

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

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
Adrenal Cortex Degeneration Cystic			
LESION RATES			
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
STATISTICAL TESTS			
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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TERMINAL SACRIFICE AT 104 WEEKS

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
Adrenal Cortex Hyperplasia			
LESION RATES			
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
STATISTICAL TESTS			
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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
Adrenal Cortex Hypertrophy			
LESION RATES			
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
STATISTICAL TESTS			
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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
Adrenal Medulla Hyperplasia			
LESION RATES			
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
STATISTICAL TESTS			
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**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Bone Marrow Hemorrhage			
<hr/>			
LESION RATES			
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/>			
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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TERMINAL SACRIFICE AT 104 WEEKS

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
Bone Marrow			
Hyperplasia			
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
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

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

Bone
Fibrous Osteodystrophy

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.76	0/43.06	2/43.92
POLY-3 PERCENT (g)	0%	0%	4.6%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	637

STATISTICAL TESTS

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
Brain Hemorrhage			
LESION RATES			
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
STATISTICAL TESTS			
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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
Brain			
Hydrocephalus			
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	---
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**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
Epididymis Granuloma Sperm			
LESION RATES			
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
STATISTICAL TESTS			
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**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Eye			
Cataract			
<hr/>			
LESION RATES			
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/>			
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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TERMINAL SACRIFICE AT 104 WEEKS

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Eye: Retina Atrophy			
<hr/>			
LESION RATES			
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/>			
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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TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Eye: Retina Dysplasia			
<hr/>			
LESION RATES			
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/>			
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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TERMINAL SACRIFICE AT 104 WEEKS

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
Harderian Gland Inflammation			
LESION RATES			
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
STATISTICAL TESTS			
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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**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
Harderian Gland: Epithelium Hyperplasia			
LESION RATES			
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)
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

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

TDMS No. 99020 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/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
Intestine Large, Cecum Inflammation			
LESION RATES			
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
STATISTICAL TESTS			
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
Intestine Large, Colon			
Parasite Metazoan			
LESION RATES			
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)
STATISTICAL TESTS			
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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Intestine Large, Rectum Parasite Metazoan			
<hr/>			
LESION RATES			
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	---
<hr/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
Kidney Cyst			
<hr/>			
LESION RATES			
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.76	0/43.06	2/43.59
POLY-3 PERCENT (g)	0%	0%	4.6%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	---	---	673
<hr/>			
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=0.215
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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Kidney			
Glomerulopathy Hyaline			
<hr/>			
LESION RATES			
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
<hr/>			
STATISTICAL TESTS			
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**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Kidney Inflammation			
LESION RATES			
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
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Kidney			
Nephropathy			
LESION RATES			
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
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Kidney: Cortex Mineralization			
LESION RATES			
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
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Kidney: Renal Tubule Degeneration			
LESION RATES			
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	---	---	---
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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			
Angiectasis			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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			
Basophilic Focus			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
POLY 3	P<0.001N**	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P<0.001N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P<0.001N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P<0.001N**	P<0.001N**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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			
Clear Cell Focus			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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			
Eosinophilic Focus			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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**

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

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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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 Inflammation			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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			
Mixed Cell Focus			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/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: Bile Duct Cyst			
LESION RATES			
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
STATISTICAL TESTS			
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

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

Liver: Bile Duct
Hyperplasia

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

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*

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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: Cervix Hemorrhage			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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: Hepatocyte Cellular Alteration Diffuse			
<hr/>			
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
<hr/>			
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**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Liver: Hepatocyte Degeneration Cystic			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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: Hepatocyte Necrosis			
<hr/>			
LESION RATES			
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
<hr/>			
STATISTICAL TESTS			
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

Liver: Hepatocyte, Centrilobular Degeneration

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

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

TDMS No. 99020 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/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: Oval Cell Hyperplasia			
LESION RATES			
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
STATISTICAL TESTS			
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
<hr/>			
Liver: Portal Fibrosis			
<hr/>			
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
<hr/>			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/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
Lung Inflammation			
LESION RATES			
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
STATISTICAL TESTS			
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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
Lung: Alveolar Epithelium Hyperplasia			
LESION RATES			
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
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/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
Lung: Alveolus Inflammation Histiocytic			
LESION RATES			
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
STATISTICAL TESTS			
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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Lung: Cervix Hyperplasia			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Lung: Interstitium Mineralization			
LESION RATES			
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
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Lymph Node, Mesenteric Hemorrhage			
LESION RATES			
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	---
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)

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

Lymph Node: Mediastinal
Degeneration Cystic

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)	---

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)

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

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)	---

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)

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Mammary Gland Hyperplasia			
LESION RATES			
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)	---	---
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Mammary Gland: Duct Dilatation			
LESION RATES			
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
STATISTICAL TESTS			
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*

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
Mesentery Necrosis			
<hr/>			
LESION RATES			
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
<hr/>			
STATISTICAL TESTS			
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

