

**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:** 09:37:47  
**First Dose M/F:** 04/09/03 / 04/10/03  
**Lab:** BAT

F1\_R2\_Rev2

<b>C Number:</b>	C99020		
<b>Lock Date:</b>	01/06/2006		
<b>Cage Range:</b>	ALL		
<b>Date Range:</b>	ALL		
<b>Reasons For Removal:</b>	ALL		
<b>Removal Date Range:</b>	ALL		
<b>Treatment Groups:</b>	Include 001 0 MG/KG	Include 002 0 MG/KG	Include 003 18.75 MG/KG
	Include 004 37.5 MG/KG	Include 005 37.5 MG/KG	Include 006 75.0 MG/KG
<b>Study Gender:</b>	Both		
<b>TDMSE Version:</b>	2.1.0		

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

### MALE RATS

#### Organ

Adrenal Cortex  
Adrenal Medulla  
Harderian Gland: Epithelium  
Intestine Large, Cecum  
Kidney

Liver

Liver: Bile Duct

Liver: Hepatocyte

Liver: Hepatocyte, Centrilobular

Liver: Oval Cell

Lung: Alveolus

Mammary Gland: Duct

Nose: Goblet Cell

Nose: Olfactory Epithelium

Pancreas: Acinus

Parathyroid Gland

Preputial Gland: Duct

Prostate: Epithelium

Skin

Stomach, Forestomach

Stomach, Glandular

### FEMALE RATS

#### Organ

Adrenal Cortex

#### Morphology

Hyperplasia  
Hyperplasia  
Hyperplasia  
Inflammation  
Glomerulopathy Hyaline  
Nephropathy  
Basophilic Focus  
Eosinophilic Focus  
Fatty Change  
Mixed Cell Focus  
Cyst  
Hyperplasia  
Cellular Alteration Diffuse  
Necrosis  
Degeneration  
Hyperplasia  
Inflammation Histiocytic  
Dilatation  
Hyperplasia  
Degeneration  
Atrophy  
Hyperplasia  
Ectasia  
Hyperplasia  
Cyst Epithelial Inclusion  
Inflammation  
Ulcer  
Mineralization

#### Morphology

Hypertrophy

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

Adrenal Medulla	Hyperplasia
Bone Marrow	Hyperplasia
Clitoral Gland	Hyperplasia
	Inflammation
Intestine Large, Colon	Parasite Metazoan
Kidney	Glomerulopathy Hyaline
	Nephropathy
Liver	Angiectasis
	Basophilic Focus
	Fatty Change
	Mixed Cell Focus
Liver: Bile Duct	Cyst
	Hyperplasia
Liver: Cervix	Hemorrhage
Liver: Hepatocyte	Cellular Alteration Diffuse
	Necrosis
Liver: Oval Cell	Hyperplasia
Liver: Portal	Fibrosis
Lung: Alveolus	Inflammation Histiocytic
Nose	Inflammation
Nose: Glands	Dilatation
Nose: Olfactory Epithelium	Degeneration
	Metaplasia Respiratory
Pancreas: Acinus	Hyperplasia
Parathyroid Gland	Hyperplasia
Pituitary Gland: Pars Distalis	Cyst
	Hyperplasia
Spleen	Hyperplasia Lymphoid
Thyroid Gland: C-Cell	Hyperplasia
Trachea	Inflammation

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

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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Adrenal Cortex</b>			
<b>Degeneration Cystic</b>			
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<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/45.76	0/43.06	2/43.39
POLY-3 PERCENT (g)	2.2%	0%	4.6%
TERMINAL (d)	1/39 (3%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	727 (T)	---	725
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<b>STATISTICAL TESTS</b>			
POLY 3	P=0.356	P=0.512N	P=0.481
POLY 1.5	P=0.360	P=0.505N	P=0.496
POLY 6	P=0.351	P=0.522N	P=0.461
COCH-ARM / FISHERS	P=0.360	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.195	P=0.174N	P=0.270

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

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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Adrenal Cortex Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	27/50 (54%)	16/50 (32%)	23/50 (46%)
POLY-3 RATE (b)	27/46.79	16/43.97	23/45.23
POLY-3 PERCENT (g)	57.7%	36.4%	50.9%
TERMINAL (d)	22/39 (56%)	13/32 (41%)	17/28 (61%)
FIRST INCIDENCE	627	605	456
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.272N	P=0.031N*	P=0.324N
POLY 1.5	P=0.230N	P=0.022N*	P=0.267N
POLY 6	P=0.348N	P=0.048N*	P=0.423N
COCH-ARM / FISHERS	P=0.240N	P=0.021N*	P=0.274N
MAX-ISO-POLY-3	P=0.118N	P=0.022N*	P=0.256N

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

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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Adrenal Cortex Hypertrophy</b>			
<b>LESION RATES</b>			
OVERALL (a)	11/50 (22%)	12/50 (24%)	16/50 (32%)
POLY-3 RATE (b)	11/45.92	12/43.55	16/45.80
POLY-3 PERCENT (g)	24%	27.6%	34.9%
TERMINAL (d)	9/39 (23%)	9/32 (28%)	9/28 (32%)
FIRST INCIDENCE	692	673	455
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.145	P=0.442	P=0.176
POLY 1.5	P=0.162	P=0.478	P=0.196
POLY 6	P=0.121	P=0.397	P=0.148
COCH-ARM / FISHERS	P=0.152	P=0.500	P=0.184
MAX-ISO-POLY-3	P=0.166	P=0.351	P=0.124

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TERMINAL SACRIFICE AT 104 WEEKS

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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Adrenal Medulla Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	22/50 (44%)	19/50 (38%)	30/50 (60%)
POLY-3 RATE (b)	22/46.33	19/44.20	30/45.60
POLY-3 PERCENT (g)	47.5%	43%	65.8%
TERMINAL (d)	19/39 (49%)	14/32 (44%)	20/28 (71%)
FIRST INCIDENCE	627	605	594
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.045*	P=0.413N	P=0.054
POLY 1.5	P=0.060	P=0.364N	P=0.075
POLY 6	P=0.030*	P=0.477N	P=0.035*
COCH-ARM / FISHERS	P=0.067	P=0.342N	P=0.080
MAX-ISO-POLY-3	P=0.028*	P=0.336N	P=0.035*

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TERMINAL SACRIFICE AT 104 WEEKS

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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Bone Marrow Hemorrhage			
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<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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TERMINAL SACRIFICE AT 104 WEEKS

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

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Bone Marrow  
Hyperplasia

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LESION RATES			
OVERALL (a)	10/50 (20%)	8/50 (16%)	9/50 (18%)
POLY-3 RATE (b)	10/46.58	8/44.48	9/45.25
POLY-3 PERCENT (g)	21.5%	18%	19.9%
TERMINAL (d)	6/39 (15%)	4/32 (13%)	2/28 (7%)
FIRST INCIDENCE	627	451	455

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STATISTICAL TESTS			
POLY 3	P=0.475N	P=0.439N	P=0.528N
POLY 1.5	P=0.446N	P=0.410N	P=0.498N
POLY 6	P=0.519N	P=0.480N	P=0.573N
COCH-ARM / FISHERS	P=0.448N	P=0.398N	P=0.500N
MAX-ISO-POLY-3	P=0.524N	P=0.342N	P=0.426N

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TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Bone</b>			
<b>Fibrous Osteodystrophy</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.76	0/43.06	2/43.92
POLY-3 PERCENT (g)	0%	0%	4.6%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	637
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.094	(e)	P=0.228
POLY 1.5	P=0.094	(e)	P=0.236
POLY 6	P=0.092	(e)	P=0.217
COCH-ARM / FISHERS	P=0.095	(e)	P=0.247
MAX-ISO-POLY-3	P=0.052	(e)	P=0.076

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TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Brain Hemorrhage</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/45.76	2/43.50	1/43.64
POLY-3 PERCENT (g)	0%	4.6%	2.3%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	622	659
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.345	P=0.226	P=0.490
POLY 1.5	P=0.358	P=0.233	P=0.498
POLY 6	P=0.327	P=0.217	P=0.480
COCH-ARM / FISHERS	P=0.360	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.197	P=0.076	P=0.158

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TERMINAL SACRIFICE AT 104 WEEKS

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

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Brain  
Hydrocephalus

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LESION RATES			
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	2/43.24	0/43.38
POLY-3 PERCENT (g)	0%	4.6%	0%
TERMINAL (d)	0/39 (0%)	1/32 (3%)	0/28 (0%)
FIRST INCIDENCE	---	682	---

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STATISTICAL TESTS			
POLY 3	P=0.651	P=0.225	(e)
POLY 1.5	P=0.665	P=0.232	(e)
POLY 6	P=0.630	P=0.215	(e)
COCH-ARM / FISHERS	P=0.669	P=0.247	(e)
MAX-ISO-POLY-3	P=0.264	P=0.076	(e)

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TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Epididymis Granuloma Sperm</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	2/45.76	2/43.64	2/44.25
POLY-3 PERCENT (g)	4.4%	4.6%	4.5%
TERMINAL (d)	2/39 (5%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	727 (T)	570	594
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.588	P=0.677	P=0.682
POLY 1.5	P=0.599	P=0.688	P=0.693
POLY 6	P=0.571	P=0.662	P=0.665
COCH-ARM / FISHERS	P=0.601	P=0.691N	P=0.691N
MAX-ISO-POLY-3	P=0.647	P=0.480	P=0.486

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TERMINAL SACRIFICE AT 104 WEEKS

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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Eye			
Cataract			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Eye: Retina Atrophy			
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<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Eye: Retina Dysplasia			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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

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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Harderian Gland Inflammation</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	2/45.76	0/43.06	2/43.86
POLY-3 PERCENT (g)	4.4%	0%	4.6%
TERMINAL (d)	2/39 (5%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	727 (T)	---	639
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.617	P=0.251N	P=0.679
POLY 1.5	P=0.621	P=0.243N	P=0.691
POLY 6	P=0.610	P=0.262N	P=0.660
COCH-ARM / FISHERS	P=0.622	P=0.247N	P=0.691N
MAX-ISO-POLY-3	P=0.369	P=0.089N	P=0.482

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Harderian Gland: Epithelium Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	3/50 (6%)	0/50 (0%)	5/50 (10%)
POLY-3 RATE (b)	3/45.76	0/43.06	5/43.38
POLY-3 PERCENT (g)	6.6%	0%	11.5%
TERMINAL (d)	3/39 (8%)	0/32 (0%)	5/28 (18%)
FIRST INCIDENCE	727 (T)	---	727 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.240	P=0.130N	P=0.327
POLY 1.5	P=0.248	P=0.123N	P=0.350
POLY 6	P=0.229	P=0.139N	P=0.296
COCH-ARM / FISHERS	P=0.252	P=0.121N	P=0.357
MAX-ISO-POLY-3	P=0.074	P=0.047N*	P=0.213

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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: 09:37:47  
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

---

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Heart			
Cardiomyopathy			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	44/50 (88%)	44/50 (88%)	48/50 (96%)
POLY-3 RATE (b)	44/47.64	44/49.02	48/49.55
POLY-3 PERCENT (g)	92.4%	89.8%	96.9%
TERMINAL (d)	36/39 (92%)	27/32 (84%)	27/28 (96%)
FIRST INCIDENCE	412	374	455
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.239	P=0.464N	P=0.287
POLY 1.5	P=0.246	P=0.471N	P=0.297
POLY 6	P=0.232	P=0.435N	P=0.276
COCH-ARM / FISHERS	P=0.114	P=0.620N	P=0.134
MAX-ISO-POLY-3	P=0.179	P=0.329N	P=0.155

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Heart: Endocardium  
Bacterium

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**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.76	0/43.06	2/43.50
POLY-3 PERCENT (g)	0%	0%	4.6%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	---	---	697

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**STATISTICAL TESTS**

POLY 3	P=0.093	(e)	P=0.226
POLY 1.5	P=0.094	(e)	P=0.235
POLY 6	P=0.092	(e)	P=0.214
COCH-ARM / FISHERS	P=0.095	(e)	P=0.247
MAX-ISO-POLY-3	P=0.052	(e)	P=0.076

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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: 09:37:47  
 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**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Intestine Large, Cecum Inflammation</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	6/49 (12%)
POLY-3 RATE (b)	0/45.76	0/43.06	6/43.29
POLY-3 PERCENT (g)	0%	0%	13.9%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	2/28 (7%)
FIRST INCIDENCE	---	---	598
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.002**	(e)	P=0.012*
POLY 1.5	P=0.002**	(e)	P=0.014*
POLY 6	P<0.001**	(e)	P=0.011*
COCH-ARM / FISHERS	P=0.002**	(e)	P=0.012*
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.004**

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: 09:37:47  
 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**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Intestine Large, Colon</b>			
<b>Parasite Metazoan</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/45.76	0/43.06	1/43.38
POLY-3 PERCENT (g)	2.2%	0%	2.3%
TERMINAL (d)	1/39 (3%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	727 (T)	---	727 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.666	P=0.512N	P=0.749
POLY 1.5	P=0.667	P=0.505N	P=0.758
POLY 6	P=0.662	P=0.522N	P=0.735
COCH-ARM / FISHERS	P=0.669	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.454	P=0.174N	P=0.484

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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Intestine Large, Rectum</b>			
<b>Parasite Metazoan</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/45.78	1/43.83	0/43.38
POLY-3 PERCENT (g)	4.4%	2.3%	0%
TERMINAL (d)	1/39 (3%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	723	451	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.154N	P=0.515N	P=0.249N
POLY 1.5	P=0.145N	P=0.504N	P=0.240N
POLY 6	P=0.167N	P=0.530N	P=0.263N
COCH-ARM / FISHERS	P=0.142N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.120N	P=0.297N	P=0.088N

