



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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

### MALE RATS

#### Organ

Adrenal Cortex  
Adrenal Medulla  
Blood Vessel  
Bone  
Eye  
Harderian Gland: Epithelium  
Heart  
  
Intestine Large, Cecum  
  
Kidney  
  
Kidney: Cortex  
Liver  
  
Liver: Bile Duct  
  
Liver: Hepatocyte  
  
Liver: Oval Cell  
Liver: Portal  
Lung: Alveolar Epithelium  
Lung: Alveolus  
Lung: Interstitium  
Nose  
Nose: Olfactory Epithelium  
Pancreas: Acinus  
  
Parathyroid Gland

#### Morphology

Hypertrophy  
Hyperplasia  
Mineralization  
Fibrous Osteodystrophy  
Inflammation  
Hyperplasia  
Cardiomyopathy  
Mineralization  
Inflammation  
Mineralization  
Ulcer  
Cyst  
Glomerulopathy Hyaline  
Nephropathy  
Mineralization  
Basophilic Focus  
Clear Cell Focus  
Mixed Cell Focus  
Cyst  
Hyperplasia  
Cellular Alteration Diffuse  
Necrosis  
Hyperplasia  
Fibrosis  
Hyperplasia  
Inflammation Histiocytic  
Mineralization  
Inflammation  
Degeneration  
Atrophy  
Hyperplasia  
Hyperplasia

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

Prostate: Epithelium  
Stomach, Forestomach

Hyperplasia  
Inflammation  
Mineralization  
Perforation  
Ulcer

Stomach, Forestomach: Epithelium  
Stomach, Glandular

Hyperplasia  
Inflammation  
Mineralization  
Hyperplasia

Thyroid Gland: C-Cell

**FEMALE RATS**

**Organ**

Adrenal Cortex

Adrenal Medulla  
Blood Vessel  
Bone Marrow  
Bone  
Eye

Heart

Intestine Large, Cecum  
Kidney

Kidney: Cortex  
Liver

Liver: Bile Duct

Liver: Hepatocyte

Liver: Oval Cell

**Morphology**

Hyperplasia  
Hypertrophy  
Hyperplasia  
Mineralization  
Hyperplasia  
Fibrous Osteodystrophy  
Hemorrhage  
Inflammation  
Inflammation  
Mineralization  
Inflammation  
Glomerulopathy Hyaline  
Nephropathy  
Mineralization  
Basophilic Focus  
Clear Cell Focus  
Fatty Change  
Mixed Cell Focus  
Cyst  
Hyperplasia  
Cellular Alteration Diffuse  
Necrosis  
Hyperplasia

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

Liver: Portal  
Lung  
Lung: Alveolar Epithelium  
Lung: Alveolus  
Lung: Interstitium  
Lymph Node, Mesenteric  
Nose  
Nose: Olfactory Epithelium

Ovary  
Pancreas: Acinus  
Parathyroid Gland  
Stomach, Glandular  
Thyroid Gland: C-Cell  
Uterus  
Uterus: Endometrium

Fibrosis  
Hemorrhage  
Hyperplasia  
Inflammation Histiocytic  
Mineralization  
Hemorrhage  
Inflammation  
Degeneration  
Metaplasia Respiratory  
Atrophy  
Atrophy  
Hyperplasia  
Mineralization  
Hyperplasia  
Hydrometra  
Hyperplasia Cystic

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

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**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Adrenal Cortex  
Hyperplasia

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**LESION RATES**

OVERALL (a)	27/50 (54%)	18/50 (36%)
POLY-3 RATE (b)	27/46.79	18/30.63
POLY-3 PERCENT (g)	57.7%	58.8%
TERMINAL (d)	22/39 (56%)	0/2 (0%)
FIRST INCIDENCE	627	360

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**STATISTICAL TESTS**

POLY 3	P=0.557
POLY 1.5	P=0.274N
POLY 6	P=0.194
COCH-ARM / FISHERS	P=0.054N
MAX-ISO-POLY-3	P=0.467

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

---

**Males**

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<b>DOSE</b>	<b>0 MG/KG</b>	<b>75 MG/KG Stop</b>
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**Adrenal Cortex  
Hypertrophy**

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**LESION RATES**

<b>OVERALL (a)</b>	11/50 (22%)	9/50 (18%)
<b>POLY-3 RATE (b)</b>	11/45.92	9/23.41
<b>POLY-3 PERCENT (g)</b>	24%	38.4%
<b>TERMINAL (d)</b>	9/39 (23%)	2/2 (100%)
<b>FIRST INCIDENCE</b>	692	366

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**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.183
<b>POLY 1.5</b>	P=0.436
<b>POLY 6</b>	P=0.043*
<b>COCH-ARM / FISHERS</b>	P=0.402N
<b>MAX-ISO-POLY-3</b>	P=0.178

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TERMINAL SACRIFICE AT 104 WEEKS**

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**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Adrenal Medulla  
Hyperplasia

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**LESION RATES**

OVERALL (a)	22/50 (44%)	31/50 (62%)
POLY-3 RATE (b)	22/46.33	31/35.80
POLY-3 PERCENT (g)	47.5%	86.6%
TERMINAL (d)	19/39 (49%)	2/2 (100%)
FIRST INCIDENCE	627	360

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**STATISTICAL TESTS**

POLY 3	P<0.001**
POLY 1.5	P=0.002**
POLY 6	P<0.001**
COCH-ARM / FISHERS	P=0.054
MAX-ISO-POLY-3	P<0.001**

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TERMINAL SACRIFICE AT 104 WEEKS**

**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Blood Vessel  
Mineralization

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**LESION RATES**

OVERALL (a)	0/50 (0%)	24/50 (48%)
POLY-3 RATE (b)	0/45.76	24/31.44
POLY-3 PERCENT (g)	0%	76.3%
TERMINAL (d)	0/39 (0%)	1/2 (50%)
FIRST INCIDENCE	---	476

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**STATISTICAL TESTS**

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

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TERMINAL SACRIFICE AT 104 WEEKS**

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**Males**

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<b>DOSE</b>	<b>0 MG/KG</b>	<b>75 MG/KG Stop</b>
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**Bone Marrow  
Hyperplasia**

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**LESION RATES**

<b>OVERALL (a)</b>	10/50 (20%)	6/50 (12%)
<b>POLY-3 RATE (b)</b>	10/46.58	6/22.51
<b>POLY-3 PERCENT (g)</b>	21.5%	26.7%
<b>TERMINAL (d)</b>	6/39 (15%)	1/2 (50%)
<b>FIRST INCIDENCE</b>	627	394

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**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.438
<b>POLY 1.5</b>	P=0.511N
<b>POLY 6</b>	P=0.188
<b>COCH-ARM / FISHERS</b>	P=0.207N
<b>MAX-ISO-POLY-3</b>	P=0.366

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TERMINAL SACRIFICE AT 104 WEEKS**

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**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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**Bone**  
**Fibrous Osteodystrophy**

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**LESION RATES**

OVERALL (a)	0/50 (0%)	34/50 (68%)
POLY-3 RATE (b)	0/45.76	34/37.44
POLY-3 PERCENT (g)	0%	90.8%
TERMINAL (d)	0/39 (0%)	2/2 (100%)
FIRST INCIDENCE	---	407

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**STATISTICAL TESTS**

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

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TERMINAL SACRIFICE AT 104 WEEKS**

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**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Brain  
Hydrocephalus

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**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/19.85
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	---	---

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**STATISTICAL TESTS**

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

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TERMINAL SACRIFICE AT 104 WEEKS**

---

**Males**

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<b>DOSE</b>	<b>0 MG/KG</b>	<b>75 MG/KG Stop</b>
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Epididymis  
Granuloma Sperm

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**LESION RATES**

<b>OVERALL (a)</b>	2/50 (4%)	2/49 (4%)
<b>POLY-3 RATE (b)</b>	2/45.76	2/20.27
<b>POLY-3 PERCENT (g)</b>	4.4%	9.9%
<b>TERMINAL (d)</b>	2/39 (5%)	1/2 (50%)
<b>FIRST INCIDENCE</b>	727 (T)	547

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**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.396
<b>POLY 1.5</b>	P=0.527
<b>POLY 6</b>	P=0.270
<b>COCH-ARM / FISHERS</b>	P=0.684
<b>MAX-ISO-POLY-3</b>	P=0.282

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TERMINAL SACRIFICE AT 104 WEEKS**

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**Males**

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<b>DOSE</b>	<b>0 MG/KG</b>	<b>75 MG/KG Stop</b>
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**Epididymis  
Inflammation**

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**LESION RATES**

<b>OVERALL (a)</b>	1/50 (2%)	2/49 (4%)
<b>POLY-3 RATE (b)</b>	1/45.76	2/20.37
<b>POLY-3 PERCENT (g)</b>	2.2%	9.8%
<b>TERMINAL (d)</b>	1/39 (3%)	0/2 (0%)
<b>FIRST INCIDENCE</b>	727 (T)	615

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**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.262
<b>POLY 1.5</b>	P=0.355
<b>POLY 6</b>	P=0.183
<b>COCH-ARM / FISHERS</b>	P=0.492
<b>MAX-ISO-POLY-3</b>	P=0.177

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

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**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
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Eye  
Hemorrhage

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**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/19.85
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	---	---

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**STATISTICAL TESTS**

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

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
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Eye  
Inflammation

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**LESION RATES**

OVERALL (a)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	0/45.76	3/20.81
POLY-3 PERCENT (g)	0%	14.4%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	---	591

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**STATISTICAL TESTS**

POLY 3	P=0.038*
POLY 1.5	P=0.062
POLY 6	P=0.024*
COCH-ARM / FISHERS	P=0.121
MAX-ISO-POLY-3	P=0.034*

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TERMINAL SACRIFICE AT 104 WEEKS**

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**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Eye: Cornea  
Inflammation

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**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.76	2/20.65
POLY-3 PERCENT (g)	0%	9.7%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	---	591

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**STATISTICAL TESTS**

POLY 3	P=0.116
POLY 1.5	P=0.159
POLY 6	P=0.086
COCH-ARM / FISHERS	P=0.247
MAX-ISO-POLY-3	P=0.072

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TERMINAL SACRIFICE AT 104 WEEKS**

**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Eye: Retina  
Atrophy

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**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/19.85
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	---	---

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**STATISTICAL TESTS**

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

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TERMINAL SACRIFICE AT 104 WEEKS**

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
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Harderian Gland  
Inflammation

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**LESION RATES**

OVERALL (a)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/45.76	0/19.85
POLY-3 PERCENT (g)	4.4%	0%
TERMINAL (d)	2/39 (5%)	0/2 (0%)
FIRST INCIDENCE	727 (T)	---

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**STATISTICAL TESTS**

POLY 3	P=0.444N
POLY 1.5	P=0.345N
POLY 6	P=0.555N
COCH-ARM / FISHERS	P=0.247N
MAX-ISO-POLY-3	P=0.267N

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
------	---------	---------------

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Harderian Gland: Epithelium  
Hyperplasia

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**LESION RATES**

OVERALL (a)	3/50 (6%)	6/50 (12%)
POLY-3 RATE (b)	3/45.76	6/24.45
POLY-3 PERCENT (g)	6.6%	24.5%
TERMINAL (d)	3/39 (8%)	0/2 (0%)
FIRST INCIDENCE	727 (T)	377

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**STATISTICAL TESTS**

POLY 3	P=0.049*
POLY 1.5	P=0.109
POLY 6	P=0.018*
COCH-ARM / FISHERS	P=0.243
MAX-ISO-POLY-3	P=0.054

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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/N)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
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Heart  
Cardiomyopathy

---

**LESION RATES**

OVERALL (a)	44/50 (88%)	50/50 (100%)
POLY-3 RATE (b)	44/47.64	50/50.00
POLY-3 PERCENT (g)	92.4%	100%
TERMINAL (d)	36/39 (92%)	2/2 (100%)
FIRST INCIDENCE	412	360

