

**TDMS No.** 99020 - 06  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** MICE/B6C3F1

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Pulegone  
**CAS Number:** 89-82-7

**Date Report Requested:** 07/23/2008  
**Time Report Requested:** 09:18:35  
**First Dose M/F:** 04/15/03 / 04/14/03  
**Lab:** BAT

F1\_\_M3

**C Number:** C99020  
**Lock Date:** 12/21/2005  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** 25022 ACCK 25021 TSAC 25020 NATD  
25019 MSAC 25018 DACC  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 2.0.0

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## HISTORICAL CONTROL STUDIES From October 2007 Report

### SAME ROUTE

88105-04 -- Isoeugenol (GAVAGE CORN OIL)  
99023-04 -- beta-Myrcene (GAVAGE CORN OIL)

### ALL ROUTES

88138-04 -- Benzophenone (ORAL FEED)  
99027-04 -- Chromium picolinate monohydrate (ORAL FEED)  
05174-06 -- Cresols (ORAL FEED)  
96011-06 -- Cumene (INHALATION AIR)  
97003-08 -- 1,2-Dibromo-2,4-dicyanobutane (SKIN ETHANOL)  
93020-08 -- Diisopropylcarbodiimide (SKIN ETHANOL)  
88004-06 -- Divinylbenzene (INHALATION AIR)  
88123-07 -- Formamide (GAVAGE WATER)  
95011-06 -- 5-(Hydroxymethyl)-2-furfural (GAVAGE WATER)  
88105-04 -- Isoeugenol (GAVAGE CORN OIL)  
97006-02 -- Methyl isobutyl ketone (INHALATION AIR)  
91005-08 -- Methylene blue trihydrate (GAVAGE METHYLCELLULOSE)  
92012-06 -- 2-Methylimidazole (ORAL FEED)  
92013-06 -- 4-Methylimidazole (ORAL FEED)  
88006-04 -- alpha-Methylstyrene (INHALATION AIR)  
99023-04 -- beta-Myrcene (GAVAGE CORN OIL)  
97008-06 -- Propargyl alcohol (INHALATION AIR)  
20114-06 -- Sodium dichromate dihydrate (VI) (ORAL WATER)  
96001-06 -- Stoddard solvent (type IIC) (INHALATION AIR)  
05109-14 -- Triethanolamine (SKIN ACETONE)  
96019-06 -- Water disinfection byproducts (Bromochloroacetic acid) (ORAL WATER)  
96018-04 -- Water disinfection byproducts (Bromodichloromethane) (ORAL WATER)  
96017-06 -- Water disinfection byproducts (Dibromoacetic acid) (ORAL WATER)

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**HISTORICAL CONTROL STUDIES**  
**From October 2007 Report**

96015-06 -- Water disinfection byproducts (Dibromoacetonitrile) (ORAL WATER)  
96010-04 -- Water disinfection byproducts (Sodium chlorate) (ORAL WATER)

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

Adrenal Cortex  
Adrenal Medulla  
Bone Marrow  
Kidney  
Liver  
Lung  
Nose  
Ovary  
Pituitary Gland  
Spleen  
Testes  
Thyroid Gland

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## SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF Pulegone

### MALE MICE

#### Organ

Liver

All Organs

#### Morphology

Hepatoblastoma  
Hepatocellular Adenoma  
Hepatocellular Carcinoma or Hepatoblastoma  
Hepatocellular Carcinoma or Hepatocellular Adenoma  
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma  
Hepatocholangiocarcinoma  
Benign Tumors  
Malignant Tumors  
Malignant and Benign Tumors

### FEMALE MICE

#### Organ

Liver

Uterus

All Organs

#### Morphology

Hepatocellular Adenoma  
Hepatocellular Carcinoma  
Hepatocellular Carcinoma or Hepatoblastoma  
Hepatocellular Carcinoma or Hepatocellular Adenoma  
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma  
Polyp Stromal  
Hemangiosarcoma  
Hemangiosarcoma or Hemangioma  
Histiocytic Sarcoma  
Osteosarcoma or Osteoma  
Malignant Tumors  
Malignant and Benign Tumors

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**Adrenal Cortex  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	1/50 (2%)	3/50 (6%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	1/44.22	3/45.07	3/47.72	0/45.98
POLY-3 PERCENT (g)	2.3%	6.7%	6.3%	0%
TERMINAL (d)	1/38 (3%)	3/36 (8%)	3/42 (7%)	0/41 (0%)
FIRST INCIDENCE	730 (T)	730 (T)	730 (T)	---
HC TUMORS SAME RTE	5/100 (5%)			
HC TUMORS ALL RTES	74/1142 (7%)			

**STATISTICAL TESTS**

POLY 3	P=0.260N	P=0.312	P=0.333	P=0.492N
POLY 1.5	P=0.270N	P=0.308	P=0.324	P=0.497N
POLY 6	P=0.247N	P=0.314	P=0.341	P=0.487N
COCH-ARM / FISHERS	P=0.279N	P=0.309	P=0.309	P=0.500N
MAX-ISO-POLY-3	P=0.173N	P=0.161	P=0.183	P=0.158N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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 Lab: BAT

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**Adrenal Medulla  
 Pheochromocytoma Benign**

**TUMOR RATES**

OVERALL (a)	1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/44.22	1/45.07	1/47.72	0/45.98
POLY-3 PERCENT (g)	2.3%	2.2%	2.1%	0%
TERMINAL (d)	1/38 (3%)	1/36 (3%)	1/42 (2%)	0/41 (0%)
FIRST INCIDENCE	730 (T)	730 (T)	730 (T)	---
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	4/1135 (0%)			

**STATISTICAL TESTS**

POLY 3	P=0.303N	P=0.756N	P=0.743N	P=0.492N
POLY 1.5	P=0.308N	P=0.759N	P=0.749N	P=0.497N
POLY 6	P=0.298N	P=0.755N	P=0.738N	P=0.487N
COCH-ARM / FISHERS	P=0.311N	P=0.753N	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.335N	P=0.494N	P=0.478N	P=0.158N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

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

**TUMOR RATES**

OVERALL (a)	1/50 (2%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/44.22	1/45.07	1/47.72	1/45.98
POLY-3 PERCENT (g)	2.3%	2.2%	2.1%	2.2%
TERMINAL (d)	1/38 (3%)	1/36 (3%)	1/42 (2%)	1/41 (2%)
FIRST INCIDENCE	730 (T)	730 (T)	730 (T)	730 (T)
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	8/1135 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.622N	P=0.756N	P=0.743N	P=0.752N
POLY 1.5	P=0.627N	P=0.759N	P=0.749N	P=0.757N
POLY 6	P=0.616N	P=0.755N	P=0.738N	P=0.746N
COCH-ARM / FISHERS	P=0.634	P=0.753N	P=0.753N	P=0.753N
MAX-ISO-POLY-3	P=0.731N	P=0.494N	P=0.478N	P=0.488N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)



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

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DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

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**Bone  
 Osteosarcoma or Osteoma**

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TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	0/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	3/1149 (0%)			

**STATISTICAL TESTS**

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

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>Harderian Gland Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	6/50 (12%)	4/50 (8%)	8/50 (16%)	7/50 (14%)
POLY-3 RATE (b)	6/44.29	4/45.07	8/48.31	7/46.5
POLY-3 PERCENT (g)	13.6%	8.9%	16.6%	15.1%
TERMINAL (d)	5/38 (13%)	4/36 (11%)	6/42 (14%)	6/41 (15%)
FIRST INCIDENCE	714	730 (T)	597	570
HC TUMORS SAME RTE	17/100 (17%)			
HC TUMORS ALL RTEs	152/1149 (13%)			

**STATISTICAL TESTS**

POLY 3	P=0.357	P=0.358N	P=0.455	P=0.538
POLY 1.5	P=0.338	P=0.366N	P=0.431	P=0.517
POLY 6	P=0.383	P=0.354N	P=0.478	P=0.562
COCH-ARM / FISHERS	P=0.319	P=0.370N	P=0.387	P=0.500
MAX-ISO-POLY-3	P=0.430	P=0.245N	P=0.349	P=0.419
HISTCONT SAME RTE	P=0.550	P=1.000	P=0.481	P=0.566
HISTCONT ALL RTEs	P=0.502	P=1.000	P=0.442	P=0.533

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>Harderian Gland Carcinoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.22	0/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	2.3%	0%	0%	0%
TERMINAL (d)	1/38 (3%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	730 (T)	---	---	---
HC TUMORS SAME RTE	5/100 (5%)			
HC TUMORS ALL RTES	30/1149 (3%)			

**STATISTICAL TESTS**

POLY 3	P=0.308N	P=0.496N	P=0.485N	P=0.492N
POLY 1.5	P=0.306N	P=0.499N	P=0.490N	P=0.497N
POLY 6	P=0.311N	P=0.495N	P=0.481N	P=0.487N
COCH-ARM / FISHERS	P=0.306N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.124N	P=0.158N	P=0.158N	P=0.158N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**Harderian Gland  
 Carcinoma or Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	7/50 (14%)	4/50 (8%)	8/50 (16%)	7/50 (14%)
POLY-3 RATE (b)	7/44.29	4/45.07	8/48.31	7/46.5
POLY-3 PERCENT (g)	15.8%	8.9%	16.6%	15.1%
TERMINAL (d)	6/38 (16%)	4/36 (11%)	6/42 (14%)	6/41 (15%)
FIRST INCIDENCE	714	730 (T)	597	570
HC TUMORS SAME RTE	21/100 (21%)			
HC TUMORS ALL RTES	176/1149 (15%)			

**STATISTICAL TESTS**

POLY 3	P=0.456	P=0.250N	P=0.572	P=0.575N
POLY 1.5	P=0.436	P=0.258N	P=0.547	P=0.596N
POLY 6	P=0.483	P=0.246N	P=0.596	P=0.550N
COCH-ARM / FISHERS	P=0.416	P=0.262N	P=0.500	P=0.613N
MAX-ISO-POLY-3	P=0.512	P=0.162N	P=0.462	P=0.461N
HISTCONT SAME RTE	P=0.641	P=1.000	P=0.613	P=1.000
HISTCONT ALL RTES	P=0.600	P=1.000	P=0.584	P=1.000

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 TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

