

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

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

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

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

MALE RATS

Organ

Adrenal Cortex
Adrenal Medulla
Blood Vessel
Bone
Eye
Harderian Gland: Epithelium
Heart

Intestine Large, Cecum

Kidney

Kidney: Cortex
Liver

Liver: Bile Duct

Liver: Hepatocyte

Liver: Oval Cell
Liver: Portal
Lung: Alveolar Epithelium
Lung: Alveolus
Lung: Interstitium
Nose
Nose: Olfactory Epithelium
Pancreas: Acinus

Parathyroid Gland

Morphology

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

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Prostate: Epithelium
Stomach, Forestomach

Hyperplasia
Inflammation
Mineralization
Perforation
Ulcer

Stomach, Forestomach: Epithelium
Stomach, Glandular

Hyperplasia
Inflammation
Mineralization
Hyperplasia

Thyroid Gland: C-Cell

FEMALE RATS

Organ

Adrenal Cortex

Adrenal Medulla
Blood Vessel
Bone Marrow
Bone
Eye

Heart

Intestine Large, Cecum
Kidney

Kidney: Cortex
Liver

Liver: Bile Duct

Liver: Hepatocyte

Liver: Oval Cell

Morphology

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

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

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

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

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

Males

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

LESION RATES

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

STATISTICAL TESTS

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

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

Adrenal Cortex
Hypertrophy

LESION RATES

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

STATISTICAL TESTS

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

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Males

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

Adrenal Medulla
Hyperplasia

LESION RATES

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

STATISTICAL TESTS

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

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Males

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

Blood Vessel
Mineralization

LESION RATES

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

STATISTICAL TESTS

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

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

DOSE	0 MG/KG	75 MG/KG Stop
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**Bone Marrow
Hyperplasia**

LESION RATES

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

STATISTICAL TESTS

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

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

Bone
Fibrous Osteodystrophy

LESION RATES

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

STATISTICAL TESTS

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

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

Brain
Hydrocephalus

LESION RATES

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

STATISTICAL TESTS

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

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

DOSE	0 MG/KG	75 MG/KG Stop
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Epididymis
Granuloma Sperm

LESION RATES

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

STATISTICAL TESTS

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

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

LESION RATES

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

STATISTICAL TESTS

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

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

LESION RATES

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

STATISTICAL TESTS

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

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

Eye
Inflammation

LESION RATES

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

STATISTICAL TESTS

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

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

Males

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

Eye: Cornea
Inflammation

LESION RATES

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

STATISTICAL TESTS

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

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

LESION RATES

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

STATISTICAL TESTS

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

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Males

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

Harderian Gland
Inflammation

LESION RATES

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

STATISTICAL TESTS

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

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

Harderian Gland: Epithelium
Hyperplasia

LESION RATES

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

STATISTICAL TESTS

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

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

Heart
Cardiomyopathy

LESION RATES

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

STATISTICAL TESTS

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

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

LESION RATES

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

STATISTICAL TESTS

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

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

DOSE	0 MG/KG	75 MG/KG Stop
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Intestine Large, Cecum
Inflammation

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Intestine Large, Cecum
Mineralization

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Intestine Large, Cecum
Ulcer

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Intestine Large, Colon
Parasite Metazoan

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Intestine Large, Rectum
Parasite Metazoan

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

DOSE	0 MG/KG	75 MG/KG Stop
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Intestine Small, Duodenum
Erosion

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Kidney
Cyst

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

DOSE	0 MG/KG	75 MG/KG Stop
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Kidney
Glomerulopathy Hyaline

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

DOSE	0 MG/KG	75 MG/KG Stop
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Kidney
Nephropathy

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

DOSE	0 MG/KG	75 MG/KG Stop
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**Kidney: Cortex
Mineralization**

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

DOSE	0 MG/KG	75 MG/KG Stop
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Liver
Basophilic Focus

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Liver
Clear Cell Focus

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Liver
Eosinophilic Focus

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Liver
Fatty Change

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Liver
Hepatodiaphragmatic Nodule

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

DOSE	0 MG/KG	75 MG/KG Stop
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Liver
Mixed Cell Focus

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Liver: Bile Duct
Cyst

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Liver: Bile Duct
Hyperplasia

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Liver: Hepatocyte
Cellular Alteration Diffuse

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

DOSE	0 MG/KG	75 MG/KG Stop
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Liver: Hepatocyte
Necrosis

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Liver: Hepatocyte, Centrilobular
Degeneration

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Liver: Oval Cell
Hyperplasia

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Liver: Portal
Fibrosis

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Lung
Congestion

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Lung
Hemorrhage

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Lung: Alveolar Epithelium
Hyperplasia

