

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Pulegone
CAS Number: 89-82-7

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

HISTORICAL CONTROL STUDIES
From November 2008 report

SAME ROUTE

88105-03 -- Isoeugenol (GAVAGE CORN OIL)
99023-03 -- beta-Myrcene (GAVAGE CORN OIL)

ALL ROUTES

99024-07 -- Androstenedione (GAVAGE METHYLCELLULOSE)
88138-03 -- Benzophenone (ORAL FEED)
99028-05 -- bis(2-Chloroethoxy)methane (SKIN ETHANOL)
20011-05 -- 1-Bromopropane (INHALATION AIR)
99027-03 -- Chromium picolinate monohydrate (ORAL FEED)
05174-05 -- Cresols (ORAL FEED)
96011-05 -- Cumene (INHALATION AIR)
97003-07 -- 1,2-Dibromo-2,4-dicyanobutane (SKIN ETHANOL)
93020-07 -- Diisopropylcarbodiimide (SKIN ETHANOL)
88004-05 -- Divinylbenzene (INHALATION AIR)
88123-05 -- Formamide (GAVAGE WATER)
20005-05 -- Ginseng (GAVAGE WATER)
99007-05 -- Goldenseal root powder (ORAL FEED)
95011-07 -- 5-(Hydroxymethyl)-2-furfural (GAVAGE WATER)
88105-03 -- Isoeugenol (GAVAGE CORN OIL)
97006-01 -- Methyl isobutyl ketone (INHALATION AIR)
91005-07 -- Methylene blue trihydrate (GAVAGE METHYLCELLULOSE)
92013-05 -- 4-Methylimidazole (ORAL FEED)
88006-03 -- alpha-Methylstyrene (INHALATION AIR)
20008-03 -- Milk thistle extract (ORAL FEED)
99023-03 -- beta-Myrcene (GAVAGE CORN OIL)
97008-05 -- Propargyl alcohol (INHALATION AIR)
20114-07 -- Sodium dichromate dihydrate (VI) (ORAL WATER)
93025-07 -- Tetralin (INHALATION AIR)
96019-05 -- Water disinfection byproducts (Bromochloroacetic acid) (ORAL WATER)

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HISTORICAL CONTROL STUDIES
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96017-05 -- Water disinfection byproducts (Dibromoacetic acid) (ORAL WATER)
96015-05 -- Water disinfection byproducts (Dibromoacetonitrile) (ORAL WATER)

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**FOR ALL DOSES THE TUMOR RATES IN THE FOLLOWING TISSUES/ORGANS ARE BASED ON NUMBER OF TISSUES EXAMINED.
IN OTHER TISSUES/ORGANS RATES ARE BASED ON THE NUMBER OF ANIMALS NECROPSIED.**

Adrenal Cortex
Adrenal Medulla
Brain
Clitoral/Preputial Gland
Heart
Islets, Pancreatic
Kidney
Liver
Lung
Nose
Pancreas
Parathyroid Gland
Pituitary Gland
Spleen
Testes
Thyroid Gland
Urinary Bladder

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

MALE RATS

Organ

Adrenal Medulla
Pituitary Gland: Pars Distalis or Unspecified Site
Thyroid Gland: C-Cell
All Organs

Morphology

Pheochromocytoma Benign
Adenoma
Adenoma
Benign Tumors
Malignant Tumors

FEMALE RATS

Organ

Mammary Gland

Pituitary Gland: Pars Distalis or Unspecified Site
Thyroid Gland: C-Cell
Urinary Bladder

All Organs

Morphology

Fibroadenoma
Fibroma, Fibroadenoma or Adenoma
Fibroma, Fibroadenoma, Carcinoma, or Adenoma
Adenoma
Adenoma
Carcinoma or Papilloma
Papilloma
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated
Benign Tumors
Malignant Tumors
Malignant and Benign Tumors

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

**Adrenal Cortex
Adenoma**

TUMOR RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/46.01	0/19.85
POLY-3 PERCENT (g)	4.4%	0%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	692	---
HC TUMORS SAME ROUTE	1/100 (1%)	
HC TUMORS ALL ROUTES	12/1348 (1%)	

STATISTICAL TESTS

POLY 3	P=0.446N
POLY 1.5	P=0.346N
POLY 6	P=0.556N
COCH-ARM / FISHERS	P=0.247N
MAX-ISO-POLY-3	P=0.268N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

DOSE	0 MG/KG	75 MG/KG Stop
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Adrenal Medulla
Pheochromocytoma Benign

TUMOR RATES

OVERALL (a)	8/50 (16%)	2/50 (4%)
POLY-3 RATE (b)	8/45.95	2/19.85
POLY-3 PERCENT (g)	17.4%	10.1%
TERMINAL (d)	6/39 (15%)	2/2 (100%)
FIRST INCIDENCE	699	727 (T)
HC TUMORS SAME ROUTE	16/100 (16%)	
HC TUMORS ALL ROUTES	197/1346 (15%)	

STATISTICAL TESTS

POLY 3	P=0.370N
POLY 1.5	P=0.171N
POLY 6	P=0.599
COCH-ARM / FISHERS	P=0.046N*
MAX-ISO-POLY-3	P=0.306N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTEs	(h)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

Clitoral/Preputial Gland
Adenoma

TUMOR RATES

OVERALL (a)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	3/46.04	1/20.53
POLY-3 PERCENT (g)	6.5%	4.9%
TERMINAL (d)	2/39 (5%)	0/2 (0%)
FIRST INCIDENCE	653	497
HC TUMORS SAME ROUTE	7/100 (7%)	
HC TUMORS ALL ROUTES	50/1345 (4%)	

STATISTICAL TESTS

POLY 3	P=0.601N
POLY 1.5	P=0.468N
POLY 6	P=0.611
COCH-ARM / FISHERS	P=0.309N
MAX-ISO-POLY-3	P=0.429N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Males

DOSE	0 MG/KG	75 MG/KG Stop
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Clitoral/Preputial Gland
Carcinoma or Adenoma

TUMOR RATES

OVERALL (a)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	4/46.04	1/20.53
POLY-3 PERCENT (g)	8.7%	4.9%
TERMINAL (d)	3/39 (8%)	0/2 (0%)
FIRST INCIDENCE	653	497
HC TUMORS SAME ROUTE	9/100 (9%)	
HC TUMORS ALL ROUTES	66/1345 (5%)	

