

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Goldenseal root powder  
**CAS Number:** GOLDENSEALRT

**Date Report Requested:** 08/14/2008  
**Time Report Requested:** 12:25:59  
**First Dose M/F:** 05/12/03 / 05/12/03  
**Lab:** SRI

F1\_Rev.1\_M3

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

### **MALE MICE**

#### **Organ**

Adrenal Cortex  
  
Bone Marrow  
Islets, Pancreatic  
Kidney  
Kidney: Renal Tubule  
Liver  
  
Liver: Hepatocyte  
Lung  
Lymph Node, Mandibular  
Mesentery: Fat  
Parathyroid Gland  
Preputial Gland  
  
Spleen  
Stomach, Glandular  
  
Testes: Germinal Epithelium  
Thymus  
Thyroid Gland: Follicle

#### **Morphology**

Hypertrophy  
Hypertrophy Focal  
Hyperplasia  
Hyperplasia  
Nephropathy  
Pigmentation  
Eosinophilic Focus  
Mixed Cell Focus  
Vacuolization Cytoplasmic  
Infiltration Cellular Lymphocyte  
Hyperplasia Lymphoid  
Necrosis  
Cyst  
Cyst  
Hyperplasia  
Hematopoietic Cell Proliferation  
Cyst  
Erosion  
Atrophy  
Atrophy  
Cyst

### **FEMALE MICE**

#### **Organ**

Adrenal Cortex  
Bone Marrow  
Kidney  
Kidney: Renal Tubule  
Liver  
  
Liver: Hepatocyte

#### **Morphology**

Hypertrophy Focal  
Myelofibrosis  
Infarct  
Accumulation, Hyaline Droplet  
Mixed Cell Focus  
Tension Lipidosis  
Vacuolization Cytoplasmic

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

Lung	Infiltration Cellular Lymphocyte
Lymph Node, Mesenteric	Ectasia
Ovary: Corpus Luteum	Hyperplasia
Ovary: Granulosa Cell	Hyperplasia
Pancreas	Infiltration Cellular Lymphocyte
Pituitary Gland: Pars Distalis	Cyst
Stomach, Forestomach: Epithelium	Hyperplasia
Stomach, Glandular	Cyst
Thyroid Gland: Follicle	Cyst
	Degeneration Focal

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex  
 Degeneration Cystic**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.67	0/46.42	0/47.71	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	---	---	---	---

**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)

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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex  
 Hypertrophy**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	0/47.67	0/46.42	3/47.71	0/48.96
POLY-3 PERCENT (g)	0%	0%	6.3%	0%
TERMINAL (d)	0/43 (0%)	0/38 (0%)	3/45 (7%)	0/45 (0%)
FIRST INCIDENCE	---	---	729 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.654N	(e)	P=0.119	(e)
POLY 1.5	P=0.661N	(e)	P=0.119	(e)
POLY 6	P=0.644N	(e)	P=0.119	(e)
COCH-ARM / FISHERS	P=0.669N	(e)	P=0.121	(e)
MAX-ISO-POLY-3	P=0.107	(e)	P=0.038*	(e)

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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS 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  
 Hypertrophy Focal**

**LESION RATES**

OVERALL (a)	13/50 (26%)	18/50 (36%)	10/50 (20%)	5/50 (10%)
POLY-3 RATE (b)	13/47.67	18/46.42	10/47.71	5/48.96
POLY-3 PERCENT (g)	27.3%	38.8%	21%	10.2%
TERMINAL (d)	13/43 (30%)	18/38 (47%)	10/45 (22%)	5/45 (11%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.003N**	P=0.165	P=0.316N	P=0.027N*
POLY 1.5	P=0.003N**	P=0.178	P=0.317N	P=0.029N*
POLY 6	P=0.002N**	P=0.146	P=0.313N	P=0.025N*
COCH-ARM / FISHERS	P=0.005N**	P=0.194	P=0.318N	P=0.033N*
MAX-ISO-POLY-3	P=0.003N**	P=0.118	P=0.236N	P=0.015N*

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 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: Capsule  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	39/50 (78%)	37/50 (74%)	41/50 (82%)	37/50 (74%)
POLY-3 RATE (b)	39/48.12	37/47.68	41/47.71	37/49.85
POLY-3 PERCENT (g)	81.1%	77.6%	85.9%	74.2%
TERMINAL (d)	37/43 (86%)	31/38 (82%)	41/45 (91%)	34/45 (76%)
FIRST INCIDENCE	632	624	729 (T)	596

**STATISTICAL TESTS**

POLY 3	P=0.246N	P=0.432N	P=0.349	P=0.283N
POLY 1.5	P=0.318N	P=0.419N	P=0.373	P=0.333N
POLY 6	P=0.167N	P=0.454N	P=0.320	P=0.225N
COCH-ARM / FISHERS	P=0.421N	P=0.408N	P=0.402	P=0.408N
MAX-ISO-POLY-3	P=0.179N	P=0.331N	P=0.250	P=0.209N

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 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

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**Adrenal Medulla  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/49 (0%)
POLY-3 RATE (b)	0/47.67	0/46.42	1/47.71	0/48.42
POLY-3 PERCENT (g)	0%	0%	2.1%	0%
TERMINAL (d)	0/43 (0%)	0/38 (0%)	1/45 (2%)	0/45 (0%)
FIRST INCIDENCE	---	---	729 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.785N	(e)	P=0.500	(e)
POLY 1.5	P=0.788N	(e)	P=0.500	(e)
POLY 6	P=0.781N	(e)	P=0.501	(e)
COCH-ARM / FISHERS	P=0.793N	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.241	(e)	P=0.158	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

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**Bone Marrow  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	6/50 (12%)	17/50 (34%)	14/50 (28%)	14/50 (28%)
POLY-3 RATE (b)	6/48.59	17/47.81	14/49.22	14/49.32
POLY-3 PERCENT (g)	12.4%	35.6%	28.4%	28.4%
TERMINAL (d)	4/43 (9%)	13/38 (34%)	11/45 (24%)	13/45 (29%)
FIRST INCIDENCE	550	563	551	631

**STATISTICAL TESTS**

POLY 3	P=0.230	P=0.006**	P=0.041*	P=0.041*
POLY 1.5	P=0.222	P=0.007**	P=0.040*	P=0.040*
POLY 6	P=0.240	P=0.005**	P=0.042*	P=0.043*
COCH-ARM / FISHERS	P=0.214	P=0.008**	P=0.039*	P=0.039*
MAX-ISO-POLY-3	P=0.018*	P=0.003**	P=0.023*	P=0.024*

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 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

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**Bone Marrow  
 Myelofibrosis**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.67	0/46.42	0/47.71	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	---	---	---	---

**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)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Harderian Gland  
 Hyperplasia Focal**

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/47.67	1/46.42	0/47.71	1/48.96
POLY-3 PERCENT (g)	0%	2.2%	0%	2%
TERMINAL (d)	0/43 (0%)	1/38 (3%)	0/45 (0%)	1/45 (2%)
FIRST INCIDENCE	---	729 (T)	---	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.463	P=0.495	(e)	P=0.505
POLY 1.5	P=0.460	P=0.497	(e)	P=0.503
POLY 6	P=0.466	P=0.491	(e)	P=0.508
COCH-ARM / FISHERS	P=0.456	P=0.500	(e)	P=0.500
MAX-ISO-POLY-3	P=0.165	P=0.158	(e)	P=0.165

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS 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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**Heart  
 Cardiomyopathy**

**LESION RATES**

OVERALL (a)	45/50 (90%)	42/50 (84%)	44/50 (88%)	44/50 (88%)
POLY-3 RATE (b)	45/49.22	42/48.77	44/48.52	44/49.55
POLY-3 PERCENT (g)	91.4%	86.1%	90.7%	88.8%
TERMINAL (d)	41/43 (95%)	34/38 (90%)	42/45 (93%)	40/45 (89%)
FIRST INCIDENCE	496	555	551	631

**STATISTICAL TESTS**

POLY 3	P=0.539N	P=0.295N	P=0.595N	P=0.460N
POLY 1.5	P=0.569N	P=0.288N	P=0.557N	P=0.481N
POLY 6	P=0.482N	P=0.302N	P=0.629N	P=0.416N
COCH-ARM / FISHERS	P=0.542	P=0.277N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.313N	P=0.191N	P=0.444N	P=0.325N

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 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

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Intestine Small, Jejunum  
 Hyperplasia Lymphoid

**LESION RATES**

OVERALL (a)	1/46 (2%)	1/43 (2%)	3/47 (6%)	2/48 (4%)
POLY-3 RATE (b)	1/44.99	1/41.03	3/45.89	2/47.44
POLY-3 PERCENT (g)	2.2%	2.4%	6.5%	4.2%
TERMINAL (d)	1/43 (2%)	1/37 (3%)	3/45 (7%)	2/45 (4%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.428	P=0.740	P=0.313	P=0.518
POLY 1.5	P=0.423	P=0.742	P=0.313	P=0.517
POLY 6	P=0.434	P=0.736	P=0.313	P=0.520
COCH-ARM / FISHERS	P=0.416	P=0.736	P=0.317	P=0.516
MAX-ISO-POLY-3	P=0.222	P=0.473	P=0.160	P=0.298

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 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Islets, Pancreatic  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	4/49 (8%)	12/50 (24%)	11/50 (22%)	4/50 (8%)
POLY-3 RATE (b)	4/46.92	12/47.71	11/47.95	4/49.04
POLY-3 PERCENT (g)	8.5%	25.2%	22.9%	8.2%
TERMINAL (d)	4/43 (9%)	9/38 (24%)	10/45 (22%)	3/45 (7%)
FIRST INCIDENCE	729 (T)	555	666	710

**STATISTICAL TESTS**

POLY 3	P=0.157N	P=0.028*	P=0.048*	P=0.618N
POLY 1.5	P=0.165N	P=0.029*	P=0.049*	P=0.623N
POLY 6	P=0.148N	P=0.026*	P=0.049*	P=0.612N
COCH-ARM / FISHERS	P=0.180N	P=0.030*	P=0.049*	P=0.631N
MAX-ISO-POLY-3	P=0.075N	P=0.014*	P=0.026*	P=0.472N

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 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Kidney  
 Casts Protein**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.67	0/46.42	0/47.71	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	---	---	---	---

**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)

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 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Kidney  
 Cyst**

**LESION RATES**

OVERALL (a)	4/50 (8%)	3/50 (6%)	9/50 (18%)	2/50 (4%)
POLY-3 RATE (b)	4/47.67	3/46.42	9/47.71	2/48.96
POLY-3 PERCENT (g)	8.4%	6.5%	18.9%	4.1%
TERMINAL (d)	4/43 (9%)	3/38 (8%)	9/45 (20%)	2/45 (4%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.285N	P=0.514N	P=0.116	P=0.325N
POLY 1.5	P=0.298N	P=0.508N	P=0.116	P=0.330N
POLY 6	P=0.268N	P=0.525N	P=0.116	P=0.319N
COCH-ARM / FISHERS	P=0.318N	P=0.500N	P=0.117	P=0.339N
MAX-ISO-POLY-3	P=0.111N	P=0.361N	P=0.067	P=0.194N

---



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Kidney  
 Hydronephrosis**

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.67	2/46.98	0/47.71	0/48.96
POLY-3 PERCENT (g)	0%	4.3%	0%	0%
TERMINAL (d)	0/43 (0%)	0/38 (0%)	0/45 (0%)	0/45 (0%)
FIRST INCIDENCE	---	625	---	---

**STATISTICAL TESTS**

POLY 3	P=0.368N	P=0.234	(e)	(e)
POLY 1.5	P=0.369N	P=0.236	(e)	(e)
POLY 6	P=0.368N	P=0.232	(e)	(e)
COCH-ARM / FISHERS	P=0.370N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.154N	P=0.075	(e)	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Kidney  
 Infarct**

**LESION RATES**

OVERALL (a)	2/50 (4%)	4/50 (8%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/47.67	4/46.42	0/47.71	1/48.96
POLY-3 PERCENT (g)	4.2%	8.6%	0%	2%
TERMINAL (d)	2/43 (5%)	4/38 (11%)	0/45 (0%)	1/45 (2%)
FIRST INCIDENCE	729 (T)	729 (T)	---	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.209N	P=0.325	P=0.237N	P=0.491N
POLY 1.5	P=0.211N	P=0.331	P=0.237N	P=0.494N
POLY 6	P=0.207N	P=0.316	P=0.236N	P=0.486N
COCH-ARM / FISHERS	P=0.216N	P=0.339	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.081N	P=0.194	P=0.075N	P=0.275N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Kidney  
 Infiltration Cellular Lymphocyte**

**LESION RATES**

OVERALL (a)	1/50 (2%)	2/50 (4%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	1/47.67	2/46.42	2/47.71	2/48.96
POLY-3 PERCENT (g)	2.1%	4.3%	4.2%	4.1%
TERMINAL (d)	1/43 (2%)	2/38 (5%)	2/45 (4%)	2/45 (4%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.498	P=0.491	P=0.500	P=0.509
POLY 1.5	P=0.490	P=0.495	P=0.500	P=0.506
POLY 6	P=0.507	P=0.484	P=0.501	P=0.514
COCH-ARM / FISHERS	P=0.480	P=0.500	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.294	P=0.275	P=0.281	P=0.290

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Kidney  
 Metaplasia Osseous**

**LESION RATES**

OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	1/47.67	1/46.42	2/47.71	3/48.96
POLY-3 PERCENT (g)	2.1%	2.2%	4.2%	6.1%
TERMINAL (d)	1/43 (2%)	1/38 (3%)	2/45 (4%)	3/45 (7%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.191	P=0.755	P=0.500	P=0.315
POLY 1.5	P=0.185	P=0.757	P=0.500	P=0.311
POLY 6	P=0.198	P=0.750	P=0.501	P=0.320
COCH-ARM / FISHERS	P=0.177	P=0.753N	P=0.500	P=0.309
MAX-ISO-POLY-3	P=0.148	P=0.491	P=0.281	P=0.164