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Kidney Cyst			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.76	0/43.06	2/43.59
POLY-3 PERCENT (g)	0%	0%	4.6%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	---	---	673
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.093	(e)	P=0.226
POLY 1.5	P=0.094	(e)	P=0.235
POLY 6	P=0.092	(e)	P=0.215
COCH-ARM / FISHERS	P=0.095	(e)	P=0.247
MAX-ISO-POLY-3	P=0.052	(e)	P=0.076

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Kidney</b>			
<b>Glomerulopathy Hyaline</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	9/50 (18%)
POLY-3 RATE (b)	0/45.76	0/43.06	9/44.09
POLY-3 PERCENT (g)	0%	0%	20.4%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	4/28 (14%)
FIRST INCIDENCE	---	---	637
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001**	(e)	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.002**
POLY 6	P<0.001**	(e)	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Kidney Inflammation</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/45.76	1/43.58	2/43.59
POLY-3 PERCENT (g)	0%	2.3%	4.6%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	570	697
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.136	P=0.490	P=0.226
POLY 1.5	P=0.141	P=0.497	P=0.235
POLY 6	P=0.130	P=0.482	P=0.215
COCH-ARM / FISHERS	P=0.142	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.104	P=0.158	P=0.076

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Kidney</b>			
<b>Nephropathy</b>			
<b>LESION RATES</b>			
OVERALL (a)	45/50 (90%)	45/50 (90%)	50/50 (100%)
POLY-3 RATE (b)	45/46.82	45/47.15	50/50.00
POLY-3 PERCENT (g)	96.1%	95.5%	100%
TERMINAL (d)	38/39 (97%)	31/32 (97%)	28/28 (100%)
FIRST INCIDENCE	632	451	455
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.153	P=0.657N	P=0.229
POLY 1.5	P=0.123	P=0.572N	P=0.164
POLY 6	P=0.204	P=0.732N	P=0.322
COCH-ARM / FISHERS	P=0.036*	P=0.630N	P=0.028*
MAX-ISO-POLY-3	P=0.105	P=0.427N	P=0.063

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Kidney: Cortex Mineralization</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	1/46.11	2/43.43	2/44.16
POLY-3 PERCENT (g)	2.2%	4.6%	4.5%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	632	644	594
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.376	P=0.479	P=0.485
POLY 1.5	P=0.389	P=0.492	P=0.498
POLY 6	P=0.358	P=0.463	P=0.467
COCH-ARM / FISHERS	P=0.390	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.387	P=0.269	P=0.272

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Kidney: Renal Tubule Degeneration</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Liver			
Angiectasis			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/45.76	0/43.06	1/44.14
POLY-3 PERCENT (g)	0%	0%	2.3%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	456
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.271	(e)	P=0.493
POLY 1.5	P=0.270	(e)	P=0.500
POLY 6	P=0.271	(e)	P=0.482
COCH-ARM / FISHERS	P=0.269	(e)	P=0.500
MAX-ISO-POLY-3	P=0.151	(e)	P=0.158

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Liver			
Basophilic Focus			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	36/50 (72%)	5/50 (10%)	2/50 (4%)
POLY-3 RATE (b)	36/46.69	5/43.83	2/43.38
POLY-3 PERCENT (g)	77.1%	11.4%	4.6%
TERMINAL (d)	34/39 (87%)	4/32 (13%)	2/28 (7%)
FIRST INCIDENCE	412	451	727 (T)
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001N**	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P<0.001N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P<0.001N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P<0.001N**	P<0.001N**

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Liver			
Clear Cell Focus			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	22/50 (44%)	22/50 (44%)	20/50 (40%)
POLY-3 RATE (b)	22/45.87	22/43.68	20/43.68
POLY-3 PERCENT (g)	48%	50.4%	45.8%
TERMINAL (d)	21/39 (54%)	19/32 (59%)	18/28 (64%)
FIRST INCIDENCE	701	644	673
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.465N	P=0.494	P=0.502N
POLY 1.5	P=0.394N	P=0.551	P=0.434N
POLY 6	P=0.520	P=0.421	P=0.572
COCH-ARM / FISHERS	P=0.381N	P=0.580N	P=0.420N
MAX-ISO-POLY-3	P=0.516N	P=0.409	P=0.417N

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Liver			
Eosinophilic Focus			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	2/50 (4%)	12/50 (24%)
POLY-3 RATE (b)	1/45.76	2/43.06	12/44.82
POLY-3 PERCENT (g)	2.2%	4.6%	26.8%
TERMINAL (d)	1/39 (3%)	2/32 (6%)	7/28 (25%)
FIRST INCIDENCE	727 (T)	727 (T)	608
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001**	P=0.479	P<0.001**
POLY 1.5	P<0.001**	P=0.492	P<0.001**
POLY 6	P<0.001**	P=0.462	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.269	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: 09:37:47  
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

---

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Liver			
Fatty Change			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	10/50 (20%)	27/50 (54%)
POLY-3 RATE (b)	1/45.90	10/44.80	27/46.09
POLY-3 PERCENT (g)	2.2%	22.3%	58.6%
TERMINAL (d)	0/39 (0%)	6/32 (19%)	17/28 (61%)
FIRST INCIDENCE	692	374	456
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001**	P=0.003**	P<0.001**
POLY 1.5	P<0.001**	P=0.004**	P<0.001**
POLY 6	P<0.001**	P=0.003**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.004**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:37:47  
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

---

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

---

Liver  
Hepatodiaphragmatic Nodule

---

LESION RATES			
OVERALL (a)	6/50 (12%)	6/50 (12%)	2/50 (4%)
POLY-3 RATE (b)	6/45.76	6/43.58	2/44.33
POLY-3 PERCENT (g)	13.1%	13.8%	4.5%
TERMINAL (d)	6/39 (15%)	5/32 (16%)	0/28 (0%)
FIRST INCIDENCE	727 (T)	570	465

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STATISTICAL TESTS			
POLY 3	P=0.125N	P=0.586	P=0.143N
POLY 1.5	P=0.113N	P=0.609	P=0.133N
POLY 6	P=0.145N	P=0.557	P=0.160N
COCH-ARM / FISHERS	P=0.114N	P=0.620N	P=0.134N
MAX-ISO-POLY-3	P=0.116N	P=0.464	P=0.078N

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Liver Inflammation			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	41/50 (82%)	36/50 (72%)	41/50 (82%)
POLY-3 RATE (b)	41/47.21	36/45.37	41/48.36
POLY-3 PERCENT (g)	86.9%	79.4%	84.8%
TERMINAL (d)	36/39 (92%)	27/32 (84%)	27/28 (96%)
FIRST INCIDENCE	412	605	455
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.449N	P=0.235N	P=0.502N
POLY 1.5	P=0.422N	P=0.173N	P=0.466N
POLY 6	P=0.509N	P=0.308N	P=0.574N
COCH-ARM / FISHERS	P=0.549	P=0.171N	P=0.602N
MAX-ISO-POLY-3	P=0.357N	P=0.160N	P=0.381N

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Liver			
Mixed Cell Focus			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	9/50 (18%)	3/50 (6%)	10/50 (20%)
POLY-3 RATE (b)	9/45.76	3/43.27	10/44.02
POLY-3 PERCENT (g)	19.7%	6.9%	22.7%
TERMINAL (d)	9/39 (23%)	2/32 (6%)	8/28 (29%)
FIRST INCIDENCE	727 (T)	673	637
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.420	P=0.072N	P=0.462
POLY 1.5	P=0.440	P=0.064N	P=0.495
POLY 6	P=0.390	P=0.084N	P=0.416
COCH-ARM / FISHERS	P=0.444	P=0.061N	P=0.500
MAX-ISO-POLY-3	P=0.166	P=0.042N*	P=0.364

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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: 09:37:47  
 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**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Liver: Bile Duct Cyst</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	11/50 (22%)
POLY-3 RATE (b)	0/45.76	0/43.06	11/43.76
POLY-3 PERCENT (g)	0%	0%	25.1%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	9/28 (32%)
FIRST INCIDENCE	---	---	673
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001**	(e)	P<0.001**
POLY 1.5	P<0.001**	(e)	P<0.001**
POLY 6	P<0.001**	(e)	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG

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Liver: Bile Duct  
Hyperplasia

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LESION RATES			
OVERALL (a)	29/50 (58%)	15/50 (30%)	37/50 (74%)
POLY-3 RATE (b)	29/46.62	15/43.74	37/46.14
POLY-3 PERCENT (g)	62.2%	34.3%	80.2%
TERMINAL (d)	25/39 (64%)	12/32 (38%)	27/28 (96%)
FIRST INCIDENCE	632	605	598

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STATISTICAL TESTS			
POLY 3	P=0.035*	P=0.005N**	P=0.040*
POLY 1.5	P=0.049*	P=0.003N**	P=0.063
POLY 6	P=0.022*	P=0.010N**	P=0.021*
COCH-ARM / FISHERS	P=0.066	P=0.004N**	P=0.069
MAX-ISO-POLY-3	P<0.001**	P=0.003N**	P=0.024*

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Liver: Cervix Hemorrhage			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:37:47  
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

---

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

---

Liver: Hepatocyte  
Cellular Alteration Diffuse

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**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	21/50 (42%)
POLY-3 RATE (b)	0/45.76	2/43.71	21/47.30
POLY-3 PERCENT (g)	0%	4.6%	44.4%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	7/28 (25%)
FIRST INCIDENCE	---	632	455

---

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.227	P<0.001**
POLY 1.5	P<0.001**	P=0.234	P<0.001**
POLY 6	P<0.001**	P=0.219	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.247	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.076	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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Liver: Hepatocyte Degeneration Cystic			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	1/45.76	1/43.06	3/43.71
POLY-3 PERCENT (g)	2.2%	2.3%	6.9%
TERMINAL (d)	1/39 (3%)	1/32 (3%)	2/28 (7%)
FIRST INCIDENCE	727 (T)	727 (T)	637
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.194	P=0.747	P=0.289
POLY 1.5	P=0.201	P=0.755	P=0.302
POLY 6	P=0.184	P=0.736	P=0.270
COCH-ARM / FISHERS	P=0.202	P=0.753N	P=0.309
MAX-ISO-POLY-3	P=0.176	P=0.482	P=0.148

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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: 09:37:47  
 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**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Liver: Hepatocyte Necrosis</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	1/50 (2%)	6/50 (12%)
POLY-3 RATE (b)	0/45.76	1/43.39	6/44.05
POLY-3 PERCENT (g)	0%	2.3%	13.6%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	2/28 (7%)
FIRST INCIDENCE	---	638	637
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.003**	P=0.489	P=0.013*
POLY 1.5	P=0.004**	P=0.496	P=0.015*
POLY 6	P=0.003**	P=0.481	P=0.011*
COCH-ARM / FISHERS	P=0.005**	P=0.500	P=0.013*
MAX-ISO-POLY-3	P=0.002**	P=0.158	P=0.004**

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: 09:37:47  
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**

---

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

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Liver: Hepatocyte, Centrilobular Degeneration

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LESION RATES			
OVERALL (a)	3/50 (6%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	3/46.24	0/43.06	1/43.84
POLY-3 PERCENT (g)	6.5%	0%	2.3%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	632	---	594

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STATISTICAL TESTS			
POLY 3	P=0.184N	P=0.132N	P=0.325N
POLY 1.5	P=0.177N	P=0.124N	P=0.310N
POLY 6	P=0.194N	P=0.143N	P=0.347N
COCH-ARM / FISHERS	P=0.176N	P=0.121N	P=0.309N
MAX-ISO-POLY-3	P=0.098N	P=0.049N*	P=0.174N

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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: 09:37:47  
 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**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Liver: Oval Cell Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	8/50 (16%)
POLY-3 RATE (b)	0/45.76	0/43.06	8/43.69
POLY-3 PERCENT (g)	0%	0%	18.3%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	6/28 (21%)
FIRST INCIDENCE	---	---	673
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001**	(e)	P=0.003**
POLY 1.5	P<0.001**	(e)	P=0.003**
POLY 6	P<0.001**	(e)	P=0.002**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.003**
MAX-ISO-POLY-3	P<0.001**	(e)	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: 09:37:47  
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

---

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

---

Liver: Portal  
Fibrosis

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LESION RATES			
OVERALL (a)	8/50 (16%)	6/50 (12%)	13/50 (26%)
POLY-3 RATE (b)	8/45.90	6/43.44	13/43.92
POLY-3 PERCENT (g)	17.4%	13.8%	29.6%
TERMINAL (d)	7/39 (18%)	4/32 (13%)	11/28 (39%)
FIRST INCIDENCE	692	644	637

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STATISTICAL TESTS			
POLY 3	P=0.099	P=0.429N	P=0.131
POLY 1.5	P=0.114	P=0.403N	P=0.155
POLY 6	P=0.080	P=0.464N	P=0.102
COCH-ARM / FISHERS	P=0.121	P=0.387N	P=0.163
MAX-ISO-POLY-3	P=0.068	P=0.324N	P=0.090

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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: 09:37:47  
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**

---

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Lung Congestion			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/46.60	1/43.93	0/43.38
POLY-3 PERCENT (g)	4.3%	2.3%	0%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	412	374	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.158N	P=0.521N	P=0.253N
POLY 1.5	P=0.148N	P=0.508N	P=0.243N
POLY 6	P=0.172N	P=0.537N	P=0.269N
COCH-ARM / FISHERS	P=0.142N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.126N	P=0.303N	P=0.092N

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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: 09:37:47  
 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**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Lung Inflammation</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/45.76	1/43.06	1/43.50
POLY-3 PERCENT (g)	0%	2.3%	2.3%
TERMINAL (d)	0/39 (0%)	1/32 (3%)	0/28 (0%)
FIRST INCIDENCE	---	727 (T)	697
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.323	P=0.488	P=0.490
POLY 1.5	P=0.330	P=0.495	P=0.498
POLY 6	P=0.312	P=0.478	P=0.479
COCH-ARM / FISHERS	P=0.331	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.267	P=0.158	P=0.158



