

**TDMS No.** 99020 - 05  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** RATS/F 344

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

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

**Date Report Requested:** 05/21/2008  
**Time Report Requested:** 09:15:32  
**First Dose M/F:** 04/09/03 / 04/10/03  
**Lab:** BAT

F1\_R2

**C Number:** C99020  
**Lock Date:** 01/06/2006  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 2.0.0

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

### MALE RATS

#### Organ

Adrenal Cortex  
Adrenal Medulla  
Blood Vessel  
Bone  
Brain  
  
Harderian Gland: Epithelium  
Heart  
Heart: Endocardium  
Intestine Large, Cecum  
  
Kidney  
  
Kidney: Cortex  
Liver  
  
Liver: Bile Duct  
  
Liver: Hepatocyte  
  
Liver: Oval Cell  
Liver: Portal  
Lung: Interstitium  
Lymph Node: Deep Cervical  
Lymph Node: Mediastinal  
Mammary Gland: Duct  
Nose: Olfactory Epithelium

#### Morphology

Hyperplasia  
Hyperplasia  
Mineralization  
Fibrous Osteodystrophy  
Hemorrhage  
Hydrocephalus  
Hyperplasia  
Mineralization  
Bacterium  
Inflammation  
Mineralization  
Cyst  
Glomerulopathy Hyaline  
Inflammation  
Mineralization  
Basophilic Focus  
Clear Cell Focus  
Eosinophilic Focus  
Fatty Change  
Inflammation  
Cyst  
Hyperplasia  
Cellular Alteration Diffuse  
Necrosis  
Hyperplasia  
Fibrosis  
Mineralization  
Hemorrhage  
Hemorrhage  
Dilatation  
Degeneration

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Pancreas: Acinus	Metaplasia Respiratory
Pancreas: Duct	Atrophy
Parathyroid Gland	Cyst
Preputial Gland: Duct	Hyperplasia
Prostate: Epithelium	Ectasia
	Cyst
Skin	Hyperplasia
Spleen	Cyst Epithelial Inclusion
Stomach, Forestomach	Fibrosis
	Inflammation
	Perforation
	Ulcer
Stomach, Glandular	Erosion
	Mineralization
Testes	Inflammation

### **FEMALE RATS**

#### **Organ**

Adrenal Cortex  
  
Adrenal Medulla  
Blood Vessel  
Bone Marrow  
Bone  
Clitoral Gland  
  
Eye  
  
Heart  
  
Intestine Large, Cecum  
Intestine Large, Colon  
Kidney

#### **Morphology**

Hyperplasia  
Hypertrophy  
Hyperplasia  
Mineralization  
Hyperplasia  
Fibrous Osteodystrophy  
Hyperplasia  
Inflammation  
Hemorrhage  
Inflammation  
Inflammation  
Mineralization  
Inflammation  
Parasite Metazoan  
Glomerulopathy Hyaline  
Nephropathy

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Kidney: Cortex	Mineralization
Liver	Angiectasis
	Basophilic Focus
	Clear Cell Focus
	Fatty Change
	Mixed Cell Focus
Liver: Bile Duct	Cyst
	Hyperplasia
Liver: Hepatocyte	Cellular Alteration Diffuse
	Necrosis
Liver: Oval Cell	Hyperplasia
Liver: Portal	Fibrosis
Lung	Hemorrhage
Lung: Alveolar Epithelium	Hyperplasia
Lung: Alveolus	Inflammation Histiocytic
Lung: Arteriole	Inflammation
Lung: Interstitium	Mineralization
Lymph Node, Mesenteric	Hemorrhage
	Inflammation
Lymph Node: Mediastinal	Degeneration Cystic
Nose	Inflammation
	Thrombosis
Nose: Glands	Dilatation
Nose: Olfactory Epithelium	Degeneration
	Metaplasia Respiratory
Ovary	Atrophy
Pancreas: Acinus	Atrophy
	Hyperplasia
Parathyroid Gland	Hyperplasia
Pituitary Gland: Pars Distalis	Cyst
	Hyperplasia
Spleen	Hematopoietic Cell Proliferation
	Hyperplasia Lymphoid
Stomach, Glandular	Erosion

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

Thyroid Gland: C-Cell  
Trachea  
Uterus  
Uterus: Endometrium

Mineralization  
Hyperplasia  
Inflammation  
Hydrometra  
Hyperplasia Cystic

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

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**Adrenal Cortex  
Degeneration Cystic**

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**LESION RATES**

OVERALL (a)	1/100 (1%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/65.62	0/43.06	2/43.39
POLY-3 PERCENT (g)	1.5%	0%	4.6%
TERMINAL (d)	1/41 (2%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	727 (T)	---	725

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**STATISTICAL TESTS**

POLY 3	P=0.244	P=0.586N	P=0.354
POLY 1.5	P=0.225	P=0.606N	P=0.322
POLY 6	P=0.260	P=0.567N	P=0.383
COCH-ARM / FISHERS	P=0.190	P=0.667N	P=0.258
MAX-ISO-POLY-3	P=0.128	P=0.211N	P=0.169

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TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Adrenal Cortex  
Hyperplasia**

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**LESION RATES**

OVERALL (a)	45/100 (45%)	16/50 (32%)	23/50 (46%)
POLY-3 RATE (b)	45/77.42	16/43.97	23/45.23
POLY-3 PERCENT (g)	58.1%	36.4%	50.9%
TERMINAL (d)	22/41 (54%)	13/32 (41%)	17/28 (61%)
FIRST INCIDENCE	360	605	456

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**STATISTICAL TESTS**

POLY 3	P=0.174N	P=0.012N*	P=0.263N
POLY 1.5	P=0.250N	P=0.026N*	P=0.367N
POLY 6	P=0.134N	P=0.006N**	P=0.207N
COCH-ARM / FISHERS	P=0.466N	P=0.088N	P=0.522
MAX-ISO-POLY-3	P=0.092N	P=0.013N*	P=0.223N

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TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Adrenal Cortex  
Hypertrophy**

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**LESION RATES**

OVERALL (a)	20/100 (20%)	12/50 (24%)	16/50 (32%)
POLY-3 RATE (b)	20/69.33	12/43.55	16/45.80
POLY-3 PERCENT (g)	28.9%	27.6%	34.9%
TERMINAL (d)	11/41 (27%)	9/32 (28%)	9/28 (32%)
FIRST INCIDENCE	366	673	455

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**STATISTICAL TESTS**

POLY 3	P=0.283	P=0.527N	P=0.306
POLY 1.5	P=0.185	P=0.541	P=0.201
POLY 6	P=0.384	P=0.426N	P=0.419
COCH-ARM / FISHERS	P=0.067	P=0.358	P=0.079
MAX-ISO-POLY-3	P=0.317	P=0.440N	P=0.243

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TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Adrenal Medulla  
Hyperplasia**

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**LESION RATES**

OVERALL (a)	53/100 (53%)	19/50 (38%)	30/50 (60%)
POLY-3 RATE (b)	53/82.14	19/44.20	30/45.60
POLY-3 PERCENT (g)	64.5%	43%	65.8%
TERMINAL (d)	21/41 (51%)	14/32 (44%)	20/28 (71%)
FIRST INCIDENCE	360	605	594

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**STATISTICAL TESTS**

POLY 3	P=0.465N	P=0.012N*	P=0.521
POLY 1.5	P=0.521N	P=0.018N*	P=0.454
POLY 6	P=0.458N	P=0.011N*	P=0.533
COCH-ARM / FISHERS	P=0.366	P=0.059N	P=0.262
MAX-ISO-POLY-3	P=0.206N	P=0.014N*	P=0.444

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 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Blood Vessel  
 Mineralization**

**LESION RATES**

OVERALL (a)	24/100 (24%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	24/77.20	0/43.06	1/43.71
POLY-3 PERCENT (g)	31.1%	0%	2.3%
TERMINAL (d)	1/41 (2%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	476	---	637

**STATISTICAL TESTS**

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

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TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Bone Marrow  
Hemorrhage**

---

**LESION RATES**

OVERALL (a)	0/100 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/65.62	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---

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**STATISTICAL TESTS**

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

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Bone Marrow  
Hyperplasia**

**LESION RATES**

OVERALL (a)	16/100 (16%)	8/50 (16%)	9/50 (18%)
POLY-3 RATE (b)	16/69.09	8/44.48	9/45.25
POLY-3 PERCENT (g)	23.2%	18%	19.9%
TERMINAL (d)	7/41 (17%)	4/32 (13%)	2/28 (7%)
FIRST INCIDENCE	394	451	455

**STATISTICAL TESTS**

POLY 3	P=0.376N	P=0.330N	P=0.425N
POLY 1.5	P=0.470N	P=0.425N	P=0.527N
POLY 6	P=0.306N	P=0.253N	P=0.340N
COCH-ARM / FISHERS	P=0.432	P=0.586	P=0.462
MAX-ISO-POLY-3	P=0.413N	P=0.257N	P=0.339N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Bone  
 Fibrous Osteodystrophy**

**LESION RATES**

OVERALL (a)	34/100 (34%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	34/83.21	0/43.06	2/43.92
POLY-3 PERCENT (g)	40.9%	0%	4.6%
TERMINAL (d)	2/41 (5%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	407	---	637

**STATISTICAL TESTS**

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

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TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Brain  
Hemorrhage**

---

**LESION RATES**

OVERALL (a)	0/100 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/65.62	2/43.50	1/43.64
POLY-3 PERCENT (g)	0%	4.6%	2.3%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	622	659

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**STATISTICAL TESTS**

POLY 3	P=0.308	P=0.145	P=0.416
POLY 1.5	P=0.262	P=0.127	P=0.396
POLY 6	P=0.356	P=0.165	P=0.435
COCH-ARM / FISHERS	P=0.190	P=0.110	P=0.333
MAX-ISO-POLY-3	P=0.148	P=0.039*	P=0.109

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TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Brain  
Hydrocephalus**

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**LESION RATES**

OVERALL (a)	0/100 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/65.62	2/43.24	0/43.38
POLY-3 PERCENT (g)	0%	4.6%	0%
TERMINAL (d)	0/41 (0%)	1/32 (3%)	0/28 (0%)
FIRST INCIDENCE	---	682	---

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**STATISTICAL TESTS**

POLY 3	P=0.656	P=0.144	(e)
POLY 1.5	P=0.601	P=0.126	(e)
POLY 6	P=0.687N	P=0.163	(e)
COCH-ARM / FISHERS	P=0.500	P=0.110	(e)
MAX-ISO-POLY-3	P=0.216	P=0.039*	(e)

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TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Epididymis  
Granuloma Sperm**

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**LESION RATES**

OVERALL (a)	4/99 (4%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	4/66.03	2/43.64	2/44.25
POLY-3 PERCENT (g)	6.1%	4.6%	4.5%
TERMINAL (d)	3/41 (7%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	547	570	594

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**STATISTICAL TESTS**

POLY 3	P=0.454N	P=0.539N	P=0.532N
POLY 1.5	P=0.497N	P=0.589N	P=0.581N
POLY 6	P=0.418N	P=0.490N	P=0.486N
COCH-ARM / FISHERS	P=0.581N	P=0.658	P=0.658
MAX-ISO-POLY-3	P=0.499N	P=0.370N	P=0.363N

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TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Epididymis  
Inflammation**

---

**LESION RATES**

OVERALL (a)	3/99 (3%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	3/66.14	1/43.49	1/43.38
POLY-3 PERCENT (g)	4.5%	2.3%	2.3%
TERMINAL (d)	1/41 (2%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	615	605	727 (T)

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**STATISTICAL TESTS**

POLY 3	P=0.362N	P=0.463N	P=0.464N
POLY 1.5	P=0.387N	P=0.502N	P=0.500N
POLY 6	P=0.344N	P=0.426N	P=0.434N
COCH-ARM / FISHERS	P=0.442N	P=0.589N	P=0.589N
MAX-ISO-POLY-3	P=0.373N	P=0.273N	P=0.275N

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TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Eye  
Cataract

---

**LESION RATES**

OVERALL (a)	0/100 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/65.62	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---

---

**STATISTICAL TESTS**

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

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Eye  
Hemorrhage

---

**LESION RATES**

OVERALL (a)	0/100 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/65.62	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---

---

**STATISTICAL TESTS**

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

---

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Eye  
 Inflammation**

**LESION RATES**

OVERALL (a)	3/100 (3%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/66.57	0/43.06	0/43.38
POLY-3 PERCENT (g)	4.5%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	591	---	---

**STATISTICAL TESTS**

POLY 3	P=0.092N	P=0.201N	P=0.199N
POLY 1.5	P=0.096N	P=0.224N	P=0.221N
POLY 6	P=0.090N	P=0.182N	P=0.183N
COCH-ARM / FISHERS	P=0.110N	P=0.293N	P=0.293N
MAX-ISO-POLY-3	P=0.070N	P=0.081N	P=0.080N

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Eye: Cornea  
Inflammation

---

**LESION RATES**

OVERALL (a)	2/100 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/66.41	0/43.06	0/43.38
POLY-3 PERCENT (g)	3%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	591	---	---

.....  
**STATISTICAL TESTS**

POLY 3	P=0.180N	P=0.334N	P=0.332N
POLY 1.5	P=0.183N	P=0.358N	P=0.355N
POLY 6	P=0.178N	P=0.312N	P=0.313N
COCH-ARM / FISHERS	P=0.196N	P=0.443N	P=0.443N
MAX-ISO-POLY-3	P=0.129N	P=0.129N	P=0.127N

.....

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Eye: Retina  
Atrophy

---

LESION RATES

OVERALL (a)	0/100 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/65.62	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---

---

STATISTICAL TESTS

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

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Eye: Retina  
Dysplasia

---

**LESION RATES**

OVERALL (a)	0/100 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/65.62	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---

---

**STATISTICAL TESTS**

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

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TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Harderian Gland  
Inflammation**

---

**LESION RATES**

OVERALL (a)	2/100 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	2/65.62	0/43.06	2/43.86
POLY-3 PERCENT (g)	3.1%	0%	4.6%
TERMINAL (d)	2/41 (5%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	727 (T)	---	639

.....  
**STATISTICAL TESTS**

POLY 3	P=0.462	P=0.330N	P=0.543
POLY 1.5	P=0.434	P=0.356N	P=0.502
POLY 6	P=0.485	P=0.306N	P=0.582
COCH-ARM / FISHERS	P=0.380	P=0.443N	P=0.407
MAX-ISO-POLY-3	P=0.274	P=0.126N	P=0.339

.....



TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Harderian Gland: Epithelium  
Hyperplasia**

---

**LESION RATES**

OVERALL (a)	9/100 (9%)	0/50 (0%)	5/50 (10%)
POLY-3 RATE (b)	9/70.21	0/43.06	5/43.38
POLY-3 PERCENT (g)	12.8%	0%	11.5%
TERMINAL (d)	3/41 (7%)	0/32 (0%)	5/28 (18%)
FIRST INCIDENCE	377	---	727 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.407N	P=0.014N*	P=0.537N
POLY 1.5	P=0.436N	P=0.020N*	P=0.591N
POLY 6	P=0.385N	P=0.011N*	P=0.490N
COCH-ARM / FISHERS	P=0.500N	P=0.023N*	P=0.528
MAX-ISO-POLY-3	P=0.151N	P=0.008N**	P=0.420N

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TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Heart  
Cardiomyopathy**

---

**LESION RATES**

OVERALL (a)	94/100 (94%)	44/50 (88%)	48/50 (96%)
POLY-3 RATE (b)	94/97.64	44/49.02	48/49.55
POLY-3 PERCENT (g)	96.3%	89.8%	96.9%
TERMINAL (d)	38/41 (93%)	27/32 (84%)	27/28 (96%)
FIRST INCIDENCE	360	374	455

.....  
**STATISTICAL TESTS**

POLY 3	P=0.519N	P=0.110N	P=0.616
POLY 1.5	P=0.498N	P=0.110N	P=0.635
POLY 6	P=0.540N	P=0.098N	P=0.588
COCH-ARM / FISHERS	P=0.500	P=0.168N	P=0.465
MAX-ISO-POLY-3	P=0.347N	P=0.082N	P=0.430

.....

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Heart  
Inflammation**

---

**LESION RATES**

OVERALL (a)	0/100 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/65.62	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---

---

**STATISTICAL TESTS**

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

---

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Heart  
 Mineralization**

**LESION RATES**

OVERALL (a)	23/100 (23%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	23/78.44	0/43.06	1/43.71
POLY-3 PERCENT (g)	29.3%	0%	2.3%
TERMINAL (d)	1/41 (2%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	360	---	637

**STATISTICAL TESTS**

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

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Heart: Endocardium  
Bacterium

---

**LESION RATES**

OVERALL (a)	0/100 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/65.62	0/43.06	2/43.50
POLY-3 PERCENT (g)	0%	0%	4.6%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	---	---	697

.....  
**STATISTICAL TESTS**

POLY 3	P=0.059	(e)	P=0.145
POLY 1.5	P=0.053	(e)	P=0.128
POLY 6	P=0.066	(e)	P=0.161
COCH-ARM / FISHERS	P=0.043*	(e)	P=0.110
MAX-ISO-POLY-3	P=0.027*	(e)	P=0.039*

.....

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Intestine Large, Cecum  
 Inflammation**

**LESION RATES**

OVERALL (a)	21/100 (21%)	0/50 (0%)	6/49 (12%)
POLY-3 RATE (b)	21/78.59	0/43.06	6/43.29
POLY-3 PERCENT (g)	26.7%	0%	13.9%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	2/28 (7%)
FIRST INCIDENCE	366	---	598

**STATISTICAL TESTS**

POLY 3	P=0.014N*	P<0.001N**	P=0.073N
POLY 1.5	P=0.016N*	P<0.001N**	P=0.088N
POLY 6	P=0.012N*	P<0.001N**	P=0.067N
COCH-ARM / FISHERS	P=0.029N*	P<0.001N**	P=0.140N
MAX-ISO-POLY-3	P=0.005N**	P<0.001N**	P=0.064N

---

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Intestine Large, Cecum  
 Mineralization**

**LESION RATES**

OVERALL (a)	4/100 (4%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	4/68.07	0/43.06	0/42.47
POLY-3 PERCENT (g)	5.9%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	511	---	---

**STATISTICAL TESTS**

POLY 3	P=0.050N*	P=0.129N	P=0.131N
POLY 1.5	P=0.054N	P=0.147N	P=0.149N
POLY 6	P=0.048N*	P=0.114N	P=0.118N
COCH-ARM / FISHERS	P=0.065N	P=0.194N	P=0.199N
MAX-ISO-POLY-3	P=0.046N*	P=0.056N	P=0.057N

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Intestine Large, Cecum  
Ulcer**

---

**LESION RATES**

OVERALL (a)	3/100 (3%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	3/67.21	0/43.06	0/42.47
POLY-3 PERCENT (g)	4.5%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	525	---	---

---

**STATISTICAL TESTS**

POLY 3	P=0.094N	P=0.203N	P=0.206N
POLY 1.5	P=0.098N	P=0.226N	P=0.227N
POLY 6	P=0.091N	P=0.185N	P=0.190N
COCH-ARM / FISHERS	P=0.112N	P=0.293N	P=0.299N
MAX-ISO-POLY-3	P=0.076N	P=0.083N	P=0.085N

---



TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Intestine Large, Colon  
Parasite Metazoan**

---

**LESION RATES**

OVERALL (a)	1/100 (1%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/65.62	0/43.06	1/43.38
POLY-3 PERCENT (g)	1.5%	0%	2.3%
TERMINAL (d)	1/41 (2%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	727 (T)	---	727 (T)

.....  
**STATISTICAL TESTS**

POLY 3	P=0.568	P=0.586N	P=0.671
POLY 1.5	P=0.545	P=0.606N	P=0.646
POLY 6	P=0.586	P=0.567N	P=0.692
COCH-ARM / FISHERS	P=0.500	P=0.667N	P=0.557
MAX-ISO-POLY-3	P=0.381	P=0.211N	P=0.383

.....

