

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

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

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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## SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF Pulegone

### MALE MICE

#### Organ

Adrenal Cortex  
Adrenal Cortex: Subcapsular  
Epididymis  
Harderian Gland  
Heart  
Islets, Pancreatic  
Kidney

Kidney: Glomerulus  
Liver

Liver: Bile Duct

Liver: Hepatocyte, Centrilobular  
Liver: Oval Cell  
Liver: Vein  
Lung  
Lung: Alveolar Epithelium  
Lymph Node, Mesenteric  
Nose  
Nose: Nerve  
Nose: Olfactory Epithelium

#### Morphology

Hypertrophy  
Hyperplasia  
Inflammation  
Infiltration Cellular Mononuclear Cell  
Infiltration Cellular Mononuclear Cell  
Hyperplasia  
Cyst  
Glomerulopathy Hyaline  
Mineralization  
Nephropathy  
Congestion  
Clear Cell Focus  
Eosinophilic Focus  
Fatty Change Diffuse  
Fatty Change Focal  
Hematopoietic Cell Proliferation  
Mixed Cell Focus  
Necrosis  
Pigmentation  
Cyst  
Fibrosis  
Hyperplasia  
Hypertrophy  
Hyperplasia  
Intravascular Hepatocyte  
Inflammation  
Hyperplasia  
Atrophy  
Inflammation  
Atrophy  
Degeneration

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## SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF Pulegone

Preputial Gland	Metaplasia
Prostate	Cyst
Prostate: Epithelium	Infiltration Cellular Mononuclear Cell
Salivary Glands	Hyperplasia
Spleen	Infiltration Cellular Mononuclear Cell
Stomach, Forestomach	Hematopoietic Cell Proliferation
	Hyperplasia
	Inflammation
	Ulcer
Urinary Bladder	Infiltration Cellular Mononuclear Cell

### **FEMALE MICE**

#### **Organ**

Bone Marrow  
Clitoral Gland  
Eye  
Eye: Anterior Chamber  
Eye: Cornea  
Harderian Gland  
Harderian Gland: Epithelium  
Heart

Islets, Pancreatic  
Kidney

Kidney: Glomerulus  
Kidney: Papilla  
Liver

#### **Morphology**

Hyperplasia  
Inflammation  
Atrophy  
Inflammation  
Inflammation  
Infiltration Cellular Mononuclear Cell  
Hyperplasia  
Cardiomyopathy  
Mineralization  
Necrosis  
Hyperplasia  
Accumulation, Hyaline Droplet  
Glomerulopathy Hyaline  
Mineralization  
Nephropathy  
Congestion  
Necrosis  
Angiectasis  
Clear Cell Focus  
Eosinophilic Focus  
Fatty Change Diffuse

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

Liver: Bile Duct	Fatty Change Focal
Liver: Hepatocyte	Fibrosis
Liver: Hepatocyte, Centrilobular	Inflammation
Liver: Oval Cell	Mixed Cell Focus
Liver: Vein	Necrosis
Lung: Alveolar Epithelium	Pigmentation
Mesentery	Tension Lipidosis
Mesentery: Fat	Cyst
Nose	Hyperplasia
Nose: Nerve	Hypertrophy
Nose: Olfactory Epithelium	Hypertrophy
Ovary	Hyperplasia
Salivary Glands	Intravascular Hepatocyte
Spleen	Hyperplasia
Stomach, Forestomach	Necrosis
Thymus	Necrosis
Uterus	Inflammation
	Atrophy
	Degeneration
	Metaplasia
	Atrophy
	Infiltration Cellular Mononuclear Cell
	Hematopoietic Cell Proliferation
	Pigmentation
	Hyperplasia
	Inflammation
	Ulcer
	Atrophy
	Angiectasis

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 Lab: BAT

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

**LESION RATES**

OVERALL (a)	17/50 (34%)	9/50 (18%)	8/50 (16%)	4/50 (8%)
POLY-3 RATE (b)	17/44.22	9/45.21	8/47.72	4/45.98
POLY-3 PERCENT (g)	38.4%	19.9%	16.8%	8.7%
TERMINAL (d)	17/38 (45%)	8/36 (22%)	8/42 (19%)	4/41 (10%)
FIRST INCIDENCE	730 (T)	693	730 (T)	730 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001N**	P=0.042N*	P=0.016N*	P<0.001N**
POLY 1.5	P<0.001N**	P=0.048N*	P=0.020N*	P<0.001N**
POLY 6	P<0.001N**	P=0.037N*	P=0.013N*	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.055N	P=0.032N*	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.026N*	P=0.011N*	P<0.001N**

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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 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

---

**Adrenal Cortex: Subcapsular  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	39/50 (78%)	40/50 (80%)	47/50 (94%)	44/50 (88%)
POLY-3 RATE (b)	39/48.13	40/47.40	47/49.29	44/48.95
POLY-3 PERCENT (g)	81%	84.4%	95.4%	89.9%
TERMINAL (d)	30/38 (79%)	32/36 (89%)	41/42 (98%)	37/41 (90%)
FIRST INCIDENCE	331	428	597	332

**STATISTICAL TESTS**

POLY 3	P=0.080	P=0.434	P=0.023*	P=0.166
POLY 1.5	P=0.061	P=0.433	P=0.021*	P=0.136
POLY 6	P=0.111	P=0.421	P=0.023*	P=0.206
COCH-ARM / FISHERS	P=0.062	P=0.500	P=0.020*	P=0.143
MAX-ISO-POLY-3	P=0.055	P=0.329	P=0.010**	P=0.105

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 TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

**Adrenal Medulla  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/44.22	2/45.07	1/47.72	2/45.98
POLY-3 PERCENT (g)	0%	4.4%	2.1%	4.4%
TERMINAL (d)	0/38 (0%)	2/36 (6%)	1/42 (2%)	2/41 (5%)
FIRST INCIDENCE	---	730 (T)	730 (T)	730 (T)

**STATISTICAL TESTS**

POLY 3	P=0.261	P=0.241	P=0.515	P=0.246
POLY 1.5	P=0.253	P=0.239	P=0.510	P=0.241
POLY 6	P=0.271	P=0.243	P=0.519	P=0.252
COCH-ARM / FISHERS	P=0.245	P=0.247	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.174	P=0.080	P=0.177	P=0.084

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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

---

**Bone Marrow  
 Hyperplasia**

**LESION 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	---	---	---	---

**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**

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

---

**Bone Marrow  
 Myelofibrosis**

**LESION RATES**

OVERALL (a)	2/50 (4%)	0/50 (0%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	2/44.22	0/45.07	3/47.72	1/45.98
POLY-3 PERCENT (g)	4.5%	0%	6.3%	2.2%
TERMINAL (d)	2/38 (5%)	0/36 (0%)	3/42 (7%)	1/41 (2%)
FIRST INCIDENCE	730 (T)	---	730 (T)	730 (T)

**STATISTICAL TESTS**

POLY 3	P=0.544N	P=0.233N	P=0.535	P=0.486N
POLY 1.5	P=0.550N	P=0.236N	P=0.523	P=0.494N
POLY 6	P=0.534N	P=0.231N	P=0.544	P=0.477N
COCH-ARM / FISHERS	P=0.556N	P=0.247N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.436N	P=0.076N	P=0.360	P=0.273N

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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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**Epididymis  
 Infiltration Cellular Mononuclear Cell**

**LESION RATES**

OVERALL (a)	23/50 (46%)	27/50 (54%)	20/50 (40%)	20/50 (40%)
POLY-3 RATE (b)	23/44.94	27/47.37	20/49.13	20/46.09
POLY-3 PERCENT (g)	51.2%	57%	40.7%	43.4%
TERMINAL (d)	20/38 (53%)	19/36 (53%)	15/42 (36%)	19/41 (46%)
FIRST INCIDENCE	573	444	597	702

**STATISTICAL TESTS**

POLY 3	P=0.147N	P=0.361	P=0.208N	P=0.295N
POLY 1.5	P=0.164N	P=0.314	P=0.254N	P=0.324N
POLY 6	P=0.129N	P=0.412	P=0.167N	P=0.264N
COCH-ARM / FISHERS	P=0.181N	P=0.274	P=0.343N	P=0.343N
MAX-ISO-POLY-3	P=0.204N	P=0.291	P=0.164N	P=0.230N

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 TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

**Epididymis  
 Inflammation**

**LESION RATES**

OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.55	0/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	4.5%	0%	0%	0%
TERMINAL (d)	1/38 (3%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	640	---	---	---

**STATISTICAL TESTS**

POLY 3	P=0.113N	P=0.235N	P=0.222N	P=0.230N
POLY 1.5	P=0.113N	P=0.237N	P=0.227N	P=0.234N
POLY 6	P=0.114N	P=0.234N	P=0.219N	P=0.225N
COCH-ARM / FISHERS	P=0.115N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.032N*	P=0.076N	P=0.076N	P=0.076N

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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 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

---

**Esophagus  
 Inflammation**

**LESION RATES**

OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/44.29	0/45.07	1/47.72	1/45.98
POLY-3 PERCENT (g)	4.5%	0%	2.1%	2.2%
TERMINAL (d)	1/38 (3%)	0/36 (0%)	1/42 (2%)	1/41 (2%)
FIRST INCIDENCE	714	---	730 (T)	730 (T)

**STATISTICAL TESTS**

POLY 3	P=0.494N	P=0.233N	P=0.474N	P=0.487N
POLY 1.5	P=0.496N	P=0.236N	P=0.483N	P=0.495N
POLY 6	P=0.491N	P=0.232N	P=0.467N	P=0.478N
COCH-ARM / FISHERS	P=0.500N	P=0.247N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.268N	P=0.076N	P=0.266N	P=0.273N

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

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

**Eye  
 Atrophy**

**LESION 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	1/46.50
POLY-3 PERCENT (g)	0%	0%	0%	2.2%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	---	---	570

**STATISTICAL TESTS**

POLY 3	P=0.205	(e)	(e)	P=0.510
POLY 1.5	P=0.202	(e)	(e)	P=0.505
POLY 6	P=0.209	(e)	(e)	P=0.517
COCH-ARM / FISHERS	P=0.198	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.141	(e)	(e)	P=0.171

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 TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Eye: Anterior Chamber  
 Inflammation

**LESION 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	---	---	---	---

**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 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG

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Eye: Cornea  
 Inflammation

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	1/44.22	0/45.07	1/48.17	3/45.98
POLY-3 PERCENT (g)	2.3%	0%	2.1%	6.5%
TERMINAL (d)	1/38 (3%)	0/36 (0%)	0/42 (0%)	3/41 (7%)
FIRST INCIDENCE	730 (T)	---	597	730 (T)

**STATISTICAL TESTS**

POLY 3	P=0.101	P=0.496N	P=0.741N	P=0.319
POLY 1.5	P=0.099	P=0.499N	P=0.748N	P=0.311
POLY 6	P=0.104	P=0.495N	P=0.735N	P=0.329
COCH-ARM / FISHERS	P=0.097	P=0.500N	P=0.753N	P=0.309
MAX-ISO-POLY-3	P=0.098	P=0.158N	P=0.476N	P=0.169

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

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

**Gallbladder  
 Infiltration Cellular Mononuclear Cell**

**LESION RATES**

OVERALL (a)	1/49 (2%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.22	0/44.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	2.3%	0%	0%	0%
TERMINAL (d)	1/37 (3%)	0/35 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	730 (T)	---	---	---

**STATISTICAL TESTS**

POLY 3	P=0.305N	P=0.496N	P=0.480N	P=0.488N
POLY 1.5	P=0.303N	P=0.499N	P=0.486N	P=0.492N
POLY 6	P=0.308N	P=0.495N	P=0.476N	P=0.482N
COCH-ARM / FISHERS	P=0.303N	P=0.500N	P=0.495N	P=0.495N
MAX-ISO-POLY-3	P=0.122N	P=0.158N	P=0.157N	P=0.157N



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

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

---

**Harderian Gland  
 Infiltration Cellular Mononuclear Cell**

**LESION RATES**

OVERALL (a)	34/50 (68%)	27/50 (54%)	23/50 (46%)	17/50 (34%)
POLY-3 RATE (b)	34/47.52	27/46.32	23/48.42	17/46.76
POLY-3 PERCENT (g)	71.6%	58.3%	47.5%	36.4%
TERMINAL (d)	28/38 (74%)	20/36 (56%)	20/42 (48%)	15/41 (37%)
FIRST INCIDENCE	331	646	639	473

**STATISTICAL TESTS**

POLY 3	P<0.001N**	P=0.124N	P=0.012N*	P<0.001N**
POLY 1.5	P<0.001N**	P=0.127N	P=0.014N*	P<0.001N**
POLY 6	P<0.001N**	P=0.121N	P=0.010N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.109N	P=0.021N*	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.087N	P=0.007N**	P<0.001N**

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

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

---

**Harderian Gland: Epithelium  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	1/50 (2%)	3/50 (6%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	1/44.36	3/46.18	1/47.72	3/45.98
POLY-3 PERCENT (g)	2.3%	6.5%	2.1%	6.5%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	1/42 (2%)	3/41 (7%)
FIRST INCIDENCE	695	428	730 (T)	730 (T)

**STATISTICAL TESTS**

POLY 3	P=0.329	P=0.320	P=0.744N	P=0.318
POLY 1.5	P=0.321	P=0.313	P=0.750N	P=0.311
POLY 6	P=0.338	P=0.325	P=0.740N	P=0.327
COCH-ARM / FISHERS	P=0.313	P=0.309	P=0.753N	P=0.309
MAX-ISO-POLY-3	P=0.270	P=0.169	P=0.479N	P=0.168

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

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

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

**Heart  
 Cardiomyopathy**

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.74	0/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	573	---	---	---

**STATISTICAL TESTS**

POLY 3	P=0.306N	P=0.499N	P=0.487N	P=0.495N
POLY 1.5	P=0.305N	P=0.500N	P=0.491N	P=0.498N
POLY 6	P=0.308N	P=0.498N	P=0.484N	P=0.490N
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=0.159N

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

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

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

**Heart  
 Infiltration Cellular Mononuclear Cell**

**LESION RATES**

OVERALL (a)	4/50 (8%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	4/44.94	0/45.07	1/47.72	1/45.98
POLY-3 PERCENT (g)	8.9%	0%	2.1%	2.2%
TERMINAL (d)	3/38 (8%)	0/36 (0%)	1/42 (2%)	1/41 (2%)
FIRST INCIDENCE	479	---	730 (T)	730 (T)

**STATISTICAL TESTS**

POLY 3	P=0.157N	P=0.060N	P=0.161N	P=0.172N
POLY 1.5	P=0.159N	P=0.061N	P=0.167N	P=0.177N
POLY 6	P=0.155N	P=0.059N	P=0.156N	P=0.165N
COCH-ARM / FISHERS	P=0.163N	P=0.059N	P=0.181N	P=0.181N
MAX-ISO-POLY-3	P=0.036N*	P=0.019N*	P=0.079N	P=0.082N

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

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

---

**Heart  
 Mineralization**

**LESION RATES**

OVERALL (a)	1/50 (2%)	1/50 (2%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	1/44.94	1/45.15	1/48.05	4/46.93
POLY-3 PERCENT (g)	2.2%	2.2%	2.1%	8.5%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	2/41 (5%)
FIRST INCIDENCE	477	709	639	332

**STATISTICAL TESTS**

POLY 3	P=0.073	P=0.760N	P=0.745N	P=0.192
POLY 1.5	P=0.070	P=0.760	P=0.751N	P=0.186
POLY 6	P=0.076	P=0.759N	P=0.741N	P=0.200
COCH-ARM / FISHERS	P=0.067	P=0.753N	P=0.753N	P=0.181
MAX-ISO-POLY-3	P=0.093	P=0.498N	P=0.481N	P=0.097

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

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

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

**Heart  
 Necrosis**

**LESION 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	---	---	---	---

**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. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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

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

**Islets, Pancreatic  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	20/50 (40%)	17/50 (34%)	21/50 (42%)	2/50 (4%)
POLY-3 RATE (b)	20/45.71	17/45.89	21/48.63	2/46.88
POLY-3 PERCENT (g)	43.8%	37.1%	43.2%	4.3%
TERMINAL (d)	16/38 (42%)	13/36 (36%)	17/42 (41%)	1/41 (2%)
FIRST INCIDENCE	477	648	588	332

**STATISTICAL TESTS**

POLY 3	P<0.001N**	P=0.329N	P=0.560N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.341N	P=0.569	P<0.001N**
POLY 6	P<0.001N**	P=0.324N	P=0.534N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.339N	P=0.500	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.257N	P=0.477N	P<0.001N**

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

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

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

**Kidney  
 Accumulation, Hyaline Droplet**

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.94	0/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	477	---	---	---

**STATISTICAL TESTS**

POLY 3	P=0.305N	P=0.499N	P=0.488N	P=0.495N
POLY 1.5	P=0.304N	P=0.501N	P=0.492N	P=0.499N
POLY 6	P=0.307N	P=0.499N	P=0.485N	P=0.491N
COCH-ARM / FISHERS	P=0.306N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.124N	P=0.159N	P=0.158N	P=0.159N



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

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

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

**Kidney  
 Cyst**

**LESION RATES**

OVERALL (a)	9/50 (18%)	3/50 (6%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	9/44.53	3/45.07	4/47.72	0/45.98
POLY-3 PERCENT (g)	20.2%	6.7%	8.4%	0%
TERMINAL (d)	8/38 (21%)	3/36 (8%)	4/42 (10%)	0/41 (0%)
FIRST INCIDENCE	646	730 (T)	730 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.002N**	P=0.056N	P=0.090N	P<0.001N**
POLY 1.5	P=0.002N**	P=0.058N	P=0.099N	P=0.002N**
POLY 6	P<0.001N**	P=0.055N	P=0.084N	P<0.001N**
COCH-ARM / FISHERS	P=0.002N**	P=0.061N	P=0.117N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.029N*	P=0.056N	P<0.001N**