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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Lung: Alveolar Epithelium Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	11/50 (22%)	9/50 (18%)	11/50 (22%)
POLY-3 RATE (b)	11/45.99	9/43.83	11/45.21
POLY-3 PERCENT (g)	23.9%	20.5%	24.3%
TERMINAL (d)	8/39 (21%)	8/32 (25%)	6/28 (21%)
FIRST INCIDENCE	692	451	455
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.533	P=0.448N	P=0.578
POLY 1.5	P=0.541N	P=0.415N	P=0.587N
POLY 6	P=0.494	P=0.495N	P=0.537
COCH-ARM / FISHERS	P=0.549	P=0.402N	P=0.595N
MAX-ISO-POLY-3	P=0.555	P=0.353N	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  
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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**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Lung: Alveolus Inflammation Histiocytic</b>			
<b>LESION RATES</b>			
OVERALL (a)	27/50 (54%)	35/50 (70%)	37/50 (74%)
POLY-3 RATE (b)	27/47.05	35/45.67	37/46.56
POLY-3 PERCENT (g)	57.4%	76.6%	79.5%
TERMINAL (d)	23/39 (59%)	26/32 (81%)	26/28 (93%)
FIRST INCIDENCE	412	570	455
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.009**	P=0.035*	P=0.015*
POLY 1.5	P=0.017*	P=0.052	P=0.025*
POLY 6	P=0.004**	P=0.023*	P=0.007**
COCH-ARM / FISHERS	P=0.022*	P=0.074	P=0.030*
MAX-ISO-POLY-3	P=0.008**	P=0.022*	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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Lung: Cervix Hyperplasia			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/46.76	0/43.06	0/43.38
POLY-3 PERCENT (g)	4.3%	0%	0%
TERMINAL (d)	1/39 (3%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	24	---	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.102N	P=0.256N	P=0.254N
POLY 1.5	P=0.098N	P=0.247N	P=0.245N
POLY 6	P=0.108N	P=0.268N	P=0.269N
COCH-ARM / FISHERS	P=0.095N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.069N	P=0.094N	P=0.092N

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Lung: Interstitium Mineralization</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/45.76	1/43.37	2/43.92
POLY-3 PERCENT (g)	0%	2.3%	4.6%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	644	637
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.137	P=0.489	P=0.228
POLY 1.5	P=0.142	P=0.496	P=0.236
POLY 6	P=0.131	P=0.481	P=0.217
COCH-ARM / FISHERS	P=0.142	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.104	P=0.158	P=0.076

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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**

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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Lymph Node, Mesenteric Hemorrhage</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	1/43.39	0/43.38
POLY-3 PERCENT (g)	0%	2.3%	0%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	639	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.721	P=0.489	(e)
POLY 1.5	P=0.728	P=0.496	(e)
POLY 6	P=0.710	P=0.481	(e)
COCH-ARM / FISHERS	P=0.731	P=0.500	(e)
MAX-ISO-POLY-3	P=0.376	P=0.158	(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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Lymph Node: Mediastinal  
Degeneration Cystic

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LESION RATES			
OVERALL (a)	0/2 (0%)	2/8 (25%)	0/3 (0%)
POLY-3 RATE (b)	0/1.66	2/7.87	0/2.33
POLY-3 PERCENT (g)	0%	25.4%	0%
TERMINAL (d)	0/1 (0%)	2/6 (33%)	0/0 (0%)
FIRST INCIDENCE	---	727 (T)	---

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STATISTICAL TESTS			
POLY 3	P=0.686N	P=0.610	(e)
POLY 1.5	P=0.669N	P=0.593	(e)
POLY 6	P=0.728N	P=0.634	(e)
COCH-ARM / FISHERS	P=0.667N	P=0.622	(e)
MAX-ISO-POLY-3	P=0.451N	P=0.313	(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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Lymph Node: Mediastinal  
Hyperplasia

---

LESION RATES			
OVERALL (a)	0/2 (0%)	3/8 (38%)	0/3 (0%)
POLY-3 RATE (b)	0/1.66	3/7.87	0/2.33
POLY-3 PERCENT (g)	0%	38.1%	0%
TERMINAL (d)	0/1 (0%)	3/6 (50%)	0/0 (0%)
FIRST INCIDENCE	---	727 (T)	---

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STATISTICAL TESTS			
POLY 3	P=0.650N	P=0.486	(e)
POLY 1.5	P=0.628N	P=0.463	(e)
POLY 6	P=0.703N	P=0.521	(e)
COCH-ARM / FISHERS	P=0.613N	P=0.467	(e)
MAX-ISO-POLY-3	P=0.379N	P=0.256	(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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Mammary Gland Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/45.76	0/43.06	0/43.38
POLY-3 PERCENT (g)	2.2%	0%	0%
TERMINAL (d)	1/39 (3%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	727 (T)	---	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.279N	P=0.512N	P=0.511N
POLY 1.5	P=0.272N	P=0.505N	P=0.502N
POLY 6	P=0.290N	P=0.522N	P=0.523N
COCH-ARM / FISHERS	P=0.269N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.169N	P=0.174N	P=0.172N

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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

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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Mammary Gland: Duct Dilatation</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	0/45.76	1/43.06	3/43.71
POLY-3 PERCENT (g)	0%	2.3%	6.9%
TERMINAL (d)	0/39 (0%)	1/32 (3%)	2/28 (7%)
FIRST INCIDENCE	---	727 (T)	636
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.056	P=0.488	P=0.111
POLY 1.5	P=0.059	P=0.495	P=0.117
POLY 6	P=0.052	P=0.478	P=0.102
COCH-ARM / FISHERS	P=0.060	P=0.500	P=0.121
MAX-ISO-POLY-3	P=0.040*	P=0.158	P=0.038*

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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

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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Mesentery</b>			
<b>Necrosis</b>			
<b>LESION RATES</b>			
OVERALL (a)	7/9 (78%)	9/11 (82%)	10/11 (91%)
POLY-3 RATE (b)	7/8.89	9/10.66	10/10.85
POLY-3 PERCENT (g)	78.8%	84.5%	92.2%
TERMINAL (d)	6/7 (86%)	6/7 (86%)	9/9 (100%)
FIRST INCIDENCE	627	580	697
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.296	P=0.603	P=0.418
POLY 1.5	P=0.305	P=0.613	P=0.423
POLY 6	P=0.282	P=0.590	P=0.411
COCH-ARM / FISHERS	P=0.308	P=0.625	P=0.421
MAX-ISO-POLY-3	P=0.289	P=0.377	P=0.205

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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

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

---

Nose  
Inflammation

---

**LESION RATES**

OVERALL (a)	25/50 (50%)	23/50 (46%)	30/46 (65%)
POLY-3 RATE (b)	25/47.42	23/46.61	30/43.33
POLY-3 PERCENT (g)	52.7%	49.4%	69.2%
TERMINAL (d)	19/39 (49%)	14/32 (44%)	18/28 (64%)
FIRST INCIDENCE	412	199	455

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**STATISTICAL TESTS**

POLY 3	P=0.070	P=0.452N	P=0.078
POLY 1.5	P=0.087	P=0.408N	P=0.098
POLY 6	P=0.054	P=0.509N	P=0.060
COCH-ARM / FISHERS	P=0.087	P=0.421N	P=0.097
MAX-ISO-POLY-3	P=0.053	P=0.371N	P=0.054

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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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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

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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Nose			
Thrombosis			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/46 (0%)
POLY-3 RATE (b)	0/45.76	0/43.06	0/40.06
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Nose: Glands Dilatation</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/46 (2%)
POLY-3 RATE (b)	0/45.76	2/43.06	1/40.06
POLY-3 PERCENT (g)	0%	4.6%	2.5%
TERMINAL (d)	0/39 (0%)	2/32 (6%)	1/28 (4%)
FIRST INCIDENCE	---	727 (T)	727 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.322	P=0.224	P=0.473
POLY 1.5	P=0.334	P=0.232	P=0.481
POLY 6	P=0.305	P=0.214	P=0.463
COCH-ARM / FISHERS	P=0.338	P=0.247	P=0.479
MAX-ISO-POLY-3	P=0.201	P=0.076	P=0.153

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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**

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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Nose: Goblet Cell Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	3/50 (6%)	0/50 (0%)	0/46 (0%)
POLY-3 RATE (b)	3/45.76	0/43.06	0/40.06
POLY-3 PERCENT (g)	6.6%	0%	0%
TERMINAL (d)	3/39 (8%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	727 (T)	---	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.042N*	P=0.130N	P=0.144N
POLY 1.5	P=0.040N*	P=0.123N	P=0.136N
POLY 6	P=0.045N*	P=0.139N	P=0.155N
COCH-ARM / FISHERS	P=0.041N*	P=0.121N	P=0.137N
MAX-ISO-POLY-3	P=0.033N*	P=0.047N*	P=0.056N

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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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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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Nose: Olfactory Epithelium Degeneration</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	5/50 (10%)	33/46 (72%)
POLY-3 RATE (b)	1/46.12	5/43.23	33/43.35
POLY-3 PERCENT (g)	2.2%	11.6%	76.1%
TERMINAL (d)	0/39 (0%)	3/32 (9%)	21/28 (75%)
FIRST INCIDENCE	627	701	455
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001**	P=0.087	P<0.001**
POLY 1.5	P<0.001**	P=0.096	P<0.001**
POLY 6	P<0.001**	P=0.077	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.102	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.041*	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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Nose: Olfactory Epithelium  
Metaplasia Respiratory

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**LESION RATES**

OVERALL (a)	2/50 (4%)	3/50 (6%)	6/46 (13%)
POLY-3 RATE (b)	2/45.90	3/43.06	6/40.81
POLY-3 PERCENT (g)	4.4%	7%	14.7%
TERMINAL (d)	1/39 (3%)	3/32 (9%)	5/28 (18%)
FIRST INCIDENCE	692	727 (T)	455

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**STATISTICAL TESTS**

POLY 3	P=0.063	P=0.471	P=0.097
POLY 1.5	P=0.069	P=0.489	P=0.107
POLY 6	P=0.055	P=0.448	P=0.085
COCH-ARM / FISHERS	P=0.071	P=0.500	P=0.109
MAX-ISO-POLY-3	P=0.061	P=0.304	P=0.053

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Pancreas Inflammation</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/45.76	0/43.06	1/43.39
POLY-3 PERCENT (g)	0%	0%	2.3%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	724
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.271	(e)	P=0.489
POLY 1.5	P=0.270	(e)	P=0.498
POLY 6	P=0.272	(e)	P=0.478
COCH-ARM / FISHERS	P=0.269	(e)	P=0.500
MAX-ISO-POLY-3	P=0.151	(e)	P=0.158

---

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: 09:37:47  
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

---

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Pancreas: Acinus Atrophy</b>			
<b>LESION RATES</b>			
OVERALL (a)	13/50 (26%)	24/50 (48%)	20/50 (40%)
POLY-3 RATE (b)	13/45.84	24/44.73	20/44.71
POLY-3 PERCENT (g)	28.4%	53.7%	44.7%
TERMINAL (d)	12/39 (31%)	16/32 (50%)	16/28 (57%)
FIRST INCIDENCE	709	611	455
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.062	P=0.010**	P=0.077
POLY 1.5	P=0.084	P=0.014*	P=0.098
POLY 6	P=0.037*	P=0.008**	P=0.053
COCH-ARM / FISHERS	P=0.090	P=0.019*	P=0.101
MAX-ISO-POLY-3	P=0.026*	P=0.006**	P=0.052

---

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: 09:37:47  
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**

---

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

---

Pancreas: Acinus  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	11/50 (22%)	8/50 (16%)	7/50 (14%)
POLY-3 RATE (b)	11/46.11	8/45.07	7/43.49
POLY-3 PERCENT (g)	23.9%	17.8%	16.1%
TERMINAL (d)	10/39 (26%)	4/32 (13%)	6/28 (21%)
FIRST INCIDENCE	632	451	701

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**STATISTICAL TESTS**

POLY 3	P=0.212N	P=0.323N	P=0.257N
POLY 1.5	P=0.185N	P=0.305N	P=0.226N
POLY 6	P=0.254N	P=0.348N	P=0.306N
COCH-ARM / FISHERS	P=0.178N	P=0.306N	P=0.218N
MAX-ISO-POLY-3	P=0.256N	P=0.240N	P=0.187N

---

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: 09:37:47  
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**

---

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

---

Pancreas: Duct  
Cyst

---

LESION RATES			
OVERALL (a)	4/50 (8%)	5/50 (10%)	1/50 (2%)
POLY-3 RATE (b)	4/45.76	5/43.24	1/43.38
POLY-3 PERCENT (g)	8.7%	11.6%	2.3%
TERMINAL (d)	4/39 (10%)	4/32 (13%)	1/28 (4%)
FIRST INCIDENCE	727 (T)	682	727 (T)

---

STATISTICAL TESTS			
POLY 3	P=0.181N	P=0.464	P=0.195N
POLY 1.5	P=0.162N	P=0.487	P=0.183N
POLY 6	P=0.210N	P=0.437	P=0.215N
COCH-ARM / FISHERS	P=0.158N	P=0.500	P=0.181N
MAX-ISO-POLY-3	P=0.117N	P=0.334	P=0.099N

---

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: 09:37:47  
 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**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Parathyroid Gland Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/49 (0%)	0/44 (0%)	3/45 (7%)
POLY-3 RATE (b)	0/44.76	0/37.96	3/39.18
POLY-3 PERCENT (g)	0%	0%	7.7%
TERMINAL (d)	0/38 (0%)	0/28 (0%)	1/25 (4%)
FIRST INCIDENCE	---	---	637
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.031*	(e)	P=0.096
POLY 1.5	P=0.031*	(e)	P=0.102
POLY 6	P=0.030*	(e)	P=0.088
COCH-ARM / FISHERS	P=0.034*	(e)	P=0.106
MAX-ISO-POLY-3	P=0.018*	(e)	P=0.034*