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Liver  
 Hemangioma

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	0/45.07	2/47.72	0/45.98
POLY-3 PERCENT (g)	0%	0%	4.2%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	2/42 (5%)	0/41 (0%)
FIRST INCIDENCE	---	---	730 (T)	---
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	4/1146 (0%)			

**STATISTICAL TESTS**

POLY 3	P=0.610	(e)	P=0.255	(e)
POLY 1.5	P=0.601	(e)	P=0.249	(e)
POLY 6	P=0.624	(e)	P=0.260	(e)
COCH-ARM / FISHERS	P=0.595	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.274	(e)	P=0.093	(e)
HISTCONT SAME RTE	P=0.362	(e)	P=0.103	(e)
HISTCONT ALL RTES	P=0.227	(e)	P=0.006**	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

Liver  
 Hepatoblastoma

**TUMOR RATES**

OVERALL (a)	1/50 (2%)	3/50 (6%)	7/50 (14%)	2/50 (4%)
POLY-3 RATE (b)	1/44.22	3/45.36	7/48.2	2/45.98
POLY-3 PERCENT (g)	2.3%	6.6%	14.5%	4.4%
TERMINAL (d)	1/38 (3%)	2/36 (6%)	4/42 (10%)	2/41 (5%)
FIRST INCIDENCE	730 (T)	652	654	730 (T)
HC TUMORS SAME RTE	7/100 (7%)			
HC TUMORS ALL RTES	43/1146 (4%)			

**STATISTICAL TESTS**

POLY 3	P=0.433	P=0.314	P=0.040*	P=0.514
POLY 1.5	P=0.416	P=0.309	P=0.037*	P=0.506
POLY 6	P=0.455	P=0.318	P=0.045*	P=0.523
COCH-ARM / FISHERS	P=0.404	P=0.309	P=0.030*	P=0.500
MAX-ISO-POLY-3	P=0.147	P=0.164	P=0.021*	P=0.296
HISTCONT SAME RTE	P=0.198	P=0.230	P=0.027*	P=0.410
HISTCONT ALL RTES	P=0.168	P=0.195	P=0.021*	P=0.370

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DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**Liver  
 Hepatocellular Adenoma**

**TUMOR RATES**

OVERALL (a)	22/50 (44%)	31/50 (62%)	35/50 (70%)	28/50 (56%)
POLY-3 RATE (b)	22/46.32	31/47.42	35/48.14	28/46.48
POLY-3 PERCENT (g)	47.5%	65.4%	72.7%	60.3%
TERMINAL (d)	17/38 (45%)	24/36 (67%)	33/42 (79%)	25/41 (61%)
FIRST INCIDENCE	479	428	654	638
HC TUMORS SAME RTE	50/100 (50%)			
HC TUMORS ALL RTES	544/1146 (48%)			

**STATISTICAL TESTS**

POLY 3	P=0.175	P=0.058	P=0.008**	P=0.150
POLY 1.5	P=0.169	P=0.053	P=0.008**	P=0.144
POLY 6	P=0.190	P=0.058	P=0.008**	P=0.162
COCH-ARM / FISHERS	P=0.192	P=0.054	P=0.007**	P=0.159
MAX-ISO-POLY-3	P=0.042*	P=0.039*	P=0.005**	P=0.106
HISTCONT SAME RTE	P=0.056	P=0.053	P=0.006**	P=0.150
HISTCONT ALL RTES	P=0.047*	P=0.042*	P=0.005**	P=0.123

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

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DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

---

**Liver  
 Hepatocellular Carcinoma**

**TUMOR RATES**

OVERALL (a)	13/50 (26%)	11/50 (22%)	18/50 (36%)	15/50 (30%)
POLY-3 RATE (b)	13/46.82	11/46.3	18/48.8	15/46.31
POLY-3 PERCENT (g)	27.8%	23.8%	36.9%	32.4%
TERMINAL (d)	8/38 (21%)	6/36 (17%)	14/42 (33%)	14/41 (34%)
FIRST INCIDENCE	535	646	588	638
HC TUMORS SAME RTE	22/100 (22%)			
HC TUMORS ALL RTES	317/1146 (28%)			

**STATISTICAL TESTS**

POLY 3	P=0.247	P=0.419N	P=0.232	P=0.398
POLY 1.5	P=0.245	P=0.421N	P=0.220	P=0.396
POLY 6	P=0.251	P=0.420N	P=0.239	P=0.401
COCH-ARM / FISHERS	P=0.254	P=0.408N	P=0.194	P=0.412
MAX-ISO-POLY-3	P=0.285	P=0.330N	P=0.176	P=0.315
HISTCONT SAME RTE	P=0.241	P=1.000	P=0.167	P=0.260
HISTCONT ALL RTES	P=0.331	P=1.000	P=0.211	P=0.396

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TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**Liver  
 Hepatocellular Carcinoma or Hepatoblastoma**

**TUMOR RATES**

OVERALL (a)	13/50 (26%)	13/50 (26%)	22/50 (44%)	17/50 (34%)
POLY-3 RATE (b)	13/46.82	13/46.59	22/49.22	17/46.31
POLY-3 PERCENT (g)	27.8%	27.9%	44.7%	36.7%
TERMINAL (d)	8/38 (21%)	7/36 (19%)	16/42 (38%)	16/41 (39%)
FIRST INCIDENCE	535	646	588	638
HC TUMORS SAME RTE	27/100 (27%)			
HC TUMORS ALL RTES	346/1146 (30%)			

**STATISTICAL TESTS**

POLY 3	P=0.137	P=0.585	P=0.064	P=0.241
POLY 1.5	P=0.137	P=0.580	P=0.057	P=0.241
POLY 6	P=0.139	P=0.589	P=0.070	P=0.243
COCH-ARM / FISHERS	P=0.148	P=0.590N	P=0.046*	P=0.257
MAX-ISO-POLY-3	P=0.149	P=0.493	P=0.045*	P=0.180
HISTCONT SAME RTE	P=0.199	P=0.648	P=0.061	P=0.253
HISTCONT ALL RTES	P=0.170	P=0.624	P=0.048*	P=0.216

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

---

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

---

**Liver  
 Hepatocellular Carcinoma or Hepatocellular Adenoma**

**TUMOR RATES**

OVERALL (a)	29/50 (58%)	36/50 (72%)	42/50 (84%)	35/50 (70%)
POLY-3 RATE (b)	29/48.31	36/48.2	42/49.22	35/46.48
POLY-3 PERCENT (g)	60%	74.7%	85.3%	75.3%
TERMINAL (d)	20/38 (53%)	26/36 (72%)	36/42 (86%)	32/41 (78%)
FIRST INCIDENCE	479	428	588	638
HC TUMORS SAME RTE	61/100 (61%)			
HC TUMORS ALL RTES	729/1146 (64%)			

**STATISTICAL TESTS**

POLY 3	P=0.060	P=0.091	P=0.004**	P=0.082
POLY 1.5	P=0.075	P=0.091	P=0.004**	P=0.096
POLY 6	P=0.047*	P=0.085	P=0.003**	P=0.070
COCH-ARM / FISHERS	P=0.134	P=0.104	P=0.004**	P=0.149
MAX-ISO-POLY-3	P=0.018*	P=0.060	P=0.002**	P=0.056
HISTCONT SAME RTE	P=0.023*	P=0.083	P=0.002**	P=0.078
HISTCONT ALL RTES	P=0.019*	P=0.067	P=0.002**	P=0.063

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TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

---

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

---

Liver  
 Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma

**TUMOR RATES**

OVERALL (a)	29/50 (58%)	37/50 (74%)	42/50 (84%)	36/50 (72%)
POLY-3 RATE (b)	29/48.31	37/48.49	42/49.22	36/46.48
POLY-3 PERCENT (g)	60%	76.3%	85.3%	77.5%
TERMINAL (d)	20/38 (53%)	26/36 (72%)	36/42 (86%)	33/41 (81%)
FIRST INCIDENCE	479	428	588	638
HC TUMORS SAME RTE	64/100 (64%)			
HC TUMORS ALL RTES	740/1146 (65%)			

**STATISTICAL TESTS**

POLY 3	P=0.038*	P=0.064	P=0.004**	P=0.051
POLY 1.5	P=0.051	P=0.061	P=0.004**	P=0.061
POLY 6	P=0.029*	P=0.064	P=0.003**	P=0.041*
COCH-ARM / FISHERS	P=0.101	P=0.069	P=0.004**	P=0.104
MAX-ISO-POLY-3	P=0.012*	P=0.041*	P=0.002**	P=0.034*
HISTCONT SAME RTE	P=0.015*	P=0.056	P=0.002**	P=0.045*
HISTCONT ALL RTES	P=0.012*	P=0.044*	P=0.002**	P=0.036*

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TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

Liver  
 Hepatocholangiocarcinoma

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/44.22	0/45.07	0/47.72	2/46.03
POLY-3 PERCENT (g)	0%	0%	0%	4.3%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	1/41 (2%)
FIRST INCIDENCE	---	---	---	716
HC TUMORS SAME RTE	2/100 (2%)			
HC TUMORS ALL RTES	9/1146 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.047*	(e)	(e)	P=0.246
POLY 1.5	P=0.046*	(e)	(e)	P=0.241
POLY 6	P=0.048*	(e)	(e)	P=0.253
COCH-ARM / FISHERS	P=0.046*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.040*	(e)	(e)	P=0.085
HISTCONT SAME RTE	P=0.054	(e)	(e)	P=0.119
HISTCONT ALL RTES	P=0.045*	(e)	(e)	P=0.097

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

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DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

---

**Lung  
 Alveolar/Bronchiolar Adenoma**

**TUMOR RATES**

OVERALL (a)	6/50 (12%)	5/50 (10%)	6/50 (12%)	5/50 (10%)
POLY-3 RATE (b)	6/44.94	5/45.21	6/47.78	5/45.98
POLY-3 PERCENT (g)	13.4%	11.1%	12.6%	10.9%
TERMINAL (d)	5/38 (13%)	4/36 (11%)	5/42 (12%)	5/41 (12%)
FIRST INCIDENCE	477	693	714	730 (T)
HC TUMORS SAME RTE	14/100 (14%)			
HC TUMORS ALL RTES	209/1148 (18%)			