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

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

---

**Kidney  
 Glomerulopathy Hyaline**

**LESION RATES**

OVERALL (a)	1/50 (2%)	19/50 (38%)	30/50 (60%)	44/50 (88%)
POLY-3 RATE (b)	1/44.22	19/46.33	30/48.60	44/47.00
POLY-3 PERCENT (g)	2.3%	41%	61.7%	93.6%
TERMINAL (d)	1/38 (3%)	13/36 (36%)	26/42 (62%)	40/41 (98%)
FIRST INCIDENCE	730 (T)	646	646	570

**STATISTICAL TESTS**

POLY 3	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	P<0.001**

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

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

---

**Kidney  
 Infarct**

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/44.22	0/45.07	0/47.72	1/45.98
POLY-3 PERCENT (g)	2.3%	0%	0%	2.2%
TERMINAL (d)	1/38 (3%)	0/36 (0%)	0/42 (0%)	1/41 (2%)
FIRST INCIDENCE	730 (T)	---	---	730 (T)

**STATISTICAL TESTS**

POLY 3	P=0.599	P=0.496N	P=0.485N	P=0.752N
POLY 1.5	P=0.597	P=0.499N	P=0.490N	P=0.757N
POLY 6	P=0.603	P=0.495N	P=0.481N	P=0.746N
COCH-ARM / FISHERS	P=0.595	P=0.500N	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.400N	P=0.158N	P=0.158N	P=0.488N

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

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

---

**Kidney  
 Metaplasia Osseous**

**LESION RATES**

OVERALL (a)	3/50 (6%)	2/50 (4%)	2/50 (4%)	4/50 (8%)
POLY-3 RATE (b)	3/44.55	2/45.07	2/47.95	4/46.30
POLY-3 PERCENT (g)	6.7%	4.4%	4.2%	8.6%
TERMINAL (d)	2/38 (5%)	2/36 (6%)	1/42 (2%)	3/41 (7%)
FIRST INCIDENCE	640	730 (T)	668	640

**STATISTICAL TESTS**

POLY 3	P=0.376	P=0.495N	P=0.467N	P=0.521
POLY 1.5	P=0.367	P=0.499N	P=0.478N	P=0.509
POLY 6	P=0.388	P=0.494N	P=0.458N	P=0.536
COCH-ARM / FISHERS	P=0.357	P=0.500N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.395	P=0.320N	P=0.301N	P=0.369

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

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

---

**Kidney  
 Mineralization**

**LESION RATES**

OVERALL (a)	30/50 (60%)	34/50 (68%)	41/50 (82%)	38/50 (76%)
POLY-3 RATE (b)	30/45.63	34/46.23	41/48.59	38/47.66
POLY-3 PERCENT (g)	65.8%	73.6%	84.4%	79.7%
TERMINAL (d)	25/38 (66%)	29/36 (81%)	38/42 (91%)	33/41 (81%)
FIRST INCIDENCE	549	606	597	473

**STATISTICAL TESTS**

POLY 3	P=0.061	P=0.274	P=0.025*	P=0.093
POLY 1.5	P=0.044*	P=0.256	P=0.020*	P=0.071
POLY 6	P=0.087	P=0.281	P=0.028*	P=0.124
COCH-ARM / FISHERS	P=0.038*	P=0.266	P=0.013*	P=0.066
MAX-ISO-POLY-3	P=0.047*	P=0.204	P=0.016*	P=0.063

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

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

**LESION RATES**

OVERALL (a)	45/50 (90%)	45/50 (90%)	49/50 (98%)	49/50 (98%)
POLY-3 RATE (b)	45/47.91	45/47.20	49/49.52	49/49.01
POLY-3 PERCENT (g)	93.9%	95.3%	98.9%	100%
TERMINAL (d)	37/38 (97%)	36/36 (100%)	42/42 (100%)	41/41 (100%)
FIRST INCIDENCE	479	606	597	332

**STATISTICAL TESTS**

POLY 3	P=0.029*	P=0.566	P=0.180	P=0.096
POLY 1.5	P=0.020*	P=0.553	P=0.146	P=0.065
POLY 6	P=0.049*	P=0.592	P=0.214	P=0.156
COCH-ARM / FISHERS	P=0.035*	P=0.630N	P=0.102	P=0.102
MAX-ISO-POLY-3	P=0.032*	P=0.366	P=0.063	P=0.025*

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

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

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

**Kidney  
 Pigmentation**

**LESION 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	2/47.92	0/45.98
POLY-3 PERCENT (g)	0%	0%	4.2%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	---	695	---

**STATISTICAL TESTS**

POLY 3	P=0.610	(e)	P=0.256	(e)
POLY 1.5	P=0.601	(e)	P=0.249	(e)
POLY 6	P=0.624	(e)	P=0.262	(e)
COCH-ARM / FISHERS	P=0.595	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.275	(e)	P=0.094	(e)

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

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

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

**Kidney  
 Vacuolization Cytoplasmic**

**LESION 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	---	---	---	---

**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. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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

---

**Kidney: Glomerulus  
 Congestion**

**LESION RATES**

OVERALL (a)	9/50 (18%)	14/50 (28%)	17/50 (34%)	44/50 (88%)
POLY-3 RATE (b)	9/46.61	14/46.13	17/48.02	44/46.52
POLY-3 PERCENT (g)	19.3%	30.4%	35.4%	94.6%
TERMINAL (d)	4/38 (11%)	10/36 (28%)	16/42 (38%)	40/41 (98%)
FIRST INCIDENCE	535	646	646	638

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.161	P=0.062	P<0.001**
POLY 1.5	P<0.001**	P=0.161	P=0.060	P<0.001**
POLY 6	P<0.001**	P=0.157	P=0.060	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.171	P=0.055	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.109	P=0.040*	P<0.001**

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

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

---

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

---

**Kidney: Papilla  
 Necrosis**

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.36	0/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	2.3%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	695	---	---	---

**STATISTICAL TESTS**

POLY 3	P=0.307N	P=0.497N	P=0.485N	P=0.493N
POLY 1.5	P=0.305N	P=0.499N	P=0.490N	P=0.497N
POLY 6	P=0.310N	P=0.496N	P=0.482N	P=0.488N
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

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

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

---

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

---

**Kidney: Pelvis  
 Inflammation**

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/44.94	0/45.07	0/47.72	2/46.88
POLY-3 PERCENT (g)	2.2%	0%	0%	4.3%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	1/41 (2%)
FIRST INCIDENCE	477	---	---	332

**STATISTICAL TESTS**

POLY 3	P=0.252	P=0.499N	P=0.488N	P=0.515
POLY 1.5	P=0.250	P=0.501N	P=0.492N	P=0.507
POLY 6	P=0.256	P=0.499N	P=0.485N	P=0.523
COCH-ARM / FISHERS	P=0.246	P=0.500N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.151	P=0.159N	P=0.158N	P=0.297

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

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

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	2/45.21	0/47.72	0/45.98
POLY-3 PERCENT (g)	0%	4.4%	0%	0%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	693	---	---

**STATISTICAL TESTS**

POLY 3	P=0.391N	P=0.242	(e)	(e)
POLY 1.5	P=0.398N	P=0.239	(e)	(e)
POLY 6	P=0.384N	P=0.244	(e)	(e)
COCH-ARM / FISHERS	P=0.405N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.255N	P=0.081	(e)	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS 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  
 Basophilic Focus

**LESION RATES**

OVERALL (a)	4/50 (8%)	5/50 (10%)	4/50 (8%)	6/50 (12%)
POLY-3 RATE (b)	4/45.59	5/45.52	4/47.72	6/46.31
POLY-3 PERCENT (g)	8.8%	11%	8.4%	13%
TERMINAL (d)	0/38 (0%)	3/36 (8%)	4/42 (10%)	5/41 (12%)
FIRST INCIDENCE	547	646	730 (T)	638

**STATISTICAL TESTS**

POLY 3	P=0.341	P=0.499	P=0.618N	P=0.380
POLY 1.5	P=0.333	P=0.497	P=0.624N	P=0.372
POLY 6	P=0.349	P=0.496	P=0.617N	P=0.387
COCH-ARM / FISHERS	P=0.327	P=0.500	P=0.643N	P=0.370
MAX-ISO-POLY-3	P=0.416	P=0.362	P=0.473N	P=0.263

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

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

---

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

---

Liver  
 Clear Cell Focus

**LESION RATES**

OVERALL (a)	15/50 (30%)	27/50 (54%)	28/50 (56%)	34/50 (68%)
POLY-3 RATE (b)	15/44.22	27/45.07	28/48.17	34/45.98
POLY-3 PERCENT (g)	33.9%	59.9%	58.1%	74%
TERMINAL (d)	15/38 (40%)	27/36 (75%)	27/42 (64%)	34/41 (83%)
FIRST INCIDENCE	730 (T)	730 (T)	597	730 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.009**	P=0.014*	P<0.001**
POLY 1.5	P<0.001**	P=0.009**	P=0.011*	P<0.001**
POLY 6	P<0.001**	P=0.009**	P=0.018*	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.013*	P=0.007**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.005**	P=0.010**	P<0.001**

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

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

---

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

---

Liver  
 Eosinophilic Focus

**LESION RATES**

OVERALL (a)	7/50 (14%)	12/50 (24%)	20/50 (40%)	36/50 (72%)
POLY-3 RATE (b)	7/45.11	12/45.25	20/47.85	36/46.41
POLY-3 PERCENT (g)	15.5%	26.5%	41.8%	77.6%
TERMINAL (d)	5/38 (13%)	10/36 (28%)	19/42 (45%)	33/41 (81%)
FIRST INCIDENCE	547	693	695	640

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.152	P=0.004**	P<0.001**
POLY 1.5	P<0.001**	P=0.150	P=0.003**	P<0.001**
POLY 6	P<0.001**	P=0.150	P=0.004**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.154	P=0.003**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.099	P=0.002**	P<0.001**

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS 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  
 Fatty Change Diffuse

**LESION RATES**

OVERALL (a)	38/50 (76%)	27/50 (54%)	21/50 (42%)	3/50 (6%)
POLY-3 RATE (b)	38/45.98	27/45.87	21/48.17	3/47.26
POLY-3 PERCENT (g)	82.7%	58.9%	43.6%	6.4%
TERMINAL (d)	33/38 (87%)	26/36 (72%)	20/42 (48%)	0/41 (0%)
FIRST INCIDENCE	479	428	597	332

**STATISTICAL TESTS**

POLY 3	P<0.001N**	P=0.007N**	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.010N**	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P=0.006N**	P<0.001N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.018N*	P<0.001N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.003N**	P<0.001N**	P<0.001N**

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

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

---

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

---

Liver  
 Fatty Change Focal

**LESION RATES**

OVERALL (a)	3/50 (6%)	8/50 (16%)	20/50 (40%)	23/50 (46%)
POLY-3 RATE (b)	3/44.55	8/45.26	20/48.17	23/46.03
POLY-3 PERCENT (g)	6.7%	17.7%	41.5%	50%
TERMINAL (d)	2/38 (5%)	6/36 (17%)	19/42 (45%)	22/41 (54%)
FIRST INCIDENCE	640	690	597	716

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.103	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.100	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.104	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.100	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.057	P<0.001**	P<0.001**

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

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

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

Liver  
 Fibrosis

**LESION 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	---	---	---	---

**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. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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

---

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

---

**Liver  
 Hematopoietic Cell Proliferation**

**LESION RATES**

OVERALL (a)	3/50 (6%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	3/44.22	0/45.07	1/47.85	2/45.98
POLY-3 PERCENT (g)	6.8%	0%	2.1%	4.4%
TERMINAL (d)	3/38 (8%)	0/36 (0%)	0/42 (0%)	2/41 (5%)
FIRST INCIDENCE	730 (T)	---	695	730 (T)

**STATISTICAL TESTS**

POLY 3	P=0.549N	P=0.115N	P=0.278N	P=0.482N
POLY 1.5	P=0.551N	P=0.118N	P=0.287N	P=0.493N
POLY 6	P=0.546N	P=0.114N	P=0.269N	P=0.470N
COCH-ARM / FISHERS	P=0.556N	P=0.121N	P=0.309N	P=0.500N
MAX-ISO-POLY-3	P=0.183N	P=0.038N*	P=0.145N	P=0.312N

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

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

**LESION RATES**

OVERALL (a)	24/50 (48%)	21/50 (42%)	20/50 (40%)	29/50 (58%)
POLY-3 RATE (b)	24/46.40	21/45.96	20/48.79	29/46.14
POLY-3 PERCENT (g)	51.7%	45.7%	41%	62.9%
TERMINAL (d)	18/38 (47%)	18/36 (50%)	17/42 (41%)	27/41 (66%)
FIRST INCIDENCE	547	606	588	702

**STATISTICAL TESTS**

POLY 3	P=0.130	P=0.354N	P=0.198N	P=0.189
POLY 1.5	P=0.128	P=0.356N	P=0.220N	P=0.188
POLY 6	P=0.132	P=0.367N	P=0.189N	P=0.188
COCH-ARM / FISHERS	P=0.135	P=0.344N	P=0.273N	P=0.212
MAX-ISO-POLY-3	P=0.081	P=0.281N	P=0.151N	P=0.137

---

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

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

---

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

---

Liver  
 Mixed Cell Focus

**LESION RATES**

OVERALL (a)	18/50 (36%)	20/50 (40%)	19/50 (38%)	34/50 (68%)
POLY-3 RATE (b)	18/44.42	20/45.38	19/48.40	34/46.42
POLY-3 PERCENT (g)	40.5%	44.1%	39.3%	73.3%
TERMINAL (d)	16/38 (42%)	19/36 (53%)	17/42 (41%)	32/41 (78%)
FIRST INCIDENCE	695	646	597	638

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.449	P=0.535N	P<0.001**
POLY 1.5	P<0.001**	P=0.429	P=0.581N	P<0.001**
POLY 6	P<0.001**	P=0.460	P=0.493N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.418	P=0.500	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.366	P=0.451N	P<0.001**

---

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

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

---

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

---

Liver  
 Necrosis

**LESION RATES**

OVERALL (a)	1/50 (2%)	8/50 (16%)	5/50 (10%)	26/50 (52%)
POLY-3 RATE (b)	1/44.83	8/45.64	5/48.20	26/45.98
POLY-3 PERCENT (g)	2.2%	17.5%	10.4%	56.6%
TERMINAL (d)	0/38 (0%)	4/36 (11%)	4/42 (10%)	26/41 (63%)
FIRST INCIDENCE	535	646	588	730 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.017*	P=0.119	P<0.001**
POLY 1.5	P<0.001**	P=0.016*	P=0.113	P<0.001**
POLY 6	P<0.001**	P=0.017*	P=0.125	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.015*	P=0.102	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.007**	P=0.061	P<0.001**

---

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

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

---

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

---

**Liver  
 Pigmentation**

**LESION RATES**

OVERALL (a)	3/50 (6%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	3/45.12	0/45.07	2/47.72	1/45.98
POLY-3 PERCENT (g)	6.7%	0%	4.2%	2.2%
TERMINAL (d)	1/38 (3%)	0/36 (0%)	2/42 (5%)	1/41 (2%)
FIRST INCIDENCE	547	---	730 (T)	730 (T)

**STATISTICAL TESTS**

POLY 3	P=0.330N	P=0.119N	P=0.475N	P=0.299N
POLY 1.5	P=0.333N	P=0.120N	P=0.482N	P=0.304N
POLY 6	P=0.324N	P=0.120N	P=0.470N	P=0.293N
COCH-ARM / FISHERS	P=0.337N	P=0.121N	P=0.500N	P=0.309N
MAX-ISO-POLY-3	P=0.187N	P=0.038N*	P=0.306N	P=0.151N

---

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

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

---

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

---

Liver  
 Tension Lipidosis

**LESION RATES**

OVERALL (a)	5/50 (10%)	6/50 (12%)	7/50 (14%)	2/50 (4%)
POLY-3 RATE (b)	5/45.39	6/46.43	7/47.72	2/46.88
POLY-3 PERCENT (g)	11%	12.9%	14.7%	4.3%
TERMINAL (d)	2/38 (5%)	3/36 (8%)	7/42 (17%)	1/41 (2%)
FIRST INCIDENCE	477	444	730 (T)	332

**STATISTICAL TESTS**

POLY 3	P=0.153N	P=0.516	P=0.415	P=0.203N
POLY 1.5	P=0.161N	P=0.507	P=0.404	P=0.210N
POLY 6	P=0.145N	P=0.521	P=0.420	P=0.197N
COCH-ARM / FISHERS	P=0.169N	P=0.500	P=0.380	P=0.218N
MAX-ISO-POLY-3	P=0.150N	P=0.389	P=0.305	P=0.114N

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

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

---

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

---

Liver: Bile Duct  
 Cyst

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	3/50 (6%)	14/50 (28%)
POLY-3 RATE (b)	0/44.22	0/45.07	3/47.78	14/46.13
POLY-3 PERCENT (g)	0%	0%	6.3%	30.4%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	2/42 (5%)	12/41 (29%)
FIRST INCIDENCE	---	---	714	702

**STATISTICAL TESTS**

POLY 3	P<0.001**	(e)	P=0.133	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.128	P<0.001**
POLY 6	P<0.001**	(e)	P=0.138	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.121	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.050*	P<0.001**

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

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

---

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

---

Liver: Bile Duct  
 Fibrosis

**LESION 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	2/45.98
POLY-3 PERCENT (g)	0%	0%	0%	4.4%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	2/41 (5%)
FIRST INCIDENCE	---	---	---	730 (T)

**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=0.252
COCH-ARM / FISHERS	P=0.046*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.039*	(e)	(e)	P=0.084

---

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

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

---

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

---

Liver: Bile Duct  
 Hyperplasia

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	35/50 (70%)
POLY-3 RATE (b)	0/44.22	0/45.07	1/47.72	35/45.98
POLY-3 PERCENT (g)	0%	0%	2.1%	76.1%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	1/42 (2%)	35/41 (85%)
FIRST INCIDENCE	---	---	730 (T)	730 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	(e)	P=0.515	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.510	P<0.001**
POLY 6	P<0.001**	(e)	P=0.519	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.500	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.177	P<0.001**

