45 (0%)
FIRST INCIDENCE	664	709	729 (T)	---
HC TUMORS SAME RTE	13/200 (7%)			
HC TUMORS ALL RTES	115/1148 (10%)			

**STATISTICAL TESTS**

POLY 3	P=0.014N*	P=0.389N	P=0.373N	P=0.014N*
POLY 1.5	P=0.015N*	P=0.380N	P=0.372N	P=0.015N*
POLY 6	P=0.013N*	P=0.403N	P=0.373N	P=0.014N*
COCH-ARM / FISHERS	P=0.017N*	P=0.370N	P=0.370N	P=0.013N*
MAX-ISO-POLY-3	P=0.014N*	P=0.273N	P=0.256N	P=0.005N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

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

**TUMOR RATES**

OVERALL (a)	10/50 (20%)	9/50 (18%)	12/50 (24%)	8/50 (16%)
POLY-3 RATE (b)	10/47.92	9/46.5	12/47.71	8/49.32
POLY-3 PERCENT (g)	20.9%	19.4%	25.2%	16.2%
TERMINAL (d)	9/43 (21%)	8/38 (21%)	12/45 (27%)	7/45 (16%)
FIRST INCIDENCE	664	709	729 (T)	631
HC TUMORS SAME RTE	55/200 (28%)			
HC TUMORS ALL RTES	309/1148 (27%)			

**STATISTICAL TESTS**

POLY 3	P=0.325N	P=0.529N	P=0.400	P=0.372N
POLY 1.5	P=0.345N	P=0.515N	P=0.402	P=0.382N
POLY 6	P=0.300N	P=0.551N	P=0.398	P=0.360N
COCH-ARM / FISHERS	P=0.371N	P=0.500N	P=0.405	P=0.398N
MAX-ISO-POLY-3	P=0.403N	P=0.427N	P=0.311	P=0.282N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)



TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

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

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	0/49 (0%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.67	0/45.52	0/47.25	0/48.96
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/43 (0%)	0/38 (0%)	0/45 (0%)	0/45 (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. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

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

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/47.67	0/46.42	0/47.71	1/49.32
POLY-3 PERCENT (g)	0%	0%	0%	2%
TERMINAL (d)	0/43 (0%)	0/38 (0%)	0/45 (0%)	0/45 (0%)
FIRST INCIDENCE	---	---	---	631
HC TUMORS SAME RTE	2/200 (1%)			
HC TUMORS ALL RTES	14/1149 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.218	(e)	(e)	P=0.507
POLY 1.5	P=0.215	(e)	(e)	P=0.504
POLY 6	P=0.223	(e)	(e)	P=0.510
COCH-ARM / FISHERS	P=0.210	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.138	(e)	(e)	P=0.167
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
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 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

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

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/47.67	0/46.42	0/47.71	1/49.32
POLY-3 PERCENT (g)	0%	0%	0%	2%
TERMINAL (d)	0/43 (0%)	0/38 (0%)	0/45 (0%)	0/45 (0%)
FIRST INCIDENCE	---	---	---	631
HC TUMORS SAME RTE	2/200 (1%)			
HC TUMORS ALL RTES	11/1149 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.218	(e)	(e)	P=0.507
POLY 1.5	P=0.215	(e)	(e)	P=0.504
POLY 6	P=0.223	(e)	(e)	P=0.510
COCH-ARM / FISHERS	P=0.210	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.138	(e)	(e)	P=0.167
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>Skin</b>				
<b>Sarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/47.67	0/46.42	0/47.71	1/49.32
POLY-3 PERCENT (g)	0%	0%	0%	2%
TERMINAL (d)	0/43 (0%)	0/38 (0%)	0/45 (0%)	0/45 (0%)
FIRST INCIDENCE	---	---	---	631
HC TUMORS SAME RTE	1/200 (1%)			
HC TUMORS ALL RTES	6/1149 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.218	(e)	(e)	P=0.507
POLY 1.5	P=0.215	(e)	(e)	P=0.504
POLY 6	P=0.223	(e)	(e)	P=0.510
COCH-ARM / FISHERS	P=0.210	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.138	(e)	(e)	P=0.167
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Spleen  
 Hemangiosarcoma**

**TUMOR RATES**

OVERALL (a)	1/50 (2%)	3/49 (6%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/47.67	3/45.98	0/47.71	1/49.04
POLY-3 PERCENT (g)	2.1%	6.5%	0%	2%
TERMINAL (d)	1/43 (2%)	2/38 (5%)	0/45 (0%)	0/45 (0%)
FIRST INCIDENCE	729 (T)	680	---	710
HC TUMORS SAME RTE	2/199 (1%)			
HC TUMORS ALL RTES	21/1136 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.412N	P=0.293	P=0.500N	P=0.754N
POLY 1.5	P=0.415N	P=0.295	P=0.500N	P=0.757N
POLY 6	P=0.409N	P=0.288	P=0.499N	P=0.751N
COCH-ARM / FISHERS	P=0.418N	P=0.301	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.263N	P=0.148	P=0.159N	P=0.491N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

---

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Stomach, Forestomach  
 Squamous Cell Papilloma**

---

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.67	2/46.42	0/47.71	0/48.96
POLY-3 PERCENT (g)	0%	4.3%	0%	0%
TERMINAL (d)	0/43 (0%)	2/38 (5%)	0/45 (0%)	0/45 (0%)
FIRST INCIDENCE	---	729 (T)	---	---
HC TUMORS SAME RTE	3/200 (2%)			
HC TUMORS ALL RTES	11/1149 (1%)			

**STATISTICAL TESTS**

---

POLY 3	P=0.370N	P=0.231	(e)	(e)
POLY 1.5	P=0.370N	P=0.234	(e)	(e)
POLY 6	P=0.372N	P=0.227	(e)	(e)
COCH-ARM / FISHERS	P=0.370N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.248N	P=0.076	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTES	(h)	(h)	(e)	(e)