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Intestine Large, Rectum  
Parasite Metazoan**

---

**LESION RATES**

OVERALL (a)	3/100 (3%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	3/65.63	1/43.83	0/43.38
POLY-3 PERCENT (g)	4.6%	2.3%	0%
TERMINAL (d)	2/41 (5%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	723	451	---

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**STATISTICAL TESTS**

POLY 3	P=0.131N	P=0.457N	P=0.196N
POLY 1.5	P=0.146N	P=0.500N	P=0.220N
POLY 6	P=0.120N	P=0.416N	P=0.177N
COCH-ARM / FISHERS	P=0.180N	P=0.593N	P=0.293N
MAX-ISO-POLY-3	P=0.106N	P=0.267N	P=0.077N

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TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Intestine Small, Duodenum  
Erosion**

---

**LESION RATES**

OVERALL (a)	2/100 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/67.34	0/43.06	0/43.38
POLY-3 PERCENT (g)	3%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	366	---	---

.....  
**STATISTICAL TESTS**

POLY 3	P=0.180N	P=0.337N	P=0.335N
POLY 1.5	P=0.184N	P=0.360N	P=0.358N
POLY 6	P=0.178N	P=0.315N	P=0.316N
COCH-ARM / FISHERS	P=0.196N	P=0.443N	P=0.443N
MAX-ISO-POLY-3	P=0.133N	P=0.132N	P=0.130N

.....

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Kidney  
 Cyst**

**LESION RATES**

OVERALL (a)	7/100 (7%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	7/68.49	0/43.06	2/43.59
POLY-3 PERCENT (g)	10.2%	0%	4.6%
TERMINAL (d)	1/41 (2%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	510	---	673

**STATISTICAL TESTS**

POLY 3	P=0.127N	P=0.033N*	P=0.231N
POLY 1.5	P=0.140N	P=0.042N*	P=0.271N
POLY 6	P=0.118N	P=0.027N*	P=0.204N
COCH-ARM / FISHERS	P=0.177N	P=0.054N	P=0.372N
MAX-ISO-POLY-3	P=0.060N	P=0.016N*	P=0.147N

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Kidney  
 Glomerulopathy Hyaline**

**LESION RATES**

OVERALL (a)	24/100 (24%)	0/50 (0%)	9/50 (18%)
POLY-3 RATE (b)	24/78.73	0/43.06	9/44.09
POLY-3 PERCENT (g)	30.5%	0%	20.4%
TERMINAL (d)	1/41 (2%)	0/32 (0%)	4/28 (14%)
FIRST INCIDENCE	394	---	637

**STATISTICAL TESTS**

POLY 3	P=0.039N*	P<0.001N**	P=0.153N
POLY 1.5	P=0.045N*	P<0.001N**	P=0.175N
POLY 6	P=0.039N*	P<0.001N**	P=0.153N
COCH-ARM / FISHERS	P=0.076N	P<0.001N**	P=0.268N
MAX-ISO-POLY-3	P=0.007N**	P<0.001N**	P=0.131N

---

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Kidney  
 Inflammation**

**LESION RATES**

OVERALL (a)	0/100 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/65.62	1/43.58	2/43.59
POLY-3 PERCENT (g)	0%	2.3%	4.6%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	570	697

**STATISTICAL TESTS**

POLY 3	P=0.096	P=0.416	P=0.145
POLY 1.5	P=0.080	P=0.395	P=0.128
POLY 6	P=0.113	P=0.437	P=0.162
COCH-ARM / FISHERS	P=0.057	P=0.333	P=0.110
MAX-ISO-POLY-3	P=0.065	P=0.109	P=0.039*

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Kidney  
Nephropathy**

---

**LESION RATES**

OVERALL (a)	95/100 (95%)	45/50 (90%)	50/50 (100%)
POLY-3 RATE (b)	95/96.82	45/47.15	50/50.00
POLY-3 PERCENT (g)	98.1%	95.5%	100%
TERMINAL (d)	40/41 (98%)	31/32 (97%)	28/28 (100%)
FIRST INCIDENCE	360	451	455

---

**STATISTICAL TESTS**

POLY 3	P=0.393	P=0.334N	P=0.415
POLY 1.5	P=0.376	P=0.220N	P=0.340
POLY 6	P=0.423	P=0.473N	P=0.505
COCH-ARM / FISHERS	P=0.217	P=0.206N	P=0.127
MAX-ISO-POLY-3	P=0.174	P=0.184N	P=0.168

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Kidney: Cortex  
Mineralization**

---

**LESION RATES**

OVERALL (a)	22/100 (22%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	22/76.48	2/43.43	2/44.16
POLY-3 PERCENT (g)	28.8%	4.6%	4.5%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	476	644	594

---

**STATISTICAL TESTS**

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

---



TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Kidney: Renal Tubule  
Degeneration**

**LESION RATES**

OVERALL (a)	0/100 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/65.62	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---

**STATISTICAL TESTS**

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

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Liver  
Angiectasis

---

**LESION RATES**

OVERALL (a)	0/100 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/65.62	0/43.06	1/44.14
POLY-3 PERCENT (g)	0%	0%	2.3%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	456

---

**STATISTICAL TESTS**

POLY 3	P=0.230	(e)	P=0.418
POLY 1.5	P=0.212	(e)	P=0.398
POLY 6	P=0.247	(e)	P=0.437
COCH-ARM / FISHERS	P=0.182	(e)	P=0.333
MAX-ISO-POLY-3	P=0.106	(e)	P=0.109

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Liver  
Basophilic Focus

---

**LESION RATES**

OVERALL (a)	38/100 (38%)	5/50 (10%)	2/50 (4%)
POLY-3 RATE (b)	38/67.77	5/43.83	2/43.38
POLY-3 PERCENT (g)	56.1%	11.4%	4.6%
TERMINAL (d)	34/41 (83%)	4/32 (13%)	2/28 (7%)
FIRST INCIDENCE	393	451	727 (T)

.....  
**STATISTICAL TESTS**

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

.....

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Liver  
 Clear Cell Focus

**LESION RATES**

OVERALL (a)	23/100 (23%)	22/50 (44%)	20/50 (40%)
POLY-3 RATE (b)	23/65.72	22/43.68	20/43.68
POLY-3 PERCENT (g)	35%	50.4%	45.8%
TERMINAL (d)	22/41 (54%)	19/32 (59%)	18/28 (64%)
FIRST INCIDENCE	701	644	673

**STATISTICAL TESTS**

POLY 3	P=0.136	P=0.065	P=0.159
POLY 1.5	P=0.059	P=0.027*	P=0.084
POLY 6	P=0.252	P=0.148	P=0.267
COCH-ARM / FISHERS	P=0.010**	P=0.008**	P=0.025*
MAX-ISO-POLY-3	P=0.115	P=0.047*	P=0.120

---

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Liver  
 Eosinophilic Focus

**LESION RATES**

OVERALL (a)	4/100 (4%)	2/50 (4%)	12/50 (24%)
POLY-3 RATE (b)	4/67.32	2/43.06	12/44.82
POLY-3 PERCENT (g)	5.9%	4.6%	26.8%
TERMINAL (d)	2/41 (5%)	2/32 (6%)	7/28 (25%)
FIRST INCIDENCE	360	727 (T)	608

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.556N	P<0.001**
POLY 1.5	P<0.001**	P=0.600N	P<0.001**
POLY 6	P<0.001**	P=0.511N	P=0.003**
COCH-ARM / FISHERS	P<0.001**	P=0.653	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.386N	P<0.001**

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Liver  
Fatty Change

---

**LESION RATES**

OVERALL (a)	3/100 (3%)	10/50 (20%)	27/50 (54%)
POLY-3 RATE (b)	3/66.73	10/44.80	27/46.09
POLY-3 PERCENT (g)	4.5%	22.3%	58.6%
TERMINAL (d)	0/41 (0%)	6/32 (19%)	17/28 (61%)
FIRST INCIDENCE	535	374	456

.....  
**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.003**	P<0.001**
POLY 1.5	P<0.001**	P=0.002**	P<0.001**
POLY 6	P<0.001**	P=0.006**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**

.....

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Liver  
Hepatodiaphragmatic Nodule

---

**LESION RATES**

OVERALL (a)	9/100 (9%)	6/50 (12%)	2/50 (4%)
POLY-3 RATE (b)	9/67.75	6/43.58	2/44.33
POLY-3 PERCENT (g)	13.3%	13.8%	4.5%
TERMINAL (d)	6/41 (15%)	5/32 (16%)	0/28 (0%)
FIRST INCIDENCE	393	570	465

.....  
**STATISTICAL TESTS**

POLY 3	P=0.104N	P=0.586	P=0.106N
POLY 1.5	P=0.143N	P=0.511	P=0.140N
POLY 6	P=0.076N	P=0.572N	P=0.082N
COCH-ARM / FISHERS	P=0.246N	P=0.378	P=0.224N
MAX-ISO-POLY-3	P=0.099N	P=0.470	P=0.063N

.....

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Liver  
Inflammation**

---

**LESION RATES**

OVERALL (a)	87/100 (87%)	36/50 (72%)	41/50 (82%)
POLY-3 RATE (b)	87/95.49	36/45.37	41/48.36
POLY-3 PERCENT (g)	91.1%	79.4%	84.8%
TERMINAL (d)	37/41 (90%)	27/32 (84%)	27/28 (96%)
FIRST INCIDENCE	360	605	455

---

**STATISTICAL TESTS**

POLY 3	P=0.102N	P=0.036N*	P=0.178N
POLY 1.5	P=0.094N	P=0.022N*	P=0.171N
POLY 6	P=0.134N	P=0.060N	P=0.224N
COCH-ARM / FISHERS	P=0.159N	P=0.023N*	P=0.280N
MAX-ISO-POLY-3	P=0.108N	P=0.037N*	P=0.143N

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TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Liver  
Mixed Cell Focus

---

**LESION RATES**

OVERALL (a)	10/100 (10%)	3/50 (6%)	10/50 (20%)
POLY-3 RATE (b)	10/66.44	3/43.27	10/44.02
POLY-3 PERCENT (g)	15.1%	6.9%	22.7%
TERMINAL (d)	9/41 (22%)	2/32 (6%)	8/28 (29%)
FIRST INCIDENCE	407	673	637

.....  
**STATISTICAL TESTS**

POLY 3	P=0.184	P=0.154N	P=0.211
POLY 1.5	P=0.141	P=0.204N	P=0.149
POLY 6	P=0.227	P=0.113N	P=0.284
COCH-ARM / FISHERS	P=0.080	P=0.313N	P=0.077
MAX-ISO-POLY-3	P=0.081	P=0.100N	P=0.150

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Liver: Bile Duct  
Cyst

---

**LESION RATES**

OVERALL (a)	9/100 (9%)	0/50 (0%)	11/50 (22%)
POLY-3 RATE (b)	9/69.15	0/43.06	11/43.76
POLY-3 PERCENT (g)	13%	0%	25.1%
TERMINAL (d)	2/41 (5%)	0/32 (0%)	9/28 (32%)
FIRST INCIDENCE	407	---	673

---

**STATISTICAL TESTS**

POLY 3	P=0.056	P=0.014N*	P=0.074
POLY 1.5	P=0.046*	P=0.019N*	P=0.052
POLY 6	P=0.064	P=0.010N**	P=0.096
COCH-ARM / FISHERS	P=0.032*	P=0.023N*	P=0.028*
MAX-ISO-POLY-3	P=0.005**	P=0.007N**	P=0.052

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Liver: Bile Duct  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	79/100 (79%)	15/50 (30%)	37/50 (74%)
POLY-3 RATE (b)	79/96.62	15/43.74	37/46.14
POLY-3 PERCENT (g)	81.8%	34.3%	80.2%
TERMINAL (d)	27/41 (66%)	12/32 (38%)	27/28 (96%)
FIRST INCIDENCE	360	605	598

.....  
**STATISTICAL TESTS**

POLY 3	P=0.092N	P<0.001N**	P=0.501N
POLY 1.5	P=0.056N	P<0.001N**	P=0.382N
POLY 6	P=0.167N	P<0.001N**	P=0.536
COCH-ARM / FISHERS	P=0.058N	P<0.001N**	P=0.311N
MAX-ISO-POLY-3	P=0.003N**	P<0.001N**	P=0.420N

---

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Liver: Hepatocyte  
 Cellular Alteration Diffuse

**LESION RATES**

OVERALL (a)	46/100 (46%)	2/50 (4%)	21/50 (42%)
POLY-3 RATE (b)	46/94.33	2/43.71	21/47.30
POLY-3 PERCENT (g)	48.8%	4.6%	44.4%
TERMINAL (d)	1/41 (2%)	0/32 (0%)	7/28 (25%)
FIRST INCIDENCE	360	632	455

**STATISTICAL TESTS**

POLY 3	P=0.094N	P<0.001N**	P=0.377N
POLY 1.5	P=0.084N	P<0.001N**	P=0.364N
POLY 6	P=0.108N	P<0.001N**	P=0.392N
COCH-ARM / FISHERS	P=0.097N	P<0.001N**	P=0.387N
MAX-ISO-POLY-3	P=0.007N**	P<0.001N**	P=0.334N

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Liver: Hepatocyte  
Degeneration Cystic

---

**LESION RATES**

OVERALL (a)	1/100 (1%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	1/65.62	1/43.06	3/43.71
POLY-3 PERCENT (g)	1.5%	2.3%	6.9%
TERMINAL (d)	1/41 (2%)	1/32 (3%)	2/28 (7%)
FIRST INCIDENCE	727 (T)	727 (T)	637

---

**STATISTICAL TESTS**

POLY 3	P=0.112	P=0.669	P=0.167
POLY 1.5	P=0.094	P=0.643	P=0.141
POLY 6	P=0.130	P=0.693	P=0.193
COCH-ARM / FISHERS	P=0.067	P=0.557	P=0.108
MAX-ISO-POLY-3	P=0.089	P=0.381	P=0.072

---

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Liver: Hepatocyte  
 Necrosis

**LESION RATES**

OVERALL (a)	16/100 (16%)	1/50 (2%)	6/50 (12%)
POLY-3 RATE (b)	16/76.18	1/43.39	6/44.05
POLY-3 PERCENT (g)	21%	2.3%	13.6%
TERMINAL (d)	1/41 (2%)	0/32 (0%)	2/28 (7%)
FIRST INCIDENCE	366	638	637

**STATISTICAL TESTS**

POLY 3	P=0.099N	P=0.004N**	P=0.216N
POLY 1.5	P=0.115N	P=0.006N**	P=0.254N
POLY 6	P=0.087N	P=0.003N**	P=0.187N
COCH-ARM / FISHERS	P=0.158N	P=0.007N**	P=0.348N
MAX-ISO-POLY-3	P=0.041N*	P=0.003N**	P=0.173N

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Liver: Hepatocyte, Centrilobular  
Degeneration

---

**LESION RATES**

OVERALL (a)	3/100 (3%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	3/66.09	0/43.06	1/43.84
POLY-3 PERCENT (g)	4.5%	0%	2.3%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	632	---	594

.....  
**STATISTICAL TESTS**

POLY 3	P=0.334N	P=0.199N	P=0.460N
POLY 1.5	P=0.347N	P=0.223N	P=0.499N
POLY 6	P=0.326N	P=0.179N	P=0.425N
COCH-ARM / FISHERS	P=0.380N	P=0.293N	P=0.593N
MAX-ISO-POLY-3	P=0.200N	P=0.080N	P=0.269N

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TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Liver: Oval Cell  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	44/100 (44%)	0/50 (0%)	8/50 (16%)
POLY-3 RATE (b)	44/91.53	0/43.06	8/43.69
POLY-3 PERCENT (g)	48.1%	0%	18.3%
TERMINAL (d)	1/41 (2%)	0/32 (0%)	6/28 (21%)
FIRST INCIDENCE	360	---	673

---

**STATISTICAL TESTS**

POLY 3	P<0.001N**	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P<0.001N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P<0.001N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P<0.001N**	P=0.002N**

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TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Liver: Portal  
Fibrosis

---

**LESION RATES**

OVERALL (a)	51/100 (51%)	6/50 (12%)	13/50 (26%)
POLY-3 RATE (b)	51/90.84	6/43.44	13/43.92
POLY-3 PERCENT (g)	56.1%	13.8%	29.6%
TERMINAL (d)	9/41 (22%)	4/32 (13%)	11/28 (39%)
FIRST INCIDENCE	360	644	637

---

**STATISTICAL TESTS**

POLY 3	P<0.001N**	P<0.001N**	P=0.003N**
POLY 1.5	P<0.001N**	P<0.001N**	P=0.002N**
POLY 6	P<0.001N**	P<0.001N**	P=0.005N**
COCH-ARM / FISHERS	P<0.001N**	P<0.001N**	P=0.003N**
MAX-ISO-POLY-3	P<0.001N**	P<0.001N**	P=0.005N**

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Liver: Serosa  
Hemorrhage

---

**LESION RATES**

OVERALL (a)	0/100 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/65.62	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---

.....  
**STATISTICAL TESTS**

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

.....