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Lung: Alveolus
Inflammation Histiocytic

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

DOSE 0 MG/KG 75 MG/KG Stop

Lung: Arteriole
Inflammation

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

DOSE	0 MG/KG	75 MG/KG Stop
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Lung: Cervix
Hyperplasia

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Lung: Interstitium
Mineralization

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Lymph Node, Mesenteric
Fibrosis

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

**Lymph Node, Mesenteric
Hemorrhage**

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

DOSE 0 MG/KG 75 MG/KG Stop

Lymph Node, Mesenteric
Inflammation

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

DOSE	0 MG/KG	75 MG/KG Stop
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Lymph Node: Deep Cervical
Hemorrhage

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

**Lymph Node: Mediastinal
Hemorrhage**

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

**Lymph Node: Pancreatic
Hemorrhage**

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

DOSE	0 MG/KG	75 MG/KG Stop
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Mesentery
Necrosis

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Nose
Thrombosis

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Nose: Glands
Dilatation

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Nose: Goblet Cell
Hyperplasia

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Nose: Olfactory Epithelium
Degeneration

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Nose: Olfactory Epithelium
Metaplasia Respiratory

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Oral Mucosa: Pharyngeal
Hyperplasia

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Pancreas: Acinus
Atrophy

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Pancreas: Acinus
Hyperplasia

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Pancreas: Duct
Cyst

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Parathyroid Gland
Hyperplasia

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Pituitary Gland: Pars Distalis
Angiectasis

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Pituitary Gland: Pars Distalis
Cyst

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Prostate: Epithelium
Hyperplasia

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Spleen
Hematopoietic Cell Proliferation

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Spleen
Hyperplasia Lymphoid

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Stomach, Forestomach
Inflammation

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

Stomach, Forestomach
Mineralization

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

**Stomach, Forestomach
Perforation**

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

**Stomach, Forestomach
Ulcer**

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

DOSE 0 MG/KG 75 MG/KG Stop

Stomach, Glandular
Erosion

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Males

DOSE	0 MG/KG	75 MG/KG Stop
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Urinary Bladder
Inflammation

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

DOSE	0 MG/KG	150 MG/KG Stop
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**Bone Marrow
Hyperplasia**

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

DOSE 0 MG/KG 150 MG/KG Stop

Eye
Inflammation

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Eye: Retina
Atrophy

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Harderian Gland: Epithelium
Hyperplasia

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

Intestine Large, Cecum
Ulcer

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Intestine Small, Duodenum
Erosion

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

**Kidney
Cyst**

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

Kidney
Glomerulopathy Hyaline

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

Liver
Basophilic Focus

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Liver
Fatty Change

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

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

STATISTICAL TESTS

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

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

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

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

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

Females

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

LESION RATES

OVERALL (a)	35/50 (70%)	33/47 (70%)
POLY-3 RATE (b)	35/46.42	33/39.00
POLY-3 PERCENT (g)	75.4%	84.6%
TERMINAL (d)	26/31 (84%)	0/0 (0%)
FIRST INCIDENCE	309	338

STATISTICAL TESTS

POLY 3	P=0.191
POLY 1.5	P=0.310
POLY 6	P=0.094
COCH-ARM / FISHERS	P=0.579
MAX-ISO-POLY-3	P=0.134

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

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

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

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

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Liver
Mixed Cell Focus

LESION RATES

OVERALL (a)	5/50 (10%)	0/47 (0%)
POLY-3 RATE (b)	5/43.01	0/21.28
POLY-3 PERCENT (g)	11.6%	0%
TERMINAL (d)	3/31 (10%)	0/0 (0%)
FIRST INCIDENCE	674	---

STATISTICAL TESTS

POLY 3	P=0.149N
POLY 1.5	P=0.082N
POLY 6	P=0.303N
COCH-ARM / FISHERS	P=0.033N*
MAX-ISO-POLY-3	P=0.117N

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Liver: Bile Duct
Cyst

LESION RATES

OVERALL (a)	1/50 (2%)	13/47 (28%)
POLY-3 RATE (b)	1/42.78	13/27.52
POLY-3 PERCENT (g)	2.3%	47.2%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	338

STATISTICAL TESTS

POLY 3	P<0.001**
POLY 1.5	P<0.001**
POLY 6	P<0.001**
COCH-ARM / FISHERS	P<0.001**
MAX-ISO-POLY-3	P<0.001**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Liver: Bile Duct
Hyperplasia

LESION RATES

OVERALL (a)	5/50 (10%)	43/47 (91%)
POLY-3 RATE (b)	5/42.91	43/44.19
POLY-3 PERCENT (g)	11.7%	97.3%
TERMINAL (d)	4/31 (13%)	0/0 (0%)
FIRST INCIDENCE	693	338