---

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thyroid Gland: Follicular Cell  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/47.67	0/46.42	1/47.71	0/48.96
POLY-3 PERCENT (g)	2.1%	0%	2.1%	0%
TERMINAL (d)	1/43 (2%)	0/38 (0%)	1/45 (2%)	0/45 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	---
HC TUMORS SAME RTE	2/200 (1%)			
HC TUMORS ALL RTES	19/1142 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.446N	P=0.505N	P=0.760N	P=0.495N
POLY 1.5	P=0.450N	P=0.503N	P=0.760N	P=0.497N
POLY 6	P=0.440N	P=0.509N	P=0.760N	P=0.492N
COCH-ARM / FISHERS	P=0.456N	P=0.500N	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.257N	P=0.165N	P=0.499N	P=0.159N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

---

	Males			
DOSE	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**All Organs  
 Hemangioma**

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TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.67	2/46.76	0/47.71	0/48.96
POLY-3 PERCENT (g)	0%	4.3%	0%	0%
TERMINAL (d)	0/43 (0%)	1/38 (3%)	0/45 (0%)	0/45 (0%)
FIRST INCIDENCE	---	636	---	---
HC TUMORS SAME RTE	0/200 (0%)			
HC TUMORS ALL RTES	9/1149 (1%)			

**STATISTICAL TESTS**

---

POLY 3	P=0.369N	P=0.233	(e)	(e)
POLY 1.5	P=0.369N	P=0.235	(e)	(e)
POLY 6	P=0.370N	P=0.230	(e)	(e)
COCH-ARM / FISHERS	P=0.370N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.250N	P=0.076	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTES	(h)	(h)	(e)	(e)

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TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>All Organs</b>				
<b>Hemangiosarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	2/50 (4%)	4/50 (8%)	3/50 (6%)	4/50 (8%)
POLY-3 RATE (b)	2/47.67	4/46.61	3/47.71	4/49.04
POLY-3 PERCENT (g)	4.2%	8.6%	6.3%	8.2%
TERMINAL (d)	2/43 (5%)	3/38 (8%)	3/45 (7%)	3/45 (7%)
FIRST INCIDENCE	729 (T)	680	729 (T)	710
HC TUMORS SAME RTE	8/200 (4%)			
HC TUMORS ALL RTES	67/1149 (6%)			

**STATISTICAL TESTS**

POLY 3	P=0.396	P=0.327	P=0.500	P=0.351
POLY 1.5	P=0.388	P=0.332	P=0.500	P=0.345
POLY 6	P=0.408	P=0.319	P=0.502	P=0.357
COCH-ARM / FISHERS	P=0.375	P=0.339	P=0.500	P=0.339
MAX-ISO-POLY-3	P=0.362	P=0.196	P=0.324	P=0.215
HISTCONT SAME RTE	P=0.194	P=0.106	P=0.222	P=0.108
HISTCONT ALL RTES	P=0.421	P=0.237	P=0.408	P=0.262

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**All Organs  
 Hemangiosarcoma or Hemangioma**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	6/50 (12%)	3/50 (6%)	4/50 (8%)
POLY-3 RATE (b)	2/47.67	6/46.95	3/47.71	4/49.04
POLY-3 PERCENT (g)	4.2%	12.8%	6.3%	8.2%
TERMINAL (d)	2/43 (5%)	4/38 (11%)	3/45 (7%)	3/45 (7%)
FIRST INCIDENCE	729 (T)	636	729 (T)	710
HC TUMORS SAME RTE	8/200 (4%)			
HC TUMORS ALL RTES	76/1149 (7%)			

**STATISTICAL TESTS**

POLY 3	P=0.540	P=0.128	P=0.500	P=0.351
POLY 1.5	P=0.532	P=0.131	P=0.500	P=0.345
POLY 6	P=0.551	P=0.124	P=0.502	P=0.357
COCH-ARM / FISHERS	P=0.519	P=0.134	P=0.500	P=0.339
MAX-ISO-POLY-3	P=0.308	P=0.067	P=0.324	P=0.215
HISTCONT SAME RTE	P=0.282	P=0.064	P=0.222	P=0.108
HISTCONT ALL RTES	P=0.360	P=0.076	P=0.408	P=0.262

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**All Organs  
 Histiocytic Sarcoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/47.67	2/46.52	2/47.71	0/48.96
POLY-3 PERCENT (g)	0%	4.3%	4.2%	0%
TERMINAL (d)	0/43 (0%)	1/38 (3%)	2/45 (4%)	0/45 (0%)
FIRST INCIDENCE	---	703	729 (T)	---
HC TUMORS SAME RTE	2/200 (1%)			
HC TUMORS ALL RTES	7/1149 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.386N	P=0.232	P=0.238	(e)
POLY 1.5	P=0.390N	P=0.234	P=0.237	(e)
POLY 6	P=0.380N	P=0.228	P=0.238	(e)
COCH-ARM / FISHERS	P=0.397N	P=0.247	P=0.247	(e)
MAX-ISO-POLY-3	P=0.273N	P=0.076	P=0.076	(e)
HISTCONT SAME RTE	(h)	(h)	(h)	(e)
HISTCONT ALL RTES	(h)	(h)	(h)	(e)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

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

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/47.92	2/46.49	1/48.25	0/48.96
POLY-3 PERCENT (g)	2.1%	4.3%	2.1%	0%
TERMINAL (d)	0/43 (0%)	1/38 (3%)	0/45 (0%)	0/45 (0%)
FIRST INCIDENCE	664	713	563	---
HC TUMORS SAME RTE	9/200 (5%)			
HC TUMORS ALL RTES	34/1149 (3%)			