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Kidney  
 Nephropathy**

**LESION RATES**

OVERALL (a)	42/50 (84%)	43/50 (86%)	46/50 (92%)	48/50 (96%)
POLY-3 RATE (b)	42/48.24	43/48.23	46/49.39	48/49.55
POLY-3 PERCENT (g)	87.1%	89.2%	93.1%	96.9%
TERMINAL (d)	41/43 (95%)	37/38 (97%)	43/45 (96%)	44/45 (98%)
FIRST INCIDENCE	550	557	551	631

**STATISTICAL TESTS**

POLY 3	P=0.039*	P=0.499	P=0.238	P=0.060
POLY 1.5	P=0.033*	P=0.502	P=0.209	P=0.052
POLY 6	P=0.056	P=0.485	P=0.287	P=0.081
COCH-ARM / FISHERS	P=0.029*	P=0.500	P=0.178	P=0.046*
MAX-ISO-POLY-3	P=0.030*	P=0.363	P=0.142	P=0.026*

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Kidney: Renal Tubule  
 Accumulation, Hyaline Droplet**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/47.67	0/46.42	1/47.71	0/48.96
POLY-3 PERCENT (g)	0%	0%	2.1%	0%
TERMINAL (d)	0/43 (0%)	0/38 (0%)	1/45 (2%)	0/45 (0%)
FIRST INCIDENCE	---	---	729 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.783N	(e)	P=0.500	(e)
POLY 1.5	P=0.786N	(e)	P=0.500	(e)
POLY 6	P=0.779N	(e)	P=0.501	(e)
COCH-ARM / FISHERS	P=0.790N	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.242	(e)	P=0.158	(e)

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Kidney: Renal Tubule  
 Pigmentation**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/47.67	0/46.42	0/47.71	2/49.45
POLY-3 PERCENT (g)	0%	0%	0%	4%
TERMINAL (d)	0/43 (0%)	0/38 (0%)	0/45 (0%)	0/45 (0%)
FIRST INCIDENCE	---	---	---	596

**STATISTICAL TESTS**

POLY 3	P=0.044*	(e)	(e)	P=0.246
POLY 1.5	P=0.042*	(e)	(e)	P=0.242
POLY 6	P=0.045*	(e)	(e)	P=0.250
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.025*	(e)	(e)	P=0.083

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver  
 Basophilic Focus

**LESION RATES**

OVERALL (a)	1/50 (2%)	3/50 (6%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	1/47.67	3/46.42	3/48.28	3/48.96
POLY-3 PERCENT (g)	2.1%	6.5%	6.2%	6.1%
TERMINAL (d)	1/43 (2%)	3/38 (8%)	2/45 (4%)	3/45 (7%)
FIRST INCIDENCE	729 (T)	729 (T)	551	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.382	P=0.296	P=0.310	P=0.315
POLY 1.5	P=0.374	P=0.301	P=0.308	P=0.311
POLY 6	P=0.392	P=0.289	P=0.313	P=0.320
COCH-ARM / FISHERS	P=0.362	P=0.309	P=0.309	P=0.309
MAX-ISO-POLY-3	P=0.182	P=0.150	P=0.159	P=0.164



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Liver  
 Clear Cell Focus

**LESION RATES**

OVERALL (a)	10/50 (20%)	10/50 (20%)	11/50 (22%)	12/50 (24%)
POLY-3 RATE (b)	10/47.67	10/46.42	11/47.71	12/48.96
POLY-3 PERCENT (g)	21%	21.5%	23.1%	24.5%
TERMINAL (d)	10/43 (23%)	10/38 (26%)	11/45 (24%)	12/45 (27%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.382	P=0.573	P=0.501	P=0.432
POLY 1.5	P=0.364	P=0.585	P=0.500	P=0.421
POLY 6	P=0.407	P=0.553	P=0.503	P=0.446
COCH-ARM / FISHERS	P=0.339	P=0.598N	P=0.500	P=0.405
MAX-ISO-POLY-3	P=0.338	P=0.472	P=0.402	P=0.340

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Liver  
 Cyst

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/47.67	1/46.42	0/47.71	1/48.96
POLY-3 PERCENT (g)	0%	2.2%	0%	2%
TERMINAL (d)	0/43 (0%)	1/38 (3%)	0/45 (0%)	1/45 (2%)
FIRST INCIDENCE	---	729 (T)	---	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.463	P=0.495	(e)	P=0.505
POLY 1.5	P=0.460	P=0.497	(e)	P=0.503
POLY 6	P=0.466	P=0.491	(e)	P=0.508
COCH-ARM / FISHERS	P=0.456	P=0.500	(e)	P=0.500
MAX-ISO-POLY-3	P=0.165	P=0.158	(e)	P=0.165

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Liver  
 Eosinophilic Focus

**LESION RATES**

OVERALL (a)	7/50 (14%)	14/50 (28%)	14/50 (28%)	24/50 (48%)
POLY-3 RATE (b)	7/47.87	14/47.12	14/48.28	24/49.42
POLY-3 PERCENT (g)	14.6%	29.7%	29%	48.6%
TERMINAL (d)	6/43 (14%)	11/38 (29%)	13/45 (29%)	23/45 (51%)
FIRST INCIDENCE	677	557	551	596

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.062	P=0.071	P<0.001**
POLY 1.5	P<0.001**	P=0.065	P=0.070	P<0.001**
POLY 6	P<0.001**	P=0.056	P=0.072	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.070	P=0.070	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.038*	P=0.043*	P<0.001**

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Liver  
 Hematopoietic Cell Proliferation**

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/47.67	1/46.96	1/47.71	0/48.96
POLY-3 PERCENT (g)	0%	2.1%	2.1%	0%
TERMINAL (d)	0/43 (0%)	0/38 (0%)	1/45 (2%)	0/45 (0%)
FIRST INCIDENCE	---	563	729 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.537N	P=0.497	P=0.500	(e)
POLY 1.5	P=0.540N	P=0.499	P=0.500	(e)
POLY 6	P=0.534N	P=0.494	P=0.501	(e)
COCH-ARM / FISHERS	P=0.544N	P=0.500	P=0.500	(e)
MAX-ISO-POLY-3	P=0.251N	P=0.158	P=0.158	(e)

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Liver  
 Infiltration Cellular Lymphocyte

**LESION RATES**

OVERALL (a)	1/50 (2%)	1/50 (2%)	4/50 (8%)	3/50 (6%)
POLY-3 RATE (b)	1/47.67	1/46.42	4/47.71	3/48.96
POLY-3 PERCENT (g)	2.1%	2.2%	8.4%	6.1%
TERMINAL (d)	1/43 (2%)	1/38 (3%)	4/45 (9%)	3/45 (7%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.229	P=0.755	P=0.179	P=0.315
POLY 1.5	P=0.222	P=0.757	P=0.179	P=0.311
POLY 6	P=0.240	P=0.750	P=0.180	P=0.320
COCH-ARM / FISHERS	P=0.211	P=0.753N	P=0.181	P=0.309
MAX-ISO-POLY-3	P=0.118	P=0.491	P=0.083	P=0.164

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Liver  
 Infiltration Cellular Mixed Cell

**LESION RATES**

OVERALL (a)	3/50 (6%)	6/50 (12%)	3/50 (6%)	4/50 (8%)
POLY-3 RATE (b)	3/47.67	6/46.42	3/47.71	4/48.96
POLY-3 PERCENT (g)	6.3%	12.9%	6.3%	8.2%
TERMINAL (d)	3/43 (7%)	6/38 (16%)	3/45 (7%)	4/45 (9%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.533N	P=0.229	P=0.662N	P=0.515
POLY 1.5	P=0.542N	P=0.236	P=0.662N	P=0.509
POLY 6	P=0.523N	P=0.219	P=0.661N	P=0.522
COCH-ARM / FISHERS	P=0.554N	P=0.243	P=0.661N	P=0.500
MAX-ISO-POLY-3	P=0.311	P=0.140	P=0.498N	P=0.361

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Liver  
 Mixed Cell Focus

**LESION RATES**

OVERALL (a)	1/50 (2%)	7/50 (14%)	9/50 (18%)	6/50 (12%)
POLY-3 RATE (b)	1/47.67	7/46.42	9/47.71	6/48.96
POLY-3 PERCENT (g)	2.1%	15.1%	18.9%	12.3%
TERMINAL (d)	1/43 (2%)	7/38 (18%)	9/45 (20%)	6/45 (13%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.261	P=0.027*	P=0.008**	P=0.061
POLY 1.5	P=0.250	P=0.029*	P=0.008**	P=0.059
POLY 6	P=0.276	P=0.025*	P=0.008**	P=0.063
COCH-ARM / FISHERS	P=0.237	P=0.030*	P=0.008**	P=0.056
MAX-ISO-POLY-3	P=0.021*	P=0.012*	P=0.003**	P=0.027*

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Liver  
 Necrosis Focal

**LESION RATES**

OVERALL (a)	2/50 (4%)	3/50 (6%)	5/50 (10%)	6/50 (12%)
POLY-3 RATE (b)	2/48.22	3/47.71	5/48.52	6/49.07
POLY-3 PERCENT (g)	4.2%	6.3%	10.3%	12.2%
TERMINAL (d)	0/43 (0%)	0/38 (0%)	3/45 (7%)	4/45 (9%)
FIRST INCIDENCE	632	557	551	710

**STATISTICAL TESTS**

POLY 3	P=0.105	P=0.495	P=0.219	P=0.139
POLY 1.5	P=0.102	P=0.498	P=0.219	P=0.137
POLY 6	P=0.109	P=0.489	P=0.221	P=0.141
COCH-ARM / FISHERS	P=0.097	P=0.500	P=0.218	P=0.134
MAX-ISO-POLY-3	P=0.075	P=0.319	P=0.122	P=0.074

---



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Liver  
 Tension Lipidosis

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.67	1/46.79	0/47.71	0/48.96
POLY-3 PERCENT (g)	0%	2.1%	0%	0%
TERMINAL (d)	0/43 (0%)	0/38 (0%)	0/45 (0%)	0/45 (0%)
FIRST INCIDENCE	---	625	---	---

**STATISTICAL TESTS**

POLY 3	P=0.573N	P=0.496	(e)	(e)
POLY 1.5	P=0.572N	P=0.498	(e)	(e)
POLY 6	P=0.575N	P=0.493	(e)	(e)
COCH-ARM / FISHERS	P=0.572N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.237N	P=0.158	(e)	(e)

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Liver: Hepatocyte  
 Vacuolization Cytoplasmic

**LESION RATES**

OVERALL (a)	6/50 (12%)	11/50 (22%)	15/50 (30%)	7/50 (14%)
POLY-3 RATE (b)	6/47.67	11/46.76	15/47.71	7/48.96
POLY-3 PERCENT (g)	12.6%	23.5%	31.4%	14.3%
TERMINAL (d)	6/43 (14%)	10/38 (26%)	15/45 (33%)	7/45 (16%)
FIRST INCIDENCE	729 (T)	636	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.384N	P=0.132	P=0.022*	P=0.520
POLY 1.5	P=0.402N	P=0.137	P=0.022*	P=0.512
POLY 6	P=0.361N	P=0.123	P=0.022*	P=0.530
COCH-ARM / FISHERS	P=0.428N	P=0.143	P=0.024*	P=0.500
MAX-ISO-POLY-3	P=0.100	P=0.084	P=0.012*	P=0.403

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Liver: Kupffer Cell  
 Pigmentation

**LESION RATES**

OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/47.67	1/46.42	2/47.95	1/48.96
POLY-3 PERCENT (g)	2.1%	2.2%	4.2%	2%
TERMINAL (d)	1/43 (2%)	1/38 (3%)	1/45 (2%)	1/45 (2%)
FIRST INCIDENCE	729 (T)	729 (T)	666	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.627N	P=0.755	P=0.502	P=0.754N
POLY 1.5	P=0.633N	P=0.757	P=0.501	P=0.757N
POLY 6	P=0.619N	P=0.750	P=0.504	P=0.752N
COCH-ARM / FISHERS	P=0.642N	P=0.753N	P=0.500	P=0.753N
MAX-ISO-POLY-3	P=0.379	P=0.491	P=0.282	P=0.491N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Goldenseal root powder  
CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
Time Report Requested: 12:25:59  
First Dose M/F: 05/12/03 / 05/12/03  
Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Lung  
Hemorrhage

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.67	0/46.42	0/47.71	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	---	---	---	---

---

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lung  
 Infiltration Cellular Histiocyte**

**LESION RATES**

OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/48.36	0/46.42	1/47.71	2/48.96
POLY-3 PERCENT (g)	4.1%	0%	2.1%	4.1%
TERMINAL (d)	1/43 (2%)	0/38 (0%)	1/45 (2%)	2/45 (4%)
FIRST INCIDENCE	496	---	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.428	P=0.247N	P=0.505N	P=0.689N
POLY 1.5	P=0.421	P=0.243N	P=0.503N	P=0.691N
POLY 6	P=0.437	P=0.252N	P=0.506N	P=0.686N
COCH-ARM / FISHERS	P=0.412	P=0.247N	P=0.500N	P=0.691N
MAX-ISO-POLY-3	P=0.264N	P=0.084N	P=0.285N	P=0.494N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lung  
 Infiltration Cellular Lymphocyte**

**LESION RATES**

OVERALL (a)	3/50 (6%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	3/47.67	0/46.42	0/47.71	1/48.96
POLY-3 PERCENT (g)	6.3%	0%	0%	2%
TERMINAL (d)	3/43 (7%)	0/38 (0%)	0/45 (0%)	1/45 (2%)
FIRST INCIDENCE	729 (T)	---	---	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.407N	P=0.124N	P=0.119N	P=0.296N
POLY 1.5	P=0.411N	P=0.121N	P=0.119N	P=0.300N
POLY 6	P=0.400N	P=0.127N	P=0.118N	P=0.291N
COCH-ARM / FISHERS	P=0.417N	P=0.121N	P=0.121N	P=0.309N
MAX-ISO-POLY-3	P=0.027N*	P=0.042N*	P=0.038N*	P=0.151N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lung: Alveolar Epithelium  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	6/50 (12%)	2/50 (4%)	3/50 (6%)	5/50 (10%)
POLY-3 RATE (b)	6/48.60	2/46.52	3/47.71	5/48.96
POLY-3 PERCENT (g)	12.4%	4.3%	6.3%	10.2%
TERMINAL (d)	4/43 (9%)	1/38 (3%)	3/45 (7%)	5/45 (11%)
FIRST INCIDENCE	496	703	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.501	P=0.148N	P=0.252N	P=0.495N
POLY 1.5	P=0.491	P=0.142N	P=0.249N	P=0.497N
POLY 6	P=0.513	P=0.157N	P=0.255N	P=0.492N
COCH-ARM / FISHERS	P=0.478	P=0.134N	P=0.243N	P=0.500N
MAX-ISO-POLY-3	P=0.169N	P=0.082N	P=0.156N	P=0.369N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lymph Node, Mandibular  
 Hyperplasia Lymphoid**