STATISTICAL TESTS

POLY 3	P<0.001**
POLY 1.5	P<0.001**
POLY 6	P<0.001**
COCH-ARM / FISHERS	P<0.001**
MAX-ISO-POLY-3	P<0.001**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE **0 MG/KG** **150 MG/KG Stop**

Liver: Hepatocyte
Cellular Alteration Diffuse

LESION RATES

OVERALL (a)	0/50 (0%)	43/47 (91%)
POLY-3 RATE (b)	0/42.78	43/44.91
POLY-3 PERCENT (g)	0%	95.8%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	338

STATISTICAL TESTS

POLY 3	P<0.001**
POLY 1.5	P<0.001**
POLY 6	P<0.001**
COCH-ARM / FISHERS	P<0.001**
MAX-ISO-POLY-3	P<0.001**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Liver: Hepatocyte
Necrosis

LESION RATES

OVERALL (a)	4/50 (8%)	15/47 (32%)
POLY-3 RATE (b)	4/43.57	15/29.19
POLY-3 PERCENT (g)	9.2%	51.4%
TERMINAL (d)	2/31 (7%)	0/0 (0%)
FIRST INCIDENCE	519	349

STATISTICAL TESTS

POLY 3	P<0.001**
POLY 1.5	P<0.001**
POLY 6	P<0.001**
COCH-ARM / FISHERS	P=0.003**
MAX-ISO-POLY-3	P<0.001**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Liver: Hepatocyte, Centrilobular
Degeneration

LESION RATES

OVERALL (a)	0/50 (0%)	0/47 (0%)
POLY-3 RATE (b)	0/42.78	0/21.28
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---

STATISTICAL TESTS

POLY 3	(e)
POLY 1.5	(e)
POLY 6	(e)
COCH-ARM / FISHERS	(e)
MAX-ISO-POLY-3	(e)

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE **0 MG/KG** **150 MG/KG Stop**

Liver: Oval Cell
Hyperplasia

LESION RATES

OVERALL (a)	0/50 (0%)	43/47 (91%)
POLY-3 RATE (b)	0/42.78	43/44.19
POLY-3 PERCENT (g)	0%	97.3%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	338

STATISTICAL TESTS

POLY 3	P<0.001**
POLY 1.5	P<0.001**
POLY 6	P<0.001**
COCH-ARM / FISHERS	P<0.001**
MAX-ISO-POLY-3	P<0.001**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Liver: Portal
Fibrosis

LESION RATES

OVERALL (a)	0/50 (0%)	35/47 (74%)
POLY-3 RATE (b)	0/42.78	35/40.32
POLY-3 PERCENT (g)	0%	86.8%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	338

STATISTICAL TESTS

POLY 3	P<0.001**
POLY 1.5	P<0.001**
POLY 6	P<0.001**
COCH-ARM / FISHERS	P<0.001**
MAX-ISO-POLY-3	P<0.001**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Lung
Congestion

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/22.19
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---

STATISTICAL TESTS

POLY 3	(e)
POLY 1.5	(e)
POLY 6	(e)
COCH-ARM / FISHERS	(e)
MAX-ISO-POLY-3	(e)

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE **0 MG/KG** **150 MG/KG Stop**

Lung
Hemorrhage

LESION RATES

OVERALL (a)	0/50 (0%)	12/50 (24%)
POLY-3 RATE (b)	0/42.78	12/29.80
POLY-3 PERCENT (g)	0%	40.3%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	349

STATISTICAL TESTS

POLY 3	P<0.001**
POLY 1.5	P<0.001**
POLY 6	P<0.001**
COCH-ARM / FISHERS	P<0.001**
MAX-ISO-POLY-3	P<0.001**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Lung: Alveolar Epithelium
Hyperplasia

LESION RATES

OVERALL (a)	8/50 (16%)	12/50 (24%)
POLY-3 RATE (b)	8/44.82	12/28.82
POLY-3 PERCENT (g)	17.9%	41.6%
TERMINAL (d)	4/31 (13%)	0/0 (0%)
FIRST INCIDENCE	309	338

STATISTICAL TESTS

POLY 3	P=0.025*
POLY 1.5	P=0.075
POLY 6	P=0.004**
COCH-ARM / FISHERS	P=0.227
MAX-ISO-POLY-3	P=0.030*

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Lung: Alveolus
Inflammation Histiocytic

LESION RATES

OVERALL (a)	40/50 (80%)	43/50 (86%)
POLY-3 RATE (b)	40/47.23	43/44.56
POLY-3 PERCENT (g)	84.7%	96.5%
TERMINAL (d)	26/31 (84%)	0/0 (0%)
FIRST INCIDENCE	495	338