---

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

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

---

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

---

Liver: Hepatocyte  
 Hypertrophy

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	1/45.07	1/47.72	0/45.98
POLY-3 PERCENT (g)	0%	2.2%	2.1%	0%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	1/42 (2%)	0/41 (0%)
FIRST INCIDENCE	---	730 (T)	730 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.582N	P=0.504	P=0.515	(e)
POLY 1.5	P=0.589N	P=0.501	P=0.510	(e)
POLY 6	P=0.575N	P=0.505	P=0.519	(e)
COCH-ARM / FISHERS	P=0.595N	P=0.500	P=0.500	(e)
MAX-ISO-POLY-3	P=0.417N	P=0.163	P=0.177	(e)

---

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

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

---

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

---

Liver: Hepatocyte, Centrilobular Hypertrophy

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	10/50 (20%)	22/50 (44%)	46/50 (92%)
POLY-3 RATE (b)	0/44.22	10/45.53	22/48.63	46/48.72
POLY-3 PERCENT (g)	0%	22%	45.2%	94.4%
TERMINAL (d)	0/38 (0%)	8/36 (22%)	19/42 (45%)	40/41 (98%)
FIRST INCIDENCE	---	646	639	141

**STATISTICAL TESTS**

POLY 3	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	P<0.001**

---

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

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

---

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

---

Liver: Oval Cell  
 Hyperplasia

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	36/50 (72%)
POLY-3 RATE (b)	1/44.54	0/45.07	1/47.72	36/45.98
POLY-3 PERCENT (g)	2.2%	0%	2.1%	78.3%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	1/42 (2%)	36/41 (88%)
FIRST INCIDENCE	641	---	730 (T)	730 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.498N	P=0.745N	P<0.001**
POLY 1.5	P<0.001**	P=0.499N	P=0.750N	P<0.001**
POLY 6	P<0.001**	P=0.497N	P=0.741N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500N	P=0.753N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.158N	P=0.480N	P<0.001**

---

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

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

---

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

---

Liver: Vein  
 Intravascular Hepatocyte

**LESION RATES**

OVERALL (a)	3/50 (6%)	1/50 (2%)	15/50 (30%)	47/50 (94%)
POLY-3 RATE (b)	3/44.22	1/45.23	15/47.72	47/47.95
POLY-3 PERCENT (g)	6.8%	2.2%	31.4%	98%
TERMINAL (d)	3/38 (8%)	0/36 (0%)	15/42 (36%)	41/41 (100%)
FIRST INCIDENCE	730 (T)	690	730 (T)	332

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.297N	P=0.002**	P<0.001**
POLY 1.5	P<0.001**	P=0.302N	P=0.002**	P<0.001**
POLY 6	P<0.001**	P=0.293N	P=0.003**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.309N	P=0.002**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.151N	P<0.001**	P<0.001**

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

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

---

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

---

**Lung  
 Inflammation**

**LESION RATES**

OVERALL (a)	0/50 (0%)	5/50 (10%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/44.22	5/46.28	2/47.72	1/46.88
POLY-3 PERCENT (g)	0%	10.8%	4.2%	2.1%
TERMINAL (d)	0/38 (0%)	2/36 (6%)	2/42 (5%)	0/41 (0%)
FIRST INCIDENCE	---	444	730 (T)	332

**STATISTICAL TESTS**

POLY 3	P=0.460N	P=0.034*	P=0.255	P=0.512
POLY 1.5	P=0.478N	P=0.033*	P=0.249	P=0.506
POLY 6	P=0.442N	P=0.036*	P=0.260	P=0.518
COCH-ARM / FISHERS	P=0.500N	P=0.028*	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.154	P=0.013*	P=0.093	P=0.173

---



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

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

**LESION RATES**

OVERALL (a)	2/50 (4%)	7/50 (14%)	2/50 (4%)	9/50 (18%)
POLY-3 RATE (b)	2/44.74	7/45.36	2/47.72	9/46.70
POLY-3 PERCENT (g)	4.5%	15.4%	4.2%	19.3%
TERMINAL (d)	1/38 (3%)	6/36 (17%)	2/42 (5%)	8/41 (20%)
FIRST INCIDENCE	573	652	730 (T)	473

**STATISTICAL TESTS**

POLY 3	P=0.044*	P=0.082	P=0.670N	P=0.030*
POLY 1.5	P=0.041*	P=0.080	P=0.678N	P=0.027*
POLY 6	P=0.048*	P=0.082	P=0.665N	P=0.033*
COCH-ARM / FISHERS	P=0.040*	P=0.080	P=0.691N	P=0.026*
MAX-ISO-POLY-3	P=0.019*	P=0.041*	P=0.474N	P=0.015*

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

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

---

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

---

Lung: Alveolus  
 Infiltration Cellular Histiocyte

**LESION RATES**

OVERALL (a)	2/50 (4%)	4/50 (8%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	2/44.22	4/45.81	3/47.72	3/45.98
POLY-3 PERCENT (g)	4.5%	8.7%	6.3%	6.5%
TERMINAL (d)	2/38 (5%)	1/36 (3%)	3/42 (7%)	3/41 (7%)
FIRST INCIDENCE	730 (T)	646	730 (T)	730 (T)

**STATISTICAL TESTS**

POLY 3	P=0.524	P=0.354	P=0.535	P=0.518
POLY 1.5	P=0.511	P=0.344	P=0.523	P=0.507
POLY 6	P=0.539	P=0.363	P=0.544	P=0.530
COCH-ARM / FISHERS	P=0.500	P=0.339	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.498	P=0.218	P=0.360	P=0.342

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

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

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	2/46.21	0/47.72	0/45.98
POLY-3 PERCENT (g)	0%	4.3%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	59	---	---

**STATISTICAL TESTS**

POLY 3	P=0.388N	P=0.247	(e)	(e)
POLY 1.5	P=0.395N	P=0.244	(e)	(e)
POLY 6	P=0.381N	P=0.249	(e)	(e)
COCH-ARM / FISHERS	P=0.405N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.260N	P=0.086	(e)	(e)

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

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

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

**Lymph Node, Mandibular Atrophy**

**LESION RATES**

OVERALL (a)	1/50 (2%)	4/50 (8%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	1/44.22	4/45.98	3/48.59	2/46.88
POLY-3 PERCENT (g)	2.3%	8.7%	6.2%	4.3%
TERMINAL (d)	1/38 (3%)	1/36 (3%)	0/42 (0%)	1/41 (2%)
FIRST INCIDENCE	730 (T)	646	639	332

**STATISTICAL TESTS**

POLY 3	P=0.582	P=0.191	P=0.340	P=0.520
POLY 1.5	P=0.565	P=0.184	P=0.327	P=0.511
POLY 6	P=0.578N	P=0.198	P=0.353	P=0.531
COCH-ARM / FISHERS	P=0.544	P=0.181	P=0.309	P=0.500
MAX-ISO-POLY-3	P=0.329	P=0.095	P=0.189	P=0.303

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

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

---

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

---

**Lymph Node, Mandibular  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.29	1/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	4.5%	2.2%	0%	0%
TERMINAL (d)	1/38 (3%)	1/36 (3%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	714	730 (T)	---	---

**STATISTICAL TESTS**

POLY 3	P=0.098N	P=0.494N	P=0.221N	P=0.229N
POLY 1.5	P=0.099N	P=0.498N	P=0.227N	P=0.234N
POLY 6	P=0.097N	P=0.492N	P=0.217N	P=0.223N
COCH-ARM / FISHERS	P=0.101N	P=0.500N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.077N	P=0.277N	P=0.076N	P=0.076N

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

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

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

**Lymph Node, Mandibular  
 Hyperplasia Lymphoid**

**LESION RATES**

OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.29	1/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	2.3%	2.2%	0%	0%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	714	730 (T)	---	---

**STATISTICAL TESTS**

POLY 3	P=0.232N	P=0.757N	P=0.485N	P=0.493N
POLY 1.5	P=0.233N	P=0.759N	P=0.490N	P=0.497N
POLY 6	P=0.230N	P=0.756N	P=0.481N	P=0.487N
COCH-ARM / FISHERS	P=0.236N	P=0.753N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.255N	P=0.494N	P=0.158N	P=0.158N

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

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

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

**Lymph Node, Mesenteric  
 Atrophy**

**LESION RATES**

OVERALL (a)	0/47 (0%)	1/49 (2%)	2/45 (4%)	3/44 (7%)
POLY-3 RATE (b)	0/41.54	1/44.68	2/43.59	3/41.78
POLY-3 PERCENT (g)	0%	2.2%	4.6%	7.2%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	1/39 (3%)	1/37 (3%)
FIRST INCIDENCE	---	646	668	332

**STATISTICAL TESTS**

POLY 3	P=0.059	P=0.515	P=0.248	P=0.119
POLY 1.5	P=0.055	P=0.511	P=0.241	P=0.113
POLY 6	P=0.064	P=0.517	P=0.255	P=0.126
COCH-ARM / FISHERS	P=0.051	P=0.510	P=0.237	P=0.109
MAX-ISO-POLY-3	P=0.064	P=0.174	P=0.089	P=0.041*

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

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

---

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

---

**Mesentery  
 Necrosis**

**LESION RATES**

OVERALL (a)	0/4 (0%)	0/2 (0%)	0/3 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/3.07	0/1.86	0/2.94	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/2 (0%)	0/1 (0%)	0/2 (0%)	0/0 (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. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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

---

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

---

Mesentery: Fat  
 Necrosis

**LESION RATES**

OVERALL (a)	3/4 (75%)	1/2 (50%)	3/3 (100%)	0/0 (0%)
POLY-3 RATE (b)	3/3.39	1/1.86	3/3.00	0/0.00
POLY-3 PERCENT (g)	88.4%	53.9%	100%	0%
TERMINAL (d)	2/2 (100%)	1/1 (100%)	2/2 (100%)	0/0 (0%)
FIRST INCIDENCE	640	730 (T)	714	---

**STATISTICAL TESTS**

POLY 3	(e)	P=0.575N	P=0.925	(e)
POLY 1.5	(e)	P=0.584N	P=0.740	(e)
POLY 6	(e)	P=0.592N	P=1.000	(e)
COCH-ARM / FISHERS	P=0.581	P=0.600N	P=0.571	(e)
MAX-ISO-POLY-3	(e)	P=0.207N	P=0.203	(e)

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

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

---

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

---

**Nose  
 Inflammation**

**LESION RATES**

OVERALL (a)	2/50 (4%)	3/50 (6%)	2/50 (4%)	22/50 (44%)
POLY-3 RATE (b)	2/44.53	3/45.07	2/47.72	22/46.36
POLY-3 PERCENT (g)	4.5%	6.7%	4.2%	47.5%
TERMINAL (d)	1/38 (3%)	3/36 (8%)	2/42 (5%)	20/41 (49%)
FIRST INCIDENCE	646	730 (T)	730 (T)	638

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.506	P=0.669N	P<0.001**
POLY 1.5	P<0.001**	P=0.501	P=0.677N	P<0.001**
POLY 6	P<0.001**	P=0.506	P=0.663N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500	P=0.691N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.329	P=0.472N	P<0.001**

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

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

---

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

---

**Nose**  
**Polyp, Inflammatory**

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	2/45.21	0/47.72	0/45.98
POLY-3 PERCENT (g)	0%	4.4%	0%	0%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	---	693	---	---

**STATISTICAL TESTS**

POLY 3	P=0.391N	P=0.242	(e)	(e)
POLY 1.5	P=0.398N	P=0.239	(e)	(e)
POLY 6	P=0.384N	P=0.244	(e)	(e)
COCH-ARM / FISHERS	P=0.405N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.255N	P=0.081	(e)	(e)

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

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

---

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

---

**Nose: Nerve  
 Atrophy**

**LESION RATES**

OVERALL (a)	1/50 (2%)	3/50 (6%)	3/50 (6%)	45/50 (90%)
POLY-3 RATE (b)	1/44.53	3/45.21	3/47.72	45/47.33
POLY-3 PERCENT (g)	2.3%	6.6%	6.3%	95.1%
TERMINAL (d)	0/38 (0%)	2/36 (6%)	3/42 (7%)	40/41 (98%)
FIRST INCIDENCE	646	693	730 (T)	570

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.311	P=0.331	P<0.001**
POLY 1.5	P<0.001**	P=0.307	P=0.322	P<0.001**
POLY 6	P<0.001**	P=0.312	P=0.337	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.309	P=0.309	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.160	P=0.180	P<0.001**

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

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

---

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

---

**Nose: Olfactory Epithelium  
 Degeneration**

**LESION RATES**

OVERALL (a)	3/50 (6%)	3/50 (6%)	11/50 (22%)	46/50 (92%)
POLY-3 RATE (b)	3/44.94	3/45.21	11/48.43	46/48.90
POLY-3 PERCENT (g)	6.7%	6.6%	22.7%	94.1%
TERMINAL (d)	2/38 (5%)	2/36 (6%)	9/42 (21%)	40/41 (98%)
FIRST INCIDENCE	477	693	588	332

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.660N	P=0.028*	P<0.001**
POLY 1.5	P<0.001**	P=0.661	P=0.025*	P<0.001**
POLY 6	P<0.001**	P=0.658N	P=0.032*	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.661N	P=0.020*	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.496N	P=0.017*	P<0.001**

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

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

---

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

---

**Nose: Olfactory Epithelium  
Metaplasia**

---

**LESION RATES**

OVERALL (a)	1/50 (2%)	5/50 (10%)	3/50 (6%)	44/50 (88%)
POLY-3 RATE (b)	1/44.53	5/45.25	3/47.72	44/48.05
POLY-3 PERCENT (g)	2.3%	11.1%	6.3%	91.6%
TERMINAL (d)	0/38 (0%)	3/36 (8%)	3/42 (7%)	38/41 (93%)
FIRST INCIDENCE	646	693	730 (T)	473

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**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.105	P=0.331	P<0.001**
POLY 1.5	P<0.001**	P=0.103	P=0.322	P<0.001**
POLY 6	P<0.001**	P=0.106	P=0.337	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.102	P=0.309	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.047*	P=0.180	P<0.001**

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

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

---

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

---

Nose: Respiratory Epithelium  
 Hyperplasia

**LESION RATES**

OVERALL (a)	38/50 (76%)	38/50 (76%)	42/50 (84%)	40/50 (80%)
POLY-3 RATE (b)	38/45.78	38/47.01	42/48.98	40/48.37
POLY-3 PERCENT (g)	83%	80.8%	85.8%	82.7%
TERMINAL (d)	33/38 (87%)	31/36 (86%)	37/42 (88%)	35/41 (85%)
FIRST INCIDENCE	477	428	597	141

**STATISTICAL TESTS**

POLY 3	P=0.515	P=0.499N	P=0.465	P=0.596N
POLY 1.5	P=0.438	P=0.558N	P=0.366	P=0.543
POLY 6	P=0.517N	P=0.453N	P=0.562	P=0.517N
COCH-ARM / FISHERS	P=0.299	P=0.592N	P=0.227	P=0.405
MAX-ISO-POLY-3	P=0.596	P=0.386N	P=0.353	P=0.482N

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

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

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

**Pancreas  
 Cytoplasmic Alteration Focal**

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/44.22	2/45.21	1/47.72	1/45.98
POLY-3 PERCENT (g)	0%	4.4%	2.1%	2.2%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	1/42 (2%)	1/41 (2%)
FIRST INCIDENCE	---	693	730 (T)	730 (T)

**STATISTICAL TESTS**

POLY 3	P=0.519	P=0.242	P=0.515	P=0.508
POLY 1.5	P=0.508	P=0.239	P=0.510	P=0.503
POLY 6	P=0.532	P=0.244	P=0.519	P=0.513
COCH-ARM / FISHERS	P=0.500	P=0.247	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.294	P=0.081	P=0.177	P=0.168



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

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

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

**Pancreas  
 Infiltration Cellular Mononuclear Cell**

**LESION RATES**

OVERALL (a)	5/50 (10%)	5/50 (10%)	4/50 (8%)	7/50 (14%)
POLY-3 RATE (b)	5/44.55	5/45.23	4/47.72	7/45.98
POLY-3 PERCENT (g)	11.2%	11.1%	8.4%	15.2%
TERMINAL (d)	4/38 (11%)	4/36 (11%)	4/42 (10%)	7/41 (17%)
FIRST INCIDENCE	640	690	730 (T)	730 (T)

**STATISTICAL TESTS**

POLY 3	P=0.327	P=0.621N	P=0.457N	P=0.401
POLY 1.5	P=0.317	P=0.627N	P=0.471N	P=0.388
POLY 6	P=0.340	P=0.618N	P=0.447N	P=0.417
COCH-ARM / FISHERS	P=0.306	P=0.630N	P=0.500N	P=0.380
MAX-ISO-POLY-3	P=0.375	P=0.489N	P=0.329N	P=0.292

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

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

**LESION 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	---	---	---	---

**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. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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

**LESION 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	---	---	---	---

**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. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	0/45.07	1/47.72	0/45.98
POLY-3 PERCENT (g)	0%	0%	2.1%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	1/42 (2%)	0/41 (0%)
FIRST INCIDENCE	---	---	730 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.705	(e)	P=0.515	(e)
POLY 1.5	P=0.698	(e)	P=0.510	(e)
POLY 6	P=0.715	(e)	P=0.519	(e)
COCH-ARM / FISHERS	P=0.694	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.407	(e)	P=0.177	(e)

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

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

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

**Preputial Gland  
 Cyst**

**LESION 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	2/45.98
POLY-3 PERCENT (g)	0%	0%	0%	4.4%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	2/41 (5%)
FIRST INCIDENCE	---	---	---	730 (T)

**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=0.252
COCH-ARM / FISHERS	P=0.046*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.039*	(e)	(e)	P=0.084