**STATISTICAL TESTS**

POLY 3	P=0.227N	P=0.489	P=0.759N	P=0.496N
POLY 1.5	P=0.230N	P=0.494	P=0.759N	P=0.497N
POLY 6	P=0.225N	P=0.481	P=0.758N	P=0.494N
COCH-ARM / FISHERS	P=0.232N	P=0.500	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.226N	P=0.275	P=0.497N	P=0.159N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>All Organs</b>				
<b>Benign Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	28/50 (56%)	27/50 (54%)	33/50 (66%)	36/50 (72%)
POLY-3 RATE (b)	28/48.15	27/48.31	33/47.95	36/49.87
POLY-3 PERCENT (g)	58.2%	55.9%	68.8%	72.2%
TERMINAL (d)	25/43 (58%)	22/38 (58%)	32/45 (71%)	32/45 (71%)
FIRST INCIDENCE	677	555	666	596
HC TUMORS SAME RTE	104/200 (52%)			
HC TUMORS ALL RTEs	753/1149 (66%)			

**STATISTICAL TESTS**

POLY 3	P=0.048*	P=0.493N	P=0.188	P=0.104
POLY 1.5	P=0.040*	P=0.492N	P=0.195	P=0.089
POLY 6	P=0.062	P=0.505N	P=0.180	P=0.123
COCH-ARM / FISHERS	P=0.032*	P=0.500N	P=0.206	P=0.072
MAX-ISO-POLY-3	P=0.077	P=0.409N	P=0.136	P=0.073
HISTCONT SAME RTE	P=0.023*	P=0.459	P=0.073	P=0.057
HISTCONT ALL RTEs	P=0.088	P=1.000	P=0.161	P=0.083

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
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 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

---

	Males			
DOSE	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**All Organs  
 Malignant Tumors**

---

TUMOR RATES	#	#	#	#
OVERALL (a)	20/50 (40%)	26/50 (52%)	26/50 (52%)	19/50 (38%)
POLY-3 RATE (b)	20/49.12	26/49.29	26/50	19/50
POLY-3 PERCENT (g)	40.7%	52.8%	52%	38%
TERMINAL (d)	15/43 (35%)	16/38 (42%)	21/45 (47%)	14/45 (31%)
FIRST INCIDENCE	550	555	551	596
HC TUMORS SAME RTE	76/200 (38%)			
HC TUMORS ALL RTES	582/1149 (51%)			

**STATISTICAL TESTS**

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POLY 3	P=0.217N	P=0.160	P=0.178	P=0.472N
POLY 1.5	P=0.229N	P=0.160	P=0.170	P=0.483N
POLY 6	P=0.204N	P=0.157	P=0.187	P=0.460N
COCH-ARM / FISHERS	P=0.246N	P=0.158	P=0.158	P=0.500N
MAX-ISO-POLY-3	P=0.242N	P=0.116	P=0.132	P=0.391N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

---

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
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 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>All Organs</b>				
<b>Malignant and Benign Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	38/50 (76%)	42/50 (84%)	43/50 (86%)	40/50 (80%)
POLY-3 RATE (b)	38/49.32	42/50	43/50	40/50
POLY-3 PERCENT (g)	77.1%	84%	86%	80%
TERMINAL (d)	32/43 (74%)	30/38 (79%)	38/45 (84%)	35/45 (78%)
FIRST INCIDENCE	550	555	551	596
HC TUMORS SAME RTE	144/200 (72%)			
HC TUMORS ALL RTES	976/1149 (85%)			

**STATISTICAL TESTS**

POLY 3	P=0.559N	P=0.268	P=0.186	P=0.455
POLY 1.5	P=0.547	P=0.252	P=0.174	P=0.437
POLY 6	P=0.546N	P=0.282	P=0.199	P=0.472
COCH-ARM / FISHERS	P=0.521	P=0.227	P=0.154	P=0.405
MAX-ISO-POLY-3	P=0.344	P=0.193	P=0.127	P=0.361
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/48 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/47.86	2/47.56	0/44.67	1/46.86
POLY-3 PERCENT (g)	0%	4.2%	0%	2.1%
TERMINAL (d)	0/45 (0%)	2/44 (5%)	0/36 (0%)	1/43 (2%)
FIRST INCIDENCE	---	729 (T)	---	729 (T)
HC TUMORS SAME RTE	1/249 (0%)			
HC TUMORS ALL RTES	5/1244 (0%)			

**STATISTICAL TESTS**

POLY 3	P=0.606	P=0.236	(e)	P=0.496
POLY 1.5	P=0.607	P=0.236	(e)	P=0.497
POLY 6	P=0.605	P=0.237	(e)	P=0.495
COCH-ARM / FISHERS	P=0.612	P=0.247	(e)	P=0.500
MAX-ISO-POLY-3	P=0.331	P=0.076	(e)	P=0.159
HISTCONT SAME RTE	P=0.404	P=0.061	(e)	P=0.156
HISTCONT ALL RTES	P=0.254	P=0.007**	(e)	P=0.103



TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>Harderian Gland Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	5/50 (10%)	1/50 (2%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	5/48.24	1/47.56	2/45.32	3/46.86
POLY-3 PERCENT (g)	10.4%	2.1%	4.4%	6.4%
TERMINAL (d)	4/45 (9%)	1/44 (2%)	2/36 (6%)	3/43 (7%)
FIRST INCIDENCE	621	729 (T)	729 (T)	729 (T)
HC TUMORS SAME RTE	23/250 (9%)			
HC TUMORS ALL RTEs	128/1249 (10%)			

**STATISTICAL TESTS**

POLY 3	P=0.536N	P=0.105N	P=0.243N	P=0.373N
POLY 1.5	P=0.533N	P=0.104N	P=0.235N	P=0.368N
POLY 6	P=0.539N	P=0.105N	P=0.255N	P=0.378N
COCH-ARM / FISHERS	P=0.529N	P=0.102N	P=0.218N	P=0.357N
MAX-ISO-POLY-3	P=0.171N	P=0.048N*	P=0.145N	P=0.248N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>Harderian Gland Carcinoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	2/47.86	0/47.56	0/45.32	2/46.86
POLY-3 PERCENT (g)	4.2%	0%	0%	4.3%
TERMINAL (d)	2/45 (4%)	0/44 (0%)	0/36 (0%)	2/43 (5%)
FIRST INCIDENCE	729 (T)	---	---	729 (T)
HC TUMORS SAME RTE	5/250 (2%)			
HC TUMORS ALL RTES	33/1249 (3%)			