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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
Nose			
Thrombosis			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Nose: Glands Dilatation			
LESION RATES			
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)
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Nose: Goblet Cell Hyperplasia			
LESION RATES			
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)	---	---
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Nose: Olfactory Epithelium Degeneration			
LESION RATES			
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
STATISTICAL TESTS			
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**

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

Nose: Olfactory Epithelium
Metaplasia Respiratory

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

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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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 Inflammation			
LESION RATES			
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
STATISTICAL TESTS			
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
Pancreas: Acinus Atrophy			
LESION RATES			
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
STATISTICAL TESTS			
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
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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
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
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
Parathyroid Gland Hyperplasia			
LESION RATES			
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
STATISTICAL TESTS			
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**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
Pituitary Gland Hemorrhage			
LESION RATES			
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	---	---	---
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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 Angiectasis			
LESION RATES			
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)	---	---
STATISTICAL TESTS			
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)
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

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

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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
Preputial Gland Inflammation			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/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
Preputial Gland: Duct Ectasia			
LESION RATES			
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)	---
STATISTICAL TESTS			
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*

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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 Inflammation			
LESION RATES			
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
STATISTICAL TESTS			
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

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

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

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

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**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Skin			
Cyst Epithelial Inclusion			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/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
Spleen Fibrosis			
LESION RATES			
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)
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Spleen			
Hyperplasia Lymphoid			
LESION RATES			
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)
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/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
Stomach, Forestomach Inflammation			
LESION RATES			
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
STATISTICAL TESTS			
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
Stomach, Forestomach Ulcer			
LESION RATES			
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
STATISTICAL TESTS			
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

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

TDMS No. 99020 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/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
Stomach, Glandular Erosion			
LESION RATES			
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
STATISTICAL TESTS			
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**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
Stomach, Glandular Inflammation			
LESION RATES			
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
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Stomach, Glandular Mineralization			
LESION RATES			
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
STATISTICAL TESTS			
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*

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

LESION RATES

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

STATISTICAL TESTS

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

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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
Testes: Interstitial Cell Hyperplasia			
<hr/>			
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
<hr/>			
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
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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

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

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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
Trachea Inflammation			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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	---
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)

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Adrenal Cortex Degeneration Cystic			
LESION RATES			
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)	---
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Adrenal Cortex Hyperplasia			
LESION RATES			
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)
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/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	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
Adrenal Cortex Hypertrophy			
LESION RATES			
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
STATISTICAL TESTS			
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**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/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	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
Adrenal Medulla Hyperplasia			
LESION RATES			
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
STATISTICAL TESTS			
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*

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
Bone Marrow Hemorrhage			
<hr/>			
LESION RATES			
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/42.78	0/45.81	2/47.50
POLY-3 PERCENT (g)	0%	0%	4.2%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)
FIRST INCIDENCE	---	---	702
<hr/>			
STATISTICAL TESTS			
POLY 3	P=0.104	(e)	P=0.261
POLY 1.5	P=0.100	(e)	P=0.251
POLY 6	P=0.110	(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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Bone Marrow Hyperplasia			
LESION RATES			
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
STATISTICAL TESTS			
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*

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/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	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG

Bone
Fibrous Osteodystrophy

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.78	0/45.81	1/47.50
POLY-3 PERCENT (g)	0%	0%	2.1%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	702

STATISTICAL TESTS

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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Brain Hemorrhage			
LESION RATES			
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
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Brain			
Hydrocephalus			
LESION RATES			
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)	---
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Clitoral Gland Hyperplasia			
LESION RATES			
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)	---
STATISTICAL TESTS			
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**

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
Clitoral Gland Inflammation			
LESION RATES			
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)
STATISTICAL TESTS			
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*

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
Clitoral Gland: Duct Cyst			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
Eye			
Cataract			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
Eye: Retina Atrophy			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

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

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

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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Harderian Gland Inflammation			
LESION RATES			
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)	---
STATISTICAL TESTS			
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)

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
Harderian Gland: Epithelium Hyperplasia			
<hr/>			
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)
<hr/>			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
Heart			
Cardiomyopathy			
<hr/>			
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
<hr/>			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Heart: Endocardium			
Bacterium			
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	---	---	---
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

TDMS No. 99020 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/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
Intestine Large, Cecum Inflammation			
LESION RATES			
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
STATISTICAL TESTS			
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**

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
Intestine Large, Colon			
Parasite Metazoan			
LESION RATES			
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)	---
STATISTICAL TESTS			
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*

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
Intestine Large, Rectum Parasite Metazoan			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
Kidney Cyst			
<hr/>			
LESION RATES			
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	---	---
<hr/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
Kidney			
Glomerulopathy Hyaline			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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**

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
Kidney Inflammation			
LESION RATES			
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)
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=0.522	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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Kidney Nephropathy			
LESION RATES			
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
STATISTICAL TESTS			
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
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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	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
Kidney: Cortex Mineralization			
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
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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	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG

Kidney: Renal Tubule Degeneration

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	---

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)

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/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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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			
Angiectasis			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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)