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

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

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

**Preputial Gland  
 Infiltration Cellular Mononuclear Cell**

**LESION RATES**

OVERALL (a)	10/50 (20%)	15/50 (30%)	12/50 (24%)	7/50 (14%)
POLY-3 RATE (b)	10/44.75	15/45.33	12/48.18	7/46.31
POLY-3 PERCENT (g)	22.4%	33.1%	24.9%	15.1%
TERMINAL (d)	7/38 (18%)	12/36 (33%)	10/42 (24%)	6/41 (15%)
FIRST INCIDENCE	641	693	639	638

**STATISTICAL TESTS**

POLY 3	P=0.119N	P=0.182	P=0.482	P=0.269N
POLY 1.5	P=0.134N	P=0.177	P=0.456	P=0.285N
POLY 6	P=0.104N	P=0.182	P=0.502	P=0.252N
COCH-ARM / FISHERS	P=0.149N	P=0.178	P=0.405	P=0.298N
MAX-ISO-POLY-3	P=0.130N	P=0.128	P=0.389	P=0.193N

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

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

---

**Preputial Gland  
 Inflammation**

**LESION RATES**

OVERALL (a)	4/50 (8%)	4/50 (8%)	3/50 (6%)	4/50 (8%)
POLY-3 RATE (b)	4/44.22	4/45.36	3/47.72	4/45.98
POLY-3 PERCENT (g)	9.1%	8.8%	6.3%	8.7%
TERMINAL (d)	4/38 (11%)	3/36 (8%)	3/42 (7%)	4/41 (10%)
FIRST INCIDENCE	730 (T)	652	730 (T)	730 (T)

**STATISTICAL TESTS**

POLY 3	P=0.532N	P=0.629N	P=0.459N	P=0.622N
POLY 1.5	P=0.543N	P=0.638N	P=0.473N	P=0.634N
POLY 6	P=0.519N	P=0.623N	P=0.447N	P=0.607N
COCH-ARM / FISHERS	P=0.554N	P=0.643N	P=0.500N	P=0.643N
MAX-ISO-POLY-3	P=0.618N	P=0.484N	P=0.317N	P=0.476N

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

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

---

Preputial Gland: Duct  
 Ectasia

**LESION RATES**

OVERALL (a)	1/50 (2%)	1/50 (2%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	1/44.54	1/45.07	3/47.78	3/46.70
POLY-3 PERCENT (g)	2.2%	2.2%	6.3%	6.4%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	2/42 (5%)	2/41 (5%)
FIRST INCIDENCE	641	730 (T)	714	473

**STATISTICAL TESTS**

POLY 3	P=0.181	P=0.758N	P=0.331	P=0.323
POLY 1.5	P=0.173	P=0.760N	P=0.322	P=0.314
POLY 6	P=0.191	P=0.758N	P=0.337	P=0.332
COCH-ARM / FISHERS	P=0.165	P=0.753N	P=0.309	P=0.309
MAX-ISO-POLY-3	P=0.276	P=0.496N	P=0.180	P=0.172

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

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

---

**Prostate  
 Infiltration Cellular Mononuclear Cell**

**LESION RATES**

OVERALL (a)	23/50 (46%)	30/50 (60%)	23/50 (46%)	14/50 (28%)
POLY-3 RATE (b)	23/46.50	30/46.01	23/47.92	14/46.56
POLY-3 PERCENT (g)	49.5%	65.2%	48%	30.1%
TERMINAL (d)	18/38 (47%)	25/36 (69%)	21/42 (50%)	12/41 (29%)
FIRST INCIDENCE	479	646	695	570

**STATISTICAL TESTS**

POLY 3	P=0.006N**	P=0.089	P=0.525N	P=0.042N*
POLY 1.5	P=0.007N**	P=0.092	P=0.539N	P=0.046N*
POLY 6	P=0.004N**	P=0.083	P=0.526N	P=0.038N*
COCH-ARM / FISHERS	P=0.009N**	P=0.115	P=0.579N	P=0.048N*
MAX-ISO-POLY-3	P=0.005N**	P=0.060	P=0.442N	P=0.026N*

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

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

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

**Prostate: Epithelium  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	6/50 (12%)	3/50 (6%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	6/44.22	3/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	13.6%	6.7%	0%	0%
TERMINAL (d)	6/38 (16%)	3/36 (8%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	730 (T)	730 (T)	---	---

**STATISTICAL TESTS**

POLY 3	P=0.003N**	P=0.232N	P=0.012N*	P=0.013N*
POLY 1.5	P=0.003N**	P=0.239N	P=0.013N*	P=0.014N*
POLY 6	P=0.002N**	P=0.228N	P=0.011N*	P=0.012N*
COCH-ARM / FISHERS	P=0.003N**	P=0.243N	P=0.013N*	P=0.013N*
MAX-ISO-POLY-3	P=0.002N**	P=0.142N	P=0.004N**	P=0.005N**

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

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

---

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

---

**Salivary Glands  
 Infiltration Cellular Mononuclear Cell**

**LESION RATES**

OVERALL (a)	40/50 (80%)	32/50 (64%)	30/50 (60%)	33/50 (66%)
POLY-3 RATE (b)	40/47.82	32/47.04	30/49.16	33/46.56
POLY-3 PERCENT (g)	83.7%	68%	61%	70.9%
TERMINAL (d)	33/38 (87%)	24/36 (67%)	26/42 (62%)	31/41 (76%)
FIRST INCIDENCE	331	606	588	570

**STATISTICAL TESTS**

POLY 3	P=0.131N	P=0.056N	P=0.009N**	P=0.100N
POLY 1.5	P=0.134N	P=0.064N	P=0.013N*	P=0.105N
POLY 6	P=0.125N	P=0.045N*	P=0.006N**	P=0.090N
COCH-ARM / FISHERS	P=0.125N	P=0.059N	P=0.024N*	P=0.088N
MAX-ISO-POLY-3	P=0.042N*	P=0.034N*	P=0.005N**	P=0.064N

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

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

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

**Skin  
 Inflammation**

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	1/45.50	2/47.72	0/45.98
POLY-3 PERCENT (g)	0%	2.2%	4.2%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	2/42 (5%)	0/41 (0%)
FIRST INCIDENCE	---	606	730 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.602N	P=0.506	P=0.255	(e)
POLY 1.5	P=0.610N	P=0.502	P=0.249	(e)
POLY 6	P=0.591N	P=0.508	P=0.260	(e)
COCH-ARM / FISHERS	P=0.616N	P=0.500	P=0.247	(e)
MAX-ISO-POLY-3	P=0.346N	P=0.166	P=0.093	(e)

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

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

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

Skin  
 Ulcer

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	1/45.50	2/47.72	0/45.98
POLY-3 PERCENT (g)	0%	2.2%	4.2%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	2/42 (5%)	0/41 (0%)
FIRST INCIDENCE	---	606	730 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.602N	P=0.506	P=0.255	(e)
POLY 1.5	P=0.610N	P=0.502	P=0.249	(e)
POLY 6	P=0.591N	P=0.508	P=0.260	(e)
COCH-ARM / FISHERS	P=0.616N	P=0.500	P=0.247	(e)
MAX-ISO-POLY-3	P=0.346N	P=0.166	P=0.093	(e)

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

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

---

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

---

**Spleen  
 Hematopoietic Cell Proliferation**

**LESION RATES**

OVERALL (a)	29/50 (58%)	32/50 (64%)	23/50 (46%)	23/50 (46%)
POLY-3 RATE (b)	29/46.35	32/47.49	23/48.68	23/47.02
POLY-3 PERCENT (g)	62.6%	67.4%	47.3%	48.9%
TERMINAL (d)	24/38 (63%)	24/36 (67%)	19/42 (45%)	21/41 (51%)
FIRST INCIDENCE	535	444	597	141

**STATISTICAL TESTS**

POLY 3	P=0.043N*	P=0.391	P=0.095N	P=0.128N
POLY 1.5	P=0.047N*	P=0.357	P=0.113N	P=0.138N
POLY 6	P=0.040N*	P=0.425	P=0.082N	P=0.119N
COCH-ARM / FISHERS	P=0.060N	P=0.341	P=0.158N	P=0.158N
MAX-ISO-POLY-3	P=0.067N	P=0.312	P=0.069N	P=0.090N

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

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

---

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

---

**Spleen  
 Hyperplasia Lymphoid**

**LESION RATES**

OVERALL (a)	2/50 (4%)	3/50 (6%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.22	3/45.84	0/47.72	0/45.98
POLY-3 PERCENT (g)	4.5%	6.5%	0%	0%
TERMINAL (d)	2/38 (5%)	2/36 (6%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	730 (T)	444	---	---

**STATISTICAL TESTS**

POLY 3	P=0.067N	P=0.516	P=0.221N	P=0.229N
POLY 1.5	P=0.069N	P=0.508	P=0.226N	P=0.234N
POLY 6	P=0.064N	P=0.522	P=0.216N	P=0.223N
COCH-ARM / FISHERS	P=0.073N	P=0.500	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.088N	P=0.341	P=0.076N	P=0.076N

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

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

---

**Spleen  
 Pigmentation**

**LESION 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	---	---	---	---

**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. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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

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

**Spleen: Lymphoid Follicle  
 Atrophy**

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	1/44.74	0/45.07	1/47.72	3/47.26
POLY-3 PERCENT (g)	2.2%	0%	2.1%	6.4%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	1/42 (2%)	0/41 (0%)
FIRST INCIDENCE	573	---	730 (T)	332

**STATISTICAL TESTS**

POLY 3	P=0.104	P=0.499N	P=0.746N	P=0.325
POLY 1.5	P=0.101	P=0.500N	P=0.751N	P=0.316
POLY 6	P=0.108	P=0.498N	P=0.743N	P=0.336
COCH-ARM / FISHERS	P=0.097	P=0.500N	P=0.753N	P=0.309
MAX-ISO-POLY-3	P=0.104	P=0.158N	P=0.481N	P=0.175

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

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

---

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

---

Spleen: Red Pulp  
 Atrophy

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	1/44.74	0/45.07	1/48.05	3/47.26
POLY-3 PERCENT (g)	2.2%	0%	2.1%	6.4%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	573	---	639	332

**STATISTICAL TESTS**

POLY 3	P=0.104	P=0.499N	P=0.744N	P=0.325
POLY 1.5	P=0.101	P=0.500N	P=0.750N	P=0.316
POLY 6	P=0.108	P=0.498N	P=0.740N	P=0.336
COCH-ARM / FISHERS	P=0.097	P=0.500N	P=0.753N	P=0.309
MAX-ISO-POLY-3	P=0.104	P=0.158N	P=0.479N	P=0.175

---

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

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

**LESION RATES**

OVERALL (a)	7/50 (14%)	10/50 (20%)	27/50 (54%)	41/50 (82%)
POLY-3 RATE (b)	7/45.73	10/45.64	27/48.68	41/48.28
POLY-3 PERCENT (g)	15.3%	21.9%	55.5%	84.9%
TERMINAL (d)	4/38 (11%)	6/36 (17%)	23/42 (55%)	34/41 (83%)
FIRST INCIDENCE	535	646	646	332

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.294	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.292	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.293	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.298	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.210	P<0.001**	P<0.001**

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

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

**LESION RATES**

OVERALL (a)	3/50 (6%)	9/50 (18%)	24/50 (48%)	39/50 (78%)
POLY-3 RATE (b)	3/44.55	9/45.64	24/48.51	39/48.28
POLY-3 PERCENT (g)	6.7%	19.7%	49.5%	80.8%
TERMINAL (d)	2/38 (5%)	5/36 (14%)	20/42 (48%)	32/41 (78%)
FIRST INCIDENCE	640	646	646	332

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.064	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.061	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.067	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.061	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.035*	P<0.001**	P<0.001**

---

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

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

**LESION RATES**

OVERALL (a)	0/50 (0%)	3/50 (6%)	9/50 (18%)	22/50 (44%)
POLY-3 RATE (b)	0/44.22	3/45.30	9/48.00	22/47.43
POLY-3 PERCENT (g)	0%	6.6%	18.8%	46.4%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	8/42 (19%)	17/41 (42%)
FIRST INCIDENCE	---	693	654	332

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.123	P=0.003**	P<0.001**
POLY 1.5	P<0.001**	P=0.120	P=0.002**	P<0.001**
POLY 6	P<0.001**	P=0.125	P=0.003**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.121	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.041*	P<0.001**	P<0.001**

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

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

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

**Stomach, Glandular  
 Mineralization**

**LESION RATES**

OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.22	1/45.07	0/47.72	0/45.98
POLY-3 PERCENT (g)	4.5%	2.2%	0%	0%
TERMINAL (d)	2/38 (5%)	1/36 (3%)	0/42 (0%)	0/41 (0%)
FIRST INCIDENCE	730 (T)	730 (T)	---	---

**STATISTICAL TESTS**

POLY 3	P=0.098N	P=0.493N	P=0.221N	P=0.229N
POLY 1.5	P=0.099N	P=0.498N	P=0.226N	P=0.234N
POLY 6	P=0.097N	P=0.491N	P=0.216N	P=0.223N
COCH-ARM / FISHERS	P=0.101N	P=0.500N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.077N	P=0.277N	P=0.076N	P=0.076N

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

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

---

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

---

**Stomach, Glandular: Glands  
 Cyst**

**LESION RATES**

OVERALL (a)	4/50 (8%)	4/50 (8%)	3/50 (6%)	5/50 (10%)
POLY-3 RATE (b)	4/44.22	4/45.07	3/47.72	5/45.98
POLY-3 PERCENT (g)	9.1%	8.9%	6.3%	10.9%
TERMINAL (d)	4/38 (11%)	4/36 (11%)	3/42 (7%)	5/41 (12%)
FIRST INCIDENCE	730 (T)	730 (T)	730 (T)	730 (T)

**STATISTICAL TESTS**

POLY 3	P=0.455	P=0.633N	P=0.459N	P=0.524
POLY 1.5	P=0.442	P=0.639N	P=0.473N	P=0.510
POLY 6	P=0.470	P=0.630N	P=0.447N	P=0.541
COCH-ARM / FISHERS	P=0.430	P=0.643N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.512	P=0.488N	P=0.317N	P=0.387

---

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

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

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

**Testes  
 Mineralization**

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.22	2/45.84	1/47.72	0/45.98
POLY-3 PERCENT (g)	0%	4.4%	2.1%	0%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	1/42 (2%)	0/41 (0%)
FIRST INCIDENCE	---	444	730 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.443N	P=0.245	P=0.515	(e)
POLY 1.5	P=0.453N	P=0.241	P=0.510	(e)
POLY 6	P=0.433N	P=0.248	P=0.519	(e)
COCH-ARM / FISHERS	P=0.461N	P=0.247	P=0.500	(e)
MAX-ISO-POLY-3	P=0.339N	P=0.084	P=0.177	(e)



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

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

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

Testes: Germinal Epithelium  
 Atrophy

**LESION RATES**

OVERALL (a)	2/50 (4%)	2/50 (4%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	2/44.22	2/46.15	3/48.02	0/45.98
POLY-3 PERCENT (g)	4.5%	4.3%	6.3%	0%
TERMINAL (d)	2/38 (5%)	0/36 (0%)	2/42 (5%)	0/41 (0%)
FIRST INCIDENCE	730 (T)	444	646	---

**STATISTICAL TESTS**

POLY 3	P=0.189N	P=0.678N	P=0.537	P=0.229N
POLY 1.5	P=0.195N	P=0.686N	P=0.524	P=0.234N
POLY 6	P=0.181N	P=0.673N	P=0.549	P=0.223N
COCH-ARM / FISHERS	P=0.199N	P=0.691N	P=0.500	P=0.247N
MAX-ISO-POLY-3	P=0.178N	P=0.482N	P=0.363	P=0.076N

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

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

---

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

---

**Thymus  
 Atrophy**

**LESION RATES**

OVERALL (a)	36/49 (73%)	35/46 (76%)	32/45 (71%)	30/42 (71%)
POLY-3 RATE (b)	36/46.08	35/43.54	32/44.55	30/39.95
POLY-3 PERCENT (g)	78.1%	80.4%	71.8%	75.1%
TERMINAL (d)	28/37 (76%)	27/33 (82%)	26/38 (68%)	27/36 (75%)
FIRST INCIDENCE	535	444	588	640

**STATISTICAL TESTS**

POLY 3	P=0.338N	P=0.498	P=0.325N	P=0.470N
POLY 1.5	P=0.368N	P=0.472	P=0.376N	P=0.498N
POLY 6	P=0.315N	P=0.505	P=0.293N	P=0.451N
COCH-ARM / FISHERS	P=0.403N	P=0.478	P=0.490N	P=0.506N
MAX-ISO-POLY-3	P=0.430N	P=0.393	P=0.244N	P=0.371N

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

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

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

**Thymus  
 Hyperplasia Lymphoid**

**LESION RATES**

OVERALL (a)	0/49 (0%)	2/46 (4%)	0/45 (0%)	0/42 (0%)
POLY-3 RATE (b)	0/43.22	2/41.23	0/42.95	0/39.45
POLY-3 PERCENT (g)	0%	4.9%	0%	0%
TERMINAL (d)	0/37 (0%)	2/33 (6%)	0/38 (0%)	0/36 (0%)
FIRST INCIDENCE	---	730 (T)	---	---

**STATISTICAL TESTS**

POLY 3	P=0.416N	P=0.226	(e)	(e)
POLY 1.5	P=0.424N	P=0.224	(e)	(e)
POLY 6	P=0.409N	P=0.228	(e)	(e)
COCH-ARM / FISHERS	P=0.434N	P=0.232	(e)	(e)
MAX-ISO-POLY-3	P=0.262N	P=0.072	(e)	(e)

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

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

---

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

---

Thymus  
 Necrosis Lymphoid

**LESION RATES**

OVERALL (a)	0/49 (0%)	2/46 (4%)	0/45 (0%)	0/42 (0%)
POLY-3 RATE (b)	0/43.22	2/42.39	0/42.95	0/39.45
POLY-3 PERCENT (g)	0%	4.7%	0%	0%
TERMINAL (d)	0/37 (0%)	0/33 (0%)	0/38 (0%)	0/36 (0%)
FIRST INCIDENCE	---	59	---	---