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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Pituitary Gland Hemorrhage			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Pituitary Gland: Pars Distalis Angiectasis</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/45.76	0/43.06	0/43.38
POLY-3 PERCENT (g)	4.4%	0%	0%
TERMINAL (d)	2/39 (5%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	727 (T)	---	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.099N	P=0.251N	P=0.249N
POLY 1.5	P=0.096N	P=0.243N	P=0.240N
POLY 6	P=0.105N	P=0.262N	P=0.263N
COCH-ARM / FISHERS	P=0.095N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.064N	P=0.089N	P=0.088N

---

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: 09:37:47  
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

---

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

---

Pituitary Gland: Pars Distalis  
Cyst

---

**LESION RATES**

OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/45.76	0/43.06	1/43.38
POLY-3 PERCENT (g)	4.4%	0%	2.3%
TERMINAL (d)	2/39 (5%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	727 (T)	---	727 (T)

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**STATISTICAL TESTS**

POLY 3	P=0.372N	P=0.251N	P=0.519N
POLY 1.5	P=0.363N	P=0.243N	P=0.504N
POLY 6	P=0.385N	P=0.262N	P=0.539N
COCH-ARM / FISHERS	P=0.360N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.223N	P=0.089N	P=0.301N

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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: 09:37:47  
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

---

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

---

Pituitary Gland: Pars Distalis  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	22/50 (44%)	24/50 (48%)	18/50 (36%)
POLY-3 RATE (b)	22/46.57	24/44.57	18/45.65
POLY-3 PERCENT (g)	47.2%	53.9%	39.4%
TERMINAL (d)	19/39 (49%)	18/32 (56%)	9/28 (32%)
FIRST INCIDENCE	627	570	598

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**STATISTICAL TESTS**

POLY 3	P=0.260N	P=0.336	P=0.292N
POLY 1.5	P=0.225N	P=0.390	P=0.259N
POLY 6	P=0.310N	P=0.272	P=0.337N
COCH-ARM / FISHERS	P=0.240N	P=0.421	P=0.270N
MAX-ISO-POLY-3	P=0.197N	P=0.267	P=0.226N

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Preputial Gland Inflammation			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	9/50 (18%)	14/50 (28%)	13/50 (26%)
POLY-3 RATE (b)	9/46.12	14/44.22	13/44.85
POLY-3 PERCENT (g)	19.5%	31.7%	29%
TERMINAL (d)	8/39 (21%)	11/32 (34%)	8/28 (29%)
FIRST INCIDENCE	627	570	465
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.178	P=0.138	P=0.209
POLY 1.5	P=0.205	P=0.158	P=0.235
POLY 6	P=0.141	P=0.115	P=0.174
COCH-ARM / FISHERS	P=0.206	P=0.171	P=0.235
MAX-ISO-POLY-3	P=0.170	P=0.096	P=0.148

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Preputial Gland: Duct Ectasia			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	3/50 (6%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	3/45.76	1/43.06	0/43.38
POLY-3 PERCENT (g)	6.6%	2.3%	0%
TERMINAL (d)	3/39 (8%)	1/32 (3%)	0/28 (0%)
FIRST INCIDENCE	727 (T)	727 (T)	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.066N	P=0.327N	P=0.128N
POLY 1.5	P=0.061N	P=0.314N	P=0.121N
POLY 6	P=0.073N	P=0.345N	P=0.140N
COCH-ARM / FISHERS	P=0.060N	P=0.309N	P=0.121N
MAX-ISO-POLY-3	P=0.050N*	P=0.177N	P=0.046N*

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Prostate Inflammation</b>			
<b>LESION RATES</b>			
OVERALL (a)	9/50 (18%)	11/50 (22%)	10/50 (20%)
POLY-3 RATE (b)	9/45.90	11/44.04	10/44.55
POLY-3 PERCENT (g)	19.6%	25%	22.5%
TERMINAL (d)	8/39 (21%)	8/32 (25%)	6/28 (21%)
FIRST INCIDENCE	692	580	632
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.419	P=0.360	P=0.471
POLY 1.5	P=0.450	P=0.388	P=0.500
POLY 6	P=0.376	P=0.327	P=0.431
COCH-ARM / FISHERS	P=0.450	P=0.402	P=0.500
MAX-ISO-POLY-3	P=0.445	P=0.275	P=0.371

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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: 09:37:47  
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

---

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

---

Prostate: Epithelium  
Cyst

---

LESION RATES			
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.76	0/43.06	2/43.38
POLY-3 PERCENT (g)	0%	0%	4.6%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	2/28 (7%)
FIRST INCIDENCE	---	---	727 (T)

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STATISTICAL TESTS			
POLY 3	P=0.093	(e)	P=0.225
POLY 1.5	P=0.094	(e)	P=0.234
POLY 6	P=0.092	(e)	P=0.213
COCH-ARM / FISHERS	P=0.095	(e)	P=0.247
MAX-ISO-POLY-3	P=0.052	(e)	P=0.076

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Prostate: Epithelium  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	15/50 (30%)	6/50 (12%)	12/50 (24%)
POLY-3 RATE (b)	15/45.87	6/43.37	12/43.60
POLY-3 PERCENT (g)	32.7%	13.8%	27.5%
TERMINAL (d)	14/39 (36%)	5/32 (16%)	9/28 (32%)
FIRST INCIDENCE	701	644	701

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**STATISTICAL TESTS**

POLY 3	P=0.305N	P=0.030N*	P=0.381N
POLY 1.5	P=0.276N	P=0.024N*	P=0.336N
POLY 6	P=0.352N	P=0.038N*	P=0.448N
COCH-ARM / FISHERS	P=0.273N	P=0.024N*	P=0.326N
MAX-ISO-POLY-3	P=0.131N	P=0.019N*	P=0.301N

---

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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Skin			
Cyst Epithelial Inclusion			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	6/50 (12%)	1/50 (2%)
POLY-3 RATE (b)	0/45.76	6/43.81	1/43.58
POLY-3 PERCENT (g)	0%	13.7%	2.3%
TERMINAL (d)	0/39 (0%)	4/32 (13%)	0/28 (0%)
FIRST INCIDENCE	---	605	675
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.368	P=0.013*	P=0.490
POLY 1.5	P=0.397	P=0.015*	P=0.498
POLY 6	P=0.329	P=0.011*	P=0.479
COCH-ARM / FISHERS	P=0.406	P=0.013*	P=0.500
MAX-ISO-POLY-3	P=0.059	P=0.004**	P=0.158

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Spleen Fibrosis			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/45.76	2/43.06	1/43.38
POLY-3 PERCENT (g)	0%	4.6%	2.3%
TERMINAL (d)	0/39 (0%)	2/32 (6%)	1/28 (4%)
FIRST INCIDENCE	---	727 (T)	727 (T)
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.343	P=0.224	P=0.489
POLY 1.5	P=0.357	P=0.232	P=0.498
POLY 6	P=0.323	P=0.214	P=0.477
COCH-ARM / FISHERS	P=0.360	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.196	P=0.076	P=0.158

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Spleen</b>			
Hyperplasia Lymphoid			
<b>LESION RATES</b>			
OVERALL (a)	3/50 (6%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	3/45.76	2/43.17	2/43.38
POLY-3 PERCENT (g)	6.6%	4.6%	4.6%
TERMINAL (d)	3/39 (8%)	1/32 (3%)	2/28 (7%)
FIRST INCIDENCE	727 (T)	701	727 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.431N	P=0.527N	P=0.524N
POLY 1.5	P=0.412N	P=0.510N	P=0.506N
POLY 6	P=0.459N	P=0.547N	P=0.551N
COCH-ARM / FISHERS	P=0.406N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.475N	P=0.351N	P=0.349N

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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: 09:37:47  
 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**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Stomach, Forestomach Inflammation</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	4/50 (8%)	8/50 (16%)
POLY-3 RATE (b)	2/45.76	4/43.93	8/45.19
POLY-3 PERCENT (g)	4.4%	9.1%	17.7%
TERMINAL (d)	2/39 (5%)	1/32 (3%)	1/28 (4%)
FIRST INCIDENCE	727 (T)	622	465
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.026*	P=0.318	P=0.043*
POLY 1.5	P=0.029*	P=0.331	P=0.047*
POLY 6	P=0.023*	P=0.304	P=0.037*
COCH-ARM / FISHERS	P=0.029*	P=0.339	P=0.046*
MAX-ISO-POLY-3	P=0.023*	P=0.191	P=0.020*

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: 09:37:47  
 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**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Stomach, Forestomach Ulcer</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	2/50 (4%)	7/50 (14%)
POLY-3 RATE (b)	0/45.76	2/43.73	7/45.06
POLY-3 PERCENT (g)	0%	4.6%	15.5%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	632	465
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.002**	P=0.227	P=0.007**
POLY 1.5	P=0.003**	P=0.234	P=0.008**
POLY 6	P=0.002**	P=0.219	P=0.006**
COCH-ARM / FISHERS	P=0.003**	P=0.247	P=0.006**
MAX-ISO-POLY-3	P<0.001**	P=0.076	P=0.002**

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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Stomach, Forestomach: Epithelium  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	16/50 (32%)	21/50 (42%)	20/50 (40%)
POLY-3 RATE (b)	16/47.34	21/44.89	20/46.90
POLY-3 PERCENT (g)	33.8%	46.8%	42.6%
TERMINAL (d)	12/39 (31%)	14/32 (44%)	8/28 (29%)
FIRST INCIDENCE	24	570	456

---

**STATISTICAL TESTS**

POLY 3	P=0.216	P=0.143	P=0.250
POLY 1.5	P=0.237	P=0.168	P=0.270
POLY 6	P=0.186	P=0.117	P=0.222
COCH-ARM / FISHERS	P=0.235	P=0.204	P=0.266
MAX-ISO-POLY-3	P=0.193	P=0.105	P=0.189

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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: 09:37:47  
 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**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Stomach, Glandular Erosion</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.76	0/43.06	2/44.15
POLY-3 PERCENT (g)	0%	0%	4.5%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	598
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.094	(e)	P=0.229
POLY 1.5	P=0.094	(e)	P=0.237
POLY 6	P=0.092	(e)	P=0.219
COCH-ARM / FISHERS	P=0.095	(e)	P=0.247
MAX-ISO-POLY-3	P=0.052	(e)	P=0.076

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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Stomach, Glandular Inflammation</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	1/45.76	3/43.24	1/43.39
POLY-3 PERCENT (g)	2.2%	6.9%	2.3%
TERMINAL (d)	1/39 (3%)	2/32 (6%)	0/28 (0%)
FIRST INCIDENCE	727 (T)	682	725
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.586	P=0.285	P=0.749
POLY 1.5	P=0.604	P=0.298	P=0.758
POLY 6	P=0.558	P=0.270	P=0.735
COCH-ARM / FISHERS	P=0.610	P=0.309	P=0.753N
MAX-ISO-POLY-3	P=0.387	P=0.147	P=0.484

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Stomach, Glandular Mineralization</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	0/45.76	1/43.37	4/43.92
POLY-3 PERCENT (g)	0%	2.3%	9.1%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	2/28 (7%)
FIRST INCIDENCE	---	644	637
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.023*	P=0.489	P=0.055
POLY 1.5	P=0.024*	P=0.496	P=0.060
POLY 6	P=0.021*	P=0.481	P=0.049*
COCH-ARM / FISHERS	P=0.026*	P=0.500	P=0.059
MAX-ISO-POLY-3	P=0.015*	P=0.158	P=0.019*

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Testes</b>			
<b>Inflammation</b>			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/45.76	1/43.06	2/43.39
POLY-3 PERCENT (g)	0%	2.3%	4.6%
TERMINAL (d)	0/39 (0%)	1/32 (3%)	1/28 (4%)
FIRST INCIDENCE	---	727 (T)	725
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.136	P=0.488	P=0.225
POLY 1.5	P=0.141	P=0.495	P=0.235
POLY 6	P=0.128	P=0.478	P=0.213
COCH-ARM / FISHERS	P=0.142	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.104	P=0.158	P=0.076

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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: 09:37:47  
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**

---

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

---

Testes: Germinal Epithelium  
Atrophy

---

LESION RATES			
OVERALL (a)	3/50 (6%)	4/50 (8%)	5/50 (10%)
POLY-3 RATE (b)	3/45.78	4/43.28	5/43.49
POLY-3 PERCENT (g)	6.6%	9.2%	11.5%
TERMINAL (d)	2/39 (5%)	3/32 (9%)	3/28 (11%)
FIRST INCIDENCE	723	672	701

---

STATISTICAL TESTS			
POLY 3	P=0.266	P=0.469	P=0.328
POLY 1.5	P=0.285	P=0.488	P=0.350
POLY 6	P=0.239	P=0.445	P=0.298
COCH-ARM / FISHERS	P=0.290	P=0.500	P=0.357
MAX-ISO-POLY-3	P=0.298	P=0.324	P=0.214

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG

---

Testes: Interstitial Cell  
Hyperplasia

---

LESION RATES			
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/46.58	0/43.06	2/44.14
POLY-3 PERCENT (g)	2.2%	0%	4.5%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	412	---	456

---

STATISTICAL TESTS			
POLY 3	P=0.356	P=0.516N	P=0.481
POLY 1.5	P=0.360	P=0.507N	P=0.495
POLY 6	P=0.350	P=0.526N	P=0.461
COCH-ARM / FISHERS	P=0.360	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.196	P=0.178N	P=0.270

---

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: 09:37:47  
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

---

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

---

Thyroid Gland: C-Cell  
Hyperplasia

---

LESION RATES			
OVERALL (a)	32/50 (64%)	34/50 (68%)	28/44 (64%)
POLY-3 RATE (b)	32/46.42	34/44.78	28/41.38
POLY-3 PERCENT (g)	68.9%	75.9%	67.7%
TERMINAL (d)	28/39 (72%)	26/32 (81%)	20/28 (71%)
FIRST INCIDENCE	632	605	455