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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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			
Basophilic Focus			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
POLY 3	P<0.001N**	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P<0.001N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P<0.001N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P<0.001N**	P<0.001N**

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

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

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

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Liver			
Clear Cell Focus			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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			
Eosinophilic Focus			
<hr/>			
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	---	---	---
<hr/>			
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Liver			
Fatty Change			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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
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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			
Hepatodiaphragmatic Nodule			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

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

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

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Liver Inflammation			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

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

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

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Liver			
Mixed Cell Focus			
<hr/>			
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)
<hr/>			
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

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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CAS Number: 89-82-7

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

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Liver: Bile Duct Cyst			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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**

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

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
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**

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

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

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

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

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

Liver: Hepatocyte
Cellular Alteration Diffuse

LESION RATES

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

STATISTICAL TESTS

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**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/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	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Liver: Hepatocyte Degeneration Cystic			
<hr/>			
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	---	---	---
<hr/>			
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Liver: Hepatocyte Necrosis			
<hr/>			
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
<hr/>			
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**

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

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	---

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)

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

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

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**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
LESION RATES			
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.78	0/45.81	1/47.48
POLY-3 PERCENT (g)	0%	0%	2.1%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	708
<hr/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Lung: Alveolar Epithelium Hyperplasia			
LESION RATES			
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
STATISTICAL TESTS			
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

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

Lung: Alveolus
Inflammation Histiocytic

LESION RATES

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

STATISTICAL TESTS

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Lung: Cervix Hyperplasia			
<hr/>			
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	---	---	---
<hr/>			
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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

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

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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
Lung: Interstitium Mineralization			
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	---	---	---
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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

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

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

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
Lymph Node, Mesenteric Hemorrhage			
LESION RATES			
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)
STATISTICAL TESTS			
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

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

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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	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Lymph Node: Mediastinal Hyperplasia			
<hr/>			
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)
<hr/>			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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 Hyperplasia			
LESION RATES			
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)	---
STATISTICAL TESTS			
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)

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/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	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Mammary Gland: Duct Dilatation			
<hr/>			
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)
<hr/>			
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

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

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

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

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Mesentery Necrosis			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/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	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
Nose Inflammation			
LESION RATES			
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
STATISTICAL TESTS			
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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
Nose			
Thrombosis			
LESION RATES			
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
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Nose: Glands Dilatation			
LESION RATES			
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
STATISTICAL TESTS			
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**

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

Nose: Goblet Cell
Hyperplasia

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	---	---	---

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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
Nose: Olfactory Epithelium Degeneration			
LESION RATES			
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
STATISTICAL TESTS			
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**

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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
Ovary Atrophy			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
Ovary Cyst			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Pancreas Inflammation			
LESION RATES			
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)
STATISTICAL TESTS			
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

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

Pancreas: Acinus
Atrophy

LESION RATES

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

STATISTICAL TESTS

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

TDMS No. 99020 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/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
Pancreas: Acinus Hyperplasia			
LESION RATES			
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)
STATISTICAL TESTS			
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**

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Pancreas: Duct Cyst			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/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
Parathyroid Gland Hyperplasia			
LESION RATES			
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
STATISTICAL TESTS			
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**

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Pituitary Gland Hemorrhage			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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)

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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
Pituitary Gland: Pars Distalis Angiectasis			
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)
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/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	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG

Pituitary Gland: Pars Distalis
Cyst

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	---	---

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*

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

Pituitary Gland: Pars Distalis
Hyperplasia

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

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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/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	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Skin			
Cyst Epithelial Inclusion			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/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/>			
Spleen Fibrosis			
<hr/>			
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)
<hr/>			
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

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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 CAS Number: 89-82-7

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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
Spleen			
Hyperplasia Lymphoid			
LESION RATES			
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)
STATISTICAL TESTS			
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

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

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Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
Stomach, Forestomach Inflammation			
LESION RATES			
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
STATISTICAL TESTS			
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

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

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 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
Stomach, Forestomach Ulcer			
LESION RATES			
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)
STATISTICAL TESTS			
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
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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	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Stomach, Forestomach: Epithelium Hyperplasia			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/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	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
Stomach, Glandular Erosion			
LESION RATES			
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	---	---
STATISTICAL TESTS			
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

TDMS No. 99020 - 05
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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
Stomach, Glandular Inflammation			
LESION RATES			
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	---	---	---
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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

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

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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
Stomach, Glandular Mineralization			
LESION RATES			
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)
STATISTICAL TESTS			
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

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

Thyroid Gland: C-Cell
Hyperplasia

LESION RATES			
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

STATISTICAL TESTS			
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**

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
<hr/>			
Trachea Inflammation			
<hr/>			
LESION RATES			
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)
<hr/>			
STATISTICAL TESTS			
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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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
Urinary Bladder: Transitional Epithelium Hyperplasia			
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)
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

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

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Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Uterus Hemorrhage			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

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

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Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
Uterus: Endometrium Hyperplasia Cystic			
LESION RATES			
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)
STATISTICAL TESTS			
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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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 ***