**STATISTICAL TESTS**

POLY 3	P=0.450N	P=0.496N	P=0.577N	P=0.484N
POLY 1.5	P=0.461N	P=0.501N	P=0.592N	P=0.496N
POLY 6	P=0.434N	P=0.493N	P=0.565N	P=0.469N
COCH-ARM / FISHERS	P=0.470N	P=0.500N	P=0.620N	P=0.500N
MAX-ISO-POLY-3	P=0.569N	P=0.370N	P=0.455N	P=0.360N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

---

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

---

**Lung  
 Alveolar/Bronchiolar Carcinoma**

**TUMOR RATES**

OVERALL (a)	3/50 (6%)	4/50 (8%)	4/50 (8%)	3/50 (6%)
POLY-3 RATE (b)	3/44.22	4/45.36	4/47.72	3/46.31
POLY-3 PERCENT (g)	6.8%	8.8%	8.4%	6.5%
TERMINAL (d)	3/38 (8%)	3/36 (8%)	4/42 (10%)	2/41 (5%)
FIRST INCIDENCE	730 (T)	652	730 (T)	638
HC TUMORS SAME RTE	7/100 (7%)			
HC TUMORS ALL RTES	115/1148 (10%)			

**STATISTICAL TESTS**

POLY 3	P=0.509N	P=0.514	P=0.541	P=0.641N
POLY 1.5	P=0.523N	P=0.505	P=0.527	P=0.653N
POLY 6	P=0.490N	P=0.520	P=0.553	P=0.626N
COCH-ARM / FISHERS	P=0.537N	P=0.500	P=0.500	P=0.661N
MAX-ISO-POLY-3	P=0.617N	P=0.362	P=0.389	P=0.476N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

---

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

---

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

**TUMOR RATES**

OVERALL (a)	9/50 (18%)	9/50 (18%)	9/50 (18%)	7/50 (14%)
POLY-3 RATE (b)	9/44.94	9/45.5	9/47.78	7/46.31
POLY-3 PERCENT (g)	20%	19.8%	18.8%	15.1%
TERMINAL (d)	8/38 (21%)	7/36 (19%)	8/42 (19%)	6/41 (15%)
FIRST INCIDENCE	477	652	714	638
HC TUMORS SAME RTE	20/100 (20%)			
HC TUMORS ALL RTES	309/1148 (27%)			

**STATISTICAL TESTS**

POLY 3	P=0.299N	P=0.592N	P=0.547N	P=0.367N
POLY 1.5	P=0.316N	P=0.602N	P=0.566N	P=0.384N
POLY 6	P=0.277N	P=0.584N	P=0.531N	P=0.345N
COCH-ARM / FISHERS	P=0.328N	P=0.602N	P=0.602N	P=0.393N
MAX-ISO-POLY-3	P=0.446N	P=0.488N	P=0.443N	P=0.273N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

---

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

---

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

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	0/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/99 (0%)			
HC TUMORS ALL RTES	3/1119 (0%)			

**STATISTICAL TESTS**

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

---



TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

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

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	1/45.84	0/47.72	0/45.98
POLY-3 PERCENT (g)	0%	2.2%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	444	---	---
HC TUMORS SAME RTE	1/100 (1%)			
HC TUMORS ALL RTES	14/1149 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.557N	P=0.507	(e)	(e)
POLY 1.5	P=0.561N	P=0.504	(e)	(e)
POLY 6	P=0.554N	P=0.510	(e)	(e)
COCH-ARM / FISHERS	P=0.567N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.394N	P=0.168	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTES	(h)	(h)	(e)	(e)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

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

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	1/45.84	0/47.72	0/45.98
POLY-3 PERCENT (g)	0%	2.2%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	444	---	---
HC TUMORS SAME RTE	1/100 (1%)			
HC TUMORS ALL RTES	11/1149 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.557N	P=0.507	(e)	(e)
POLY 1.5	P=0.561N	P=0.504	(e)	(e)
POLY 6	P=0.554N	P=0.510	(e)	(e)
COCH-ARM / FISHERS	P=0.567N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.394N	P=0.168	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTES	(h)	(h)	(e)	(e)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**Skin  
 Sarcoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	1/45.84	0/47.72	0/45.98
POLY-3 PERCENT (g)	0%	2.2%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	444	---	---
HC TUMORS SAME RTE	1/100 (1%)			
HC TUMORS ALL RTES	6/1149 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.557N	P=0.507	(e)	(e)
POLY 1.5	P=0.561N	P=0.504	(e)	(e)
POLY 6	P=0.554N	P=0.510	(e)	(e)
COCH-ARM / FISHERS	P=0.567N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.394N	P=0.168	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTES	(h)	(h)	(e)	(e)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**Skin  
 Schwannoma Malignant**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	0/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	1/1149 (0%)			

**STATISTICAL TESTS**

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

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**Spleen  
 Hemangiosarcoma**

**TUMOR RATES**

OVERALL (a)	2/50 (4%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/44.55	2/45.11	1/47.72	1/45.98
POLY-3 PERCENT (g)	4.5%	4.4%	2.1%	2.2%
TERMINAL (d)	1/38 (3%)	1/36 (3%)	1/42 (2%)	1/41 (2%)
FIRST INCIDENCE	640	721	730 (T)	730 (T)
HC TUMORS SAME RTE	1/99 (1%)			
HC TUMORS ALL RTES	21/1136 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.327N	P=0.689N	P=0.476N	P=0.489N
POLY 1.5	P=0.332N	P=0.693N	P=0.484N	P=0.496N
POLY 6	P=0.321N	P=0.689N	P=0.471N	P=0.481N
COCH-ARM / FISHERS	P=0.337N	P=0.691N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.435N	P=0.494N	P=0.267N	P=0.274N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**Stomach, Forestomach  
 Squamous Cell Carcinoma or Papilloma Squamous**

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/44.22	2/45.23	0/47.72	2/45.98
POLY-3 PERCENT (g)	2.3%	4.4%	0%	4.4%
TERMINAL (d)	1/38 (3%)	1/36 (3%)	0/42 (0%)	2/41 (5%)
FIRST INCIDENCE	730 (T)	690	---	730 (T)
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	13/1149 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.484	P=0.508	P=0.485N	P=0.514
POLY 1.5	P=0.477	P=0.503	P=0.490N	P=0.506
POLY 6	P=0.492	P=0.511	P=0.481N	P=0.523
COCH-ARM / FISHERS	P=0.469	P=0.500	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.435	P=0.289	P=0.158N	P=0.296
HISTCONT SAME RTE	P=0.157	P=0.093	(e)	P=0.091
HISTCONT ALL RTES	P=0.173	P=0.098	(e)	P=0.099

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**Stomach, Forestomach  
 Squamous Cell Papilloma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/44.22	2/45.23	0/47.72	2/45.98
POLY-3 PERCENT (g)	0%	4.4%	0%	4.4%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	0/42 (0%)	2/41 (5%)
FIRST INCIDENCE	---	690	---	730 (T)
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	11/1149 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.260	P=0.242	(e)	P=0.246
POLY 1.5	P=0.253	P=0.239	(e)	P=0.241
POLY 6	P=0.268	P=0.244	(e)	P=0.252
COCH-ARM / FISHERS	P=0.247	P=0.247	(e)	P=0.247
MAX-ISO-POLY-3	P=0.133	P=0.081	(e)	P=0.084
HISTCONT SAME RTE	P=0.179	P=0.109	(e)	P=0.108
HISTCONT ALL RTES	P=0.142	P=0.087	(e)	P=0.087

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**Thyroid Gland: Follicular Cell  
 Carcinoma**

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	1/45.07	2/48.05	0/45.98
POLY-3 PERCENT (g)	0%	2.2%	4.2%	0%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	1/42 (2%)	0/41 (0%)
FIRST INCIDENCE	---	730 (T)	639	---
HC TUMORS SAME RTE	2/100 (2%)			
HC TUMORS ALL RTES	3/1142 (0%)			

**STATISTICAL TESTS**

POLY 3	P=0.601N	P=0.504	P=0.256	(e)
POLY 1.5	P=0.610N	P=0.501	P=0.249	(e)
POLY 6	P=0.590N	P=0.505	P=0.262	(e)
COCH-ARM / FISHERS	P=0.616N	P=0.500	P=0.247	(e)
MAX-ISO-POLY-3	P=0.345N	P=0.163	P=0.094	(e)
HISTCONT SAME RTE	(h)	(h)	(h)	(e)
HISTCONT ALL RTES	(h)	(h)	(h)	(e)



TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

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

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	1/45.07	2/48.05	0/45.98
POLY-3 PERCENT (g)	0%	2.2%	4.2%	0%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	1/42 (2%)	0/41 (0%)
FIRST INCIDENCE	---	730 (T)	639	---
HC TUMORS SAME RTE	2/100 (2%)			
HC TUMORS ALL RTES	22/1142 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.601N	P=0.504	P=0.256	(e)
POLY 1.5	P=0.610N	P=0.501	P=0.249	(e)
POLY 6	P=0.590N	P=0.505	P=0.262	(e)
COCH-ARM / FISHERS	P=0.616N	P=0.500	P=0.247	(e)
MAX-ISO-POLY-3	P=0.345N	P=0.163	P=0.094	(e)
HISTCONT SAME RTE	(h)	(h)	(h)	(e)
HISTCONT ALL RTES	(h)	(h)	(h)	(e)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**All Organs  
 Hemangioma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	0/45.07	2/47.72	0/45.98
POLY-3 PERCENT (g)	0%	0%	4.2%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	2/42 (5%)	0/41 (0%)
FIRST INCIDENCE	---	---	730 (T)	---
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	9/1149 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.610	(e)	P=0.255	(e)
POLY 1.5	P=0.601	(e)	P=0.249	(e)
POLY 6	P=0.624	(e)	P=0.260	(e)
COCH-ARM / FISHERS	P=0.595	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.274	(e)	P=0.093	(e)
HISTCONT SAME RTE	P=0.362	(e)	P=0.103	(e)
HISTCONT ALL RTES	P=0.318	(e)	P=0.042*	(e)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>All Organs</b>				
<b>Hemangiosarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	3/50 (6%)	4/50 (8%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	3/44.55	4/45.25	2/47.72	1/45.98
POLY-3 PERCENT (g)	6.7%	8.8%	4.2%	2.2%
TERMINAL (d)	2/38 (5%)	2/36 (6%)	2/42 (5%)	1/41 (2%)
FIRST INCIDENCE	640	693	730 (T)	730 (T)
HC TUMORS SAME RTE	10/100 (10%)			
HC TUMORS ALL RTES	67/1149 (6%)			