**LESION RATES**

OVERALL (a)	0/46 (0%)	3/46 (7%)	2/50 (4%)	2/49 (4%)
POLY-3 RATE (b)	0/44.49	3/43.56	2/47.71	2/48.42
POLY-3 PERCENT (g)	0%	6.9%	4.2%	4.1%
TERMINAL (d)	0/41 (0%)	2/36 (6%)	2/45 (4%)	2/45 (4%)
FIRST INCIDENCE	---	624	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.472	P=0.115	P=0.253	P=0.256
POLY 1.5	P=0.467	P=0.117	P=0.254	P=0.255
POLY 6	P=0.478	P=0.112	P=0.252	P=0.259
COCH-ARM / FISHERS	P=0.460	P=0.121	P=0.269	P=0.263
MAX-ISO-POLY-3	P=0.107	P=0.038*	P=0.086	P=0.090



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Lymph Node, Mesenteric  
 Ectasia

---

**LESION RATES**

OVERALL (a)	0/48 (0%)	0/44 (0%)	0/49 (0%)	0/48 (0%)
POLY-3 RATE (b)	0/45.67	0/41.78	0/47.28	0/46.99
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/41 (0%)	0/36 (0%)	0/45 (0%)	0/44 (0%)
FIRST INCIDENCE	---	---	---	---

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lymph Node, Mesenteric  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	2/48 (4%)	0/44 (0%)	2/49 (4%)	1/48 (2%)
POLY-3 RATE (b)	2/45.67	0/41.78	2/47.28	1/47.12
POLY-3 PERCENT (g)	4.4%	0%	4.2%	2.1%
TERMINAL (d)	2/41 (5%)	0/36 (0%)	2/45 (4%)	0/44 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	697

**STATISTICAL TESTS**

POLY 3	P=0.564N	P=0.257N	P=0.681N	P=0.489N
POLY 1.5	P=0.569N	P=0.257N	P=0.683N	P=0.494N
POLY 6	P=0.557N	P=0.259N	P=0.678N	P=0.483N
COCH-ARM / FISHERS	P=0.576N	P=0.269N	P=0.684N	P=0.500N
MAX-ISO-POLY-3	P=0.256N	P=0.090N	P=0.484N	P=0.274N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lymph Node, Mesenteric  
 Hyperplasia Lymphoid**

**LESION RATES**

OVERALL (a)	3/48 (6%)	2/44 (5%)	2/49 (4%)	2/48 (4%)
POLY-3 RATE (b)	3/45.67	2/41.78	2/47.28	2/46.99
POLY-3 PERCENT (g)	6.6%	4.8%	4.2%	4.3%
TERMINAL (d)	3/41 (7%)	2/36 (6%)	2/45 (4%)	2/44 (5%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.454N	P=0.540N	P=0.484N	P=0.487N
POLY 1.5	P=0.459N	P=0.539N	P=0.487N	P=0.492N
POLY 6	P=0.447N	P=0.543N	P=0.480N	P=0.481N
COCH-ARM / FISHERS	P=0.466N	P=0.542N	P=0.490N	P=0.500N
MAX-ISO-POLY-3	P=0.305N	P=0.362N	P=0.311N	P=0.314N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Mesentery: Fat  
 Necrosis

**LESION RATES**

OVERALL (a)	5/6 (83%)	1/3 (33%)	6/12 (50%)	0/1 (0%)
POLY-3 RATE (b)	5/5.43	1/2.71	6/10.52	0/0.97
POLY-3 PERCENT (g)	92.1%	36.9%	57%	0%
TERMINAL (d)	4/4 (100%)	0/0 (0%)	6/9 (67%)	0/0 (0%)
FIRST INCIDENCE	632	709	729 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.136N	P=0.151N	P=0.172N	P=0.108N
POLY 1.5	P=0.153N	P=0.179N	P=0.180N	P=0.194N
POLY 6	P=0.114N	P=0.133N	P=0.175N	P=0.016N*
COCH-ARM / FISHERS	P=0.174N	P=0.226N	P=0.199N	P=0.286N
MAX-ISO-POLY-3	P=0.067N	P=0.037N*	P=0.084N	P=0.002N**

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Nose: Glands  
 Degeneration Cystic**

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.67	1/46.42	0/47.71	0/48.96
POLY-3 PERCENT (g)	0%	2.2%	0%	0%
TERMINAL (d)	0/43 (0%)	1/38 (3%)	0/45 (0%)	0/45 (0%)
FIRST INCIDENCE	---	729 (T)	---	---

**STATISTICAL TESTS**

POLY 3	P=0.574N	P=0.495	(e)	(e)
POLY 1.5	P=0.573N	P=0.497	(e)	(e)
POLY 6	P=0.577N	P=0.491	(e)	(e)
COCH-ARM / FISHERS	P=0.572N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.236N	P=0.158	(e)	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pancreas  
 Infiltration Cellular Lymphocyte**

**LESION RATES**

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/46.92	0/46.42	0/47.71	1/48.96
POLY-3 PERCENT (g)	0%	0%	0%	2%
TERMINAL (d)	0/43 (0%)	0/38 (0%)	0/45 (0%)	1/45 (2%)
FIRST INCIDENCE	---	---	---	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.218	(e)	(e)	P=0.509
POLY 1.5	P=0.216	(e)	(e)	P=0.507
POLY 6	P=0.221	(e)	(e)	P=0.510
COCH-ARM / FISHERS	P=0.212	(e)	(e)	P=0.505
MAX-ISO-POLY-3	P=0.085	(e)	(e)	P=0.168

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pancreas: Acinus  
 Cytoplasmic Alteration**

**LESION RATES**

OVERALL (a)	2/49 (4%)	5/50 (10%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	2/47.27	5/47.39	0/47.71	2/49.45
POLY-3 PERCENT (g)	4.2%	10.6%	0%	4%
TERMINAL (d)	1/43 (2%)	1/38 (3%)	0/45 (0%)	0/45 (0%)
FIRST INCIDENCE	632	625	---	596

**STATISTICAL TESTS**

POLY 3	P=0.344N	P=0.218	P=0.235N	P=0.677N
POLY 1.5	P=0.347N	P=0.221	P=0.234N	P=0.681N
POLY 6	P=0.341N	P=0.212	P=0.237N	P=0.674N
COCH-ARM / FISHERS	P=0.353N	P=0.226	P=0.242N	P=0.684N
MAX-ISO-POLY-3	P=0.107N	P=0.120	P=0.075N	P=0.480N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Parathyroid Gland  
 Cyst**

**LESION RATES**

OVERALL (a)	0/45 (0%)	0/45 (0%)	3/47 (6%)	0/49 (0%)
POLY-3 RATE (b)	0/44.28	0/42.32	3/44.95	0/47.96
POLY-3 PERCENT (g)	0%	0%	6.7%	0%
TERMINAL (d)	0/41 (0%)	0/35 (0%)	2/42 (5%)	0/44 (0%)
FIRST INCIDENCE	---	---	666	---

**STATISTICAL TESTS**

POLY 3	P=0.641N	(e)	P=0.121	(e)
POLY 1.5	P=0.644N	(e)	P=0.123	(e)
POLY 6	P=0.637N	(e)	P=0.120	(e)
COCH-ARM / FISHERS	P=0.645N	(e)	P=0.129	(e)
MAX-ISO-POLY-3	P=0.111	(e)	P=0.040*	(e)



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Pituitary Gland: Pars Distalis  
 Cyst**

**LESION RATES**

OVERALL (a)	2/50 (4%)	2/49 (4%)	1/49 (2%)	3/50 (6%)
POLY-3 RATE (b)	2/47.67	2/45.52	1/47.25	3/48.96
POLY-3 PERCENT (g)	4.2%	4.4%	2.1%	6.1%
TERMINAL (d)	2/43 (5%)	2/38 (5%)	1/45 (2%)	3/45 (7%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.403	P=0.677	P=0.503N	P=0.512
POLY 1.5	P=0.396	P=0.681	P=0.505N	P=0.507
POLY 6	P=0.411	P=0.670	P=0.500N	P=0.518
COCH-ARM / FISHERS	P=0.387	P=0.684	P=0.508N	P=0.500
MAX-ISO-POLY-3	P=0.268	P=0.479	P=0.283N	P=0.335

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pituitary Gland: Pars Distalis  
 Hyperplasia Focal**

**LESION RATES**

OVERALL (a)	2/50 (4%)	0/49 (0%)	0/49 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/47.67	0/45.52	0/47.25	1/48.96
POLY-3 PERCENT (g)	4.2%	0%	0%	2%
TERMINAL (d)	2/43 (5%)	0/38 (0%)	0/45 (0%)	1/45 (2%)
FIRST INCIDENCE	729 (T)	---	---	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.614N	P=0.248N	P=0.239N	P=0.491N
POLY 1.5	P=0.617N	P=0.245N	P=0.240N	P=0.494N
POLY 6	P=0.609N	P=0.252N	P=0.238N	P=0.486N
COCH-ARM / FISHERS	P=0.621N	P=0.253N	P=0.253N	P=0.500N
MAX-ISO-POLY-3	P=0.086N	P=0.084N	P=0.076N	P=0.275N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Preputial Gland  
 Cyst**

**LESION RATES**

OVERALL (a)	19/50 (38%)	17/50 (34%)	26/50 (52%)	13/50 (26%)
POLY-3 RATE (b)	19/48.02	17/47.89	26/48.52	13/49.57
POLY-3 PERCENT (g)	39.6%	35.5%	53.6%	26.2%
TERMINAL (d)	18/43 (42%)	14/38 (37%)	24/45 (53%)	10/45 (22%)
FIRST INCIDENCE	632	557	551	596

**STATISTICAL TESTS**

POLY 3	P=0.089N	P=0.421N	P=0.118	P=0.117N
POLY 1.5	P=0.103N	P=0.417N	P=0.116	P=0.127N
POLY 6	P=0.073N	P=0.432N	P=0.122	P=0.105N
COCH-ARM / FISHERS	P=0.126N	P=0.418N	P=0.114	P=0.142N
MAX-ISO-POLY-3	P=0.044N*	P=0.338N	P=0.082	P=0.082N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS 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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**Preputial Gland  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	0/47.67	1/46.42	4/47.71	2/48.96
POLY-3 PERCENT (g)	0%	2.2%	8.4%	4.1%
TERMINAL (d)	0/43 (0%)	1/38 (3%)	4/45 (9%)	2/45 (4%)
FIRST INCIDENCE	---	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.277	P=0.495	P=0.061	P=0.243
POLY 1.5	P=0.269	P=0.497	P=0.061	P=0.241
POLY 6	P=0.289	P=0.491	P=0.061	P=0.246
COCH-ARM / FISHERS	P=0.259	P=0.500	P=0.059	P=0.247
MAX-ISO-POLY-3	P=0.052	P=0.158	P=0.019*	P=0.081

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Preputial Gland  
 Inflammation**

**LESION RATES**

OVERALL (a)	1/50 (2%)	3/50 (6%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	1/47.67	3/46.79	4/47.71	2/48.96
POLY-3 PERCENT (g)	2.1%	6.4%	8.4%	4.1%
TERMINAL (d)	1/43 (2%)	2/38 (5%)	4/45 (9%)	2/45 (4%)
FIRST INCIDENCE	729 (T)	624	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.594	P=0.299	P=0.179	P=0.509
POLY 1.5	P=0.586	P=0.302	P=0.179	P=0.506
POLY 6	P=0.605	P=0.293	P=0.180	P=0.514
COCH-ARM / FISHERS	P=0.573	P=0.309	P=0.181	P=0.500
MAX-ISO-POLY-3	P=0.181	P=0.151	P=0.083	P=0.290

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Preputial Gland  
 Inflammation Chronic**

**LESION RATES**

OVERALL (a)	1/50 (2%)	4/50 (8%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	1/47.67	4/46.42	3/47.71	2/48.96
POLY-3 PERCENT (g)	2.1%	8.6%	6.3%	4.1%
TERMINAL (d)	1/43 (2%)	4/38 (11%)	3/45 (7%)	2/45 (4%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.543N	P=0.171	P=0.306	P=0.509
POLY 1.5	P=0.550N	P=0.175	P=0.306	P=0.506
POLY 6	P=0.534N	P=0.165	P=0.307	P=0.514
COCH-ARM / FISHERS	P=0.560N	P=0.181	P=0.309	P=0.500
MAX-ISO-POLY-3	P=0.180	P=0.081	P=0.154	P=0.290

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Prostate  
 Inflammation Chronic**

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.67	2/46.79	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	---	625	---	---

**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=0.153N	P=0.075	(e)	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Prostate: Epithelium  
 Hyperplasia

**LESION RATES**

OVERALL (a)	2/50 (4%)	1/50 (2%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	2/47.67	1/46.42	1/47.71	3/49.44
POLY-3 PERCENT (g)	4.2%	2.2%	2.1%	6.1%
TERMINAL (d)	2/43 (5%)	1/38 (3%)	1/45 (2%)	1/45 (2%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	631

**STATISTICAL TESTS**

POLY 3	P=0.304	P=0.509N	P=0.500N	P=0.517
POLY 1.5	P=0.296	P=0.505N	P=0.500N	P=0.510
POLY 6	P=0.315	P=0.516N	P=0.499N	P=0.526
COCH-ARM / FISHERS	P=0.285	P=0.500N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.200	P=0.290N	P=0.280N	P=0.340

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Salivary Glands  
 Infiltration Cellular Lymphocyte**