**STATISTICAL TESTS**

POLY 3	P=0.394	P=0.239N	P=0.250N	P=0.686
POLY 1.5	P=0.395	P=0.239N	P=0.246N	P=0.688
POLY 6	P=0.392	P=0.238N	P=0.255N	P=0.685
COCH-ARM / FISHERS	P=0.397	P=0.247N	P=0.247N	P=0.691N
MAX-ISO-POLY-3	P=0.276	P=0.077N	P=0.088N	P=0.491
HISTCONT SAME RTE	P=0.290	(e)	(e)	P=0.224
HISTCONT ALL RTES	P=0.321	(e)	(e)	P=0.437

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>Harderian Gland Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	7/50 (14%)	1/50 (2%)	2/50 (4%)	5/50 (10%)
POLY-3 RATE (b)	7/48.24	1/47.56	2/45.32	5/46.86
POLY-3 PERCENT (g)	14.5%	2.1%	4.4%	10.7%
TERMINAL (d)	6/45 (13%)	1/44 (2%)	2/36 (6%)	5/43 (12%)
FIRST INCIDENCE	621	729 (T)	729 (T)	729 (T)
HC TUMORS SAME RTE	28/250 (11%)			
HC TUMORS ALL RTES	160/1249 (13%)			

**STATISTICAL TESTS**

POLY 3	P=0.500	P=0.032N*	P=0.095N	P=0.400N
POLY 1.5	P=0.503	P=0.032N*	P=0.091N	P=0.394N
POLY 6	P=0.496	P=0.032N*	P=0.103N	P=0.406N
COCH-ARM / FISHERS	P=0.508	P=0.030N*	P=0.080N	P=0.380N
MAX-ISO-POLY-3	P=0.091N	P=0.013N*	P=0.053N	P=0.291N
HISTCONT SAME RTE	P=0.511	P=1.000	P=1.000	P=1.000
HISTCONT ALL RTES	P=0.490	P=1.000	P=1.000	P=1.000

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>Intestine Small: Duodenum Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.86	0/47.56	0/45.32	0/46.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/45 (0%)	0/44 (0%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/250 (0%)			
HC TUMORS ALL RTES	3/1249 (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. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Intestine Small: Jejunum  
 Carcinoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.86	0/47.56	0/45.32	0/46.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/45 (0%)	0/44 (0%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	1/250 (0%)			
HC TUMORS ALL RTES	4/1249 (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. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Intestine Small: Site Unspecified  
 Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.86	0/47.56	0/45.32	0/46.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/45 (0%)	0/44 (0%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/250 (0%)			
HC TUMORS ALL RTES	3/1249 (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. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Intestine Small: Site Unspecified  
 Carcinoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.86	0/47.56	0/45.32	0/46.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/45 (0%)	0/44 (0%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	1/250 (0%)			
HC TUMORS ALL RTES	6/1249 (1%)			

**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. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Intestine Small: Site Unspecified  
 Carcinoma or Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.86	0/47.56	0/45.32	0/46.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/45 (0%)	0/44 (0%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	1/250 (0%)			
HC TUMORS ALL RTES	9/1249 (1%)			

**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. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

---

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Liver  
 Hemangiosarcoma

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.86	0/47.56	0/44.52	0/46.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/45 (0%)	0/44 (0%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/250 (0%)			
HC TUMORS ALL RTES	11/1245 (1%)			

**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. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver  
 Hepatoblastoma

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.86	0/47.56	0/44.52	0/46.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/45 (0%)	0/44 (0%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/250 (0%)			
HC TUMORS ALL RTES	6/1245 (1%)			

**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. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver  
 Hepatocellular Adenoma

**TUMOR RATES**

OVERALL (a)	3/50 (6%)	6/50 (12%)	7/49 (14%)	7/50 (14%)
POLY-3 RATE (b)	3/47.86	6/47.56	7/44.8	7/46.86
POLY-3 PERCENT (g)	6.3%	12.6%	15.6%	14.9%
TERMINAL (d)	3/45 (7%)	6/44 (14%)	6/36 (17%)	7/43 (16%)
FIRST INCIDENCE	729 (T)	729 (T)	654	729 (T)
HC TUMORS SAME RTE	17/250 (7%)			
HC TUMORS ALL RTES	345/1245 (28%)			

**STATISTICAL TESTS**

POLY 3	P=0.197	P=0.239	P=0.132	P=0.149
POLY 1.5	P=0.201	P=0.240	P=0.136	P=0.152
POLY 6	P=0.193	P=0.241	P=0.126	P=0.148
COCH-ARM / FISHERS	P=0.210	P=0.243	P=0.151	P=0.159
MAX-ISO-POLY-3	P=0.150	P=0.146	P=0.079	P=0.087
HISTCONT SAME RTE	P=0.101	P=0.166	P=0.096	P=0.107
HISTCONT ALL RTES	P=0.173	P=0.173	P=0.089	P=0.100

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>Liver</b>				
<b>Hepatocellular Carcinoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	3/50 (6%)	3/50 (6%)	1/49 (2%)	1/50 (2%)
POLY-3 RATE (b)	3/47.86	3/47.6	1/44.52	1/46.86
POLY-3 PERCENT (g)	6.3%	6.3%	2.3%	2.1%
TERMINAL (d)	3/45 (7%)	2/44 (5%)	1/36 (3%)	1/43 (2%)
FIRST INCIDENCE	729 (T)	719	729 (T)	729 (T)
HC TUMORS SAME RTE	7/250 (3%)			
HC TUMORS ALL RTES	131/1245 (11%)			