**STATISTICAL TESTS**

POLY 3	P=0.151N	P=0.509	P=0.469N	P=0.294N
POLY 1.5	P=0.157N	P=0.503	P=0.479N	P=0.301N
POLY 6	P=0.145N	P=0.511	P=0.462N	P=0.286N
COCH-ARM / FISHERS	P=0.162N	P=0.500	P=0.500N	P=0.309N
MAX-ISO-POLY-3	P=0.201N	P=0.356	P=0.303N	P=0.150N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**All Organs  
 Hemangiosarcoma or Hemangioma**

TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	4/50 (8%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	3/44.55	4/45.25	4/47.72	1/45.98
POLY-3 PERCENT (g)	6.7%	8.8%	8.4%	2.2%
TERMINAL (d)	2/38 (5%)	2/36 (6%)	4/42 (10%)	1/41 (2%)
FIRST INCIDENCE	640	693	730 (T)	730 (T)
HC TUMORS SAME RTE	10/100 (10%)			
HC TUMORS ALL RTES	76/1149 (7%)			

**STATISTICAL TESTS**

POLY 3	P=0.196N	P=0.509	P=0.537	P=0.294N
POLY 1.5	P=0.204N	P=0.503	P=0.525	P=0.301N
POLY 6	P=0.186N	P=0.511	P=0.546	P=0.286N
COCH-ARM / FISHERS	P=0.210N	P=0.500	P=0.500	P=0.309N
MAX-ISO-POLY-3	P=0.221N	P=0.356	P=0.386	P=0.150N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**All Organs  
 Histiocytic Sarcoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	2/45.07	1/47.72	0/45.98
POLY-3 PERCENT (g)	0%	4.4%	2.1%	0%
TERMINAL (d)	0/38 (0%)	2/36 (6%)	1/42 (2%)	0/41 (0%)
FIRST INCIDENCE	---	730 (T)	730 (T)	---
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	7/1149 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.444N	P=0.241	P=0.515	(e)
POLY 1.5	P=0.453N	P=0.239	P=0.510	(e)
POLY 6	P=0.435N	P=0.243	P=0.519	(e)
COCH-ARM / FISHERS	P=0.461N	P=0.247	P=0.500	(e)
MAX-ISO-POLY-3	P=0.336N	P=0.080	P=0.177	(e)
HISTCONT SAME RTE	(h)	(h)	(h)	(e)
HISTCONT ALL RTES	(h)	(h)	(h)	(e)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

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

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/44.94	1/45.15	0/47.72	2/45.98
POLY-3 PERCENT (g)	2.2%	2.2%	0%	4.4%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	2/41 (5%)
FIRST INCIDENCE	477	709	---	730 (T)
HC TUMORS SAME RTE	1/100 (1%)			
HC TUMORS ALL RTES	34/1149 (3%)			

**STATISTICAL TESTS**

POLY 3	P=0.374	P=0.760N	P=0.488N	P=0.508
POLY 1.5	P=0.370	P=0.760	P=0.492N	P=0.502
POLY 6	P=0.379	P=0.759N	P=0.485N	P=0.515
COCH-ARM / FISHERS	P=0.366	P=0.753N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.285	P=0.498N	P=0.158N	P=0.289
HISTCONT SAME RTE	P=0.171	P=0.347	(e)	P=0.133
HISTCONT ALL RTES	P=0.331	P=1.000	(e)	P=0.362

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**All Organs  
 Osteoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.22	0/45.07	0/47.72	1/45.98
POLY-3 PERCENT (g)	0%	0%	0%	2.2%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	1/41 (2%)
FIRST INCIDENCE	---	---	---	730 (T)
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	0/1149 (0%)			

**STATISTICAL TESTS**

POLY 3	P=0.203	(e)	(e)	P=0.508
POLY 1.5	P=0.201	(e)	(e)	P=0.503
POLY 6	P=0.207	(e)	(e)	P=0.513
COCH-ARM / FISHERS	P=0.198	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.137	(e)	(e)	P=0.168
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**All Organs  
 Osteosarcoma or Osteoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.22	0/45.07	0/47.72	1/45.98
POLY-3 PERCENT (g)	0%	0%	0%	2.2%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	1/41 (2%)
FIRST INCIDENCE	---	---	---	730 (T)
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	3/1149 (0%)			

**STATISTICAL TESTS**

POLY 3	P=0.203	(e)	(e)	P=0.508
POLY 1.5	P=0.201	(e)	(e)	P=0.503
POLY 6	P=0.207	(e)	(e)	P=0.513
COCH-ARM / FISHERS	P=0.198	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.137	(e)	(e)	P=0.168
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)



TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>All Organs</b>				
<b>Benign Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	30/50 (60%)	35/50 (70%)	37/50 (74%)	37/50 (74%)
POLY-3 RATE (b)	30/47.1	35/47.42	37/48.65	37/47
POLY-3 PERCENT (g)	63.7%	73.8%	76.1%	78.7%
TERMINAL (d)	23/38 (61%)	28/36 (78%)	33/42 (79%)	33/41 (81%)
FIRST INCIDENCE	477	428	597	570
HC TUMORS SAME RTE	66/100 (66%)			
HC TUMORS ALL RTES	753/1149 (66%)			

**STATISTICAL TESTS**

POLY 3	P=0.073	P=0.196	P=0.131	P=0.078
POLY 1.5	P=0.072	P=0.190	P=0.122	P=0.075
POLY 6	P=0.083	P=0.187	P=0.133	P=0.087
COCH-ARM / FISHERS	P=0.093	P=0.201	P=0.101	P=0.101
MAX-ISO-POLY-3	P=0.073	P=0.140	P=0.092	P=0.049*
HISTCONT SAME RTE	P=0.098	P=0.199	P=0.130	P=0.068
HISTCONT ALL RTES	P=0.083	P=0.168	P=0.107	P=0.054

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>All Organs</b>				
<b>Malignant Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	19/50 (38%)	24/50 (48%)	28/50 (56%)	22/50 (44%)
POLY-3 RATE (b)	19/47.87	24/47.77	28/49.55	22/46.36
POLY-3 PERCENT (g)	39.7%	50.2%	56.5%	47.5%
TERMINAL (d)	12/38 (32%)	13/36 (36%)	21/42 (50%)	20/41 (49%)
FIRST INCIDENCE	477	444	588	638
HC TUMORS SAME RTE	50/100 (50%)			
HC TUMORS ALL RTES	582/1149 (51%)			

**STATISTICAL TESTS**

POLY 3	P=0.282	P=0.203	P=0.071	P=0.291
POLY 1.5	P=0.296	P=0.198	P=0.065	P=0.301
POLY 6	P=0.270	P=0.209	P=0.076	P=0.282
COCH-ARM / FISHERS	P=0.342	P=0.210	P=0.054	P=0.342
MAX-ISO-POLY-3	P=0.189	P=0.150	P=0.049*	P=0.228
HISTCONT SAME RTE	P=0.254	P=0.212	P=0.068	P=0.320
HISTCONT ALL RTES	P=0.218	P=0.178	P=0.054	P=0.280

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Males			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**All Organs  
 Malignant and Benign Tumors**

TUMOR RATES	#	#	#	#
OVERALL (a)	38/50 (76%)	43/50 (86%)	44/50 (88%)	43/50 (86%)
POLY-3 RATE (b)	38/49.09	43/48.57	44/50	43/47
POLY-3 PERCENT (g)	77.4%	88.5%	88%	91.5%
TERMINAL (d)	27/38 (71%)	31/36 (86%)	36/42 (86%)	39/41 (95%)
FIRST INCIDENCE	477	428	588	570
HC TUMORS SAME RTE	86/100 (86%)			
HC TUMORS ALL RTES	976/1149 (85%)			

**STATISTICAL TESTS**

POLY 3	P=0.047*	P=0.114	P=0.129	P=0.048*
POLY 1.5	P=0.066	P=0.116	P=0.120	P=0.066
POLY 6	P=0.035*	P=0.106	P=0.133	P=0.035*
COCH-ARM / FISHERS	P=0.148	P=0.154	P=0.096	P=0.154
MAX-ISO-POLY-3	P=0.036*	P=0.071	P=0.083	P=0.028*
HISTCONT SAME RTE	P=0.049*	P=0.099	P=0.116	P=0.038*
HISTCONT ALL RTES	P=0.041*	P=0.080	P=0.095	P=0.030*

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**Adrenal Cortex  
 Adenoma**

**TUMOR RATES**

OVERALL (a)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/45.13	0/46.68	0/45.08	0/44.78
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	1/35 (3%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	---	---	---
HC TUMORS SAME RTE	1/98 (1%)			
HC TUMORS ALL RTES	5/1244 (0%)			

**STATISTICAL TESTS**

POLY 3	P=0.303N	P=0.493N	P=0.500N	P=0.502N
POLY 1.5	P=0.303N	P=0.494N	P=0.499N	P=0.501N
POLY 6	P=0.304N	P=0.491N	P=0.500N	P=0.502N
COCH-ARM / FISHERS	P=0.303N	P=0.495N	P=0.495N	P=0.495N
MAX-ISO-POLY-3	P=0.127N	P=0.157N	P=0.160N	P=0.162N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

Adrenal Medulla  
 Pheochromocytoma Benign

TUMOR RATES

OVERALL (a)	1/49 (2%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/45.13	2/47	0/45.08	1/44.78
POLY-3 PERCENT (g)	2.2%	4.3%	0%	2.2%
TERMINAL (d)	1/35 (3%)	1/41 (2%)	0/38 (0%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	640	---	729 (T)
HC TUMORS SAME RTE	0/98 (0%)			
HC TUMORS ALL RTES	14/1239 (1%)			

STATISTICAL TESTS

POLY 3	P=0.501N	P=0.514	P=0.500N	P=0.759
POLY 1.5	P=0.501N	P=0.511	P=0.499N	P=0.759
POLY 6	P=0.502N	P=0.520	P=0.500N	P=0.759
COCH-ARM / FISHERS	P=0.495N	P=0.508	P=0.495N	P=0.747N
MAX-ISO-POLY-3	P=0.400N	P=0.295	P=0.160N	P=0.497
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