STATISTICAL TESTS

POLY 3	P=0.485N
POLY 1.5	P=0.334N
POLY 6	P=0.649N
COCH-ARM / FISHERS	P=0.181N
MAX-ISO-POLY-3	P=0.355N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTEs	(h)

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

**Islets, Pancreatic
Adenoma**

TUMOR RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/46.12	0/19.85
POLY-3 PERCENT (g)	4.3%	0%
TERMINAL (d)	1/39 (3%)	0/2 (0%)
FIRST INCIDENCE	627	---
HC TUMORS SAME ROUTE	6/100 (6%)	
HC TUMORS ALL ROUTES	84/1345 (6%)	

STATISTICAL TESTS

POLY 3	P=0.446N
POLY 1.5	P=0.346N
POLY 6	P=0.557N
COCH-ARM / FISHERS	P=0.247N
MAX-ISO-POLY-3	P=0.269N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

DOSE	0 MG/KG	75 MG/KG Stop
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Kidney: Renal Tubule
Adenoma

TUMOR RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/45.76	2/20.34
POLY-3 PERCENT (g)	2.2%	9.8%
TERMINAL (d)	1/39 (3%)	0/2 (0%)
FIRST INCIDENCE	727 (T)	650
HC TUMORS SAME ROUTE	0/100 (0%)	
HC TUMORS ALL ROUTES	7/1344 (1%)	

STATISTICAL TESTS

POLY 3	P=0.262
POLY 1.5	P=0.358
POLY 6	P=0.182
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.179
HISTCONT SAME RTE	P=0.213
HISTCONT ALL RTES	P=0.024*

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Males

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

Liver
Hepatocellular Adenoma

TUMOR RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/45.76	1/20.39
POLY-3 PERCENT (g)	2.2%	4.9%
TERMINAL (d)	1/39 (3%)	0/2 (0%)
FIRST INCIDENCE	727 (T)	561
HC TUMORS SAME ROUTE	1/100 (1%)	
HC TUMORS ALL ROUTES	16/1349 (1%)	

STATISTICAL TESTS

POLY 3	P=0.562
POLY 1.5	P=0.657
POLY 6	P=0.456
COCH-ARM / FISHERS	P=0.753N
MAX-ISO-POLY-3	P=0.344
HISTCONT SAME RTE	P=0.283
HISTCONT ALL RTEs	P=0.331

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

DOSE	0 MG/KG	75 MG/KG Stop
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Lung
Alveolar/Bronchiolar Adenoma

TUMOR 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	---	---
HC TUMORS SAME ROUTE	6/100 (6%)	
HC TUMORS ALL ROUTES	34/1349 (3%)	

STATISTICAL TESTS

POLY 3	(e)
POLY 1.5	(e)
POLY 6	(e)
COCH-ARM / FISHERS	(e)
MAX-ISO-POLY-3	(e)
HISTCONT SAME RTE	(e)
HISTCONT ALL RTES	(e)

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

Lung
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma

TUMOR 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)	---
HC TUMORS SAME ROUTE	7/100 (7%)	
HC TUMORS ALL ROUTES	46/1349 (3%)	

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
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

**Mammary Gland
Adenoma**

TUMOR 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	---	---
HC TUMORS SAME ROUTE	0/100 (0%)	
HC TUMORS ALL ROUTES	4/1349 (0%)	

STATISTICAL TESTS

POLY 3	(e)
POLY 1.5	(e)
POLY 6	(e)
COCH-ARM / FISHERS	(e)
MAX-ISO-POLY-3	(e)
HISTCONT SAME RTE	(e)
HISTCONT ALL RTES	(e)

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

**Mammary Gland
Fibroadenoma**

TUMOR RATES	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/46.11	1/20.32
POLY-3 PERCENT (g)	2.2%	4.9%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	632	587
HC TUMORS SAME ROUTE	4/100 (4%)	
HC TUMORS ALL ROUTES	48/1349 (4%)	

STATISTICAL TESTS

POLY 3	P=0.559
POLY 1.5	P=0.655
POLY 6	P=0.453
COCH-ARM / FISHERS	P=0.753N
MAX-ISO-POLY-3	P=0.342
HISTCONT SAME RTE	P=0.474
HISTCONT ALL RTEs	P=0.435

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

**Mammary Gland
Fibroma, Fibroadenoma or Adenoma**

TUMOR RATES	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/46.11	1/20.32
POLY-3 PERCENT (g)	2.2%	4.9%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	632	587
HC TUMORS SAME ROUTE	4/100 (4%)	
HC TUMORS ALL ROUTES	54/1349 (4%)	

STATISTICAL TESTS

POLY 3	P=0.559
POLY 1.5	P=0.655
POLY 6	P=0.453
COCH-ARM / FISHERS	P=0.753N
MAX-ISO-POLY-3	P=0.342
HISTCONT SAME RTE	P=0.474
HISTCONT ALL RTEs	P=0.435

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

**Mammary Gland
Fibroma, Fibroadenoma, Carcinoma, or Adenoma**

TUMOR RATES	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/46.11	1/20.32
POLY-3 PERCENT (g)	2.2%	4.9%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	632	587
HC TUMORS SAME ROUTE	4/100 (4%)	
HC TUMORS ALL ROUTES	60/1349 (4%)	

STATISTICAL TESTS

POLY 3	P=0.559
POLY 1.5	P=0.655
POLY 6	P=0.453
COCH-ARM / FISHERS	P=0.753N
MAX-ISO-POLY-3	P=0.342
HISTCONT SAME RTE	P=0.474
HISTCONT ALL RTEs	P=0.435

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

**Pancreas
Adenoma**

TUMOR 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)	---
HC TUMORS SAME ROUTE	8/100 (8%)	
HC TUMORS ALL ROUTES	22/1344 (2%)	

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
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

Parathyroid Gland
Adenoma

TUMOR RATES

OVERALL (a)	1/49 (2%)	0/48 (0%)
POLY-3 RATE (b)	1/44.76	0/19.36
POLY-3 PERCENT (g)	2.2%	0%
TERMINAL (d)	1/38 (3%)	0/2 (0%)
FIRST INCIDENCE	727 (T)	---
HC TUMORS SAME ROUTE	1/92 (1%)	
HC TUMORS ALL ROUTES	5/1285 (0%)	