---

**STATISTICAL TESTS**

POLY 3	P=0.064
POLY 1.5	P=0.059
POLY 6	P=0.074
COCH-ARM / FISHERS	P=0.013*
MAX-ISO-POLY-3	P=0.021*

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
------	---------	---------------

---

Heart  
Inflammation

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/19.85
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	---	---

---

**STATISTICAL TESTS**

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

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
------	---------	---------------

---

Heart  
Mineralization

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	23/50 (46%)
POLY-3 RATE (b)	0/45.76	23/32.67
POLY-3 PERCENT (g)	0%	70.4%
TERMINAL (d)	0/39 (0%)	1/2 (50%)
FIRST INCIDENCE	---	360

---

**STATISTICAL TESTS**

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

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
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---

Intestine Large, Cecum  
Inflammation

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	21/50 (42%)
POLY-3 RATE (b)	0/45.76	21/32.83
POLY-3 PERCENT (g)	0%	64%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	---	366

---

**STATISTICAL TESTS**

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

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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---

Intestine Large, Cecum  
Mineralization

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	4/50 (8%)
POLY-3 RATE (b)	0/45.76	4/22.30
POLY-3 PERCENT (g)	0%	17.9%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	---	511

---

**STATISTICAL TESTS**

POLY 3	P=0.014*
POLY 1.5	P=0.026*
POLY 6	P=0.007**
COCH-ARM / FISHERS	P=0.059
MAX-ISO-POLY-3	P=0.016*

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

**DOSE**                      **0 MG/KG**                      **75 MG/KG Stop**

Intestine Large, Cecum  
Ulcer

**LESION RATES**

OVERALL (a)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	0/45.76	3/21.44
POLY-3 PERCENT (g)	0%	14%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	---	525

**STATISTICAL TESTS**

POLY 3	P=0.040*
POLY 1.5	P=0.064
POLY 6	P=0.025*
COCH-ARM / FISHERS	P=0.121
MAX-ISO-POLY-3	P=0.035*

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Intestine Large, Colon  
Parasite Metazoan

---

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/45.76	0/19.85
POLY-3 PERCENT (g)	2.2%	0%
TERMINAL (d)	1/39 (3%)	0/2 (0%)
FIRST INCIDENCE	727 (T)	---

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**STATISTICAL TESTS**

POLY 3	P=0.643N
POLY 1.5	P=0.583N
POLY 6	P=0.700N
COCH-ARM / FISHERS	P=0.500N
MAX-ISO-POLY-3	P=0.330N

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Intestine Large, Rectum  
Parasite Metazoan

---

**LESION RATES**

OVERALL (a)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/45.78	1/19.85
POLY-3 PERCENT (g)	4.4%	5%
TERMINAL (d)	1/39 (3%)	1/2 (50%)
FIRST INCIDENCE	723	727 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.672
POLY 1.5	P=0.644N
POLY 6	P=0.532
COCH-ARM / FISHERS	P=0.500N
MAX-ISO-POLY-3	P=0.467

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

**DOSE**                      **0 MG/KG**                      **75 MG/KG Stop**

Intestine Small, Duodenum  
Erosion

**LESION RATES**

<b>OVERALL (a)</b>	0/50 (0%)	2/50 (4%)
<b>POLY-3 RATE (b)</b>	0/45.76	2/21.57
<b>POLY-3 PERCENT (g)</b>	0%	9.3%
<b>TERMINAL (d)</b>	0/39 (0%)	0/2 (0%)
<b>FIRST INCIDENCE</b>	---	366

**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.120
<b>POLY 1.5</b>	P=0.162
<b>POLY 6</b>	P=0.088
<b>COCH-ARM / FISHERS</b>	P=0.247
<b>MAX-ISO-POLY-3</b>	P=0.072

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

**DOSE**                      **0 MG/KG**                      **75 MG/KG Stop**

**Kidney  
Cyst**

**LESION RATES**

<b>OVERALL (a)</b>	0/50 (0%)	7/50 (14%)
<b>POLY-3 RATE (b)</b>	0/45.76	7/22.73
<b>POLY-3 PERCENT (g)</b>	0%	30.8%
<b>TERMINAL (d)</b>	0/39 (0%)	1/2 (50%)
<b>FIRST INCIDENCE</b>	---	510

**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
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---

Kidney  
Glomerulopathy Hyaline

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	24/50 (48%)
POLY-3 RATE (b)	0/45.76	24/32.96
POLY-3 PERCENT (g)	0%	72.8%
TERMINAL (d)	0/39 (0%)	1/2 (50%)
FIRST INCIDENCE	---	394

---

**STATISTICAL TESTS**

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

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
------	---------	---------------

---

Kidney  
Inflammation

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/19.85
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	---	---

---

**STATISTICAL TESTS**

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

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
------	---------	---------------

---

Kidney  
Nephropathy

---

**LESION RATES**

OVERALL (a)	45/50 (90%)	50/50 (100%)
POLY-3 RATE (b)	45/46.82	50/50.00
POLY-3 PERCENT (g)	96.1%	100%
TERMINAL (d)	38/39 (97%)	2/2 (100%)
FIRST INCIDENCE	632	360

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**STATISTICAL TESTS**

POLY 3	P=0.229
POLY 1.5	P=0.164
POLY 6	P=0.322
COCH-ARM / FISHERS	P=0.028*
MAX-ISO-POLY-3	P=0.062

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
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---

**Kidney: Cortex  
Mineralization**

---

**LESION RATES**

OVERALL (a)	1/50 (2%)	21/50 (42%)
POLY-3 RATE (b)	1/46.11	21/30.37
POLY-3 PERCENT (g)	2.2%	69.2%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	632	476

---

**STATISTICAL TESTS**

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

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
------	---------	---------------

---

Liver  
Basophilic Focus

---

**LESION RATES**

OVERALL (a)	36/50 (72%)	2/50 (4%)
POLY-3 RATE (b)	36/46.69	2/21.09
POLY-3 PERCENT (g)	77.1%	9.5%
TERMINAL (d)	34/39 (87%)	0/2 (0%)
FIRST INCIDENCE	412	393

---

**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
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---

Liver  
Clear Cell Focus

---

**LESION RATES**

OVERALL (a)	22/50 (44%)	1/50 (2%)
POLY-3 RATE (b)	22/45.87	1/19.85
POLY-3 PERCENT (g)	48%	5%
TERMINAL (d)	21/39 (54%)	1/2 (50%)
FIRST INCIDENCE	701	727 (T)

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**STATISTICAL TESTS**

POLY 3	P=0.002N**
POLY 1.5	P<0.001N**
POLY 6	P=0.075N
COCH-ARM / FISHERS	P<0.001N**
MAX-ISO-POLY-3	P=0.008N**

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
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---

Liver  
Eosinophilic Focus

---

**LESION RATES**

OVERALL (a)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	1/45.76	3/21.55
POLY-3 PERCENT (g)	2.2%	13.9%
TERMINAL (d)	1/39 (3%)	1/2 (50%)
FIRST INCIDENCE	727 (T)	360

---

**STATISTICAL TESTS**

POLY 3	P=0.116
POLY 1.5	P=0.183
POLY 6	P=0.068
COCH-ARM / FISHERS	P=0.309
MAX-ISO-POLY-3	P=0.093

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
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---

Liver  
Fatty Change

---

**LESION RATES**

OVERALL (a)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/45.90	2/20.83
POLY-3 PERCENT (g)	2.2%	9.6%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	692	535

---

**STATISTICAL TESTS**

POLY 3	P=0.266
POLY 1.5	P=0.361
POLY 6	P=0.186
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.180

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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---

Liver  
Hepatodiaphragmatic Nodule

---

**LESION RATES**

OVERALL (a)	6/50 (12%)	3/50 (6%)
POLY-3 RATE (b)	6/45.76	3/21.99
POLY-3 PERCENT (g)	13.1%	13.6%
TERMINAL (d)	6/39 (15%)	0/2 (0%)
FIRST INCIDENCE	727 (T)	393

---

**STATISTICAL TESTS**

POLY 3	P=0.612
POLY 1.5	P=0.464N
POLY 6	P=0.394
COCH-ARM / FISHERS	P=0.243N
MAX-ISO-POLY-3	P=0.481

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

**DOSE**                      **0 MG/KG**                      **75 MG/KG Stop**

Liver  
Inflammation

**LESION RATES**

<b>OVERALL (a)</b>	41/50 (82%)	46/50 (92%)
<b>POLY-3 RATE (b)</b>	41/47.21	46/48.28
<b>POLY-3 PERCENT (g)</b>	86.9%	95.3%
<b>TERMINAL (d)</b>	36/39 (92%)	1/2 (50%)
<b>FIRST INCIDENCE</b>	412	360

**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.123
<b>POLY 1.5</b>	P=0.153
<b>POLY 6</b>	P=0.110
<b>COCH-ARM / FISHERS</b>	P=0.117
<b>MAX-ISO-POLY-3</b>	P=0.063

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
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---

Liver  
Mixed Cell Focus

---

**LESION RATES**

OVERALL (a)	9/50 (18%)	1/50 (2%)
POLY-3 RATE (b)	9/45.76	1/20.68
POLY-3 PERCENT (g)	19.7%	4.8%
TERMINAL (d)	9/39 (23%)	0/2 (0%)
FIRST INCIDENCE	727 (T)	407

---

**STATISTICAL TESTS**

POLY 3	P=0.147N
POLY 1.5	P=0.047N*
POLY 6	P=0.364N
COCH-ARM / FISHERS	P=0.008N**
MAX-ISO-POLY-3	P=0.142N

---



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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
------	---------	---------------

---

Liver: Bile Duct  
Cyst

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	9/50 (18%)
POLY-3 RATE (b)	0/45.76	9/23.39
POLY-3 PERCENT (g)	0%	38.5%
TERMINAL (d)	0/39 (0%)	2/2 (100%)
FIRST INCIDENCE	---	407

---

**STATISTICAL TESTS**

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

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
------	---------	---------------

---

Liver: Bile Duct  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	29/50 (58%)	50/50 (100%)
POLY-3 RATE (b)	29/46.62	50/50.00
POLY-3 PERCENT (g)	62.2%	100%
TERMINAL (d)	25/39 (64%)	2/2 (100%)
FIRST INCIDENCE	632	360

---

**STATISTICAL TESTS**

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

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
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Liver: Hepatocyte  
Cellular Alteration Diffuse

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	46/50 (92%)
POLY-3 RATE (b)	0/45.76	46/48.57
POLY-3 PERCENT (g)	0%	94.7%
TERMINAL (d)	0/39 (0%)	1/2 (50%)
FIRST INCIDENCE	---	360

---

**STATISTICAL TESTS**

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

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

**DOSE**                      **0 MG/KG**                      **75 MG/KG Stop**

Liver: Hepatocyte  
Necrosis

**LESION RATES**

OVERALL (a)	0/50 (0%)	16/50 (32%)
POLY-3 RATE (b)	0/45.76	16/30.41
POLY-3 PERCENT (g)	0%	52.6%
TERMINAL (d)	0/39 (0%)	1/2 (50%)
FIRST INCIDENCE	---	366

**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
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Liver: Hepatocyte, Centrilobular  
Degeneration

---

**LESION RATES**

OVERALL (a)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	3/46.24	0/19.85
POLY-3 PERCENT (g)	6.5%	0%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	632	---

---

**STATISTICAL TESTS**

POLY 3	P=0.330N
POLY 1.5	P=0.219N
POLY 6	P=0.471N
COCH-ARM / FISHERS	P=0.121N
MAX-ISO-POLY-3	P=0.223N

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
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---

Liver: Oval Cell  
Hyperplasia

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**LESION RATES**

OVERALL (a)	0/50 (0%)	44/50 (88%)
POLY-3 RATE (b)	0/45.76	44/45.77
POLY-3 PERCENT (g)	0%	96.1%
TERMINAL (d)	0/39 (0%)	1/2 (50%)
FIRST INCIDENCE	---	360

---

**STATISTICAL TESTS**

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

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
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Liver: Portal  
Fibrosis