**LESION RATES**

OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/47.67	1/46.42	2/47.71	1/48.96
POLY-3 PERCENT (g)	2.1%	2.2%	4.2%	2%
TERMINAL (d)	1/43 (2%)	1/38 (3%)	2/45 (4%)	1/45 (2%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.627N	P=0.755	P=0.500	P=0.754N
POLY 1.5	P=0.633N	P=0.757	P=0.500	P=0.757N
POLY 6	P=0.619N	P=0.750	P=0.501	P=0.752N
COCH-ARM / FISHERS	P=0.642N	P=0.753N	P=0.500	P=0.753N
MAX-ISO-POLY-3	P=0.378	P=0.491	P=0.281	P=0.491N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Spleen  
 Atrophy**

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/49 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/47.67	2/46.21	1/47.71	0/48.96
POLY-3 PERCENT (g)	0%	4.3%	2.1%	0%
TERMINAL (d)	0/43 (0%)	0/38 (0%)	1/45 (2%)	0/45 (0%)
FIRST INCIDENCE	---	636	729 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.378N	P=0.230	P=0.500	(e)
POLY 1.5	P=0.381N	P=0.232	P=0.500	(e)
POLY 6	P=0.375N	P=0.228	P=0.501	(e)
COCH-ARM / FISHERS	P=0.385N	P=0.242	P=0.500	(e)
MAX-ISO-POLY-3	P=0.201N	P=0.074	P=0.158	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Spleen  
 Hematopoietic Cell Proliferation**

**LESION RATES**

OVERALL (a)	23/50 (46%)	33/49 (67%)	27/50 (54%)	20/50 (40%)
POLY-3 RATE (b)	23/48.87	33/48.58	27/49.46	20/50.00
POLY-3 PERCENT (g)	47.1%	67.9%	54.6%	40%
TERMINAL (d)	19/43 (44%)	24/38 (63%)	23/45 (51%)	15/45 (33%)
FIRST INCIDENCE	550	555	551	596

**STATISTICAL TESTS**

POLY 3	P=0.044N*	P=0.028*	P=0.294	P=0.308N
POLY 1.5	P=0.049N*	P=0.027*	P=0.286	P=0.322N
POLY 6	P=0.038N*	P=0.029*	P=0.304	P=0.290N
COCH-ARM / FISHERS	P=0.060N	P=0.026*	P=0.274	P=0.343N
MAX-ISO-POLY-3	P=0.040N*	P=0.017*	P=0.229	P=0.243N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Spleen  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	2/50 (4%)	0/49 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/47.67	0/45.79	0/47.71	1/48.96
POLY-3 PERCENT (g)	4.2%	0%	0%	2%
TERMINAL (d)	2/43 (5%)	0/38 (0%)	0/45 (0%)	1/45 (2%)
FIRST INCIDENCE	729 (T)	---	---	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.615N	P=0.246N	P=0.237N	P=0.491N
POLY 1.5	P=0.618N	P=0.244N	P=0.237N	P=0.494N
POLY 6	P=0.611N	P=0.250N	P=0.236N	P=0.486N
COCH-ARM / FISHERS	P=0.622N	P=0.253N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.085N	P=0.083N	P=0.075N	P=0.275N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Spleen: Lymphoid Follicle  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	4/50 (8%)	3/49 (6%)	4/50 (8%)	3/50 (6%)
POLY-3 RATE (b)	4/47.67	3/45.79	4/47.71	3/49.32
POLY-3 PERCENT (g)	8.4%	6.6%	8.4%	6.1%
TERMINAL (d)	4/43 (9%)	3/38 (8%)	4/45 (9%)	2/45 (4%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	631

**STATISTICAL TESTS**

POLY 3	P=0.451N	P=0.522N	P=0.642N	P=0.482N
POLY 1.5	P=0.463N	P=0.517N	P=0.643N	P=0.489N
POLY 6	P=0.436N	P=0.530N	P=0.641N	P=0.472N
COCH-ARM / FISHERS	P=0.478N	P=0.511N	P=0.643N	P=0.500N
MAX-ISO-POLY-3	P=0.332N	P=0.368N	P=0.498N	P=0.332N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Stomach, Forestomach  
 Cyst**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.67	0/46.42	0/47.71	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	---	---	---	---

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Stomach, Forestomach  
 Ulcer**

**LESION RATES**

OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/47.67	2/46.98	0/47.71	0/48.96
POLY-3 PERCENT (g)	2.1%	4.3%	0%	0%
TERMINAL (d)	1/43 (2%)	1/38 (3%)	0/45 (0%)	0/45 (0%)
FIRST INCIDENCE	729 (T)	555	---	---

**STATISTICAL TESTS**

POLY 3	P=0.201N	P=0.495	P=0.500N	P=0.495N
POLY 1.5	P=0.202N	P=0.498	P=0.500N	P=0.497N
POLY 6	P=0.200N	P=0.490	P=0.499N	P=0.492N
COCH-ARM / FISHERS	P=0.204N	P=0.500	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.106N	P=0.277	P=0.158N	P=0.158N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Stomach, Forestomach: Epithelium  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	3/50 (6%)	5/50 (10%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	3/48.34	5/47.00	3/48.25	2/48.96
POLY-3 PERCENT (g)	6.2%	10.6%	6.2%	4.1%
TERMINAL (d)	1/43 (2%)	3/38 (8%)	2/45 (4%)	2/45 (4%)
FIRST INCIDENCE	550	625	563	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.265N	P=0.342	P=0.661	P=0.494N
POLY 1.5	P=0.269N	P=0.349	P=0.661	P=0.496N
POLY 6	P=0.260N	P=0.332	P=0.661	P=0.492N
COCH-ARM / FISHERS	P=0.274N	P=0.357	P=0.661N	P=0.500N
MAX-ISO-POLY-3	P=0.199N	P=0.222	P=0.498	P=0.318N



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Stomach, Glandular  
 Cyst**

**LESION RATES**

OVERALL (a)	0/50 (0%)	5/50 (10%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	0/47.67	5/46.79	3/47.71	1/48.96
POLY-3 PERCENT (g)	0%	10.7%	6.3%	2%
TERMINAL (d)	0/43 (0%)	4/38 (11%)	3/45 (7%)	1/45 (2%)
FIRST INCIDENCE	---	624	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.370N	P=0.029*	P=0.119	P=0.505
POLY 1.5	P=0.376N	P=0.030*	P=0.119	P=0.503
POLY 6	P=0.363N	P=0.028*	P=0.119	P=0.508
COCH-ARM / FISHERS	P=0.385N	P=0.028*	P=0.121	P=0.500
MAX-ISO-POLY-3	P=0.072	P=0.010**	P=0.038*	P=0.165

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Stomach, Glandular  
 Erosion**

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	4/50 (8%)
POLY-3 RATE (b)	1/48.02	0/46.42	0/47.71	4/49.20
POLY-3 PERCENT (g)	2.1%	0%	0%	8.1%
TERMINAL (d)	0/43 (0%)	0/38 (0%)	0/45 (0%)	1/45 (2%)
FIRST INCIDENCE	632	---	---	697

**STATISTICAL TESTS**

POLY 3	P=0.016*	P=0.507N	P=0.501N	P=0.187
POLY 1.5	P=0.016*	P=0.504N	P=0.501N	P=0.184
POLY 6	P=0.017*	P=0.512N	P=0.502N	P=0.190
COCH-ARM / FISHERS	P=0.016*	P=0.500N	P=0.500N	P=0.181
MAX-ISO-POLY-3	P=0.010**	P=0.167N	P=0.160N	P=0.090

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Testes: Germinal Epithelium  
 Atrophy

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	5/50 (10%)	2/50 (4%)
POLY-3 RATE (b)	1/47.67	0/46.42	5/47.71	2/48.96
POLY-3 PERCENT (g)	2.1%	0%	10.5%	4.1%
TERMINAL (d)	1/43 (2%)	0/38 (0%)	5/45 (11%)	2/45 (4%)
FIRST INCIDENCE	729 (T)	---	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.338	P=0.505N	P=0.102	P=0.509
POLY 1.5	P=0.327	P=0.503N	P=0.102	P=0.506
POLY 6	P=0.353	P=0.509N	P=0.102	P=0.514
COCH-ARM / FISHERS	P=0.314	P=0.500N	P=0.102	P=0.500
MAX-ISO-POLY-3	P=0.064	P=0.165N	P=0.045*	P=0.290

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thymus  
 Atrophy**

**LESION RATES**

OVERALL (a)	3/44 (7%)	8/39 (21%)	1/43 (2%)	2/41 (5%)
POLY-3 RATE (b)	3/43.90	8/38.29	1/41.32	2/40.52
POLY-3 PERCENT (g)	6.8%	20.9%	2.4%	4.9%
TERMINAL (d)	1/41 (2%)	3/32 (9%)	1/40 (3%)	1/38 (3%)
FIRST INCIDENCE	496	555	729 (T)	710

**STATISTICAL TESTS**

POLY 3	P=0.138N	P=0.060	P=0.327N	P=0.536N
POLY 1.5	P=0.137N	P=0.061	P=0.322N	P=0.534N
POLY 6	P=0.141N	P=0.057	P=0.333N	P=0.539N
COCH-ARM / FISHERS	P=0.140N	P=0.065	P=0.317N	P=0.534N
MAX-ISO-POLY-3	P=0.054N	P=0.034*	P=0.175N	P=0.358N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
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 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thymus  
 Cyst**

**LESION RATES**

OVERALL (a)	0/44 (0%)	0/39 (0%)	2/43 (5%)	0/41 (0%)
POLY-3 RATE (b)	0/42.65	0/36.88	2/41.32	0/40.45
POLY-3 PERCENT (g)	0%	0%	4.8%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	2/40 (5%)	0/38 (0%)
FIRST INCIDENCE	---	---	729 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.708N	(e)	P=0.230	(e)
POLY 1.5	P=0.711N	(e)	P=0.231	(e)
POLY 6	P=0.704N	(e)	P=0.229	(e)
COCH-ARM / FISHERS	P=0.715N	(e)	P=0.241	(e)
MAX-ISO-POLY-3	P=0.156	(e)	P=0.074	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thymus  
 Hyperplasia Lymphoid**

**LESION RATES**

OVERALL (a)	0/44 (0%)	1/39 (3%)	0/43 (0%)	0/41 (0%)
POLY-3 RATE (b)	0/42.65	1/36.88	0/41.32	0/40.45
POLY-3 PERCENT (g)	0%	2.7%	0%	0%
TERMINAL (d)	0/41 (0%)	1/32 (3%)	0/40 (0%)	0/38 (0%)
FIRST INCIDENCE	---	729 (T)	---	---

**STATISTICAL TESTS**

POLY 3	P=0.579N	P=0.471	(e)	(e)
POLY 1.5	P=0.577N	P=0.474	(e)	(e)
POLY 6	P=0.582N	P=0.466	(e)	(e)
COCH-ARM / FISHERS	P=0.576N	P=0.470	(e)	(e)
MAX-ISO-POLY-3	P=0.233N	P=0.150	(e)	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thyroid Gland: Follicle  
 Cyst**

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	0/47.67	2/46.52	4/47.71	0/48.96
POLY-3 PERCENT (g)	0%	4.3%	8.4%	0%
TERMINAL (d)	0/43 (0%)	1/38 (3%)	4/45 (9%)	0/45 (0%)
FIRST INCIDENCE	---	703	729 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.387N	P=0.232	P=0.061	(e)
POLY 1.5	P=0.395N	P=0.234	P=0.061	(e)
POLY 6	P=0.377N	P=0.228	P=0.061	(e)
COCH-ARM / FISHERS	P=0.407N	P=0.247	P=0.059	(e)
MAX-ISO-POLY-3	P=0.115N	P=0.075	P=0.019*	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
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 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Thyroid Gland: Follicle  
 Degeneration Focal**

**LESION RATES**

OVERALL (a)	5/50 (10%)	6/50 (12%)	6/50 (12%)	4/50 (8%)
POLY-3 RATE (b)	5/48.02	6/47.33	6/47.71	4/48.96
POLY-3 PERCENT (g)	10.4%	12.7%	12.6%	8.2%
TERMINAL (d)	4/43 (9%)	4/38 (11%)	6/45 (13%)	4/45 (9%)
FIRST INCIDENCE	632	563	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.349N	P=0.490	P=0.496	P=0.488N
POLY 1.5	P=0.356N	P=0.495	P=0.497	P=0.493N
POLY 6	P=0.339N	P=0.480	P=0.494	P=0.483N
COCH-ARM / FISHERS	P=0.367N	P=0.500	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.281N	P=0.364	P=0.369	P=0.352N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

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**Urinary Bladder  
 Infiltration Cellular Lymphocyte**

**LESION RATES**

OVERALL (a)	0/49 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/46.86	1/46.42	1/47.71	1/48.96
POLY-3 PERCENT (g)	0%	2.2%	2.1%	2%
TERMINAL (d)	0/43 (0%)	1/38 (3%)	1/45 (2%)	1/45 (2%)
FIRST INCIDENCE	---	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.485	P=0.498	P=0.504	P=0.509
POLY 1.5	P=0.480	P=0.501	P=0.504	P=0.507
POLY 6	P=0.490	P=0.494	P=0.504	P=0.511
COCH-ARM / FISHERS	P=0.473	P=0.505	P=0.505	P=0.505
MAX-ISO-POLY-3	P=0.209	P=0.159	P=0.161	P=0.168

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex  
 Degeneration Cystic**

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	2/48 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/47.86	0/47.56	2/44.67	1/46.86
POLY-3 PERCENT (g)	2.1%	0%	4.5%	2.1%
TERMINAL (d)	1/45 (2%)	0/44 (0%)	2/36 (6%)	1/43 (2%)
FIRST INCIDENCE	729 (T)	---	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.533	P=0.501N	P=0.476	P=0.756
POLY 1.5	P=0.536	P=0.501N	P=0.480	P=0.757
POLY 6	P=0.531	P=0.501N	P=0.470	P=0.755
COCH-ARM / FISHERS	P=0.542	P=0.500N	P=0.485	P=0.753N
MAX-ISO-POLY-3	P=0.373	P=0.160N	P=0.265	P=0.493

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Adrenal Cortex  
 Hypertrophy**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/48 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.86	0/47.56	0/44.67	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	---	---	---	---

**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)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex  
 Hypertrophy Focal**