STATISTICAL TESTS

POLY 3	P=0.644N
POLY 1.5	P=0.585N
POLY 6	P=0.700N
COCH-ARM / FISHERS	P=0.505N
MAX-ISO-POLY-3	P=0.330N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 or Unspecified Site
Adenoma

TUMOR RATES

OVERALL (a)	11/50 (22%)	1/50 (2%)
POLY-3 RATE (b)	11/45.90	1/20.14
POLY-3 PERCENT (g)	24%	5%
TERMINAL (d)	10/39 (26%)	0/2 (0%)
FIRST INCIDENCE	692	650
HC TUMORS SAME ROUTE	25/100 (25%)	
HC TUMORS ALL ROUTES	624/1344 (46%)	

STATISTICAL TESTS

POLY 3	P=0.095N
POLY 1.5	P=0.021N*
POLY 6	P=0.307N
COCH-ARM / FISHERS	P=0.002N**
MAX-ISO-POLY-3	P=0.105N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTEs	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

Skin

Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma

TUMOR RATES

	#	#
OVERALL (a)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	3/45.76	2/20.06
POLY-3 PERCENT (g)	6.6%	10%
TERMINAL (d)	3/39 (8%)	1/2 (50%)
FIRST INCIDENCE	727 (T)	673
HC TUMORS SAME ROUTE	11/100 (11%)	
HC TUMORS ALL ROUTES	123/1349 (9%)	

STATISTICAL TESTS

POLY 3	P=0.508
POLY 1.5	P=0.663
POLY 6	P=0.342
COCH-ARM / FISHERS	P=0.500N
MAX-ISO-POLY-3	P=0.373
HISTCONT SAME RTE	P=0.512
HISTCONT ALL RTES	P=0.475

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

**Skin
Fibroma**

TUMOR 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)	---
HC TUMORS SAME ROUTE	8/100 (8%)	
HC TUMORS ALL ROUTES	124/1349 (9%)	

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
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

Skin
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma

TUMOR RATES	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	3/45.76	1/20.39
POLY-3 PERCENT (g)	6.6%	4.9%
TERMINAL (d)	3/39 (8%)	0/2 (0%)
FIRST INCIDENCE	727 (T)	561
HC TUMORS SAME ROUTE	11/100 (11%)	
HC TUMORS ALL ROUTES	154/1349 (11%)	

STATISTICAL TESTS

POLY 3	P=0.601N
POLY 1.5	P=0.468N
POLY 6	P=0.612
COCH-ARM / FISHERS	P=0.309N
MAX-ISO-POLY-3	P=0.429N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS

Males

DOSE 0 MG/KG 75 MG/KG Stop

Skin
Keratoacanthoma

TUMOR 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)	---
HC TUMORS SAME ROUTE	9/100 (9%)	
HC TUMORS ALL ROUTES	73/1349 (5%)	

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
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Pulegone
 CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

Males		
DOSE	0 MG/KG	75 MG/KG Stop
Skin		
Schwannoma Malignant		
<hr/>		
TUMOR RATES	#	#
OVERALL (a)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	3/46.30	0/19.85
POLY-3 PERCENT (g)	6.5%	0%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	627	---
HC TUMORS SAME ROUTE	0/100 (0%)	
HC TUMORS ALL ROUTES	8/1349 (1%)	
<hr/>		
STATISTICAL TESTS		
POLY 3		P=0.330N
POLY 1.5		P=0.219N
POLY 6		P=0.472N
COCH-ARM / FISHERS		P=0.121N
MAX-ISO-POLY-3		P=0.223N
HISTCONT SAME RTE		(h)
HISTCONT ALL RTEs		(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

Skin
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma

TUMOR RATES	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	3/45.76	1/19.85
POLY-3 PERCENT (g)	6.6%	5%
TERMINAL (d)	3/39 (8%)	1/2 (50%)
FIRST INCIDENCE	727 (T)	727 (T)
HC TUMORS SAME ROUTE	9/100 (9%)	
HC TUMORS ALL ROUTES	98/1349 (7%)	

STATISTICAL TESTS

POLY 3	P=0.609N
POLY 1.5	P=0.472N
POLY 6	P=0.595
COCH-ARM / FISHERS	P=0.309N
MAX-ISO-POLY-3	P=0.436N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Pulegone
 CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

Skin
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma

TUMOR RATES	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	3/45.76	1/19.85
POLY-3 PERCENT (g)	6.6%	5%
TERMINAL (d)	3/39 (8%)	1/2 (50%)
FIRST INCIDENCE	727 (T)	727 (T)
HC TUMORS SAME ROUTE	9/100 (9%)	
HC TUMORS ALL ROUTES	90/1349 (7%)	

STATISTICAL TESTS

POLY 3	P=0.609N
POLY 1.5	P=0.472N
POLY 6	P=0.595
COCH-ARM / FISHERS	P=0.309N
MAX-ISO-POLY-3	P=0.436N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

**Spleen
Hemangiosarcoma**

TUMOR 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	---	---
HC TUMORS SAME ROUTE	1/100 (1%)	
HC TUMORS ALL ROUTES	3/1346 (0%)	

STATISTICAL TESTS

POLY 3	(e)
POLY 1.5	(e)
POLY 6	(e)
COCH-ARM / FISHERS	(e)
MAX-ISO-POLY-3	(e)
HISTCONT SAME RTE	(e)
HISTCONT ALL RTES	(e)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Males

DOSE	0 MG/KG	75 MG/KG Stop
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Testes
Adenoma

TUMOR RATES

OVERALL (a)	46/50 (92%)	44/49 (90%)
POLY-3 RATE (b)	46/47.05	44/44.75
POLY-3 PERCENT (g)	97.8%	98.3%
TERMINAL (d)	39/39 (100%)	2/2 (100%)
FIRST INCIDENCE	627	360
HC TUMORS SAME ROUTE	93/100 (93%)	
HC TUMORS ALL ROUTES	1124/1349 (83%)	

STATISTICAL TESTS

POLY 3	P=0.784
POLY 1.5	P=0.613N
POLY 6	P=0.686
COCH-ARM / FISHERS	P=0.487N
MAX-ISO-POLY-3	P=0.397
HISTCONT SAME RTE	P=0.108
HISTCONT ALL RTES	P=0.244