---

**LESION RATES**

OVERALL (a)	8/50 (16%)	43/50 (86%)
POLY-3 RATE (b)	8/45.90	43/44.94
POLY-3 PERCENT (g)	17.4%	95.7%
TERMINAL (d)	7/39 (18%)	2/2 (100%)
FIRST INCIDENCE	692	360

---

**STATISTICAL TESTS**

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

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
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---

Lung  
Congestion

---

**LESION RATES**

OVERALL (a)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/46.60	0/19.85
POLY-3 PERCENT (g)	4.3%	0%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	412	---

---

**STATISTICAL TESTS**

POLY 3	P=0.449N
POLY 1.5	P=0.348N
POLY 6	P=0.558N
COCH-ARM / FISHERS	P=0.247N
MAX-ISO-POLY-3	P=0.271N

---



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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
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---

Lung  
Hemorrhage

---

**LESION RATES**

OVERALL (a)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/46.76	1/20.06
POLY-3 PERCENT (g)	2.1%	5%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	29	673

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**STATISTICAL TESTS**

POLY 3	P=0.553
POLY 1.5	P=0.649
POLY 6	P=0.447
COCH-ARM / FISHERS	P=0.753N
MAX-ISO-POLY-3	P=0.339

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Lung: Alveolar Epithelium  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	11/50 (22%)	11/50 (22%)
POLY-3 RATE (b)	11/45.99	11/25.24
POLY-3 PERCENT (g)	23.9%	43.6%
TERMINAL (d)	8/39 (21%)	1/2 (50%)
FIRST INCIDENCE	692	377

---

**STATISTICAL TESTS**

POLY 3	P=0.085
POLY 1.5	P=0.256
POLY 6	P=0.016*
COCH-ARM / FISHERS	P=0.595N
MAX-ISO-POLY-3	P=0.094

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
------	---------	---------------

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Lung: Alveolus  
Inflammation Histiocytic

---

**LESION RATES**

OVERALL (a)	27/50 (54%)	36/50 (72%)
POLY-3 RATE (b)	27/47.05	36/39.99
POLY-3 PERCENT (g)	57.4%	90%
TERMINAL (d)	23/39 (59%)	2/2 (100%)
FIRST INCIDENCE	412	360

---

**STATISTICAL TESTS**

POLY 3	P<0.001**
POLY 1.5	P=0.003**
POLY 6	P<0.001**
COCH-ARM / FISHERS	P=0.048*
MAX-ISO-POLY-3	P<0.001**

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

Males

DOSE                      0 MG/KG                      75 MG/KG Stop

Lung: Arteriole  
Inflammation

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/19.85
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	---	---

STATISTICAL TESTS

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
------	---------	---------------

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Lung: Cervix  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/46.76	0/19.85
POLY-3 PERCENT (g)	4.3%	0%
TERMINAL (d)	1/39 (3%)	0/2 (0%)
FIRST INCIDENCE	24	---

---

**STATISTICAL TESTS**

POLY 3	P=0.449N
POLY 1.5	P=0.351N
POLY 6	P=0.558N
COCH-ARM / FISHERS	P=0.247N
MAX-ISO-POLY-3	P=0.272N

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
------	---------	---------------

---

Lung: Interstitium  
Mineralization

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	16/50 (32%)
POLY-3 RATE (b)	0/45.76	16/27.03
POLY-3 PERCENT (g)	0%	59.2%
TERMINAL (d)	0/39 (0%)	1/2 (50%)
FIRST INCIDENCE	---	503

---

**STATISTICAL TESTS**

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

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
------	---------	---------------

---

Lymph Node, Mesenteric  
Fibrosis

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.76	2/20.53
POLY-3 PERCENT (g)	0%	9.7%
TERMINAL (d)	0/39 (0%)	1/2 (50%)
FIRST INCIDENCE	---	497

---

**STATISTICAL TESTS**

POLY 3	P=0.116
POLY 1.5	P=0.158
POLY 6	P=0.084
COCH-ARM / FISHERS	P=0.247
MAX-ISO-POLY-3	P=0.072

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

**DOSE**                      **0 MG/KG**                      **75 MG/KG Stop**

**Lymph Node, Mesenteric  
Hemorrhage**

**LESION RATES**

<b>OVERALL (a)</b>	0/50 (0%)	1/50 (2%)
<b>POLY-3 RATE (b)</b>	0/45.76	1/20.53
<b>POLY-3 PERCENT (g)</b>	0%	4.9%
<b>TERMINAL (d)</b>	0/39 (0%)	0/2 (0%)
<b>FIRST INCIDENCE</b>	---	497

**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.360
<b>POLY 1.5</b>	P=0.419
<b>POLY 6</b>	P=0.304
<b>COCH-ARM / FISHERS</b>	P=0.500
<b>MAX-ISO-POLY-3</b>	P=0.156



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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
------	---------	---------------

---

Lymph Node, Mesenteric  
Inflammation

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/19.85
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	---	---

---

**STATISTICAL TESTS**

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

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
------	---------	---------------

---

Lymph Node: Deep Cervical  
Hemorrhage

---

**LESION RATES**

OVERALL (a)	0/2 (0%)	2/6 (33%)
POLY-3 RATE (b)	0/1.66	2/3.57
POLY-3 PERCENT (g)	0%	56.1%
TERMINAL (d)	0/1 (0%)	0/0 (0%)
FIRST INCIDENCE	---	407

---

**STATISTICAL TESTS**

POLY 3	P=0.385
POLY 1.5	P=0.434
POLY 6	P=0.328
COCH-ARM / FISHERS	P=0.536
MAX-ISO-POLY-3	P=0.104

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

**DOSE**                      **0 MG/KG**                      **75 MG/KG Stop**

**Lymph Node: Mediastinal  
Hemorrhage**

**LESION RATES**

<b>OVERALL (a)</b>	0/2 (0%)	2/6 (33%)
<b>POLY-3 RATE (b)</b>	0/1.66	2/3.40
<b>POLY-3 PERCENT (g)</b>	0%	58.9%
<b>TERMINAL (d)</b>	0/1 (0%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	---	414

**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.364
<b>POLY 1.5</b>	P=0.424
<b>POLY 6</b>	P=0.297
<b>COCH-ARM / FISHERS</b>	P=0.536
<b>MAX-ISO-POLY-3</b>	P=0.086

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Lymph Node: Pancreatic  
Hemorrhage

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**LESION RATES**

OVERALL (a)	0/2 (0%)	1/6 (17%)
POLY-3 RATE (b)	0/1.66	1/2.74
POLY-3 PERCENT (g)	0%	36.5%
TERMINAL (d)	0/1 (0%)	0/0 (0%)
FIRST INCIDENCE	---	539

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**STATISTICAL TESTS**

POLY 3	P=0.618
POLY 1.5	P=0.661
POLY 6	P=0.566
COCH-ARM / FISHERS	P=0.750
MAX-ISO-POLY-3	P=0.184

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Males**

---

<b>DOSE</b>	<b>0 MG/KG</b>	<b>75 MG/KG Stop</b>
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**Mammary Gland: Duct  
Dilatation**

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**LESION RATES**

<b>OVERALL (a)</b>	0/50 (0%)	0/50 (0%)
<b>POLY-3 RATE (b)</b>	0/45.76	0/19.85
<b>POLY-3 PERCENT (g)</b>	0%	0%
<b>TERMINAL (d)</b>	0/39 (0%)	0/2 (0%)
<b>FIRST INCIDENCE</b>	---	---

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**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

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<b>DOSE</b>	<b>0 MG/KG</b>	<b>75 MG/KG Stop</b>
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**Mesentery  
Necrosis**

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**LESION RATES**

<b>OVERALL (a)</b>	7/9 (78%)	2/4 (50%)
<b>POLY-3 RATE (b)</b>	7/8.89	2/2.82
<b>POLY-3 PERCENT (g)</b>	78.8%	71%
<b>TERMINAL (d)</b>	6/7 (86%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	627	407

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**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.693N
<b>POLY 1.5</b>	P=0.548N
<b>POLY 6</b>	P=0.737
<b>COCH-ARM / FISHERS</b>	P=0.354N
<b>MAX-ISO-POLY-3</b>	P=0.420N

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Nose  
Inflammation

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**LESION RATES**

OVERALL (a)	25/50 (50%)	28/50 (56%)
POLY-3 RATE (b)	25/47.42	28/36.39
POLY-3 PERCENT (g)	52.7%	76.9%
TERMINAL (d)	19/39 (49%)	2/2 (100%)
FIRST INCIDENCE	412	360

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**STATISTICAL TESTS**

POLY 3	P=0.015*
POLY 1.5	P=0.091
POLY 6	P<0.001**
COCH-ARM / FISHERS	P=0.344
MAX-ISO-POLY-3	P=0.016*

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

Males

DOSE                      0 MG/KG                      75 MG/KG Stop

Nose  
Thrombosis

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/19.85
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	---	---

STATISTICAL TESTS

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



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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Nose: Glands  
Dilatation

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**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/45.76	1/20.52
POLY-3 PERCENT (g)	0%	4.9%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	---	503

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**STATISTICAL TESTS**

POLY 3	P=0.360
POLY 1.5	P=0.419
POLY 6	P=0.304
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.156

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Nose: Goblet Cell  
Hyperplasia

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**LESION RATES**

OVERALL (a)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	3/45.76	0/19.85
POLY-3 PERCENT (g)	6.6%	0%
TERMINAL (d)	3/39 (8%)	0/2 (0%)
FIRST INCIDENCE	727 (T)	---

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**STATISTICAL TESTS**

POLY 3	P=0.327N
POLY 1.5	P=0.217N
POLY 6	P=0.468N
COCH-ARM / FISHERS	P=0.121N
MAX-ISO-POLY-3	P=0.220N

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Nose: Olfactory Epithelium  
Degeneration

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**LESION RATES**

OVERALL (a)	1/50 (2%)	19/50 (38%)
POLY-3 RATE (b)	1/46.12	19/32.38
POLY-3 PERCENT (g)	2.2%	58.7%
TERMINAL (d)	0/39 (0%)	1/2 (50%)
FIRST INCIDENCE	627	360

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**STATISTICAL TESTS**

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

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Nose: Olfactory Epithelium  
Metaplasia Respiratory

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**LESION RATES**

OVERALL (a)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/45.90	0/19.85
POLY-3 PERCENT (g)	4.4%	0%
TERMINAL (d)	1/39 (3%)	0/2 (0%)
FIRST INCIDENCE	692	---

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**STATISTICAL TESTS**

POLY 3	P=0.445N
POLY 1.5	P=0.346N
POLY 6	P=0.556N
COCH-ARM / FISHERS	P=0.247N
MAX-ISO-POLY-3	P=0.268N

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Oral Mucosa: Pharyngeal  
Hyperplasia

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**LESION RATES**

OVERALL (a)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---

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**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Pancreas: Acinus  
Atrophy

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**LESION RATES**

OVERALL (a)	13/50 (26%)	18/50 (36%)
POLY-3 RATE (b)	13/45.84	18/29.65
POLY-3 PERCENT (g)	28.4%	60.7%
TERMINAL (d)	12/39 (31%)	1/2 (50%)
FIRST INCIDENCE	709	360

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**STATISTICAL TESTS**

POLY 3	P=0.005**
POLY 1.5	P=0.034*
POLY 6	P<0.001**
COCH-ARM / FISHERS	P=0.194
MAX-ISO-POLY-3	P=0.008**

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

**DOSE**                      **0 MG/KG**                      **75 MG/KG Stop**

**Pancreas: Acinus  
Hyperplasia**

**LESION RATES**

<b>OVERALL (a)</b>	11/50 (22%)	1/50 (2%)
<b>POLY-3 RATE (b)</b>	11/46.11	1/20.52
<b>POLY-3 PERCENT (g)</b>	23.9%	4.9%
<b>TERMINAL (d)</b>	10/39 (26%)	0/2 (0%)
<b>FIRST INCIDENCE</b>	632	502