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STATISTICAL TESTS			
POLY 3	P=0.506N	P=0.299	P=0.542N
POLY 1.5	P=0.467N	P=0.377	P=0.506N
POLY 6	P=0.534	P=0.216	P=0.594N
COCH-ARM / FISHERS	P=0.536N	P=0.417	P=0.570N
MAX-ISO-POLY-3	P=0.432N	P=0.225	P=0.449N

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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: 09:37:47  
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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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Trachea Inflammation			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	2/45.90	3/43.70	3/44.79
POLY-3 PERCENT (g)	4.4%	6.9%	6.7%
TERMINAL (d)	1/39 (3%)	1/32 (3%)	0/28 (0%)
FIRST INCIDENCE	692	605	456
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.401	P=0.478	P=0.489
POLY 1.5	P=0.415	P=0.492	P=0.502
POLY 6	P=0.381	P=0.460	P=0.469
COCH-ARM / FISHERS	P=0.412	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.436	P=0.308	P=0.316

---

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: 09:37:47  
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**

---

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

---

Urinary Bladder: Transitional Epithelium  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	1/43.37	0/43.38
POLY-3 PERCENT (g)	0%	2.3%	0%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	644	---

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**STATISTICAL TESTS**

POLY 3	P=0.721	P=0.489	(e)
POLY 1.5	P=0.728	P=0.496	(e)
POLY 6	P=0.710	P=0.481	(e)
COCH-ARM / FISHERS	P=0.731	P=0.500	(e)
MAX-ISO-POLY-3	P=0.376	P=0.158	(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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Adrenal Cortex Degeneration Cystic</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	1/42.78	4/45.81	0/47.40
POLY-3 PERCENT (g)	2.3%	8.7%	0%
TERMINAL (d)	1/31 (3%)	4/37 (11%)	0/38 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.333N	P=0.200	P=0.480N
POLY 1.5	P=0.356N	P=0.190	P=0.488N
POLY 6	P=0.304N	P=0.213	P=0.468N
COCH-ARM / FISHERS	P=0.390N	P=0.181	P=0.500N
MAX-ISO-POLY-3	P=0.118N	P=0.104	P=0.158N

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Adrenal Cortex Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	10/50 (20%)	7/50 (14%)	6/50 (12%)
POLY-3 RATE (b)	10/43.61	7/46.35	6/47.40
POLY-3 PERCENT (g)	22.9%	15.1%	12.7%
TERMINAL (d)	7/31 (23%)	4/37 (11%)	6/38 (16%)
FIRST INCIDENCE	634	652	728 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.127N	P=0.249N	P=0.156N
POLY 1.5	P=0.142N	P=0.272N	P=0.175N
POLY 6	P=0.111N	P=0.224N	P=0.134N
COCH-ARM / FISHERS	P=0.166N	P=0.298N	P=0.207N
MAX-ISO-POLY-3	P=0.144N	P=0.179N	P=0.107N

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Adrenal Cortex Hypertrophy</b>			
<b>LESION RATES</b>			
OVERALL (a)	20/50 (40%)	14/50 (28%)	34/50 (68%)
POLY-3 RATE (b)	20/45.53	14/46.08	34/47.86
POLY-3 PERCENT (g)	43.9%	30.4%	71%
TERMINAL (d)	10/31 (32%)	12/37 (32%)	30/38 (79%)
FIRST INCIDENCE	538	674	668
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.003**	P=0.128N	P=0.005**
POLY 1.5	P=0.002**	P=0.136N	P=0.004**
POLY 6	P=0.003**	P=0.125N	P=0.006**
COCH-ARM / FISHERS	P=0.003**	P=0.146N	P=0.004**
MAX-ISO-POLY-3	P<0.001**	P=0.089N	P=0.003**

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Adrenal Medulla Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	6/50 (12%)	11/50 (22%)	17/50 (34%)
POLY-3 RATE (b)	6/42.91	11/46.51	17/47.87
POLY-3 PERCENT (g)	14%	23.7%	35.5%
TERMINAL (d)	5/31 (16%)	9/37 (24%)	12/38 (32%)
FIRST INCIDENCE	693	561	695
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.011*	P=0.185	P=0.015*
POLY 1.5	P=0.008**	P=0.164	P=0.011*
POLY 6	P=0.017*	P=0.213	P=0.023*
COCH-ARM / FISHERS	P=0.006**	P=0.143	P=0.008**
MAX-ISO-POLY-3	P=0.014*	P=0.131	P=0.011*

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Bone Marrow Hemorrhage			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/42.78	0/45.81	2/47.50
POLY-3 PERCENT (g)	0%	0%	4.2%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)
FIRST INCIDENCE	---	---	702
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.104	(e)	P=0.261
POLY 1.5	P=0.100	(e)	P=0.251
POLY 6	P=0.110	(e)	P=0.275
COCH-ARM / FISHERS	P=0.095	(e)	P=0.247
MAX-ISO-POLY-3	P=0.077	(e)	P=0.099

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Bone Marrow Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	8/50 (16%)	8/50 (16%)	20/50 (40%)
POLY-3 RATE (b)	8/44.43	8/47.76	20/49.49
POLY-3 PERCENT (g)	18%	16.8%	40.4%
TERMINAL (d)	4/31 (13%)	2/37 (5%)	12/38 (32%)
FIRST INCIDENCE	519	561	428
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.006**	P=0.546N	P=0.014*
POLY 1.5	P=0.004**	P=0.576N	P=0.010**
POLY 6	P=0.008**	P=0.508N	P=0.021*
COCH-ARM / FISHERS	P=0.004**	P=0.607N	P=0.007**
MAX-ISO-POLY-3	P=0.007**	P=0.437N	P=0.011*

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Bone</b>			
<b>Fibrous Osteodystrophy</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.78	0/45.81	1/47.50
POLY-3 PERCENT (g)	0%	0%	2.1%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	702
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.288	(e)	P=0.521
POLY 1.5	P=0.281	(e)	P=0.512
POLY 6	P=0.299	(e)	P=0.532
COCH-ARM / FISHERS	P=0.269	(e)	P=0.500
MAX-ISO-POLY-3	P=0.187	(e)	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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Brain Hemorrhage</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/43.06	0/45.81	1/47.52
POLY-3 PERCENT (g)	2.3%	0%	2.1%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	650	---	698
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.665N	P=0.488N	P=0.738N
POLY 1.5	P=0.666N	P=0.494N	P=0.747N
POLY 6	P=0.665N	P=0.481N	P=0.726N
COCH-ARM / FISHERS	P=0.669	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.442N	P=0.158N	P=0.472N

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Brain</b>			
<b>Hydrocephalus</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/43.75	1/45.81	0/47.40
POLY-3 PERCENT (g)	4.6%	2.2%	0%
TERMINAL (d)	0/31 (0%)	1/37 (3%)	0/38 (0%)
FIRST INCIDENCE	495	728 (T)	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.133N	P=0.484N	P=0.220N
POLY 1.5	P=0.137N	P=0.492N	P=0.227N
POLY 6	P=0.128N	P=0.474N	P=0.211N
COCH-ARM / FISHERS	P=0.142N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.104N	P=0.271N	P=0.076N

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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: 09:37:47  
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**

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Clitoral Gland Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	3/50 (6%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	3/43.14	1/45.81	0/47.40
POLY-3 PERCENT (g)	7%	2.2%	0%
TERMINAL (d)	1/31 (3%)	1/37 (3%)	0/38 (0%)
FIRST INCIDENCE	634	728 (T)	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.054N	P=0.284N	P=0.103N
POLY 1.5	P=0.056N	P=0.294N	P=0.109N
POLY 6	P=0.051N	P=0.272N	P=0.095N
COCH-ARM / FISHERS	P=0.060N	P=0.309N	P=0.121N
MAX-ISO-POLY-3	P=0.040N*	P=0.146N	P=0.038N*

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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Clitoral Gland Inflammation</b>			
<b>LESION RATES</b>			
OVERALL (a)	6/50 (12%)	7/50 (14%)	1/50 (2%)
POLY-3 RATE (b)	6/43.27	7/45.87	1/47.40
POLY-3 PERCENT (g)	13.9%	15.3%	2.1%
TERMINAL (d)	4/31 (13%)	6/37 (16%)	1/38 (3%)
FIRST INCIDENCE	634	713	728 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.040N*	P=0.545	P=0.043N*
POLY 1.5	P=0.047N*	P=0.523	P=0.048N*
POLY 6	P=0.033N*	P=0.569	P=0.037N*
COCH-ARM / FISHERS	P=0.061N	P=0.500	P=0.056N
MAX-ISO-POLY-3	P=0.039N*	P=0.427	P=0.021N*

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Clitoral Gland: Duct Cyst			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/43.12	2/45.87	1/47.40
POLY-3 PERCENT (g)	4.6%	4.4%	2.1%
TERMINAL (d)	1/31 (3%)	1/37 (3%)	1/38 (3%)
FIRST INCIDENCE	634	713	728 (T)
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.360N	P=0.672N	P=0.467N
POLY 1.5	P=0.372N	P=0.682N	P=0.480N
POLY 6	P=0.344N	P=0.659N	P=0.450N
COCH-ARM / FISHERS	P=0.390N	P=0.691N	P=0.500N
MAX-ISO-POLY-3	P=0.380N	P=0.475N	P=0.263N

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Eye			
Cataract			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	1/42.78	3/45.86	2/47.40
POLY-3 PERCENT (g)	2.3%	6.5%	4.2%
TERMINAL (d)	1/31 (3%)	2/37 (5%)	2/38 (5%)
FIRST INCIDENCE	728 (T)	716	728 (T)
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.456	P=0.331	P=0.536
POLY 1.5	P=0.433	P=0.318	P=0.521
POLY 6	P=0.487	P=0.346	P=0.555
COCH-ARM / FISHERS	P=0.399	P=0.309	P=0.500
MAX-ISO-POLY-3	P=0.356	P=0.180	P=0.319

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Eye: Retina Atrophy			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	4/50 (8%)	3/50 (6%)
POLY-3 RATE (b)	2/42.78	4/46.19	3/47.40
POLY-3 PERCENT (g)	4.7%	8.7%	6.3%
TERMINAL (d)	2/31 (7%)	2/37 (5%)	3/38 (8%)
FIRST INCIDENCE	728 (T)	637	728 (T)
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.480	P=0.373	P=0.547
POLY 1.5	P=0.454	P=0.356	P=0.527
POLY 6	P=0.515	P=0.395	P=0.572
COCH-ARM / FISHERS	P=0.417	P=0.339	P=0.500
MAX-ISO-POLY-3	P=0.426	P=0.237	P=0.372

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG

---

Eye: Retina  
Dysplasia

---

LESION RATES			
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/42.78	0/45.81	2/47.45
POLY-3 PERCENT (g)	0%	0%	4.2%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)
FIRST INCIDENCE	---	---	716

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STATISTICAL TESTS			
POLY 3	P=0.104	(e)	P=0.261
POLY 1.5	P=0.100	(e)	P=0.251
POLY 6	P=0.109	(e)	P=0.275
COCH-ARM / FISHERS	P=0.095	(e)	P=0.247
MAX-ISO-POLY-3	P=0.076	(e)	P=0.099

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Harderian Gland Inflammation</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	1/45.81	0/47.40
POLY-3 PERCENT (g)	0%	2.2%	0%
TERMINAL (d)	0/31 (0%)	1/37 (3%)	0/38 (0%)
FIRST INCIDENCE	---	728 (T)	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.712N	P=0.514	(e)
POLY 1.5	P=0.720N	P=0.507	(e)
POLY 6	P=0.702N	P=0.522	(e)
COCH-ARM / FISHERS	P=0.731	P=0.500	(e)
MAX-ISO-POLY-3	P=0.385N	P=0.175	(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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Harderian Gland: Epithelium Hyperplasia			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.78	0/45.81	1/47.40
POLY-3 PERCENT (g)	0%	0%	2.1%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)
FIRST INCIDENCE	---	---	728 (T)
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.288	(e)	P=0.520
POLY 1.5	P=0.280	(e)	P=0.512
POLY 6	P=0.298	(e)	P=0.532
COCH-ARM / FISHERS	P=0.269	(e)	P=0.500
MAX-ISO-POLY-3	P=0.186	(e)	P=0.183

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG

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Heart  
Cardiomyopathy

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LESION RATES			
OVERALL (a)	48/50 (96%)	45/50 (90%)	47/50 (94%)
POLY-3 RATE (b)	48/49.71	45/47.77	47/49.10
POLY-3 PERCENT (g)	96.6%	94.2%	95.7%
TERMINAL (d)	30/31 (97%)	37/37 (100%)	37/38 (97%)
FIRST INCIDENCE	309	561	497

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STATISTICAL TESTS			
POLY 3	P=0.518N	P=0.468N	P=0.627N
POLY 1.5	P=0.485N	P=0.387N	P=0.587N
POLY 6	P=0.534N	P=0.623N	P=0.647N
COCH-ARM / FISHERS	P=0.421N	P=0.218N	P=0.500N
MAX-ISO-POLY-3	P=0.466N	P=0.271N	P=0.409N

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Heart: Endocardium			
Bacterium			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 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**

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Intestine Large, Cecum Inflammation</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	1/50 (2%)	3/49 (6%)
POLY-3 RATE (b)	0/42.78	1/45.81	3/46.58
POLY-3 PERCENT (g)	0%	2.2%	6.4%
TERMINAL (d)	0/31 (0%)	1/37 (3%)	2/38 (5%)
FIRST INCIDENCE	---	728 (T)	708
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.069	P=0.514	P=0.135
POLY 1.5	P=0.064	P=0.507	P=0.126
POLY 6	P=0.076	P=0.522	P=0.147
COCH-ARM / FISHERS	P=0.058	P=0.500	P=0.117
MAX-ISO-POLY-3	P=0.057	P=0.175	P=0.052