STATISTICAL TESTS

POLY 3	P=0.037*
POLY 1.5	P=0.080
POLY 6	P=0.022*
COCH-ARM / FISHERS	P=0.298
MAX-ISO-POLY-3	P=0.017*

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE **0 MG/KG** **150 MG/KG Stop**

**Lung: Arteriole
Inflammation**

LESION RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/42.78	2/23.45
POLY-3 PERCENT (g)	0%	8.5%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	523

STATISTICAL TESTS

POLY 3	P=0.135
POLY 1.5	P=0.173
POLY 6	P=0.096
COCH-ARM / FISHERS	P=0.247
MAX-ISO-POLY-3	P=0.072

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE **0 MG/KG** **150 MG/KG Stop**

Lung: Cervix
Hyperplasia

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/22.19
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---

STATISTICAL TESTS

POLY 3	(e)
POLY 1.5	(e)
POLY 6	(e)
COCH-ARM / FISHERS	(e)
MAX-ISO-POLY-3	(e)

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Lung: Interstitium
Mineralization

LESION RATES

OVERALL (a)	0/50 (0%)	16/50 (32%)
POLY-3 RATE (b)	0/42.78	16/29.86
POLY-3 PERCENT (g)	0%	53.6%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	516

STATISTICAL TESTS

POLY 3	P<0.001**
POLY 1.5	P<0.001**
POLY 6	P<0.001**
COCH-ARM / FISHERS	P<0.001**
MAX-ISO-POLY-3	P<0.001**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Lymph Node, Mesenteric
Fibrosis

LESION RATES

OVERALL (a)	0/50 (0%)	0/45 (0%)
POLY-3 RATE (b)	0/42.78	0/20.48
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---

STATISTICAL TESTS

POLY 3	(e)
POLY 1.5	(e)
POLY 6	(e)
COCH-ARM / FISHERS	(e)
MAX-ISO-POLY-3	(e)

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Lymph Node, Mesenteric
Hemorrhage

LESION RATES

OVERALL (a)	2/50 (4%)	18/45 (40%)
POLY-3 RATE (b)	2/43.27	18/29.90
POLY-3 PERCENT (g)	4.6%	60.2%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	581	349

STATISTICAL TESTS

POLY 3	P<0.001**
POLY 1.5	P<0.001**
POLY 6	P<0.001**
COCH-ARM / FISHERS	P<0.001**
MAX-ISO-POLY-3	P<0.001**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE **0 MG/KG** **150 MG/KG Stop**

**Lymph Node, Mesenteric
Inflammation**

LESION RATES

OVERALL (a)	0/50 (0%)	2/45 (4%)
POLY-3 RATE (b)	0/42.78	2/21.45
POLY-3 PERCENT (g)	0%	9.3%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	537

STATISTICAL TESTS

POLY 3	P=0.122
POLY 1.5	P=0.156
POLY 6	P=0.087
COCH-ARM / FISHERS	P=0.222
MAX-ISO-POLY-3	P=0.067

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Lymph Node: Deep Cervical
Hemorrhage

LESION RATES

OVERALL (a)	0/2 (0%)	3/11 (27%)
POLY-3 RATE (b)	0/2.00	3/6.91
POLY-3 PERCENT (g)	0%	43.4%
TERMINAL (d)	0/2 (0%)	0/0 (0%)
FIRST INCIDENCE	---	352

STATISTICAL TESTS

POLY 3	P=0.362
POLY 1.5	P=0.448
POLY 6	P=0.202
COCH-ARM / FISHERS	P=0.577
MAX-ISO-POLY-3	P=0.120

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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**Lymph Node: Mediastinal
Hemorrhage**

LESION RATES

OVERALL (a)	0/2 (0%)	2/11 (18%)
POLY-3 RATE (b)	0/2.00	2/5.94
POLY-3 PERCENT (g)	0%	33.7%
TERMINAL (d)	0/2 (0%)	0/0 (0%)
FIRST INCIDENCE	---	604

STATISTICAL TESTS

POLY 3	P=0.497
POLY 1.5	P=0.578
POLY 6	P=0.344
COCH-ARM / FISHERS	P=0.705
MAX-ISO-POLY-3	P=0.156

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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**Lymph Node: Pancreatic
Hemorrhage**

LESION RATES

OVERALL (a)	0/2 (0%)	3/11 (27%)
POLY-3 RATE (b)	0/2.00	3/6.54
POLY-3 PERCENT (g)	0%	45.9%
TERMINAL (d)	0/2 (0%)	0/0 (0%)
FIRST INCIDENCE	---	559