Adrenal Medulla  
 Pheochromocytoma: Benign, Complex, Malignant, NOS

TUMOR RATES

OVERALL (a)	1/49 (2%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/45.13	2/47	0/45.08	1/44.78
POLY-3 PERCENT (g)	2.2%	4.3%	0%	2.2%
TERMINAL (d)	1/35 (3%)	1/41 (2%)	0/38 (0%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	640	---	729 (T)
HC TUMORS SAME RTE	0/98 (0%)			
HC TUMORS ALL RTES	22/1239 (2%)			

STATISTICAL TESTS

POLY 3	P=0.501N	P=0.514	P=0.500N	P=0.759
POLY 1.5	P=0.501N	P=0.511	P=0.499N	P=0.759
POLY 6	P=0.502N	P=0.520	P=0.500N	P=0.759
COCH-ARM / FISHERS	P=0.495N	P=0.508	P=0.495N	P=0.747N
MAX-ISO-POLY-3	P=0.400N	P=0.295	P=0.160N	P=0.497
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>Bone</b>				
<b>Osteosarcoma or Osteoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/49 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/45.13	0/46.68	2/45.86	1/44.78
POLY-3 PERCENT (g)	0%	0%	4.4%	2.2%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	1/38 (3%)	1/37 (3%)
FIRST INCIDENCE	---	---	439	729 (T)
HC TUMORS SAME RTE	1/99 (1%)			
HC TUMORS ALL RTES	7/1249 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.236	(e)	P=0.241	P=0.498
POLY 1.5	P=0.238	(e)	P=0.240	P=0.499
POLY 6	P=0.234	(e)	P=0.242	P=0.498
COCH-ARM / FISHERS	P=0.249	(e)	P=0.253	P=0.505
MAX-ISO-POLY-3	P=0.178	(e)	P=0.078	P=0.160
HISTCONT SAME RTE	P=0.239	(e)	P=0.109	P=0.225
HISTCONT ALL RTES	P=0.050*	(e)	P=0.014*	P=0.159

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>Harderian Gland Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	7/49 (14%)	6/50 (12%)	4/50 (8%)	6/50 (12%)
POLY-3 RATE (b)	7/45.89	6/47.14	4/45.51	6/45.25
POLY-3 PERCENT (g)	15.3%	12.7%	8.8%	13.3%
TERMINAL (d)	6/35 (17%)	4/41 (10%)	2/38 (5%)	5/37 (14%)
FIRST INCIDENCE	450	640	642	589
HC TUMORS SAME RTE	7/99 (7%)			
HC TUMORS ALL RTES	128/1249 (10%)			

**STATISTICAL TESTS**

POLY 3	P=0.440N	P=0.479N	P=0.266N	P=0.511N
POLY 1.5	P=0.436N	P=0.483N	P=0.263N	P=0.508N
POLY 6	P=0.443N	P=0.469N	P=0.262N	P=0.511N
COCH-ARM / FISHERS	P=0.414N	P=0.484N	P=0.251N	P=0.484N
MAX-ISO-POLY-3	P=0.441N	P=0.364N	P=0.174N	P=0.393N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)



TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
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 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>Harderian Gland Carcinoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/49 (2%)	0/50 (0%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	1/45.13	0/46.68	2/45.43	2/45.72
POLY-3 PERCENT (g)	2.2%	0%	4.4%	4.4%
TERMINAL (d)	1/35 (3%)	0/41 (0%)	1/38 (3%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	---	631	589
HC TUMORS SAME RTE	1/99 (1%)			
HC TUMORS ALL RTES	33/1249 (3%)			

**STATISTICAL TESTS**

POLY 3	P=0.245	P=0.493N	P=0.502	P=0.505
POLY 1.5	P=0.244	P=0.494N	P=0.502	P=0.502
POLY 6	P=0.247	P=0.491N	P=0.505	P=0.508
COCH-ARM / FISHERS	P=0.249	P=0.495N	P=0.508	P=0.508
MAX-ISO-POLY-3	P=0.272	P=0.157N	P=0.283	P=0.285
HISTCONT SAME RTE	P=0.201	(e)	P=0.139	P=0.138
HISTCONT ALL RTES	P=0.315	(e)	P=0.353	P=0.355

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

---

**Harderian Gland  
 Carcinoma or Adenoma**

**TUMOR RATES**

	#	#	#	#
OVERALL (a)	8/49 (16%)	6/50 (12%)	6/50 (12%)	8/50 (16%)
POLY-3 RATE (b)	8/45.89	6/47.14	6/45.86	8/46.19
POLY-3 PERCENT (g)	17.4%	12.7%	13.1%	17.3%
TERMINAL (d)	7/35 (20%)	4/41 (10%)	3/38 (8%)	5/37 (14%)
FIRST INCIDENCE	450	640	631	589
HC TUMORS SAME RTE	8/99 (8%)			
HC TUMORS ALL RTES	160/1249 (13%)			

**STATISTICAL TESTS**

POLY 3	P=0.498	P=0.366N	P=0.387N	P=0.602N
POLY 1.5	P=0.496	P=0.370N	P=0.386N	P=0.606N
POLY 6	P=0.504	P=0.355N	P=0.379N	P=0.593N
COCH-ARM / FISHERS	P=0.514	P=0.371N	P=0.371N	P=0.590N
MAX-ISO-POLY-3	P=0.541N	P=0.266N	P=0.284N	P=0.493N
HISTCONT SAME RTE	P=0.123	P=0.382	P=0.363	P=0.169
HISTCONT ALL RTES	P=0.630	P=1.000	P=1.000	P=0.437

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TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

Liver  
 Hemangioma

**TUMOR RATES**

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.13	0/46.68	0/45.08	0/44.78
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/99 (0%)			
HC TUMORS ALL RTES	6/1245 (1%)			

**STATISTICAL TESTS**

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

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
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 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>Liver</b>				
<b>Hepatoblastoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/49 (0%)	1/50 (2%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	0/45.13	1/46.68	2/45.43	2/44.78
POLY-3 PERCENT (g)	0%	2.1%	4.4%	4.5%
TERMINAL (d)	0/35 (0%)	1/41 (2%)	1/38 (3%)	2/37 (5%)
FIRST INCIDENCE	---	729 (T)	631	729 (T)
HC TUMORS SAME RTE	0/99 (0%)			
HC TUMORS ALL RTES	6/1245 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.154	P=0.507	P=0.239	P=0.235
POLY 1.5	P=0.155	P=0.506	P=0.239	P=0.236
POLY 6	P=0.153	P=0.509	P=0.240	P=0.235
COCH-ARM / FISHERS	P=0.163	P=0.505	P=0.253	P=0.253
MAX-ISO-POLY-3	P=0.160	P=0.166	P=0.077	P=0.077
HISTCONT SAME RTE	P=0.143	P=0.110	P=0.108	P=0.108
HISTCONT ALL RTES	P<0.001**	P=0.135	P=0.011*	P=0.011*

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>Liver</b>				
<b>Hepatocellular Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	13/49 (27%)	15/50 (30%)	13/50 (26%)	27/50 (54%)
POLY-3 RATE (b)	13/45.56	15/47.22	13/45.61	27/45.77
POLY-3 PERCENT (g)	28.5%	31.8%	28.5%	59%
TERMINAL (d)	10/35 (29%)	12/41 (29%)	10/38 (26%)	24/37 (65%)
FIRST INCIDENCE	663	645	631	566
HC TUMORS SAME RTE	17/99 (17%)			
HC TUMORS ALL RTES	345/1245 (28%)			

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.455	P=0.590N	P=0.002**
POLY 1.5	P<0.001**	P=0.447	P=0.586N	P=0.002**
POLY 6	P<0.001**	P=0.469	P=0.589N	P=0.002**
COCH-ARM / FISHERS	P=0.002**	P=0.437	P=0.567N	P=0.005**
MAX-ISO-POLY-3	P<0.001**	P=0.368	P=0.498N	P<0.001**
HISTCONT SAME RTE	P=0.002**	P=0.187	P=0.266	P<0.001**
HISTCONT ALL RTES	P<0.001**	P=0.465	P=1.000	P<0.001**

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**Liver  
 Hepatocellular Carcinoma**

**TUMOR RATES**

OVERALL (a)	5/49 (10%)	1/50 (2%)	4/50 (8%)	8/50 (16%)
POLY-3 RATE (b)	5/45.42	1/46.68	4/45.67	8/46.08
POLY-3 PERCENT (g)	11%	2.1%	8.8%	17.4%
TERMINAL (d)	3/35 (9%)	1/41 (2%)	2/38 (5%)	3/37 (8%)
FIRST INCIDENCE	681	729 (T)	631	589
HC TUMORS SAME RTE	4/99 (4%)			
HC TUMORS ALL RTES	131/1245 (11%)			

**STATISTICAL TESTS**

POLY 3	P=0.076	P=0.095N	P=0.497N	P=0.285
POLY 1.5	P=0.076	P=0.096N	P=0.496N	P=0.281
POLY 6	P=0.078	P=0.094N	P=0.493N	P=0.292
COCH-ARM / FISHERS	P=0.081	P=0.098N	P=0.487N	P=0.290
MAX-ISO-POLY-3	P=0.061	P=0.042N*	P=0.360N	P=0.193
HISTCONT SAME RTE	P=0.071	P=1.000	P=0.317	P=0.103
HISTCONT ALL RTES	P=0.068	P=1.000	P=1.000	P=0.234

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**Liver  
 Hepatocellular Carcinoma or Hepatoblastoma**

**TUMOR RATES**

OVERALL (a)	5/49 (10%)	2/50 (4%)	5/50 (10%)	10/50 (20%)
POLY-3 RATE (b)	5/45.42	2/46.68	5/45.67	10/46.08
POLY-3 PERCENT (g)	11%	4.3%	11%	21.7%
TERMINAL (d)	3/35 (9%)	2/41 (5%)	3/38 (8%)	5/37 (14%)
FIRST INCIDENCE	681	729 (T)	631	589
HC TUMORS SAME RTE	4/99 (4%)			
HC TUMORS ALL RTES	136/1245 (11%)			