**STATISTICAL TESTS**

POLY 3	P=0.412N	P=0.233	(e)	(e)
POLY 1.5	P=0.421N	P=0.229	(e)	(e)
POLY 6	P=0.404N	P=0.235	(e)	(e)
COCH-ARM / FISHERS	P=0.434N	P=0.232	(e)	(e)
MAX-ISO-POLY-3	P=0.267N	P=0.075	(e)	(e)

---

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

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

---

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

---

Tooth  
 Dysplasia

**LESION RATES**

OVERALL (a)	37/37 (100%)	37/37 (100%)	35/35 (100%)	20/20 (100%)
POLY-3 RATE (b)	37/37.00	37/37.00	35/35.00	20/20.00
POLY-3 PERCENT (g)	100%	100%	100%	100%
TERMINAL (d)	34/34 (100%)	32/32 (100%)	33/33 (100%)	19/19 (100%)
FIRST INCIDENCE	646	652	668	640

**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. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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

---

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

---

**Urinary Bladder  
 Infiltration Cellular Mononuclear Cell**

**LESION RATES**

OVERALL (a)	28/50 (56%)	19/50 (38%)	19/50 (38%)	31/50 (62%)
POLY-3 RATE (b)	28/45.49	19/45.86	19/48.56	31/47.25
POLY-3 PERCENT (g)	61.6%	41.4%	39.1%	65.6%
TERMINAL (d)	24/38 (63%)	15/36 (42%)	15/42 (36%)	26/41 (63%)
FIRST INCIDENCE	549	646	639	473

**STATISTICAL TESTS**

POLY 3	P=0.201	P=0.039N*	P=0.022N*	P=0.424
POLY 1.5	P=0.179	P=0.046N*	P=0.030N*	P=0.375
POLY 6	P=0.231	P=0.035N*	P=0.017N*	P=0.482
COCH-ARM / FISHERS	P=0.163	P=0.054N	P=0.054N	P=0.342
MAX-ISO-POLY-3	P=0.057	P=0.025N*	P=0.015N*	P=0.343

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

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

**LESION RATES**

OVERALL (a)	0/49 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/45.13	1/46.68	1/45.32	1/44.78
POLY-3 PERCENT (g)	0%	2.1%	2.2%	2.2%
TERMINAL (d)	0/35 (0%)	1/41 (2%)	0/38 (0%)	1/37 (3%)
FIRST INCIDENCE	---	729 (T)	667	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.377	P=0.507	P=0.501	P=0.498
POLY 1.5	P=0.378	P=0.506	P=0.501	P=0.499
POLY 6	P=0.375	P=0.509	P=0.502	P=0.498
COCH-ARM / FISHERS	P=0.388	P=0.505	P=0.505	P=0.505
MAX-ISO-POLY-3	P=0.336	P=0.166	P=0.160	P=0.160

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

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

**LESION RATES**

OVERALL (a)	49/49 (100%)	50/50 (100%)	49/50 (98%)	49/50 (98%)
POLY-3 RATE (b)	49/49.00	50/50.00	49/49.42	49/49.00
POLY-3 PERCENT (g)	100%	100%	99.2%	100%
TERMINAL (d)	35/35 (100%)	41/41 (100%)	38/38 (100%)	37/37 (100%)
FIRST INCIDENCE	450	493	268	404

**STATISTICAL TESTS**

POLY 3	P=0.924N	(e)	P=0.920N	P=0.505N
POLY 1.5	P=0.804N	(e)	P=0.711N	P=1.000N
POLY 6	P=1.000N	(e)	P=1.000N	P=0.505N
COCH-ARM / FISHERS	P=0.238N	(e)	P=0.505N	P=0.505N
MAX-ISO-POLY-3	P=0.391N	(e)	P=0.162N	P=0.163N



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

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

**LESION RATES**

OVERALL (a)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/45.23	0/46.68	0/45.08	0/44.78
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	702	---	---	---

**STATISTICAL TESTS**

POLY 3	P=0.303N	P=0.494N	P=0.501N	P=0.502N
POLY 1.5	P=0.303N	P=0.495N	P=0.500N	P=0.501N
POLY 6	P=0.304N	P=0.492N	P=0.501N	P=0.503N
COCH-ARM / FISHERS	P=0.303N	P=0.495N	P=0.495N	P=0.495N
MAX-ISO-POLY-3	P=0.128N	P=0.157N	P=0.161N	P=0.162N

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

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

---

**Bone Marrow  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	2/49 (4%)	9/50 (18%)	4/50 (8%)	5/50 (10%)
POLY-3 RATE (b)	2/45.32	9/48.76	4/46.65	5/45.58
POLY-3 PERCENT (g)	4.4%	18.5%	8.6%	11%
TERMINAL (d)	0/35 (0%)	4/41 (10%)	1/38 (3%)	1/37 (3%)
FIRST INCIDENCE	695	493	439	591

**STATISTICAL TESTS**

POLY 3	P=0.433	P=0.034*	P=0.351	P=0.218
POLY 1.5	P=0.431	P=0.032*	P=0.348	P=0.217
POLY 6	P=0.438	P=0.038*	P=0.356	P=0.221
COCH-ARM / FISHERS	P=0.448	P=0.028*	P=0.349	P=0.226
MAX-ISO-POLY-3	P=0.159	P=0.019*	P=0.213	P=0.122

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

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

---

**Bone Marrow  
 Myelofibrosis**

**LESION RATES**

OVERALL (a)	20/49 (41%)	17/50 (34%)	17/50 (34%)	14/50 (28%)
POLY-3 RATE (b)	20/45.58	17/47.00	17/45.52	14/45.45
POLY-3 PERCENT (g)	43.9%	36.2%	37.4%	30.8%
TERMINAL (d)	19/35 (54%)	16/41 (39%)	15/38 (40%)	12/37 (32%)
FIRST INCIDENCE	598	640	667	589

**STATISTICAL TESTS**

POLY 3	P=0.137N	P=0.292N	P=0.336N	P=0.139N
POLY 1.5	P=0.138N	P=0.301N	P=0.333N	P=0.142N
POLY 6	P=0.135N	P=0.276N	P=0.328N	P=0.133N
COCH-ARM / FISHERS	P=0.120N	P=0.311N	P=0.311N	P=0.129N
MAX-ISO-POLY-3	P=0.156N	P=0.226N	P=0.263N	P=0.098N

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

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

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

**Clitoral Gland  
 Inflammation**

**LESION RATES**

OVERALL (a)	0/47 (0%)	1/50 (2%)	1/49 (2%)	3/49 (6%)
POLY-3 RATE (b)	0/43.45	1/46.68	1/44.67	3/44.25
POLY-3 PERCENT (g)	0%	2.1%	2.2%	6.8%
TERMINAL (d)	0/35 (0%)	1/41 (2%)	0/38 (0%)	3/37 (8%)
FIRST INCIDENCE	---	729 (T)	667	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.053	P=0.514	P=0.506	P=0.122
POLY 1.5	P=0.053	P=0.514	P=0.506	P=0.122
POLY 6	P=0.052	P=0.516	P=0.507	P=0.121
COCH-ARM / FISHERS	P=0.056	P=0.515	P=0.510	P=0.129
MAX-ISO-POLY-3	P=0.042*	P=0.173	P=0.163	P=0.039*

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

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

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

**Esophagus  
 Inflammation**

**LESION 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	---	---	---	---

**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. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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

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

**Eye  
 Atrophy**

**LESION RATES**

OVERALL (a)	0/49 (0%)	2/50 (4%)	1/49 (2%)	3/50 (6%)
POLY-3 RATE (b)	0/45.13	2/47.09	1/44.33	3/45.65
POLY-3 PERCENT (g)	0%	4.3%	2.3%	6.6%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	1/38 (3%)	0/37 (0%)
FIRST INCIDENCE	---	640	729 (T)	589

**STATISTICAL TESTS**

POLY 3	P=0.104	P=0.247	P=0.496	P=0.121
POLY 1.5	P=0.103	P=0.245	P=0.497	P=0.120
POLY 6	P=0.105	P=0.251	P=0.497	P=0.123
COCH-ARM / FISHERS	P=0.106	P=0.253	P=0.500	P=0.125
MAX-ISO-POLY-3	P=0.062	P=0.084	P=0.159	P=0.039*

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

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

---

Eye: Anterior Chamber  
 Inflammation

**LESION RATES**

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/49 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.13	0/46.68	0/44.33	2/44.78
POLY-3 PERCENT (g)	0%	0%	0%	4.5%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	2/37 (5%)
FIRST INCIDENCE	---	---	---	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.045*	(e)	(e)	P=0.235
POLY 1.5	P=0.045*	(e)	(e)	P=0.236
POLY 6	P=0.044*	(e)	(e)	P=0.235
COCH-ARM / FISHERS	P=0.047*	(e)	(e)	P=0.253
MAX-ISO-POLY-3	P=0.033*	(e)	(e)	P=0.077

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

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

---

Eye: Cornea  
 Inflammation

**LESION RATES**

OVERALL (a)	2/49 (4%)	0/50 (0%)	0/49 (0%)	9/50 (18%)
POLY-3 RATE (b)	2/45.20	0/46.68	0/44.33	9/45.94
POLY-3 PERCENT (g)	4.4%	0%	0%	19.6%
TERMINAL (d)	1/35 (3%)	0/41 (0%)	0/38 (0%)	6/37 (16%)
FIRST INCIDENCE	710	---	---	589

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.230N	P=0.241N	P=0.026*
POLY 1.5	P<0.001**	P=0.231N	P=0.241N	P=0.026*
POLY 6	P<0.001**	P=0.228N	P=0.241N	P=0.028*
COCH-ARM / FISHERS	P<0.001**	P=0.242N	P=0.247N	P=0.028*
MAX-ISO-POLY-3	P<0.001**	P=0.075N	P=0.080N	P=0.012*

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

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

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

**Gallbladder  
 Infiltration Cellular Mononuclear Cell**

**LESION RATES**

OVERALL (a)	1/48 (2%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/44.13	2/46.68	0/45.08	1/44.78
POLY-3 PERCENT (g)	2.3%	4.3%	0%	2.2%
TERMINAL (d)	1/34 (3%)	2/41 (5%)	0/38 (0%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	---	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.496N	P=0.520	P=0.496N	P=0.757N
POLY 1.5	P=0.495N	P=0.517	P=0.495N	P=0.757N
POLY 6	P=0.496N	P=0.524	P=0.495N	P=0.758N
COCH-ARM / FISHERS	P=0.490N	P=0.515	P=0.490N	P=0.742N
MAX-ISO-POLY-3	P=0.394N	P=0.300	P=0.156N	P=0.495N

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

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

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

**Harderian Gland  
 Infiltration Cellular Mononuclear Cell**

**LESION RATES**

OVERALL (a)	30/49 (61%)	22/50 (44%)	17/49 (35%)	15/50 (30%)
POLY-3 RATE (b)	30/46.35	22/47.00	17/45.30	15/45.19
POLY-3 PERCENT (g)	64.7%	46.8%	37.5%	33.2%
TERMINAL (d)	23/35 (66%)	21/41 (51%)	14/38 (37%)	13/37 (35%)
FIRST INCIDENCE	598	640	541	666

**STATISTICAL TESTS**

POLY 3	P=0.002N**	P=0.058N	P=0.006N**	P<0.001N**
POLY 1.5	P=0.002N**	P=0.059N	P=0.006N**	P<0.001N**
POLY 6	P=0.002N**	P=0.058N	P=0.006N**	P=0.002N**
COCH-ARM / FISHERS	P<0.001N**	P=0.065N	P=0.007N**	P=0.002N**
MAX-ISO-POLY-3	P=0.002N**	P=0.037N*	P=0.003N**	P<0.001N**

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

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

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

**Harderian Gland: Epithelium  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	3/49 (6%)	0/50 (0%)	0/49 (0%)	4/50 (8%)
POLY-3 RATE (b)	3/45.13	0/46.68	0/44.33	4/45.09
POLY-3 PERCENT (g)	6.7%	0%	0%	8.9%
TERMINAL (d)	3/35 (9%)	0/41 (0%)	0/38 (0%)	2/37 (5%)
FIRST INCIDENCE	729 (T)	---	---	676

**STATISTICAL TESTS**

POLY 3	P=0.233	P=0.113N	P=0.122N	P=0.499
POLY 1.5	P=0.234	P=0.114N	P=0.122N	P=0.499
POLY 6	P=0.231	P=0.111N	P=0.121N	P=0.502
COCH-ARM / FISHERS	P=0.242	P=0.117N	P=0.121N	P=0.511
MAX-ISO-POLY-3	P=0.077	P=0.037N*	P=0.040N*	P=0.347

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

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

---

**Heart  
Cardiomyopathy**

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**LESION RATES**

OVERALL (a)	1/49 (2%)	2/50 (4%)	1/50 (2%)	5/50 (10%)
POLY-3 RATE (b)	1/45.13	2/46.68	1/45.08	5/44.88
POLY-3 PERCENT (g)	2.2%	4.3%	2.2%	11.1%
TERMINAL (d)	1/35 (3%)	2/41 (5%)	1/38 (3%)	4/37 (11%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	703

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**STATISTICAL TESTS**

POLY 3	P=0.045*	P=0.512	P=0.760	P=0.100
POLY 1.5	P=0.045*	P=0.510	P=0.760N	P=0.101
POLY 6	P=0.044*	P=0.515	P=0.761N	P=0.099
COCH-ARM / FISHERS	P=0.049*	P=0.508	P=0.747N	P=0.107
MAX-ISO-POLY-3	P=0.040*	P=0.293	P=0.499	P=0.045*

.....

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

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

---

**Heart  
Infiltration Cellular Mononuclear Cell**

**LESION RATES**

OVERALL (a)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/45.39	0/46.68	0/45.08	0/44.78
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	659	---	---	---

**STATISTICAL TESTS**

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POLY 3	P=0.303N	P=0.494N	P=0.501N	P=0.503N
POLY 1.5	P=0.302N	P=0.495N	P=0.500N	P=0.502N
POLY 6	P=0.303N	P=0.493N	P=0.502N	P=0.504N
COCH-ARM / FISHERS	P=0.303N	P=0.495N	P=0.495N	P=0.495N
MAX-ISO-POLY-3	P=0.129N	P=0.157N	P=0.162N	P=0.163N

---

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

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

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

**Heart  
 Mineralization**

**LESION RATES**

OVERALL (a)	2/49 (4%)	0/50 (0%)	2/50 (4%)	8/50 (16%)
POLY-3 RATE (b)	2/45.44	0/46.68	2/45.73	8/45.75
POLY-3 PERCENT (g)	4.4%	0%	4.4%	17.5%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	5/37 (14%)
FIRST INCIDENCE	666	---	544	566

**STATISTICAL TESTS**

POLY 3	P=0.002**	P=0.231N	P=0.692N	P=0.046*
POLY 1.5	P=0.002**	P=0.232N	P=0.691N	P=0.046*
POLY 6	P=0.002**	P=0.230N	P=0.691N	P=0.047*
COCH-ARM / FISHERS	P=0.003**	P=0.242N	P=0.684N	P=0.049*
MAX-ISO-POLY-3	P=0.002**	P=0.075N	P=0.497N	P=0.022*

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

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

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

**Heart  
 Necrosis**

**LESION RATES**

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.13	0/46.68	0/45.08	2/45.36
POLY-3 PERCENT (g)	0%	0%	0%	4.4%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	566

**STATISTICAL TESTS**

POLY 3	P=0.045*	(e)	(e)	P=0.238
POLY 1.5	P=0.045*	(e)	(e)	P=0.238
POLY 6	P=0.045*	(e)	(e)	P=0.239
COCH-ARM / FISHERS	P=0.047*	(e)	(e)	P=0.253
MAX-ISO-POLY-3	P=0.033*	(e)	(e)	P=0.077

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

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

---

**Islets, Pancreatic  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	5/49 (10%)	2/50 (4%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	5/45.23	2/46.68	3/45.67	1/44.98
POLY-3 PERCENT (g)	11.1%	4.3%	6.6%	2.2%
TERMINAL (d)	4/35 (11%)	2/41 (5%)	2/38 (5%)	0/37 (0%)
FIRST INCIDENCE	702	729 (T)	544	676

**STATISTICAL TESTS**

POLY 3	P=0.097N	P=0.204N	P=0.351N	P=0.102N
POLY 1.5	P=0.097N	P=0.206N	P=0.351N	P=0.102N
POLY 6	P=0.098N	P=0.200N	P=0.348N	P=0.102N
COCH-ARM / FISHERS	P=0.091N	P=0.210N	P=0.346N	P=0.098N
MAX-ISO-POLY-3	P=0.063N	P=0.113N	P=0.227N	P=0.046N*

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

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

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

**Kidney  
 Accumulation, Hyaline Droplet**

**LESION RATES**

OVERALL (a)	2/49 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/45.26	0/46.68	0/45.08	0/44.78
POLY-3 PERCENT (g)	4.4%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	710	---	---	---

**STATISTICAL TESTS**

POLY 3	P=0.112N	P=0.230N	P=0.238N	P=0.239N
POLY 1.5	P=0.112N	P=0.231N	P=0.237N	P=0.239N
POLY 6	P=0.113N	P=0.229N	P=0.238N	P=0.240N
COCH-ARM / FISHERS	P=0.113N	P=0.242N	P=0.242N	P=0.242N
MAX-ISO-POLY-3	P=0.035N*	P=0.075N	P=0.078N	P=0.079N

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

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

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

**Kidney  
 Cyst**

**LESION 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	2/46.06	0/44.78
POLY-3 PERCENT (g)	0%	0%	4.3%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	439	---