**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.091N
<b>POLY 1.5</b>	P=0.020N*
<b>POLY 6</b>	P=0.296N
<b>COCH-ARM / FISHERS</b>	P=0.002N**
<b>MAX-ISO-POLY-3</b>	P=0.101N

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
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Pancreas: Duct  
Cyst

---

**LESION RATES**

OVERALL (a)	4/50 (8%)	5/50 (10%)
POLY-3 RATE (b)	4/45.76	5/23.37
POLY-3 PERCENT (g)	8.7%	21.4%
TERMINAL (d)	4/39 (10%)	0/2 (0%)
FIRST INCIDENCE	727 (T)	388

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**STATISTICAL TESTS**

POLY 3	P=0.158
POLY 1.5	P=0.286
POLY 6	P=0.072
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.142

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

**DOSE**                      **0 MG/KG**                      **75 MG/KG Stop**

Parathyroid Gland  
Hyperplasia

**LESION RATES**

OVERALL (a)	0/49 (0%)	36/48 (75%)
POLY-3 RATE (b)	0/44.76	36/38.99
POLY-3 PERCENT (g)	0%	92.3%
TERMINAL (d)	0/38 (0%)	2/2 (100%)
FIRST INCIDENCE	---	360

**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

**DOSE**                      **0 MG/KG**                      **75 MG/KG Stop**

**Pituitary Gland: Pars Distalis  
Angiectasis**

**LESION RATES**

<b>OVERALL (a)</b>	2/50 (4%)	0/50 (0%)
<b>POLY-3 RATE (b)</b>	2/45.76	0/19.85
<b>POLY-3 PERCENT (g)</b>	4.4%	0%
<b>TERMINAL (d)</b>	2/39 (5%)	0/2 (0%)
<b>FIRST INCIDENCE</b>	727 (T)	---

**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.444N
<b>POLY 1.5</b>	P=0.345N
<b>POLY 6</b>	P=0.555N
<b>COCH-ARM / FISHERS</b>	P=0.247N
<b>MAX-ISO-POLY-3</b>	P=0.267N

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

**DOSE**                      **0 MG/KG**                      **75 MG/KG Stop**

**Pituitary Gland: Pars Distalis  
Cyst**

**LESION RATES**

<b>OVERALL (a)</b>	2/50 (4%)	1/50 (2%)
<b>POLY-3 RATE (b)</b>	2/45.76	1/20.18
<b>POLY-3 PERCENT (g)</b>	4.4%	5%
<b>TERMINAL (d)</b>	2/39 (5%)	0/2 (0%)
<b>FIRST INCIDENCE</b>	727 (T)	635

**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.676
<b>POLY 1.5</b>	P=0.642N
<b>POLY 6</b>	P=0.542
<b>COCH-ARM / FISHERS</b>	P=0.500N
<b>MAX-ISO-POLY-3</b>	P=0.470

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Pituitary Gland: Pars Distalis  
Hyperplasia

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**LESION RATES**

OVERALL (a)	22/50 (44%)	14/50 (28%)
POLY-3 RATE (b)	22/46.57	14/26.72
POLY-3 PERCENT (g)	47.2%	52.4%
TERMINAL (d)	19/39 (49%)	1/2 (50%)
FIRST INCIDENCE	627	407

---

**STATISTICAL TESTS**

POLY 3	P=0.430
POLY 1.5	P=0.374N
POLY 6	P=0.114
COCH-ARM / FISHERS	P=0.072N
MAX-ISO-POLY-3	P=0.366

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
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Preputial Gland  
Inflammation

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**LESION RATES**

OVERALL (a)	9/50 (18%)	8/50 (16%)
POLY-3 RATE (b)	9/46.12	8/24.97
POLY-3 PERCENT (g)	19.5%	32.1%
TERMINAL (d)	8/39 (21%)	0/2 (0%)
FIRST INCIDENCE	627	393

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**STATISTICAL TESTS**

POLY 3	P=0.204
POLY 1.5	P=0.409
POLY 6	P=0.071
COCH-ARM / FISHERS	P=0.500N
MAX-ISO-POLY-3	P=0.188

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Preputial Gland: Duct  
Ectasia

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**LESION RATES**

OVERALL (a)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	3/45.76	1/20.43
POLY-3 PERCENT (g)	6.6%	4.9%
TERMINAL (d)	3/39 (8%)	0/2 (0%)
FIRST INCIDENCE	727 (T)	545

---

**STATISTICAL TESTS**

POLY 3	P=0.600N
POLY 1.5	P=0.468N
POLY 6	P=0.612
COCH-ARM / FISHERS	P=0.309N
MAX-ISO-POLY-3	P=0.428N

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Males**

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<b>DOSE</b>	<b>0 MG/KG</b>	<b>75 MG/KG Stop</b>
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**Prostate  
Inflammation**

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**LESION RATES**

<b>OVERALL (a)</b>	9/50 (18%)	3/49 (6%)
<b>POLY-3 RATE (b)</b>	9/45.90	3/21.58
<b>POLY-3 PERCENT (g)</b>	19.6%	13.9%
<b>TERMINAL (d)</b>	8/39 (21%)	0/2 (0%)
<b>FIRST INCIDENCE</b>	692	360

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**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.419N
<b>POLY 1.5</b>	P=0.212N
<b>POLY 6</b>	P=0.549
<b>COCH-ARM / FISHERS</b>	P=0.065N
<b>MAX-ISO-POLY-3</b>	P=0.343N

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Prostate: Epithelium  
Hyperplasia

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**LESION RATES**

OVERALL (a)	15/50 (30%)	3/49 (6%)
POLY-3 RATE (b)	15/45.87	3/21.45
POLY-3 PERCENT (g)	32.7%	14%
TERMINAL (d)	14/39 (36%)	0/2 (0%)
FIRST INCIDENCE	701	476

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**STATISTICAL TESTS**

POLY 3	P=0.116N
POLY 1.5	P=0.023N*
POLY 6	P=0.384N
COCH-ARM / FISHERS	P=0.002N**
MAX-ISO-POLY-3	P=0.126N

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

**DOSE**                      **0 MG/KG**                      **75 MG/KG Stop**

**Spleen**  
**Hematopoietic Cell Proliferation**

**LESION RATES**

<b>OVERALL (a)</b>	0/50 (0%)	0/50 (0%)
<b>POLY-3 RATE (b)</b>	0/45.76	0/19.85
<b>POLY-3 PERCENT (g)</b>	0%	0%
<b>TERMINAL (d)</b>	0/39 (0%)	0/2 (0%)
<b>FIRST INCIDENCE</b>	---	---

**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Spleen  
Hyperplasia Lymphoid

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**LESION RATES**

OVERALL (a)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	3/45.76	0/19.85
POLY-3 PERCENT (g)	6.6%	0%
TERMINAL (d)	3/39 (8%)	0/2 (0%)
FIRST INCIDENCE	727 (T)	---

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**STATISTICAL TESTS**

POLY 3	P=0.327N
POLY 1.5	P=0.217N
POLY 6	P=0.468N
COCH-ARM / FISHERS	P=0.121N
MAX-ISO-POLY-3	P=0.220N

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Stomach, Forestomach  
Inflammation

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**LESION RATES**

OVERALL (a)	2/50 (4%)	23/50 (46%)
POLY-3 RATE (b)	2/45.76	23/35.83
POLY-3 PERCENT (g)	4.4%	64.2%
TERMINAL (d)	2/39 (5%)	2/2 (100%)
FIRST INCIDENCE	727 (T)	360

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**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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---

Stomach, Forestomach  
Mineralization

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	4/50 (8%)
POLY-3 RATE (b)	0/45.76	4/21.61
POLY-3 PERCENT (g)	0%	18.5%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	---	545

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**STATISTICAL TESTS**

POLY 3	P=0.013*
POLY 1.5	P=0.025*
POLY 6	P=0.007**
COCH-ARM / FISHERS	P=0.059
MAX-ISO-POLY-3	P=0.016*

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

**DOSE**                      **0 MG/KG**                      **75 MG/KG Stop**

**Stomach, Forestomach  
Perforation**

**LESION RATES**

<b>OVERALL (a)</b>	0/50 (0%)	5/50 (10%)
<b>POLY-3 RATE (b)</b>	0/45.76	5/24.05
<b>POLY-3 PERCENT (g)</b>	0%	20.8%
<b>TERMINAL (d)</b>	0/39 (0%)	0/2 (0%)
<b>FIRST INCIDENCE</b>	---	366

**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.005**
<b>POLY 1.5</b>	P=0.011*
<b>POLY 6</b>	P=0.002**
<b>COCH-ARM / FISHERS</b>	P=0.028*
<b>MAX-ISO-POLY-3</b>	P=0.008**

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

**DOSE**                      **0 MG/KG**                      **75 MG/KG Stop**

**Stomach, Forestomach  
Ulcer**

**LESION RATES**

<b>OVERALL (a)</b>	0/50 (0%)	16/50 (32%)
<b>POLY-3 RATE (b)</b>	0/45.76	16/32.34
<b>POLY-3 PERCENT (g)</b>	0%	49.5%
<b>TERMINAL (d)</b>	0/39 (0%)	0/2 (0%)
<b>FIRST INCIDENCE</b>	---	360

**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Stomach, Forestomach: Epithelium  
Hyperplasia

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**LESION RATES**

OVERALL (a)	16/50 (32%)	23/50 (46%)
POLY-3 RATE (b)	16/47.34	23/37.62
POLY-3 PERCENT (g)	33.8%	61.1%
TERMINAL (d)	12/39 (31%)	0/2 (0%)
FIRST INCIDENCE	24	360

---

**STATISTICAL TESTS**

POLY 3	P=0.008**
POLY 1.5	P=0.033*
POLY 6	P<0.001**
COCH-ARM / FISHERS	P=0.109
MAX-ISO-POLY-3	P=0.009**

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
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Stomach, Glandular  
Erosion

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/19.85
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	---	---

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**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

**DOSE**                      **0 MG/KG**                      **75 MG/KG Stop**

**Stomach, Glandular  
Inflammation**

**LESION RATES**

<b>OVERALL (a)</b>	1/50 (2%)	6/50 (12%)
<b>POLY-3 RATE (b)</b>	1/45.76	6/23.95
<b>POLY-3 PERCENT (g)</b>	2.2%	25.1%
<b>TERMINAL (d)</b>	1/39 (3%)	0/2 (0%)
<b>FIRST INCIDENCE</b>	727 (T)	360

**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.007**
<b>POLY 1.5</b>	P=0.019*
<b>POLY 6</b>	P=0.002**
<b>COCH-ARM / FISHERS</b>	P=0.056
<b>MAX-ISO-POLY-3</b>	P=0.011*

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Stomach, Glandular  
Mineralization

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**LESION RATES**

OVERALL (a)	0/50 (0%)	21/50 (42%)
POLY-3 RATE (b)	0/45.76	21/29.95
POLY-3 PERCENT (g)	0%	70.1%
TERMINAL (d)	0/39 (0%)	1/2 (50%)
FIRST INCIDENCE	---	476

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**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

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DOSE	0 MG/KG	75 MG/KG Stop
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Testes: Germinal Epithelium  
Atrophy

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**LESION RATES**

OVERALL (a)	3/50 (6%)	4/49 (8%)
POLY-3 RATE (b)	3/45.78	4/21.64
POLY-3 PERCENT (g)	6.6%	18.5%
TERMINAL (d)	2/39 (5%)	0/2 (0%)
FIRST INCIDENCE	723	503

---

**STATISTICAL TESTS**

POLY 3	P=0.170
POLY 1.5	P=0.290
POLY 6	P=0.087
COCH-ARM / FISHERS	P=0.489
MAX-ISO-POLY-3	P=0.147

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
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Thyroid Gland: C-Cell  
Hyperplasia

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**LESION RATES**

OVERALL (a)	32/50 (64%)	20/47 (43%)
POLY-3 RATE (b)	32/46.42	20/30.49
POLY-3 PERCENT (g)	68.9%	65.6%
TERMINAL (d)	28/39 (72%)	2/2 (100%)
FIRST INCIDENCE	632	360