**STATISTICAL TESTS**

POLY 3	P=0.027*	P=0.205N	P=0.627N	P=0.135
POLY 1.5	P=0.026*	P=0.207N	P=0.626N	P=0.133
POLY 6	P=0.027*	P=0.203N	P=0.624N	P=0.140
COCH-ARM / FISHERS	P=0.030*	P=0.210N	P=0.617N	P=0.140
MAX-ISO-POLY-3	P=0.027*	P=0.114N	P=0.496N	P=0.083
HISTCONT SAME RTE	P=0.036*	P=1.000	P=0.207	P=0.089
HISTCONT ALL RTES	P=0.030*	P=1.000	P=1.000	P=0.095

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**Liver  
 Hepatocellular Carcinoma or Hepatocellular Adenoma**

**TUMOR RATES**

OVERALL (a)	17/49 (35%)	15/50 (30%)	15/50 (30%)	32/50 (64%)
POLY-3 RATE (b)	17/45.74	15/47.22	15/45.84	32/46.85
POLY-3 PERCENT (g)	37.2%	31.8%	32.7%	68.3%
TERMINAL (d)	13/35 (37%)	12/41 (29%)	11/38 (29%)	25/37 (68%)
FIRST INCIDENCE	663	645	631	566
HC TUMORS SAME RTE	20/99 (20%)			
HC TUMORS ALL RTEs	419/1245 (34%)			

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.371N	P=0.410N	P=0.002**
POLY 1.5	P<0.001**	P=0.379N	P=0.408N	P=0.002**
POLY 6	P<0.001**	P=0.360N	P=0.406N	P=0.002**
COCH-ARM / FISHERS	P<0.001**	P=0.388N	P=0.388N	P=0.003**
MAX-ISO-POLY-3	P<0.001**	P=0.294N	P=0.328N	P<0.001**
HISTCONT SAME RTE	P<0.001**	P=0.338	P=0.319	P<0.001**
HISTCONT ALL RTEs	P<0.001**	P=1.000	P=1.000	P<0.001**



TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

Liver  
 Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma

**TUMOR RATES**

OVERALL (a)	17/49 (35%)	15/50 (30%)	15/50 (30%)	33/50 (66%)
POLY-3 RATE (b)	17/45.74	15/47.22	15/45.84	33/46.85
POLY-3 PERCENT (g)	37.2%	31.8%	32.7%	70.4%
TERMINAL (d)	13/35 (37%)	12/41 (29%)	11/38 (29%)	26/37 (70%)
FIRST INCIDENCE	663	645	631	566
HC TUMORS SAME RTE	20/99 (20%)			
HC TUMORS ALL RTES	421/1245 (34%)			

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.371N	P=0.410N	P<0.001**
POLY 1.5	P<0.001**	P=0.379N	P=0.408N	P<0.001**
POLY 6	P<0.001**	P=0.360N	P=0.406N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.388N	P=0.388N	P=0.002**
MAX-ISO-POLY-3	P<0.001**	P=0.294N	P=0.328N	P<0.001**
HISTCONT SAME RTE	P<0.001**	P=0.338	P=0.319	P<0.001**
HISTCONT ALL RTES	P<0.001**	P=1.000	P=1.000	P<0.001**

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

Liver  
 Hepatocholangiocarcinoma

**TUMOR RATES**

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/45.13	0/46.68	0/45.08	1/44.78
POLY-3 PERCENT (g)	0%	0%	0%	2.2%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	1/37 (3%)
FIRST INCIDENCE	---	---	---	729 (T)
HC TUMORS SAME RTE	0/99 (0%)			
HC TUMORS ALL RTES	2/1245 (0%)			

**STATISTICAL TESTS**

POLY 3	P=0.196	(e)	(e)	P=0.498
POLY 1.5	P=0.197	(e)	(e)	P=0.499
POLY 6	P=0.195	(e)	(e)	P=0.498
COCH-ARM / FISHERS	P=0.200	(e)	(e)	P=0.505
MAX-ISO-POLY-3	P=0.124	(e)	(e)	P=0.160
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
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 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

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**Lung  
 Alveolar/Bronchiolar Adenoma**

**TUMOR RATES**

OVERALL (a)	1/49 (2%)	5/50 (10%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	1/45.13	5/46.68	2/45.57	3/44.78
POLY-3 PERCENT (g)	2.2%	10.7%	4.4%	6.7%
TERMINAL (d)	1/35 (3%)	5/41 (12%)	1/38 (3%)	3/37 (8%)
FIRST INCIDENCE	729 (T)	729 (T)	584	729 (T)
HC TUMORS SAME RTE	8/98 (8%)			
HC TUMORS ALL RTES	65/1248 (5%)			

**STATISTICAL TESTS**

POLY 3	P=0.428	P=0.109	P=0.503	P=0.302
POLY 1.5	P=0.430	P=0.108	P=0.503	P=0.304
POLY 6	P=0.427	P=0.111	P=0.506	P=0.302
COCH-ARM / FISHERS	P=0.445	P=0.107	P=0.508	P=0.316
MAX-ISO-POLY-3	P=0.256	P=0.051	P=0.283	P=0.154
HISTCONT SAME RTE	P=0.339	P=0.069	P=0.394	P=0.218
HISTCONT ALL RTES	P=0.296	P=0.055	P=0.354	P=0.183

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TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
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 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**Lung  
 Alveolar/Bronchiolar Carcinoma**

**TUMOR RATES**

OVERALL (a)	2/49 (4%)	1/50 (2%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	2/45.63	1/46.68	2/45.57	3/44.78
POLY-3 PERCENT (g)	4.4%	2.1%	4.4%	6.7%
TERMINAL (d)	0/35 (0%)	1/41 (2%)	1/38 (3%)	3/37 (8%)
FIRST INCIDENCE	598	729 (T)	584	729 (T)
HC TUMORS SAME RTE	2/98 (2%)			
HC TUMORS ALL RTES	47/1248 (4%)			

**STATISTICAL TESTS**

POLY 3	P=0.303	P=0.492N	P=0.693	P=0.491
POLY 1.5	P=0.307	P=0.492N	P=0.693N	P=0.495
POLY 6	P=0.299	P=0.491N	P=0.694	P=0.487
COCH-ARM / FISHERS	P=0.319	P=0.492N	P=0.684N	P=0.510
MAX-ISO-POLY-3	P=0.351	P=0.275N	P=0.499	P=0.319
HISTCONT SAME RTE	P=0.175	P=1.000	P=0.340	P=0.178
HISTCONT ALL RTES	P=0.408	P=1.000	P=0.607	P=0.390

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
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 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

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

**TUMOR RATES**

OVERALL (a)	3/49 (6%)	6/50 (12%)	3/50 (6%)	6/50 (12%)
POLY-3 RATE (b)	3/45.63	6/46.68	3/45.57	6/44.78
POLY-3 PERCENT (g)	6.6%	12.9%	6.6%	13.4%
TERMINAL (d)	1/35 (3%)	6/41 (15%)	2/38 (5%)	6/37 (16%)
FIRST INCIDENCE	598	729 (T)	584	729 (T)
HC TUMORS SAME RTE	10/98 (10%)			
HC TUMORS ALL RTES	107/1248 (9%)			

**STATISTICAL TESTS**

POLY 3	P=0.264	P=0.253	P=0.662	P=0.232
POLY 1.5	P=0.269	P=0.253	P=0.661N	P=0.237
POLY 6	P=0.259	P=0.254	P=0.662	P=0.227
COCH-ARM / FISHERS	P=0.288	P=0.254	P=0.651N	P=0.254
MAX-ISO-POLY-3	P=0.230	P=0.157	P=0.499	P=0.143
HISTCONT SAME RTE	P=0.306	P=0.221	P=0.653	P=0.202
HISTCONT ALL RTES	P=0.265	P=0.186	P=0.629	P=0.169

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**Ovary  
 Cystadenoma**

**TUMOR RATES**

OVERALL (a)	1/49 (2%)	2/49 (4%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/45.31	2/45.68	0/45.08	2/44.78
POLY-3 PERCENT (g)	2.2%	4.4%	0%	4.5%
TERMINAL (d)	0/35 (0%)	2/40 (5%)	0/38 (0%)	2/37 (5%)
FIRST INCIDENCE	681	729 (T)	---	729 (T)
HC TUMORS SAME RTE	5/98 (5%)			
HC TUMORS ALL RTES	46/1221 (4%)			

**STATISTICAL TESTS**

POLY 3	P=0.466	P=0.503	P=0.501N	P=0.496
POLY 1.5	P=0.468	P=0.502	P=0.500N	P=0.498
POLY 6	P=0.464	P=0.505	P=0.501N	P=0.494
COCH-ARM / FISHERS	P=0.477	P=0.500	P=0.495N	P=0.508
MAX-ISO-POLY-3	P=0.418	P=0.284	P=0.161N	P=0.279
HISTCONT SAME RTE	P=0.538	P=0.395	(e)	P=0.389
HISTCONT ALL RTES	P=0.489	P=0.354	(e)	P=0.348

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
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 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

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

**TUMOR RATES**

OVERALL (a)	2/49 (4%)	2/50 (4%)	0/49 (0%)	0/49 (0%)
POLY-3 RATE (b)	2/45.58	2/46.68	0/44.33	0/43.78
POLY-3 PERCENT (g)	4.4%	4.3%	0%	0%
TERMINAL (d)	1/35 (3%)	2/41 (5%)	0/38 (0%)	0/36 (0%)
FIRST INCIDENCE	598	729 (T)	---	---
HC TUMORS SAME RTE	5/97 (5%)			
HC TUMORS ALL RTES	97/1216 (8%)			

**STATISTICAL TESTS**

POLY 3	P=0.089N	P=0.685N	P=0.243N	P=0.246N
POLY 1.5	P=0.089N	P=0.686N	P=0.242N	P=0.244N
POLY 6	P=0.090N	P=0.684N	P=0.244N	P=0.248N
COCH-ARM / FISHERS	P=0.086N	P=0.684N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.133N	P=0.489N	P=0.082N	P=0.085N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
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 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

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

TUMOR RATES	#	#	#	#
OVERALL (a)	2/49 (4%)	2/50 (4%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/45.13	2/46.91	1/45.67	2/45.19
POLY-3 PERCENT (g)	4.4%	4.3%	2.2%	4.4%
TERMINAL (d)	2/35 (6%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	694	541	666
HC TUMORS SAME RTE	5/99 (5%)			
HC TUMORS ALL RTES	53/1249 (4%)			