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Lung  
Congestion**

---

**LESION RATES**

OVERALL (a)	2/100 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/66.45	1/43.93	0/43.38
POLY-3 PERCENT (g)	3%	2.3%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	412	374	---

---

**STATISTICAL TESTS**

POLY 3	P=0.240N	P=0.646N	P=0.332N
POLY 1.5	P=0.258N	P=0.679N	P=0.355N
POLY 6	P=0.226N	P=0.613N	P=0.312N
COCH-ARM / FISHERS	P=0.299N	P=0.707	P=0.443N
MAX-ISO-POLY-3	P=0.196N	P=0.407N	P=0.127N

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Lung  
Hemorrhage**

---

**LESION RATES**

OVERALL (a)	2/100 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/66.82	0/43.06	1/43.50
POLY-3 PERCENT (g)	3%	0%	2.3%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	29	---	697

---

**STATISTICAL TESTS**

POLY 3	P=0.534N	P=0.335N	P=0.651N
POLY 1.5	P=0.545N	P=0.360N	P=0.681N
POLY 6	P=0.528N	P=0.312N	P=0.623N
COCH-ARM / FISHERS	P=0.570N	P=0.443N	P=0.707
MAX-ISO-POLY-3	P=0.356N	P=0.130N	P=0.413N

---

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Lung  
 Inflammation**

**LESION RATES**

OVERALL (a)	0/100 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/65.62	1/43.06	1/43.50
POLY-3 PERCENT (g)	0%	2.3%	2.3%
TERMINAL (d)	0/41 (0%)	1/32 (3%)	0/28 (0%)
FIRST INCIDENCE	---	727 (T)	697

**STATISTICAL TESTS**

POLY 3	P=0.284	P=0.413	P=0.415
POLY 1.5	P=0.250	P=0.393	P=0.396
POLY 6	P=0.317	P=0.433	P=0.434
COCH-ARM / FISHERS	P=0.196	P=0.333	P=0.333
MAX-ISO-POLY-3	P=0.218	P=0.109	P=0.109

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Lung: Alveolar Epithelium  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	22/100 (22%)	9/50 (18%)	11/50 (22%)
POLY-3 RATE (b)	22/71.23	9/43.83	11/45.21
POLY-3 PERCENT (g)	30.9%	20.5%	24.3%
TERMINAL (d)	9/41 (22%)	8/32 (25%)	6/28 (21%)
FIRST INCIDENCE	377	451	455

---

**STATISTICAL TESTS**

POLY 3	P=0.231N	P=0.149N	P=0.282N
POLY 1.5	P=0.311N	P=0.213N	P=0.380N
POLY 6	P=0.176N	P=0.108N	P=0.211N
COCH-ARM / FISHERS	P=0.500N	P=0.366N	P=0.578
MAX-ISO-POLY-3	P=0.228N	P=0.117N	P=0.225N

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Lung: Alveolus  
Inflammation Histiocytic

---

**LESION RATES**

OVERALL (a)	63/100 (63%)	35/50 (70%)	37/50 (74%)
POLY-3 RATE (b)	63/87.04	35/45.67	37/46.56
POLY-3 PERCENT (g)	72.4%	76.6%	79.5%
TERMINAL (d)	25/41 (61%)	26/32 (81%)	26/28 (93%)
FIRST INCIDENCE	360	570	455

.....  
**STATISTICAL TESTS**

POLY 3	P=0.193	P=0.367	P=0.232
POLY 1.5	P=0.176	P=0.339	P=0.214
POLY 6	P=0.172	P=0.369	P=0.210
COCH-ARM / FISHERS	P=0.093	P=0.254	P=0.122
MAX-ISO-POLY-3	P=0.268	P=0.311	P=0.199

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Lung: Arteriole  
Inflammation**

---

**LESION RATES**

OVERALL (a)	0/100 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/65.62	1/43.58	1/43.50
POLY-3 PERCENT (g)	0%	2.3%	2.3%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	570	697

---

**STATISTICAL TESTS**

POLY 3	P=0.284	P=0.416	P=0.415
POLY 1.5	P=0.250	P=0.395	P=0.396
POLY 6	P=0.317	P=0.437	P=0.434
COCH-ARM / FISHERS	P=0.196	P=0.333	P=0.333
MAX-ISO-POLY-3	P=0.220	P=0.109	P=0.109

---



TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Lung: Interstitium  
 Mineralization**

**LESION RATES**

OVERALL (a)	16/100 (16%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	16/72.80	1/43.37	2/43.92
POLY-3 PERCENT (g)	22%	2.3%	4.6%
TERMINAL (d)	1/41 (2%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	503	644	637

**STATISTICAL TESTS**

POLY 3	P=0.002N**	P=0.003N**	P=0.009N**
POLY 1.5	P=0.002N**	P=0.004N**	P=0.013N*
POLY 6	P<0.001N**	P=0.002N**	P=0.007N**
COCH-ARM / FISHERS	P=0.005N**	P=0.007N**	P=0.025N*
MAX-ISO-POLY-3	P=0.002N**	P=0.002N**	P=0.007N**

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Lung: Serosa  
Hyperplasia**

---

**LESION RATES**

OVERALL (a)	2/100 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/66.62	0/43.06	0/43.38
POLY-3 PERCENT (g)	3%	0%	0%
TERMINAL (d)	1/41 (2%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	24	---	---

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**STATISTICAL TESTS**

POLY 3	P=0.180N	P=0.334N	P=0.332N
POLY 1.5	P=0.184N	P=0.360N	P=0.357N
POLY 6	P=0.178N	P=0.311N	P=0.312N
COCH-ARM / FISHERS	P=0.196N	P=0.443N	P=0.443N
MAX-ISO-POLY-3	P=0.130N	P=0.129N	P=0.128N

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
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First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Lymph Node, Mesenteric  
Fibrosis**

---

**LESION RATES**

OVERALL (a)	2/100 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/66.30	0/43.06	0/43.38
POLY-3 PERCENT (g)	3%	0%	0%
TERMINAL (d)	1/41 (2%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	497	---	---

.....  
**STATISTICAL TESTS**

POLY 3	P=0.180N	P=0.333N	P=0.331N
POLY 1.5	P=0.183N	P=0.358N	P=0.355N
POLY 6	P=0.178N	P=0.310N	P=0.311N
COCH-ARM / FISHERS	P=0.196N	P=0.443N	P=0.443N
MAX-ISO-POLY-3	P=0.129N	P=0.128N	P=0.127N

.....

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Lymph Node, Mesenteric  
Hemorrhage**

---

**LESION RATES**

OVERALL (a)	1/100 (1%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/66.30	1/43.39	0/43.38
POLY-3 PERCENT (g)	1.5%	2.3%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	497	639	---

.....  
**STATISTICAL TESTS**

POLY 3	P=0.435N	P=0.668	P=0.587N
POLY 1.5	P=0.456N	P=0.643	P=0.605N
POLY 6	P=0.417N	P=0.692	P=0.571N
COCH-ARM / FISHERS	P=0.500N	P=0.557	P=0.667N
MAX-ISO-POLY-3	P=0.298N	P=0.380	P=0.211N

.....

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Lymph Node, Mesenteric  
Inflammation**

---

**LESION RATES**

OVERALL (a)	0/100 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/65.62	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---

.....  
**STATISTICAL TESTS**

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

.....

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Lymph Node: Deep Cervical  
Hemorrhage

---

**LESION RATES**

OVERALL (a)	2/8 (25%)	0/8 (0%)	0/3 (0%)
POLY-3 RATE (b)	2/5.23	0/7.87	0/2.33
POLY-3 PERCENT (g)	38.3%	0%	0%
TERMINAL (d)	0/1 (0%)	0/6 (0%)	0/0 (0%)
FIRST INCIDENCE	407	---	---

.....  
**STATISTICAL TESTS**

POLY 3	P=0.117N	P=0.130N	P=0.415N
POLY 1.5	P=0.130N	P=0.163N	P=0.432N
POLY 6	P=0.095N	P=0.099N	P=0.421N
COCH-ARM / FISHERS	P=0.154N	P=0.233N	P=0.509N
MAX-ISO-POLY-3	P=0.143N	P=0.050N*	P=0.159N

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Lymph Node: Mediastinal  
Degeneration Cystic**

---

**LESION RATES**

OVERALL (a)	0/8 (0%)	2/8 (25%)	0/3 (0%)
POLY-3 RATE (b)	0/3.81	2/7.87	0/2.33
POLY-3 PERCENT (g)	0%	25.4%	0%
TERMINAL (d)	0/1 (0%)	2/6 (33%)	0/0 (0%)
FIRST INCIDENCE	---	727 (T)	---

.....  
**STATISTICAL TESTS**

POLY 3	P=0.746	P=0.413	(e)
POLY 1.5	P=0.645	P=0.329	(e)
POLY 6	P=0.716N	P=0.511	(e)
COCH-ARM / FISHERS	P=0.489	P=0.233	(e)
MAX-ISO-POLY-3	P=0.378	P=0.231	(e)

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Lymph Node: Mediastinal Hemorrhage**

---

**LESION RATES**

OVERALL (a)	2/8 (25%)	0/8 (0%)	0/3 (0%)
POLY-3 RATE (b)	2/5.06	0/7.87	0/2.33
POLY-3 PERCENT (g)	39.6%	0%	0%
TERMINAL (d)	0/1 (0%)	0/6 (0%)	0/0 (0%)
FIRST INCIDENCE	414	---	---

.....  
**STATISTICAL TESTS**

POLY 3	P=0.118N	P=0.124N	P=0.404N
POLY 1.5	P=0.130N	P=0.158N	P=0.425N
POLY 6	P=0.096N	P=0.094N	P=0.407N
COCH-ARM / FISHERS	P=0.154N	P=0.233N	P=0.509N
MAX-ISO-POLY-3	P=0.131N	P=0.050N*	P=0.148N

---



TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Lymph Node: Mediastinal  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	0/8 (0%)	3/8 (38%)	0/3 (0%)
POLY-3 RATE (b)	0/3.81	3/7.87	0/2.33
POLY-3 PERCENT (g)	0%	38.1%	0%
TERMINAL (d)	0/1 (0%)	3/6 (50%)	0/0 (0%)
FIRST INCIDENCE	---	727 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.723	P=0.270	(e)
POLY 1.5	P=0.591	P=0.176	(e)
POLY 6	P=0.666N	P=0.395	(e)
COCH-ARM / FISHERS	P=0.399	P=0.100	(e)
MAX-ISO-POLY-3	P=0.290	P=0.162	(e)

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Lymph Node: Pancreatic  
Hemorrhage

---

**LESION RATES**

OVERALL (a)	1/8 (13%)	0/8 (0%)	0/3 (0%)
POLY-3 RATE (b)	1/4.40	0/7.87	0/2.33
POLY-3 PERCENT (g)	22.7%	0%	0%
TERMINAL (d)	0/1 (0%)	0/6 (0%)	0/0 (0%)
FIRST INCIDENCE	539	---	---

.....  
**STATISTICAL TESTS**

POLY 3	P=0.382N	P=0.388N	P=0.638N
POLY 1.5	P=0.370N	P=0.431N	P=0.657N
POLY 6	P=0.385N	P=0.345N	P=0.635N
COCH-ARM / FISHERS	P=0.367N	P=0.500N	P=0.727N
MAX-ISO-POLY-3	P=0.237N	P=0.148N	P=0.229N

.....

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Mammary Gland  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	1/100 (1%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/65.62	0/43.06	0/43.38
POLY-3 PERCENT (g)	1.5%	0%	0%
TERMINAL (d)	1/41 (2%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	727 (T)	---	---

**STATISTICAL TESTS**

POLY 3	P=0.381N	P=0.586N	P=0.585N
POLY 1.5	P=0.379N	P=0.606N	P=0.604N
POLY 6	P=0.386N	P=0.567N	P=0.567N
COCH-ARM / FISHERS	P=0.381N	P=0.667N	P=0.667N
MAX-ISO-POLY-3	P=0.244N	P=0.211N	P=0.209N

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Mammary Gland: Duct  
Dilatation**

**LESION RATES**

OVERALL (a)	0/100 (0%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	0/65.62	1/43.06	3/43.71
POLY-3 PERCENT (g)	0%	2.3%	6.9%
TERMINAL (d)	0/41 (0%)	1/32 (3%)	2/28 (7%)
FIRST INCIDENCE	---	727 (T)	636

**STATISTICAL TESTS**

POLY 3	P=0.031*	P=0.413	P=0.053
POLY 1.5	P=0.025*	P=0.393	P=0.043*
POLY 6	P=0.038*	P=0.433	P=0.064
COCH-ARM / FISHERS	P=0.017*	P=0.333	P=0.036*
MAX-ISO-POLY-3	P=0.019*	P=0.109	P=0.015*

---

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Mesentery  
 Necrosis**

**LESION RATES**

OVERALL (a)	9/13 (69%)	9/11 (82%)	10/11 (91%)
POLY-3 RATE (b)	9/11.70	9/10.66	10/10.85
POLY-3 PERCENT (g)	76.9%	84.5%	92.2%
TERMINAL (d)	6/7 (86%)	6/7 (86%)	9/9 (100%)
FIRST INCIDENCE	407	580	697

**STATISTICAL TESTS**

POLY 3	P=0.232	P=0.535	P=0.326
POLY 1.5	P=0.190	P=0.479	P=0.271
POLY 6	P=0.290	P=0.602	P=0.403
COCH-ARM / FISHERS	P=0.141	P=0.410	P=0.215
MAX-ISO-POLY-3	P=0.206	P=0.320	P=0.142

---

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Nose  
 Inflammation**

**LESION RATES**

OVERALL (a)	53/100 (53%)	23/50 (46%)	30/46 (65%)
POLY-3 RATE (b)	53/83.81	23/46.61	30/43.33
POLY-3 PERCENT (g)	63.2%	49.4%	69.2%
TERMINAL (d)	21/41 (51%)	14/32 (44%)	18/28 (64%)
FIRST INCIDENCE	360	199	455

**STATISTICAL TESTS**

POLY 3	P=0.388	P=0.076N	P=0.306
POLY 1.5	P=0.305	P=0.118N	P=0.230
POLY 6	P=0.469	P=0.052N	P=0.392
COCH-ARM / FISHERS	P=0.159	P=0.263N	P=0.114
MAX-ISO-POLY-3	P=0.181	P=0.071N	P=0.263

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Nose  
Thrombosis**

**LESION RATES**

OVERALL (a)	0/100 (0%)	0/50 (0%)	0/46 (0%)
POLY-3 RATE (b)	0/65.62	0/43.06	0/40.06
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---

**STATISTICAL TESTS**

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

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Nose: Glands  
Dilatation

---

**LESION RATES**

OVERALL (a)	1/100 (1%)	2/50 (4%)	1/46 (2%)
POLY-3 RATE (b)	1/66.28	2/43.06	1/40.06
POLY-3 PERCENT (g)	1.5%	4.6%	2.5%
TERMINAL (d)	0/41 (0%)	2/32 (6%)	1/28 (4%)
FIRST INCIDENCE	503	727 (T)	727 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.492	P=0.348	P=0.649
POLY 1.5	P=0.442	P=0.317	P=0.625
POLY 6	P=0.537	P=0.379	P=0.671
COCH-ARM / FISHERS	P=0.355	P=0.258	P=0.532
MAX-ISO-POLY-3	P=0.373	P=0.167	P=0.361

---



TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Nose: Goblet Cell  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	3/100 (3%)	0/50 (0%)	0/46 (0%)
POLY-3 RATE (b)	3/65.62	0/43.06	0/40.06
POLY-3 PERCENT (g)	4.6%	0%	0%
TERMINAL (d)	3/41 (7%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	727 (T)	---	---

**STATISTICAL TESTS**

POLY 3	P=0.097N	P=0.198N	P=0.213N
POLY 1.5	P=0.102N	P=0.223N	P=0.238N
POLY 6	P=0.095N	P=0.176N	P=0.190N
COCH-ARM / FISHERS	P=0.117N	P=0.293N	P=0.318N
MAX-ISO-POLY-3	P=0.079N	P=0.078N	P=0.088N

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Nose: Olfactory Epithelium  
Degeneration**

---

**LESION RATES**

OVERALL (a)	20/100 (20%)	5/50 (10%)	33/46 (72%)
POLY-3 RATE (b)	20/78.50	5/43.23	33/43.35
POLY-3 PERCENT (g)	25.5%	11.6%	76.1%
TERMINAL (d)	1/41 (2%)	3/32 (9%)	21/28 (75%)
FIRST INCIDENCE	360	701	455

---

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.051N	P<0.001**
POLY 1.5	P<0.001**	P=0.063N	P<0.001**
POLY 6	P<0.001**	P=0.044N*	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.091N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.046N*	P<0.001**

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Nose: Olfactory Epithelium  
Metaplasia Respiratory**

---

**LESION RATES**

OVERALL (a)	2/100 (2%)	3/50 (6%)	6/46 (13%)
POLY-3 RATE (b)	2/65.75	3/43.06	6/40.81
POLY-3 PERCENT (g)	3%	7%	14.7%
TERMINAL (d)	1/41 (2%)	3/32 (9%)	5/28 (18%)
FIRST INCIDENCE	692	727 (T)	455

.....  
**STATISTICAL TESTS**

POLY 3	P=0.020*	P=0.308	P=0.026*
POLY 1.5	P=0.013*	P=0.269	P=0.018*
POLY 6	P=0.028*	P=0.348	P=0.037*
COCH-ARM / FISHERS	P=0.007**	P=0.207	P=0.012*
MAX-ISO-POLY-3	P=0.018*	P=0.172	P=0.012*

.....

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Oral Mucosa: Pharyngeal  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	0/0 (0%)	0/1 (0%)	1/3 (33%)
POLY-3 RATE (b)	0/0.00	0/1.00	1/2.23
POLY-3 PERCENT (g)	0%	0%	44.8%
TERMINAL (d)	0/0 (0%)	0/1 (0%)	1/1 (100%)
FIRST INCIDENCE	---	---	727 (T)

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.748	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Pancreas  
Inflammation**

---

**LESION RATES**

OVERALL (a)	0/100 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/65.62	0/43.06	1/43.39
POLY-3 PERCENT (g)	0%	0%	2.3%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	724

---

**STATISTICAL TESTS**

POLY 3	P=0.227	(e)	P=0.415
POLY 1.5	P=0.210	(e)	P=0.396
POLY 6	P=0.243	(e)	P=0.432
COCH-ARM / FISHERS	P=0.182	(e)	P=0.333
MAX-ISO-POLY-3	P=0.106	(e)	P=0.109

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Pancreas: Acinus  
Atrophy**

---

**LESION RATES**

OVERALL (a)	31/100 (31%)	24/50 (48%)	20/50 (40%)
POLY-3 RATE (b)	31/75.48	24/44.73	20/44.71
POLY-3 PERCENT (g)	41.1%	53.7%	44.7%
TERMINAL (d)	13/41 (32%)	16/32 (50%)	16/28 (57%)
FIRST INCIDENCE	360	611	455

---

**STATISTICAL TESTS**

POLY 3	P=0.335	P=0.113	P=0.416
POLY 1.5	P=0.244	P=0.071	P=0.333
POLY 6	P=0.399	P=0.170	P=0.471
COCH-ARM / FISHERS	P=0.101	P=0.032*	P=0.180
MAX-ISO-POLY-3	P=0.285	P=0.096	P=0.351

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Pancreas: Acinus  
Hyperplasia**

---

**LESION RATES**

OVERALL (a)	12/100 (12%)	8/50 (16%)	7/50 (14%)
POLY-3 RATE (b)	12/66.63	8/45.07	7/43.49
POLY-3 PERCENT (g)	18%	17.8%	16.1%
TERMINAL (d)	10/41 (24%)	4/32 (13%)	6/28 (21%)
FIRST INCIDENCE	502	451	701

---

**STATISTICAL TESTS**

POLY 3	P=0.456N	P=0.589N	P=0.499N
POLY 1.5	P=0.545N	P=0.507	P=0.585N
POLY 6	P=0.384N	P=0.477N	P=0.424N
COCH-ARM / FISHERS	P=0.378	P=0.330	P=0.457
MAX-ISO-POLY-3	P=0.547N	P=0.485N	P=0.396N

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Pancreas: Duct  
Cyst**

---

**LESION RATES**

OVERALL (a)	9/100 (9%)	5/50 (10%)	1/50 (2%)
POLY-3 RATE (b)	9/69.13	5/43.24	1/43.38
POLY-3 PERCENT (g)	13%	11.6%	2.3%
TERMINAL (d)	4/41 (10%)	4/32 (13%)	1/28 (4%)
FIRST INCIDENCE	388	682	727 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.047N*	P=0.527N	P=0.048N*
POLY 1.5	P=0.064N	P=0.589N	P=0.062N
POLY 6	P=0.036N*	P=0.467N	P=0.038N*
COCH-ARM / FISHERS	P=0.112N	P=0.528	P=0.096N
MAX-ISO-POLY-3	P=0.047N*	P=0.411N	P=0.028N*

---



TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Parathyroid Gland  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	36/97 (37%)	0/44 (0%)	3/45 (7%)
POLY-3 RATE (b)	36/83.75	0/37.96	3/39.18
POLY-3 PERCENT (g)	43%	0%	7.7%
TERMINAL (d)	2/40 (5%)	0/28 (0%)	1/25 (4%)
FIRST INCIDENCE	360	---	637

**STATISTICAL TESTS**

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

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Pituitary Gland  
Hemorrhage**

---

**LESION RATES**

OVERALL (a)	0/100 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/65.62	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---

.....  
**STATISTICAL TESTS**

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

.....