STATISTICAL TESTS

POLY 3	P=0.337
POLY 1.5	P=0.432
POLY 6	P=0.182
COCH-ARM / FISHERS	P=0.577
MAX-ISO-POLY-3	P=0.102

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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**Mammary Gland: Duct
Dilatation**

LESION RATES

OVERALL (a)	2/50 (4%)	0/49 (0%)
POLY-3 RATE (b)	2/43.27	0/21.84
POLY-3 PERCENT (g)	4.6%	0%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	634	---

STATISTICAL TESTS

POLY 3	P=0.408N
POLY 1.5	P=0.328N
POLY 6	P=0.526N
COCH-ARM / FISHERS	P=0.253N
MAX-ISO-POLY-3	P=0.233N

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Mesentery
Necrosis

LESION RATES

OVERALL (a)	5/6 (83%)	1/1 (100%)
POLY-3 RATE (b)	5/5.51	1/1.00
POLY-3 PERCENT (g)	90.8%	100%
TERMINAL (d)	4/4 (100%)	0/0 (0%)
FIRST INCIDENCE	674	352

STATISTICAL TESTS

POLY 3	P=0.979
POLY 1.5	P=0.919
POLY 6	P=1.000
COCH-ARM / FISHERS	P=0.857
MAX-ISO-POLY-3	P=0.383

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE **0 MG/KG** **150 MG/KG Stop**

**Nose
Inflammation**

LESION RATES

OVERALL (a)	12/50 (24%)	26/41 (63%)
POLY-3 RATE (b)	12/43.68	26/32.12
POLY-3 PERCENT (g)	27.5%	81%
TERMINAL (d)	9/31 (29%)	0/0 (0%)
FIRST INCIDENCE	581	19

STATISTICAL TESTS

POLY 3	P<0.001**
POLY 1.5	P<0.001**
POLY 6	P<0.001**
COCH-ARM / FISHERS	P<0.001**
MAX-ISO-POLY-3	P<0.001**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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**Nose
Thrombosis**

LESION RATES

OVERALL (a)	0/50 (0%)	2/41 (5%)
POLY-3 RATE (b)	0/42.78	2/19.34
POLY-3 PERCENT (g)	0%	10.3%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	524

STATISTICAL TESTS

POLY 3	P=0.108
POLY 1.5	P=0.139
POLY 6	P=0.077
COCH-ARM / FISHERS	P=0.200
MAX-ISO-POLY-3	P=0.061

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Nose: Glands
Dilatation

LESION RATES

OVERALL (a)	0/50 (0%)	2/41 (5%)
POLY-3 RATE (b)	0/42.78	2/19.17
POLY-3 PERCENT (g)	0%	10.4%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	594

STATISTICAL TESTS

POLY 3	P=0.107
POLY 1.5	P=0.138
POLY 6	P=0.077
COCH-ARM / FISHERS	P=0.200
MAX-ISO-POLY-3	P=0.061

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Nose: Goblet Cell
Hyperplasia

LESION RATES

OVERALL (a)	0/50 (0%)	0/41 (0%)
POLY-3 RATE (b)	0/42.78	0/18.48
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---

STATISTICAL TESTS

POLY 3	(e)
POLY 1.5	(e)
POLY 6	(e)
COCH-ARM / FISHERS	(e)
MAX-ISO-POLY-3	(e)

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE **0 MG/KG** **150 MG/KG Stop**

**Nose: Olfactory Epithelium
Degeneration**

LESION RATES

OVERALL (a)	2/50 (4%)	37/41 (90%)
POLY-3 RATE (b)	2/43.06	37/38.40
POLY-3 PERCENT (g)	4.6%	96.4%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	650	19

STATISTICAL TESTS

POLY 3	P<0.001**
POLY 1.5	P<0.001**
POLY 6	P<0.001**
COCH-ARM / FISHERS	P<0.001**
MAX-ISO-POLY-3	P<0.001**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Nose: Olfactory Epithelium
Metaplasia Respiratory

LESION RATES

OVERALL (a)	1/50 (2%)	36/41 (88%)
POLY-3 RATE (b)	1/42.78	36/37.40
POLY-3 PERCENT (g)	2.3%	96.3%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	338

STATISTICAL TESTS

POLY 3	P<0.001**
POLY 1.5	P<0.001**
POLY 6	P<0.001**
COCH-ARM / FISHERS	P<0.001**
MAX-ISO-POLY-3	P<0.001**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE **0 MG/KG** **150 MG/KG Stop**

Oral Mucosa: Pharyngeal
Hyperplasia

LESION RATES

OVERALL (a)	1/1 (100%)	2/2 (100%)
POLY-3 RATE (b)	1/1.00	2/2.00
POLY-3 PERCENT (g)	100%	100%
TERMINAL (d)	1/1 (100%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	604