**STATISTICAL TESTS**

POLY 3	P=0.581	(e)	P=0.242	(e)
POLY 1.5	P=0.583	(e)	P=0.241	(e)
POLY 6	P=0.577	(e)	P=0.244	(e)
COCH-ARM / FISHERS	P=0.598	(e)	P=0.253	(e)
MAX-ISO-POLY-3	P=0.258	(e)	P=0.079	(e)

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

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

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

**Kidney  
 Glomerulopathy Hyaline**

**LESION RATES**

OVERALL (a)	0/49 (0%)	3/50 (6%)	15/50 (30%)	41/50 (82%)
POLY-3 RATE (b)	0/45.13	3/46.82	15/45.28	41/48.01
POLY-3 PERCENT (g)	0%	6.4%	33.1%	85.4%
TERMINAL (d)	0/35 (0%)	2/41 (5%)	14/38 (37%)	32/37 (87%)
FIRST INCIDENCE	---	694	677	404

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.125	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.124	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.128	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.125	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.043*	P<0.001**	P<0.001**

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

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

---

**Kidney  
 Infarct**

**LESION RATES**

OVERALL (a)	3/49 (6%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	3/45.13	2/46.68	1/45.08	1/44.98
POLY-3 PERCENT (g)	6.7%	4.3%	2.2%	2.2%
TERMINAL (d)	3/35 (9%)	2/41 (5%)	1/38 (3%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	676

**STATISTICAL TESTS**

POLY 3	P=0.202N	P=0.485N	P=0.306N	P=0.306N
POLY 1.5	P=0.201N	P=0.487N	P=0.304N	P=0.306N
POLY 6	P=0.202N	P=0.480N	P=0.305N	P=0.305N
COCH-ARM / FISHERS	P=0.194N	P=0.490N	P=0.301N	P=0.301N
MAX-ISO-POLY-3	P=0.226N	P=0.312N	P=0.156N	P=0.157N

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

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

---

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

---

**Kidney  
 Metaplasia Osseous**

**LESION RATES**

OVERALL (a)	1/49 (2%)	2/50 (4%)	2/50 (4%)	4/50 (8%)
POLY-3 RATE (b)	1/45.13	2/46.99	2/45.08	4/44.98
POLY-3 PERCENT (g)	2.2%	4.3%	4.4%	8.9%
TERMINAL (d)	1/35 (3%)	1/41 (2%)	2/38 (5%)	3/37 (8%)
FIRST INCIDENCE	729 (T)	645	729 (T)	676

**STATISTICAL TESTS**

POLY 3	P=0.109	P=0.514	P=0.500	P=0.178
POLY 1.5	P=0.110	P=0.511	P=0.501	P=0.178
POLY 6	P=0.108	P=0.519	P=0.500	P=0.178
COCH-ARM / FISHERS	P=0.116	P=0.508	P=0.508	P=0.187
MAX-ISO-POLY-3	P=0.117	P=0.295	P=0.281	P=0.084

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

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

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

**Kidney  
 Mineralization**

**LESION RATES**

OVERALL (a)	1/49 (2%)	0/50 (0%)	3/50 (6%)	20/50 (40%)
POLY-3 RATE (b)	1/45.13	0/46.68	3/45.08	20/45.94
POLY-3 PERCENT (g)	2.2%	0%	6.7%	43.5%
TERMINAL (d)	1/35 (3%)	0/41 (0%)	3/38 (8%)	17/37 (46%)
FIRST INCIDENCE	729 (T)	---	729 (T)	589

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.493N	P=0.305	P<0.001**
POLY 1.5	P<0.001**	P=0.494N	P=0.306	P<0.001**
POLY 6	P<0.001**	P=0.491N	P=0.305	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.495N	P=0.316	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.157N	P=0.155	P<0.001**

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

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

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

**Kidney  
 Nephropathy**

**LESION RATES**

OVERALL (a)	13/49 (27%)	19/50 (38%)	12/50 (24%)	25/50 (50%)
POLY-3 RATE (b)	13/45.99	19/46.82	12/45.25	25/45.26
POLY-3 PERCENT (g)	28.3%	40.6%	26.5%	55.2%
TERMINAL (d)	10/35 (29%)	18/41 (44%)	10/38 (26%)	22/37 (60%)
FIRST INCIDENCE	500	694	701	676

**STATISTICAL TESTS**

POLY 3	P=0.010**	P=0.150	P=0.519N	P=0.006**
POLY 1.5	P=0.011*	P=0.152	P=0.507N	P=0.007**
POLY 6	P=0.008**	P=0.150	P=0.524N	P=0.005**
COCH-ARM / FISHERS	P=0.019*	P=0.157	P=0.477N	P=0.014*
MAX-ISO-POLY-3	P=0.005**	P=0.105	P=0.425N	P=0.003**

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

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

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

**Kidney  
 Pigmentation**

**LESION RATES**

OVERALL (a)	1/49 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/45.80	1/46.68	0/45.08	0/44.78
POLY-3 PERCENT (g)	2.2%	2.1%	0%	0%
TERMINAL (d)	0/35 (0%)	1/41 (2%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	500	729 (T)	---	---

**STATISTICAL TESTS**

POLY 3	P=0.237N	P=0.756N	P=0.503N	P=0.505N
POLY 1.5	P=0.236N	P=0.756N	P=0.501N	P=0.503N
POLY 6	P=0.238N	P=0.755N	P=0.504N	P=0.506N
COCH-ARM / FISHERS	P=0.233N	P=0.747N	P=0.495N	P=0.495N
MAX-ISO-POLY-3	P=0.265N	P=0.494N	P=0.164N	P=0.165N



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

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

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

**Kidney  
 Vacuolization Cytoplasmic**

**LESION RATES**

OVERALL (a)	0/49 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/45.13	1/46.77	2/45.67	0/44.78
POLY-3 PERCENT (g)	0%	2.1%	4.4%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	1/38 (3%)	0/37 (0%)
FIRST INCIDENCE	---	706	544	---

**STATISTICAL TESTS**

POLY 3	P=0.624N	P=0.507	P=0.240	(e)
POLY 1.5	P=0.623N	P=0.506	P=0.240	(e)
POLY 6	P=0.626N	P=0.510	P=0.241	(e)
COCH-ARM / FISHERS	P=0.612N	P=0.505	P=0.253	(e)
MAX-ISO-POLY-3	P=0.337	P=0.166	P=0.077	(e)

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

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

---

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

---

**Kidney: Glomerulus  
 Congestion**

**LESION RATES**

OVERALL (a)	5/49 (10%)	2/50 (4%)	12/50 (24%)	37/50 (74%)
POLY-3 RATE (b)	5/45.23	2/47.05	12/45.98	37/45.97
POLY-3 PERCENT (g)	11.1%	4.3%	26.1%	80.5%
TERMINAL (d)	4/35 (11%)	1/41 (2%)	10/38 (26%)	32/37 (87%)
FIRST INCIDENCE	702	624	544	589

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.201N	P=0.055	P<0.001**
POLY 1.5	P<0.001**	P=0.204N	P=0.055	P<0.001**
POLY 6	P<0.001**	P=0.195N	P=0.057	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.210N	P=0.059	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.112N	P=0.031*	P<0.001**

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

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

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

**Kidney: Papilla  
 Necrosis**

**LESION RATES**

OVERALL (a)	3/49 (6%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	3/45.24	1/46.92	1/45.08	0/44.78
POLY-3 PERCENT (g)	6.6%	2.1%	2.2%	0%
TERMINAL (d)	1/35 (3%)	0/41 (0%)	1/38 (3%)	0/37 (0%)
FIRST INCIDENCE	715	666	729 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.074N	P=0.292N	P=0.306N	P=0.120N
POLY 1.5	P=0.073N	P=0.295N	P=0.305N	P=0.120N
POLY 6	P=0.075N	P=0.288N	P=0.307N	P=0.121N
COCH-ARM / FISHERS	P=0.071N	P=0.301N	P=0.301N	P=0.117N
MAX-ISO-POLY-3	P=0.044N*	P=0.148N	P=0.157N	P=0.040N*

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

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

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

**Kidney: Pelvis  
 Inflammation**

**LESION 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	---	---	---	---

**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. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS 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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Liver  
 Angiectasis

**LESION RATES**

OVERALL (a)	0/49 (0%)	1/50 (2%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	0/45.13	1/46.68	3/45.19	1/44.78
POLY-3 PERCENT (g)	0%	2.1%	6.6%	2.2%
TERMINAL (d)	0/35 (0%)	1/41 (2%)	2/38 (5%)	1/37 (3%)
FIRST INCIDENCE	---	729 (T)	701	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.338	P=0.507	P=0.119	P=0.498
POLY 1.5	P=0.340	P=0.506	P=0.120	P=0.499
POLY 6	P=0.336	P=0.509	P=0.119	P=0.498
COCH-ARM / FISHERS	P=0.356	P=0.505	P=0.125	P=0.505
MAX-ISO-POLY-3	P=0.160	P=0.166	P=0.039*	P=0.160

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

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

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

Liver  
 Basophilic Focus

**LESION RATES**

OVERALL (a)	1/49 (2%)	3/50 (6%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/45.13	3/46.68	0/45.08	1/44.78
POLY-3 PERCENT (g)	2.2%	6.4%	0%	2.2%
TERMINAL (d)	1/35 (3%)	3/41 (7%)	0/38 (0%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	---	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.411N	P=0.318	P=0.500N	P=0.759
POLY 1.5	P=0.411N	P=0.315	P=0.499N	P=0.759
POLY 6	P=0.411N	P=0.321	P=0.500N	P=0.759
COCH-ARM / FISHERS	P=0.404N	P=0.316	P=0.495N	P=0.747N
MAX-ISO-POLY-3	P=0.284N	P=0.166	P=0.160N	P=0.497

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

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

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

Liver  
 Clear Cell Focus

**LESION RATES**

OVERALL (a)	0/49 (0%)	6/50 (12%)	23/50 (46%)	32/50 (64%)
POLY-3 RATE (b)	0/45.13	6/46.68	23/45.19	32/44.78
POLY-3 PERCENT (g)	0%	12.9%	50.9%	71.5%
TERMINAL (d)	0/35 (0%)	6/41 (15%)	22/38 (58%)	32/37 (87%)
FIRST INCIDENCE	---	729 (T)	701	729 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.017*	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.017*	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.018*	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.014*	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.006**	P<0.001**	P<0.001**

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

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

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

Liver  
 Eosinophilic Focus

**LESION RATES**

OVERALL (a)	3/49 (6%)	7/50 (14%)	10/50 (20%)	31/50 (62%)
POLY-3 RATE (b)	3/45.13	7/46.68	10/45.08	31/45.48
POLY-3 PERCENT (g)	6.7%	15%	22.2%	68.2%
TERMINAL (d)	3/35 (9%)	7/41 (17%)	10/38 (26%)	29/37 (78%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	591

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.171	P=0.034*	P<0.001**
POLY 1.5	P<0.001**	P=0.169	P=0.035*	P<0.001**
POLY 6	P<0.001**	P=0.175	P=0.033*	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.167	P=0.039*	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.102	P=0.017*	P<0.001**



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

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

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

Liver  
 Fatty Change Diffuse

**LESION RATES**

OVERALL (a)	36/49 (73%)	31/50 (62%)	34/50 (68%)	3/50 (6%)
POLY-3 RATE (b)	36/47.48	31/47.79	34/47.42	3/45.97
POLY-3 PERCENT (g)	75.8%	64.9%	71.7%	6.5%
TERMINAL (d)	30/35 (86%)	27/41 (66%)	28/38 (74%)	0/37 (0%)
FIRST INCIDENCE	450	575	439	566

**STATISTICAL TESTS**

POLY 3	P<0.001N**	P=0.166N	P=0.409N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.166N	P=0.400N	P<0.001N**
POLY 6	P<0.001N**	P=0.154N	P=0.400N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.157N	P=0.353N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.115N	P=0.320N	P<0.001N**

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

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

---

Liver  
 Fatty Change Focal

**LESION RATES**

OVERALL (a)	1/49 (2%)	2/50 (4%)	20/50 (40%)	12/50 (24%)
POLY-3 RATE (b)	1/45.39	2/46.68	20/45.89	12/45.25
POLY-3 PERCENT (g)	2.2%	4.3%	43.6%	26.5%
TERMINAL (d)	0/35 (0%)	2/41 (5%)	18/38 (47%)	11/37 (30%)
FIRST INCIDENCE	659	729 (T)	584	589

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.510	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.509	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.512	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.508	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.291	P<0.001**	P<0.001**

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

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

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

Liver  
 Fibrosis

**LESION RATES**

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.13	0/46.68	0/45.08	2/45.36
POLY-3 PERCENT (g)	0%	0%	0%	4.4%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	566

**STATISTICAL TESTS**

POLY 3	P=0.045*	(e)	(e)	P=0.238
POLY 1.5	P=0.045*	(e)	(e)	P=0.238
POLY 6	P=0.045*	(e)	(e)	P=0.239
COCH-ARM / FISHERS	P=0.047*	(e)	(e)	P=0.253
MAX-ISO-POLY-3	P=0.033*	(e)	(e)	P=0.077

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS 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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Liver  
 Hematopoietic Cell Proliferation

**LESION RATES**

OVERALL (a)	1/49 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/45.18	0/46.68	0/45.08	1/45.25
POLY-3 PERCENT (g)	2.2%	0%	0%	2.2%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	715	---	---	591

**STATISTICAL TESTS**

POLY 3	P=0.593	P=0.494N	P=0.500N	P=0.760N
POLY 1.5	P=0.593	P=0.495N	P=0.500N	P=0.760N
POLY 6	P=0.592	P=0.492N	P=0.500N	P=0.760N
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=0.499N

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

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

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

**Liver  
 Inflammation**

**LESION RATES**

OVERALL (a)	40/49 (82%)	40/50 (80%)	14/50 (28%)	31/50 (62%)
POLY-3 RATE (b)	40/48.08	40/48.10	14/46.27	31/46.37
POLY-3 PERCENT (g)	83.2%	83.2%	30.3%	66.9%
TERMINAL (d)	32/35 (91%)	36/41 (88%)	12/38 (32%)	26/37 (70%)
FIRST INCIDENCE	450	513	268	589

**STATISTICAL TESTS**

POLY 3	P=0.003N**	P=0.610N	P<0.001N**	P=0.048N*
POLY 1.5	P=0.003N**	P=0.575N	P<0.001N**	P=0.043N*
POLY 6	P=0.003N**	P=0.598	P<0.001N**	P=0.051N
COCH-ARM / FISHERS	P=0.004N**	P=0.520N	P<0.001N**	P=0.025N*
MAX-ISO-POLY-3	P<0.001N**	P=0.498N	P<0.001N**	P=0.031N*

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

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

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

Liver  
 Mixed Cell Focus

**LESION RATES**

OVERALL (a)	4/49 (8%)	8/50 (16%)	16/50 (32%)	20/50 (40%)
POLY-3 RATE (b)	4/45.13	8/46.77	16/45.08	20/45.16
POLY-3 PERCENT (g)	8.9%	17.1%	35.5%	44.3%
TERMINAL (d)	4/35 (11%)	7/41 (17%)	16/38 (42%)	18/37 (49%)
FIRST INCIDENCE	729 (T)	706	729 (T)	676

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.194	P=0.002**	P<0.001**
POLY 1.5	P<0.001**	P=0.191	P=0.002**	P<0.001**
POLY 6	P<0.001**	P=0.200	P=0.002**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.188	P=0.003**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.124	P<0.001**	P<0.001**

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS 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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Liver  
 Necrosis

**LESION RATES**

OVERALL (a)	5/49 (10%)	2/50 (4%)	4/50 (8%)	27/50 (54%)
POLY-3 RATE (b)	5/45.94	2/47.01	4/46.04	27/46.32
POLY-3 PERCENT (g)	10.9%	4.3%	8.7%	58.3%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	1/38 (3%)	21/37 (57%)
FIRST INCIDENCE	659	666	439	589

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.207N	P=0.499N	P<0.001**
POLY 1.5	P<0.001**	P=0.208N	P=0.496N	P<0.001**
POLY 6	P<0.001**	P=0.206N	P=0.502N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.210N	P=0.487N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.114N	P=0.362N	P<0.001**

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

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

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

**Liver  
 Pigmentation**

**LESION RATES**

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	46/50 (92%)
POLY-3 RATE (b)	0/45.13	0/46.68	0/45.08	46/47.19
POLY-3 PERCENT (g)	0%	0%	0%	97.5%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	37/37 (100%)
FIRST INCIDENCE	---	---	---	589

**STATISTICAL TESTS**

POLY 3	P<0.001**	(e)	(e)	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	P<0.001**
POLY 6	P<0.001**	(e)	(e)	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P<0.001**



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

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

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

Liver  
 Tension Lipidosis

**LESION RATES**

OVERALL (a)	5/49 (10%)	5/50 (10%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	5/45.58	5/46.77	4/46.03	0/44.78
POLY-3 PERCENT (g)	11%	10.7%	8.7%	0%
TERMINAL (d)	4/35 (11%)	4/41 (10%)	3/38 (8%)	0/37 (0%)
FIRST INCIDENCE	598	706	268	---

**STATISTICAL TESTS**

POLY 3	P=0.026N*	P=0.614N	P=0.494N	P=0.032N*
POLY 1.5	P=0.025N*	P=0.615N	P=0.491N	P=0.031N*
POLY 6	P=0.027N*	P=0.610N	P=0.496N	P=0.032N*
COCH-ARM / FISHERS	P=0.023N*	P=0.617N	P=0.487N	P=0.027N*
MAX-ISO-POLY-3	P=0.040N*	P=0.482N	P=0.357N	P=0.011N*

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

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

---

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

---

Liver: Bile Duct  
 Cyst

**LESION RATES**

OVERALL (a)	0/49 (0%)	0/50 (0%)	4/50 (8%)	38/50 (76%)
POLY-3 RATE (b)	0/45.13	0/46.68	4/45.28	38/45.17
POLY-3 PERCENT (g)	0%	0%	8.8%	84.1%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	3/38 (8%)	35/37 (95%)
FIRST INCIDENCE	---	---	677	666