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Pituitary Gland: Pars Distalis  
 Angiectasis**

**LESION RATES**

OVERALL (a)	2/100 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/65.62	0/43.06	0/43.38
POLY-3 PERCENT (g)	3.1%	0%	0%
TERMINAL (d)	2/41 (5%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	727 (T)	---	---

**STATISTICAL TESTS**

POLY 3	P=0.179N	P=0.330N	P=0.329N
POLY 1.5	P=0.183N	P=0.356N	P=0.353N
POLY 6	P=0.179N	P=0.306N	P=0.307N
COCH-ARM / FISHERS	P=0.196N	P=0.443N	P=0.443N
MAX-ISO-POLY-3	P=0.125N	P=0.126N	P=0.124N

---

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Pituitary Gland: Pars Distalis  
 Cyst**

**LESION RATES**

OVERALL (a)	3/100 (3%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	3/65.95	0/43.06	1/43.38
POLY-3 PERCENT (g)	4.6%	0%	2.3%
TERMINAL (d)	2/41 (5%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	635	---	727 (T)

**STATISTICAL TESTS**

POLY 3	P=0.335N	P=0.199N	P=0.463N
POLY 1.5	P=0.348N	P=0.223N	P=0.501N
POLY 6	P=0.327N	P=0.178N	P=0.430N
COCH-ARM / FISHERS	P=0.380N	P=0.293N	P=0.593N
MAX-ISO-POLY-3	P=0.203N	P=0.079N	P=0.273N

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Pituitary Gland: Pars Distalis  
Hyperplasia**

**LESION RATES**

OVERALL (a)	36/100 (36%)	24/50 (48%)	18/50 (36%)
POLY-3 RATE (b)	36/73.29	24/44.57	18/45.65
POLY-3 PERCENT (g)	49.1%	53.9%	39.4%
TERMINAL (d)	20/41 (49%)	18/32 (56%)	9/28 (32%)
FIRST INCIDENCE	407	570	598

**STATISTICAL TESTS**

POLY 3	P=0.188N	P=0.372	P=0.186N
POLY 1.5	P=0.321N	P=0.250	P=0.303N
POLY 6	P=0.105N	P=0.493	P=0.110N
COCH-ARM / FISHERS	P=0.431	P=0.108	P=0.569
MAX-ISO-POLY-3	P=0.159N	P=0.311	P=0.151N

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Preputial Gland  
Inflammation**

---

**LESION RATES**

OVERALL (a)	17/100 (17%)	14/50 (28%)	13/50 (26%)
POLY-3 RATE (b)	17/71.09	14/44.22	13/44.85
POLY-3 PERCENT (g)	23.9%	31.7%	29%
TERMINAL (d)	8/41 (20%)	11/32 (34%)	8/28 (29%)
FIRST INCIDENCE	393	570	465

.....  
**STATISTICAL TESTS**

POLY 3	P=0.297	P=0.234	P=0.343
POLY 1.5	P=0.212	P=0.168	P=0.262
POLY 6	P=0.378	P=0.309	P=0.418
COCH-ARM / FISHERS	P=0.090	P=0.089	P=0.140
MAX-ISO-POLY-3	P=0.325	P=0.186	P=0.275

.....

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Preputial Gland: Duct  
Ectasia

---

**LESION RATES**

OVERALL (a)	4/100 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	4/66.19	1/43.06	0/43.38
POLY-3 PERCENT (g)	6%	2.3%	0%
TERMINAL (d)	3/41 (7%)	1/32 (3%)	0/28 (0%)
FIRST INCIDENCE	545	727 (T)	---

.....  
**STATISTICAL TESTS**

POLY 3	P=0.073N	P=0.325N	P=0.122N
POLY 1.5	P=0.083N	P=0.365N	P=0.141N
POLY 6	P=0.066N	P=0.289N	P=0.106N
COCH-ARM / FISHERS	P=0.110N	P=0.459N	P=0.194N
MAX-ISO-POLY-3	P=0.060N	P=0.185N	P=0.050N*

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Prostate  
Inflammation**

---

**LESION RATES**

OVERALL (a)	12/99 (12%)	11/50 (22%)	10/50 (20%)
POLY-3 RATE (b)	12/67.48	11/44.04	10/44.55
POLY-3 PERCENT (g)	17.8%	25%	22.5%
TERMINAL (d)	8/41 (20%)	8/32 (25%)	6/28 (21%)
FIRST INCIDENCE	360	580	632

---

**STATISTICAL TESTS**

POLY 3	P=0.310	P=0.241	P=0.353
POLY 1.5	P=0.218	P=0.170	P=0.268
POLY 6	P=0.409	P=0.327	P=0.443
COCH-ARM / FISHERS	P=0.098	P=0.093	P=0.150
MAX-ISO-POLY-3	P=0.322	P=0.180	P=0.272

---



TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Prostate: Epithelium  
Cyst

---

**LESION RATES**

OVERALL (a)	0/99 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/65.46	0/43.06	2/43.38
POLY-3 PERCENT (g)	0%	0%	4.6%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	2/28 (7%)
FIRST INCIDENCE	---	---	727 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.060	(e)	P=0.145
POLY 1.5	P=0.053	(e)	P=0.129
POLY 6	P=0.066	(e)	P=0.161
COCH-ARM / FISHERS	P=0.044*	(e)	P=0.111
MAX-ISO-POLY-3	P=0.028*	(e)	P=0.040*

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Prostate: Epithelium  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	18/99 (18%)	6/50 (12%)	12/50 (24%)
POLY-3 RATE (b)	18/67.32	6/43.37	12/43.60
POLY-3 PERCENT (g)	26.7%	13.8%	27.5%
TERMINAL (d)	14/41 (34%)	5/32 (16%)	9/28 (32%)
FIRST INCIDENCE	476	644	701

.....  
**STATISTICAL TESTS**

POLY 3	P=0.551	P=0.076N	P=0.553
POLY 1.5	P=0.464	P=0.121N	P=0.447
POLY 6	P=0.487N	P=0.045N*	P=0.537N
COCH-ARM / FISHERS	P=0.300	P=0.235N	P=0.265
MAX-ISO-POLY-3	P=0.328N	P=0.054N	P=0.463

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Skin  
Cyst Epithelial Inclusion**

---

**LESION RATES**

OVERALL (a)	1/100 (1%)	6/50 (12%)	1/50 (2%)
POLY-3 RATE (b)	1/65.99	6/43.81	1/43.58
POLY-3 PERCENT (g)	1.5%	13.7%	2.3%
TERMINAL (d)	0/41 (0%)	4/32 (13%)	0/28 (0%)
FIRST INCIDENCE	622	605	675

---

**STATISTICAL TESTS**

POLY 3	P=0.479	P=0.012*	P=0.670
POLY 1.5	P=0.392	P=0.008**	P=0.646
POLY 6	P=0.559	P=0.018*	P=0.691
COCH-ARM / FISHERS	P=0.257	P=0.006**	P=0.557
MAX-ISO-POLY-3	P=0.093	P=0.004**	P=0.382

---

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
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 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Spleen  
 Fibrosis**

**LESION RATES**

OVERALL (a)	0/100 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/65.62	2/43.06	1/43.38
POLY-3 PERCENT (g)	0%	4.6%	2.3%
TERMINAL (d)	0/41 (0%)	2/32 (6%)	1/28 (4%)
FIRST INCIDENCE	---	727 (T)	727 (T)

**STATISTICAL TESTS**

POLY 3	P=0.305	P=0.143	P=0.415
POLY 1.5	P=0.260	P=0.126	P=0.396
POLY 6	P=0.350	P=0.161	P=0.432
COCH-ARM / FISHERS	P=0.190	P=0.110	P=0.333
MAX-ISO-POLY-3	P=0.147	P=0.039*	P=0.109

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Spleen  
Hematopoietic Cell Proliferation**

**LESION RATES**

OVERALL (a)	0/100 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/65.62	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---

**STATISTICAL TESTS**

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

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Spleen  
Hyperplasia Lymphoid**

---

**LESION RATES**

OVERALL (a)	3/100 (3%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	3/65.62	2/43.17	2/43.38
POLY-3 PERCENT (g)	4.6%	4.6%	4.6%
TERMINAL (d)	3/41 (7%)	1/32 (3%)	2/28 (7%)
FIRST INCIDENCE	727 (T)	701	727 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.600	P=0.679	P=0.681
POLY 1.5	P=0.551	P=0.637	P=0.641
POLY 6	P=0.575N	P=0.647N	P=0.651N
COCH-ARM / FISHERS	P=0.454	P=0.541	P=0.541
MAX-ISO-POLY-3	P=0.660	P=0.493	P=0.495

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Stomach, Forestomach  
Inflammation**

**LESION RATES**

OVERALL (a)	25/100 (25%)	4/50 (8%)	8/50 (16%)
POLY-3 RATE (b)	25/81.59	4/43.93	8/45.19
POLY-3 PERCENT (g)	30.6%	9.1%	17.7%
TERMINAL (d)	4/41 (10%)	1/32 (3%)	1/28 (4%)
FIRST INCIDENCE	360	622	465

**STATISTICAL TESTS**

POLY 3	P=0.028N*	P=0.004N**	P=0.078N
POLY 1.5	P=0.035N*	P=0.006N**	P=0.097N
POLY 6	P=0.021N*	P=0.003N**	P=0.061N
COCH-ARM / FISHERS	P=0.056N	P=0.009N**	P=0.148N
MAX-ISO-POLY-3	P=0.023N*	P=0.006N**	P=0.070N

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Stomach, Forestomach  
Mineralization**

---

**LESION RATES**

OVERALL (a)	4/100 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	4/67.37	1/43.37	0/43.38
POLY-3 PERCENT (g)	5.9%	2.3%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	545	644	---

---

**STATISTICAL TESTS**

POLY 3	P=0.075N	P=0.330N	P=0.125N
POLY 1.5	P=0.084N	P=0.368N	P=0.143N
POLY 6	P=0.068N	P=0.297N	P=0.112N
COCH-ARM / FISHERS	P=0.110N	P=0.459N	P=0.194N
MAX-ISO-POLY-3	P=0.064N	P=0.189N	P=0.053N

---



TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Stomach, Forestomach  
Perforation**

**LESION RATES**

OVERALL (a)	5/100 (5%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	5/69.81	0/43.06	0/43.38
POLY-3 PERCENT (g)	7.2%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	366	---	---

**STATISTICAL TESTS**

POLY 3	P=0.027N*	P=0.085N	P=0.084N
POLY 1.5	P=0.030N*	P=0.100N	P=0.098N
POLY 6	P=0.025N*	P=0.073N	P=0.073N
COCH-ARM / FISHERS	P=0.038N*	P=0.127N	P=0.127N
MAX-ISO-POLY-3	P=0.028N*	P=0.040N*	P=0.039N*

---

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Stomach, Forestomach  
 Ulcer**

**LESION RATES**

OVERALL (a)	16/100 (16%)	2/50 (4%)	7/50 (14%)
POLY-3 RATE (b)	16/78.10	2/43.73	7/45.06
POLY-3 PERCENT (g)	20.5%	4.6%	15.5%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	360	632	465

**STATISTICAL TESTS**

POLY 3	P=0.196N	P=0.014N*	P=0.326N
POLY 1.5	P=0.222N	P=0.019N*	P=0.373N
POLY 6	P=0.172N	P=0.010N**	P=0.283N
COCH-ARM / FISHERS	P=0.281N	P=0.025N*	P=0.476N
MAX-ISO-POLY-3	P=0.100N	P=0.013N*	P=0.263N

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Stomach, Forestomach: Epithelium  
Hyperplasia**

---

**LESION RATES**

OVERALL (a)	39/100 (39%)	21/50 (42%)	20/50 (40%)
POLY-3 RATE (b)	39/84.96	21/44.89	20/46.90
POLY-3 PERCENT (g)	45.9%	46.8%	42.6%
TERMINAL (d)	12/41 (29%)	14/32 (44%)	8/28 (29%)
FIRST INCIDENCE	24	570	456

.....  
**STATISTICAL TESTS**

POLY 3	P=0.406N	P=0.537	P=0.427N
POLY 1.5	P=0.482N	P=0.484	P=0.499N
POLY 6	P=0.324N	P=0.548N	P=0.348N
COCH-ARM / FISHERS	P=0.465	P=0.428	P=0.522
MAX-ISO-POLY-3	P=0.492N	P=0.464	P=0.368N

.....

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Stomach, Glandular  
Erosion**

---

**LESION RATES**

OVERALL (a)	0/100 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/65.62	0/43.06	2/44.15
POLY-3 PERCENT (g)	0%	0%	4.5%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	598

---

**STATISTICAL TESTS**

POLY 3	P=0.060	(e)	P=0.147
POLY 1.5	P=0.053	(e)	P=0.129
POLY 6	P=0.068	(e)	P=0.167
COCH-ARM / FISHERS	P=0.043*	(e)	P=0.110
MAX-ISO-POLY-3	P=0.027*	(e)	P=0.039*

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

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First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Stomach, Glandular  
Inflammation**

---

**LESION RATES**

OVERALL (a)	7/100 (7%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	7/69.71	3/43.24	1/43.39
POLY-3 PERCENT (g)	10%	6.9%	2.3%
TERMINAL (d)	1/41 (2%)	2/32 (6%)	0/28 (0%)
FIRST INCIDENCE	360	682	725

.....  
**STATISTICAL TESTS**

POLY 3	P=0.086N	P=0.409N	P=0.111N
POLY 1.5	P=0.105N	P=0.460N	P=0.133N
POLY 6	P=0.073N	P=0.361N	P=0.094N
COCH-ARM / FISHERS	P=0.152N	P=0.559N	P=0.188N
MAX-ISO-POLY-3	P=0.092N	P=0.293N	P=0.064N

.....

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
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 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Stomach, Glandular  
 Mineralization**

**LESION RATES**

OVERALL (a)	21/100 (21%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	21/75.71	1/43.37	4/43.92
POLY-3 PERCENT (g)	27.7%	2.3%	9.1%
TERMINAL (d)	1/41 (2%)	0/32 (0%)	2/28 (7%)
FIRST INCIDENCE	476	644	637

**STATISTICAL TESTS**

POLY 3	P=0.002N**	P<0.001N**	P=0.011N*
POLY 1.5	P=0.002N**	P<0.001N**	P=0.016N*
POLY 6	P<0.001N**	P<0.001N**	P=0.010N**
COCH-ARM / FISHERS	P=0.006N**	P<0.001N**	P=0.033N*
MAX-ISO-POLY-3	P<0.001N**	P<0.001N**	P=0.010N**

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Testes  
Inflammation**

---

**LESION RATES**

OVERALL (a)	0/99 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/65.46	1/43.06	2/43.39
POLY-3 PERCENT (g)	0%	2.3%	4.6%
TERMINAL (d)	0/41 (0%)	1/32 (3%)	1/28 (4%)
FIRST INCIDENCE	---	727 (T)	725

---

**STATISTICAL TESTS**

POLY 3	P=0.096	P=0.414	P=0.145
POLY 1.5	P=0.081	P=0.394	P=0.129
POLY 6	P=0.111	P=0.433	P=0.161
COCH-ARM / FISHERS	P=0.058	P=0.336	P=0.111
MAX-ISO-POLY-3	P=0.066	P=0.110	P=0.040*

---

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Testes: Germinal Epithelium  
Atrophy

---

**LESION RATES**

OVERALL (a)	7/99 (7%)	4/50 (8%)	5/50 (10%)
POLY-3 RATE (b)	7/67.42	4/43.28	5/43.49
POLY-3 PERCENT (g)	10.4%	9.2%	11.5%
TERMINAL (d)	2/41 (5%)	3/32 (9%)	3/28 (11%)
FIRST INCIDENCE	503	672	701

---

**STATISTICAL TESTS**

POLY 3	P=0.502	P=0.553N	P=0.553
POLY 1.5	P=0.443	P=0.611N	P=0.494
POLY 6	P=0.549	P=0.498N	P=0.601
COCH-ARM / FISHERS	P=0.325	P=0.537	P=0.372
MAX-ISO-POLY-3	P=0.546	P=0.422N	P=0.426

---



TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Testes: Interstitial Cell  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	2/99 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	2/67.12	0/43.06	2/44.14
POLY-3 PERCENT (g)	3%	0%	4.5%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	393	---	456

---

**STATISTICAL TESTS**

POLY 3	P=0.458	P=0.336N	P=0.537
POLY 1.5	P=0.433	P=0.359N	P=0.500
POLY 6	P=0.478	P=0.315N	P=0.569
COCH-ARM / FISHERS	P=0.384	P=0.440N	P=0.411
MAX-ISO-POLY-3	P=0.273	P=0.132N	P=0.335

---

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Thyroid Gland: C-Cell  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	52/97 (54%)	34/50 (68%)	28/44 (64%)
POLY-3 RATE (b)	52/76.91	34/44.78	28/41.38
POLY-3 PERCENT (g)	67.6%	75.9%	67.7%
TERMINAL (d)	30/41 (73%)	26/32 (81%)	20/28 (71%)
FIRST INCIDENCE	360	605	455

**STATISTICAL TESTS**

POLY 3	P=0.492	P=0.199	P=0.586
POLY 1.5	P=0.313	P=0.132	P=0.419
POLY 6	P=0.425N	P=0.295	P=0.431N
COCH-ARM / FISHERS	P=0.098	P=0.066	P=0.176
MAX-ISO-POLY-3	P=0.435	P=0.165	P=0.496

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TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Trachea  
Inflammation

---

**LESION RATES**

OVERALL (a)	5/100 (5%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	5/67.91	3/43.70	3/44.79
POLY-3 PERCENT (g)	7.4%	6.9%	6.7%
TERMINAL (d)	1/41 (2%)	1/32 (3%)	0/28 (0%)
FIRST INCIDENCE	377	605	456

.....  
**STATISTICAL TESTS**

POLY 3	P=0.530N	P=0.612N	P=0.597N
POLY 1.5	P=0.579	P=0.637	P=0.649
POLY 6	P=0.485N	P=0.559N	P=0.547N
COCH-ARM / FISHERS	P=0.463	P=0.535	P=0.535
MAX-ISO-POLY-3	P=0.604N	P=0.460N	P=0.445N

.....