**LESION RATES**

OVERALL (a)	1/50 (2%)	1/50 (2%)	0/48 (0%)	4/50 (8%)
POLY-3 RATE (b)	1/47.86	1/47.56	0/44.67	4/46.86
POLY-3 PERCENT (g)	2.1%	2.1%	0%	8.5%
TERMINAL (d)	1/45 (2%)	1/44 (2%)	0/36 (0%)	4/43 (9%)
FIRST INCIDENCE	729 (T)	729 (T)	---	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.043*	P=0.759	P=0.514N	P=0.173
POLY 1.5	P=0.044*	P=0.759	P=0.512N	P=0.174
POLY 6	P=0.043*	P=0.760	P=0.517N	P=0.171
COCH-ARM / FISHERS	P=0.046*	P=0.753N	P=0.510N	P=0.181
MAX-ISO-POLY-3	P=0.040*	P=0.497	P=0.173N	P=0.082

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex: Capsule  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	49/50 (98%)	50/50 (100%)	47/48 (98%)	49/50 (98%)
POLY-3 RATE (b)	49/49.36	50/50.00	47/47.80	49/49.86
POLY-3 PERCENT (g)	99.3%	100%	98.3%	98.3%
TERMINAL (d)	45/45 (100%)	44/44 (100%)	36/36 (100%)	43/43 (100%)
FIRST INCIDENCE	535	428	359	307

**STATISTICAL TESTS**

POLY 3	P=0.435N	P=0.964	P=0.728N	P=0.706N
POLY 1.5	P=0.477N	P=0.749	P=0.734N	P=0.730N
POLY 6	P=0.411N	P=1.000	P=0.764N	P=0.704N
COCH-ARM / FISHERS	P=0.542N	P=0.500	P=0.742N	P=0.753N
MAX-ISO-POLY-3	P=0.359N	P=0.160	P=0.300N	P=0.298N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Medulla  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	1/50 (2%)	2/50 (4%)	2/49 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/47.86	2/47.56	2/45.32	0/46.86
POLY-3 PERCENT (g)	2.1%	4.2%	4.4%	0%
TERMINAL (d)	1/45 (2%)	2/44 (5%)	2/36 (6%)	0/43 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.259N	P=0.498	P=0.481	P=0.504N
POLY 1.5	P=0.258N	P=0.498	P=0.486	P=0.503N
POLY 6	P=0.261N	P=0.499	P=0.473	P=0.505N
COCH-ARM / FISHERS	P=0.252N	P=0.500	P=0.492	P=0.500N
MAX-ISO-POLY-3	P=0.234N	P=0.280	P=0.269	P=0.164N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Bone Marrow  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	2/49 (4%)	2/50 (4%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/47.93	2/47.82	1/45.43	2/47.40
POLY-3 PERCENT (g)	4.2%	4.2%	2.2%	4.2%
TERMINAL (d)	1/45 (2%)	0/44 (0%)	0/36 (0%)	1/43 (2%)
FIRST INCIDENCE	604	696	703	563

**STATISTICAL TESTS**

POLY 3	P=0.617	P=0.693	P=0.519N	P=0.690
POLY 1.5	P=0.619	P=0.692N	P=0.511N	P=0.693
POLY 6	P=0.614	P=0.692	P=0.529N	P=0.687
COCH-ARM / FISHERS	P=0.624N	P=0.684N	P=0.492N	P=0.684N
MAX-ISO-POLY-3	P=0.629N	P=0.498	P=0.302N	P=0.495

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS 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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**Bone Marrow  
 Myelofibrosis**

**LESION RATES**

OVERALL (a)	6/49 (12%)	1/50 (2%)	5/50 (10%)	5/50 (10%)
POLY-3 RATE (b)	6/47.50	1/47.56	5/45.32	5/46.86
POLY-3 PERCENT (g)	12.6%	2.1%	11%	10.7%
TERMINAL (d)	6/45 (13%)	1/44 (2%)	5/36 (14%)	5/43 (12%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.413	P=0.056N	P=0.533N	P=0.509N
POLY 1.5	P=0.418	P=0.055N	P=0.520N	P=0.502N
POLY 6	P=0.407	P=0.056N	P=0.552N	P=0.515N
COCH-ARM / FISHERS	P=0.427	P=0.053N	P=0.486N	P=0.486N
MAX-ISO-POLY-3	P=0.344N	P=0.024N*	P=0.407N	P=0.384N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
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 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS 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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**Clitoral Gland  
 Cyst**

**LESION RATES**

OVERALL (a)	2/50 (4%)	3/50 (6%)	4/49 (8%)	0/50 (0%)
POLY-3 RATE (b)	2/47.86	3/47.56	4/45.32	0/46.86
POLY-3 PERCENT (g)	4.2%	6.3%	8.8%	0%
TERMINAL (d)	2/45 (4%)	3/44 (7%)	4/36 (11%)	0/43 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.149N	P=0.497	P=0.313	P=0.242N
POLY 1.5	P=0.147N	P=0.497	P=0.319	P=0.241N
POLY 6	P=0.151N	P=0.499	P=0.302	P=0.243N
COCH-ARM / FISHERS	P=0.143N	P=0.500	P=0.329	P=0.247N
MAX-ISO-POLY-3	P=0.118N	P=0.322	P=0.187	P=0.081N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS 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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**Harderian Gland  
 Hyperplasia Focal**

**LESION RATES**

OVERALL (a)	5/50 (10%)	2/49 (4%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	5/47.86	2/46.60	4/45.32	2/46.86
POLY-3 PERCENT (g)	10.5%	4.3%	8.8%	4.3%
TERMINAL (d)	5/45 (11%)	2/44 (5%)	4/36 (11%)	2/43 (5%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.278N	P=0.228N	P=0.534N	P=0.225N
POLY 1.5	P=0.276N	P=0.228N	P=0.525N	P=0.223N
POLY 6	P=0.281N	P=0.226N	P=0.548N	P=0.227N
COCH-ARM / FISHERS	P=0.270N	P=0.226N	P=0.500N	P=0.218N
MAX-ISO-POLY-3	P=0.196N	P=0.129N	P=0.397N	P=0.128N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Heart  
 Cardiomyopathy**

**LESION RATES**

OVERALL (a)	39/50 (78%)	38/50 (76%)	37/50 (74%)	33/50 (66%)
POLY-3 RATE (b)	39/47.94	38/47.82	37/45.98	33/47.50
POLY-3 PERCENT (g)	81.4%	79.5%	80.5%	69.5%
TERMINAL (d)	38/45 (84%)	36/44 (82%)	33/36 (92%)	32/43 (74%)
FIRST INCIDENCE	709	696	633	521

**STATISTICAL TESTS**

POLY 3	P=0.079N	P=0.510N	P=0.564N	P=0.126N
POLY 1.5	P=0.085N	P=0.515N	P=0.529N	P=0.132N
POLY 6	P=0.075N	P=0.483N	P=0.609	P=0.119N
COCH-ARM / FISHERS	P=0.093N	P=0.500N	P=0.408N	P=0.133N
MAX-ISO-POLY-3	P=0.119N	P=0.404N	P=0.454N	P=0.083N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Intestine Small, Jejunum  
 Hyperplasia Lymphoid**

**LESION RATES**

OVERALL (a)	0/48 (0%)	1/46 (2%)	2/43 (5%)	0/48 (0%)
POLY-3 RATE (b)	0/46.50	1/45.74	2/40.89	0/45.14
POLY-3 PERCENT (g)	0%	2.2%	4.9%	0%
TERMINAL (d)	0/44 (0%)	1/44 (2%)	2/36 (6%)	0/43 (0%)
FIRST INCIDENCE	---	729 (T)	729 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.538N	P=0.497	P=0.209	(e)
POLY 1.5	P=0.534N	P=0.495	P=0.210	(e)
POLY 6	P=0.541N	P=0.499	P=0.207	(e)
COCH-ARM / FISHERS	P=0.524N	P=0.489	P=0.221	(e)
MAX-ISO-POLY-3	P=0.322	P=0.157	P=0.070	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
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 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Islets, Pancreatic  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	4/48 (8%)	2/49 (4%)	1/48 (2%)	1/50 (2%)
POLY-3 RATE (b)	4/46.50	2/47.99	1/44.80	1/46.86
POLY-3 PERCENT (g)	8.6%	4.2%	2.2%	2.1%
TERMINAL (d)	4/44 (9%)	1/44 (2%)	0/36 (0%)	1/43 (2%)
FIRST INCIDENCE	729 (T)	522	654	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.166N	P=0.323N	P=0.190N	P=0.177N
POLY 1.5	P=0.163N	P=0.326N	P=0.186N	P=0.174N
POLY 6	P=0.169N	P=0.320N	P=0.196N	P=0.179N
COCH-ARM / FISHERS	P=0.158N	P=0.329N	P=0.181N	P=0.168N
MAX-ISO-POLY-3	P=0.101N	P=0.192N	P=0.095N	P=0.084N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Kidney  
 Casts Protein**

**LESION RATES**

OVERALL (a)	2/50 (4%)	0/49 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/47.86	0/47.36	1/45.32	0/46.86
POLY-3 PERCENT (g)	4.2%	0%	2.2%	0%
TERMINAL (d)	2/45 (4%)	0/44 (0%)	1/36 (3%)	0/43 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.262N	P=0.240N	P=0.519N	P=0.242N
POLY 1.5	P=0.261N	P=0.241N	P=0.514N	P=0.241N
POLY 6	P=0.264N	P=0.238N	P=0.527N	P=0.243N
COCH-ARM / FISHERS	P=0.257N	P=0.253N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.086N	P=0.077N	P=0.302N	P=0.081N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Kidney  
 Cyst**

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/47.86	0/47.36	0/45.32	0/46.86
POLY-3 PERCENT (g)	2.1%	0%	0%	0%
TERMINAL (d)	1/45 (2%)	0/44 (0%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	729 (T)	---	---	---

**STATISTICAL TESTS**

POLY 3	P=0.448N	P=0.502N	P=0.511N	P=0.504N
POLY 1.5	P=0.447N	P=0.503N	P=0.508N	P=0.503N
POLY 6	P=0.448N	P=0.501N	P=0.515N	P=0.505N
COCH-ARM / FISHERS	P=0.447N	P=0.505N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.134N	P=0.160N	P=0.172N	P=0.164N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Kidney  
 Hydronephrosis**

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/49 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.86	1/47.36	0/45.32	0/46.86
POLY-3 PERCENT (g)	0%	2.1%	0%	0%
TERMINAL (d)	0/45 (0%)	1/44 (2%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	---	729 (T)	---	---

**STATISTICAL TESTS**

POLY 3	P=0.570N	P=0.498	(e)	(e)
POLY 1.5	P=0.570N	P=0.497	(e)	(e)
POLY 6	P=0.569N	P=0.499	(e)	(e)
COCH-ARM / FISHERS	P=0.571N	P=0.495	(e)	(e)
MAX-ISO-POLY-3	P=0.395N	P=0.157	(e)	(e)



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Kidney  
 Infarct**

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/49 (2%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	0/47.86	1/47.36	3/45.32	0/46.86
POLY-3 PERCENT (g)	0%	2.1%	6.6%	0%
TERMINAL (d)	0/45 (0%)	1/44 (2%)	3/36 (8%)	0/43 (0%)
FIRST INCIDENCE	---	729 (T)	729 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.530N	P=0.498	P=0.109	(e)
POLY 1.5	P=0.527N	P=0.497	P=0.112	(e)
POLY 6	P=0.533N	P=0.499	P=0.105	(e)
COCH-ARM / FISHERS	P=0.518N	P=0.495	P=0.121	(e)
MAX-ISO-POLY-3	P=0.222	P=0.157	P=0.038*	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Kidney  
 Infiltration Cellular Lymphocyte**

**LESION RATES**

OVERALL (a)	7/50 (14%)	7/49 (14%)	4/50 (8%)	9/50 (18%)
POLY-3 RATE (b)	7/48.29	7/47.40	4/45.36	9/46.86
POLY-3 PERCENT (g)	14.5%	14.8%	8.8%	19.2%
TERMINAL (d)	6/45 (13%)	6/44 (14%)	3/36 (8%)	9/43 (21%)
FIRST INCIDENCE	604	719	719	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.287	P=0.598	P=0.298N	P=0.368
POLY 1.5	P=0.294	P=0.597	P=0.288N	P=0.376
POLY 6	P=0.279	P=0.600	P=0.315N	P=0.360
COCH-ARM / FISHERS	P=0.308	P=0.597	P=0.262N	P=0.393
MAX-ISO-POLY-3	P=0.306	P=0.484	P=0.206N	P=0.274

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Kidney  
 Metaplasia Osseous**

**LESION RATES**

OVERALL (a)	1/50 (2%)	1/49 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/47.86	1/47.36	1/45.32	0/46.86
POLY-3 PERCENT (g)	2.1%	2.1%	2.2%	0%
TERMINAL (d)	1/45 (2%)	1/44 (2%)	1/36 (3%)	0/43 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.325N	P=0.758	P=0.748	P=0.504N
POLY 1.5	P=0.323N	P=0.757	P=0.751	P=0.503N
POLY 6	P=0.326N	P=0.760	P=0.743	P=0.505N
COCH-ARM / FISHERS	P=0.318N	P=0.747	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.337N	P=0.496	P=0.484	P=0.164N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Kidney  
 Nephropathy**

**LESION RATES**

OVERALL (a)	13/50 (26%)	19/49 (39%)	15/50 (30%)	15/50 (30%)
POLY-3 RATE (b)	13/48.29	19/47.36	15/45.36	15/46.86
POLY-3 PERCENT (g)	26.9%	40.1%	33.1%	32%
TERMINAL (d)	12/45 (27%)	19/44 (43%)	14/36 (39%)	15/43 (35%)
FIRST INCIDENCE	604	729 (T)	719	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.544N	P=0.124	P=0.336	P=0.375
POLY 1.5	P=0.529N	P=0.124	P=0.358	P=0.387
POLY 6	P=0.542	P=0.124	P=0.304	P=0.364
COCH-ARM / FISHERS	P=0.497N	P=0.126	P=0.412	P=0.412
MAX-ISO-POLY-3	P=0.326	P=0.086	P=0.265	P=0.297

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Kidney: Renal Tubule  
 Accumulation, Hyaline Droplet**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/47.86	0/47.36	0/45.32	2/47.50
POLY-3 PERCENT (g)	0%	0%	0%	4.2%
TERMINAL (d)	0/45 (0%)	0/44 (0%)	0/36 (0%)	1/43 (2%)
FIRST INCIDENCE	---	---	---	521