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

**Thyroid Gland: C-Cell
Adenoma**

TUMOR RATES

OVERALL (a)	8/50 (16%)	1/47 (2%)
POLY-3 RATE (b)	8/46.59	1/19.48
POLY-3 PERCENT (g)	17.2%	5.1%
TERMINAL (d)	4/39 (10%)	0/2 (0%)
FIRST INCIDENCE	627	388
HC TUMORS SAME ROUTE	21/100 (21%)	
HC TUMORS ALL ROUTES	164/1342 (12%)	

STATISTICAL TESTS

POLY 3	P=0.218N
POLY 1.5	P=0.088N
POLY 6	P=0.439N
COCH-ARM / FISHERS	P=0.019N*
MAX-ISO-POLY-3	P=0.194N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTEs	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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
Carcinoma

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/45.76	0/19.69
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	---	---
HC TUMORS SAME ROUTE	0/100 (0%)	
HC TUMORS ALL ROUTES	1/1347 (0%)	

STATISTICAL TESTS

POLY 3	(e)
POLY 1.5	(e)
POLY 6	(e)
COCH-ARM / FISHERS	(e)
MAX-ISO-POLY-3	(e)
HISTCONT SAME RTE	(e)
HISTCONT ALL RTES	(e)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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
Carcinoma or Papilloma

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/45.76	0/19.69
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	---	---
HC TUMORS SAME ROUTE	1/100 (1%)	
HC TUMORS ALL ROUTES	4/1347 (0%)	

STATISTICAL TESTS

POLY 3	(e)
POLY 1.5	(e)
POLY 6	(e)
COCH-ARM / FISHERS	(e)
MAX-ISO-POLY-3	(e)
HISTCONT SAME RTE	(e)
HISTCONT ALL RTES	(e)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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
Papilloma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/45.76	0/19.69
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/39 (0%)	0/2 (0%)
FIRST INCIDENCE	---	---
HC TUMORS SAME ROUTE	1/100 (1%)	
HC TUMORS ALL ROUTES	3/1347 (0%)	

STATISTICAL TESTS

POLY 3	(e)
POLY 1.5	(e)
POLY 6	(e)
COCH-ARM / FISHERS	(e)
MAX-ISO-POLY-3	(e)
HISTCONT SAME RTE	(e)
HISTCONT ALL RTES	(e)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS

Males

DOSE 0 MG/KG 75 MG/KG Stop

All Organs
Hemangiosarcoma

TUMOR 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	---	---
HC TUMORS SAME ROUTE	1/100 (1%)	
HC TUMORS ALL ROUTES	7/1349 (1%)	

STATISTICAL TESTS

POLY 3	(e)
POLY 1.5	(e)
POLY 6	(e)
COCH-ARM / FISHERS	(e)
MAX-ISO-POLY-3	(e)
HISTCONT SAME RTE	(e)
HISTCONT ALL RTES	(e)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

All Organs
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated

TUMOR RATES	#	#
OVERALL (a)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	4/46.20	0/19.85
POLY-3 PERCENT (g)	8.7%	0%
TERMINAL (d)	2/39 (5%)	0/2 (0%)
FIRST INCIDENCE	627	---
HC TUMORS SAME ROUTE	19/100 (19%)	
HC TUMORS ALL ROUTES	549/1349 (41%)	

STATISTICAL TESTS

POLY 3	P=0.250N
POLY 1.5	P=0.141N
POLY 6	P=0.408N
COCH-ARM / FISHERS	P=0.059N
MAX-ISO-POLY-3	P=0.187N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTEs	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

All Organs
Mesothelioma: Benign, Malignant, NOS

TUMOR RATES	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/45.88	1/20.06
POLY-3 PERCENT (g)	4.4%	5%
TERMINAL (d)	1/39 (3%)	0/2 (0%)
FIRST INCIDENCE	699	673
HC TUMORS SAME ROUTE	5/100 (5%)	
HC TUMORS ALL ROUTES	35/1349 (3%)	

STATISTICAL TESTS

POLY 3	P=0.674
POLY 1.5	P=0.643N
POLY 6	P=0.538
COCH-ARM / FISHERS	P=0.500N
MAX-ISO-POLY-3	P=0.468
HISTCONT SAME RTE	P=0.622
HISTCONT ALL RTEs	P=0.495

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

All Organs
Mesothelioma: Malignant

TUMOR RATES	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/45.88	1/20.06
POLY-3 PERCENT (g)	4.4%	5%
TERMINAL (d)	1/39 (3%)	0/2 (0%)
FIRST INCIDENCE	699	673
HC TUMORS SAME ROUTE	5/100 (5%)	
HC TUMORS ALL ROUTES	34/1349 (3%)	

STATISTICAL TESTS

POLY 3	P=0.674
POLY 1.5	P=0.643N
POLY 6	P=0.538
COCH-ARM / FISHERS	P=0.500N
MAX-ISO-POLY-3	P=0.468
HISTCONT SAME RTE	P=0.622
HISTCONT ALL RTES	P=0.492

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Males		
DOSE	0 MG/KG	75 MG/KG Stop

All Organs		
Benign Tumors		
<hr/>		
TUMOR RATES	#	#
OVERALL (a)	47/50 (94%)	44/50 (88%)
POLY-3 RATE (b)	47/47.18	44/44.91
POLY-3 PERCENT (g)	99.6%	98%
TERMINAL (d)	39/39 (100%)	2/2 (100%)
FIRST INCIDENCE	627	360
HC TUMORS SAME ROUTE	98/100 (98%)	
HC TUMORS ALL ROUTES	1308/1349 (97%)	
<hr/>		
STATISTICAL TESTS		
POLY 3		P=0.719N
POLY 1.5		P=0.189N
POLY 6		P=1.000N
COCH-ARM / FISHERS		P=0.243N
MAX-ISO-POLY-3		P=0.041N*
HISTCONT SAME RTE		(h)
HISTCONT ALL RTEs		(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Males		
DOSE	0 MG/KG	75 MG/KG Stop

All Organs		
Malignant Tumors		
<hr/>		
TUMOR RATES	#	#
OVERALL (a)	10/50 (20%)	3/50 (6%)
POLY-3 RATE (b)	10/46.55	3/21.44
POLY-3 PERCENT (g)	21.5%	14%
TERMINAL (d)	5/39 (13%)	0/2 (0%)
FIRST INCIDENCE	627	394
HC TUMORS SAME ROUTE	52/100 (52%)	
HC TUMORS ALL ROUTES	788/1349 (58%)	
<hr/>		
STATISTICAL TESTS		
POLY 3		P=0.363N
POLY 1.5		P=0.156N
POLY 6		P=0.573
COCH-ARM / FISHERS		P=0.036N*
MAX-ISO-POLY-3		P=0.307N
HISTCONT SAME RTE		(h)
HISTCONT ALL RTES		(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Males