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

**Urinary Bladder  
Inflammation**

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**LESION RATES**

OVERALL (a)	2/99 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/66.12	1/43.37	0/43.38
POLY-3 PERCENT (g)	3%	2.3%	0%
TERMINAL (d)	1/41 (2%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	503	644	---

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**STATISTICAL TESTS**

POLY 3	P=0.239N	P=0.649N	P=0.331N
POLY 1.5	P=0.257N	P=0.680N	P=0.354N
POLY 6	P=0.225N	P=0.616N	P=0.311N
COCH-ARM / FISHERS	P=0.297N	P=0.710	P=0.440N
MAX-ISO-POLY-3	P=0.196N	P=0.410N	P=0.127N

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Males		
	75 CHG 0 MG/KG	18.75 MG/KG	37.5 MG/KG

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**Urinary Bladder: Transitional Epithelium  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	0/99 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/65.46	1/43.37	0/43.38
POLY-3 PERCENT (g)	0%	2.3%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	644	---

**STATISTICAL TESTS**

POLY 3	P=0.732	P=0.415	(e)
POLY 1.5	P=0.693	P=0.395	(e)
POLY 6	P=0.758N	P=0.436	(e)
COCH-ARM / FISHERS	P=0.620	P=0.336	(e)
MAX-ISO-POLY-3	P=0.334	P=0.110	(e)

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Adrenal Cortex  
 Degeneration Cystic**

**LESION RATES**

OVERALL (a)	1/50 (2%)	4/50 (8%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	1/42.78	4/45.81	0/47.40	0/22.06
POLY-3 PERCENT (g)	2.3%	8.7%	0%	0%
TERMINAL (d)	1/31 (3%)	4/37 (11%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	---	---

**STATISTICAL TESTS**

POLY 3	P=0.195N	P=0.200	P=0.480N	P=0.620N
POLY 1.5	P=0.160N	P=0.190	P=0.488N	P=0.570N
POLY 6	P=0.237N	P=0.213	P=0.468N	P=0.684N
COCH-ARM / FISHERS	P=0.128N	P=0.181	P=0.500N	P=0.505N
MAX-ISO-POLY-3	P=0.315N	P=0.104	P=0.158N	P=0.302N

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

**Adrenal Cortex  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	10/50 (20%)	7/50 (14%)	6/50 (12%)	14/49 (29%)
POLY-3 RATE (b)	10/43.61	7/46.35	6/47.40	14/28.75
POLY-3 PERCENT (g)	22.9%	15.1%	12.7%	48.7%
TERMINAL (d)	7/31 (23%)	4/37 (11%)	6/38 (16%)	0/0 (0%)
FIRST INCIDENCE	634	652	728 (T)	516

**STATISTICAL TESTS**

POLY 3	P=0.039*	P=0.249N	P=0.156N	P=0.020*
POLY 1.5	P=0.053	P=0.272N	P=0.175N	P=0.067
POLY 6	P=0.042*	P=0.224N	P=0.134N	P=0.003**
COCH-ARM / FISHERS	P=0.116	P=0.298N	P=0.207N	P=0.224
MAX-ISO-POLY-3	P=0.008**	P=0.179N	P=0.107N	P=0.025*

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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**Adrenal Cortex  
 Hypertrophy**

**LESION RATES**

OVERALL (a)	20/50 (40%)	14/50 (28%)	34/50 (68%)	20/49 (41%)
POLY-3 RATE (b)	20/45.53	14/46.08	34/47.86	20/31.63
POLY-3 PERCENT (g)	43.9%	30.4%	71%	63.2%
TERMINAL (d)	10/31 (32%)	12/37 (32%)	30/38 (79%)	0/0 (0%)
FIRST INCIDENCE	538	674	668	470

**STATISTICAL TESTS**

POLY 3	P=0.002**	P=0.128N	P=0.005**	P=0.069
POLY 1.5	P=0.019*	P=0.136N	P=0.004**	P=0.212
POLY 6	P<0.001**	P=0.125N	P=0.006**	P=0.009**
COCH-ARM / FISHERS	P=0.219	P=0.146N	P=0.004**	P=0.548
MAX-ISO-POLY-3	P=0.003**	P=0.089N	P=0.003**	P=0.068

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Adrenal Medulla  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	6/50 (12%)	11/50 (22%)	17/50 (34%)	27/49 (55%)
POLY-3 RATE (b)	6/42.91	11/46.51	17/47.87	27/34.92
POLY-3 PERCENT (g)	14%	23.7%	35.5%	77.3%
TERMINAL (d)	5/31 (16%)	9/37 (24%)	12/38 (32%)	0/0 (0%)
FIRST INCIDENCE	693	561	695	470

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.185	P=0.015*	P<0.001**
POLY 1.5	P<0.001**	P=0.164	P=0.011*	P<0.001**
POLY 6	P<0.001**	P=0.213	P=0.023*	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.143	P=0.008**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.131	P=0.011*	P<0.001**

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

**Blood Vessel  
 Mineralization**

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	20/50 (40%)
POLY-3 RATE (b)	0/42.78	1/45.96	0/47.40	20/31.81
POLY-3 PERCENT (g)	0%	2.2%	0%	62.9%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	689	---	349

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.514	(e)	P<0.001**
POLY 1.5	P<0.001**	P=0.507	(e)	P<0.001**
POLY 6	P<0.001**	P=0.523	(e)	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500	(e)	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.176	(e)	P<0.001**

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Bone Marrow  
 Hemorrhage**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	2/47.50	0/22.19
POLY-3 PERCENT (g)	0%	0%	4.2%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	---	---	702	---

**STATISTICAL TESTS**

POLY 3	P=0.239	(e)	P=0.261	(e)
POLY 1.5	P=0.364	(e)	P=0.251	(e)
POLY 6	P=0.134	(e)	P=0.275	(e)
COCH-ARM / FISHERS	P=0.595	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.386	(e)	P=0.099	(e)

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

**Bone Marrow  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	8/50 (16%)	8/50 (16%)	20/50 (40%)	38/50 (76%)
POLY-3 RATE (b)	8/44.43	8/47.76	20/49.49	38/42.06
POLY-3 PERCENT (g)	18%	16.8%	40.4%	90.4%
TERMINAL (d)	4/31 (13%)	2/37 (5%)	12/38 (32%)	0/0 (0%)
FIRST INCIDENCE	519	561	428	349

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.546N	P=0.014*	P<0.001**
POLY 1.5	P<0.001**	P=0.576N	P=0.010**	P<0.001**
POLY 6	P<0.001**	P=0.508N	P=0.021*	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.607N	P=0.007**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.437N	P=0.011*	P<0.001**

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Bone  
 Fibrous Osteodystrophy**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	27/50 (54%)
POLY-3 RATE (b)	0/42.78	0/45.81	1/47.50	27/34.32
POLY-3 PERCENT (g)	0%	0%	2.1%	78.7%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	702	516

**STATISTICAL TESTS**

POLY 3	P<0.001**	(e)	P=0.521	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.512	P<0.001**
POLY 6	P<0.001**	(e)	P=0.532	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=0.184	P<0.001**

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Brain  
 Hemorrhage**

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/43.06	0/45.81	1/47.52	1/22.67
POLY-3 PERCENT (g)	2.3%	0%	2.1%	4.4%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	650	---	698	586

**STATISTICAL TESTS**

POLY 3	P=0.418	P=0.488N	P=0.738N	P=0.602
POLY 1.5	P=0.433	P=0.494N	P=0.747N	P=0.678
POLY 6	P=0.477	P=0.481N	P=0.726N	P=0.488
COCH-ARM / FISHERS	P=0.539	P=0.500N	P=0.753N	P=0.753N
MAX-ISO-POLY-3	P=0.435	P=0.158N	P=0.472N	P=0.366

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

**Brain  
 Hydrocephalus**

**LESION RATES**

OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/43.75	1/45.81	0/47.40	0/22.19
POLY-3 PERCENT (g)	4.6%	2.2%	0%	0%
TERMINAL (d)	0/31 (0%)	1/37 (3%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	495	728 (T)	---	---

**STATISTICAL TESTS**

POLY 3	P=0.098N	P=0.484N	P=0.220N	P=0.407N
POLY 1.5	P=0.096N	P=0.492N	P=0.227N	P=0.326N
POLY 6	P=0.098N	P=0.474N	P=0.211N	P=0.527N
COCH-ARM / FISHERS	P=0.101N	P=0.500N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.156N	P=0.271N	P=0.076N	P=0.234N

---

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Clitoral Gland  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	3/50 (6%)	1/50 (2%)	0/50 (0%)	1/49 (2%)
POLY-3 RATE (b)	3/43.14	1/45.81	0/47.40	1/22.61
POLY-3 PERCENT (g)	7%	2.2%	0%	4.4%
TERMINAL (d)	1/31 (3%)	1/37 (3%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	634	728 (T)	---	559

**STATISTICAL TESTS**

POLY 3	P=0.173N	P=0.284N	P=0.103N	P=0.549N
POLY 1.5	P=0.193N	P=0.294N	P=0.109N	P=0.440N
POLY 6	P=0.124N	P=0.272N	P=0.095N	P=0.662
COCH-ARM / FISHERS	P=0.204N	P=0.309N	P=0.121N	P=0.316N
MAX-ISO-POLY-3	P=0.278N	P=0.146N	P=0.038N*	P=0.382N



TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Clitoral Gland  
 Inflammation**

**LESION RATES**

OVERALL (a)	6/50 (12%)	7/50 (14%)	1/50 (2%)	3/49 (6%)
POLY-3 RATE (b)	6/43.27	7/45.87	1/47.40	3/23.04
POLY-3 PERCENT (g)	13.9%	15.3%	2.1%	13%
TERMINAL (d)	4/31 (13%)	6/37 (16%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	634	713	728 (T)	580

**STATISTICAL TESTS**

POLY 3	P=0.150N	P=0.545	P=0.043N*	P=0.602N
POLY 1.5	P=0.139N	P=0.523	P=0.048N*	P=0.439N
POLY 6	P=0.116N	P=0.569	P=0.037N*	P=0.431
COCH-ARM / FISHERS	P=0.097N	P=0.500	P=0.056N	P=0.254N
MAX-ISO-POLY-3	P=0.241N	P=0.427	P=0.021N*	P=0.471N

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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**Clitoral Gland: Duct  
 Cyst**

**LESION RATES**

OVERALL (a)	2/50 (4%)	2/50 (4%)	1/50 (2%)	0/49 (0%)
POLY-3 RATE (b)	2/43.12	2/45.87	1/47.40	0/22.06
POLY-3 PERCENT (g)	4.6%	4.4%	2.1%	0%
TERMINAL (d)	1/31 (3%)	1/37 (3%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	634	713	728 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.215N	P=0.672N	P=0.467N	P=0.404N
POLY 1.5	P=0.171N	P=0.682N	P=0.480N	P=0.326N
POLY 6	P=0.275N	P=0.659N	P=0.450N	P=0.523N
COCH-ARM / FISHERS	P=0.128N	P=0.691N	P=0.500N	P=0.253N
MAX-ISO-POLY-3	P=0.348N	P=0.475N	P=0.263N	P=0.231N

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

Eye  
 Cataract

**LESION RATES**

OVERALL (a)	1/50 (2%)	3/50 (6%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/42.78	3/45.86	2/47.40	1/22.44
POLY-3 PERCENT (g)	2.3%	6.5%	4.2%	4.5%
TERMINAL (d)	1/31 (3%)	2/37 (5%)	2/38 (5%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	716	728 (T)	662

**STATISTICAL TESTS**

POLY 3	P=0.466	P=0.331	P=0.536	P=0.601
POLY 1.5	P=0.552	P=0.318	P=0.521	P=0.678
POLY 6	P=0.423	P=0.346	P=0.555	P=0.486
COCH-ARM / FISHERS	P=0.474N	P=0.309	P=0.500	P=0.753N
MAX-ISO-POLY-3	P=0.573	P=0.180	P=0.319	P=0.366

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

Eye  
 Hemorrhage

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40	3/24.03
POLY-3 PERCENT (g)	0%	0%	0%	12.5%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	338

**STATISTICAL TESTS**

POLY 3	P=0.015*	(e)	(e)	P=0.049*
POLY 1.5	P=0.009**	(e)	(e)	P=0.073
POLY 6	P=0.056	(e)	(e)	P=0.029*
COCH-ARM / FISHERS	P=0.012*	(e)	(e)	P=0.121
MAX-ISO-POLY-3	P=0.008**	(e)	(e)	P=0.035*

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Eye  
 Inflammation**

**LESION RATES**

OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	9/50 (18%)
POLY-3 RATE (b)	1/43.37	1/46.10	0/47.40	9/26.96
POLY-3 PERCENT (g)	2.3%	2.2%	0%	33.4%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	538	650	---	338

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.747N	P=0.482N	P<0.001**
POLY 1.5	P<0.001**	P=0.754N	P=0.490N	P=0.002**
POLY 6	P<0.001**	P=0.738N	P=0.473N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.753N	P=0.500N	P=0.008**
MAX-ISO-POLY-3	P<0.001**	P=0.482N	P=0.158N	P<0.001**

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

Eye: Cornea  
 Inflammation

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40	0/22.19
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (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)

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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Eye: Retina  
 Atrophy

**LESION RATES**

OVERALL (a)	2/50 (4%)	4/50 (8%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	2/42.78	4/46.19	3/47.40	2/23.25
POLY-3 PERCENT (g)	4.7%	8.7%	6.3%	8.6%
TERMINAL (d)	2/31 (7%)	2/37 (5%)	3/38 (8%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	637	728 (T)	538

**STATISTICAL TESTS**

POLY 3	P=0.408	P=0.373	P=0.547	P=0.464
POLY 1.5	P=0.498	P=0.356	P=0.527	P=0.569
POLY 6	P=0.375	P=0.395	P=0.572	P=0.323
COCH-ARM / FISHERS	P=0.479N	P=0.339	P=0.500	P=0.691N
MAX-ISO-POLY-3	P=0.544	P=0.237	P=0.372	P=0.319

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

Eye: Retina  
 Dysplasia

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	2/47.45	0/22.19
POLY-3 PERCENT (g)	0%	0%	4.2%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	---	---	716	---

**STATISTICAL TESTS**

POLY 3	P=0.239	(e)	P=0.261	(e)
POLY 1.5	P=0.364	(e)	P=0.251	(e)
POLY 6	P=0.134	(e)	P=0.275	(e)
COCH-ARM / FISHERS	P=0.595	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.386	(e)	P=0.099	(e)



TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Harderian Gland  
 Inflammation**

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	1/45.81	0/47.40	0/22.19
POLY-3 PERCENT (g)	0%	2.2%	0%	0%
TERMINAL (d)	0/31 (0%)	1/37 (3%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	728 (T)	---	---

**STATISTICAL TESTS**

POLY 3	P=0.593N	P=0.514	(e)	(e)
POLY 1.5	P=0.550N	P=0.507	(e)	(e)
POLY 6	P=0.672N	P=0.522	(e)	(e)
COCH-ARM / FISHERS	P=0.567N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.569N	P=0.175	(e)	(e)

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

Harderian Gland: Epithelium  
 Hyperplasia

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	1/47.40	0/22.19
POLY-3 PERCENT (g)	0%	0%	2.1%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	---	---	728 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.407	(e)	P=0.520	(e)
POLY 1.5	P=0.502	(e)	P=0.512	(e)
POLY 6	P=0.328	(e)	P=0.532	(e)
COCH-ARM / FISHERS	P=0.694	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.519	(e)	P=0.183	(e)

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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**Heart  
 Cardiomyopathy**

**LESION RATES**

OVERALL (a)	48/50 (96%)	45/50 (90%)	47/50 (94%)	44/50 (88%)
POLY-3 RATE (b)	48/49.71	45/47.77	47/49.10	44/45.88
POLY-3 PERCENT (g)	96.6%	94.2%	95.7%	95.9%
TERMINAL (d)	30/31 (97%)	37/37 (100%)	37/38 (97%)	0/0 (0%)
FIRST INCIDENCE	309	561	497	338

**STATISTICAL TESTS**

POLY 3	P=0.599N	P=0.468N	P=0.627N	P=0.670N
POLY 1.5	P=0.427N	P=0.387N	P=0.587N	P=0.453N
POLY 6	P=0.478	P=0.623N	P=0.647N	P=0.673
COCH-ARM / FISHERS	P=0.145N	P=0.218N	P=0.500N	P=0.134N
MAX-ISO-POLY-3	P=0.580N	P=0.271N	P=0.409N	P=0.423N

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Heart  
 Inflammation**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	4/50 (8%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40	4/25.20
POLY-3 PERCENT (g)	0%	0%	0%	15.9%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	349

**STATISTICAL TESTS**

POLY 3	P=0.004**	(e)	(e)	P=0.019*
POLY 1.5	P=0.002**	(e)	(e)	P=0.032*
POLY 6	P=0.018*	(e)	(e)	P=0.009**
COCH-ARM / FISHERS	P=0.003**	(e)	(e)	P=0.059
MAX-ISO-POLY-3	P=0.002**	(e)	(e)	P=0.017*

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Heart  
 Mineralization**

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	11/50 (22%)
POLY-3 RATE (b)	0/42.78	1/45.96	1/47.40	11/27.83
POLY-3 PERCENT (g)	0%	2.2%	2.1%	39.5%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	---	689	728 (T)	516

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.514	P=0.520	P<0.001**
POLY 1.5	P<0.001**	P=0.507	P=0.512	P<0.001**
POLY 6	P<0.001**	P=0.523	P=0.532	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500	P=0.500	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.176	P=0.183	P<0.001**

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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Heart: Endocardium  
Bacterium

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**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40	0/22.19
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (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 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Intestine Large, Cecum  
 Inflammation**

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	3/49 (6%)	12/45 (27%)
POLY-3 RATE (b)	0/42.78	1/45.81	3/46.58	12/26.76
POLY-3 PERCENT (g)	0%	2.2%	6.4%	44.8%
TERMINAL (d)	0/31 (0%)	1/37 (3%)	2/38 (5%)	0/0 (0%)
FIRST INCIDENCE	---	728 (T)	708	349

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.514	P=0.135	P<0.001**
POLY 1.5	P<0.001**	P=0.507	P=0.126	P<0.001**
POLY 6	P<0.001**	P=0.522	P=0.147	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500	P=0.117	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.175	P=0.052	P<0.001**

TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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**Intestine Large, Cecum  
Mineralization**

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**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/45 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/46.50	0/20.48
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (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)

---



TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

Intestine Large, Cecum  
 Ulcer

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)	1/45 (2%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/46.50	1/20.90
POLY-3 PERCENT (g)	0%	0%	0%	4.8%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	604

**STATISTICAL TESTS**

POLY 3	P=0.188	(e)	(e)	P=0.370
POLY 1.5	P=0.151	(e)	(e)	P=0.416
POLY 6	P=0.346	(e)	(e)	P=0.311
COCH-ARM / FISHERS	P=0.184	(e)	(e)	P=0.474
MAX-ISO-POLY-3	P=0.110	(e)	(e)	P=0.149