**STATISTICAL TESTS**

POLY 3	P=0.201N	P=0.659	P=0.332N	P=0.313N
POLY 1.5	P=0.200N	P=0.659	P=0.327N	P=0.311N
POLY 6	P=0.202N	P=0.661	P=0.339N	P=0.314N
COCH-ARM / FISHERS	P=0.195N	P=0.661N	P=0.316N	P=0.309N
MAX-ISO-POLY-3	P=0.263N	P=0.496	P=0.180N	P=0.162N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>Liver</b>				
<b>Hepatocellular Carcinoma or Hepatoblastoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	3/50 (6%)	3/50 (6%)	1/49 (2%)	1/50 (2%)
POLY-3 RATE (b)	3/47.86	3/47.6	1/44.52	1/46.86
POLY-3 PERCENT (g)	6.3%	6.3%	2.3%	2.1%
TERMINAL (d)	3/45 (7%)	2/44 (5%)	1/36 (3%)	1/43 (2%)
FIRST INCIDENCE	729 (T)	719	729 (T)	729 (T)
HC TUMORS SAME RTE	7/250 (3%)			
HC TUMORS ALL RTES	136/1245 (11%)			

**STATISTICAL TESTS**

POLY 3	P=0.201N	P=0.659	P=0.332N	P=0.313N
POLY 1.5	P=0.200N	P=0.659	P=0.327N	P=0.311N
POLY 6	P=0.202N	P=0.661	P=0.339N	P=0.314N
COCH-ARM / FISHERS	P=0.195N	P=0.661N	P=0.316N	P=0.309N
MAX-ISO-POLY-3	P=0.263N	P=0.496	P=0.180N	P=0.162N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Liver  
 Hepatocellular Carcinoma or Hepatocellular Adenoma**

**TUMOR RATES**

OVERALL (a)	6/50 (12%)	9/50 (18%)	7/49 (14%)	7/50 (14%)
POLY-3 RATE (b)	6/47.86	9/47.6	7/44.8	7/46.86
POLY-3 PERCENT (g)	12.5%	18.9%	15.6%	14.9%
TERMINAL (d)	6/45 (13%)	8/44 (18%)	6/36 (17%)	7/43 (16%)
FIRST INCIDENCE	729 (T)	719	654	729 (T)
HC TUMORS SAME RTE	22/250 (9%)			
HC TUMORS ALL RTES	419/1245 (34%)			

**STATISTICAL TESTS**

POLY 3	P=0.557N	P=0.284	P=0.449	P=0.484
POLY 1.5	P=0.552N	P=0.284	P=0.457	P=0.488
POLY 6	P=0.562N	P=0.287	P=0.438	P=0.481
COCH-ARM / FISHERS	P=0.539N	P=0.288	P=0.484	P=0.500
MAX-ISO-POLY-3	P=0.478	P=0.198	P=0.339	P=0.368
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver  
 Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma

**TUMOR RATES**

OVERALL (a)	6/50 (12%)	9/50 (18%)	7/49 (14%)	7/50 (14%)
POLY-3 RATE (b)	6/47.86	9/47.6	7/44.8	7/46.86
POLY-3 PERCENT (g)	12.5%	18.9%	15.6%	14.9%
TERMINAL (d)	6/45 (13%)	8/44 (18%)	6/36 (17%)	7/43 (16%)
FIRST INCIDENCE	729 (T)	719	654	729 (T)
HC TUMORS SAME RTE	22/250 (9%)			
HC TUMORS ALL RTES	421/1245 (34%)			

**STATISTICAL TESTS**

POLY 3	P=0.557N	P=0.284	P=0.449	P=0.484
POLY 1.5	P=0.552N	P=0.284	P=0.457	P=0.488
POLY 6	P=0.562N	P=0.287	P=0.438	P=0.481
COCH-ARM / FISHERS	P=0.539N	P=0.288	P=0.484	P=0.500
MAX-ISO-POLY-3	P=0.478	P=0.198	P=0.339	P=0.368
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

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DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

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**Lung  
 Alveolar/Bronchiolar Adenoma**

**TUMOR RATES**

OVERALL (a)	4/50 (8%)	2/50 (4%)	5/50 (10%)	1/50 (2%)
POLY-3 RATE (b)	4/47.86	2/47.6	5/45.95	1/46.86
POLY-3 PERCENT (g)	8.4%	4.2%	10.9%	2.1%
TERMINAL (d)	4/45 (9%)	1/44 (2%)	3/36 (8%)	1/43 (2%)
FIRST INCIDENCE	729 (T)	719	633	729 (T)
HC TUMORS SAME RTE	10/250 (4%)			
HC TUMORS ALL RTES	65/1248 (5%)			

**STATISTICAL TESTS**

POLY 3	P=0.210N	P=0.340N	P=0.475	P=0.185N
POLY 1.5	P=0.208N	P=0.340N	P=0.479	P=0.184N
POLY 6	P=0.213N	P=0.338N	P=0.467	P=0.187N
COCH-ARM / FISHERS	P=0.202N	P=0.339N	P=0.500	P=0.181N
MAX-ISO-POLY-3	P=0.176N	P=0.204N	P=0.343	P=0.090N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lung  
 Alveolar/Bronchiolar Carcinoma**

**TUMOR RATES**

OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/47.86	1/47.56	0/45.32	1/46.86
POLY-3 PERCENT (g)	2.1%	2.1%	0%	2.1%
TERMINAL (d)	1/45 (2%)	1/44 (2%)	0/36 (0%)	1/43 (2%)
FIRST INCIDENCE	729 (T)	729 (T)	---	729 (T)
HC TUMORS SAME RTE	7/250 (3%)			
HC TUMORS ALL RTES	47/1248 (4%)			