---

**STATISTICAL TESTS**

POLY 3	P=0.476N
POLY 1.5	P=0.152N
POLY 6	P=0.282
COCH-ARM / FISHERS	P=0.028N*
MAX-ISO-POLY-3	P=0.390N

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

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<b>DOSE</b>	<b>0 MG/KG</b>	<b>75 MG/KG Stop</b>
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Trachea  
Inflammation

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**LESION RATES**

<b>OVERALL (a)</b>	2/50 (4%)	3/50 (6%)
<b>POLY-3 RATE (b)</b>	2/45.90	3/22.01
<b>POLY-3 PERCENT (g)</b>	4.4%	13.6%
<b>TERMINAL (d)</b>	1/39 (3%)	0/2 (0%)
<b>FIRST INCIDENCE</b>	692	377

---

**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.219
<b>POLY 1.5</b>	P=0.331
<b>POLY 6</b>	P=0.130
<b>COCH-ARM / FISHERS</b>	P=0.500
<b>MAX-ISO-POLY-3</b>	P=0.171

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Males**

---

DOSE	0 MG/KG	75 MG/KG Stop
------	---------	---------------

---

Urinary Bladder  
Inflammation

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**LESION RATES**

OVERALL (a)	1/50 (2%)	1/49 (2%)
POLY-3 RATE (b)	1/45.76	1/20.36
POLY-3 PERCENT (g)	2.2%	4.9%
TERMINAL (d)	1/39 (3%)	0/2 (0%)
FIRST INCIDENCE	727 (T)	503

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**STATISTICAL TESTS**

POLY 3	P=0.562
POLY 1.5	P=0.654
POLY 6	P=0.456
COCH-ARM / FISHERS	P=0.747
MAX-ISO-POLY-3	P=0.343

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Adrenal Cortex  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	10/50 (20%)	14/49 (29%)
POLY-3 RATE (b)	10/43.61	14/28.75
POLY-3 PERCENT (g)	22.9%	48.7%
TERMINAL (d)	7/31 (23%)	0/0 (0%)
FIRST INCIDENCE	634	516

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**STATISTICAL TESTS**

POLY 3	P=0.020*
POLY 1.5	P=0.067
POLY 6	P=0.003**
COCH-ARM / FISHERS	P=0.224
MAX-ISO-POLY-3	P=0.025*

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Adrenal Cortex  
Hypertrophy

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**LESION RATES**

OVERALL (a)	20/50 (40%)	20/49 (41%)
POLY-3 RATE (b)	20/45.53	20/31.63
POLY-3 PERCENT (g)	43.9%	63.2%
TERMINAL (d)	10/31 (32%)	0/0 (0%)
FIRST INCIDENCE	538	470

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**STATISTICAL TESTS**

POLY 3	P=0.069
POLY 1.5	P=0.212
POLY 6	P=0.009**
COCH-ARM / FISHERS	P=0.548
MAX-ISO-POLY-3	P=0.068

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

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

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Lab: BAT

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

**Females**

---

DOSE	0 MG/KG	150 MG/KG Stop
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---

Adrenal Medulla  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	6/50 (12%)	27/49 (55%)
POLY-3 RATE (b)	6/42.91	27/34.92
POLY-3 PERCENT (g)	14%	77.3%
TERMINAL (d)	5/31 (16%)	0/0 (0%)
FIRST INCIDENCE	693	470

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**STATISTICAL TESTS**

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

---

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

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

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

**Females**

---

DOSE	0 MG/KG	150 MG/KG Stop
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Blood Vessel  
Mineralization

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**LESION RATES**

OVERALL (a)	0/50 (0%)	20/50 (40%)
POLY-3 RATE (b)	0/42.78	20/31.81
POLY-3 PERCENT (g)	0%	62.9%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	349

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**STATISTICAL TESTS**

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

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

**Females**

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<b>DOSE</b>	<b>0 MG/KG</b>	<b>150 MG/KG Stop</b>
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**Bone Marrow  
Hyperplasia**

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**LESION RATES**

<b>OVERALL (a)</b>	8/50 (16%)	38/50 (76%)
<b>POLY-3 RATE (b)</b>	8/44.43	38/42.06
<b>POLY-3 PERCENT (g)</b>	18%	90.4%
<b>TERMINAL (d)</b>	4/31 (13%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	519	349

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**STATISTICAL TESTS**

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

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
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Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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**Bone**  
**Fibrous Osteodystrophy**

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**LESION RATES**

OVERALL (a)	0/50 (0%)	27/50 (54%)
POLY-3 RATE (b)	0/42.78	27/34.32
POLY-3 PERCENT (g)	0%	78.7%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	516

---

**STATISTICAL TESTS**

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

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
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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/N)  
TERMINAL SACRIFICE AT 104 WEEKS**

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Brain  
Hydrocephalus

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**LESION RATES**

OVERALL (a)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/43.75	0/22.19
POLY-3 PERCENT (g)	4.6%	0%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	495	---

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**STATISTICAL TESTS**

POLY 3	P=0.407N
POLY 1.5	P=0.326N
POLY 6	P=0.527N
COCH-ARM / FISHERS	P=0.247N
MAX-ISO-POLY-3	P=0.233N

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Clitoral Gland  
Hyperplasia

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**LESION RATES**

OVERALL (a)	3/50 (6%)	1/49 (2%)
POLY-3 RATE (b)	3/43.14	1/22.61
POLY-3 PERCENT (g)	7%	4.4%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	634	559

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**STATISTICAL TESTS**

POLY 3	P=0.549N
POLY 1.5	P=0.440N
POLY 6	P=0.662
COCH-ARM / FISHERS	P=0.316N
MAX-ISO-POLY-3	P=0.381N

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Clitoral Gland  
Inflammation

---

**LESION RATES**

OVERALL (a)	6/50 (12%)	3/49 (6%)
POLY-3 RATE (b)	6/43.27	3/23.04
POLY-3 PERCENT (g)	13.9%	13%
TERMINAL (d)	4/31 (13%)	0/0 (0%)
FIRST INCIDENCE	634	580

---

**STATISTICAL TESTS**

POLY 3	P=0.602N
POLY 1.5	P=0.439N
POLY 6	P=0.431
COCH-ARM / FISHERS	P=0.254N
MAX-ISO-POLY-3	P=0.470N

---

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

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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/N)  
TERMINAL SACRIFICE AT 104 WEEKS**

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Clitoral Gland: Duct  
Cyst

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**LESION RATES**

OVERALL (a)	2/50 (4%)	0/49 (0%)
POLY-3 RATE (b)	2/43.12	0/22.06
POLY-3 PERCENT (g)	4.6%	0%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	634	---

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**STATISTICAL TESTS**

POLY 3	P=0.404N
POLY 1.5	P=0.326N
POLY 6	P=0.523N
COCH-ARM / FISHERS	P=0.253N
MAX-ISO-POLY-3	P=0.230N

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

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Pulegone  
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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/N)  
TERMINAL SACRIFICE AT 104 WEEKS**

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Eye  
Hemorrhage

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**LESION RATES**

OVERALL (a)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	0/42.78	3/24.03
POLY-3 PERCENT (g)	0%	12.5%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	338

---

**STATISTICAL TESTS**

POLY 3	P=0.049*
POLY 1.5	P=0.073
POLY 6	P=0.029*
COCH-ARM / FISHERS	P=0.121
MAX-ISO-POLY-3	P=0.035*

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

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/N)  
TERMINAL SACRIFICE AT 104 WEEKS**

**Females**

**DOSE**                      **0 MG/KG**                      **150 MG/KG Stop**

**Eye  
Inflammation**

**LESION RATES**

<b>OVERALL (a)</b>	1/50 (2%)	9/50 (18%)
<b>POLY-3 RATE (b)</b>	1/43.37	9/26.96
<b>POLY-3 PERCENT (g)</b>	2.3%	33.4%
<b>TERMINAL (d)</b>	0/31 (0%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	538	338

**STATISTICAL TESTS**

<b>POLY 3</b>	P<0.001**
<b>POLY 1.5</b>	P=0.002**
<b>POLY 6</b>	P<0.001**
<b>COCH-ARM / FISHERS</b>	P=0.008**
<b>MAX-ISO-POLY-3</b>	P<0.001**

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

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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/N)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Eye: Cornea  
Inflammation

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**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/22.19
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---

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**STATISTICAL TESTS**

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

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

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

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

---

**Females**

---

DOSE	0 MG/KG	150 MG/KG Stop
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---

Eye: Retina  
Atrophy

---

**LESION RATES**

OVERALL (a)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	2/42.78	2/23.25
POLY-3 PERCENT (g)	4.7%	8.6%
TERMINAL (d)	2/31 (7%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	538

---

**STATISTICAL TESTS**

POLY 3	P=0.464
POLY 1.5	P=0.569
POLY 6	P=0.323
COCH-ARM / FISHERS	P=0.691N
MAX-ISO-POLY-3	P=0.317

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TDMS No. 99020 - 05  
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Species/Strain: RATS/F 344/N

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Pulegone  
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Lab: BAT

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

**Females**

---

DOSE	0 MG/KG	150 MG/KG Stop
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---

Harderian Gland  
Inflammation

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/22.19
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---

---

**STATISTICAL TESTS**

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

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
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Lab: BAT

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

**Females**

**DOSE**                      **0 MG/KG**                      **150 MG/KG Stop**

Harderian Gland: Epithelium  
Hyperplasia

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/22.19
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---

**STATISTICAL TESTS**

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

TDMS No. 99020 - 05  
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Species/Strain: RATS/F 344/N

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

**Females**

---

DOSE	0 MG/KG	150 MG/KG Stop
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Heart  
Cardiomyopathy

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**LESION RATES**

OVERALL (a)	48/50 (96%)	44/50 (88%)
POLY-3 RATE (b)	48/49.71	44/45.88
POLY-3 PERCENT (g)	96.6%	95.9%
TERMINAL (d)	30/31 (97%)	0/0 (0%)
FIRST INCIDENCE	309	338

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**STATISTICAL TESTS**

POLY 3	P=0.670N
POLY 1.5	P=0.453N
POLY 6	P=0.673
COCH-ARM / FISHERS	P=0.134N
MAX-ISO-POLY-3	P=0.423N

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TDMS No. 99020 - 05  
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Species/Strain: RATS/F 344/N

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Lab: BAT

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

**Females**

---

DOSE	0 MG/KG	150 MG/KG Stop
------	---------	----------------

---

Heart  
Inflammation

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	4/50 (8%)
POLY-3 RATE (b)	0/42.78	4/25.20
POLY-3 PERCENT (g)	0%	15.9%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	349

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**STATISTICAL TESTS**

POLY 3	P=0.019*
POLY 1.5	P=0.032*
POLY 6	P=0.009**
COCH-ARM / FISHERS	P=0.059
MAX-ISO-POLY-3	P=0.016*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Pulegone  
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Lab: BAT

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

**Females**

---

DOSE	0 MG/KG	150 MG/KG Stop
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Heart  
Mineralization

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**LESION RATES**

OVERALL (a)	0/50 (0%)	11/50 (22%)
POLY-3 RATE (b)	0/42.78	11/27.83
POLY-3 PERCENT (g)	0%	39.5%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	516

---

**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Intestine Large, Cecum  
Inflammation

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**LESION RATES**

OVERALL (a)	0/50 (0%)	12/45 (27%)
POLY-3 RATE (b)	0/42.78	12/26.76
POLY-3 PERCENT (g)	0%	44.8%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	349

---

**STATISTICAL TESTS**

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

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

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/N)  
TERMINAL SACRIFICE AT 104 WEEKS**

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Intestine Large, Cecum  
Mineralization

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**LESION RATES**

OVERALL (a)	0/50 (0%)	0/45 (0%)
POLY-3 RATE (b)	0/42.78	0/20.48
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---

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**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Intestine Large, Cecum  
Ulcer