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

**Intestine Large, Colon  
 Parasite Metazoan**

**LESION RATES**

OVERALL (a)	3/50 (6%)	2/50 (4%)	0/49 (0%)	0/45 (0%)
POLY-3 RATE (b)	3/42.78	2/45.81	0/46.50	0/20.48
POLY-3 PERCENT (g)	7%	4.4%	0%	0%
TERMINAL (d)	3/31 (10%)	2/37 (5%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	---	---

**STATISTICAL TESTS**

POLY 3	P=0.047N*	P=0.469N	P=0.104N	P=0.296N
POLY 1.5	P=0.046N*	P=0.484N	P=0.112N	P=0.216N
POLY 6	P=0.045N*	P=0.451N	P=0.095N	P=0.433N
COCH-ARM / FISHERS	P=0.045N*	P=0.500N	P=0.125N	P=0.142N
MAX-ISO-POLY-3	P=0.073N	P=0.302N	P=0.038N*	P=0.191N

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

**Intestine Large, Rectum  
 Parasite Metazoan**

**LESION RATES**

OVERALL (a)	4/50 (8%)	6/50 (12%)	7/50 (14%)	1/49 (2%)
POLY-3 RATE (b)	4/42.98	6/46.25	7/47.40	1/22.95
POLY-3 PERCENT (g)	9.3%	13%	14.8%	4.4%
TERMINAL (d)	3/31 (10%)	5/37 (14%)	7/38 (18%)	0/0 (0%)
FIRST INCIDENCE	674	600	728 (T)	352

**STATISTICAL TESTS**

POLY 3	P=0.532N	P=0.416	P=0.320	P=0.415N
POLY 1.5	P=0.341N	P=0.394	P=0.295	P=0.299N
POLY 6	P=0.377	P=0.443	P=0.353	P=0.596N
COCH-ARM / FISHERS	P=0.146N	P=0.370	P=0.262	P=0.187N
MAX-ISO-POLY-3	P=0.409N	P=0.299	P=0.226	P=0.298N

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

Intestine Small, Duodenum  
 Erosion

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/45 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/46.50	0/20.48
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (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)

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Kidney  
 Cyst**

**LESION RATES**

OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	2/49 (4%)
POLY-3 RATE (b)	2/43.70	0/45.81	0/47.40	2/22.86
POLY-3 PERCENT (g)	4.6%	0%	0%	8.8%
TERMINAL (d)	1/31 (3%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	309	---	---	611

**STATISTICAL TESTS**

POLY 3	P=0.540	P=0.227N	P=0.220N	P=0.451
POLY 1.5	P=0.473	P=0.233N	P=0.228N	P=0.557
POLY 6	P=0.517N	P=0.219N	P=0.209N	P=0.312
COCH-ARM / FISHERS	P=0.494	P=0.247N	P=0.247N	P=0.684
MAX-ISO-POLY-3	P=0.180	P=0.076N	P=0.076N	P=0.311

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

**Kidney  
 Glomerulopathy Hyaline**

**LESION RATES**

OVERALL (a)	0/50 (0%)	17/50 (34%)	49/50 (98%)	48/49 (98%)
POLY-3 RATE (b)	0/42.78	17/46.95	49/49.20	48/48.00
POLY-3 PERCENT (g)	0%	36.2%	99.6%	100%
TERMINAL (d)	0/31 (0%)	12/37 (32%)	38/38 (100%)	0/0 (0%)
FIRST INCIDENCE	---	561	497	338

**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 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Kidney  
 Inflammation**

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	2/49 (4%)
POLY-3 RATE (b)	0/42.78	1/45.81	1/47.40	2/22.90
POLY-3 PERCENT (g)	0%	2.2%	2.1%	8.7%
TERMINAL (d)	0/31 (0%)	1/37 (3%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	---	728 (T)	728 (T)	537

**STATISTICAL TESTS**

POLY 3	P=0.088	P=0.514	P=0.520	P=0.132
POLY 1.5	P=0.095	P=0.507	P=0.512	P=0.170
POLY 6	P=0.124	P=0.522	P=0.532	P=0.093
COCH-ARM / FISHERS	P=0.148	P=0.500	P=0.500	P=0.242
MAX-ISO-POLY-3	P=0.117	P=0.175	P=0.183	P=0.072

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Kidney  
 Nephropathy**

**LESION RATES**

OVERALL (a)	42/50 (84%)	44/50 (88%)	49/50 (98%)	48/49 (98%)
POLY-3 RATE (b)	42/47.79	44/47.90	49/49.20	48/48.00
POLY-3 PERCENT (g)	87.9%	91.9%	99.6%	100%
TERMINAL (d)	30/31 (97%)	36/37 (97%)	38/38 (100%)	0/0 (0%)
FIRST INCIDENCE	309	561	497	338

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.367	P=0.010**	P=0.008**
POLY 1.5	P<0.001**	P=0.331	P=0.010**	P=0.006**
POLY 6	P=0.002**	P=0.453	P=0.016*	P=0.016*
COCH-ARM / FISHERS	P=0.004**	P=0.387	P=0.015*	P=0.017*
MAX-ISO-POLY-3	P=0.002**	P=0.238	P=0.002**	P=0.002**



TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

**Kidney: Cortex  
 Mineralization**

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	26/49 (53%)
POLY-3 RATE (b)	0/42.78	1/45.96	1/47.40	26/34.81
POLY-3 PERCENT (g)	0%	2.2%	2.1%	74.7%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	---	689	728 (T)	390

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.514	P=0.520	P<0.001**
POLY 1.5	P<0.001**	P=0.507	P=0.512	P<0.001**
POLY 6	P<0.001**	P=0.523	P=0.532	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500	P=0.500	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.176	P=0.183	P<0.001**

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Kidney: Renal Tubule  
 Degeneration**

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/42.78	2/45.96	0/47.40	0/22.06
POLY-3 PERCENT (g)	0%	4.4%	0%	0%
TERMINAL (d)	0/31 (0%)	1/37 (3%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	689	---	---

**STATISTICAL TESTS**

POLY 3	P=0.483N	P=0.253	(e)	(e)
POLY 1.5	P=0.432N	P=0.246	(e)	(e)
POLY 6	P=0.562N	P=0.263	(e)	(e)
COCH-ARM / FISHERS	P=0.409N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.489N	P=0.092	(e)	(e)

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

Liver  
 Angiectasis

**LESION RATES**

OVERALL (a)	0/50 (0%)	5/50 (10%)	0/50 (0%)	0/47 (0%)
POLY-3 RATE (b)	0/42.78	5/45.81	0/47.40	0/21.28
POLY-3 PERCENT (g)	0%	10.9%	0%	0%
TERMINAL (d)	0/31 (0%)	5/37 (14%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	728 (T)	---	---

**STATISTICAL TESTS**

POLY 3	P=0.336N	P=0.037*	(e)	(e)
POLY 1.5	P=0.270N	P=0.034*	(e)	(e)
POLY 6	P=0.419N	P=0.040*	(e)	(e)
COCH-ARM / FISHERS	P=0.212N	P=0.028*	(e)	(e)
MAX-ISO-POLY-3	P=0.337N	P=0.014*	(e)	(e)

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

Liver  
 Basophilic Focus

**LESION RATES**

OVERALL (a)	44/50 (88%)	21/50 (42%)	3/50 (6%)	2/47 (4%)
POLY-3 RATE (b)	44/47.23	21/46.81	3/47.40	2/22.31
POLY-3 PERCENT (g)	93.2%	44.9%	6.3%	9%
TERMINAL (d)	29/31 (94%)	18/37 (49%)	3/38 (8%)	0/0 (0%)
FIRST INCIDENCE	519	573	728 (T)	559

**STATISTICAL TESTS**

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

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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Liver  
 Clear Cell Focus

**LESION RATES**

OVERALL (a)	8/50 (16%)	12/50 (24%)	4/50 (8%)	1/47 (2%)
POLY-3 RATE (b)	8/44.29	12/45.81	4/47.40	1/22.01
POLY-3 PERCENT (g)	18.1%	26.2%	8.4%	4.5%
TERMINAL (d)	5/31 (16%)	12/37 (32%)	4/38 (11%)	0/0 (0%)
FIRST INCIDENCE	538	728 (T)	728 (T)	470

**STATISTICAL TESTS**

POLY 3	P=0.037N*	P=0.250	P=0.145N	P=0.150N
POLY 1.5	P=0.017N*	P=0.237	P=0.158N	P=0.067N
POLY 6	P=0.067N	P=0.263	P=0.130N	P=0.357N
COCH-ARM / FISHERS	P=0.004N**	P=0.227	P=0.178N	P=0.019N*
MAX-ISO-POLY-3	P=0.057N	P=0.180	P=0.093N	P=0.135N

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TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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Liver  
Eosinophilic Focus

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**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/47 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40	0/21.28
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (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 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

Liver  
 Fatty Change

**LESION RATES**

OVERALL (a)	7/50 (14%)	25/50 (50%)	35/50 (70%)	11/47 (23%)
POLY-3 RATE (b)	7/44.63	25/47.36	35/48.60	11/26.60
POLY-3 PERCENT (g)	15.7%	52.8%	72%	41.4%
TERMINAL (d)	4/31 (13%)	20/37 (54%)	30/38 (79%)	0/0 (0%)
FIRST INCIDENCE	495	85	497	470

**STATISTICAL TESTS**

POLY 3	P<0.001**	P<0.001**	P<0.001**	P=0.018*
POLY 1.5	P=0.009**	P<0.001**	P<0.001**	P=0.054
POLY 6	P<0.001**	P<0.001**	P<0.001**	P=0.003**
COCH-ARM / FISHERS	P=0.339	P<0.001**	P<0.001**	P=0.176
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	P=0.024*

---

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

Liver  
 Hepatodiaphragmatic Nodule

**LESION RATES**

OVERALL (a)	3/50 (6%)	6/50 (12%)	7/50 (14%)	2/47 (4%)
POLY-3 RATE (b)	3/42.78	6/46.32	7/47.53	2/22.67
POLY-3 PERCENT (g)	7%	13%	14.7%	8.8%
TERMINAL (d)	3/31 (10%)	5/37 (14%)	6/38 (16%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	573	695	19

**STATISTICAL TESTS**

POLY 3	P=0.322	P=0.283	P=0.204	P=0.582
POLY 1.5	P=0.495	P=0.263	P=0.184	P=0.658N
POLY 6	P=0.194	P=0.307	P=0.232	P=0.413
COCH-ARM / FISHERS	P=0.375N	P=0.243	P=0.159	P=0.530N
MAX-ISO-POLY-3	P=0.502	P=0.187	P=0.134	P=0.421

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

**Liver  
 Inflammation**

**LESION RATES**

OVERALL (a)	35/50 (70%)	31/50 (62%)	37/50 (74%)	33/47 (70%)
POLY-3 RATE (b)	35/46.42	31/46.45	37/48.60	33/39.00
POLY-3 PERCENT (g)	75.4%	66.7%	76.1%	84.6%
TERMINAL (d)	26/31 (84%)	28/37 (76%)	32/38 (84%)	0/0 (0%)
FIRST INCIDENCE	309	652	497	338

**STATISTICAL TESTS**

POLY 3	P=0.104	P=0.235N	P=0.564	P=0.191
POLY 1.5	P=0.171	P=0.265N	P=0.490	P=0.310
POLY 6	P=0.062	P=0.194N	P=0.528N	P=0.094
COCH-ARM / FISHERS	P=0.390	P=0.263N	P=0.412	P=0.579
MAX-ISO-POLY-3	P=0.126	P=0.168N	P=0.465	P=0.135

---

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

Liver  
 Mixed Cell Focus

**LESION RATES**

OVERALL (a)	5/50 (10%)	0/50 (0%)	4/50 (8%)	0/47 (0%)
POLY-3 RATE (b)	5/43.01	0/45.81	4/47.40	0/21.28
POLY-3 PERCENT (g)	11.6%	0%	8.4%	0%
TERMINAL (d)	3/31 (10%)	0/37 (0%)	4/38 (11%)	0/0 (0%)
FIRST INCIDENCE	674	---	728 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.189N	P=0.025N*	P=0.439N	P=0.149N
POLY 1.5	P=0.122N	P=0.028N*	P=0.464N	P=0.082N
POLY 6	P=0.290N	P=0.023N*	P=0.408N	P=0.303N
COCH-ARM / FISHERS	P=0.067N	P=0.028N*	P=0.500N	P=0.033N*
MAX-ISO-POLY-3	P=0.169N	P=0.009N**	P=0.316N	P=0.118N

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

Liver: Bile Duct  
 Cyst

**LESION RATES**

OVERALL (a)	1/50 (2%)	6/50 (12%)	38/50 (76%)	13/47 (28%)
POLY-3 RATE (b)	1/42.78	6/45.81	38/48.80	13/27.52
POLY-3 PERCENT (g)	2.3%	13.1%	77.9%	47.2%
TERMINAL (d)	1/31 (3%)	6/37 (16%)	31/38 (82%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	497	338

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.067	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.062	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.075	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.056	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.033*	P<0.001**	P<0.001**

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

Liver: Bile Duct  
 Hyperplasia

**LESION RATES**

OVERALL (a)	5/50 (10%)	4/50 (8%)	49/50 (98%)	43/47 (91%)
POLY-3 RATE (b)	5/42.91	4/45.96	49/49.20	43/44.19
POLY-3 PERCENT (g)	11.7%	8.7%	99.6%	97.3%
TERMINAL (d)	4/31 (13%)	3/37 (8%)	38/38 (100%)	0/0 (0%)
FIRST INCIDENCE	693	689	497	338

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.457N	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.478N	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.432N	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500N	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.329N	P<0.001**	P<0.001**

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

Liver: Hepatocyte  
 Cellular Alteration Diffuse

**LESION RATES**

OVERALL (a)	0/50 (0%)	4/50 (8%)	45/50 (90%)	43/47 (91%)
POLY-3 RATE (b)	0/42.78	4/47.03	45/48.52	43/44.91
POLY-3 PERCENT (g)	0%	8.5%	92.7%	95.8%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	35/38 (92%)	0/0 (0%)
FIRST INCIDENCE	---	561	668	338

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.073	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.067	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.082	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.059	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.030*	P<0.001**	P<0.001**

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

Liver: Hepatocyte  
 Degeneration Cystic

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/47 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40	0/21.28
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (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 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

Liver: Hepatocyte  
 Necrosis

**LESION RATES**

OVERALL (a)	4/50 (8%)	2/50 (4%)	20/50 (40%)	15/47 (32%)
POLY-3 RATE (b)	4/43.57	2/46.10	20/47.58	15/29.19
POLY-3 PERCENT (g)	9.2%	4.3%	42%	51.4%
TERMINAL (d)	2/31 (7%)	1/37 (3%)	18/38 (47%)	0/0 (0%)
FIRST INCIDENCE	519	650	702	349

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.311N	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.324N	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.296N	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.339N	P<0.001**	P=0.003**
MAX-ISO-POLY-3	P<0.001**	P=0.187N	P<0.001**	P<0.001**

---

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

Liver: Hepatocyte, Centrilobular  
 Degeneration

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/47 (0%)
POLY-3 RATE (b)	0/42.78	1/46.10	0/47.40	0/21.28
POLY-3 PERCENT (g)	0%	2.2%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	650	---	---

**STATISTICAL TESTS**

POLY 3	P=0.594N	P=0.515	(e)	(e)
POLY 1.5	P=0.556N	P=0.508	(e)	(e)
POLY 6	P=0.670N	P=0.524	(e)	(e)
COCH-ARM / FISHERS	P=0.577N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.574N	P=0.177	(e)	(e)



TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

Liver: Oval Cell  
 Hyperplasia

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	45/50 (90%)	43/47 (91%)
POLY-3 RATE (b)	0/42.78	0/45.81	45/48.30	43/44.19
POLY-3 PERCENT (g)	0%	0%	93.2%	97.3%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	37/38 (97%)	0/0 (0%)
FIRST INCIDENCE	---	---	668	338

**STATISTICAL TESTS**

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

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

Liver: Portal  
 Fibrosis

**LESION RATES**

OVERALL (a)	0/50 (0%)	3/50 (6%)	28/50 (56%)	35/47 (74%)
POLY-3 RATE (b)	0/42.78	3/45.81	28/47.73	35/40.32
POLY-3 PERCENT (g)	0%	6.6%	58.7%	86.8%
TERMINAL (d)	0/31 (0%)	3/37 (8%)	26/38 (68%)	0/0 (0%)
FIRST INCIDENCE	---	728 (T)	668	338

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.131	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.125	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.139	P<0.001**	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=0.049*	P<0.001**	P<0.001**

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

Liver: Serosa  
 Hemorrhage

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	3/50 (6%)	0/47 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	3/47.40	0/21.28
POLY-3 PERCENT (g)	0%	0%	6.3%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	3/38 (8%)	0/0 (0%)
FIRST INCIDENCE	---	---	728 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.149	(e)	P=0.138	(e)
POLY 1.5	P=0.275	(e)	P=0.130	(e)
POLY 6	P=0.060	(e)	P=0.150	(e)
COCH-ARM / FISHERS	P=0.523	(e)	P=0.121	(e)
MAX-ISO-POLY-3	P=0.240	(e)	P=0.054	(e)

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

Lung  
 Congestion

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	1/47.48	0/22.19
POLY-3 PERCENT (g)	0%	0%	2.1%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	708	---

**STATISTICAL TESTS**

POLY 3	P=0.407	(e)	P=0.521	(e)
POLY 1.5	P=0.502	(e)	P=0.512	(e)
POLY 6	P=0.329	(e)	P=0.532	(e)
COCH-ARM / FISHERS	P=0.694	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.519	(e)	P=0.184	(e)

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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Lung  
 Hemorrhage

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	12/50 (24%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40	12/29.80
POLY-3 PERCENT (g)	0%	0%	0%	40.3%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	349

**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**

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Lung  
 Inflammation**

**LESION RATES**

OVERALL (a)	1/50 (2%)	3/50 (6%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/43.20	3/45.81	0/47.40	1/23.06
POLY-3 PERCENT (g)	2.3%	6.6%	0%	4.3%
TERMINAL (d)	0/31 (0%)	3/37 (8%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	607	728 (T)	---	369

**STATISTICAL TESTS**

POLY 3	P=0.459N	P=0.327	P=0.481N	P=0.606
POLY 1.5	P=0.443N	P=0.316	P=0.489N	P=0.680
POLY 6	P=0.443N	P=0.339	P=0.472N	P=0.491
COCH-ARM / FISHERS	P=0.409N	P=0.309	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.516N	P=0.176	P=0.158N	P=0.368

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Lung: Alveolar Epithelium  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	8/50 (16%)	14/50 (28%)	10/50 (20%)	12/50 (24%)
POLY-3 RATE (b)	8/44.82	14/45.92	10/47.50	12/28.82
POLY-3 PERCENT (g)	17.9%	30.5%	21.1%	41.6%
TERMINAL (d)	4/31 (13%)	13/37 (35%)	9/38 (24%)	0/0 (0%)
FIRST INCIDENCE	309	701	702	338

**STATISTICAL TESTS**

POLY 3	P=0.065	P=0.121	P=0.450	P=0.025*
POLY 1.5	P=0.126	P=0.114	P=0.426	P=0.075
POLY 6	P=0.040*	P=0.130	P=0.485	P=0.004**
COCH-ARM / FISHERS	P=0.322	P=0.114	P=0.398	P=0.227
MAX-ISO-POLY-3	P=0.064	P=0.081	P=0.352	P=0.030*

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

Lung: Alveolus  
 Inflammation Histiocytic

**LESION RATES**

OVERALL (a)	40/50 (80%)	44/50 (88%)	49/50 (98%)	43/50 (86%)
POLY-3 RATE (b)	40/47.23	44/47.34	49/49.20	43/44.56
POLY-3 PERCENT (g)	84.7%	93%	99.6%	96.5%
TERMINAL (d)	26/31 (84%)	36/37 (97%)	38/38 (100%)	0/0 (0%)
FIRST INCIDENCE	495	600	497	338

**STATISTICAL TESTS**

POLY 3	P=0.007**	P=0.151	P=0.004**	P=0.037*
POLY 1.5	P=0.027*	P=0.158	P=0.003**	P=0.080
POLY 6	P=0.003**	P=0.131	P=0.007**	P=0.022*
COCH-ARM / FISHERS	P=0.231	P=0.207	P=0.004**	P=0.298
MAX-ISO-POLY-3	P=0.003**	P=0.082	P<0.001**	P=0.017*



TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Lung: Arteriole  
 Inflammation**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40	2/23.45
POLY-3 PERCENT (g)	0%	0%	0%	8.5%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	523

**STATISTICAL TESTS**

POLY 3	P=0.053	(e)	(e)	P=0.135
POLY 1.5	P=0.038*	(e)	(e)	P=0.173
POLY 6	P=0.143	(e)	(e)	P=0.096
COCH-ARM / FISHERS	P=0.046*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.032*	(e)	(e)	P=0.073

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

Lung: Interstitium  
 Mineralization

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	16/50 (32%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40	16/29.86
POLY-3 PERCENT (g)	0%	0%	0%	53.6%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	516

**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 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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Lung: Serosa  
Hyperplasia

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**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40	0/22.19
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (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)

.....