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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Intestine Large, Colon</b>			
<b>Parasite Metazoan</b>			
<b>LESION RATES</b>			
OVERALL (a)	3/50 (6%)	2/50 (4%)	0/49 (0%)
POLY-3 RATE (b)	3/42.78	2/45.81	0/46.50
POLY-3 PERCENT (g)	7%	4.4%	0%
TERMINAL (d)	3/31 (10%)	2/37 (5%)	0/38 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.071N	P=0.469N	P=0.104N
POLY 1.5	P=0.076N	P=0.484N	P=0.112N
POLY 6	P=0.064N	P=0.451N	P=0.095N
COCH-ARM / FISHERS	P=0.084N	P=0.500N	P=0.125N
MAX-ISO-POLY-3	P=0.063N	P=0.302N	P=0.038N*

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Intestine Large, Rectum Parasite Metazoan			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	4/50 (8%)	6/50 (12%)	7/50 (14%)
POLY-3 RATE (b)	4/42.98	6/46.25	7/47.40
POLY-3 PERCENT (g)	9.3%	13%	14.8%
TERMINAL (d)	3/31 (10%)	5/37 (14%)	7/38 (18%)
FIRST INCIDENCE	674	600	728 (T)
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.273	P=0.416	P=0.320
POLY 1.5	P=0.249	P=0.394	P=0.295
POLY 6	P=0.305	P=0.443	P=0.353
COCH-ARM / FISHERS	P=0.215	P=0.370	P=0.262
MAX-ISO-POLY-3	P=0.319	P=0.299	P=0.226

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Kidney Cyst</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/43.70	0/45.81	0/47.40
POLY-3 PERCENT (g)	4.6%	0%	0%
TERMINAL (d)	1/31 (3%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	309	---	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.094N	P=0.227N	P=0.220N
POLY 1.5	P=0.094N	P=0.233N	P=0.228N
POLY 6	P=0.093N	P=0.219N	P=0.209N
COCH-ARM / FISHERS	P=0.095N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.052N	P=0.076N	P=0.076N

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Kidney			
Glomerulopathy Hyaline			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	17/50 (34%)	49/50 (98%)
POLY-3 RATE (b)	0/42.78	17/46.95	49/49.20
POLY-3 PERCENT (g)	0%	36.2%	99.6%
TERMINAL (d)	0/31 (0%)	12/37 (32%)	38/38 (100%)
FIRST INCIDENCE	---	561	497
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Kidney Inflammation</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/42.78	1/45.81	1/47.40
POLY-3 PERCENT (g)	0%	2.2%	2.1%
TERMINAL (d)	0/31 (0%)	1/37 (3%)	1/38 (3%)
FIRST INCIDENCE	---	728 (T)	728 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.368	P=0.514	P=0.520
POLY 1.5	P=0.353	P=0.507	P=0.512
POLY 6	P=0.389	P=0.522	P=0.532
COCH-ARM / FISHERS	P=0.331	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.297	P=0.175	P=0.183

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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: 09:37:47  
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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Kidney</b>			
<b>Nephropathy</b>			
<b>LESION RATES</b>			
OVERALL (a)	42/50 (84%)	44/50 (88%)	49/50 (98%)
POLY-3 RATE (b)	42/47.79	44/47.90	49/49.20
POLY-3 PERCENT (g)	87.9%	91.9%	99.6%
TERMINAL (d)	30/31 (97%)	36/37 (97%)	38/38 (100%)
FIRST INCIDENCE	309	561	497
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.008**	P=0.367	P=0.010**
POLY 1.5	P=0.008**	P=0.331	P=0.010**
POLY 6	P=0.013*	P=0.453	P=0.016*
COCH-ARM / FISHERS	P=0.015*	P=0.387	P=0.015*
MAX-ISO-POLY-3	P=0.006**	P=0.238	P=0.002**

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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG

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**Kidney: Cortex  
Mineralization**

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**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/42.78	1/45.96	1/47.40
POLY-3 PERCENT (g)	0%	2.2%	2.1%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)
FIRST INCIDENCE	---	689	728 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.368	P=0.514	P=0.520
POLY 1.5	P=0.353	P=0.507	P=0.512
POLY 6	P=0.389	P=0.523	P=0.532
COCH-ARM / FISHERS	P=0.331	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.298	P=0.176	P=0.183

---



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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG

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**Kidney: Renal Tubule Degeneration**

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**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	2/45.96	0/47.40
POLY-3 PERCENT (g)	0%	4.4%	0%
TERMINAL (d)	0/31 (0%)	1/37 (3%)	0/38 (0%)
FIRST INCIDENCE	---	689	---

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**STATISTICAL TESTS**

POLY 3	P=0.633N	P=0.253	(e)
POLY 1.5	P=0.648N	P=0.246	(e)
POLY 6	P=0.612N	P=0.263	(e)
COCH-ARM / FISHERS	P=0.669	P=0.247	(e)
MAX-ISO-POLY-3	P=0.278N	P=0.092	(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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Liver			
Angiectasis			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	5/50 (10%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	5/45.81	0/47.40
POLY-3 PERCENT (g)	0%	10.9%	0%
TERMINAL (d)	0/31 (0%)	5/37 (14%)	0/38 (0%)
FIRST INCIDENCE	---	728 (T)	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.541N	P=0.037*	(e)
POLY 1.5	P=0.571N	P=0.034*	(e)
POLY 6	P=0.501N	P=0.040*	(e)
COCH-ARM / FISHERS	P=0.610	P=0.028*	(e)
MAX-ISO-POLY-3	P=0.113N	P=0.014*	(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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Liver			
Basophilic Focus			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	44/50 (88%)	21/50 (42%)	3/50 (6%)
POLY-3 RATE (b)	44/47.23	21/46.81	3/47.40
POLY-3 PERCENT (g)	93.2%	44.9%	6.3%
TERMINAL (d)	29/31 (94%)	18/37 (49%)	3/38 (8%)
FIRST INCIDENCE	519	573	728 (T)
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001N**	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P<0.001N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P<0.001N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P<0.001N**	P<0.001N**

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Liver			
Clear Cell Focus			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	8/50 (16%)	12/50 (24%)	4/50 (8%)
POLY-3 RATE (b)	8/44.29	12/45.81	4/47.40
POLY-3 PERCENT (g)	18.1%	26.2%	8.4%
TERMINAL (d)	5/31 (16%)	12/37 (32%)	4/38 (11%)
FIRST INCIDENCE	538	728 (T)	728 (T)
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.123N	P=0.250	P=0.145N
POLY 1.5	P=0.140N	P=0.237	P=0.158N
POLY 6	P=0.103N	P=0.263	P=0.130N
COCH-ARM / FISHERS	P=0.170N	P=0.227	P=0.178N
MAX-ISO-POLY-3	P=0.059N	P=0.180	P=0.093N

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Liver			
Eosinophilic Focus			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Liver			
Fatty Change			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	7/50 (14%)	25/50 (50%)	35/50 (70%)
POLY-3 RATE (b)	7/44.63	25/47.36	35/48.60
POLY-3 PERCENT (g)	15.7%	52.8%	72%
TERMINAL (d)	4/31 (13%)	20/37 (54%)	30/38 (79%)
FIRST INCIDENCE	495	85	497
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Liver			
Hepatodiaphragmatic Nodule			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	3/50 (6%)	6/50 (12%)	7/50 (14%)
POLY-3 RATE (b)	3/42.78	6/46.32	7/47.53
POLY-3 PERCENT (g)	7%	13%	14.7%
TERMINAL (d)	3/31 (10%)	5/37 (14%)	6/38 (16%)
FIRST INCIDENCE	728 (T)	573	695
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.175	P=0.283	P=0.204
POLY 1.5	P=0.155	P=0.263	P=0.184
POLY 6	P=0.204	P=0.307	P=0.232
COCH-ARM / FISHERS	P=0.128	P=0.243	P=0.159
MAX-ISO-POLY-3	P=0.197	P=0.187	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: 09:37:47  
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

---

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Liver Inflammation			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	35/50 (70%)	31/50 (62%)	37/50 (74%)
POLY-3 RATE (b)	35/46.42	31/46.45	37/48.60
POLY-3 PERCENT (g)	75.4%	66.7%	76.1%
TERMINAL (d)	26/31 (84%)	28/37 (76%)	32/38 (84%)
FIRST INCIDENCE	309	652	497
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.503	P=0.235N	P=0.564
POLY 1.5	P=0.438	P=0.265N	P=0.490
POLY 6	P=0.499N	P=0.194N	P=0.528N
COCH-ARM / FISHERS	P=0.373	P=0.263N	P=0.412
MAX-ISO-POLY-3	P=0.397	P=0.168N	P=0.465

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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: 09:37:47  
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

---

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

---

Liver  
Mixed Cell Focus

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LESION RATES			
OVERALL (a)	5/50 (10%)	0/50 (0%)	4/50 (8%)
POLY-3 RATE (b)	5/43.01	0/45.81	4/47.40
POLY-3 PERCENT (g)	11.6%	0%	8.4%
TERMINAL (d)	3/31 (10%)	0/37 (0%)	4/38 (11%)
FIRST INCIDENCE	674	---	728 (T)

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STATISTICAL TESTS			
POLY 3	P=0.397N	P=0.025N*	P=0.439N
POLY 1.5	P=0.404N	P=0.028N*	P=0.464N
POLY 6	P=0.388N	P=0.023N*	P=0.408N
COCH-ARM / FISHERS	P=0.417N	P=0.028N*	P=0.500N
MAX-ISO-POLY-3	P=0.122N	P=0.009N**	P=0.316N

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Liver: Bile Duct Cyst			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	6/50 (12%)	38/50 (76%)
POLY-3 RATE (b)	1/42.78	6/45.81	38/48.80
POLY-3 PERCENT (g)	2.3%	13.1%	77.9%
TERMINAL (d)	1/31 (3%)	6/37 (16%)	31/38 (82%)
FIRST INCIDENCE	728 (T)	728 (T)	497
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001**	P=0.067	P<0.001**
POLY 1.5	P<0.001**	P=0.062	P<0.001**
POLY 6	P<0.001**	P=0.075	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.056	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.033*	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: 09:37:47  
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

---

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

---

Liver: Bile Duct  
Hyperplasia

---

LESION RATES			
OVERALL (a)	5/50 (10%)	4/50 (8%)	49/50 (98%)
POLY-3 RATE (b)	5/42.91	4/45.96	49/49.20
POLY-3 PERCENT (g)	11.7%	8.7%	99.6%
TERMINAL (d)	4/31 (13%)	3/37 (8%)	38/38 (100%)
FIRST INCIDENCE	693	689	497

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STATISTICAL TESTS			
POLY 3	P<0.001**	P=0.457N	P<0.001**
POLY 1.5	P<0.001**	P=0.478N	P<0.001**
POLY 6	P<0.001**	P=0.432N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.329N	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: 09:37:47  
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

---

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

---

Liver: Cervix  
Hemorrhage

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	0/42.78	0/45.81	3/47.40
POLY-3 PERCENT (g)	0%	0%	6.3%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	3/38 (8%)
FIRST INCIDENCE	---	---	728 (T)

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**STATISTICAL TESTS**

POLY 3	P=0.040*	(e)	P=0.138
POLY 1.5	P=0.038*	(e)	P=0.130
POLY 6	P=0.043*	(e)	P=0.150
COCH-ARM / FISHERS	P=0.037*	(e)	P=0.121
MAX-ISO-POLY-3	P=0.033*	(e)	P=0.054

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Liver: Hepatocyte Cellular Alteration Diffuse			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	4/50 (8%)	45/50 (90%)
POLY-3 RATE (b)	0/42.78	4/47.03	45/48.52
POLY-3 PERCENT (g)	0%	8.5%	92.7%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	35/38 (92%)
FIRST INCIDENCE	---	561	668
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001**	P=0.073	P<0.001**
POLY 1.5	P<0.001**	P=0.067	P<0.001**
POLY 6	P<0.001**	P=0.082	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.059	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.030*	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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Liver: Hepatocyte Degeneration Cystic			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:37:47  
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

---

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

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Liver: Hepatocyte  
Necrosis

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**LESION RATES**

OVERALL (a)	4/50 (8%)	2/50 (4%)	20/50 (40%)
POLY-3 RATE (b)	4/43.57	2/46.10	20/47.58
POLY-3 PERCENT (g)	9.2%	4.3%	42%
TERMINAL (d)	2/31 (7%)	1/37 (3%)	18/38 (47%)
FIRST INCIDENCE	519	650	702

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**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.311N	P<0.001**
POLY 1.5	P<0.001**	P=0.324N	P<0.001**
POLY 6	P<0.001**	P=0.296N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.339N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.187N	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: 09:37:47  
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

---

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

---

Liver: Hepatocyte, Centrilobular Degeneration

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**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	1/46.10	0/47.40
POLY-3 PERCENT (g)	0%	2.2%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	---	650	---

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**STATISTICAL TESTS**

POLY 3	P=0.712N	P=0.515	(e)
POLY 1.5	P=0.720N	P=0.508	(e)
POLY 6	P=0.702N	P=0.524	(e)
COCH-ARM / FISHERS	P=0.731	P=0.500	(e)
MAX-ISO-POLY-3	P=0.386N	P=0.177	(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: 09:37:47  
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

---

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Liver: Oval Cell Hyperplasia			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	45/50 (90%)
POLY-3 RATE (b)	0/42.78	0/45.81	45/48.30
POLY-3 PERCENT (g)	0%	0%	93.2%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	37/38 (97%)
FIRST INCIDENCE	---	---	668
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001**	(e)	P<0.001**
POLY 1.5	P<0.001**	(e)	P<0.001**
POLY 6	P<0.001**	(e)	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	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: 09:37:47  
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