**STATISTICAL TESTS**

POLY 3	P=0.041*	(e)	(e)	P=0.236
POLY 1.5	P=0.041*	(e)	(e)	P=0.236
POLY 6	P=0.041*	(e)	(e)	P=0.236
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.035*	(e)	(e)	P=0.076

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Kidney: Renal Tubule  
 Pigmentation**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.86	0/47.36	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	---	---	---	---

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Liver  
 Basophilic Focus

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	3/49 (6%)	1/50 (2%)
POLY-3 RATE (b)	1/47.86	0/47.56	3/44.52	1/46.86
POLY-3 PERCENT (g)	2.1%	0%	6.7%	2.1%
TERMINAL (d)	1/45 (2%)	0/44 (0%)	3/36 (8%)	1/43 (2%)
FIRST INCIDENCE	729 (T)	---	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.532	P=0.501N	P=0.280	P=0.756
POLY 1.5	P=0.535	P=0.501N	P=0.284	P=0.757
POLY 6	P=0.529	P=0.501N	P=0.273	P=0.755
COCH-ARM / FISHERS	P=0.542	P=0.500N	P=0.301	P=0.753N
MAX-ISO-POLY-3	P=0.258	P=0.160N	P=0.144	P=0.493

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Liver  
 Clear Cell Focus

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/49 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/47.86	2/47.56	0/44.52	2/46.86
POLY-3 PERCENT (g)	0%	4.2%	0%	4.3%
TERMINAL (d)	0/45 (0%)	2/44 (5%)	0/36 (0%)	2/43 (5%)
FIRST INCIDENCE	---	729 (T)	---	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.277	P=0.236	(e)	P=0.233
POLY 1.5	P=0.279	P=0.236	(e)	P=0.234
POLY 6	P=0.276	P=0.237	(e)	P=0.232
COCH-ARM / FISHERS	P=0.283	P=0.247	(e)	P=0.247
MAX-ISO-POLY-3	P=0.123	P=0.076	(e)	P=0.076

---



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Liver  
 Cyst

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/49 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/47.86	0/47.56	1/44.52	2/46.86
POLY-3 PERCENT (g)	0%	0%	2.3%	4.3%
TERMINAL (d)	0/45 (0%)	0/44 (0%)	1/36 (3%)	2/43 (5%)
FIRST INCIDENCE	---	---	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.079	(e)	P=0.486	P=0.233
POLY 1.5	P=0.079	(e)	P=0.488	P=0.234
POLY 6	P=0.078	(e)	P=0.482	P=0.232
COCH-ARM / FISHERS	P=0.081	(e)	P=0.495	P=0.247
MAX-ISO-POLY-3	P=0.080	(e)	P=0.157	P=0.076

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Liver  
 Eosinophilic Focus

**LESION RATES**

OVERALL (a)	3/50 (6%)	3/50 (6%)	2/49 (4%)	4/50 (8%)
POLY-3 RATE (b)	3/47.86	3/47.69	2/44.52	4/46.86
POLY-3 PERCENT (g)	6.3%	6.3%	4.5%	8.5%
TERMINAL (d)	3/45 (7%)	2/44 (5%)	2/36 (6%)	4/43 (9%)
FIRST INCIDENCE	729 (T)	696	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.393	P=0.660	P=0.533N	P=0.489
POLY 1.5	P=0.396	P=0.660	P=0.527N	P=0.491
POLY 6	P=0.390	P=0.661N	P=0.542N	P=0.487
COCH-ARM / FISHERS	P=0.403	P=0.661N	P=0.510N	P=0.500
MAX-ISO-POLY-3	P=0.466	P=0.497	P=0.357N	P=0.339

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Liver  
 Hematopoietic Cell Proliferation**

**LESION RATES**

OVERALL (a)	3/50 (6%)	2/50 (4%)	2/49 (4%)	1/50 (2%)
POLY-3 RATE (b)	3/47.94	2/47.73	2/44.56	1/46.86
POLY-3 PERCENT (g)	6.3%	4.2%	4.5%	2.1%
TERMINAL (d)	2/45 (4%)	0/44 (0%)	1/36 (3%)	1/43 (2%)
FIRST INCIDENCE	709	696	719	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.271N	P=0.502N	P=0.533N	P=0.314N
POLY 1.5	P=0.269N	P=0.502N	P=0.527N	P=0.312N
POLY 6	P=0.274N	P=0.500N	P=0.542N	P=0.316N
COCH-ARM / FISHERS	P=0.263N	P=0.500N	P=0.510N	P=0.309N
MAX-ISO-POLY-3	P=0.266N	P=0.326N	P=0.358N	P=0.163N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver  
 Infiltration Cellular Lymphocyte

**LESION RATES**

OVERALL (a)	24/50 (48%)	24/50 (48%)	26/49 (53%)	21/50 (42%)
POLY-3 RATE (b)	24/48.29	24/47.56	26/45.44	21/47.00
POLY-3 PERCENT (g)	49.7%	50.5%	57.2%	44.7%
TERMINAL (d)	23/45 (51%)	24/44 (55%)	24/36 (67%)	20/43 (47%)
FIRST INCIDENCE	604	729 (T)	359	695

**STATISTICAL TESTS**

POLY 3	P=0.315N	P=0.552	P=0.300	P=0.388N
POLY 1.5	P=0.305N	P=0.559	P=0.322	P=0.375N
POLY 6	P=0.325N	P=0.548	P=0.258	P=0.399N
COCH-ARM / FISHERS	P=0.279N	P=0.579N	P=0.381	P=0.344N
MAX-ISO-POLY-3	P=0.369N	P=0.469	P=0.237	P=0.314N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Liver  
 Infiltration Cellular Mixed Cell

**LESION RATES**

OVERALL (a)	7/50 (14%)	9/50 (18%)	10/49 (20%)	6/50 (12%)
POLY-3 RATE (b)	7/47.86	9/47.56	10/44.52	6/46.86
POLY-3 PERCENT (g)	14.6%	18.9%	22.5%	12.8%
TERMINAL (d)	7/45 (16%)	9/44 (21%)	10/36 (28%)	6/43 (14%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.356N	P=0.387	P=0.242	P=0.516N
POLY 1.5	P=0.351N	P=0.388	P=0.252	P=0.512N
POLY 6	P=0.360N	P=0.390	P=0.227	P=0.519N
COCH-ARM / FISHERS	P=0.337N	P=0.393	P=0.282	P=0.500N
MAX-ISO-POLY-3	P=0.373N	P=0.289	P=0.174	P=0.398N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver  
 Mixed Cell Focus

**LESION RATES**

OVERALL (a)	0/50 (0%)	3/50 (6%)	2/49 (4%)	4/50 (8%)
POLY-3 RATE (b)	0/47.86	3/47.56	2/44.52	4/46.86
POLY-3 PERCENT (g)	0%	6.3%	4.5%	8.5%
TERMINAL (d)	0/45 (0%)	3/44 (7%)	2/36 (6%)	4/43 (9%)
FIRST INCIDENCE	---	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.098	P=0.118	P=0.221	P=0.058
POLY 1.5	P=0.100	P=0.118	P=0.224	P=0.059
POLY 6	P=0.097	P=0.118	P=0.217	P=0.057
COCH-ARM / FISHERS	P=0.104	P=0.121	P=0.242	P=0.059
MAX-ISO-POLY-3	P=0.043*	P=0.038*	P=0.075	P=0.019*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver  
 Necrosis Focal

**LESION RATES**

OVERALL (a)	1/50 (2%)	1/50 (2%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/47.86	1/47.56	0/44.52	0/46.86
POLY-3 PERCENT (g)	2.1%	2.1%	0%	0%
TERMINAL (d)	1/45 (2%)	1/44 (2%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---	---

**STATISTICAL TESTS**

POLY 3	P=0.293N	P=0.759	P=0.514N	P=0.504N
POLY 1.5	P=0.293N	P=0.759	P=0.512N	P=0.503N
POLY 6	P=0.293N	P=0.760	P=0.518N	P=0.505N
COCH-ARM / FISHERS	P=0.291N	P=0.753N	P=0.505N	P=0.500N
MAX-ISO-POLY-3	P=0.265N	P=0.497	P=0.175N	P=0.164N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver  
 Tension Lipidosis

**LESION RATES**

OVERALL (a)	3/50 (6%)	1/50 (2%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/47.86	1/47.56	0/44.52	0/46.86
POLY-3 PERCENT (g)	6.3%	2.1%	0%	0%
TERMINAL (d)	3/45 (7%)	1/44 (2%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---	---

**STATISTICAL TESTS**

POLY 3	P=0.087N	P=0.308N	P=0.132N	P=0.123N
POLY 1.5	P=0.086N	P=0.308N	P=0.130N	P=0.122N
POLY 6	P=0.087N	P=0.307N	P=0.136N	P=0.123N
COCH-ARM / FISHERS	P=0.087N	P=0.309N	P=0.125N	P=0.121N
MAX-ISO-POLY-3	P=0.028N*	P=0.157N	P=0.049N*	P=0.041N*



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver: Hepatocyte  
 Vacuolization Cytoplasmic

**LESION RATES**

OVERALL (a)	1/50 (2%)	3/50 (6%)	7/49 (14%)	4/50 (8%)
POLY-3 RATE (b)	1/47.86	3/48.19	7/46.89	4/47.58
POLY-3 PERCENT (g)	2.1%	6.2%	14.9%	8.4%
TERMINAL (d)	1/45 (2%)	2/44 (5%)	1/36 (3%)	2/43 (5%)
FIRST INCIDENCE	729 (T)	522	359	544

**STATISTICAL TESTS**

POLY 3	P=0.235	P=0.308	P=0.028*	P=0.177
POLY 1.5	P=0.235	P=0.306	P=0.027*	P=0.177
POLY 6	P=0.236	P=0.311	P=0.028*	P=0.179
COCH-ARM / FISHERS	P=0.242	P=0.309	P=0.028*	P=0.181
MAX-ISO-POLY-3	P=0.067	P=0.157	P=0.011*	P=0.083

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS 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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Liver: Kupffer Cell  
 Pigmentation

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/47.86	0/47.56	0/44.52	1/46.86
POLY-3 PERCENT (g)	0%	0%	0%	2.1%
TERMINAL (d)	0/45 (0%)	0/44 (0%)	0/36 (0%)	1/43 (2%)
FIRST INCIDENCE	---	---	---	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.209	(e)	(e)	P=0.496
POLY 1.5	P=0.210	(e)	(e)	P=0.497
POLY 6	P=0.208	(e)	(e)	P=0.495
COCH-ARM / FISHERS	P=0.211	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.127	(e)	(e)	P=0.159

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lung  
 Hemorrhage**

**LESION RATES**

OVERALL (a)	2/50 (4%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/48.46	0/47.56	2/45.32	1/46.86
POLY-3 PERCENT (g)	4.1%	0%	4.4%	2.1%
TERMINAL (d)	1/45 (2%)	0/44 (0%)	2/36 (6%)	1/43 (2%)
FIRST INCIDENCE	535	---	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.594N	P=0.242N	P=0.669	P=0.512N
POLY 1.5	P=0.592N	P=0.240N	P=0.676	P=0.508N
POLY 6	P=0.597N	P=0.242N	P=0.659	P=0.515N
COCH-ARM / FISHERS	P=0.588N	P=0.247N	P=0.691N	P=0.500N
MAX-ISO-POLY-3	P=0.444N	P=0.080N	P=0.473	P=0.294N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lung  
 Infiltration Cellular Histiocyte**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/47.86	0/47.56	0/45.32	1/46.86
POLY-3 PERCENT (g)	0%	0%	0%	2.1%
TERMINAL (d)	0/45 (0%)	0/44 (0%)	0/36 (0%)	1/43 (2%)
FIRST INCIDENCE	---	---	---	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.208	(e)	(e)	P=0.496
POLY 1.5	P=0.209	(e)	(e)	P=0.497
POLY 6	P=0.207	(e)	(e)	P=0.495
COCH-ARM / FISHERS	P=0.210	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.126	(e)	(e)	P=0.159

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Lung  
 Infiltration Cellular Lymphocyte**

**LESION RATES**

OVERALL (a)	7/50 (14%)	2/50 (4%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	7/47.86	2/47.56	1/46.20	2/46.86
POLY-3 PERCENT (g)	14.6%	4.2%	2.2%	4.3%
TERMINAL (d)	7/45 (16%)	2/44 (5%)	0/36 (0%)	2/43 (5%)
FIRST INCIDENCE	729 (T)	729 (T)	359	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.120N	P=0.081N	P=0.034N*	P=0.084N
POLY 1.5	P=0.120N	P=0.081N	P=0.033N*	P=0.083N
POLY 6	P=0.121N	P=0.080N	P=0.036N*	P=0.085N
COCH-ARM / FISHERS	P=0.121N	P=0.080N	P=0.030N*	P=0.080N
MAX-ISO-POLY-3	P=0.018N*	P=0.040N*	P=0.015N*	P=0.043N*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lung: Alveolar Epithelium  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	1/50 (2%)	3/50 (6%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/47.86	3/47.56	2/45.36	0/46.86
POLY-3 PERCENT (g)	2.1%	6.3%	4.4%	0%
TERMINAL (d)	1/45 (2%)	3/44 (7%)	1/36 (3%)	0/43 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	719	---

**STATISTICAL TESTS**

POLY 3	P=0.195N	P=0.303	P=0.481	P=0.504N
POLY 1.5	P=0.194N	P=0.304	P=0.486	P=0.503N
POLY 6	P=0.197N	P=0.304	P=0.474	P=0.505N
COCH-ARM / FISHERS	P=0.189N	P=0.309	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.195N	P=0.154	P=0.270	P=0.164N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lymph Node, Mandibular  
 Hyperplasia Lymphoid**

**LESION RATES**

OVERALL (a)	6/50 (12%)	2/49 (4%)	4/48 (8%)	7/49 (14%)
POLY-3 RATE (b)	6/47.86	2/46.69	4/44.11	7/45.86
POLY-3 PERCENT (g)	12.5%	4.3%	9.1%	15.3%
TERMINAL (d)	6/45 (13%)	2/44 (5%)	4/36 (11%)	7/42 (17%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.187	P=0.142N	P=0.422N	P=0.467
POLY 1.5	P=0.191	P=0.142N	P=0.417N	P=0.472
POLY 6	P=0.183	P=0.140N	P=0.432N	P=0.464
COCH-ARM / FISHERS	P=0.197	P=0.141N	P=0.397N	P=0.484
MAX-ISO-POLY-3	P=0.231	P=0.076N	P=0.303N	P=0.354