**STATISTICAL TESTS**

POLY 3	P<0.001**	(e)	P=0.061	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.061	P<0.001**
POLY 6	P<0.001**	(e)	P=0.061	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.061	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.020*	P<0.001**

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

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

---

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

---

Liver: Bile Duct  
Fibrosis

---

**LESION 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	---	---	---	---

.....  
**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. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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

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

Liver: Bile Duct  
 Hyperplasia

**LESION RATES**

OVERALL (a)	0/49 (0%)	0/50 (0%)	2/50 (4%)	47/50 (94%)
POLY-3 RATE (b)	0/45.13	0/46.68	2/45.19	47/47.70
POLY-3 PERCENT (g)	0%	0%	4.4%	98.5%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	1/38 (3%)	37/37 (100%)
FIRST INCIDENCE	---	---	701	566

**STATISTICAL TESTS**

POLY 3	P<0.001**	(e)	P=0.237	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.238	P<0.001**
POLY 6	P<0.001**	(e)	P=0.238	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.253	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.077	P<0.001**

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

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

---

Liver: Hepatocyte  
 Hypertrophy

**LESION RATES**

OVERALL (a)	0/49 (0%)	1/50 (2%)	5/50 (10%)	11/50 (22%)
POLY-3 RATE (b)	0/45.13	1/46.68	5/45.33	11/45.25
POLY-3 PERCENT (g)	0%	2.1%	11%	24.3%
TERMINAL (d)	0/35 (0%)	1/41 (2%)	4/38 (11%)	10/37 (27%)
FIRST INCIDENCE	---	729 (T)	662	589

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.507	P=0.031*	P<0.001**
POLY 1.5	P<0.001**	P=0.506	P=0.031*	P<0.001**
POLY 6	P<0.001**	P=0.509	P=0.031*	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.505	P=0.030*	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.166	P=0.010**	P<0.001**

---

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

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

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

Liver: Hepatocyte, Centrilobular Hypertrophy

**LESION RATES**

OVERALL (a)	0/49 (0%)	3/50 (6%)	7/50 (14%)	18/50 (36%)
POLY-3 RATE (b)	0/45.13	3/46.68	7/45.08	18/46.54
POLY-3 PERCENT (g)	0%	6.4%	15.5%	38.7%
TERMINAL (d)	0/35 (0%)	3/41 (7%)	7/38 (18%)	14/37 (38%)
FIRST INCIDENCE	---	729 (T)	729 (T)	404

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.125	P=0.007**	P<0.001**
POLY 1.5	P<0.001**	P=0.124	P=0.008**	P<0.001**
POLY 6	P<0.001**	P=0.127	P=0.007**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.125	P=0.007**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.042*	P=0.002**	P<0.001**

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

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

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

Liver: Oval Cell  
 Hyperplasia

**LESION RATES**

OVERALL (a)	0/49 (0%)	0/50 (0%)	3/50 (6%)	46/50 (92%)
POLY-3 RATE (b)	0/45.13	0/46.68	3/45.19	46/47.23
POLY-3 PERCENT (g)	0%	0%	6.6%	97.4%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	2/38 (5%)	37/37 (100%)
FIRST INCIDENCE	---	---	701	566

**STATISTICAL TESTS**

POLY 3	P<0.001**	(e)	P=0.119	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.120	P<0.001**
POLY 6	P<0.001**	(e)	P=0.119	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.125	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.039*	P<0.001**

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

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

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

Liver: Vein  
 Intravascular Hepatocyte

**LESION RATES**

OVERALL (a)	0/49 (0%)	2/50 (4%)	20/50 (40%)	46/50 (92%)
POLY-3 RATE (b)	0/45.13	2/46.68	20/45.46	46/47.42
POLY-3 PERCENT (g)	0%	4.3%	44%	97%
TERMINAL (d)	0/35 (0%)	2/41 (5%)	18/38 (47%)	37/37 (100%)
FIRST INCIDENCE	---	729 (T)	642	589

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.245	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.244	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.247	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.253	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.082	P<0.001**	P<0.001**



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

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

---

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

---

**Lung  
 Inflammation**

**LESION RATES**

OVERALL (a)	2/49 (4%)	4/50 (8%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/45.58	4/46.68	2/45.51	0/44.78
POLY-3 PERCENT (g)	4.4%	8.6%	4.4%	0%
TERMINAL (d)	1/35 (3%)	4/41 (10%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	598	729 (T)	642	---

**STATISTICAL TESTS**

POLY 3	P=0.117N	P=0.348	P=0.693	P=0.241N
POLY 1.5	P=0.115N	P=0.348	P=0.693N	P=0.240N
POLY 6	P=0.118N	P=0.350	P=0.694N	P=0.243N
COCH-ARM / FISHERS	P=0.108N	P=0.349	P=0.684N	P=0.242N
MAX-ISO-POLY-3	P=0.107N	P=0.211	P=0.499	P=0.081N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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 Epithelium  
Hyperplasia

---

LESION RATES

OVERALL (a)	1/49 (2%)	3/50 (6%)	2/50 (4%)	7/50 (14%)
POLY-3 RATE (b)	1/45.20	3/46.68	2/45.40	7/44.78
POLY-3 PERCENT (g)	2.2%	6.4%	4.4%	15.6%
TERMINAL (d)	0/35 (0%)	3/41 (7%)	1/38 (3%)	7/37 (19%)
FIRST INCIDENCE	710	729 (T)	642	729 (T)

STATISTICAL TESTS

POLY 3	P=0.013*	P=0.317	P=0.502	P=0.029*
POLY 1.5	P=0.013*	P=0.315	P=0.502	P=0.029*
POLY 6	P=0.012*	P=0.320	P=0.503	P=0.028*
COCH-ARM / FISHERS	P=0.015*	P=0.316	P=0.508	P=0.032*
MAX-ISO-POLY-3	P=0.010**	P=0.165	P=0.282	P=0.012*

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

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

---

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

---

Lung: Alveolus  
Infiltration Cellular Histiocyte

---

**LESION 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	---	---	---	---

---

**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. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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

---

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

---

**Lung: Serosa  
 Inflammation**

**LESION 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	---	---	---	---

**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. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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

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

**Lymph Node, Mandibular Atrophy**

**LESION RATES**

OVERALL (a)	0/49 (0%)	1/50 (2%)	0/49 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.13	1/46.77	0/44.33	2/46.06
POLY-3 PERCENT (g)	0%	2.1%	0%	4.3%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	706	---	404

**STATISTICAL TESTS**

POLY 3	P=0.141	P=0.507	(e)	P=0.242
POLY 1.5	P=0.141	P=0.506	(e)	P=0.240
POLY 6	P=0.142	P=0.510	(e)	P=0.244
COCH-ARM / FISHERS	P=0.142	P=0.505	(e)	P=0.253
MAX-ISO-POLY-3	P=0.082	P=0.166	(e)	P=0.079

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

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

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

**Lymph Node, Mandibular  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.13	0/46.68	0/44.33	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	---	---	---	---

**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. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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

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

**Lymph Node, Mandibular  
 Hyperplasia Lymphoid**

**LESION RATES**

OVERALL (a)	2/49 (4%)	0/50 (0%)	1/49 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/45.13	0/46.68	1/44.33	2/45.36
POLY-3 PERCENT (g)	4.4%	0%	2.3%	4.4%
TERMINAL (d)	2/35 (6%)	0/41 (0%)	1/38 (3%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	589

**STATISTICAL TESTS**

POLY 3	P=0.466	P=0.230N	P=0.506N	P=0.692N
POLY 1.5	P=0.467	P=0.231N	P=0.505N	P=0.693N
POLY 6	P=0.466	P=0.227N	P=0.504N	P=0.690N
COCH-ARM / FISHERS	P=0.474	P=0.242N	P=0.500N	P=0.684N
MAX-ISO-POLY-3	P=0.419N	P=0.075N	P=0.287N	P=0.497N

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

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

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

**Lymph Node, Mesenteric  
 Atrophy**

**LESION RATES**

OVERALL (a)	0/47 (0%)	0/49 (0%)	2/50 (4%)	1/49 (2%)
POLY-3 RATE (b)	0/43.31	0/45.68	2/45.28	1/45.06
POLY-3 PERCENT (g)	0%	0%	4.4%	2.2%
TERMINAL (d)	0/34 (0%)	0/40 (0%)	1/38 (3%)	0/37 (0%)
FIRST INCIDENCE	---	---	677	596

**STATISTICAL TESTS**

POLY 3	P=0.250	(e)	P=0.247	P=0.508
POLY 1.5	P=0.248	(e)	P=0.248	P=0.507
POLY 6	P=0.251	(e)	P=0.248	P=0.509
COCH-ARM / FISHERS	P=0.252	(e)	P=0.263	P=0.510
MAX-ISO-POLY-3	P=0.181	(e)	P=0.082	P=0.166



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

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

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

**Mesentery  
 Necrosis**

**LESION RATES**

OVERALL (a)	2/6 (33%)	0/12 (0%)	0/11 (0%)	0/2 (0%)
POLY-3 RATE (b)	2/5.79	0/10.81	0/9.73	0/2.00
POLY-3 PERCENT (g)	34.5%	0%	0%	0%
TERMINAL (d)	2/4 (50%)	0/8 (0%)	0/7 (0%)	0/2 (0%)
FIRST INCIDENCE	729 (T)	---	---	---

**STATISTICAL TESTS**

POLY 3	P=0.096N	P=0.082N	P=0.099N	P=0.491N
POLY 1.5	P=0.091N	P=0.079N	P=0.095N	P=0.495N
POLY 6	P=0.102N	P=0.084N	P=0.102N	P=0.482N
COCH-ARM / FISHERS	P=0.106N	P=0.098N	P=0.110N	P=0.536N
MAX-ISO-POLY-3	P=0.093N	P=0.023N*	P=0.026N*	P=0.229N

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

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

---

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

---

Mesentery: Fat  
 Necrosis

**LESION RATES**

OVERALL (a)	4/6 (67%)	11/12 (92%)	10/11 (91%)	1/2 (50%)
POLY-3 RATE (b)	4/6.00	11/11.35	10/10.22	1/2.00
POLY-3 PERCENT (g)	66.7%	96.9%	97.9%	50%
TERMINAL (d)	2/4 (50%)	8/8 (100%)	7/7 (100%)	1/2 (50%)
FIRST INCIDENCE	695	645	642	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.745N	P=0.131	P=0.132	P=0.644N
POLY 1.5	P=0.713N	P=0.174	P=0.176	P=0.644N
POLY 6	P=0.758	P=0.099	P=0.108	P=0.644N
COCH-ARM / FISHERS	P=0.647N	P=0.245	P=0.272	P=0.643N
MAX-ISO-POLY-3	P=0.112N	P=0.043*	P=0.040*	P=0.380N

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

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

---

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

---

**Nose  
 Inflammation**

**LESION RATES**

OVERALL (a)	2/49 (4%)	1/50 (2%)	4/50 (8%)	27/50 (54%)
POLY-3 RATE (b)	2/45.37	1/46.68	4/45.32	27/46.13
POLY-3 PERCENT (g)	4.4%	2.1%	8.8%	58.5%
TERMINAL (d)	1/35 (3%)	1/41 (2%)	3/38 (8%)	21/37 (57%)
FIRST INCIDENCE	666	729 (T)	667	566

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.490N	P=0.337	P<0.001**
POLY 1.5	P<0.001**	P=0.491N	P=0.339	P<0.001**
POLY 6	P<0.001**	P=0.488N	P=0.337	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.492N	P=0.349	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.274N	P=0.202	P<0.001**

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

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

---

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

---

**Nose  
 Polyp, Inflammatory**

**LESION 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	---	---	---	---

**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. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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

---

**Nose: Nerve  
 Atrophy**

**LESION RATES**

OVERALL (a)	0/49 (0%)	1/50 (2%)	2/50 (4%)	49/50 (98%)
POLY-3 RATE (b)	0/45.13	1/47.37	2/45.08	49/49.00
POLY-3 PERCENT (g)	0%	2.1%	4.4%	100%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	2/38 (5%)	37/37 (100%)
FIRST INCIDENCE	---	493	729 (T)	404

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.510	P=0.237	P<0.001**
POLY 1.5	P<0.001**	P=0.507	P=0.238	P<0.001**
POLY 6	P<0.001**	P=0.513	P=0.237	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.505	P=0.253	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.169	P=0.077	P<0.001**

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

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

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

**Nose: Olfactory Epithelium  
 Degeneration**

**LESION RATES**

OVERALL (a)	0/49 (0%)	5/50 (10%)	22/50 (44%)	48/50 (96%)
POLY-3 RATE (b)	0/45.13	5/47.51	22/45.81	48/48.17
POLY-3 PERCENT (g)	0%	10.5%	48%	99.7%
TERMINAL (d)	0/35 (0%)	3/41 (7%)	19/38 (50%)	37/37 (100%)
FIRST INCIDENCE	---	493	631	566

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.035*	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.034*	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.037*	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.030*	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.013*	P<0.001**	P<0.001**

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

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

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

**Nose: Olfactory Epithelium  
 Metaplasia**

**LESION RATES**

OVERALL (a)	1/49 (2%)	2/50 (4%)	4/50 (8%)	49/50 (98%)
POLY-3 RATE (b)	1/45.13	2/46.68	4/45.08	49/49.00
POLY-3 PERCENT (g)	2.2%	4.3%	8.9%	100%
TERMINAL (d)	1/35 (3%)	2/41 (5%)	4/38 (11%)	37/37 (100%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	404

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.512	P=0.178	P<0.001**
POLY 1.5	P<0.001**	P=0.510	P=0.180	P<0.001**
POLY 6	P<0.001**	P=0.515	P=0.178	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.508	P=0.187	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.293	P=0.085	P<0.001**

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

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

---

Nose: Respiratory Epithelium  
Hyperplasia

---

**LESION 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	---	---	---	---

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**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. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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

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

**Ovary  
 Atrophy**

**LESION RATES**

OVERALL (a)	11/49 (22%)	10/49 (20%)	24/50 (48%)	39/50 (78%)
POLY-3 RATE (b)	11/47.64	10/45.91	24/46.32	39/46.23
POLY-3 PERCENT (g)	23.1%	21.8%	51.8%	84.4%
TERMINAL (d)	1/35 (3%)	8/40 (20%)	21/38 (55%)	33/37 (89%)
FIRST INCIDENCE	450	694	541	591

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.538N	P=0.003**	P<0.001**
POLY 1.5	P<0.001**	P=0.522N	P=0.004**	P<0.001**
POLY 6	P<0.001**	P=0.559N	P=0.002**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500N	P=0.007**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.440N	P=0.002**	P<0.001**

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

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

---

Ovary  
 Cyst

**LESION RATES**

OVERALL (a)	6/49 (12%)	7/49 (14%)	9/50 (18%)	7/50 (14%)
POLY-3 RATE (b)	6/45.99	7/46.56	9/45.28	7/45.47
POLY-3 PERCENT (g)	13.1%	15%	19.9%	15.4%
TERMINAL (d)	3/35 (9%)	5/40 (13%)	8/38 (21%)	5/37 (14%)
FIRST INCIDENCE	500	575	677	591

**STATISTICAL TESTS**

POLY 3	P=0.414	P=0.509	P=0.275	P=0.491
POLY 1.5	P=0.421	P=0.505	P=0.283	P=0.494
POLY 6	P=0.409	P=0.518	P=0.271	P=0.490
COCH-ARM / FISHERS	P=0.452	P=0.500	P=0.303	P=0.516
MAX-ISO-POLY-3	P=0.446	P=0.391	P=0.193	P=0.374

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

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

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

**Pancreas  
 Cytoplasmic Alteration Focal**

**LESION RATES**

OVERALL (a)	1/49 (2%)	2/50 (4%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/45.13	2/46.68	0/45.08	2/44.78
POLY-3 PERCENT (g)	2.2%	4.3%	0%	4.5%
TERMINAL (d)	1/35 (3%)	2/41 (5%)	0/38 (0%)	2/37 (5%)
FIRST INCIDENCE	729 (T)	729 (T)	---	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.465	P=0.512	P=0.500N	P=0.497
POLY 1.5	P=0.466	P=0.510	P=0.499N	P=0.498
POLY 6	P=0.464	P=0.515	P=0.500N	P=0.497
COCH-ARM / FISHERS	P=0.475	P=0.508	P=0.495N	P=0.508
MAX-ISO-POLY-3	P=0.416	P=0.293	P=0.160N	P=0.280

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

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

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

**Pancreas  
 Infiltration Cellular Mononuclear Cell**

**LESION RATES**

OVERALL (a)	12/49 (24%)	16/50 (32%)	15/50 (30%)	11/50 (22%)
POLY-3 RATE (b)	12/45.80	16/47.47	15/45.19	11/45.63
POLY-3 PERCENT (g)	26.2%	33.7%	33.2%	24.1%
TERMINAL (d)	11/35 (31%)	14/41 (34%)	14/38 (37%)	8/37 (22%)
FIRST INCIDENCE	500	513	701	589

**STATISTICAL TESTS**

POLY 3	P=0.373N	P=0.286	P=0.308	P=0.504N
POLY 1.5	P=0.371N	P=0.280	P=0.319	P=0.505N
POLY 6	P=0.369N	P=0.298	P=0.304	P=0.497N
COCH-ARM / FISHERS	P=0.334N	P=0.272	P=0.349	P=0.478N
MAX-ISO-POLY-3	P=0.379N	P=0.218	P=0.235	P=0.408N

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

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

**LESION RATES**

OVERALL (a)	3/49 (6%)	3/50 (6%)	1/49 (2%)	2/49 (4%)
POLY-3 RATE (b)	3/45.13	3/46.68	1/44.33	2/43.78
POLY-3 PERCENT (g)	6.7%	6.4%	2.3%	4.6%
TERMINAL (d)	3/35 (9%)	3/41 (7%)	1/38 (3%)	2/36 (6%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.358N	P=0.647N	P=0.312N	P=0.514N
POLY 1.5	P=0.357N	P=0.649N	P=0.311N	P=0.512N
POLY 6	P=0.360N	P=0.642N	P=0.310N	P=0.515N
COCH-ARM / FISHERS	P=0.346N	P=0.651N	P=0.309N	P=0.500N
MAX-ISO-POLY-3	P=0.399N	P=0.482N	P=0.161N	P=0.338N