---

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

---

Liver: Portal  
Fibrosis

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	3/50 (6%)	28/50 (56%)
POLY-3 RATE (b)	0/42.78	3/45.81	28/47.73
POLY-3 PERCENT (g)	0%	6.6%	58.7%
TERMINAL (d)	0/31 (0%)	3/37 (8%)	26/38 (68%)
FIRST INCIDENCE	---	728 (T)	668

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**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.131	P<0.001**
POLY 1.5	P<0.001**	P=0.125	P<0.001**
POLY 6	P<0.001**	P=0.139	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.121	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.049*	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: 09:37:47  
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

---

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Lung Congestion			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.78	0/45.81	1/47.48
POLY-3 PERCENT (g)	0%	0%	2.1%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	708
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.288	(e)	P=0.521
POLY 1.5	P=0.281	(e)	P=0.512
POLY 6	P=0.299	(e)	P=0.532
COCH-ARM / FISHERS	P=0.269	(e)	P=0.500
MAX-ISO-POLY-3	P=0.187	(e)	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: 09:37:47  
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**

---

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Lung Inflammation			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	1/43.20	3/45.81	0/47.40
POLY-3 PERCENT (g)	2.3%	6.6%	0%
TERMINAL (d)	0/31 (0%)	3/37 (8%)	0/38 (0%)
FIRST INCIDENCE	607	728 (T)	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.336N	P=0.327	P=0.481N
POLY 1.5	P=0.353N	P=0.316	P=0.489N
POLY 6	P=0.315N	P=0.339	P=0.472N
COCH-ARM / FISHERS	P=0.378N	P=0.309	P=0.500N
MAX-ISO-POLY-3	P=0.155N	P=0.176	P=0.158N

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Lung: Alveolar Epithelium Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	8/50 (16%)	14/50 (28%)	10/50 (20%)
POLY-3 RATE (b)	8/44.82	14/45.92	10/47.50
POLY-3 PERCENT (g)	17.9%	30.5%	21.1%
TERMINAL (d)	4/31 (13%)	13/37 (35%)	9/38 (24%)
FIRST INCIDENCE	309	701	702
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.425	P=0.121	P=0.450
POLY 1.5	P=0.393	P=0.114	P=0.426
POLY 6	P=0.470	P=0.130	P=0.485
COCH-ARM / FISHERS	P=0.357	P=0.114	P=0.398
MAX-ISO-POLY-3	P=0.267	P=0.081	P=0.352

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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: 09:37:47  
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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Lung: Alveolus Inflammation Histiocytic</b>			
<b>LESION RATES</b>			
OVERALL (a)	40/50 (80%)	44/50 (88%)	49/50 (98%)
POLY-3 RATE (b)	40/47.23	44/47.34	49/49.20
POLY-3 PERCENT (g)	84.7%	93%	99.6%
TERMINAL (d)	26/31 (84%)	36/37 (97%)	38/38 (100%)
FIRST INCIDENCE	495	600	497
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.002**	P=0.151	P=0.004**
POLY 1.5	P=0.002**	P=0.158	P=0.003**
POLY 6	P=0.002**	P=0.131	P=0.007**
COCH-ARM / FISHERS	P=0.004**	P=0.207	P=0.004**
MAX-ISO-POLY-3	P<0.001**	P=0.082	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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Lung: Cervix Hyperplasia			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Lung: Interstitium Mineralization			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:37:47  
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**

---

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Lymph Node, Mesenteric Hemorrhage</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/43.27	0/45.81	1/47.40
POLY-3 PERCENT (g)	4.6%	0%	2.1%
TERMINAL (d)	1/31 (3%)	0/37 (0%)	1/38 (3%)
FIRST INCIDENCE	581	---	728 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.355N	P=0.225N	P=0.468N
POLY 1.5	P=0.357N	P=0.231N	P=0.481N
POLY 6	P=0.353N	P=0.218N	P=0.451N
COCH-ARM / FISHERS	P=0.360N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.189N	P=0.076N	P=0.263N

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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: 09:37:47  
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**

---

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

---

Lymph Node: Mediastinal  
Degeneration Cystic

---

**LESION RATES**

OVERALL (a)	1/2 (50%)	0/3 (0%)	1/5 (20%)
POLY-3 RATE (b)	1/2.00	0/2.13	1/4.88
POLY-3 PERCENT (g)	50%	0%	20.5%
TERMINAL (d)	1/2 (50%)	0/1 (0%)	1/4 (25%)
FIRST INCIDENCE	728 (T)	---	728 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.448N	P=0.487N	P=0.553N
POLY 1.5	P=0.453N	P=0.451N	P=0.550N
POLY 6	P=0.447N	P=0.539N	P=0.559N
COCH-ARM / FISHERS	P=0.460N	P=0.400N	P=0.524N
MAX-ISO-POLY-3	P=0.283N	P=0.145N	P=0.281N

---

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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG

---

Lymph Node: Mediastinal  
Hyperplasia

---

LESION RATES			
OVERALL (a)	0/2 (0%)	0/3 (0%)	2/5 (40%)
POLY-3 RATE (b)	0/2.00	0/2.13	2/4.88
POLY-3 PERCENT (g)	0%	0%	41%
TERMINAL (d)	0/2 (0%)	0/1 (0%)	2/4 (50%)
FIRST INCIDENCE	---	---	728 (T)

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STATISTICAL TESTS			
POLY 3	P=0.225	(e)	P=0.444
POLY 1.5	P=0.210	(e)	P=0.448
POLY 6	P=0.244	(e)	P=0.437
COCH-ARM / FISHERS	P=0.181	(e)	P=0.476
MAX-ISO-POLY-3	P=0.223	(e)	P=0.199

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Mammary Gland Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	2/45.81	0/47.40
POLY-3 PERCENT (g)	0%	4.4%	0%
TERMINAL (d)	0/31 (0%)	2/37 (5%)	0/38 (0%)
FIRST INCIDENCE	---	728 (T)	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.633N	P=0.253	(e)
POLY 1.5	P=0.648N	P=0.245	(e)
POLY 6	P=0.613N	P=0.262	(e)
COCH-ARM / FISHERS	P=0.669	P=0.247	(e)
MAX-ISO-POLY-3	P=0.277N	P=0.091	(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: 09:37:47  
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

---

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

---

Mammary Gland: Duct  
Dilatation

---

**LESION RATES**

OVERALL (a)	2/50 (4%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	2/43.27	4/45.81	1/47.40
POLY-3 PERCENT (g)	4.6%	8.7%	2.1%
TERMINAL (d)	0/31 (0%)	4/37 (11%)	1/38 (3%)
FIRST INCIDENCE	634	728 (T)	728 (T)

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**STATISTICAL TESTS**

POLY 3	P=0.358N	P=0.364	P=0.468N
POLY 1.5	P=0.378N	P=0.351	P=0.481N
POLY 6	P=0.335N	P=0.378	P=0.452N
COCH-ARM / FISHERS	P=0.406N	P=0.339	P=0.500N
MAX-ISO-POLY-3	P=0.239N	P=0.228	P=0.263N

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Mesentery Necrosis			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	5/6 (83%)	12/12 (100%)	5/5 (100%)
POLY-3 RATE (b)	5/5.51	12/12.00	5/5.00
POLY-3 PERCENT (g)	90.8%	100%	100%
TERMINAL (d)	4/4 (100%)	10/10 (100%)	4/4 (100%)
FIRST INCIDENCE	674	600	702
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.541	P=0.737	P=0.833
POLY 1.5	P=0.364	P=0.520	P=0.675
POLY 6	P=0.945	P=0.995	P=0.996
COCH-ARM / FISHERS	P=0.249	P=0.333	P=0.545
MAX-ISO-POLY-3	P=0.115	P=0.109	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: 09:37:47  
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**

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Nose Inflammation</b>			
<b>LESION RATES</b>			
OVERALL (a)	12/50 (24%)	22/50 (44%)	39/50 (78%)
POLY-3 RATE (b)	12/43.68	22/46.67	39/49.07
POLY-3 PERCENT (g)	27.5%	47.1%	79.5%
TERMINAL (d)	9/31 (29%)	17/37 (46%)	29/38 (76%)
FIRST INCIDENCE	581	637	497
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001**	P=0.040*	P<0.001**
POLY 1.5	P<0.001**	P=0.032*	P<0.001**
POLY 6	P<0.001**	P=0.052	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.028*	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.028*	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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Nose			
Thrombosis			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/42.78	1/46.14	2/47.50
POLY-3 PERCENT (g)	0%	2.2%	4.2%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)
FIRST INCIDENCE	---	637	702
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.165	P=0.515	P=0.261
POLY 1.5	P=0.155	P=0.508	P=0.251
POLY 6	P=0.178	P=0.524	P=0.275
COCH-ARM / FISHERS	P=0.142	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.136	P=0.177	P=0.099

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Nose: Glands Dilatation			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	6/50 (12%)	6/50 (12%)
POLY-3 RATE (b)	0/42.78	6/45.81	6/47.58
POLY-3 PERCENT (g)	0%	13.1%	12.6%
TERMINAL (d)	0/31 (0%)	6/37 (16%)	4/38 (11%)
FIRST INCIDENCE	---	728 (T)	702
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.032*	P=0.019*	P=0.022*
POLY 1.5	P=0.026*	P=0.017*	P=0.019*
POLY 6	P=0.042*	P=0.021*	P=0.026*
COCH-ARM / FISHERS	P=0.021*	P=0.013*	P=0.013*
MAX-ISO-POLY-3	P=0.026*	P=0.008**	P=0.010**

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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

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

---

Nose: Goblet Cell  
Hyperplasia

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**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---

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**STATISTICAL TESTS**

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

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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: 09:37:47  
 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**

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Nose: Olfactory Epithelium Degeneration</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	40/50 (80%)	48/50 (96%)
POLY-3 RATE (b)	2/43.06	40/48.29	48/49.10
POLY-3 PERCENT (g)	4.6%	82.8%	97.8%
TERMINAL (d)	1/31 (3%)	31/37 (84%)	38/38 (100%)
FIRST INCIDENCE	650	561	497
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG

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Nose: Olfactory Epithelium  
Metaplasia Respiratory

---

**LESION RATES**

OVERALL (a)	1/50 (2%)	8/50 (16%)	46/50 (92%)
POLY-3 RATE (b)	1/42.78	8/45.81	46/48.19
POLY-3 PERCENT (g)	2.3%	17.5%	95.5%
TERMINAL (d)	1/31 (3%)	8/37 (22%)	38/38 (100%)
FIRST INCIDENCE	728 (T)	728 (T)	695

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**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.020*	P<0.001**
POLY 1.5	P<0.001**	P=0.018*	P<0.001**
POLY 6	P<0.001**	P=0.024*	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.015*	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.010**	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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Ovary Atrophy			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	5/50 (10%)	5/50 (10%)	4/49 (8%)
POLY-3 RATE (b)	5/44.42	5/46.43	4/46.74
POLY-3 PERCENT (g)	11.3%	10.8%	8.6%
TERMINAL (d)	2/31 (7%)	3/37 (8%)	2/38 (5%)
FIRST INCIDENCE	495	637	695
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.401N	P=0.602N	P=0.468N
POLY 1.5	P=0.420N	P=0.617N	P=0.487N
POLY 6	P=0.376N	P=0.583N	P=0.441N
COCH-ARM / FISHERS	P=0.444N	P=0.630N	P=0.513N
MAX-ISO-POLY-3	P=0.470N	P=0.470N	P=0.338N

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Ovary Cyst			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	6/50 (12%)	4/50 (8%)	5/49 (10%)
POLY-3 RATE (b)	6/43.19	4/45.86	5/46.88
POLY-3 PERCENT (g)	13.9%	8.7%	10.7%
TERMINAL (d)	4/31 (13%)	3/37 (8%)	2/38 (5%)
FIRST INCIDENCE	674	716	668
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.391N	P=0.332N	P=0.443N
POLY 1.5	P=0.414N	P=0.350N	P=0.472N
POLY 6	P=0.362N	P=0.312N	P=0.404N
COCH-ARM / FISHERS	P=0.447N	P=0.370N	P=0.514N
MAX-ISO-POLY-3	P=0.381N	P=0.228N	P=0.328N

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Pancreas</b>			
<b>Inflammation</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/49 (4%)
POLY-3 RATE (b)	0/42.78	0/45.81	2/46.50
POLY-3 PERCENT (g)	0%	0%	4.3%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	2/38 (5%)
FIRST INCIDENCE	---	---	728 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.101	(e)	P=0.256
POLY 1.5	P=0.097	(e)	P=0.246
POLY 6	P=0.107	(e)	P=0.270
COCH-ARM / FISHERS	P=0.093	(e)	P=0.242
MAX-ISO-POLY-3	P=0.072	(e)	P=0.095

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Pancreas: Acinus Atrophy</b>			
<b>LESION RATES</b>			
OVERALL (a)	11/50 (22%)	12/50 (24%)	15/49 (31%)
POLY-3 RATE (b)	11/45.56	12/46.34	15/46.83
POLY-3 PERCENT (g)	24.2%	25.9%	32%
TERMINAL (d)	5/31 (16%)	8/37 (22%)	13/38 (34%)
FIRST INCIDENCE	495	670	668
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.231	P=0.519	P=0.271
POLY 1.5	P=0.215	P=0.506	P=0.253
POLY 6	P=0.254	P=0.534	P=0.297
COCH-ARM / FISHERS	P=0.193	P=0.500	P=0.228
MAX-ISO-POLY-3	P=0.282	P=0.422	P=0.205

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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: 09:37:47  
 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**