**STATISTICAL TESTS**

POLY 3	P=0.675	P=0.759	P=0.511N	P=0.756
POLY 1.5	P=0.676	P=0.759	P=0.508N	P=0.757
POLY 6	P=0.673	P=0.760	P=0.515N	P=0.755
COCH-ARM / FISHERS	P=0.680	P=0.753N	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.552N	P=0.497	P=0.172N	P=0.493
HISTCONT SAME RTE	P=0.733	P=0.638	(e)	P=0.634
HISTCONT ALL RTES	P=0.721	P=0.628	(e)	P=0.623

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

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

**TUMOR RATES**

OVERALL (a)	5/50 (10%)	3/50 (6%)	5/50 (10%)	2/50 (4%)
POLY-3 RATE (b)	5/47.86	3/47.6	5/45.95	2/46.86
POLY-3 PERCENT (g)	10.5%	6.3%	10.9%	4.3%
TERMINAL (d)	5/45 (11%)	2/44 (5%)	3/36 (8%)	2/43 (5%)
FIRST INCIDENCE	729 (T)	719	633	729 (T)
HC TUMORS SAME RTE	15/250 (6%)			
HC TUMORS ALL RTES	107/1248 (9%)			

**STATISTICAL TESTS**

POLY 3	P=0.238N	P=0.360N	P=0.604	P=0.225N
POLY 1.5	P=0.236N	P=0.360N	P=0.609	P=0.223N
POLY 6	P=0.241N	P=0.357N	P=0.596	P=0.227N
COCH-ARM / FISHERS	P=0.228N	P=0.357N	P=0.630N	P=0.218N
MAX-ISO-POLY-3	P=0.220N	P=0.235N	P=0.472	P=0.128N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Ovary  
 Cystadenoma**

**TUMOR RATES**

OVERALL (a)	3/49 (6%)	2/48 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	3/46.86	2/46.99	1/45.32	0/46.86
POLY-3 PERCENT (g)	6.4%	4.3%	2.2%	0%
TERMINAL (d)	3/44 (7%)	1/43 (2%)	1/36 (3%)	0/43 (0%)
FIRST INCIDENCE	729 (T)	522	729 (T)	---
HC TUMORS SAME RTE	4/245 (2%)			
HC TUMORS ALL RTES	46/1221 (4%)			

**STATISTICAL TESTS**

POLY 3	P=0.081N	P=0.499N	P=0.317N	P=0.119N
POLY 1.5	P=0.080N	P=0.503N	P=0.313N	P=0.118N
POLY 6	P=0.083N	P=0.493N	P=0.326N	P=0.119N
COCH-ARM / FISHERS	P=0.078N	P=0.510N	P=0.301N	P=0.117N
MAX-ISO-POLY-3	P=0.065N	P=0.324N	P=0.168N	P=0.039N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

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

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	2/49 (4%)	2/49 (4%)	1/49 (2%)
POLY-3 RATE (b)	0/47.86	2/46.56	2/45.54	1/45.86
POLY-3 PERCENT (g)	0%	4.3%	4.4%	2.2%
TERMINAL (d)	0/45 (0%)	2/43 (5%)	1/36 (3%)	1/42 (2%)
FIRST INCIDENCE	---	729 (T)	672	729 (T)
HC TUMORS SAME RTE	11/246 (5%)			
HC TUMORS ALL RTES	97/1216 (8%)			

**STATISTICAL TESTS**

POLY 3	P=0.582	P=0.231	P=0.226	P=0.492
POLY 1.5	P=0.585	P=0.231	P=0.229	P=0.493
POLY 6	P=0.579	P=0.232	P=0.222	P=0.491
COCH-ARM / FISHERS	P=0.593	P=0.242	P=0.242	P=0.495
MAX-ISO-POLY-3	P=0.233	P=0.075	P=0.075	P=0.157
HISTCONT SAME RTE	P=0.284	P=0.091	P=0.091	P=0.200
HISTCONT ALL RTES	P=0.270	P=0.085	P=0.085	P=0.187

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

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

TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	3/48.54	1/47.69	1/45.36	1/47.5
POLY-3 PERCENT (g)	6.2%	2.1%	2.2%	2.1%
TERMINAL (d)	1/45 (2%)	0/44 (0%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	535	696	719	521
HC TUMORS SAME RTE	10/250 (4%)			
HC TUMORS ALL RTES	53/1249 (4%)			

**STATISTICAL TESTS**

POLY 3	P=0.328N	P=0.312N	P=0.330N	P=0.313N
POLY 1.5	P=0.328N	P=0.310N	P=0.323N	P=0.311N
POLY 6	P=0.329N	P=0.312N	P=0.341N	P=0.315N
COCH-ARM / FISHERS	P=0.326N	P=0.309N	P=0.309N	P=0.309N
MAX-ISO-POLY-3	P=0.209N	P=0.161N	P=0.180N	P=0.163N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

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

TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	3/48.54	1/47.69	1/45.36	1/47.5
POLY-3 PERCENT (g)	6.2%	2.1%	2.2%	2.1%
TERMINAL (d)	1/45 (2%)	0/44 (0%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	535	696	719	521
HC TUMORS SAME RTE	10/250 (4%)			
HC TUMORS ALL RTES	53/1249 (4%)			