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

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

**LESION RATES**

OVERALL (a)	0/49 (0%)	2/50 (4%)	0/49 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/45.13	2/46.68	0/44.33	0/43.78
POLY-3 PERCENT (g)	0%	4.3%	0%	0%
TERMINAL (d)	0/35 (0%)	2/41 (5%)	0/38 (0%)	0/36 (0%)
FIRST INCIDENCE	---	729 (T)	---	---

**STATISTICAL TESTS**

POLY 3	P=0.410N	P=0.245	(e)	(e)
POLY 1.5	P=0.410N	P=0.244	(e)	(e)
POLY 6	P=0.409N	P=0.247	(e)	(e)
COCH-ARM / FISHERS	P=0.406N	P=0.253	(e)	(e)
MAX-ISO-POLY-3	P=0.269N	P=0.082	(e)	(e)

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

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

**LESION RATES**

OVERALL (a)	7/49 (14%)	4/50 (8%)	5/49 (10%)	4/49 (8%)
POLY-3 RATE (b)	7/45.13	4/46.92	5/44.33	4/43.78
POLY-3 PERCENT (g)	15.5%	8.5%	11.3%	9.1%
TERMINAL (d)	7/35 (20%)	3/41 (7%)	5/38 (13%)	4/36 (11%)
FIRST INCIDENCE	729 (T)	666	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.287N	P=0.239N	P=0.391N	P=0.278N
POLY 1.5	P=0.284N	P=0.244N	P=0.390N	P=0.277N
POLY 6	P=0.292N	P=0.230N	P=0.387N	P=0.279N
COCH-ARM / FISHERS	P=0.265N	P=0.251N	P=0.380N	P=0.262N
MAX-ISO-POLY-3	P=0.282N	P=0.155N	P=0.282N	P=0.185N

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

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

---

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

---

**Salivary Glands  
 Infiltration Cellular Mononuclear Cell**

**LESION RATES**

OVERALL (a)	39/49 (80%)	29/50 (58%)	28/49 (57%)	26/50 (52%)
POLY-3 RATE (b)	39/48.74	29/48.23	28/46.29	26/45.90
POLY-3 PERCENT (g)	80%	60.1%	60.5%	56.7%
TERMINAL (d)	28/35 (80%)	24/41 (59%)	24/38 (63%)	23/37 (62%)
FIRST INCIDENCE	450	493	268	589

**STATISTICAL TESTS**

POLY 3	P=0.019N*	P=0.024N*	P=0.027N*	P=0.010N**
POLY 1.5	P=0.015N*	P=0.021N*	P=0.021N*	P=0.007N**
POLY 6	P=0.027N*	P=0.029N*	P=0.037N*	P=0.016N*
COCH-ARM / FISHERS	P=0.008N**	P=0.017N*	P=0.014N*	P=0.003N**
MAX-ISO-POLY-3	P=0.014N*	P=0.015N*	P=0.018N*	P=0.007N**

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

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

---

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

---

**Skin  
Inflammation**

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**LESION 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	---	---	---	---

---

**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. 99020 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

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

---

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

---

Skin  
Ulcer

---

**LESION 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	---	---	---	---

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**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. 99020 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: MICE/B6C3F1

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

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

**Spleen  
 Hematopoietic Cell Proliferation**

**LESION RATES**

OVERALL (a)	24/49 (49%)	29/50 (58%)	25/50 (50%)	40/50 (80%)
POLY-3 RATE (b)	24/46.66	29/47.38	25/46.57	40/46.75
POLY-3 PERCENT (g)	51.4%	61.2%	53.7%	85.6%
TERMINAL (d)	18/35 (51%)	26/41 (63%)	22/38 (58%)	33/37 (89%)
FIRST INCIDENCE	500	640	439	589

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.225	P=0.496	P<0.001**
POLY 1.5	P<0.001**	P=0.231	P=0.509	P<0.001**
POLY 6	P<0.001**	P=0.222	P=0.480	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.243	P=0.540	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.168	P=0.412	P<0.001**

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

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

---

**Spleen  
 Hyperplasia Lymphoid**

**LESION RATES**

OVERALL (a)	6/49 (12%)	3/50 (6%)	9/50 (18%)	3/50 (6%)
POLY-3 RATE (b)	6/45.13	3/46.68	9/45.57	3/44.78
POLY-3 PERCENT (g)	13.3%	6.4%	19.8%	6.7%
TERMINAL (d)	6/35 (17%)	3/41 (7%)	8/38 (21%)	3/37 (8%)
FIRST INCIDENCE	729 (T)	729 (T)	584	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.349N	P=0.225N	P=0.293	P=0.245N
POLY 1.5	P=0.345N	P=0.229N	P=0.294	P=0.245N
POLY 6	P=0.353N	P=0.220N	P=0.298	P=0.245N
COCH-ARM / FISHERS	P=0.323N	P=0.233N	P=0.303	P=0.233N
MAX-ISO-POLY-3	P=0.266N	P=0.137N	P=0.205	P=0.151N

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

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

---

**Spleen  
 Pigmentation**

**LESION RATES**

OVERALL (a)	0/49 (0%)	1/50 (2%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	0/45.13	1/46.82	3/45.40	2/45.61
POLY-3 PERCENT (g)	0%	2.1%	6.6%	4.4%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	2/38 (5%)	1/37 (3%)
FIRST INCIDENCE	---	694	642	404

**STATISTICAL TESTS**

POLY 3	P=0.162	P=0.507	P=0.120	P=0.239
POLY 1.5	P=0.161	P=0.506	P=0.120	P=0.239
POLY 6	P=0.161	P=0.510	P=0.121	P=0.240
COCH-ARM / FISHERS	P=0.167	P=0.505	P=0.125	P=0.253
MAX-ISO-POLY-3	P=0.112	P=0.167	P=0.039*	P=0.077

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

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

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

Spleen: Lymphoid Follicle  
 Atrophy

**LESION 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	1/45.61
POLY-3 PERCENT (g)	0%	0%	0%	2.2%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	404

**STATISTICAL TESTS**

POLY 3	P=0.198	(e)	(e)	P=0.502
POLY 1.5	P=0.198	(e)	(e)	P=0.501
POLY 6	P=0.198	(e)	(e)	P=0.503
COCH-ARM / FISHERS	P=0.200	(e)	(e)	P=0.505
MAX-ISO-POLY-3	P=0.125	(e)	(e)	P=0.160

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

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

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

**Spleen: Red Pulp  
 Atrophy**

**LESION RATES**

OVERALL (a)	1/49 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/45.89	0/46.68	0/45.08	1/45.61
POLY-3 PERCENT (g)	2.2%	0%	0%	2.2%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	450	---	---	404

**STATISTICAL TESTS**

POLY 3	P=0.593	P=0.497N	P=0.504N	P=0.759
POLY 1.5	P=0.594	P=0.497N	P=0.502N	P=0.760
POLY 6	P=0.592	P=0.495N	P=0.504N	P=0.759
COCH-ARM / FISHERS	P=0.598	P=0.495N	P=0.495N	P=0.747N
MAX-ISO-POLY-3	P=0.407	P=0.157N	P=0.164N	P=0.497

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

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

**LESION RATES**

OVERALL (a)	13/49 (27%)	1/50 (2%)	10/50 (20%)	26/50 (52%)
POLY-3 RATE (b)	13/47.47	1/46.68	10/46.21	26/47.10
POLY-3 PERCENT (g)	27.4%	2.1%	21.6%	55.2%
TERMINAL (d)	5/35 (14%)	1/41 (2%)	7/38 (18%)	20/37 (54%)
FIRST INCIDENCE	450	729 (T)	544	404

**STATISTICAL TESTS**

POLY 3	P<0.001**	P<0.001N**	P=0.343N	P=0.004**
POLY 1.5	P<0.001**	P<0.001N**	P=0.329N	P=0.005**
POLY 6	P<0.001**	P<0.001N**	P=0.357N	P=0.004**
COCH-ARM / FISHERS	P<0.001**	P<0.001N**	P=0.298N	P=0.008**
MAX-ISO-POLY-3	P<0.001**	P<0.001N**	P=0.264N	P=0.002**



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

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

**LESION RATES**

OVERALL (a)	10/49 (20%)	0/50 (0%)	7/50 (14%)	20/50 (40%)
POLY-3 RATE (b)	10/46.97	0/46.68	7/46.15	20/46.57
POLY-3 PERCENT (g)	21.3%	0%	15.2%	43%
TERMINAL (d)	4/35 (11%)	0/41 (0%)	5/38 (13%)	15/37 (41%)
FIRST INCIDENCE	450	---	544	404

**STATISTICAL TESTS**

POLY 3	P<0.001**	P<0.001N**	P=0.311N	P=0.019*
POLY 1.5	P<0.001**	P<0.001N**	P=0.303N	P=0.021*
POLY 6	P<0.001**	P<0.001N**	P=0.316N	P=0.018*
COCH-ARM / FISHERS	P<0.001**	P<0.001N**	P=0.282N	P=0.028*
MAX-ISO-POLY-3	P<0.001**	P<0.001N**	P=0.227N	P=0.011*

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

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

**LESION RATES**

OVERALL (a)	8/49 (16%)	0/50 (0%)	4/50 (8%)	10/50 (20%)
POLY-3 RATE (b)	8/46.97	0/46.68	4/45.57	10/45.69
POLY-3 PERCENT (g)	17%	0%	8.8%	21.9%
TERMINAL (d)	2/35 (6%)	0/41 (0%)	3/38 (8%)	7/37 (19%)
FIRST INCIDENCE	450	---	584	591

**STATISTICAL TESTS**

POLY 3	P=0.088	P=0.004N**	P=0.192N	P=0.372
POLY 1.5	P=0.089	P=0.004N**	P=0.185N	P=0.381
POLY 6	P=0.087	P=0.004N**	P=0.198N	P=0.364
COCH-ARM / FISHERS	P=0.102	P=0.003N**	P=0.168N	P=0.416
MAX-ISO-POLY-3	P=0.034*	P<0.001N**	P=0.124N	P=0.282

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

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

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

**Stomach, Glandular  
 Mineralization**

**LESION RATES**

OVERALL (a)	0/49 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/45.13	0/46.68	1/45.28	0/44.78
POLY-3 PERCENT (g)	0%	0%	2.2%	0%
TERMINAL (d)	0/35 (0%)	0/41 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	677	---

**STATISTICAL TESTS**

POLY 3	P=0.684	(e)	P=0.501	(e)
POLY 1.5	P=0.686	(e)	P=0.501	(e)
POLY 6	P=0.682	(e)	P=0.502	(e)
COCH-ARM / FISHERS	P=0.697	(e)	P=0.505	(e)
MAX-ISO-POLY-3	P=0.390	(e)	P=0.160	(e)

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

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

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

**Stomach, Glandular: Glands  
 Cyst**

**LESION RATES**

OVERALL (a)	2/49 (4%)	3/50 (6%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	2/45.13	3/46.68	3/45.08	2/44.98
POLY-3 PERCENT (g)	4.4%	6.4%	6.7%	4.5%
TERMINAL (d)	2/35 (6%)	3/41 (7%)	3/38 (8%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	676

**STATISTICAL TESTS**

POLY 3	P=0.551N	P=0.515	P=0.500	P=0.693
POLY 1.5	P=0.549N	P=0.513	P=0.501	P=0.693
POLY 6	P=0.551N	P=0.520	P=0.500	P=0.694
COCH-ARM / FISHERS	P=0.536N	P=0.510	P=0.510	P=0.684N
MAX-ISO-POLY-3	P=0.603	P=0.339	P=0.324	P=0.498

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

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

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

**Thymus  
 Atrophy**

**LESION RATES**

OVERALL (a)	28/48 (58%)	21/49 (43%)	20/49 (41%)	13/46 (28%)
POLY-3 RATE (b)	28/46.72	21/47.33	20/46.96	13/43.53
POLY-3 PERCENT (g)	59.9%	44.4%	42.6%	29.9%
TERMINAL (d)	20/35 (57%)	15/40 (38%)	12/37 (32%)	7/35 (20%)
FIRST INCIDENCE	598	575	439	404

**STATISTICAL TESTS**

POLY 3	P=0.003N**	P=0.094N	P=0.068N	P=0.003N**
POLY 1.5	P=0.003N**	P=0.094N	P=0.068N	P=0.003N**
POLY 6	P=0.003N**	P=0.091N	P=0.066N	P=0.003N**
COCH-ARM / FISHERS	P=0.003N**	P=0.093N	P=0.064N	P=0.003N**
MAX-ISO-POLY-3	P=0.003N**	P=0.064N	P=0.045N*	P=0.002N**

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

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

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

**Thymus  
 Hyperplasia Lymphoid**

**LESION RATES**

OVERALL (a)	4/48 (8%)	5/49 (10%)	2/49 (4%)	1/46 (2%)
POLY-3 RATE (b)	4/44.89	5/45.68	2/44.08	1/41.41
POLY-3 PERCENT (g)	8.9%	11%	4.5%	2.4%
TERMINAL (d)	4/35 (11%)	5/40 (13%)	2/37 (5%)	1/35 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

**STATISTICAL TESTS**

POLY 3	P=0.095N	P=0.511	P=0.345N	P=0.204N
POLY 1.5	P=0.094N	P=0.511	P=0.341N	P=0.203N
POLY 6	P=0.095N	P=0.514	P=0.347N	P=0.203N
COCH-ARM / FISHERS	P=0.086N	P=0.513	P=0.329N	P=0.194N
MAX-ISO-POLY-3	P=0.141N	P=0.373	P=0.210N	P=0.105N

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

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

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

Thymus  
 Necrosis Lymphoid

**LESION RATES**

OVERALL (a)	0/48 (0%)	0/49 (0%)	0/49 (0%)	0/46 (0%)
POLY-3 RATE (b)	0/44.89	0/45.68	0/44.08	0/41.41
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/40 (0%)	0/37 (0%)	0/35 (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. 99020 - 06  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS 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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**Tooth  
Dysplasia**

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**LESION RATES**

OVERALL (a)	3/3 (100%)	1/1 (100%)	2/2 (100%)	1/1 (100%)
POLY-3 RATE (b)	3/3.00	1/1.00	2/2.00	1/1.00
POLY-3 PERCENT (g)	100%	100%	100%	100%
TERMINAL (d)	3/3 (100%)	1/1 (100%)	2/2 (100%)	1/1 (100%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

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**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. 99020 - 06  
 Test Type: CHRONIC  
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 Species/Strain: MICE/B6C3F1

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS 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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**Urinary Bladder  
 Infiltration Cellular Mononuclear Cell**

**LESION RATES**

OVERALL (a)	37/49 (76%)	33/49 (67%)	30/50 (60%)	30/50 (60%)
POLY-3 RATE (b)	37/47.24	33/46.38	30/46.82	30/45.86
POLY-3 PERCENT (g)	78.3%	71.2%	64.1%	65.4%
TERMINAL (d)	30/35 (86%)	31/40 (78%)	25/38 (66%)	26/37 (70%)
FIRST INCIDENCE	450	624	544	591

**STATISTICAL TESTS**

POLY 3	P=0.094N	P=0.281N	P=0.090N	P=0.115N
POLY 1.5	P=0.090N	P=0.272N	P=0.090N	P=0.109N
POLY 6	P=0.093N	P=0.279N	P=0.079N	P=0.115N
COCH-ARM / FISHERS	P=0.063N	P=0.251N	P=0.075N	P=0.075N
MAX-ISO-POLY-3	P=0.118N	P=0.207N	P=0.059N	P=0.079N

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TDMS No. 99020 - 06  
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

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

**Uterus  
 Angiectasis**

**LESION RATES**

OVERALL (a)	3/49 (6%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/45.13	0/45.68	0/45.08	0/44.78
POLY-3 PERCENT (g)	6.7%	0%	0%	0%
TERMINAL (d)	3/35 (9%)	0/40 (0%)	0/38 (0%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	---	---	---

**STATISTICAL TESTS**

POLY 3	P=0.044N*	P=0.116N	P=0.119N	P=0.120N
POLY 1.5	P=0.044N*	P=0.118N	P=0.118N	P=0.120N
POLY 6	P=0.045N*	P=0.115N	P=0.118N	P=0.120N
COCH-ARM / FISHERS	P=0.046N*	P=0.121N	P=0.117N	P=0.117N
MAX-ISO-POLY-3	P=0.010N**	P=0.038N*	P=0.039N*	P=0.040N*

TDMS No. 99020 - 06  
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
 TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Uterus: Endometrium  
 Hyperplasia Cystic

**LESION RATES**

OVERALL (a)	32/49 (65%)	32/49 (65%)	40/50 (80%)	35/50 (70%)
POLY-3 RATE (b)	32/45.99	32/46.51	40/48.86	35/47.21
POLY-3 PERCENT (g)	69.6%	68.8%	81.9%	74.1%
TERMINAL (d)	28/35 (80%)	29/40 (73%)	31/38 (82%)	28/37 (76%)
FIRST INCIDENCE	598	624	268	404

**STATISTICAL TESTS**

POLY 3	P=0.262	P=0.559N	P=0.114	P=0.395
POLY 1.5	P=0.240	P=0.570N	P=0.097	P=0.370
POLY 6	P=0.290	P=0.536N	P=0.145	P=0.429
COCH-ARM / FISHERS	P=0.265	P=0.584N	P=0.078	P=0.388
MAX-ISO-POLY-3	P=0.259	P=0.466N	P=0.078	P=0.308

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**TDMS No.** 99020 - 06  
**Test Type:** CHRONIC  
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**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

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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.
  - (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 \*\*\*