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Lymph Node, Mesenteric  
 Ectasia

**LESION RATES**

OVERALL (a)	0/48 (0%)	3/43 (7%)	3/48 (6%)	2/49 (4%)
POLY-3 RATE (b)	0/45.86	3/41.40	3/44.52	2/46.00
POLY-3 PERCENT (g)	0%	7.3%	6.7%	4.4%
TERMINAL (d)	0/43 (0%)	3/39 (8%)	3/36 (8%)	2/43 (5%)
FIRST INCIDENCE	---	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.459	P=0.101	P=0.113	P=0.238
POLY 1.5	P=0.462	P=0.100	P=0.116	P=0.239
POLY 6	P=0.458	P=0.102	P=0.110	P=0.238
COCH-ARM / FISHERS	P=0.471	P=0.102	P=0.121	P=0.253
MAX-ISO-POLY-3	P=0.130	P=0.034*	P=0.038*	P=0.077



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Lymph Node, Mesenteric  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	1/48 (2%)	1/43 (2%)	1/48 (2%)	1/49 (2%)
POLY-3 RATE (b)	1/46.24	1/41.40	1/44.71	1/46.54
POLY-3 PERCENT (g)	2.2%	2.4%	2.2%	2.2%
TERMINAL (d)	0/43 (0%)	1/39 (3%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	621	729 (T)	679	563

**STATISTICAL TESTS**

POLY 3	P=0.643N	P=0.736	P=0.753	P=0.759N
POLY 1.5	P=0.643N	P=0.736	P=0.756	P=0.758N
POLY 6	P=0.643N	P=0.736	P=0.748	P=0.759N
COCH-ARM / FISHERS	P=0.641N	P=0.725	P=0.753N	P=0.747N
MAX-ISO-POLY-3	P=0.729N	P=0.468	P=0.490	P=0.497N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lymph Node, Mesenteric  
 Hyperplasia Lymphoid**

**LESION RATES**

OVERALL (a)	4/48 (8%)	1/43 (2%)	3/48 (6%)	4/49 (8%)
POLY-3 RATE (b)	4/45.86	1/41.40	3/44.52	4/46.00
POLY-3 PERCENT (g)	8.7%	2.4%	6.7%	8.7%
TERMINAL (d)	4/43 (9%)	1/39 (3%)	3/36 (8%)	4/43 (9%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.392	P=0.211N	P=0.516N	P=0.641N
POLY 1.5	P=0.395	P=0.212N	P=0.510N	P=0.639N
POLY 6	P=0.389	P=0.209N	P=0.526N	P=0.642N
COCH-ARM / FISHERS	P=0.403	P=0.217N	P=0.500N	P=0.631N
MAX-ISO-POLY-3	P=0.461	P=0.108N	P=0.364N	P=0.497N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Mesentery: Fat  
 Necrosis

**LESION RATES**

OVERALL (a)	8/10 (80%)	6/6 (100%)	7/9 (78%)	2/2 (100%)
POLY-3 RATE (b)	8/9.36	6/6.00	7/8.72	2/2.00
POLY-3 PERCENT (g)	85.5%	100%	80.3%	100%
TERMINAL (d)	8/9 (89%)	6/6 (100%)	6/7 (86%)	2/2 (100%)
FIRST INCIDENCE	729 (T)	729 (T)	516	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.724	P=0.477	P=0.630N	P=0.741
POLY 1.5	P=0.685	P=0.418	P=0.640N	P=0.696
POLY 6	P=0.756	P=0.543	P=0.635N	P=0.779
COCH-ARM / FISHERS	P=0.625	P=0.375	P=0.667N	P=0.682
MAX-ISO-POLY-3	P=0.510	P=0.171	P=0.381N	P=0.322

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Nose: Glands  
 Degeneration Cystic**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/47.86	0/47.56	2/45.32	1/46.86
POLY-3 PERCENT (g)	0%	0%	4.4%	2.1%
TERMINAL (d)	0/45 (0%)	0/44 (0%)	2/36 (6%)	1/43 (2%)
FIRST INCIDENCE	---	---	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.323	(e)	P=0.225	P=0.496
POLY 1.5	P=0.325	(e)	P=0.228	P=0.497
POLY 6	P=0.320	(e)	P=0.220	P=0.495
COCH-ARM / FISHERS	P=0.331	(e)	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.169	(e)	P=0.076	P=0.159

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Ovary  
 Cyst

**LESION RATES**

OVERALL (a)	10/49 (20%)	15/48 (31%)	10/50 (20%)	13/50 (26%)
POLY-3 RATE (b)	10/46.94	15/46.36	10/45.70	13/47.79
POLY-3 PERCENT (g)	21.3%	32.4%	21.9%	27.2%
TERMINAL (d)	9/44 (21%)	15/43 (35%)	8/36 (22%)	12/43 (28%)
FIRST INCIDENCE	709	729 (T)	654	307

**STATISTICAL TESTS**

POLY 3	P=0.477	P=0.166	P=0.573	P=0.334
POLY 1.5	P=0.480	P=0.163	P=0.583	P=0.336
POLY 6	P=0.471	P=0.169	P=0.556	P=0.331
COCH-ARM / FISHERS	P=0.482	P=0.162	P=0.579N	P=0.337
MAX-ISO-POLY-3	P=0.413	P=0.114	P=0.473	P=0.254

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Ovary  
 Hemorrhage**

**LESION RATES**

OVERALL (a)	10/49 (20%)	6/48 (13%)	7/50 (14%)	5/50 (10%)
POLY-3 RATE (b)	10/46.86	6/46.36	7/45.67	5/46.86
POLY-3 PERCENT (g)	21.3%	12.9%	15.3%	10.7%
TERMINAL (d)	10/44 (23%)	6/43 (14%)	6/36 (17%)	5/43 (12%)
FIRST INCIDENCE	729 (T)	729 (T)	633	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.168N	P=0.212N	P=0.317N	P=0.129N
POLY 1.5	P=0.164N	P=0.216N	P=0.309N	P=0.128N
POLY 6	P=0.171N	P=0.208N	P=0.330N	P=0.130N
COCH-ARM / FISHERS	P=0.155N	P=0.219N	P=0.282N	P=0.122N
MAX-ISO-POLY-3	P=0.121N	P=0.142N	P=0.233N	P=0.080N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Ovary: Corpus Luteum  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	4/49 (8%)	1/48 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	4/46.86	1/46.36	0/45.32	2/46.86
POLY-3 PERCENT (g)	8.5%	2.2%	0%	4.3%
TERMINAL (d)	4/44 (9%)	1/43 (2%)	0/36 (0%)	2/43 (5%)
FIRST INCIDENCE	729 (T)	729 (T)	---	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.434N	P=0.182N	P=0.065N	P=0.337N
POLY 1.5	P=0.432N	P=0.184N	P=0.063N	P=0.335N
POLY 6	P=0.437N	P=0.180N	P=0.068N	P=0.339N
COCH-ARM / FISHERS	P=0.429N	P=0.187N	P=0.056N	P=0.329N
MAX-ISO-POLY-3	P=0.084N	P=0.086N	P=0.023N*	P=0.202N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
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 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Ovary: Granulosa Cell  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	0/49 (0%)	0/48 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/46.86	0/46.36	0/45.32	2/46.86
POLY-3 PERCENT (g)	0%	0%	0%	4.3%
TERMINAL (d)	0/44 (0%)	0/43 (0%)	0/36 (0%)	2/43 (5%)
FIRST INCIDENCE	---	---	---	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.042*	(e)	(e)	P=0.237
POLY 1.5	P=0.042*	(e)	(e)	P=0.238
POLY 6	P=0.041*	(e)	(e)	P=0.237
COCH-ARM / FISHERS	P=0.044*	(e)	(e)	P=0.253
MAX-ISO-POLY-3	P=0.036*	(e)	(e)	P=0.077



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
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 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pancreas  
 Infiltration Cellular Lymphocyte**

**LESION RATES**

OVERALL (a)	0/48 (0%)	0/48 (0%)	0/47 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/46.50	0/46.40	0/43.74	2/46.86
POLY-3 PERCENT (g)	0%	0%	0%	4.3%
TERMINAL (d)	0/44 (0%)	0/44 (0%)	0/36 (0%)	2/43 (5%)
FIRST INCIDENCE	---	---	---	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.043*	(e)	(e)	P=0.239
POLY 1.5	P=0.044*	(e)	(e)	P=0.241
POLY 6	P=0.043*	(e)	(e)	P=0.237
COCH-ARM / FISHERS	P=0.046*	(e)	(e)	P=0.258
MAX-ISO-POLY-3	P=0.037*	(e)	(e)	P=0.078

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Pancreas: Acinus  
 Cytoplasmic Alteration**

**LESION RATES**

OVERALL (a)	4/48 (8%)	2/48 (4%)	1/47 (2%)	1/50 (2%)
POLY-3 RATE (b)	4/46.88	2/46.40	1/43.74	1/46.86
POLY-3 PERCENT (g)	8.5%	4.3%	2.3%	2.1%
TERMINAL (d)	3/44 (7%)	2/44 (5%)	1/36 (3%)	1/43 (2%)
FIRST INCIDENCE	621	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.163N	P=0.342N	P=0.201N	P=0.179N
POLY 1.5	P=0.161N	P=0.341N	P=0.195N	P=0.175N
POLY 6	P=0.165N	P=0.343N	P=0.209N	P=0.183N
COCH-ARM / FISHERS	P=0.156N	P=0.339N	P=0.187N	P=0.168N
MAX-ISO-POLY-3	P=0.106N	P=0.206N	P=0.103N	P=0.086N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Parathyroid Gland  
 Cyst**

**LESION RATES**

OVERALL (a)	0/45 (0%)	1/44 (2%)	0/48 (0%)	1/47 (2%)
POLY-3 RATE (b)	0/43.50	1/41.56	0/43.73	1/44.40
POLY-3 PERCENT (g)	0%	2.4%	0%	2.3%
TERMINAL (d)	0/41 (0%)	1/38 (3%)	0/36 (0%)	0/40 (0%)
FIRST INCIDENCE	---	729 (T)	---	563

**STATISTICAL TESTS**

POLY 3	P=0.462	P=0.491	(e)	P=0.504
POLY 1.5	P=0.464	P=0.492	(e)	P=0.505
POLY 6	P=0.462	P=0.490	(e)	P=0.504
COCH-ARM / FISHERS	P=0.468	P=0.494	(e)	P=0.511
MAX-ISO-POLY-3	P=0.262	P=0.157	(e)	P=0.161

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
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 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pituitary Gland: Pars Distalis  
 Cyst**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/49 (0%)	2/49 (4%)	3/49 (6%)
POLY-3 RATE (b)	0/47.86	0/46.56	2/45.59	3/45.86
POLY-3 PERCENT (g)	0%	0%	4.4%	6.5%
TERMINAL (d)	0/45 (0%)	0/43 (0%)	1/36 (3%)	3/42 (7%)
FIRST INCIDENCE	---	---	657	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.031*	(e)	P=0.227	P=0.111
POLY 1.5	P=0.032*	(e)	P=0.229	P=0.112
POLY 6	P=0.031*	(e)	P=0.223	P=0.111
COCH-ARM / FISHERS	P=0.034*	(e)	P=0.242	P=0.117
MAX-ISO-POLY-3	P=0.042*	(e)	P=0.075	P=0.037*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pituitary Gland: Pars Distalis  
 Hyperplasia Focal**

**LESION RATES**

OVERALL (a)	8/50 (16%)	5/49 (10%)	6/49 (12%)	4/49 (8%)
POLY-3 RATE (b)	8/47.86	5/46.56	6/45.32	4/45.86
POLY-3 PERCENT (g)	16.7%	10.7%	13.2%	8.7%
TERMINAL (d)	8/45 (18%)	5/43 (12%)	6/36 (17%)	4/42 (10%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.224N	P=0.294N	P=0.429N	P=0.198N
POLY 1.5	P=0.221N	P=0.294N	P=0.418N	P=0.196N
POLY 6	P=0.227N	P=0.292N	P=0.447N	P=0.200N
COCH-ARM / FISHERS	P=0.213N	P=0.290N	P=0.403N	P=0.188N
MAX-ISO-POLY-3	P=0.202N	P=0.203N	P=0.324N	P=0.128N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Salivary Glands  
 Infiltration Cellular Lymphocyte**

**LESION RATES**

OVERALL (a)	2/50 (4%)	2/50 (4%)	5/50 (10%)	3/50 (6%)
POLY-3 RATE (b)	2/47.86	2/47.56	5/45.32	3/46.86
POLY-3 PERCENT (g)	4.2%	4.2%	11%	6.4%
TERMINAL (d)	2/45 (4%)	2/44 (5%)	5/36 (14%)	3/43 (7%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.401	P=0.691	P=0.195	P=0.490
POLY 1.5	P=0.405	P=0.691	P=0.201	P=0.493
POLY 6	P=0.398	P=0.693	P=0.186	P=0.489
COCH-ARM / FISHERS	P=0.415	P=0.691N	P=0.218	P=0.500
MAX-ISO-POLY-3	P=0.304	P=0.497	P=0.111	P=0.317

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

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 Goldenseal root powder  
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Spleen  
 Atrophy**

**LESION RATES**

OVERALL (a)	0/48 (0%)	0/48 (0%)	1/47 (2%)	0/49 (0%)
POLY-3 RATE (b)	0/46.50	0/46.40	1/44.45	0/46.01
POLY-3 PERCENT (g)	0%	0%	2.3%	0%
TERMINAL (d)	0/44 (0%)	0/44 (0%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	---	---	516	---

**STATISTICAL TESTS**

POLY 3	P=0.790N	(e)	P=0.491	(e)
POLY 1.5	P=0.788N	(e)	P=0.493	(e)
POLY 6	P=0.791N	(e)	P=0.488	(e)
COCH-ARM / FISHERS	P=0.785N	(e)	P=0.495	(e)
MAX-ISO-POLY-3	P=0.386	(e)	P=0.157	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Spleen  
 Hematopoietic Cell Proliferation**