**STATISTICAL TESTS**

POLY 3	P=0.578N	P=0.680N	P=0.496N	P=0.693N
POLY 1.5	P=0.578N	P=0.683N	P=0.496N	P=0.694
POLY 6	P=0.578N	P=0.675N	P=0.493N	P=0.691N
COCH-ARM / FISHERS	P=0.571N	P=0.684N	P=0.492N	P=0.684N
MAX-ISO-POLY-3	P=0.611N	P=0.484N	P=0.277N	P=0.499N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)



TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

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

TUMOR RATES	#	#	#	#
OVERALL (a)	2/49 (4%)	2/50 (4%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/45.13	2/46.91	1/45.67	2/45.19
POLY-3 PERCENT (g)	4.4%	4.3%	2.2%	4.4%
TERMINAL (d)	2/35 (6%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	694	541	666
HC TUMORS SAME RTE	5/99 (5%)			
HC TUMORS ALL RTES	53/1249 (4%)			

**STATISTICAL TESTS**

POLY 3	P=0.578N	P=0.680N	P=0.496N	P=0.693N
POLY 1.5	P=0.578N	P=0.683N	P=0.496N	P=0.694
POLY 6	P=0.578N	P=0.675N	P=0.493N	P=0.691N
COCH-ARM / FISHERS	P=0.571N	P=0.684N	P=0.492N	P=0.684N
MAX-ISO-POLY-3	P=0.611N	P=0.484N	P=0.277N	P=0.499N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>Skin</b>				
<b>Sarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/49 (0%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/45.13	2/46.91	1/45.67	1/44.95
POLY-3 PERCENT (g)	0%	4.3%	2.2%	2.2%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	694	541	684
HC TUMORS SAME RTE	4/99 (4%)			
HC TUMORS ALL RTES	27/1249 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.494	P=0.246	P=0.502	P=0.499
POLY 1.5	P=0.494	P=0.244	P=0.502	P=0.499
POLY 6	P=0.494	P=0.249	P=0.504	P=0.500
COCH-ARM / FISHERS	P=0.505	P=0.253	P=0.505	P=0.505
MAX-ISO-POLY-3	P=0.285	P=0.083	P=0.160	P=0.160
HISTCONT SAME RTE	P=0.376	P=0.116	P=0.225	P=0.225
HISTCONT ALL RTES	P=0.331	P=0.095	P=0.190	P=0.190

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**Skin  
 Schwannoma Malignant**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/49 (4%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/45.51	1/46.68	1/45.08	0/44.78
POLY-3 PERCENT (g)	4.4%	2.1%	2.2%	0%
TERMINAL (d)	0/35 (0%)	1/41 (2%)	1/38 (3%)	0/37 (0%)
FIRST INCIDENCE	663	729 (T)	729 (T)	---
HC TUMORS SAME RTE	0/99 (0%)			
HC TUMORS ALL RTES	6/1249 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.157N	P=0.491N	P=0.503N	P=0.241N
POLY 1.5	P=0.155N	P=0.492N	P=0.500N	P=0.239N
POLY 6	P=0.158N	P=0.490N	P=0.505N	P=0.243N
COCH-ARM / FISHERS	P=0.150N	P=0.492N	P=0.492N	P=0.242N
MAX-ISO-POLY-3	P=0.128N	P=0.274N	P=0.285N	P=0.080N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

---

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

---

**Spleen  
 Hemangiosarcoma**

**TUMOR RATES**

OVERALL (a)	1/49 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/45.13	0/46.68	0/45.08	1/45.25
POLY-3 PERCENT (g)	2.2%	0%	0%	2.2%
TERMINAL (d)	1/35 (3%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	---	---	591
HC TUMORS SAME RTE	1/97 (1%)			
HC TUMORS ALL RTES	24/1230 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.593	P=0.493N	P=0.500N	P=0.760N
POLY 1.5	P=0.593	P=0.494N	P=0.499N	P=0.760N
POLY 6	P=0.592	P=0.491N	P=0.500N	P=0.759N
COCH-ARM / FISHERS	P=0.598	P=0.495N	P=0.495N	P=0.747N
MAX-ISO-POLY-3	P=0.405N	P=0.157N	P=0.160N	P=0.498N
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

---

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**Stomach, Forestomach  
 Squamous Cell Carcinoma or Papilloma Squamous**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/49 (4%)	4/50 (8%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/45.13	4/46.68	2/45.08	1/44.78
POLY-3 PERCENT (g)	4.4%	8.6%	4.4%	2.2%
TERMINAL (d)	2/35 (6%)	4/41 (10%)	2/38 (5%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
HC TUMORS SAME RTE	2/99 (2%)			
HC TUMORS ALL RTES	22/1249 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.270N	P=0.353	P=0.694	P=0.503N
POLY 1.5	P=0.268N	P=0.350	P=0.693N	P=0.502N
POLY 6	P=0.271N	P=0.358	P=0.694N	P=0.503N
COCH-ARM / FISHERS	P=0.257N	P=0.349	P=0.684N	P=0.492N
MAX-ISO-POLY-3	P=0.286N	P=0.216	P=0.499	P=0.284N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**Stomach, Forestomach  
 Squamous Cell Papilloma**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/49 (4%)	4/50 (8%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/45.13	4/46.68	2/45.08	1/44.78
POLY-3 PERCENT (g)	4.4%	8.6%	4.4%	2.2%
TERMINAL (d)	2/35 (6%)	4/41 (10%)	2/38 (5%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
HC TUMORS SAME RTE	2/99 (2%)			
HC TUMORS ALL RTES	20/1249 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.270N	P=0.353	P=0.694	P=0.503N
POLY 1.5	P=0.268N	P=0.350	P=0.693N	P=0.502N
POLY 6	P=0.271N	P=0.358	P=0.694N	P=0.503N
COCH-ARM / FISHERS	P=0.257N	P=0.349	P=0.684N	P=0.492N
MAX-ISO-POLY-3	P=0.286N	P=0.216	P=0.499	P=0.284N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**Thyroid Gland: Follicular Cell  
 Carcinoma**

**TUMOR RATES**

OVERALL (a)	1/49 (2%)	0/50 (0%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/45.13	0/46.68	0/44.33	0/44.78
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	1/35 (3%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	---	---	---
HC TUMORS SAME RTE	0/98 (0%)			
HC TUMORS ALL RTES	3/1234 (0%)			

**STATISTICAL TESTS**

POLY 3	P=0.304N	P=0.493N	P=0.504N	P=0.502N
POLY 1.5	P=0.304N	P=0.494N	P=0.503N	P=0.501N
POLY 6	P=0.305N	P=0.491N	P=0.503N	P=0.502N
COCH-ARM / FISHERS	P=0.304N	P=0.495N	P=0.500N	P=0.495N
MAX-ISO-POLY-3	P=0.128N	P=0.157N	P=0.163N	P=0.162N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

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

**TUMOR RATES**

OVERALL (a)	2/49 (4%)	1/50 (2%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/45.13	1/46.68	0/44.33	0/44.78
POLY-3 PERCENT (g)	4.4%	2.1%	0%	0%
TERMINAL (d)	2/35 (6%)	1/41 (2%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---	---
HC TUMORS SAME RTE	1/98 (1%)			
HC TUMORS ALL RTES	32/1234 (3%)			

**STATISTICAL TESTS**

POLY 3	P=0.101N	P=0.488N	P=0.241N	P=0.239N
POLY 1.5	P=0.101N	P=0.490N	P=0.241N	P=0.238N
POLY 6	P=0.101N	P=0.485N	P=0.240N	P=0.239N
COCH-ARM / FISHERS	P=0.099N	P=0.492N	P=0.247N	P=0.242N
MAX-ISO-POLY-3	P=0.081N	P=0.273N	P=0.080N	P=0.079N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)



TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>Uterus</b>				
<b>Polyp Stromal</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/49 (0%)	0/50 (0%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	0/45.13	0/46.68	3/45.08	0/44.78
POLY-3 PERCENT (g)	0%	0%	6.7%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	3/38 (8%)	0/37 (0%)
FIRST INCIDENCE	---	---	729 (T)	---
HC TUMORS SAME RTE	0/99 (0%)			
HC TUMORS ALL RTES	33/1249 (3%)			

**STATISTICAL TESTS**

POLY 3	P=0.524	(e)	P=0.118	(e)
POLY 1.5	P=0.527	(e)	P=0.119	(e)
POLY 6	P=0.521	(e)	P=0.118	(e)
COCH-ARM / FISHERS	P=0.543	(e)	P=0.125	(e)
MAX-ISO-POLY-3	P=0.169	(e)	P=0.039*	(e)
HISTCONT SAME RTE	P=0.228	(e)	P=0.053	(e)
HISTCONT ALL RTES	P=0.195	(e)	P=0.041*	(e)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>All Organs</b>				
<b>Hemangioma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/49 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/45.13	0/46.68	1/45.08	0/44.78
POLY-3 PERCENT (g)	2.2%	0%	2.2%	0%
TERMINAL (d)	1/35 (3%)	0/41 (0%)	1/38 (3%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	---
HC TUMORS SAME RTE	2/99 (2%)			
HC TUMORS ALL RTES	20/1249 (2%)			

**STATISTICAL TESTS**

POLY 3	P=0.409N	P=0.493N	P=0.760	P=0.502N
POLY 1.5	P=0.407N	P=0.494N	P=0.760N	P=0.501N
POLY 6	P=0.411N	P=0.491N	P=0.761N	P=0.502N
COCH-ARM / FISHERS	P=0.402N	P=0.495N	P=0.747N	P=0.495N
MAX-ISO-POLY-3	P=0.259N	P=0.157N	P=0.499	P=0.162N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>All Organs</b>				
<b>Hemangiosarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	3/49 (6%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	3/45.18	0/46.68	1/45.08	2/45.25
POLY-3 PERCENT (g)	6.6%	0%	2.2%	4.4%
TERMINAL (d)	2/35 (6%)	0/41 (0%)	1/38 (3%)	1/37 (3%)
FIRST INCIDENCE	716	---	729 (T)	591
HC TUMORS SAME RTE	2/99 (2%)			
HC TUMORS ALL RTES	60/1249 (5%)			