**STATISTICAL TESTS**

POLY 3	P=0.328N	P=0.312N	P=0.330N	P=0.313N
POLY 1.5	P=0.328N	P=0.310N	P=0.323N	P=0.311N
POLY 6	P=0.329N	P=0.312N	P=0.341N	P=0.315N
COCH-ARM / FISHERS	P=0.326N	P=0.309N	P=0.309N	P=0.309N
MAX-ISO-POLY-3	P=0.209N	P=0.161N	P=0.180N	P=0.163N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>Skin</b>				
<b>Sarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/47.94	1/47.69	1/45.36	1/47.5
POLY-3 PERCENT (g)	4.2%	2.1%	2.2%	2.1%
TERMINAL (d)	1/45 (2%)	0/44 (0%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	709	696	719	521
HC TUMORS SAME RTE	2/250 (1%)			
HC TUMORS ALL RTES	27/1249 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.478N	P=0.502N	P=0.519N	P=0.503N
POLY 1.5	P=0.478N	P=0.502N	P=0.514N	P=0.503N
POLY 6	P=0.479N	P=0.500N	P=0.527N	P=0.503N
COCH-ARM / FISHERS	P=0.477N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.429N	P=0.283N	P=0.302N	P=0.284N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>Spleen Hemangiosarcoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	1/48 (2%)	0/48 (0%)	1/47 (2%)	0/49 (0%)
POLY-3 RATE (b)	1/46.5	0/46.4	1/43.81	0/46.01
POLY-3 PERCENT (g)	2.2%	0%	2.3%	0%
TERMINAL (d)	1/44 (2%)	0/44 (0%)	1/36 (3%)	0/43 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	---
HC TUMORS SAME RTE	5/247 (2%)			
HC TUMORS ALL RTES	24/1230 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.458N	P=0.500N	P=0.747	P=0.502N
POLY 1.5	P=0.456N	P=0.501N	P=0.750	P=0.500N
POLY 6	P=0.459N	P=0.500N	P=0.743	P=0.503N
COCH-ARM / FISHERS	P=0.451N	P=0.500N	P=0.747	P=0.495N
MAX-ISO-POLY-3	P=0.266N	P=0.159N	P=0.483	P=0.163N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)



TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

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DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

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**Stomach, Forestomach  
 Squamous Cell Papilloma**

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TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.86	0/47.56	0/45.32	0/46.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/45 (0%)	0/44 (0%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	5/250 (2%)			
HC TUMORS ALL RTES	20/1249 (2%)			

**STATISTICAL TESTS**

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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)

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TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
 Time Report Requested: 13:40:20  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thyroid Gland: Follicular Cell  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/48 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.86	2/47.56	0/43.73	0/46.86
POLY-3 PERCENT (g)	0%	4.2%	0%	0%
TERMINAL (d)	0/45 (0%)	2/44 (5%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	---	729 (T)	---	---
HC TUMORS SAME RTE	2/247 (1%)			
HC TUMORS ALL RTES	29/1234 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.374N	P=0.236	(e)	(e)
POLY 1.5	P=0.373N	P=0.236	(e)	(e)
POLY 6	P=0.374N	P=0.237	(e)	(e)
COCH-ARM / FISHERS	P=0.371N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.263N	P=0.076	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTES	(h)	(h)	(e)	(e)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
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 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>Uterus</b>				
<b>Polyp Stromal</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/48.46	1/47.56	0/45.32	1/46.86
POLY-3 PERCENT (g)	4.1%	2.1%	0%	2.1%
TERMINAL (d)	1/45 (2%)	1/44 (2%)	0/36 (0%)	1/43 (2%)
FIRST INCIDENCE	535	729 (T)	---	729 (T)
HC TUMORS SAME RTE	6/250 (2%)			
HC TUMORS ALL RTES	33/1249 (3%)			

**STATISTICAL TESTS**

POLY 3	P=0.481N	P=0.507N	P=0.253N	P=0.512N
POLY 1.5	P=0.481N	P=0.505N	P=0.248N	P=0.508N
POLY 6	P=0.483N	P=0.507N	P=0.259N	P=0.515N
COCH-ARM / FISHERS	P=0.479N	P=0.500N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.252N	P=0.288N	P=0.091N	P=0.294N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
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P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>All Organs</b>				
<b>Hemangioma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.86	0/47.56	0/45.32	0/46.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/45 (0%)	0/44 (0%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/250 (0%)			
HC TUMORS ALL RTES	20/1249 (2%)			

**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. 99007 - 06  
 Test Type: CHRONIC  
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 Species/Strain: MICE/B6C3F1

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>All Organs</b>				
<b>Hemangiosarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/47.86	0/47.56	1/45.32	0/46.86
POLY-3 PERCENT (g)	2.1%	0%	2.2%	0%
TERMINAL (d)	1/45 (2%)	0/44 (0%)	1/36 (3%)	0/43 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	---
HC TUMORS SAME RTE	10/250 (4%)			
HC TUMORS ALL RTES	60/1249 (5%)			

**STATISTICAL TESTS**

POLY 3	P=0.459N	P=0.501N	P=0.748	P=0.504N
POLY 1.5	P=0.458N	P=0.501N	P=0.751	P=0.503N
POLY 6	P=0.460N	P=0.501N	P=0.743	P=0.505N
COCH-ARM / FISHERS	P=0.456N	P=0.500N	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.266N	P=0.160N	P=0.484	P=0.164N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
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 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**All Organs  
 Hemangiosarcoma or Hemangioma**

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/47.86	0/47.56	1/45.32	0/46.86
POLY-3 PERCENT (g)	2.1%	0%	2.2%	0%
TERMINAL (d)	1/45 (2%)	0/44 (0%)	1/36 (3%)	0/43 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	---
HC TUMORS SAME RTE	10/250 (4%)			
HC TUMORS ALL RTES	79/1249 (6%)			

**STATISTICAL TESTS**

POLY 3	P=0.459N	P=0.501N	P=0.748	P=0.504N
POLY 1.5	P=0.458N	P=0.501N	P=0.751	P=0.503N
POLY 6	P=0.460N	P=0.501N	P=0.743	P=0.505N
COCH-ARM / FISHERS	P=0.456N	P=0.500N	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.266N	P=0.160N	P=0.484	P=0.164N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**All Organs  
 Histiocytic Sarcoma**

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TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	3/50 (6%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/47.86	3/47.6	0/45.32	1/47.4
POLY-3 PERCENT (g)	0%	6.3%	0%	2.1%
TERMINAL (d)	0/45 (0%)	2/44 (5%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	---	719	---	563
HC TUMORS SAME RTE	4/250 (2%)			
HC TUMORS ALL RTES	31/1249 (3%)			