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**LESION RATES**

OVERALL (a)	0/50 (0%)	1/45 (2%)
POLY-3 RATE (b)	0/42.78	1/20.90
POLY-3 PERCENT (g)	0%	4.8%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	604

---

**STATISTICAL TESTS**

POLY 3	P=0.370
POLY 1.5	P=0.416
POLY 6	P=0.311
COCH-ARM / FISHERS	P=0.474
MAX-ISO-POLY-3	P=0.149

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Females**

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<b>DOSE</b>	<b>0 MG/KG</b>	<b>150 MG/KG Stop</b>
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Intestine Large, Colon  
Parasite Metazoan

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**LESION RATES**

<b>OVERALL (a)</b>	3/50 (6%)	0/45 (0%)
<b>POLY-3 RATE (b)</b>	3/42.78	0/20.48
<b>POLY-3 PERCENT (g)</b>	7%	0%
<b>TERMINAL (d)</b>	3/31 (10%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	728 (T)	---

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**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.296N
<b>POLY 1.5</b>	P=0.216N
<b>POLY 6</b>	P=0.433N
<b>COCH-ARM / FISHERS</b>	P=0.142N
<b>MAX-ISO-POLY-3</b>	P=0.190N

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Intestine Large, Rectum  
Parasite Metazoan

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**LESION RATES**

OVERALL (a)	4/50 (8%)	1/49 (2%)
POLY-3 RATE (b)	4/42.98	1/22.95
POLY-3 PERCENT (g)	9.3%	4.4%
TERMINAL (d)	3/31 (10%)	0/0 (0%)
FIRST INCIDENCE	674	352

---

**STATISTICAL TESTS**

POLY 3	P=0.415N
POLY 1.5	P=0.299N
POLY 6	P=0.596N
COCH-ARM / FISHERS	P=0.187N
MAX-ISO-POLY-3	P=0.296N

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

**DOSE**                      **0 MG/KG**                      **150 MG/KG Stop**

**Intestine Small, Duodenum  
Erosion**

**LESION RATES**

<b>OVERALL (a)</b>	0/50 (0%)	0/45 (0%)
<b>POLY-3 RATE (b)</b>	0/42.78	0/20.48
<b>POLY-3 PERCENT (g)</b>	0%	0%
<b>TERMINAL (d)</b>	0/31 (0%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	---	---

**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Kidney  
Cyst

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**LESION RATES**

OVERALL (a)	2/50 (4%)	2/49 (4%)
POLY-3 RATE (b)	2/43.70	2/22.86
POLY-3 PERCENT (g)	4.6%	8.8%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	309	611

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**STATISTICAL TESTS**

POLY 3	P=0.451
POLY 1.5	P=0.557
POLY 6	P=0.312
COCH-ARM / FISHERS	P=0.684
MAX-ISO-POLY-3	P=0.309

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

**DOSE**                      **0 MG/KG**                      **150 MG/KG Stop**

**Kidney**  
**Glomerulopathy Hyaline**

**LESION RATES**

<b>OVERALL (a)</b>	0/50 (0%)	48/49 (98%)
<b>POLY-3 RATE (b)</b>	0/42.78	48/48.00
<b>POLY-3 PERCENT (g)</b>	0%	100%
<b>TERMINAL (d)</b>	0/31 (0%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	---	338

**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Kidney  
Inflammation

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**LESION RATES**

OVERALL (a)	0/50 (0%)	2/49 (4%)
POLY-3 RATE (b)	0/42.78	2/22.90
POLY-3 PERCENT (g)	0%	8.7%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	537

---

**STATISTICAL TESTS**

POLY 3	P=0.132
POLY 1.5	P=0.170
POLY 6	P=0.093
COCH-ARM / FISHERS	P=0.242
MAX-ISO-POLY-3	P=0.071

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Kidney  
Nephropathy

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**LESION RATES**

OVERALL (a)	42/50 (84%)	48/49 (98%)
POLY-3 RATE (b)	42/47.79	48/48.00
POLY-3 PERCENT (g)	87.9%	100%
TERMINAL (d)	30/31 (97%)	0/0 (0%)
FIRST INCIDENCE	309	338

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**STATISTICAL TESTS**

POLY 3	P=0.008**
POLY 1.5	P=0.006**
POLY 6	P=0.016*
COCH-ARM / FISHERS	P=0.017*
MAX-ISO-POLY-3	P=0.002**

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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**Kidney: Cortex  
Mineralization**

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**LESION RATES**

OVERALL (a)	0/50 (0%)	26/49 (53%)
POLY-3 RATE (b)	0/42.78	26/34.81
POLY-3 PERCENT (g)	0%	74.7%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	390

---

**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Liver  
Basophilic Focus

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**LESION RATES**

OVERALL (a)	44/50 (88%)	2/47 (4%)
POLY-3 RATE (b)	44/47.23	2/22.31
POLY-3 PERCENT (g)	93.2%	9%
TERMINAL (d)	29/31 (94%)	0/0 (0%)
FIRST INCIDENCE	519	559

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**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Liver  
Clear Cell Focus

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**LESION RATES**

OVERALL (a)	8/50 (16%)	1/47 (2%)
POLY-3 RATE (b)	8/44.29	1/22.01
POLY-3 PERCENT (g)	18.1%	4.5%
TERMINAL (d)	5/31 (16%)	0/0 (0%)
FIRST INCIDENCE	538	470

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**STATISTICAL TESTS**

POLY 3	P=0.150N
POLY 1.5	P=0.067N
POLY 6	P=0.357N
COCH-ARM / FISHERS	P=0.019N*
MAX-ISO-POLY-3	P=0.134N

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

**DOSE**                      **0 MG/KG**                      **150 MG/KG Stop**

Liver  
Eosinophilic Focus

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/47 (0%)
POLY-3 RATE (b)	0/42.78	0/21.28
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---

**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

**DOSE**                      **0 MG/KG**                      **150 MG/KG Stop**

Liver  
Fatty Change

**LESION RATES**

<b>OVERALL (a)</b>	7/50 (14%)	11/47 (23%)
<b>POLY-3 RATE (b)</b>	7/44.63	11/26.60
<b>POLY-3 PERCENT (g)</b>	15.7%	41.4%
<b>TERMINAL (d)</b>	4/31 (13%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	495	470

**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.018*
<b>POLY 1.5</b>	P=0.054
<b>POLY 6</b>	P=0.003**
<b>COCH-ARM / FISHERS</b>	P=0.176
<b>MAX-ISO-POLY-3</b>	P=0.024*



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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Liver  
Hepatodiaphragmatic Nodule

**LESION RATES**

OVERALL (a)	3/50 (6%)	2/47 (4%)
POLY-3 RATE (b)	3/42.78	2/22.67
POLY-3 PERCENT (g)	7%	8.8%
TERMINAL (d)	3/31 (10%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	19

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**STATISTICAL TESTS**

POLY 3	P=0.582
POLY 1.5	P=0.658N
POLY 6	P=0.413
COCH-ARM / FISHERS	P=0.530N
MAX-ISO-POLY-3	P=0.421

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Liver  
Inflammation

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**LESION RATES**

OVERALL (a)	35/50 (70%)	33/47 (70%)
POLY-3 RATE (b)	35/46.42	33/39.00
POLY-3 PERCENT (g)	75.4%	84.6%
TERMINAL (d)	26/31 (84%)	0/0 (0%)
FIRST INCIDENCE	309	338

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**STATISTICAL TESTS**

POLY 3	P=0.191
POLY 1.5	P=0.310
POLY 6	P=0.094
COCH-ARM / FISHERS	P=0.579
MAX-ISO-POLY-3	P=0.134

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Liver  
Mixed Cell Focus

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**LESION RATES**

OVERALL (a)	5/50 (10%)	0/47 (0%)
POLY-3 RATE (b)	5/43.01	0/21.28
POLY-3 PERCENT (g)	11.6%	0%
TERMINAL (d)	3/31 (10%)	0/0 (0%)
FIRST INCIDENCE	674	---

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**STATISTICAL TESTS**

POLY 3	P=0.149N
POLY 1.5	P=0.082N
POLY 6	P=0.303N
COCH-ARM / FISHERS	P=0.033N*
MAX-ISO-POLY-3	P=0.117N

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

**DOSE**                      **0 MG/KG**                      **150 MG/KG Stop**

Liver: Bile Duct  
Cyst

**LESION RATES**

OVERALL (a)	1/50 (2%)	13/47 (28%)
POLY-3 RATE (b)	1/42.78	13/27.52
POLY-3 PERCENT (g)	2.3%	47.2%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	338

**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Liver: Bile Duct  
Hyperplasia

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**LESION RATES**

OVERALL (a)	5/50 (10%)	43/47 (91%)
POLY-3 RATE (b)	5/42.91	43/44.19
POLY-3 PERCENT (g)	11.7%	97.3%
TERMINAL (d)	4/31 (13%)	0/0 (0%)
FIRST INCIDENCE	693	338

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**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

**DOSE**                      **0 MG/KG**                      **150 MG/KG Stop**

Liver: Hepatocyte  
Cellular Alteration Diffuse

**LESION RATES**

OVERALL (a)	0/50 (0%)	43/47 (91%)
POLY-3 RATE (b)	0/42.78	43/44.91
POLY-3 PERCENT (g)	0%	95.8%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	338

**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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---

Liver: Hepatocyte  
Necrosis

---

**LESION RATES**

OVERALL (a)	4/50 (8%)	15/47 (32%)
POLY-3 RATE (b)	4/43.57	15/29.19
POLY-3 PERCENT (g)	9.2%	51.4%
TERMINAL (d)	2/31 (7%)	0/0 (0%)
FIRST INCIDENCE	519	349

---

**STATISTICAL TESTS**

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

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Females**

---

<b>DOSE</b>	<b>0 MG/KG</b>	<b>150 MG/KG Stop</b>
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---

Liver: Hepatocyte, Centrilobular  
Degeneration

---

**LESION RATES**

<b>OVERALL (a)</b>	0/50 (0%)	0/47 (0%)
<b>POLY-3 RATE (b)</b>	0/42.78	0/21.28
<b>POLY-3 PERCENT (g)</b>	0%	0%
<b>TERMINAL (d)</b>	0/31 (0%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	---	---

---

**STATISTICAL TESTS**

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

---



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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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---

Liver: Oval Cell  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	43/47 (91%)
POLY-3 RATE (b)	0/42.78	43/44.19
POLY-3 PERCENT (g)	0%	97.3%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	338

---

**STATISTICAL TESTS**

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

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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---

Liver: Portal  
Fibrosis

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	35/47 (74%)
POLY-3 RATE (b)	0/42.78	35/40.32
POLY-3 PERCENT (g)	0%	86.8%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	338

---

**STATISTICAL TESTS**

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

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

---

DOSE	0 MG/KG	150 MG/KG Stop
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---

Lung  
Congestion

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/22.19
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---

---

**STATISTICAL TESTS**

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

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Lung  
Hemorrhage

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**LESION RATES**

OVERALL (a)	0/50 (0%)	12/50 (24%)
POLY-3 RATE (b)	0/42.78	12/29.80
POLY-3 PERCENT (g)	0%	40.3%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	349

---

**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Lung: Alveolar Epithelium  
Hyperplasia

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**LESION RATES**

OVERALL (a)	8/50 (16%)	12/50 (24%)
POLY-3 RATE (b)	8/44.82	12/28.82
POLY-3 PERCENT (g)	17.9%	41.6%
TERMINAL (d)	4/31 (13%)	0/0 (0%)
FIRST INCIDENCE	309	338

---

**STATISTICAL TESTS**

POLY 3	P=0.025*
POLY 1.5	P=0.075
POLY 6	P=0.004**
COCH-ARM / FISHERS	P=0.227
MAX-ISO-POLY-3	P=0.030*

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Lung: Alveolus  
Inflammation Histiocytic

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**LESION RATES**

OVERALL (a)	40/50 (80%)	43/50 (86%)
POLY-3 RATE (b)	40/47.23	43/44.56
POLY-3 PERCENT (g)	84.7%	96.5%
TERMINAL (d)	26/31 (84%)	0/0 (0%)
FIRST INCIDENCE	495	338