**STATISTICAL TESTS**

POLY 3	P=0.558N	P=0.113N	P=0.306N	P=0.499N
POLY 1.5	P=0.556N	P=0.114N	P=0.305N	P=0.500N
POLY 6	P=0.559N	P=0.111N	P=0.306N	P=0.498N
COCH-ARM / FISHERS	P=0.550N	P=0.117N	P=0.301N	P=0.490N
MAX-ISO-POLY-3	P=0.190N	P=0.037N*	P=0.156N	P=0.324N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**All Organs  
 Hemangiosarcoma or Hemangioma**

TUMOR RATES	#	#	#	#
OVERALL (a)	4/49 (8%)	0/50 (0%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	4/45.18	0/46.68	2/45.08	2/45.25
POLY-3 PERCENT (g)	8.9%	0%	4.4%	4.4%
TERMINAL (d)	3/35 (9%)	0/41 (0%)	2/38 (5%)	1/37 (3%)
FIRST INCIDENCE	716	---	729 (T)	591
HC TUMORS SAME RTE	4/99 (4%)			
HC TUMORS ALL RTES	79/1249 (6%)			

**STATISTICAL TESTS**

POLY 3	P=0.406N	P=0.056N	P=0.338N	P=0.336N
POLY 1.5	P=0.405N	P=0.057N	P=0.336N	P=0.337N
POLY 6	P=0.408N	P=0.055N	P=0.338N	P=0.335N
COCH-ARM / FISHERS	P=0.397N	P=0.056N	P=0.329N	P=0.329N
MAX-ISO-POLY-3	P=0.134N	P=0.019N*	P=0.203N	P=0.201N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**All Organs  
 Histiocytic Sarcoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	3/49 (6%)	1/50 (2%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	3/45.44	1/46.92	0/45.08	3/45.29
POLY-3 PERCENT (g)	6.6%	2.1%	0%	6.6%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	1/37 (3%)
FIRST INCIDENCE	681	666	---	596
HC TUMORS SAME RTE	0/99 (0%)			
HC TUMORS ALL RTES	31/1249 (3%)			

**STATISTICAL TESTS**

POLY 3	P=0.523	P=0.294N	P=0.120N	P=0.661
POLY 1.5	P=0.525	P=0.296N	P=0.119N	P=0.661
POLY 6	P=0.520	P=0.291N	P=0.121N	P=0.661
COCH-ARM / FISHERS	P=0.532	P=0.301N	P=0.117N	P=0.651N
MAX-ISO-POLY-3	P=0.290	P=0.148N	P=0.040N*	P=0.498
HISTCONT SAME RTE	P=0.169	P=0.455	(e)	P=0.165
HISTCONT ALL RTES	P=0.289	P=1.000	(e)	P=0.199

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
 Time Report Requested: 09:18:35  
 First Dose M/F: 04/15/03 / 04/14/03  
 Lab: BAT

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

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	Females			
DOSE	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

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

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TUMOR RATES	#	#	#	#
OVERALL (a)	6/49 (12%)	2/50 (4%)	4/50 (8%)	6/50 (12%)
POLY-3 RATE (b)	6/45.7	2/47.88	4/45.14	6/45.84
POLY-3 PERCENT (g)	13.1%	4.2%	8.9%	13.1%
TERMINAL (d)	3/35 (9%)	0/41 (0%)	3/38 (8%)	2/37 (5%)
FIRST INCIDENCE	659	493	714	566
HC TUMORS SAME RTE	18/99 (18%)			
HC TUMORS ALL RTES	284/1249 (23%)			

**STATISTICAL TESTS**

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POLY 3	P=0.390	P=0.119N	P=0.377N	P=0.619N
POLY 1.5	P=0.393	P=0.122N	P=0.372N	P=0.620N
POLY 6	P=0.388	P=0.115N	P=0.382N	P=0.616N
COCH-ARM / FISHERS	P=0.411	P=0.128N	P=0.357N	P=0.606N
MAX-ISO-POLY-3	P=0.377	P=0.063N	P=0.262N	P=0.497N
HISTCONT SAME RTE	P=0.490	P=1.000	P=1.000	P=1.000
HISTCONT ALL RTES	P=0.439	P=1.000	P=1.000	P=1.000

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TDMS No. 99020 - 06  
 Test Type: CHRONIC  
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 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
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 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**All Organs  
 Osteoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/49 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/45.13	0/46.68	2/45.08	0/44.78
POLY-3 PERCENT (g)	0%	0%	4.4%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	2/38 (5%)	0/37 (0%)
FIRST INCIDENCE	---	---	729 (T)	---
HC TUMORS SAME RTE	0/99 (0%)			
HC TUMORS ALL RTES	2/1249 (0%)			

**STATISTICAL TESTS**

POLY 3	P=0.582	(e)	P=0.237	(e)
POLY 1.5	P=0.584	(e)	P=0.238	(e)
POLY 6	P=0.580	(e)	P=0.237	(e)
COCH-ARM / FISHERS	P=0.598	(e)	P=0.253	(e)
MAX-ISO-POLY-3	P=0.253	(e)	P=0.077	(e)
HISTCONT SAME RTE	P=0.336	(e)	P=0.108	(e)
HISTCONT ALL RTES	P=0.121	(e)	P<0.001**	(e)

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
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 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**All Organs  
 Osteosarcoma or Osteoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/49 (0%)	0/50 (0%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	0/45.13	0/46.68	3/45.86	1/44.78
POLY-3 PERCENT (g)	0%	0%	6.5%	2.2%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	2/38 (5%)	1/37 (3%)
FIRST INCIDENCE	---	---	439	729 (T)
HC TUMORS SAME RTE	1/99 (1%)			
HC TUMORS ALL RTES	9/1249 (1%)			

**STATISTICAL TESTS**

POLY 3	P=0.234	(e)	P=0.122	P=0.498
POLY 1.5	P=0.236	(e)	P=0.121	P=0.499
POLY 6	P=0.231	(e)	P=0.122	P=0.498
COCH-ARM / FISHERS	P=0.251	(e)	P=0.125	P=0.505
MAX-ISO-POLY-3	P=0.123	(e)	P=0.040*	P=0.160
HISTCONT SAME RTE	P=0.166	(e)	P=0.054	P=0.225
HISTCONT ALL RTES	P=0.043*	(e)	P=0.003**	P=0.190



TDMS No. 99020 - 06  
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P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
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Date Report Requested: 07/23/2008  
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 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>All Organs</b>				
<b>Benign Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	27/49 (55%)	22/50 (44%)	24/50 (48%)	32/50 (64%)
POLY-3 RATE (b)	27/46.96	22/47.54	24/46.41	32/46.25
POLY-3 PERCENT (g)	57.5%	46.3%	51.7%	69.2%
TERMINAL (d)	21/35 (60%)	18/41 (44%)	19/38 (50%)	28/37 (76%)
FIRST INCIDENCE	450	640	584	566
HC TUMORS SAME RTE	41/99 (41%)			
HC TUMORS ALL RTES	644/1249 (52%)			

**STATISTICAL TESTS**

POLY 3	P=0.072	P=0.186N	P=0.361N	P=0.164
POLY 1.5	P=0.080	P=0.186N	P=0.349N	P=0.178
POLY 6	P=0.065	P=0.179N	P=0.360N	P=0.152
COCH-ARM / FISHERS	P=0.118	P=0.183N	P=0.307N	P=0.243
MAX-ISO-POLY-3	P=0.068	P=0.135N	P=0.288N	P=0.119
HISTCONT SAME RTE	P=0.043*	P=0.607	P=0.341	P=0.087
HISTCONT ALL RTES	P=0.077	P=1.000	P=1.000	P=0.139

TDMS No. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 07/23/2008  
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 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>All Organs</b>				
<b>Malignant Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	20/49 (41%)	11/50 (22%)	17/50 (34%)	23/50 (46%)
POLY-3 RATE (b)	20/46.93	11/48.35	17/48.17	23/47.7
POLY-3 PERCENT (g)	42.6%	22.8%	35.3%	48.2%
TERMINAL (d)	10/35 (29%)	6/41 (15%)	10/38 (26%)	13/37 (35%)
FIRST INCIDENCE	598	493	439	566
HC TUMORS SAME RTE	35/99 (35%)			
HC TUMORS ALL RTEs	629/1249 (50%)			

**STATISTICAL TESTS**

POLY 3	P=0.121	P=0.030N*	P=0.301N	P=0.367
POLY 1.5	P=0.117	P=0.031N*	P=0.308N	P=0.356
POLY 6	P=0.127	P=0.030N*	P=0.297N	P=0.381
COCH-ARM / FISHERS	P=0.133	P=0.035N*	P=0.311N	P=0.376
MAX-ISO-POLY-3	P=0.087	P=0.019N*	P=0.235N	P=0.293
HISTCONT SAME RTE	P=0.117	P=1.000	P=1.000	P=0.232
HISTCONT ALL RTEs	P=0.098	P=1.000	P=1.000	P=0.367

TDMS No. 99020 - 06  
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P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

**All Organs  
 Malignant and Benign Tumors**

TUMOR RATES	#	#	#	#
OVERALL (a)	40/49 (82%)	26/50 (52%)	34/50 (68%)	41/50 (82%)
POLY-3 RATE (b)	40/48.15	26/48.98	34/48.6	41/48.17
POLY-3 PERCENT (g)	83.1%	53.1%	70%	85.1%
TERMINAL (d)	28/35 (80%)	19/41 (46%)	25/38 (66%)	30/37 (81%)
FIRST INCIDENCE	450	493	439	566
HC TUMORS SAME RTE	64/99 (65%)			
HC TUMORS ALL RTES	939/1249 (75%)			

**STATISTICAL TESTS**

POLY 3	P=0.117	P<0.001N**	P=0.097N	P=0.502
POLY 1.5	P=0.116	P<0.001N**	P=0.098N	P=0.494
POLY 6	P=0.124	P<0.001N**	P=0.094N	P=0.524
COCH-ARM / FISHERS	P=0.171	P=0.002N**	P=0.091N	P=0.584
MAX-ISO-POLY-3	P=0.038*	P<0.001N**	P=0.061N	P=0.391
HISTCONT SAME RTE	P=0.051	P=1.000	P=0.556	P=0.168
HISTCONT ALL RTES	P=0.043*	P=1.000	P=1.000	P=0.418

**TDMS No.** 99020 - 06  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** MICE/B6C3F1

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
Pulegone  
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## **LEGEND**

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

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