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

All Organs
Malignant and Benign Tumors

TUMOR RATES	#	#
OVERALL (a)	47/50 (94%)	45/50 (90%)
POLY-3 RATE (b)	47/47.18	45/45.75
POLY-3 PERCENT (g)	99.6%	98.4%
TERMINAL (d)	39/39 (100%)	2/2 (100%)
FIRST INCIDENCE	627	360
HC TUMORS SAME ROUTE	100/100 (100%)	
HC TUMORS ALL ROUTES	1343/1349 (100%)	

STATISTICAL TESTS

POLY 3	P=0.856N
POLY 1.5	P=0.302N
POLY 6	P=1.000N
COCH-ARM / FISHERS	P=0.357N
MAX-ISO-POLY-3	P=0.071N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

**Adrenal Cortex
Adenoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/42.78	0/22.06
POLY-3 PERCENT (g)	0%	0%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---
HC TUMORS SAME ROUTE	0/100 (0%)	
HC TUMORS ALL ROUTES	24/1296 (2%)	

STATISTICAL TESTS

POLY 3	(e)
POLY 1.5	(e)
POLY 6	(e)
COCH-ARM / FISHERS	(e)
MAX-ISO-POLY-3	(e)
HISTCONT SAME RTE	(e)
HISTCONT ALL RTES	(e)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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
Pheochromocytoma Benign

TUMOR RATES

OVERALL (a)	3/50 (6%)	0/49 (0%)
POLY-3 RATE (b)	3/42.78	0/22.06
POLY-3 PERCENT (g)	7%	0%
TERMINAL (d)	3/31 (10%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	---
HC TUMORS SAME ROUTE	3/100 (3%)	
HC TUMORS ALL ROUTES	33/1288 (3%)	

STATISTICAL TESTS

POLY 3	P=0.278N
POLY 1.5	P=0.197N
POLY 6	P=0.422N
COCH-ARM / FISHERS	P=0.125N
MAX-ISO-POLY-3	P=0.178N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTEs	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Clitoral/Preputial Gland
Adenoma

TUMOR RATES

OVERALL (a)	3/50 (6%)	1/49 (2%)
POLY-3 RATE (b)	3/43.62	1/22.45
POLY-3 PERCENT (g)	6.9%	4.5%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	495	617
HC TUMORS SAME ROUTE	10/98 (10%)	
HC TUMORS ALL ROUTES	122/1297 (9%)	

STATISTICAL TESTS

POLY 3	P=0.555N
POLY 1.5	P=0.444N
POLY 6	P=0.655
COCH-ARM / FISHERS	P=0.316N
MAX-ISO-POLY-3	P=0.387N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

**Clitoral/Preputial Gland
Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	3/50 (6%)	1/49 (2%)
POLY-3 RATE (b)	3/43.62	1/22.45
POLY-3 PERCENT (g)	6.9%	4.5%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	495	617
HC TUMORS SAME ROUTE	12/98 (12%)	
HC TUMORS ALL ROUTES	158/1297 (12%)	

STATISTICAL TESTS

POLY 3	P=0.555N
POLY 1.5	P=0.444N
POLY 6	P=0.655
COCH-ARM / FISHERS	P=0.316N
MAX-ISO-POLY-3	P=0.387N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTEs	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Islets, Pancreatic
Adenoma

TUMOR RATES

OVERALL (a)	1/50 (2%)	0/46 (0%)
POLY-3 RATE (b)	1/42.78	0/20.85
POLY-3 PERCENT (g)	2.3%	0%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	---
HC TUMORS SAME ROUTE	1/100 (1%)	
HC TUMORS ALL ROUTES	20/1290 (2%)	

STATISTICAL TESTS

POLY 3	P=0.630N
POLY 1.5	P=0.582N
POLY 6	P=0.690N
COCH-ARM / FISHERS	P=0.521N
MAX-ISO-POLY-3	P=0.307N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTEs	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

DOSE	0 MG/KG	150 MG/KG Stop
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Kidney: Renal Tubule
Adenoma

TUMOR RATES

OVERALL (a)	0/50 (0%)	1/49 (2%)
POLY-3 RATE (b)	0/42.78	1/22.52
POLY-3 PERCENT (g)	0%	4.4%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	593
HC TUMORS SAME ROUTE	0/100 (0%)	
HC TUMORS ALL ROUTES	1/1290 (0%)	

STATISTICAL TESTS

POLY 3	P=0.382
POLY 1.5	P=0.431
POLY 6	P=0.319
COCH-ARM / FISHERS	P=0.495
MAX-ISO-POLY-3	P=0.155
HISTCONT SAME RTE	P=0.210
HISTCONT ALL RTEs	P=0.014*

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE 0 MG/KG 150 MG/KG Stop

Liver
Hepatocellular Adenoma

TUMOR RATES

OVERALL (a)	1/50 (2%)	3/47 (6%)
POLY-3 RATE (b)	1/42.78	3/22.77
POLY-3 PERCENT (g)	2.3%	13.2%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	470
HC TUMORS SAME ROUTE	0/100 (0%)	
HC TUMORS ALL ROUTES	15/1300 (1%)	

STATISTICAL TESTS

POLY 3	P=0.132
POLY 1.5	P=0.188
POLY 6	P=0.077
COCH-ARM / FISHERS	P=0.285
MAX-ISO-POLY-3	P=0.095
HISTCONT SAME RTE	P=0.134
HISTCONT ALL RTES	P=0.095

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

Lung
Alveolar/Bronchiolar Adenoma

TUMOR RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/43.27	0/22.19
POLY-3 PERCENT (g)	4.6%	0%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	581	---
HC TUMORS SAME ROUTE	5/100 (5%)	
HC TUMORS ALL ROUTES	26/1300 (2%)	

STATISTICAL TESTS

POLY 3	P=0.404N
POLY 1.5	P=0.324N
POLY 6	P=0.524N
COCH-ARM / FISHERS	P=0.247N
MAX-ISO-POLY-3	P=0.230N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTEs	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