STATISTICAL TESTS

POLY 3	(e)
POLY 1.5	(e)
POLY 6	(e)
COCH-ARM / FISHERS	(e)
MAX-ISO-POLY-3	(e)

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Ovary
Atrophy

LESION RATES

OVERALL (a)	5/50 (10%)	16/46 (35%)
POLY-3 RATE (b)	5/44.42	16/28.43
POLY-3 PERCENT (g)	11.3%	56.3%
TERMINAL (d)	2/31 (7%)	0/0 (0%)
FIRST INCIDENCE	495	468

STATISTICAL TESTS

POLY 3	P<0.001**
POLY 1.5	P<0.001**
POLY 6	P<0.001**
COCH-ARM / FISHERS	P=0.003**
MAX-ISO-POLY-3	P<0.001**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Ovary
Cyst

LESION RATES

OVERALL (a)	6/50 (12%)	5/46 (11%)
POLY-3 RATE (b)	6/43.19	5/23.82
POLY-3 PERCENT (g)	13.9%	21%
TERMINAL (d)	4/31 (13%)	0/0 (0%)
FIRST INCIDENCE	674	468

STATISTICAL TESTS

POLY 3	P=0.351
POLY 1.5	P=0.500
POLY 6	P=0.175
COCH-ARM / FISHERS	P=0.559N
MAX-ISO-POLY-3	P=0.282

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Pancreas: Acinus
Atrophy

LESION RATES

OVERALL (a)	11/50 (22%)	17/46 (37%)
POLY-3 RATE (b)	11/45.56	17/29.33
POLY-3 PERCENT (g)	24.2%	58%
TERMINAL (d)	5/31 (16%)	0/0 (0%)
FIRST INCIDENCE	495	349

STATISTICAL TESTS

POLY 3	P=0.003**
POLY 1.5	P=0.013*
POLY 6	P<0.001**
COCH-ARM / FISHERS	P=0.083
MAX-ISO-POLY-3	P=0.005**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Pancreas: Acinus
Hyperplasia

LESION RATES

OVERALL (a)	7/50 (14%)	2/46 (4%)
POLY-3 RATE (b)	7/42.98	2/21.79
POLY-3 PERCENT (g)	16.3%	9.2%
TERMINAL (d)	6/31 (19%)	0/0 (0%)
FIRST INCIDENCE	674	559

STATISTICAL TESTS

POLY 3	P=0.357N
POLY 1.5	P=0.219N
POLY 6	P=0.587N
COCH-ARM / FISHERS	P=0.101N
MAX-ISO-POLY-3	P=0.283N

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Pancreas: Duct
Cyst

LESION RATES

OVERALL (a)	2/50 (4%)	3/46 (7%)
POLY-3 RATE (b)	2/42.78	3/22.59
POLY-3 PERCENT (g)	4.7%	13.3%
TERMINAL (d)	2/31 (7%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	393

STATISTICAL TESTS

POLY 3	P=0.243
POLY 1.5	P=0.331
POLY 6	P=0.144
COCH-ARM / FISHERS	P=0.460
MAX-ISO-POLY-3	P=0.177

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Parathyroid Gland
Hyperplasia

LESION RATES

OVERALL (a)	0/46 (0%)	31/49 (63%)
POLY-3 RATE (b)	0/38.78	31/36.71
POLY-3 PERCENT (g)	0%	84.4%
TERMINAL (d)	0/27 (0%)	0/0 (0%)
FIRST INCIDENCE	---	338

STATISTICAL TESTS

POLY 3	P<0.001**
POLY 1.5	P<0.001**
POLY 6	P<0.001**
COCH-ARM / FISHERS	P<0.001**
MAX-ISO-POLY-3	P<0.001**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
------	---------	----------------

Pituitary Gland: Pars Distalis
Angiectasis

LESION RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.78	1/22.80
POLY-3 PERCENT (g)	0%	4.4%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	533

STATISTICAL TESTS

POLY 3	P=0.384
POLY 1.5	P=0.434
POLY 6	P=0.321
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.157

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Pituitary Gland: Pars Distalis
Cyst

LESION RATES

OVERALL (a)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	4/43.69	1/22.58
POLY-3 PERCENT (g)	9.2%	4.4%
TERMINAL (d)	2/31 (7%)	0/0 (0%)
FIRST INCIDENCE	581	617

STATISTICAL TESTS

POLY 3	P=0.428N
POLY 1.5	P=0.305N
POLY 6	P=0.610N
COCH-ARM / FISHERS	P=0.181N
MAX-ISO-POLY-3	P=0.308N

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
------	---------	----------------