---

**STATISTICAL TESTS**

POLY 3	P=0.037*
POLY 1.5	P=0.080
POLY 6	P=0.022*
COCH-ARM / FISHERS	P=0.298
MAX-ISO-POLY-3	P=0.017*

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

**DOSE**                      **0 MG/KG**                      **150 MG/KG Stop**

**Lung: Arteriole  
Inflammation**

**LESION RATES**

<b>OVERALL (a)</b>	0/50 (0%)	2/50 (4%)
<b>POLY-3 RATE (b)</b>	0/42.78	2/23.45
<b>POLY-3 PERCENT (g)</b>	0%	8.5%
<b>TERMINAL (d)</b>	0/31 (0%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	---	523

**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.135
<b>POLY 1.5</b>	P=0.173
<b>POLY 6</b>	P=0.096
<b>COCH-ARM / FISHERS</b>	P=0.247
<b>MAX-ISO-POLY-3</b>	P=0.072

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Females**

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<b>DOSE</b>	<b>0 MG/KG</b>	<b>150 MG/KG Stop</b>
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Lung: Cervix  
Hyperplasia

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**LESION RATES**

<b>OVERALL (a)</b>	0/50 (0%)	0/50 (0%)
<b>POLY-3 RATE (b)</b>	0/42.78	0/22.19
<b>POLY-3 PERCENT (g)</b>	0%	0%
<b>TERMINAL (d)</b>	0/31 (0%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	---	---

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**STATISTICAL TESTS**

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

---



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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Lung: Interstitium  
Mineralization

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**LESION RATES**

OVERALL (a)	0/50 (0%)	16/50 (32%)
POLY-3 RATE (b)	0/42.78	16/29.86
POLY-3 PERCENT (g)	0%	53.6%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	516

---

**STATISTICAL TESTS**

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

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Lymph Node, Mesenteric  
Fibrosis

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/45 (0%)
POLY-3 RATE (b)	0/42.78	0/20.48
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---

---

**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

**DOSE**                      **0 MG/KG**                      **150 MG/KG Stop**

**Lymph Node, Mesenteric  
Hemorrhage**

**LESION RATES**

<b>OVERALL (a)</b>	2/50 (4%)	18/45 (40%)
<b>POLY-3 RATE (b)</b>	2/43.27	18/29.90
<b>POLY-3 PERCENT (g)</b>	4.6%	60.2%
<b>TERMINAL (d)</b>	1/31 (3%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	581	349

**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

**DOSE**                      **0 MG/KG**                      **150 MG/KG Stop**

**Lymph Node, Mesenteric  
Inflammation**

**LESION RATES**

<b>OVERALL (a)</b>	0/50 (0%)	2/45 (4%)
<b>POLY-3 RATE (b)</b>	0/42.78	2/21.45
<b>POLY-3 PERCENT (g)</b>	0%	9.3%
<b>TERMINAL (d)</b>	0/31 (0%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	---	537

**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.122
<b>POLY 1.5</b>	P=0.156
<b>POLY 6</b>	P=0.087
<b>COCH-ARM / FISHERS</b>	P=0.222
<b>MAX-ISO-POLY-3</b>	P=0.067

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Lymph Node: Deep Cervical  
Hemorrhage

**LESION RATES**

OVERALL (a)	0/2 (0%)	3/11 (27%)
POLY-3 RATE (b)	0/2.00	3/6.91
POLY-3 PERCENT (g)	0%	43.4%
TERMINAL (d)	0/2 (0%)	0/0 (0%)
FIRST INCIDENCE	---	352

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**STATISTICAL TESTS**

POLY 3	P=0.362
POLY 1.5	P=0.448
POLY 6	P=0.202
COCH-ARM / FISHERS	P=0.577
MAX-ISO-POLY-3	P=0.120

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Females**

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<b>DOSE</b>	<b>0 MG/KG</b>	<b>150 MG/KG Stop</b>
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**Lymph Node: Mediastinal  
Hemorrhage**

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**LESION RATES**

<b>OVERALL (a)</b>	0/2 (0%)	2/11 (18%)
<b>POLY-3 RATE (b)</b>	0/2.00	2/5.94
<b>POLY-3 PERCENT (g)</b>	0%	33.7%
<b>TERMINAL (d)</b>	0/2 (0%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	---	604

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**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.497
<b>POLY 1.5</b>	P=0.578
<b>POLY 6</b>	P=0.344
<b>COCH-ARM / FISHERS</b>	P=0.705
<b>MAX-ISO-POLY-3</b>	P=0.156

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Females**

---

DOSE	0 MG/KG	150 MG/KG Stop
------	---------	----------------

---

Lymph Node: Pancreatic  
Hemorrhage

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**LESION RATES**

OVERALL (a)	0/2 (0%)	3/11 (27%)
POLY-3 RATE (b)	0/2.00	3/6.54
POLY-3 PERCENT (g)	0%	45.9%
TERMINAL (d)	0/2 (0%)	0/0 (0%)
FIRST INCIDENCE	---	559

---

**STATISTICAL TESTS**

POLY 3	P=0.337
POLY 1.5	P=0.432
POLY 6	P=0.182
COCH-ARM / FISHERS	P=0.577
MAX-ISO-POLY-3	P=0.102

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Females**

---

DOSE	0 MG/KG	150 MG/KG Stop
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**Mammary Gland: Duct  
Dilatation**

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**LESION RATES**

OVERALL (a)	2/50 (4%)	0/49 (0%)
POLY-3 RATE (b)	2/43.27	0/21.84
POLY-3 PERCENT (g)	4.6%	0%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	634	---

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**STATISTICAL TESTS**

POLY 3	P=0.408N
POLY 1.5	P=0.328N
POLY 6	P=0.526N
COCH-ARM / FISHERS	P=0.253N
MAX-ISO-POLY-3	P=0.233N

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

**DOSE**                      **0 MG/KG**                      **150 MG/KG Stop**

**Mesentery  
Necrosis**

**LESION RATES**

<b>OVERALL (a)</b>	5/6 (83%)	1/1 (100%)
<b>POLY-3 RATE (b)</b>	5/5.51	1/1.00
<b>POLY-3 PERCENT (g)</b>	90.8%	100%
<b>TERMINAL (d)</b>	4/4 (100%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	674	352

**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.979
<b>POLY 1.5</b>	P=0.919
<b>POLY 6</b>	P=1.000
<b>COCH-ARM / FISHERS</b>	P=0.857
<b>MAX-ISO-POLY-3</b>	P=0.383

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Nose  
Inflammation

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**LESION RATES**

OVERALL (a)	12/50 (24%)	26/41 (63%)
POLY-3 RATE (b)	12/43.68	26/32.12
POLY-3 PERCENT (g)	27.5%	81%
TERMINAL (d)	9/31 (29%)	0/0 (0%)
FIRST INCIDENCE	581	19

---

**STATISTICAL TESTS**

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

---

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Nose  
Thrombosis

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/41 (5%)
POLY-3 RATE (b)	0/42.78	2/19.34
POLY-3 PERCENT (g)	0%	10.3%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	524

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**STATISTICAL TESTS**

POLY 3	P=0.108
POLY 1.5	P=0.139
POLY 6	P=0.077
COCH-ARM / FISHERS	P=0.200
MAX-ISO-POLY-3	P=0.061

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Nose: Glands  
Dilatation

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**LESION RATES**

OVERALL (a)	0/50 (0%)	2/41 (5%)
POLY-3 RATE (b)	0/42.78	2/19.17
POLY-3 PERCENT (g)	0%	10.4%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	594

---

**STATISTICAL TESTS**

POLY 3	P=0.107
POLY 1.5	P=0.138
POLY 6	P=0.077
COCH-ARM / FISHERS	P=0.200
MAX-ISO-POLY-3	P=0.061

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Nose: Goblet Cell  
Hyperplasia

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**LESION RATES**

OVERALL (a)	0/50 (0%)	0/41 (0%)
POLY-3 RATE (b)	0/42.78	0/18.48
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---

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**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Females**

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<b>DOSE</b>	<b>0 MG/KG</b>	<b>150 MG/KG Stop</b>
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**Nose: Olfactory Epithelium  
Degeneration**

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**LESION RATES**

<b>OVERALL (a)</b>	2/50 (4%)	37/41 (90%)
<b>POLY-3 RATE (b)</b>	2/43.06	37/38.40
<b>POLY-3 PERCENT (g)</b>	4.6%	96.4%
<b>TERMINAL (d)</b>	1/31 (3%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	650	19

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**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Nose: Olfactory Epithelium  
Metaplasia Respiratory

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**LESION RATES**

OVERALL (a)	1/50 (2%)	36/41 (88%)
POLY-3 RATE (b)	1/42.78	36/37.40
POLY-3 PERCENT (g)	2.3%	96.3%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	338

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**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

**DOSE**                      **0 MG/KG**                      **150 MG/KG Stop**

Oral Mucosa: Pharyngeal  
Hyperplasia

**LESION RATES**

<b>OVERALL (a)</b>	1/1 (100%)	2/2 (100%)
<b>POLY-3 RATE (b)</b>	1/1.00	2/2.00
<b>POLY-3 PERCENT (g)</b>	100%	100%
<b>TERMINAL (d)</b>	1/1 (100%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	728 (T)	604

**STATISTICAL TESTS**

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



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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Ovary  
Atrophy

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**LESION RATES**

OVERALL (a)	5/50 (10%)	16/46 (35%)
POLY-3 RATE (b)	5/44.42	16/28.43
POLY-3 PERCENT (g)	11.3%	56.3%
TERMINAL (d)	2/31 (7%)	0/0 (0%)
FIRST INCIDENCE	495	468

---

**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Females**

---

DOSE	0 MG/KG	150 MG/KG Stop
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---

Ovary  
Cyst

---

**LESION RATES**

OVERALL (a)	6/50 (12%)	5/46 (11%)
POLY-3 RATE (b)	6/43.19	5/23.82
POLY-3 PERCENT (g)	13.9%	21%
TERMINAL (d)	4/31 (13%)	0/0 (0%)
FIRST INCIDENCE	674	468

---

**STATISTICAL TESTS**

POLY 3	P=0.351
POLY 1.5	P=0.500
POLY 6	P=0.175
COCH-ARM / FISHERS	P=0.559N
MAX-ISO-POLY-3	P=0.282

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Pancreas: Acinus  
Atrophy

---

**LESION RATES**

OVERALL (a)	11/50 (22%)	17/46 (37%)
POLY-3 RATE (b)	11/45.56	17/29.33
POLY-3 PERCENT (g)	24.2%	58%
TERMINAL (d)	5/31 (16%)	0/0 (0%)
FIRST INCIDENCE	495	349

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**STATISTICAL TESTS**

POLY 3	P=0.003**
POLY 1.5	P=0.013*
POLY 6	P<0.001**
COCH-ARM / FISHERS	P=0.083
MAX-ISO-POLY-3	P=0.005**

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Pancreas: Acinus  
Hyperplasia

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**LESION RATES**

OVERALL (a)	7/50 (14%)	2/46 (4%)
POLY-3 RATE (b)	7/42.98	2/21.79
POLY-3 PERCENT (g)	16.3%	9.2%
TERMINAL (d)	6/31 (19%)	0/0 (0%)
FIRST INCIDENCE	674	559

---

**STATISTICAL TESTS**

POLY 3	P=0.357N
POLY 1.5	P=0.219N
POLY 6	P=0.587N
COCH-ARM / FISHERS	P=0.101N
MAX-ISO-POLY-3	P=0.283N

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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---

Pancreas: Duct  
Cyst

---

**LESION RATES**

OVERALL (a)	2/50 (4%)	3/46 (7%)
POLY-3 RATE (b)	2/42.78	3/22.59
POLY-3 PERCENT (g)	4.7%	13.3%
TERMINAL (d)	2/31 (7%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	393