Lung
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma

TUMOR RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/43.27	0/22.19
POLY-3 PERCENT (g)	4.6%	0%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	581	---
HC TUMORS SAME ROUTE	5/100 (5%)	
HC TUMORS ALL ROUTES	32/1300 (3%)	

STATISTICAL TESTS

POLY 3	P=0.404N
POLY 1.5	P=0.324N
POLY 6	P=0.524N
COCH-ARM / FISHERS	P=0.247N
MAX-ISO-POLY-3	P=0.230N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

**Mammary Gland
Adenoma**

TUMOR RATES	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/43.03	0/22.19
POLY-3 PERCENT (g)	4.7%	0%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	659	---
HC TUMORS SAME ROUTE	0/100 (0%)	
HC TUMORS ALL ROUTES	17/1300 (1%)	

STATISTICAL TESTS

POLY 3	P=0.403N
POLY 1.5	P=0.323N
POLY 6	P=0.523N
COCH-ARM / FISHERS	P=0.247N
MAX-ISO-POLY-3	P=0.229N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Pulegone
 CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

**Mammary Gland
 Fibroadenoma**

TUMOR RATES	#	#
OVERALL (a)	21/50 (42%)	0/50 (0%)
POLY-3 RATE (b)	21/44.49	0/22.19
POLY-3 PERCENT (g)	47.2%	0%
TERMINAL (d)	14/31 (45%)	0/0 (0%)
FIRST INCIDENCE	604	---
HC TUMORS SAME ROUTE	43/100 (43%)	
HC TUMORS ALL ROUTES	676/1300 (52%)	

STATISTICAL TESTS

POLY 3	P<0.001N**
POLY 1.5	P<0.001N**
POLY 6	P=0.015N*
COCH-ARM / FISHERS	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Pulegone
 CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

**Mammary Gland
 Fibroma, Fibroadenoma or Adenoma**

TUMOR RATES	#	#
OVERALL (a)	22/50 (44%)	0/50 (0%)
POLY-3 RATE (b)	22/44.75	0/22.19
POLY-3 PERCENT (g)	49.2%	0%
TERMINAL (d)	14/31 (45%)	0/0 (0%)
FIRST INCIDENCE	604	---
HC TUMORS SAME ROUTE	43/100 (43%)	
HC TUMORS ALL ROUTES	685/1300 (53%)	

STATISTICAL TESTS

POLY 3	P<0.001N**
POLY 1.5	P<0.001N**
POLY 6	P=0.013N*
COCH-ARM / FISHERS	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

**Mammary Gland
Fibroma, Fibroadenoma, Carcinoma, or Adenoma**

TUMOR RATES	#	#
OVERALL (a)	22/50 (44%)	0/50 (0%)
POLY-3 RATE (b)	22/44.75	0/22.19
POLY-3 PERCENT (g)	49.2%	0%
TERMINAL (d)	14/31 (45%)	0/0 (0%)
FIRST INCIDENCE	604	---
HC TUMORS SAME ROUTE	45/100 (45%)	
HC TUMORS ALL ROUTES	720/1300 (55%)	

STATISTICAL TESTS

POLY 3	P<0.001N**
POLY 1.5	P<0.001N**
POLY 6	P=0.013N*
COCH-ARM / FISHERS	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

**Pancreas
Adenoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	1/46 (2%)
POLY-3 RATE (b)	0/42.78	1/21.24
POLY-3 PERCENT (g)	0%	4.7%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	617
HC TUMORS SAME ROUTE	0/100 (0%)	
HC TUMORS ALL ROUTES	1/1291 (0%)	

STATISTICAL TESTS

POLY 3	P=0.372
POLY 1.5	P=0.419
POLY 6	P=0.313
COCH-ARM / FISHERS	P=0.479
MAX-ISO-POLY-3	P=0.151
HISTCONT SAME RTE	P=0.211
HISTCONT ALL RTEs	P=0.012*

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

Parathyroid Gland
Adenoma

TUMOR RATES

OVERALL (a)	2/46 (4%)	0/49 (0%)
POLY-3 RATE (b)	2/38.78	0/22.06
POLY-3 PERCENT (g)	5.2%	0%
TERMINAL (d)	2/27 (7%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	---
HC TUMORS SAME ROUTE	0/94 (0%)	
HC TUMORS ALL ROUTES	0/1221 (0%)	

STATISTICAL TESTS

POLY 3	P=0.378N
POLY 1.5	P=0.302N
POLY 6	P=0.501N
COCH-ARM / FISHERS	P=0.232N
MAX-ISO-POLY-3	P=0.210N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTEs	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

**Pituitary Gland: Pars Distalis or Unspecified Site
Adenoma**

TUMOR RATES

OVERALL (a)	27/50 (54%)	3/50 (6%)
POLY-3 RATE (b)	27/46.04	3/23.50
POLY-3 PERCENT (g)	58.6%	12.8%
TERMINAL (d)	17/31 (55%)	0/0 (0%)
FIRST INCIDENCE	495	470
HC TUMORS SAME ROUTE	50/100 (50%)	
HC TUMORS ALL ROUTES	713/1294 (55%)	

STATISTICAL TESTS

POLY 3	P<0.001N**
POLY 1.5	P<0.001N**
POLY 6	P=0.034N*
COCH-ARM / FISHERS	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

Skin

Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma

TUMOR RATES

	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/42.78	2/22.91
POLY-3 PERCENT (g)	2.3%	8.7%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	586
HC TUMORS SAME ROUTE	1/100 (1%)	
HC TUMORS ALL ROUTES	25/1300 (2%)	

STATISTICAL TESTS

POLY 3	P=0.304
POLY 1.5	P=0.386
POLY 6	P=0.208
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.192
HISTCONT SAME RTE	P=0.212
HISTCONT ALL RTEs	P=0.207

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

**Skin
Fibroma**

TUMOR RATES	#	#
OVERALL (a)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	3/43.20	0/22.19
POLY-3 PERCENT (g)	7%	0%
TERMINAL (d)	2/31 (7%)	0/0 (0%)
FIRST INCIDENCE	607	---
HC TUMORS SAME ROUTE	2/100 (2%)	
HC TUMORS ALL ROUTES	23/1300 (2%)	

STATISTICAL TESTS

POLY 3	P=0.279N
POLY 1.5	P=0.196N
POLY 6	P=0.426N
COCH-ARM / FISHERS	P=0.121N
MAX-ISO-POLY-3	P=0.180N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTEs	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