---

**STATISTICAL TESTS**

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POLY 3	P=0.606N	P=0.118	(e)	P=0.498
POLY 1.5	P=0.606N	P=0.118	(e)	P=0.498
POLY 6	P=0.605N	P=0.119	(e)	P=0.498
COCH-ARM / FISHERS	P=0.603N	P=0.121	(e)	P=0.500
MAX-ISO-POLY-3	P=0.269	P=0.038*	(e)	P=0.159
HISTCONT SAME RTE	(h)	(h)	(e)	(h)
HISTCONT ALL RTES	(h)	(h)	(e)	(h)

---

TDMS No. 99007 - 06  
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P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

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

TUMOR RATES	#	#	#	#
OVERALL (a)	6/50 (12%)	5/50 (10%)	1/50 (2%)	10/50 (20%)
POLY-3 RATE (b)	6/48.5	5/48.27	1/45.54	10/47.77
POLY-3 PERCENT (g)	12.4%	10.4%	2.2%	20.9%
TERMINAL (d)	5/45 (11%)	4/44 (9%)	0/36 (0%)	7/43 (16%)
FIRST INCIDENCE	516	482	672	544
HC TUMORS SAME RTE	33/250 (13%)			
HC TUMORS ALL RTES	284/1249 (23%)			

**STATISTICAL TESTS**

POLY 3	P=0.066	P=0.503N	P=0.067N	P=0.197
POLY 1.5	P=0.067	P=0.503N	P=0.064N	P=0.199
POLY 6	P=0.067	P=0.501N	P=0.071N	P=0.198
COCH-ARM / FISHERS	P=0.072	P=0.500N	P=0.056N	P=0.207
MAX-ISO-POLY-3	P=0.042*	P=0.377N	P=0.033N*	P=0.132
HISTCONT SAME RTE	P=0.050*	P=1.000	P=1.000	P=0.093
HISTCONT ALL RTES	P=0.048*	P=1.000	P=1.000	P=0.155



TDMS No. 99007 - 06  
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>All Organs</b>				
<b>Benign Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	17/50 (34%)	17/50 (34%)	13/50 (26%)	14/50 (28%)
POLY-3 RATE (b)	17/49.28	17/48.23	13/46.45	14/46.86
POLY-3 PERCENT (g)	34.5%	35.3%	28%	29.9%
TERMINAL (d)	14/45 (31%)	15/44 (34%)	9/36 (25%)	14/43 (33%)
FIRST INCIDENCE	535	522	633	729 (T)
HC TUMORS SAME RTE	78/250 (31%)			
HC TUMORS ALL RTES	644/1249 (52%)			

**STATISTICAL TESTS**

POLY 3	P=0.322N	P=0.553	P=0.321N	P=0.395N
POLY 1.5	P=0.304N	P=0.563	P=0.305N	P=0.373N
POLY 6	P=0.344N	P=0.545	P=0.344N	P=0.420N
COCH-ARM / FISHERS	P=0.271N	P=0.583N	P=0.257N	P=0.333N
MAX-ISO-POLY-3	P=0.437N	P=0.469	P=0.254N	P=0.319N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99007 - 06  
 Test Type: CHRONIC  
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 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**All Organs  
 Malignant Tumors**

TUMOR RATES	#	#	#	#
OVERALL (a)	13/50 (26%)	13/50 (26%)	6/50 (12%)	16/50 (32%)
POLY-3 RATE (b)	13/49.19	13/48.57	6/45.8	16/48.94
POLY-3 PERCENT (g)	26.4%	26.8%	13.1%	32.7%
TERMINAL (d)	10/45 (22%)	9/44 (21%)	2/36 (6%)	11/43 (26%)
FIRST INCIDENCE	516	482	672	521
HC TUMORS SAME RTE	90/250 (36%)			
HC TUMORS ALL RTES	629/1249 (50%)			

**STATISTICAL TESTS**

POLY 3	P=0.240	P=0.575	P=0.085N	P=0.324
POLY 1.5	P=0.237	P=0.578	P=0.078N	P=0.322
POLY 6	P=0.245	P=0.577	P=0.094N	P=0.331
COCH-ARM / FISHERS	P=0.241	P=0.590N	P=0.062N	P=0.330
MAX-ISO-POLY-3	P=0.184	P=0.484	P=0.057N	P=0.251
HISTCONT SAME RTE	P=0.224	P=0.623	P=1.000	P=0.325
HISTCONT ALL RTES	P=0.213	P=0.612	P=1.000	P=0.309

TDMS No. 99007 - 06  
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 Lab: SRI

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

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**All Organs  
 Malignant and Benign Tumors**

TUMOR RATES	#	#	#	#
OVERALL (a)	26/50 (52%)	28/50 (56%)	17/50 (34%)	25/50 (50%)
POLY-3 RATE (b)	26/50	28/49.2	17/46.71	25/48.94
POLY-3 PERCENT (g)	52%	56.9%	36.4%	51.1%
TERMINAL (d)	21/45 (47%)	23/44 (52%)	10/36 (28%)	20/43 (47%)
FIRST INCIDENCE	516	482	633	521
HC TUMORS SAME RTE	137/250 (55%)			
HC TUMORS ALL RTEs	939/1249 (75%)			

**STATISTICAL TESTS**

POLY 3	P=0.423N	P=0.387	P=0.089N	P=0.543N
POLY 1.5	P=0.417N	P=0.398	P=0.078N	P=0.532N
POLY 6	P=0.428N	P=0.380	P=0.104N	P=0.551N
COCH-ARM / FISHERS	P=0.396N	P=0.421	P=0.053N	P=0.500N
MAX-ISO-POLY-3	P=0.239N	P=0.315	P=0.066N	P=0.463N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

**TDMS No.** 99007 - 06  
**Test Type:** CHRONIC  
**Route:** DOSED FEED  
**Species/Strain:** MICE/B6C3F1

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
Goldenseal root powder  
**CAS Number:** GOLDENSEALRT

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## **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 \*\*\*