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**STATISTICAL TESTS**

POLY 3	P=0.243
POLY 1.5	P=0.331
POLY 6	P=0.144
COCH-ARM / FISHERS	P=0.460
MAX-ISO-POLY-3	P=0.177

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Parathyroid Gland  
Hyperplasia

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**LESION RATES**

OVERALL (a)	0/46 (0%)	31/49 (63%)
POLY-3 RATE (b)	0/38.78	31/36.71
POLY-3 PERCENT (g)	0%	84.4%
TERMINAL (d)	0/27 (0%)	0/0 (0%)
FIRST INCIDENCE	---	338

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**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Pituitary Gland: Pars Distalis  
Angiectasis

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.78	1/22.80
POLY-3 PERCENT (g)	0%	4.4%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	533

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**STATISTICAL TESTS**

POLY 3	P=0.384
POLY 1.5	P=0.434
POLY 6	P=0.321
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.157

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

**DOSE**                      **0 MG/KG**                      **150 MG/KG Stop**

**Pituitary Gland: Pars Distalis  
Cyst**

**LESION RATES**

<b>OVERALL (a)</b>	4/50 (8%)	1/50 (2%)
<b>POLY-3 RATE (b)</b>	4/43.69	1/22.58
<b>POLY-3 PERCENT (g)</b>	9.2%	4.4%
<b>TERMINAL (d)</b>	2/31 (7%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	581	617

**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.428N
<b>POLY 1.5</b>	P=0.305N
<b>POLY 6</b>	P=0.610N
<b>COCH-ARM / FISHERS</b>	P=0.181N
<b>MAX-ISO-POLY-3</b>	P=0.308N



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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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---

Pituitary Gland: Pars Distalis  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	17/50 (34%)	12/50 (24%)
POLY-3 RATE (b)	17/45.13	12/28.77
POLY-3 PERCENT (g)	37.7%	41.7%
TERMINAL (d)	12/31 (39%)	0/0 (0%)
FIRST INCIDENCE	309	338

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**STATISTICAL TESTS**

POLY 3	P=0.459
POLY 1.5	P=0.479N
POLY 6	P=0.161
COCH-ARM / FISHERS	P=0.189N
MAX-ISO-POLY-3	P=0.384

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

**DOSE**                      **0 MG/KG**                      **150 MG/KG Stop**

**Spleen**  
**Hematopoietic Cell Proliferation**

**LESION RATES**

<b>OVERALL (a)</b>	0/50 (0%)	2/46 (4%)
<b>POLY-3 RATE (b)</b>	0/42.78	2/21.71
<b>POLY-3 PERCENT (g)</b>	0%	9.2%
<b>TERMINAL (d)</b>	0/31 (0%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	---	523

**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.124
<b>POLY 1.5</b>	P=0.159
<b>POLY 6</b>	P=0.088
<b>COCH-ARM / FISHERS</b>	P=0.227
<b>MAX-ISO-POLY-3</b>	P=0.068

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Spleen  
Hyperplasia Lymphoid

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**LESION RATES**

OVERALL (a)	3/50 (6%)	2/46 (4%)
POLY-3 RATE (b)	3/43.37	2/21.87
POLY-3 PERCENT (g)	6.9%	9.2%
TERMINAL (d)	2/31 (7%)	0/0 (0%)
FIRST INCIDENCE	538	538

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**STATISTICAL TESTS**

POLY 3	P=0.562
POLY 1.5	P=0.673
POLY 6	P=0.400
COCH-ARM / FISHERS	P=0.540N
MAX-ISO-POLY-3	P=0.406

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Stomach, Forestomach  
Inflammation

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**LESION RATES**

OVERALL (a)	3/50 (6%)	3/46 (7%)
POLY-3 RATE (b)	3/43.95	3/22.37
POLY-3 PERCENT (g)	6.8%	13.4%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	495	471

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**STATISTICAL TESTS**

POLY 3	P=0.347
POLY 1.5	P=0.465
POLY 6	P=0.209
COCH-ARM / FISHERS	P=0.621
MAX-ISO-POLY-3	P=0.259

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Females**

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<b>DOSE</b>	<b>0 MG/KG</b>	<b>150 MG/KG Stop</b>
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**Stomach, Forestomach  
Mineralization**

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**LESION RATES**

<b>OVERALL (a)</b>	1/50 (2%)	0/46 (0%)
<b>POLY-3 RATE (b)</b>	1/43.41	0/20.85
<b>POLY-3 PERCENT (g)</b>	2.3%	0%
<b>TERMINAL (d)</b>	0/31 (0%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	519	---

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**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.632N
<b>POLY 1.5</b>	P=0.583N
<b>POLY 6</b>	P=0.692N
<b>COCH-ARM / FISHERS</b>	P=0.521N
<b>MAX-ISO-POLY-3</b>	P=0.310N

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Stomach, Forestomach  
Perforation

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**LESION RATES**

OVERALL (a)	0/50 (0%)	0/46 (0%)
POLY-3 RATE (b)	0/42.78	0/20.85
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---

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**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

**DOSE**                      **0 MG/KG**                      **150 MG/KG Stop**

**Stomach, Forestomach  
Ulcer**

**LESION RATES**

<b>OVERALL (a)</b>	3/50 (6%)	3/46 (7%)
<b>POLY-3 RATE (b)</b>	3/43.91	3/22.06
<b>POLY-3 PERCENT (g)</b>	6.8%	13.6%
<b>TERMINAL (d)</b>	1/31 (3%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	519	580

**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.342
<b>POLY 1.5</b>	P=0.462
<b>POLY 6</b>	P=0.204
<b>COCH-ARM / FISHERS</b>	P=0.621
<b>MAX-ISO-POLY-3</b>	P=0.256

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

**DOSE**                      **0 MG/KG**                      **150 MG/KG Stop**

**Stomach, Forestomach: Epithelium  
Hyperplasia**

**LESION RATES**

<b>OVERALL (a)</b>	11/50 (22%)	9/46 (20%)
<b>POLY-3 RATE (b)</b>	11/44.59	9/26.22
<b>POLY-3 PERCENT (g)</b>	24.7%	34.3%
<b>TERMINAL (d)</b>	8/31 (26%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	495	352

**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.281
<b>POLY 1.5</b>	P=0.466
<b>POLY 6</b>	P=0.097
<b>COCH-ARM / FISHERS</b>	P=0.484N
<b>MAX-ISO-POLY-3</b>	P=0.242



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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Stomach, Glandular  
Erosion

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**LESION RATES**

OVERALL (a)	1/50 (2%)	3/46 (7%)
POLY-3 RATE (b)	1/42.99	3/22.37
POLY-3 PERCENT (g)	2.3%	13.4%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	672	523

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**STATISTICAL TESTS**

POLY 3	P=0.127
POLY 1.5	P=0.182
POLY 6	P=0.075
COCH-ARM / FISHERS	P=0.278
MAX-ISO-POLY-3	P=0.092

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Stomach, Glandular  
Inflammation

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/46 (2%)
POLY-3 RATE (b)	0/42.78	1/21.58
POLY-3 PERCENT (g)	0%	4.6%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	471

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**STATISTICAL TESTS**

POLY 3	P=0.375
POLY 1.5	P=0.421
POLY 6	P=0.315
COCH-ARM / FISHERS	P=0.479
MAX-ISO-POLY-3	P=0.151

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Stomach, Glandular  
Mineralization

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**LESION RATES**

OVERALL (a)	1/50 (2%)	13/46 (28%)
POLY-3 RATE (b)	1/43.41	13/27.26
POLY-3 PERCENT (g)	2.3%	47.7%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	519	349

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**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Thyroid Gland: C-Cell  
Hyperplasia

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**LESION RATES**

OVERALL (a)	39/50 (78%)	3/49 (6%)
POLY-3 RATE (b)	39/46.72	3/23.47
POLY-3 PERCENT (g)	83.5%	12.8%
TERMINAL (d)	29/31 (94%)	0/0 (0%)
FIRST INCIDENCE	495	569

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**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Trachea  
Inflammation

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**LESION RATES**

OVERALL (a)	5/50 (10%)	3/50 (6%)
POLY-3 RATE (b)	5/44.08	3/24.22
POLY-3 PERCENT (g)	11.3%	12.4%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	519	19

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**STATISTICAL TESTS**

POLY 3	P=0.596
POLY 1.5	P=0.538N
POLY 6	P=0.378
COCH-ARM / FISHERS	P=0.357N
MAX-ISO-POLY-3	P=0.459

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Urinary Bladder  
Inflammation

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**LESION RATES**

OVERALL (a)	1/50 (2%)	2/47 (4%)
POLY-3 RATE (b)	1/42.78	2/21.97
POLY-3 PERCENT (g)	2.3%	9.1%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	593

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**STATISTICAL TESTS**

POLY 3	P=0.292
POLY 1.5	P=0.369
POLY 6	P=0.201
COCH-ARM / FISHERS	P=0.477
MAX-ISO-POLY-3	P=0.185

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

**DOSE**                      **0 MG/KG**                      **150 MG/KG Stop**

Uterus  
Hemorrhage

**LESION RATES**

OVERALL (a)	2/50 (4%)	1/47 (2%)
POLY-3 RATE (b)	2/43.21	1/21.65
POLY-3 PERCENT (g)	4.6%	4.6%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	604	617

**STATISTICAL TESTS**

POLY 3	P=0.713N
POLY 1.5	P=0.634N
POLY 6	P=0.581
COCH-ARM / FISHERS	P=0.523N
MAX-ISO-POLY-3	P=0.498N

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

**Females**

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<b>DOSE</b>	<b>0 MG/KG</b>	<b>150 MG/KG Stop</b>
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Uterus  
Hydrometra

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**LESION RATES**

<b>OVERALL (a)</b>	0/50 (0%)	3/47 (6%)
<b>POLY-3 RATE (b)</b>	0/42.78	3/23.28
<b>POLY-3 PERCENT (g)</b>	0%	12.9%
<b>TERMINAL (d)</b>	0/31 (0%)	0/0 (0%)
<b>FIRST INCIDENCE</b>	---	352

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**STATISTICAL TESTS**

<b>POLY 3</b>	P=0.046*
<b>POLY 1.5</b>	P=0.067
<b>POLY 6</b>	P=0.027*
<b>COCH-ARM / FISHERS</b>	P=0.110
<b>MAX-ISO-POLY-3</b>	P=0.033*

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

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

Date Report Requested: 08/25/2009  
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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/N)  
TERMINAL SACRIFICE AT 104 WEEKS**

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Uterus  
Inflammation

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**LESION RATES**

OVERALL (a)	0/50 (0%)	2/47 (4%)
POLY-3 RATE (b)	0/42.78	2/22.54
POLY-3 PERCENT (g)	0%	8.9%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	352

---

**STATISTICAL TESTS**

POLY 3	P=0.128
POLY 1.5	P=0.164
POLY 6	P=0.091
COCH-ARM / FISHERS	P=0.232
MAX-ISO-POLY-3	P=0.069

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

**Females**

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DOSE	0 MG/KG	150 MG/KG Stop
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Uterus: Endometrium  
Hyperplasia Cystic

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**LESION RATES**

OVERALL (a)	1/50 (2%)	5/47 (11%)
POLY-3 RATE (b)	1/42.78	5/23.23
POLY-3 PERCENT (g)	2.3%	21.5%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	580

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**STATISTICAL TESTS**

POLY 3	P=0.021*
POLY 1.5	P=0.040*
POLY 6	P=0.008**
COCH-ARM / FISHERS	P=0.088
MAX-ISO-POLY-3	P=0.022*

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:39:42  
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.
  - (e) Value of Statistic cannot be computed.
  - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
  - (g) Poly-3 adjusted lifetime tumor incidence.
  - (I) Interim sacrifice
  - (T) Terminal sacrifice
  - # Tumor rates based on numbers of animals necropsied.
  - \* To the right of any statistical result, indicates significance at ( $P \leq 0.05$ ).
  - \*\* To the right of any statistical result, indicates significance at ( $P \leq 0.01$ ).
  - N Indicates a negative trend for all tests
- The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

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