Skin
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma

TUMOR RATES	#	#
OVERALL (a)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	3/43.20	0/22.19
POLY-3 PERCENT (g)	7%	0%
TERMINAL (d)	2/31 (7%)	0/0 (0%)
FIRST INCIDENCE	607	---
HC TUMORS SAME ROUTE	3/100 (3%)	
HC TUMORS ALL ROUTES	31/1300 (2%)	

STATISTICAL TESTS

POLY 3	P=0.279N
POLY 1.5	P=0.196N
POLY 6	P=0.426N
COCH-ARM / FISHERS	P=0.121N
MAX-ISO-POLY-3	P=0.180N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
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 PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE 0 MG/KG 150 MG/KG Stop

Skin
Keratoacanthoma

TUMOR RATES	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.78	1/22.67
POLY-3 PERCENT (g)	0%	4.4%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	586
HC TUMORS SAME ROUTE	0/100 (0%)	
HC TUMORS ALL ROUTES	10/1300 (1%)	

STATISTICAL TESTS

POLY 3	P=0.384
POLY 1.5	P=0.434
POLY 6	P=0.320
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.156
HISTCONT SAME RTE	P=0.211
HISTCONT ALL RTES	P=0.186

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS

Females

DOSE 0 MG/KG 150 MG/KG Stop

Skin
Schwannoma Malignant

TUMOR 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	---	---
HC TUMORS SAME ROUTE	0/100 (0%)	
HC TUMORS ALL ROUTES	3/1300 (0%)	

STATISTICAL TESTS

POLY 3	(e)
POLY 1.5	(e)
POLY 6	(e)
COCH-ARM / FISHERS	(e)
MAX-ISO-POLY-3	(e)
HISTCONT SAME RTE	(e)
HISTCONT ALL RTES	(e)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

Skin
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma

TUMOR RATES	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/42.78	2/22.91
POLY-3 PERCENT (g)	2.3%	8.7%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	586
HC TUMORS SAME ROUTE	0/100 (0%)	
HC TUMORS ALL ROUTES	17/1300 (1%)	

STATISTICAL TESTS

POLY 3	P=0.304
POLY 1.5	P=0.386
POLY 6	P=0.208
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.192
HISTCONT SAME RTE	P=0.191
HISTCONT ALL RTES	P=0.119

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

Skin
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma

TUMOR RATES	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/42.78	2/22.91
POLY-3 PERCENT (g)	2.3%	8.7%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	586
HC TUMORS SAME ROUTE	0/100 (0%)	
HC TUMORS ALL ROUTES	14/1300 (1%)	

STATISTICAL TESTS

POLY 3	P=0.304
POLY 1.5	P=0.386
POLY 6	P=0.208
COCH-ARM / FISHERS	P=0.500
MAX-ISO-POLY-3	P=0.192
HISTCONT SAME RTE	P=0.191
HISTCONT ALL RTEs	P=0.115

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

**Spleen
Hemangiosarcoma**

TUMOR RATES

OVERALL (a)	2/50 (4%)	0/46 (0%)
POLY-3 RATE (b)	2/43.41	0/20.85
POLY-3 PERCENT (g)	4.6%	0%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	519	---
HC TUMORS SAME ROUTE	0/100 (0%)	
HC TUMORS ALL ROUTES	1/1293 (0%)	

STATISTICAL TESTS

POLY 3	P=0.419N
POLY 1.5	P=0.342N
POLY 6	P=0.533N
COCH-ARM / FISHERS	P=0.269N
MAX-ISO-POLY-3	P=0.240N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
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 PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

**Thyroid Gland: C-Cell
Adenoma**

TUMOR RATES

OVERALL (a)	8/50 (16%)	0/49 (0%)
POLY-3 RATE (b)	8/42.78	0/22.06
POLY-3 PERCENT (g)	18.7%	0%
TERMINAL (d)	8/31 (26%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	---
HC TUMORS SAME ROUTE	12/100 (12%)	
HC TUMORS ALL ROUTES	128/1288 (10%)	

STATISTICAL TESTS

POLY 3	P=0.050N*
POLY 1.5	P=0.017N*
POLY 6	P=0.177N
COCH-ARM / FISHERS	P=0.003N**
MAX-ISO-POLY-3	P=0.053N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTEs	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

**Urinary Bladder
Carcinoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	2/47 (4%)
POLY-3 RATE (b)	0/42.78	2/22.70
POLY-3 PERCENT (g)	0%	8.8%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	390
HC TUMORS SAME ROUTE	0/100 (0%)	
HC TUMORS ALL ROUTES	0/1297 (0%)	

STATISTICAL TESTS

POLY 3	P=0.129
POLY 1.5	P=0.165
POLY 6	P=0.092
COCH-ARM / FISHERS	P=0.232
MAX-ISO-POLY-3	P=0.069
HISTCONT SAME RTE	P=0.097
HISTCONT ALL RTES	P=0.002**

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

**Urinary Bladder
Carcinoma or Papilloma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	5/47 (11%)
POLY-3 RATE (b)	0/42.78	5/24.04
POLY-3 PERCENT (g)	0%	20.8%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	390
HC TUMORS SAME ROUTE	0/100 (0%)	
HC TUMORS ALL ROUTES	0/1297 (0%)	

STATISTICAL TESTS

POLY 3	P=0.005**
POLY 1.5	P=0.011*
POLY 6	P=0.002**
COCH-ARM / FISHERS	P=0.024*
MAX-ISO-POLY-3	P=0.007**
HISTCONT SAME RTE	P=0.008**
HISTCONT ALL RTEs	P<0.001**

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

**Urinary Bladder
Papilloma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	3/47 (6%)
POLY-3 RATE (b)	0/42.78	3/22.63
POLY-3 PERCENT (g)	0%	13.3%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	---	578
HC TUMORS SAME ROUTE	0/100 (0%)	
HC TUMORS ALL ROUTES	0/1297 (0%)	

STATISTICAL TESTS

POLY 3	P=0.044*
POLY 1.5	P=0.065
POLY 6	P=0.026*
COCH-ARM / FISHERS	P=0.110
MAX-ISO-POLY-3	P=0.033*
HISTCONT SAME RTE	P=0.044*
HISTCONT ALL RTEs	P=0.002**

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Pulegone
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