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Lymph Node, Mesenteric  
 Fibrosis**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/45 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40	0/20.48
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (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)

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Lymph Node, Mesenteric  
 Hemorrhage**

**LESION RATES**

OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)	18/45 (40%)
POLY-3 RATE (b)	2/43.27	0/45.81	1/47.40	18/29.90
POLY-3 PERCENT (g)	4.6%	0%	2.1%	60.2%
TERMINAL (d)	1/31 (3%)	0/37 (0%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	581	---	728 (T)	349

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.225N	P=0.468N	P<0.001**
POLY 1.5	P<0.001**	P=0.231N	P=0.481N	P<0.001**
POLY 6	P<0.001**	P=0.218N	P=0.451N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.247N	P=0.500N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.076N	P=0.263N	P<0.001**

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Lymph Node, Mesenteric  
 Inflammation**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/45 (4%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40	2/21.45
POLY-3 PERCENT (g)	0%	0%	0%	9.3%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	537

**STATISTICAL TESTS**

POLY 3	P=0.047*	(e)	(e)	P=0.122
POLY 1.5	P=0.033*	(e)	(e)	P=0.156
POLY 6	P=0.133	(e)	(e)	P=0.087
COCH-ARM / FISHERS	P=0.038*	(e)	(e)	P=0.222
MAX-ISO-POLY-3	P=0.025*	(e)	(e)	P=0.067

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

Lymph Node: Deep Cervical  
 Hemorrhage

**LESION RATES**

OVERALL (a)	0/2 (0%)	1/3 (33%)	0/5 (0%)	3/11 (27%)
POLY-3 RATE (b)	0/2.00	1/2.13	0/4.88	3/6.91
POLY-3 PERCENT (g)	0%	47%	0%	43.4%
TERMINAL (d)	0/2 (0%)	1/1 (100%)	0/4 (0%)	0/0 (0%)
FIRST INCIDENCE	---	728 (T)	---	352

**STATISTICAL TESTS**

POLY 3	P=0.174	P=0.513	(e)	P=0.362
POLY 1.5	P=0.242	P=0.545	(e)	P=0.448
POLY 6	P=0.131	P=0.458	(e)	P=0.202
COCH-ARM / FISHERS	P=0.331	P=0.600	(e)	P=0.577
MAX-ISO-POLY-3	P=0.181	P=0.167	(e)	P=0.121

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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**Lymph Node: Mediastinal  
 Degeneration Cystic**

**LESION RATES**

OVERALL (a)	1/2 (50%)	0/3 (0%)	1/5 (20%)	0/11 (0%)
POLY-3 RATE (b)	1/2.00	0/2.13	1/4.88	0/5.12
POLY-3 PERCENT (g)	50%	0%	20.5%	0%
TERMINAL (d)	1/2 (50%)	0/1 (0%)	1/4 (25%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	---	728 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.155N	P=0.487N	P=0.553N	P=0.229N
POLY 1.5	P=0.109N	P=0.451N	P=0.550N	P=0.155N
POLY 6	P=0.280N	P=0.539N	P=0.559N	P=0.418N
COCH-ARM / FISHERS	P=0.107N	P=0.400N	P=0.524N	P=0.154N
MAX-ISO-POLY-3	P=0.055N	P=0.145N	P=0.281N	P=0.010N**

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

**Lymph Node: Mediastinal  
 Hemorrhage**

**LESION RATES**

OVERALL (a)	0/2 (0%)	0/3 (0%)	0/5 (0%)	2/11 (18%)
POLY-3 RATE (b)	0/2.00	0/2.13	0/4.88	2/5.94
POLY-3 PERCENT (g)	0%	0%	0%	33.7%
TERMINAL (d)	0/2 (0%)	0/1 (0%)	0/4 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	604

**STATISTICAL TESTS**

POLY 3	P=0.148	(e)	(e)	P=0.497
POLY 1.5	P=0.167	(e)	(e)	P=0.578
POLY 6	P=0.180	(e)	(e)	P=0.344
COCH-ARM / FISHERS	P=0.211	(e)	(e)	P=0.705
MAX-ISO-POLY-3	P=0.193	(e)	(e)	P=0.156

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Lymph Node: Mediastinal  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	0/2 (0%)	0/3 (0%)	2/5 (40%)	0/11 (0%)
POLY-3 RATE (b)	0/2.00	0/2.13	2/4.88	0/5.12
POLY-3 PERCENT (g)	0%	0%	41%	0%
TERMINAL (d)	0/2 (0%)	0/1 (0%)	2/4 (50%)	0/0 (0%)
FIRST INCIDENCE	---	---	728 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.667	(e)	P=0.444	(e)
POLY 1.5	P=0.550N	(e)	P=0.448	(e)
POLY 6	P=0.394	(e)	P=0.437	(e)
COCH-ARM / FISHERS	P=0.413N	(e)	P=0.476	(e)
MAX-ISO-POLY-3	P=0.326N	(e)	P=0.199	(e)

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

Lymph Node: Pancreatic  
 Hemorrhage

**LESION RATES**

OVERALL (a)	0/2 (0%)	0/3 (0%)	0/5 (0%)	3/11 (27%)
POLY-3 RATE (b)	0/2.00	0/2.13	0/4.88	3/6.54
POLY-3 PERCENT (g)	0%	0%	0%	45.9%
TERMINAL (d)	0/2 (0%)	0/1 (0%)	0/4 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	559

**STATISTICAL TESTS**

POLY 3	P=0.054	(e)	(e)	P=0.337
POLY 1.5	P=0.073	(e)	(e)	P=0.432
POLY 6	P=0.052	(e)	(e)	P=0.182
COCH-ARM / FISHERS	P=0.110	(e)	(e)	P=0.577
MAX-ISO-POLY-3	P=0.084	(e)	(e)	P=0.102

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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**Mammary Gland  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/42.78	2/45.81	0/47.40	0/21.84
POLY-3 PERCENT (g)	0%	4.4%	0%	0%
TERMINAL (d)	0/31 (0%)	2/37 (5%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	728 (T)	---	---

**STATISTICAL TESTS**

POLY 3	P=0.485N	P=0.253	(e)	(e)
POLY 1.5	P=0.432N	P=0.245	(e)	(e)
POLY 6	P=0.564N	P=0.262	(e)	(e)
COCH-ARM / FISHERS	P=0.409N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.492N	P=0.091	(e)	(e)

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Mammary Gland: Duct  
 Dilatation**

**LESION RATES**

OVERALL (a)	2/50 (4%)	4/50 (8%)	1/50 (2%)	0/49 (0%)
POLY-3 RATE (b)	2/43.27	4/45.81	1/47.40	0/21.84
POLY-3 PERCENT (g)	4.6%	8.7%	2.1%	0%
TERMINAL (d)	0/31 (0%)	4/37 (11%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	634	728 (T)	728 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.188N	P=0.364	P=0.468N	P=0.408N
POLY 1.5	P=0.137N	P=0.351	P=0.481N	P=0.328N
POLY 6	P=0.254N	P=0.378	P=0.452N	P=0.526N
COCH-ARM / FISHERS	P=0.089N	P=0.339	P=0.500N	P=0.253N
MAX-ISO-POLY-3	P=0.303N	P=0.228	P=0.263N	P=0.234N

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

**Mesentery  
 Necrosis**

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**LESION RATES**

OVERALL (a)	5/6 (83%)	12/12 (100%)	5/5 (100%)	1/1 (100%)
POLY-3 RATE (b)	5/5.51	12/12.00	5/5.00	1/1.00
POLY-3 PERCENT (g)	90.8%	100%	100%	100%
TERMINAL (d)	4/4 (100%)	10/10 (100%)	4/4 (100%)	0/0 (0%)
FIRST INCIDENCE	674	600	702	352

**STATISTICAL TESTS**

POLY 3	P=0.850	P=0.737	P=0.833	P=0.979
POLY 1.5	P=0.649	P=0.520	P=0.675	P=0.919
POLY 6	P=0.999	P=0.995	P=0.996	P=1.000
COCH-ARM / FISHERS	P=0.463	P=0.333	P=0.545	P=0.857
MAX-ISO-POLY-3	P=0.432	P=0.109	P=0.184	P=0.383

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Nose  
 Inflammation**

**LESION RATES**

OVERALL (a)	12/50 (24%)	22/50 (44%)	39/50 (78%)	26/41 (63%)
POLY-3 RATE (b)	12/43.68	22/46.67	39/49.07	26/32.12
POLY-3 PERCENT (g)	27.5%	47.1%	79.5%	81%
TERMINAL (d)	9/31 (29%)	17/37 (46%)	29/38 (76%)	0/0 (0%)
FIRST INCIDENCE	581	637	497	19

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.040*	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.032*	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.052	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.028*	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.028*	P<0.001**	P<0.001**

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Nose  
 Thrombosis**

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	2/41 (5%)
POLY-3 RATE (b)	0/42.78	1/46.14	2/47.50	2/19.34
POLY-3 PERCENT (g)	0%	2.2%	4.2%	10.3%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	---	637	702	524

**STATISTICAL TESTS**

POLY 3	P=0.050*	P=0.515	P=0.261	P=0.108
POLY 1.5	P=0.062	P=0.508	P=0.251	P=0.139
POLY 6	P=0.060	P=0.524	P=0.275	P=0.077
COCH-ARM / FISHERS	P=0.115	P=0.500	P=0.247	P=0.200
MAX-ISO-POLY-3	P=0.078	P=0.177	P=0.099	P=0.062



TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

Nose: Glands  
 Dilatation

**LESION RATES**

OVERALL (a)	0/50 (0%)	6/50 (12%)	6/50 (12%)	2/41 (5%)
POLY-3 RATE (b)	0/42.78	6/45.81	6/47.58	2/19.17
POLY-3 PERCENT (g)	0%	13.1%	12.6%	10.4%
TERMINAL (d)	0/31 (0%)	6/37 (16%)	4/38 (11%)	0/0 (0%)
FIRST INCIDENCE	---	728 (T)	702	594

**STATISTICAL TESTS**

POLY 3	P=0.065	P=0.019*	P=0.022*	P=0.107
POLY 1.5	P=0.135	P=0.017*	P=0.019*	P=0.138
POLY 6	P=0.031*	P=0.021*	P=0.026*	P=0.077
COCH-ARM / FISHERS	P=0.350	P=0.013*	P=0.013*	P=0.200
MAX-ISO-POLY-3	P=0.101	P=0.008**	P=0.010**	P=0.062

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TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

Nose: Goblet Cell  
Hyperplasia

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**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/41 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40	0/18.48
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (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 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Nose: Olfactory Epithelium  
 Degeneration**

**LESION RATES**

OVERALL (a)	2/50 (4%)	40/50 (80%)	48/50 (96%)	37/41 (90%)
POLY-3 RATE (b)	2/43.06	40/48.29	48/49.10	37/38.40
POLY-3 PERCENT (g)	4.6%	82.8%	97.8%	96.4%
TERMINAL (d)	1/31 (3%)	31/37 (84%)	38/38 (100%)	0/0 (0%)
FIRST INCIDENCE	650	561	497	19

**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 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

**Nose: Olfactory Epithelium  
 Metaplasia Respiratory**

**LESION RATES**

OVERALL (a)	1/50 (2%)	8/50 (16%)	46/50 (92%)	36/41 (88%)
POLY-3 RATE (b)	1/42.78	8/45.81	46/48.19	36/37.40
POLY-3 PERCENT (g)	2.3%	17.5%	95.5%	96.3%
TERMINAL (d)	1/31 (3%)	8/37 (22%)	38/38 (100%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	695	338

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.020*	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.018*	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.024*	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.015*	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.010**	P<0.001**	P<0.001**

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TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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**Oral Mucosa: Pharyngeal  
Hyperplasia**

---

**LESION RATES**

OVERALL (a)	1/1 (100%)	0/0 (0%)	0/0 (0%)	2/2 (100%)
POLY-3 RATE (b)	1/1.00	0/0.00	0/0.00	2/2.00
POLY-3 PERCENT (g)	100%	0%	0%	100%
TERMINAL (d)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	---	---	604

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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 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

**Ovary  
 Atrophy**

**LESION RATES**

OVERALL (a)	5/50 (10%)	5/50 (10%)	4/49 (8%)	16/46 (35%)
POLY-3 RATE (b)	5/44.42	5/46.43	4/46.74	16/28.43
POLY-3 PERCENT (g)	11.3%	10.8%	8.6%	56.3%
TERMINAL (d)	2/31 (7%)	3/37 (8%)	2/38 (5%)	0/0 (0%)
FIRST INCIDENCE	495	637	695	468

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.602N	P=0.468N	P<0.001**
POLY 1.5	P<0.001**	P=0.617N	P=0.487N	P<0.001**
POLY 6	P<0.001**	P=0.583N	P=0.441N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.630N	P=0.513N	P=0.003**
MAX-ISO-POLY-3	P<0.001**	P=0.470N	P=0.338N	P<0.001**

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

Ovary  
 Cyst

**LESION RATES**

OVERALL (a)	6/50 (12%)	4/50 (8%)	5/49 (10%)	5/46 (11%)
POLY-3 RATE (b)	6/43.19	4/45.86	5/46.88	5/23.82
POLY-3 PERCENT (g)	13.9%	8.7%	10.7%	21%
TERMINAL (d)	4/31 (13%)	3/37 (8%)	2/38 (5%)	0/0 (0%)
FIRST INCIDENCE	674	716	668	468

**STATISTICAL TESTS**

POLY 3	P=0.344	P=0.332N	P=0.443N	P=0.351
POLY 1.5	P=0.406	P=0.350N	P=0.472N	P=0.500
POLY 6	P=0.357	P=0.312N	P=0.404N	P=0.175
COCH-ARM / FISHERS	P=0.561N	P=0.370N	P=0.514N	P=0.559N
MAX-ISO-POLY-3	P=0.331	P=0.228N	P=0.328N	P=0.283

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Pancreas  
 Inflammation**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/49 (4%)	0/46 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	2/46.50	0/20.85
POLY-3 PERCENT (g)	0%	0%	4.3%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	2/38 (5%)	0/0 (0%)
FIRST INCIDENCE	---	---	728 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.233	(e)	P=0.256	(e)
POLY 1.5	P=0.353	(e)	P=0.246	(e)
POLY 6	P=0.133	(e)	P=0.270	(e)
COCH-ARM / FISHERS	P=0.578	(e)	P=0.242	(e)
MAX-ISO-POLY-3	P=0.377	(e)	P=0.095	(e)



TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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Pancreas: Acinus  
Atrophy

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**LESION RATES**

OVERALL (a)	11/50 (22%)	12/50 (24%)	15/49 (31%)	17/46 (37%)
POLY-3 RATE (b)	11/45.56	12/46.34	15/46.83	17/29.33
POLY-3 PERCENT (g)	24.2%	25.9%	32%	58%
TERMINAL (d)	5/31 (16%)	8/37 (22%)	13/38 (34%)	0/0 (0%)
FIRST INCIDENCE	495	670	668	349

.....  
**STATISTICAL TESTS**

POLY 3	P=0.003**	P=0.519	P=0.271	P=0.003**
POLY 1.5	P=0.009**	P=0.506	P=0.253	P=0.013*
POLY 6	P<0.001**	P=0.534	P=0.297	P<0.001**
COCH-ARM / FISHERS	P=0.047*	P=0.500	P=0.228	P=0.083
MAX-ISO-POLY-3	P=0.005**	P=0.422	P=0.205	P=0.005**

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Pancreas: Acinus  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	7/50 (14%)	1/50 (2%)	1/49 (2%)	2/46 (4%)
POLY-3 RATE (b)	7/42.98	1/45.81	1/46.50	2/21.79
POLY-3 PERCENT (g)	16.3%	2.2%	2.2%	9.2%
TERMINAL (d)	6/31 (19%)	1/37 (3%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	674	728 (T)	728 (T)	559

**STATISTICAL TESTS**

POLY 3	P=0.068N	P=0.023N*	P=0.022N*	P=0.357N
POLY 1.5	P=0.078N	P=0.027N*	P=0.026N*	P=0.219N
POLY 6	P=0.039N*	P=0.020N*	P=0.018N*	P=0.587N
COCH-ARM / FISHERS	P=0.077N	P=0.030N*	P=0.032N*	P=0.101N
MAX-ISO-POLY-3	P=0.106N	P=0.011N*	P=0.011N*	P=0.284N

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Pancreas: Duct  
 Cyst**

**LESION RATES**

OVERALL (a)	2/50 (4%)	4/50 (8%)	3/49 (6%)	3/46 (7%)
POLY-3 RATE (b)	2/42.78	4/45.92	3/46.61	3/22.59
POLY-3 PERCENT (g)	4.7%	8.7%	6.4%	13.3%
TERMINAL (d)	2/31 (7%)	3/37 (8%)	2/38 (5%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	701	702	393

**STATISTICAL TESTS**

POLY 3	P=0.247	P=0.370	P=0.539	P=0.243
POLY 1.5	P=0.303	P=0.354	P=0.519	P=0.331
POLY 6	P=0.249	P=0.390	P=0.566	P=0.144
COCH-ARM / FISHERS	P=0.454	P=0.339	P=0.490	P=0.460
MAX-ISO-POLY-3	P=0.321	P=0.234	P=0.365	P=0.177