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Pancreas: Acinus Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	7/50 (14%)	1/50 (2%)	1/49 (2%)
POLY-3 RATE (b)	7/42.98	1/45.81	1/46.50
POLY-3 PERCENT (g)	16.3%	2.2%	2.2%
TERMINAL (d)	6/31 (19%)	1/37 (3%)	1/38 (3%)
FIRST INCIDENCE	674	728 (T)	728 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.008N**	P=0.023N*	P=0.022N*
POLY 1.5	P=0.008N**	P=0.027N*	P=0.026N*
POLY 6	P=0.007N**	P=0.020N*	P=0.018N*
COCH-ARM / FISHERS	P=0.011N*	P=0.030N*	P=0.032N*
MAX-ISO-POLY-3	P=0.006N**	P=0.011N*	P=0.011N*

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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Pancreas: Duct Cyst			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	4/50 (8%)	3/49 (6%)
POLY-3 RATE (b)	2/42.78	4/45.92	3/46.61
POLY-3 PERCENT (g)	4.7%	8.7%	6.4%
TERMINAL (d)	2/31 (7%)	3/37 (8%)	2/38 (5%)
FIRST INCIDENCE	728 (T)	701	702
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.472	P=0.370	P=0.539
POLY 1.5	P=0.445	P=0.354	P=0.519
POLY 6	P=0.509	P=0.390	P=0.566
COCH-ARM / FISHERS	P=0.407	P=0.339	P=0.490
MAX-ISO-POLY-3	P=0.419	P=0.234	P=0.365

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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: 09:37:47  
 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**

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Parathyroid Gland Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/46 (0%)	1/47 (2%)	11/49 (22%)
POLY-3 RATE (b)	0/38.78	1/42.87	11/47.66
POLY-3 PERCENT (g)	0%	2.3%	23.1%
TERMINAL (d)	0/27 (0%)	1/35 (3%)	6/38 (16%)
FIRST INCIDENCE	---	728 (T)	695
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001**	P=0.520	P<0.001**
POLY 1.5	P<0.001**	P=0.512	P<0.001**
POLY 6	P<0.001**	P=0.529	P=0.002**
COCH-ARM / FISHERS	P<0.001**	P=0.505	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.182	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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Pituitary Gland Hemorrhage			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	2/45.92	0/47.40
POLY-3 PERCENT (g)	0%	4.4%	0%
TERMINAL (d)	0/31 (0%)	1/37 (3%)	0/38 (0%)
FIRST INCIDENCE	---	701	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.633N	P=0.253	(e)
POLY 1.5	P=0.648N	P=0.245	(e)
POLY 6	P=0.612N	P=0.263	(e)
COCH-ARM / FISHERS	P=0.669	P=0.247	(e)
MAX-ISO-POLY-3	P=0.278N	P=0.091	(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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG

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Pituitary Gland: Pars Distalis  
Angiectasis

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**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.78	0/45.81	1/47.40
POLY-3 PERCENT (g)	0%	0%	2.1%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)
FIRST INCIDENCE	---	---	728 (T)

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**STATISTICAL TESTS**

POLY 3	P=0.288	(e)	P=0.520
POLY 1.5	P=0.280	(e)	P=0.512
POLY 6	P=0.298	(e)	P=0.532
COCH-ARM / FISHERS	P=0.269	(e)	P=0.500
MAX-ISO-POLY-3	P=0.186	(e)	P=0.183

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG

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Pituitary Gland: Pars Distalis  
Cyst

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**LESION RATES**

OVERALL (a)	4/50 (8%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	4/43.69	0/45.81	0/47.40
POLY-3 PERCENT (g)	9.2%	0%	0%
TERMINAL (d)	2/31 (7%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	581	---	---

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**STATISTICAL TESTS**

POLY 3	P=0.013N*	P=0.054N	P=0.051N
POLY 1.5	P=0.013N*	P=0.057N	P=0.054N
POLY 6	P=0.012N*	P=0.051N	P=0.046N*
COCH-ARM / FISHERS	P=0.015N*	P=0.059N	P=0.059N
MAX-ISO-POLY-3	P=0.007N**	P=0.019N*	P=0.019N*

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG

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Pituitary Gland: Pars Distalis  
Hyperplasia

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**LESION RATES**

OVERALL (a)	17/50 (34%)	26/50 (52%)	24/50 (48%)
POLY-3 RATE (b)	17/45.13	26/47.46	24/47.68
POLY-3 PERCENT (g)	37.7%	54.8%	50.3%
TERMINAL (d)	12/31 (39%)	20/37 (54%)	21/38 (55%)
FIRST INCIDENCE	309	561	695

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**STATISTICAL TESTS**

POLY 3	P=0.138	P=0.070	P=0.151
POLY 1.5	P=0.116	P=0.057	P=0.130
POLY 6	P=0.178	P=0.092	P=0.187
COCH-ARM / FISHERS	P=0.096	P=0.053	P=0.111
MAX-ISO-POLY-3	P=0.107	P=0.050*	P=0.112

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Skin			
Cyst Epithelial Inclusion			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/42.98	0/45.81	0/47.40
POLY-3 PERCENT (g)	2.3%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	674	---	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.274N	P=0.487N	P=0.481N
POLY 1.5	P=0.272N	P=0.493N	P=0.488N
POLY 6	P=0.277N	P=0.480N	P=0.470N
COCH-ARM / FISHERS	P=0.269N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.151N	P=0.158N	P=0.158N

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Spleen Fibrosis			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.78	0/45.81	1/47.40
POLY-3 PERCENT (g)	0%	0%	2.1%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)
FIRST INCIDENCE	---	---	728 (T)
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.288	(e)	P=0.520
POLY 1.5	P=0.280	(e)	P=0.512
POLY 6	P=0.298	(e)	P=0.532
COCH-ARM / FISHERS	P=0.269	(e)	P=0.500
MAX-ISO-POLY-3	P=0.186	(e)	P=0.183

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Spleen			
Hyperplasia Lymphoid			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	3/50 (6%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	3/43.37	0/45.81	1/47.40
POLY-3 PERCENT (g)	6.9%	0%	2.1%
TERMINAL (d)	2/31 (7%)	0/37 (0%)	1/38 (3%)
FIRST INCIDENCE	538	---	728 (T)
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.169N	P=0.109N	P=0.274N
POLY 1.5	P=0.172N	P=0.114N	P=0.287N
POLY 6	P=0.167N	P=0.103N	P=0.258N
COCH-ARM / FISHERS	P=0.176N	P=0.121N	P=0.309N
MAX-ISO-POLY-3	P=0.076N	P=0.038N*	P=0.143N

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Stomach, Forestomach Inflammation</b>			
<b>LESION RATES</b>			
OVERALL (a)	3/50 (6%)	3/50 (6%)	7/49 (14%)
POLY-3 RATE (b)	3/43.95	3/45.87	7/46.73
POLY-3 PERCENT (g)	6.8%	6.5%	15%
TERMINAL (d)	1/31 (3%)	2/37 (5%)	6/38 (16%)
FIRST INCIDENCE	495	713	668
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.121	P=0.643N	P=0.183
POLY 1.5	P=0.112	P=0.653N	P=0.169
POLY 6	P=0.134	P=0.630N	P=0.205
COCH-ARM / FISHERS	P=0.101	P=0.661N	P=0.151
MAX-ISO-POLY-3	P=0.133	P=0.478N	P=0.116

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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: 09:37:47  
 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**

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Stomach, Forestomach Ulcer</b>			
<b>LESION RATES</b>			
OVERALL (a)	3/50 (6%)	1/50 (2%)	3/49 (6%)
POLY-3 RATE (b)	3/43.91	1/46.14	3/46.50
POLY-3 PERCENT (g)	6.8%	2.2%	6.5%
TERMINAL (d)	1/31 (3%)	0/37 (0%)	3/38 (8%)
FIRST INCIDENCE	519	637	728 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.583N	P=0.288N	P=0.636N
POLY 1.5	P=0.590N	P=0.297N	P=0.650N
POLY 6	P=0.572N	P=0.277N	P=0.615N
COCH-ARM / FISHERS	P=0.585	P=0.309N	P=0.651
MAX-ISO-POLY-3	P=0.418N	P=0.147N	P=0.471N

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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Stomach, Forestomach: Epithelium Hyperplasia			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	11/50 (22%)	7/50 (14%)	15/49 (31%)
POLY-3 RATE (b)	11/44.59	7/46.25	15/46.96
POLY-3 PERCENT (g)	24.7%	15.1%	31.9%
TERMINAL (d)	8/31 (26%)	4/37 (11%)	11/38 (29%)
FIRST INCIDENCE	495	637	668
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.225	P=0.190N	P=0.295
POLY 1.5	P=0.206	P=0.205N	P=0.265
POLY 6	P=0.256	P=0.171N	P=0.343
COCH-ARM / FISHERS	P=0.184	P=0.218N	P=0.228
MAX-ISO-POLY-3	P=0.126	P=0.131N	P=0.228

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Stomach, Glandular Erosion</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	1/42.99	0/45.81	0/46.50
POLY-3 PERCENT (g)	2.3%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	672	---	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.276N	P=0.487N	P=0.484N
POLY 1.5	P=0.275N	P=0.493N	P=0.492N
POLY 6	P=0.279N	P=0.480N	P=0.474N
COCH-ARM / FISHERS	P=0.272N	P=0.500N	P=0.505N
MAX-ISO-POLY-3	P=0.152N	P=0.158N	P=0.160N

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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: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Stomach, Glandular Inflammation</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/46.50
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:37:47  
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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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Stomach, Glandular Mineralization</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	3/50 (6%)	1/49 (2%)
POLY-3 RATE (b)	1/43.41	3/45.96	1/46.50
POLY-3 PERCENT (g)	2.3%	6.5%	2.2%
TERMINAL (d)	0/31 (0%)	2/37 (5%)	1/38 (3%)
FIRST INCIDENCE	519	689	728 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.577N	P=0.326	P=0.745N
POLY 1.5	P=0.594N	P=0.316	P=0.753N
POLY 6	P=0.554N	P=0.339	P=0.733N
COCH-ARM / FISHERS	P=0.603	P=0.309	P=0.747
MAX-ISO-POLY-3	P=0.399N	P=0.175	P=0.480N

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TDMS No. 99020 - 05  
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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 104 WEEKS

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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Thyroid Gland: C-Cell Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	39/50 (78%)	32/50 (64%)	19/50 (38%)
POLY-3 RATE (b)	39/46.72	32/47.30	19/47.61
POLY-3 PERCENT (g)	83.5%	67.7%	39.9%
TERMINAL (d)	29/31 (94%)	27/37 (73%)	17/38 (45%)
FIRST INCIDENCE	495	561	702
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001N**	P=0.052N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.071N	P<0.001N**
POLY 6	P<0.001N**	P=0.032N*	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.093N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.031N*	P<0.001N**

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TDMS No. 99020 - 05  
Test Type: CHRONIC  
Route: GAVAGE  
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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Trachea Inflammation</b>			
<b>LESION RATES</b>			
OVERALL (a)	5/50 (10%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	5/44.08	1/45.81	1/47.40
POLY-3 PERCENT (g)	11.3%	2.2%	2.1%
TERMINAL (d)	1/31 (3%)	1/37 (3%)	1/38 (3%)
FIRST INCIDENCE	519	728 (T)	728 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.042N*	P=0.092N	P=0.086N
POLY 1.5	P=0.044N*	P=0.097N	P=0.092N
POLY 6	P=0.040N*	P=0.088N	P=0.078N
COCH-ARM / FISHERS	P=0.049N*	P=0.102N	P=0.102N
MAX-ISO-POLY-3	P=0.033N*	P=0.042N*	P=0.041N*

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

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Pulegone  
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Date Report Requested: 08/25/2009  
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Lab: BAT

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

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

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Urinary Bladder: Transitional Epithelium  
Hyperplasia

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**LESION RATES**

OVERALL (a)	0/50 (0%)	0/49 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/42.78	0/44.81	2/47.40
POLY-3 PERCENT (g)	0%	0%	4.2%
TERMINAL (d)	0/31 (0%)	0/36 (0%)	2/38 (5%)
FIRST INCIDENCE	---	---	728 (T)

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**STATISTICAL TESTS**

POLY 3	P=0.105	(e)	P=0.261
POLY 1.5	P=0.101	(e)	P=0.251
POLY 6	P=0.110	(e)	P=0.274
COCH-ARM / FISHERS	P=0.096	(e)	P=0.247
MAX-ISO-POLY-3	P=0.077	(e)	P=0.098

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TDMS No. 99020 - 05  
Test Type: CHRONIC  
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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**

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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Uterus Hemorrhage			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/43.21	1/45.81	0/47.40
POLY-3 PERCENT (g)	4.6%	2.2%	0%
TERMINAL (d)	1/31 (3%)	1/37 (3%)	0/38 (0%)
FIRST INCIDENCE	604	728 (T)	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.132N	P=0.480N	P=0.217N
POLY 1.5	P=0.136N	P=0.489N	P=0.225N
POLY 6	P=0.127N	P=0.468N	P=0.207N
COCH-ARM / FISHERS	P=0.142N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.104N	P=0.269N	P=0.076N

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TDMS No. 99020 - 05  
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Route: GAVAGE  
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**

---

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Uterus: Endometrium Hyperplasia Cystic</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	1/42.78	3/46.02	2/47.40
POLY-3 PERCENT (g)	2.3%	6.5%	4.2%
TERMINAL (d)	1/31 (3%)	2/37 (5%)	2/38 (5%)
FIRST INCIDENCE	728 (T)	674	728 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.456	P=0.332	P=0.536
POLY 1.5	P=0.433	P=0.319	P=0.521
POLY 6	P=0.487	P=0.348	P=0.555
COCH-ARM / FISHERS	P=0.399	P=0.309	P=0.500
MAX-ISO-POLY-3	P=0.357	P=0.181	P=0.319

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

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## LEGEND

- (a) Number of tumor-bearing animals/number of animals examined at site.
  - (b) Number of tumor-bearing animals/Poly-3 number
  - (d) Observed incidence at terminal kill.
  - (e) Value of Statistic cannot be computed.
  - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
  - (g) Poly-3 adjusted lifetime tumor incidence.
  - (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 \*\*\*