Uterus
Polyp Stromal

TUMOR RATES	#	#
OVERALL (a)	5/50 (10%)	2/50 (4%)
POLY-3 RATE (b)	5/42.91	2/23.21
POLY-3 PERCENT (g)	11.7%	8.6%
TERMINAL (d)	4/31 (13%)	0/0 (0%)
FIRST INCIDENCE	693	538
HC TUMORS SAME ROUTE	16/100 (16%)	
HC TUMORS ALL ROUTES	236/1300 (18%)	

STATISTICAL TESTS

POLY 3	P=0.513N
POLY 1.5	P=0.370N
POLY 6	P=0.573
COCH-ARM / FISHERS	P=0.218N
MAX-ISO-POLY-3	P=0.386N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
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 PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

All Organs
Hemangiosarcoma

TUMOR RATES	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/43.41	0/22.19
POLY-3 PERCENT (g)	4.6%	0%
TERMINAL (d)	1/31 (3%)	0/0 (0%)
FIRST INCIDENCE	519	---
HC TUMORS SAME ROUTE	0/100 (0%)	
HC TUMORS ALL ROUTES	4/1300 (0%)	

STATISTICAL TESTS

POLY 3	P=0.405N
POLY 1.5	P=0.325N
POLY 6	P=0.524N
COCH-ARM / FISHERS	P=0.247N
MAX-ISO-POLY-3	P=0.231N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

All Organs
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated

TUMOR RATES	#	#
OVERALL (a)	4/50 (8%)	9/50 (18%)
POLY-3 RATE (b)	4/42.99	9/26.54
POLY-3 PERCENT (g)	9.3%	33.9%
TERMINAL (d)	3/31 (10%)	0/0 (0%)
FIRST INCIDENCE	672	450
HC TUMORS SAME ROUTE	13/100 (13%)	
HC TUMORS ALL ROUTES	293/1300 (23%)	

STATISTICAL TESTS

POLY 3	P=0.014*
POLY 1.5	P=0.038*
POLY 6	P=0.002**
COCH-ARM / FISHERS	P=0.117
MAX-ISO-POLY-3	P=0.018*
HISTCONT SAME RTE	P=0.024*
HISTCONT ALL RTES	P=0.019*

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
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Lab: BAT

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

All Organs
Mesothelioma: Benign, Malignant, NOS

TUMOR RATES	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/43.27	0/22.19
POLY-3 PERCENT (g)	2.3%	0%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	581	---
HC TUMORS SAME ROUTE	1/100 (1%)	
HC TUMORS ALL ROUTES	4/1300 (0%)	

STATISTICAL TESTS

POLY 3	P=0.621N
POLY 1.5	P=0.569N
POLY 6	P=0.685N
COCH-ARM / FISHERS	P=0.500N
MAX-ISO-POLY-3	P=0.302N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

All Organs
Mesothelioma: Malignant

TUMOR RATES	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/43.27	0/22.19
POLY-3 PERCENT (g)	2.3%	0%
TERMINAL (d)	0/31 (0%)	0/0 (0%)
FIRST INCIDENCE	581	---
HC TUMORS SAME ROUTE	1/100 (1%)	
HC TUMORS ALL ROUTES	3/1300 (0%)	

STATISTICAL TESTS

POLY 3	P=0.621N
POLY 1.5	P=0.569N
POLY 6	P=0.685N
COCH-ARM / FISHERS	P=0.500N
MAX-ISO-POLY-3	P=0.302N
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 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 PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

All Organs
 Benign Tumors

TUMOR RATES	#	#
OVERALL (a)	42/50 (84%)	12/50 (24%)
POLY-3 RATE (b)	42/47.50	12/27.35
POLY-3 PERCENT (g)	88.4%	43.9%
TERMINAL (d)	27/31 (87%)	0/0 (0%)
FIRST INCIDENCE	495	470
HC TUMORS SAME ROUTE	81/100 (81%)	
HC TUMORS ALL ROUTES	1133/1300 (87%)	

STATISTICAL TESTS

POLY 3	P<0.001N**
POLY 1.5	P<0.001N**
POLY 6	P=0.004N**
COCH-ARM / FISHERS	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**
HISTCONT SAME RTE	(h)
HISTCONT ALL RTES	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Pulegone
 CAS Number: 89-82-7

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

**All Organs
 Malignant Tumors**

TUMOR RATES	#	#
OVERALL (a)	8/50 (16%)	11/50 (22%)
POLY-3 RATE (b)	8/44.72	11/27.95
POLY-3 PERCENT (g)	17.9%	39.4%
TERMINAL (d)	4/31 (13%)	0/0 (0%)
FIRST INCIDENCE	519	390
HC TUMORS SAME ROUTE	29/100 (29%)	
HC TUMORS ALL ROUTES	485/1300 (37%)	

STATISTICAL TESTS

POLY 3	P=0.042*
POLY 1.5	P=0.115
POLY 6	P=0.007**
COCH-ARM / FISHERS	P=0.306
MAX-ISO-POLY-3	P=0.048*
HISTCONT SAME RTE	P=0.065
HISTCONT ALL RTES	P=0.052

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

Date Report Requested: 08/25/2009
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

Females

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

All Organs
Malignant and Benign Tumors

TUMOR RATES	#	#
OVERALL (a)	44/50 (88%)	20/50 (40%)
POLY-3 RATE (b)	44/48.74	20/32.27
POLY-3 PERCENT (g)	90.3%	62%
TERMINAL (d)	27/31 (87%)	0/0 (0%)
FIRST INCIDENCE	495	390
HC TUMORS SAME ROUTE	91/100 (91%)	
HC TUMORS ALL ROUTES	1225/1300 (94%)	

STATISTICAL TESTS

POLY 3	P<0.001N**
POLY 1.5	P<0.001N**
POLY 6	P=0.059N
COCH-ARM / FISHERS	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**
HISTCONT SAME RTE	(h)
HISTCONT ALL RTEs	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
Pulegone
CAS Number: 89-82-7

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LEGEND

- (a) Number of tumor-bearing animals/number of animals examined at site.
- (b) Number of tumor-bearing animals/Poly-3 number
- (d) Observed incidence at terminal kill.
- (e) Value of Statistic cannot be computed.
- (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
- (g) Poly-3 adjusted lifetime tumor incidence.
- (h) Value of Historical Controls statistic is only calculated when Poly-3 trend is positive and when there is more than one tumor in the treatment groups.
- (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 ***