**LESION RATES**

OVERALL (a)	5/48 (10%)	7/48 (15%)	8/47 (17%)	4/49 (8%)
POLY-3 RATE (b)	5/47.62	7/46.66	8/43.99	4/46.64
POLY-3 PERCENT (g)	10.5%	15%	18.2%	8.6%
TERMINAL (d)	2/44 (5%)	5/44 (11%)	6/36 (17%)	3/43 (7%)
FIRST INCIDENCE	535	696	693	521

**STATISTICAL TESTS**

POLY 3	P=0.332N	P=0.365	P=0.227	P=0.513N
POLY 1.5	P=0.323N	P=0.370	P=0.240	P=0.505N
POLY 6	P=0.342N	P=0.362	P=0.210	P=0.521N
COCH-ARM / FISHERS	P=0.303N	P=0.379	P=0.262	P=0.487N
MAX-ISO-POLY-3	P=0.326N	P=0.260	P=0.155	P=0.377N



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Goldenseal root powder  
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Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

Spleen  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	0/48 (0%)	0/48 (0%)	0/47 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/46.50	0/46.40	0/43.81	0/46.01
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/44 (0%)	0/44 (0%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	---	---	---	---

.....  
**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)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Spleen: Lymphoid Follicle  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	24/48 (50%)	26/48 (54%)	18/47 (38%)	22/49 (45%)
POLY-3 RATE (b)	24/46.50	26/46.40	18/43.81	22/46.01
POLY-3 PERCENT (g)	51.6%	56%	41.1%	47.8%
TERMINAL (d)	24/44 (55%)	26/44 (59%)	18/36 (50%)	22/43 (51%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.313N	P=0.413	P=0.213N	P=0.438N
POLY 1.5	P=0.299N	P=0.413	P=0.197N	P=0.422N
POLY 6	P=0.324N	P=0.418	P=0.238N	P=0.448N
COCH-ARM / FISHERS	P=0.266N	P=0.419	P=0.173N	P=0.382N
MAX-ISO-POLY-3	P=0.303N	P=0.334	P=0.163N	P=0.358N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Stomach, Forestomach  
 Cyst**

**LESION RATES**

OVERALL (a)	0/49 (0%)	0/50 (0%)	2/48 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/46.86	0/47.56	2/44.62	0/46.86
POLY-3 PERCENT (g)	0%	0%	4.5%	0%
TERMINAL (d)	0/44 (0%)	0/44 (0%)	1/36 (3%)	0/43 (0%)
FIRST INCIDENCE	---	---	703	---

**STATISTICAL TESTS**

POLY 3	P=0.713N	(e)	P=0.226	(e)
POLY 1.5	P=0.712N	(e)	P=0.229	(e)
POLY 6	P=0.715N	(e)	P=0.223	(e)
COCH-ARM / FISHERS	P=0.706N	(e)	P=0.242	(e)
MAX-ISO-POLY-3	P=0.247	(e)	P=0.075	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Stomach, Forestomach  
 Ulcer**

**LESION RATES**

OVERALL (a)	0/49 (0%)	1/50 (2%)	2/48 (4%)	2/50 (4%)
POLY-3 RATE (b)	0/46.86	1/47.69	2/45.25	2/47.59
POLY-3 PERCENT (g)	0%	2.1%	4.4%	4.2%
TERMINAL (d)	0/44 (0%)	0/44 (0%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	---	696	516	544

**STATISTICAL TESTS**

POLY 3	P=0.220	P=0.504	P=0.229	P=0.241
POLY 1.5	P=0.219	P=0.503	P=0.231	P=0.240
POLY 6	P=0.221	P=0.505	P=0.227	P=0.242
COCH-ARM / FISHERS	P=0.221	P=0.505	P=0.242	P=0.253
MAX-ISO-POLY-3	P=0.158	P=0.162	P=0.075	P=0.078

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Stomach, Forestomach: Epithelium  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	0/49 (0%)	3/50 (6%)	3/48 (6%)	2/50 (4%)
POLY-3 RATE (b)	0/46.86	3/48.49	3/44.65	2/48.08
POLY-3 PERCENT (g)	0%	6.2%	6.7%	4.2%
TERMINAL (d)	0/44 (0%)	1/44 (2%)	1/36 (3%)	0/43 (0%)
FIRST INCIDENCE	---	428	708	521

**STATISTICAL TESTS**

POLY 3	P=0.449	P=0.125	P=0.110	P=0.243
POLY 1.5	P=0.446	P=0.124	P=0.112	P=0.242
POLY 6	P=0.453	P=0.127	P=0.107	P=0.245
COCH-ARM / FISHERS	P=0.447	P=0.125	P=0.117	P=0.253
MAX-ISO-POLY-3	P=0.140	P=0.042*	P=0.037*	P=0.081

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Stomach, Glandular  
 Cyst**

**LESION RATES**

OVERALL (a)	7/49 (14%)	4/49 (8%)	2/48 (4%)	6/50 (12%)
POLY-3 RATE (b)	7/46.86	4/46.60	2/44.52	6/46.86
POLY-3 PERCENT (g)	14.9%	8.6%	4.5%	12.8%
TERMINAL (d)	7/44 (16%)	4/44 (9%)	2/36 (6%)	6/43 (14%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.543	P=0.265N	P=0.092N	P=0.500N
POLY 1.5	P=0.545	P=0.265N	P=0.089N	P=0.496N
POLY 6	P=0.539	P=0.262N	P=0.096N	P=0.502N
COCH-ARM / FISHERS	P=0.552	P=0.262N	P=0.084N	P=0.484N
MAX-ISO-POLY-3	P=0.261N	P=0.172N	P=0.049N*	P=0.382N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Stomach, Glandular  
 Erosion**

**LESION RATES**

OVERALL (a)	0/49 (0%)	0/49 (0%)	0/48 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.86	0/46.60	0/44.52	0/46.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/44 (0%)	0/44 (0%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	---	---	---	---

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thymus  
 Atrophy**

**LESION RATES**

OVERALL (a)	0/49 (0%)	1/48 (2%)	1/50 (2%)	0/48 (0%)
POLY-3 RATE (b)	0/46.86	1/46.19	1/45.97	0/44.86
POLY-3 PERCENT (g)	0%	2.2%	2.2%	0%
TERMINAL (d)	0/44 (0%)	0/42 (0%)	0/36 (0%)	0/41 (0%)
FIRST INCIDENCE	---	522	516	---

**STATISTICAL TESTS**

POLY 3	P=0.553N	P=0.497	P=0.496	(e)
POLY 1.5	P=0.551N	P=0.496	P=0.498	(e)
POLY 6	P=0.554N	P=0.499	P=0.493	(e)
COCH-ARM / FISHERS	P=0.547N	P=0.495	P=0.505	(e)
MAX-ISO-POLY-3	P=0.411	P=0.157	P=0.160	(e)



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thymus  
 Cyst**

**LESION RATES**

OVERALL (a)	0/49 (0%)	0/48 (0%)	0/50 (0%)	0/48 (0%)
POLY-3 RATE (b)	0/46.86	0/45.56	0/45.32	0/44.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/44 (0%)	0/42 (0%)	0/36 (0%)	0/41 (0%)
FIRST INCIDENCE	---	---	---	---

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thymus  
 Hyperplasia Lymphoid**

**LESION RATES**

OVERALL (a)	4/49 (8%)	2/48 (4%)	4/50 (8%)	7/48 (15%)
POLY-3 RATE (b)	4/46.86	2/45.56	4/45.32	7/44.86
POLY-3 PERCENT (g)	8.5%	4.4%	8.8%	15.6%
TERMINAL (d)	4/44 (9%)	2/42 (5%)	4/36 (11%)	7/41 (17%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.077	P=0.350N	P=0.625	P=0.237
POLY 1.5	P=0.078	P=0.350N	P=0.632	P=0.240
POLY 6	P=0.075	P=0.349N	P=0.612	P=0.234
COCH-ARM / FISHERS	P=0.082	P=0.349N	P=0.631N	P=0.250
MAX-ISO-POLY-3	P=0.110	P=0.213N	P=0.480	P=0.153

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thyroid Gland: Follicle  
 Cyst**

**LESION RATES**

OVERALL (a)	0/50 (0%)	3/50 (6%)	2/48 (4%)	2/50 (4%)
POLY-3 RATE (b)	0/47.86	3/47.56	2/44.01	2/46.86
POLY-3 PERCENT (g)	0%	6.3%	4.5%	4.3%
TERMINAL (d)	0/45 (0%)	3/44 (7%)	1/36 (3%)	2/43 (5%)
FIRST INCIDENCE	---	729 (T)	654	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.422	P=0.118	P=0.219	P=0.233
POLY 1.5	P=0.425	P=0.118	P=0.221	P=0.234
POLY 6	P=0.420	P=0.118	P=0.216	P=0.232
COCH-ARM / FISHERS	P=0.433	P=0.121	P=0.237	P=0.247
MAX-ISO-POLY-3	P=0.161	P=0.038*	P=0.074	P=0.076

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thyroid Gland: Follicle  
 Degeneration Focal**

**LESION RATES**

OVERALL (a)	18/50 (36%)	18/50 (36%)	16/48 (33%)	10/50 (20%)
POLY-3 RATE (b)	18/48.75	18/47.69	16/43.77	10/48.62
POLY-3 PERCENT (g)	36.9%	37.8%	36.6%	20.6%
TERMINAL (d)	15/45 (33%)	17/44 (39%)	15/36 (42%)	7/43 (16%)
FIRST INCIDENCE	604	696	719	521

**STATISTICAL TESTS**

POLY 3	P=0.028N*	P=0.550	P=0.571N	P=0.058N
POLY 1.5	P=0.029N*	P=0.561	P=0.544N	P=0.059N
POLY 6	P=0.026N*	P=0.541	P=0.560	P=0.058N
COCH-ARM / FISHERS	P=0.032N*	P=0.582N	P=0.474N	P=0.059N
MAX-ISO-POLY-3	P=0.044N*	P=0.466	P=0.485N	P=0.036N*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Urinary Bladder  
 Infiltration Cellular Lymphocyte**

**LESION RATES**

OVERALL (a)	7/49 (14%)	6/49 (12%)	5/50 (10%)	3/50 (6%)
POLY-3 RATE (b)	7/46.86	6/47.53	5/45.32	3/47.04
POLY-3 PERCENT (g)	14.9%	12.6%	11%	6.4%
TERMINAL (d)	7/44 (16%)	4/44 (9%)	5/36 (14%)	2/43 (5%)
FIRST INCIDENCE	729 (T)	696	729 (T)	684

**STATISTICAL TESTS**

POLY 3	P=0.125N	P=0.489N	P=0.403N	P=0.156N
POLY 1.5	P=0.123N	P=0.494N	P=0.393N	P=0.155N
POLY 6	P=0.126N	P=0.481N	P=0.419N	P=0.156N
COCH-ARM / FISHERS	P=0.117N	P=0.500N	P=0.365N	P=0.151N
MAX-ISO-POLY-3	P=0.154N	P=0.372N	P=0.294N	P=0.090N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Uterus  
 Hyperplasia Cystic**

**LESION RATES**

OVERALL (a)	48/50 (96%)	46/49 (94%)	45/50 (90%)	44/50 (88%)
POLY-3 RATE (b)	48/49.36	46/48.96	45/47.51	44/49.09
POLY-3 PERCENT (g)	97.3%	94%	94.7%	89.6%
TERMINAL (d)	44/45 (98%)	42/44 (96%)	36/36 (100%)	40/43 (93%)
FIRST INCIDENCE	535	482	359	307

**STATISTICAL TESTS**

POLY 3	P=0.091N	P=0.377N	P=0.446N	P=0.118N
POLY 1.5	P=0.089N	P=0.420N	P=0.376N	P=0.120N
POLY 6	P=0.101N	P=0.339N	P=0.608N	P=0.126N
COCH-ARM / FISHERS	P=0.100N	P=0.490N	P=0.218N	P=0.134N
MAX-ISO-POLY-3	P=0.074N	P=0.207N	P=0.235N	P=0.053N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Goldenseal root powder  
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008  
 Time Report Requested: 12:25:59  
 First Dose M/F: 05/12/03 / 05/12/03  
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

---

**Uterus  
 Thrombosis**

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/49 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/47.86	2/47.36	1/45.59	0/46.86
POLY-3 PERCENT (g)	0%	4.2%	2.2%	0%
TERMINAL (d)	0/45 (0%)	2/44 (5%)	0/36 (0%)	0/43 (0%)
FIRST INCIDENCE	---	729 (T)	657	---

**STATISTICAL TESTS**

POLY 3	P=0.391N	P=0.235	P=0.490	(e)
POLY 1.5	P=0.389N	P=0.234	P=0.493	(e)
POLY 6	P=0.391N	P=0.236	P=0.487	(e)
COCH-ARM / FISHERS	P=0.385N	P=0.242	P=0.500	(e)
MAX-ISO-POLY-3	P=0.332	P=0.075	P=0.159	(e)

---

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
Goldenseal root powder  
**CAS Number:** GOLDENSEALRT

**Date Report Requested:** 08/14/2008  
**Time Report Requested:** 12:25:59  
**First Dose M/F:** 05/12/03 / 05/12/03  
**Lab:** SRI

## **LEGEND**

- (a) Number of tumor-bearing animals/number of animals examined at site.
  - (b) Number of tumor-bearing animals/Poly-3 number
  - (d) Observed incidence at terminal kill.
  - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group. The life table analysis regards tumors in animals dying prior to terminal kill as being (directly or indirectly) the cause of death.
  - (e) Value of Statistic cannot be computed.
  - (g) Poly-3 adjusted lifetime tumor incidence.
  - (I) Interim sacrifice
  - (T) Terminal sacrifice
  - # Tumor rates based on numbers of animals necropsied.
  - \* To the right of any statistical result, indicates significance at ( $P \leq 0.05$ ).
  - \*\* To the right of any statistical result, indicates significance at ( $P \leq 0.01$ ).
  - N Indicates a negative trend for all tests
- Logistic regression is an alternative method for analyzing the incidence of non-fatal tumors.  
The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

\*\*\* END OF REPORT \*\*\*