Pituitary Gland: Pars Distalis
Hyperplasia

LESION RATES

OVERALL (a)	17/50 (34%)	12/50 (24%)
POLY-3 RATE (b)	17/45.13	12/28.77
POLY-3 PERCENT (g)	37.7%	41.7%
TERMINAL (d)	12/31 (39%)	0/0 (0%)
FIRST INCIDENCE	309	338

STATISTICAL TESTS

POLY 3	P=0.459
POLY 1.5	P=0.479N
POLY 6	P=0.161
COCH-ARM / FISHERS	P=0.189N
MAX-ISO-POLY-3	P=0.384

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Spleen
Hematopoietic Cell Proliferation

LESION RATES

OVERALL (a)	0/50 (0%)	2/46 (4%)
POLY-3 RATE (b)	0/42.78	2/21.71
POLY-3 PERCENT (g)	0%	9.2%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	523

STATISTICAL TESTS

POLY 3	P=0.124
POLY 1.5	P=0.159
POLY 6	P=0.088
COCH-ARM / FISHERS	P=0.227
MAX-ISO-POLY-3	P=0.068

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE **0 MG/KG** **150 MG/KG Stop**

Spleen
Hyperplasia Lymphoid

LESION RATES

OVERALL (a)	3/50 (6%)	2/46 (4%)
POLY-3 RATE (b)	3/43.37	2/21.87
POLY-3 PERCENT (g)	6.9%	9.2%
TERMINAL (d)	2/31 (7%)	0/0 (0%)
FIRST INCIDENCE	538	538

STATISTICAL TESTS

POLY 3	P=0.562
POLY 1.5	P=0.673
POLY 6	P=0.400
COCH-ARM / FISHERS	P=0.540N
MAX-ISO-POLY-3	P=0.406

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Stomach, Forestomach
Inflammation

LESION RATES

OVERALL (a)	3/50 (6%)	3/46 (7%)
POLY-3 RATE (b)	3/43.95	3/22.37
POLY-3 PERCENT (g)	6.8%	13.4%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	495	471

STATISTICAL TESTS

POLY 3	P=0.347
POLY 1.5	P=0.465
POLY 6	P=0.209
COCH-ARM / FISHERS	P=0.621
MAX-ISO-POLY-3	P=0.259

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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**Stomach, Forestomach
Mineralization**

LESION RATES

OVERALL (a)	1/50 (2%)	0/46 (0%)
POLY-3 RATE (b)	1/43.41	0/20.85
POLY-3 PERCENT (g)	2.3%	0%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	519	---

STATISTICAL TESTS

POLY 3	P=0.632N
POLY 1.5	P=0.583N
POLY 6	P=0.692N
COCH-ARM / FISHERS	P=0.521N
MAX-ISO-POLY-3	P=0.310N

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Stomach, Forestomach
Perforation

LESION RATES

OVERALL (a)	0/50 (0%)	0/46 (0%)
POLY-3 RATE (b)	0/42.78	0/20.85
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---

STATISTICAL TESTS

POLY 3	(e)
POLY 1.5	(e)
POLY 6	(e)
COCH-ARM / FISHERS	(e)
MAX-ISO-POLY-3	(e)

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
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First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Stomach, Forestomach
Ulcer

LESION RATES

OVERALL (a)	3/50 (6%)	3/46 (7%)
POLY-3 RATE (b)	3/43.91	3/22.06
POLY-3 PERCENT (g)	6.8%	13.6%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	519	580

STATISTICAL TESTS

POLY 3	P=0.342
POLY 1.5	P=0.462
POLY 6	P=0.204
COCH-ARM / FISHERS	P=0.621
MAX-ISO-POLY-3	P=0.256

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Stomach, Forestomach: Epithelium
Hyperplasia

LESION RATES

OVERALL (a)	11/50 (22%)	9/46 (20%)
POLY-3 RATE (b)	11/44.59	9/26.22
POLY-3 PERCENT (g)	24.7%	34.3%
TERMINAL (d)	8/31 (26%)	0/0 (0%)
FIRST INCIDENCE	495	352

STATISTICAL TESTS

POLY 3	P=0.281
POLY 1.5	P=0.466
POLY 6	P=0.097
COCH-ARM / FISHERS	P=0.484N
MAX-ISO-POLY-3	P=0.242

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Stomach, Glandular
Erosion

LESION RATES

OVERALL (a)	1/50 (2%)	3/46 (7%)
POLY-3 RATE (b)	1/42.99	3/22.37
POLY-3 PERCENT (g)	2.3%	13.4%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	672	523

STATISTICAL TESTS

POLY 3	P=0.127
POLY 1.5	P=0.182
POLY 6	P=0.075
COCH-ARM / FISHERS	P=0.278
MAX-ISO-POLY-3	P=0.092

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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**Stomach, Glandular
Inflammation**