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Parathyroid Gland  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	0/46 (0%)	1/47 (2%)	11/49 (22%)	31/49 (63%)
POLY-3 RATE (b)	0/38.78	1/42.87	11/47.66	31/36.71
POLY-3 PERCENT (g)	0%	2.3%	23.1%	84.4%
TERMINAL (d)	0/27 (0%)	1/35 (3%)	6/38 (16%)	0/0 (0%)
FIRST INCIDENCE	---	728 (T)	695	338

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.520	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.512	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.529	P=0.002**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.505	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.182	P<0.001**	P<0.001**

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Pituitary Gland  
 Hemorrhage**

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.78	2/45.92	0/47.40	1/22.44
POLY-3 PERCENT (g)	0%	4.4%	0%	4.5%
TERMINAL (d)	0/31 (0%)	1/37 (3%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	701	---	662

**STATISTICAL TESTS**

POLY 3	P=0.444	P=0.253	(e)	P=0.382
POLY 1.5	P=0.445	P=0.245	(e)	P=0.433
POLY 6	P=0.528	P=0.263	(e)	P=0.318
COCH-ARM / FISHERS	P=0.539	P=0.247	(e)	P=0.500
MAX-ISO-POLY-3	P=0.331	P=0.091	(e)	P=0.157

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Pituitary Gland: Pars Distalis  
 Angiectasis**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/42.78	0/45.81	1/47.40	1/22.80
POLY-3 PERCENT (g)	0%	0%	2.1%	4.4%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	---	---	728 (T)	533

**STATISTICAL TESTS**

POLY 3	P=0.130	(e)	P=0.520	P=0.384
POLY 1.5	P=0.149	(e)	P=0.512	P=0.434
POLY 6	P=0.154	(e)	P=0.532	P=0.321
COCH-ARM / FISHERS	P=0.236	(e)	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.210	(e)	P=0.183	P=0.157

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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**Pituitary Gland: Pars Distalis  
 Cyst**

**LESION RATES**

OVERALL (a)	4/50 (8%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	4/43.69	0/45.81	0/47.40	1/22.58
POLY-3 PERCENT (g)	9.2%	0%	0%	4.4%
TERMINAL (d)	2/31 (7%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	581	---	---	617

**STATISTICAL TESTS**

POLY 3	P=0.080N	P=0.054N	P=0.051N	P=0.428N
POLY 1.5	P=0.102N	P=0.057N	P=0.054N	P=0.305N
POLY 6	P=0.044N*	P=0.051N	P=0.046N*	P=0.610N
COCH-ARM / FISHERS	P=0.125N	P=0.059N	P=0.059N	P=0.181N
MAX-ISO-POLY-3	P=0.126N	P=0.019N*	P=0.019N*	P=0.309N

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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**Pituitary Gland: Pars Distalis  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	17/50 (34%)	26/50 (52%)	24/50 (48%)	12/50 (24%)
POLY-3 RATE (b)	17/45.13	26/47.46	24/47.68	12/28.77
POLY-3 PERCENT (g)	37.7%	54.8%	50.3%	41.7%
TERMINAL (d)	12/31 (39%)	20/37 (54%)	21/38 (55%)	0/0 (0%)
FIRST INCIDENCE	309	561	695	338

**STATISTICAL TESTS**

POLY 3	P=0.374	P=0.070	P=0.151	P=0.459
POLY 1.5	P=0.385N	P=0.057	P=0.130	P=0.479N
POLY 6	P=0.137	P=0.092	P=0.187	P=0.161
COCH-ARM / FISHERS	P=0.068N	P=0.053	P=0.111	P=0.189N
MAX-ISO-POLY-3	P=0.342	P=0.050*	P=0.112	P=0.385

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TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
Time Report Requested: 09:15:32  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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**Skin  
Cyst Epithelial Inclusion**

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**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/42.98	0/45.81	0/47.40	0/22.19
POLY-3 PERCENT (g)	2.3%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	674	---	---	---

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**STATISTICAL TESTS**

POLY 3	P=0.240N	P=0.487N	P=0.481N	P=0.620N
POLY 1.5	P=0.246N	P=0.493N	P=0.488N	P=0.568N
POLY 6	P=0.248N	P=0.480N	P=0.470N	P=0.684N
COCH-ARM / FISHERS	P=0.306N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.376N	P=0.158N	P=0.158N	P=0.303N

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Spleen  
 Fibrosis**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/46 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	1/47.40	0/20.85
POLY-3 PERCENT (g)	0%	0%	2.1%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	---	---	728 (T)	---

**STATISTICAL TESTS**

POLY 3	P=0.404	(e)	P=0.520	(e)
POLY 1.5	P=0.497	(e)	P=0.512	(e)
POLY 6	P=0.330	(e)	P=0.532	(e)
COCH-ARM / FISHERS	P=0.686	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.521	(e)	P=0.183	(e)

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Spleen  
 Hematopoietic Cell Proliferation**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	2/46 (4%)
POLY-3 RATE (b)	0/42.78	0/45.81	1/47.50	2/21.71
POLY-3 PERCENT (g)	0%	0%	2.1%	9.2%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	702	523

**STATISTICAL TESTS**

POLY 3	P=0.038*	(e)	P=0.521	P=0.124
POLY 1.5	P=0.038*	(e)	P=0.512	P=0.159
POLY 6	P=0.068	(e)	P=0.532	P=0.088
COCH-ARM / FISHERS	P=0.060	(e)	P=0.500	P=0.227
MAX-ISO-POLY-3	P=0.059	(e)	P=0.184	P=0.069

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Spleen  
 Hyperplasia Lymphoid**

**LESION RATES**

OVERALL (a)	3/50 (6%)	0/50 (0%)	1/50 (2%)	2/46 (4%)
POLY-3 RATE (b)	3/43.37	0/45.81	1/47.40	2/21.87
POLY-3 PERCENT (g)	6.9%	0%	2.1%	9.2%
TERMINAL (d)	2/31 (7%)	0/37 (0%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	538	---	728 (T)	538

**STATISTICAL TESTS**

POLY 3	P=0.569N	P=0.109N	P=0.274N	P=0.562
POLY 1.5	P=0.578	P=0.114N	P=0.287N	P=0.673
POLY 6	P=0.485N	P=0.103N	P=0.258N	P=0.400
COCH-ARM / FISHERS	P=0.587N	P=0.121N	P=0.309N	P=0.540N
MAX-ISO-POLY-3	P=0.329	P=0.038N*	P=0.143N	P=0.406

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Stomach, Forestomach  
 Inflammation**

**LESION RATES**

OVERALL (a)	3/50 (6%)	3/50 (6%)	7/49 (14%)	3/46 (7%)
POLY-3 RATE (b)	3/43.95	3/45.87	7/46.73	3/22.37
POLY-3 PERCENT (g)	6.8%	6.5%	15%	13.4%
TERMINAL (d)	1/31 (3%)	2/37 (5%)	6/38 (16%)	0/0 (0%)
FIRST INCIDENCE	495	713	668	471

**STATISTICAL TESTS**

POLY 3	P=0.122	P=0.643N	P=0.183	P=0.347
POLY 1.5	P=0.215	P=0.653N	P=0.169	P=0.465
POLY 6	P=0.074	P=0.630N	P=0.205	P=0.209
COCH-ARM / FISHERS	P=0.446	P=0.661N	P=0.151	P=0.621
MAX-ISO-POLY-3	P=0.196	P=0.478N	P=0.116	P=0.259

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Stomach, Forestomach  
 Mineralization**

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/49 (0%)	0/46 (0%)
POLY-3 RATE (b)	1/43.41	0/45.81	0/46.50	0/20.85
POLY-3 PERCENT (g)	2.3%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	519	---	---	---

**STATISTICAL TESTS**

POLY 3	P=0.244N	P=0.489N	P=0.486N	P=0.632N
POLY 1.5	P=0.252N	P=0.495N	P=0.494N	P=0.583N
POLY 6	P=0.252N	P=0.483N	P=0.476N	P=0.692N
COCH-ARM / FISHERS	P=0.315N	P=0.500N	P=0.505N	P=0.521N
MAX-ISO-POLY-3	P=0.391N	P=0.158N	P=0.160N	P=0.312N

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Stomach, Forestomach  
 Perforation**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/46 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/46.50	0/20.85
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (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)

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Stomach, Forestomach  
 Ulcer**

**LESION RATES**

OVERALL (a)	3/50 (6%)	1/50 (2%)	3/49 (6%)	3/46 (7%)
POLY-3 RATE (b)	3/43.91	1/46.14	3/46.50	3/22.06
POLY-3 PERCENT (g)	6.8%	2.2%	6.5%	13.6%
TERMINAL (d)	1/31 (3%)	0/37 (0%)	3/38 (8%)	0/0 (0%)
FIRST INCIDENCE	519	637	728 (T)	580

**STATISTICAL TESTS**

POLY 3	P=0.251	P=0.288N	P=0.636N	P=0.342
POLY 1.5	P=0.286	P=0.297N	P=0.650N	P=0.462
POLY 6	P=0.285	P=0.277N	P=0.615N	P=0.204
COCH-ARM / FISHERS	P=0.414	P=0.309N	P=0.651	P=0.621
MAX-ISO-POLY-3	P=0.271	P=0.147N	P=0.471N	P=0.257



TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

**Stomach, Forestomach: Epithelium  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	11/50 (22%)	7/50 (14%)	15/49 (31%)	9/46 (20%)
POLY-3 RATE (b)	11/44.59	7/46.25	15/46.96	9/26.22
POLY-3 PERCENT (g)	24.7%	15.1%	31.9%	34.3%
TERMINAL (d)	8/31 (26%)	4/37 (11%)	11/38 (29%)	0/0 (0%)
FIRST INCIDENCE	495	637	668	352

**STATISTICAL TESTS**

POLY 3	P=0.108	P=0.190N	P=0.295	P=0.281
POLY 1.5	P=0.214	P=0.205N	P=0.265	P=0.466
POLY 6	P=0.055	P=0.171N	P=0.343	P=0.097
COCH-ARM / FISHERS	P=0.477	P=0.218N	P=0.228	P=0.484N
MAX-ISO-POLY-3	P=0.172	P=0.131N	P=0.228	P=0.243

---

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

**Stomach, Glandular  
 Erosion**

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/49 (0%)	3/46 (7%)
POLY-3 RATE (b)	1/42.99	0/45.81	0/46.50	3/22.37
POLY-3 PERCENT (g)	2.3%	0%	0%	13.4%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	672	---	---	523

**STATISTICAL TESTS**

POLY 3	P=0.095	P=0.487N	P=0.484N	P=0.127
POLY 1.5	P=0.068	P=0.493N	P=0.492N	P=0.182
POLY 6	P=0.227	P=0.480N	P=0.474N	P=0.075
COCH-ARM / FISHERS	P=0.074	P=0.500N	P=0.505N	P=0.278
MAX-ISO-POLY-3	P=0.025*	P=0.158N	P=0.160N	P=0.093

---

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Stomach, Glandular  
 Inflammation**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)	1/46 (2%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/46.50	1/21.58
POLY-3 PERCENT (g)	0%	0%	0%	4.6%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	471

**STATISTICAL TESTS**

POLY 3	P=0.187	(e)	(e)	P=0.375
POLY 1.5	P=0.154	(e)	(e)	P=0.421
POLY 6	P=0.342	(e)	(e)	P=0.315
COCH-ARM / FISHERS	P=0.187	(e)	(e)	P=0.479
MAX-ISO-POLY-3	P=0.112	(e)	(e)	P=0.151

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

**Stomach, Glandular  
 Mineralization**

**LESION RATES**

OVERALL (a)	1/50 (2%)	3/50 (6%)	1/49 (2%)	13/46 (28%)
POLY-3 RATE (b)	1/43.41	3/45.96	1/46.50	13/27.26
POLY-3 PERCENT (g)	2.3%	6.5%	2.2%	47.7%
TERMINAL (d)	0/31 (0%)	2/37 (5%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	519	689	728 (T)	349

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.326	P=0.745N	P<0.001**
POLY 1.5	P<0.001**	P=0.316	P=0.753N	P<0.001**
POLY 6	P<0.001**	P=0.339	P=0.733N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.309	P=0.747	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.175	P=0.480N	P<0.001**

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

**Thyroid Gland: C-Cell  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	39/50 (78%)	32/50 (64%)	19/50 (38%)	3/49 (6%)
POLY-3 RATE (b)	39/46.72	32/47.30	19/47.61	3/23.47
POLY-3 PERCENT (g)	83.5%	67.7%	39.9%	12.8%
TERMINAL (d)	29/31 (94%)	27/37 (73%)	17/38 (45%)	0/0 (0%)
FIRST INCIDENCE	495	561	702	569

**STATISTICAL TESTS**

POLY 3	P<0.001N**	P=0.052N	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.071N	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P=0.032N*	P<0.001N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.093N	P<0.001N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.031N*	P<0.001N**	P<0.001N**

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Trachea  
 Inflammation**

**LESION RATES**

OVERALL (a)	5/50 (10%)	1/50 (2%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	5/44.08	1/45.81	1/47.40	3/24.22
POLY-3 PERCENT (g)	11.3%	2.2%	2.1%	12.4%
TERMINAL (d)	1/31 (3%)	1/37 (3%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	519	728 (T)	728 (T)	19

**STATISTICAL TESTS**

POLY 3	P=0.370N	P=0.092N	P=0.086N	P=0.596
POLY 1.5	P=0.394N	P=0.097N	P=0.092N	P=0.538N
POLY 6	P=0.271N	P=0.088N	P=0.078N	P=0.378
COCH-ARM / FISHERS	P=0.371N	P=0.102N	P=0.102N	P=0.357N
MAX-ISO-POLY-3	P=0.332	P=0.042N*	P=0.041N*	P=0.461

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Urinary Bladder  
 Inflammation**

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/49 (0%)	0/50 (0%)	2/47 (4%)
POLY-3 RATE (b)	1/42.78	0/44.81	0/47.40	2/21.97
POLY-3 PERCENT (g)	2.3%	0%	0%	9.1%
TERMINAL (d)	1/31 (3%)	0/36 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	---	---	593

**STATISTICAL TESTS**

POLY 3	P=0.270	P=0.491N	P=0.480N	P=0.292
POLY 1.5	P=0.216	P=0.497N	P=0.488N	P=0.369
POLY 6	P=0.465	P=0.483N	P=0.468N	P=0.201
COCH-ARM / FISHERS	P=0.232	P=0.505N	P=0.500N	P=0.477
MAX-ISO-POLY-3	P=0.093	P=0.160N	P=0.158N	P=0.186

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Urinary Bladder: Transitional Epithelium  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/49 (0%)	2/50 (4%)	1/47 (2%)
POLY-3 RATE (b)	0/42.78	0/44.81	2/47.40	1/21.74
POLY-3 PERCENT (g)	0%	0%	4.2%	4.6%
TERMINAL (d)	0/31 (0%)	0/36 (0%)	2/38 (5%)	0/0 (0%)
FIRST INCIDENCE	---	---	728 (T)	593

**STATISTICAL TESTS**

POLY 3	P=0.085	(e)	P=0.261	P=0.376
POLY 1.5	P=0.123	(e)	P=0.251	P=0.424
POLY 6	P=0.071	(e)	P=0.274	P=0.315
COCH-ARM / FISHERS	P=0.232	(e)	P=0.247	P=0.485
MAX-ISO-POLY-3	P=0.134	(e)	P=0.098	P=0.153



TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

Uterus  
 Hemorrhage

**LESION RATES**

OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	1/47 (2%)
POLY-3 RATE (b)	2/43.21	1/45.81	0/47.40	1/21.65
POLY-3 PERCENT (g)	4.6%	2.2%	0%	4.6%
TERMINAL (d)	1/31 (3%)	1/37 (3%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	604	728 (T)	---	617

**STATISTICAL TESTS**

POLY 3	P=0.339N	P=0.480N	P=0.217N	P=0.713N
POLY 1.5	P=0.364N	P=0.489N	P=0.225N	P=0.634N
POLY 6	P=0.274N	P=0.468N	P=0.207N	P=0.581
COCH-ARM / FISHERS	P=0.383N	P=0.500N	P=0.247N	P=0.523N
MAX-ISO-POLY-3	P=0.491N	P=0.269N	P=0.076N	P=0.499N

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

---

Uterus  
 Hydrometra

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	3/47 (6%)
POLY-3 RATE (b)	0/42.78	0/45.81	1/47.40	3/23.28
POLY-3 PERCENT (g)	0%	0%	2.1%	12.9%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	---	---	728 (T)	352

**STATISTICAL TESTS**

POLY 3	P=0.011*	(e)	P=0.520	P=0.046*
POLY 1.5	P=0.010**	(e)	P=0.512	P=0.067
POLY 6	P=0.026*	(e)	P=0.532	P=0.027*
COCH-ARM / FISHERS	P=0.017*	(e)	P=0.500	P=0.110
MAX-ISO-POLY-3	P=0.016*	(e)	P=0.183	P=0.033*

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TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Uterus  
 Inflammation**

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	2/47 (4%)
POLY-3 RATE (b)	0/42.78	1/46.35	0/47.40	2/22.54
POLY-3 PERCENT (g)	0%	2.2%	0%	8.9%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	561	---	352

**STATISTICAL TESTS**

POLY 3	P=0.121	P=0.516	(e)	P=0.128
POLY 1.5	P=0.104	P=0.508	(e)	P=0.164
POLY 6	P=0.224	P=0.525	(e)	P=0.091
COCH-ARM / FISHERS	P=0.128	P=0.500	(e)	P=0.232
MAX-ISO-POLY-3	P=0.070	P=0.178	(e)	P=0.070

TDMS No. 99020 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Pulegone  
 CAS Number: 89-82-7

Date Report Requested: 05/21/2008  
 Time Report Requested: 09:15:32  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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Uterus: Endometrium  
 Hyperplasia Cystic

**LESION RATES**

OVERALL (a)	1/50 (2%)	3/50 (6%)	2/50 (4%)	5/47 (11%)
POLY-3 RATE (b)	1/42.78	3/46.02	2/47.40	5/23.23
POLY-3 PERCENT (g)	2.3%	6.5%	4.2%	21.5%
TERMINAL (d)	1/31 (3%)	2/37 (5%)	2/38 (5%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	674	728 (T)	580

**STATISTICAL TESTS**

POLY 3	P=0.032*	P=0.332	P=0.536	P=0.021*
POLY 1.5	P=0.035*	P=0.319	P=0.521	P=0.040*
POLY 6	P=0.052	P=0.348	P=0.555	P=0.008**
COCH-ARM / FISHERS	P=0.065	P=0.309	P=0.500	P=0.088
MAX-ISO-POLY-3	P=0.031*	P=0.181	P=0.319	P=0.023*

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**TDMS No.** 99020 - 05  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** RATS/F 344

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

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

**Date Report Requested:** 05/21/2008  
**Time Report Requested:** 09:15:32  
**First Dose M/F:** 04/09/03 / 04/10/03  
**Lab:** BAT

**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 \*\*\*