LESION RATES

OVERALL (a)	0/50 (0%)	1/46 (2%)
POLY-3 RATE (b)	0/42.78	1/21.58
POLY-3 PERCENT (g)	0%	4.6%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	471

STATISTICAL TESTS

POLY 3	P=0.375
POLY 1.5	P=0.421
POLY 6	P=0.315
COCH-ARM / FISHERS	P=0.479
MAX-ISO-POLY-3	P=0.151

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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**Stomach, Glandular
Mineralization**

LESION RATES

OVERALL (a)	1/50 (2%)	13/46 (28%)
POLY-3 RATE (b)	1/43.41	13/27.26
POLY-3 PERCENT (g)	2.3%	47.7%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	519	349

STATISTICAL TESTS

POLY 3	P<0.001**
POLY 1.5	P<0.001**
POLY 6	P<0.001**
COCH-ARM / FISHERS	P<0.001**
MAX-ISO-POLY-3	P<0.001**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Thyroid Gland: C-Cell
Hyperplasia

LESION RATES

OVERALL (a)	39/50 (78%)	3/49 (6%)
POLY-3 RATE (b)	39/46.72	3/23.47
POLY-3 PERCENT (g)	83.5%	12.8%
TERMINAL (d)	29/31 (94%)	0/0 (0%)
FIRST INCIDENCE	495	569

STATISTICAL TESTS

POLY 3	P<0.001N**
POLY 1.5	P<0.001N**
POLY 6	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Trachea
Inflammation

LESION RATES

OVERALL (a)	5/50 (10%)	3/50 (6%)
POLY-3 RATE (b)	5/44.08	3/24.22
POLY-3 PERCENT (g)	11.3%	12.4%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	519	19

STATISTICAL TESTS

POLY 3	P=0.596
POLY 1.5	P=0.538N
POLY 6	P=0.378
COCH-ARM / FISHERS	P=0.357N
MAX-ISO-POLY-3	P=0.459

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE **0 MG/KG** **150 MG/KG Stop**

**Urinary Bladder
Inflammation**

LESION RATES

OVERALL (a)	1/50 (2%)	2/47 (4%)
POLY-3 RATE (b)	1/42.78	2/21.97
POLY-3 PERCENT (g)	2.3%	9.1%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	593

STATISTICAL TESTS

POLY 3	P=0.292
POLY 1.5	P=0.369
POLY 6	P=0.201
COCH-ARM / FISHERS	P=0.477
MAX-ISO-POLY-3	P=0.185

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
Time Report Requested: 09:39:42
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Uterus
Hemorrhage

LESION RATES

OVERALL (a)	2/50 (4%)	1/47 (2%)
POLY-3 RATE (b)	2/43.21	1/21.65
POLY-3 PERCENT (g)	4.6%	4.6%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	604	617

STATISTICAL TESTS

POLY 3	P=0.713N
POLY 1.5	P=0.634N
POLY 6	P=0.581
COCH-ARM / FISHERS	P=0.523N
MAX-ISO-POLY-3	P=0.498N

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE **0 MG/KG** **150 MG/KG Stop**

Uterus
Hydrometra

LESION RATES

OVERALL (a)	0/50 (0%)	3/47 (6%)
POLY-3 RATE (b)	0/42.78	3/23.28
POLY-3 PERCENT (g)	0%	12.9%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	352

STATISTICAL TESTS

POLY 3	P=0.046*
POLY 1.5	P=0.067
POLY 6	P=0.027*
COCH-ARM / FISHERS	P=0.110
MAX-ISO-POLY-3	P=0.033*

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/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**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Uterus
Inflammation

LESION RATES

OVERALL (a)	0/50 (0%)	2/47 (4%)
POLY-3 RATE (b)	0/42.78	2/22.54
POLY-3 PERCENT (g)	0%	8.9%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	352

STATISTICAL TESTS

POLY 3	P=0.128
POLY 1.5	P=0.164
POLY 6	P=0.091
COCH-ARM / FISHERS	P=0.232
MAX-ISO-POLY-3	P=0.069

TDMS No. 99020 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Pulegone
CAS Number: 89-82-7

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First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Uterus: Endometrium
Hyperplasia Cystic

LESION RATES

OVERALL (a)	1/50 (2%)	5/47 (11%)
POLY-3 RATE (b)	1/42.78	5/23.23
POLY-3 PERCENT (g)	2.3%	21.5%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	580

STATISTICAL TESTS

POLY 3	P=0.021*
POLY 1.5	P=0.040*
POLY 6	P=0.008**
COCH-ARM / FISHERS	P=0.088
MAX-ISO-POLY-3	P=0.022*

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

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 ***