

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Pulegone
CAS Number: 89-82-7

Date Report Requested: 05/21/2008
Time Report Requested: 09:15:32
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

F1_R2

C Number: C99020
Lock Date: 01/06/2006
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.0.0

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HISTORICAL CONTROL STUDIES From October 2007 Report

SAME ROUTE

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

ALL ROUTES

88138-03 -- Benzophenone (ORAL FEED)
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)
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)
92012-05 -- 2-Methylimidazole (ORAL FEED)
92013-05 -- 4-Methylimidazole (ORAL FEED)
88006-03 -- alpha-Methylstyrene (INHALATION AIR)
99023-03 -- beta-Myrcene (GAVAGE CORN OIL)
97008-05 -- Propargyl alcohol (INHALATION AIR)
20114-07 -- Sodium dichromate dihydrate (VI) (ORAL WATER)
96001-05 -- Stoddard solvent (type IIC) (INHALATION AIR)
96019-05 -- Water disinfection byproducts (Bromochloroacetic acid) (ORAL WATER)
96018-03 -- Water disinfection byproducts (Bromodichloromethane) (ORAL WATER)
96017-05 -- Water disinfection byproducts (Dibromoacetic acid) (ORAL WATER)
96015-05 -- Water disinfection byproducts (Dibromoacetonitrile) (ORAL WATER)

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HISTORICAL CONTROL STUDIES
From October 2007 Report

96010-03 -- Water disinfection byproducts (Sodium chlorate) (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
Ovary
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

Lung

Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva)

Pituitary Gland: Pars Distalis or Unspecified Site
Skin

Testes
Thyroid Gland: Follicular Cell
Tongue
All Organs

Morphology

Pheochromocytoma Benign
Pheochromocytoma Malignant
Pheochromocytoma: Benign, Complex, Malignant, NOS
Alveolar/Bronchiolar Adenoma
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma
Papilloma Squamous or Papilloma

Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma
Adenoma

Basal Cell Carcinoma
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous
Tumor (malignant or NOS), or Carcinoma

Squamous Cell Papilloma, Papilloma, or Keratoacanthoma
Adenoma

Adenoma
Squamous Cell Papilloma
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated
Mesothelioma: Benign
Malignant Tumors

FEMALE RATS

Organ

Mammary Gland

Pituitary Gland: Pars Distalis or Unspecified Site
Skin

Thyroid Gland: C-Cell

Morphology

Fibroadenoma
Fibroma, Fibroadenoma or Adenoma
Fibroma, Fibroadenoma, Carcinoma, or Adenoma
Adenoma
Fibroma
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous
Histiocytoma
Lipoma
Adenoma

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

Urinary Bladder

Carcinoma
Carcinoma or Papilloma
Papilloma

All Organs

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)
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Adrenal Cortex
 Adenoma**

TUMOR RATES

OVERALL (a)	2/100 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/65.86	0/43.06	1/43.38
POLY-3 PERCENT (g)	3%	0%	2.3%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	692	---	727 (T)
HC TUMORS SAME RTE	1/100 (1%)		
HC TUMORS ALL RTES	6/1197 (1%)		

STATISTICAL TESTS

POLY 3	P=0.533N	P=0.331N	P=0.647N
POLY 1.5	P=0.543N	P=0.357N	P=0.678N
POLY 6	P=0.528N	P=0.308N	P=0.620N
COCH-ARM / FISHERS	P=0.570N	P=0.443N	P=0.707
MAX-ISO-POLY-3	P=0.350N	P=0.127N	P=0.408N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)

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

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

**Adrenal Medulla
 Pheochromocytoma Benign**

TUMOR RATES

OVERALL (a)	10/100 (10%)	13/50 (26%)	12/50 (24%)
POLY-3 RATE (b)	10/65.8	13/43.83	12/44.44
POLY-3 PERCENT (g)	15.2%	29.7%	27%
TERMINAL (d)	8/41 (20%)	10/32 (31%)	7/28 (25%)
FIRST INCIDENCE	699	611	608
HC TUMORS SAME RTE	16/100 (16%)		
HC TUMORS ALL RTES	181/1196 (15%)		

STATISTICAL TESTS

POLY 3	P=0.084	P=0.048*	P=0.090
POLY 1.5	P=0.042*	P=0.026*	P=0.054
POLY 6	P=0.146	P=0.086	P=0.143
COCH-ARM / FISHERS	P=0.011*	P=0.012*	P=0.023*
MAX-ISO-POLY-3	P=0.071	P=0.031*	P=0.059
HISTCONT SAME RTE	P=0.096	P=0.042*	P=0.082
HISTCONT ALL RTES	P=0.008**	P=0.032*	P=0.066

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

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

Adrenal Medulla
Pheochromocytoma Malignant

TUMOR RATES

OVERALL (a)	0/100 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/65.62	2/43.6	1/43.38
POLY-3 PERCENT (g)	0%	4.6%	2.3%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	---	638	727 (T)
HC TUMORS SAME RTE	5/100 (5%)		
HC TUMORS ALL RTES	27/1196 (2%)		

STATISTICAL TESTS

POLY 3	P=0.305	P=0.145	P=0.415
POLY 1.5	P=0.260	P=0.127	P=0.396
POLY 6	P=0.350	P=0.166	P=0.432
COCH-ARM / FISHERS	P=0.190	P=0.110	P=0.333
MAX-ISO-POLY-3	P=0.149	P=0.039*	P=0.109
HISTCONT SAME RTE	P=0.202	P=0.053	P=0.154
HISTCONT ALL RTES	P=0.170	P=0.042*	P=0.127

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 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Adrenal Medulla
 Pheochromocytoma: Benign, Complex, Malignant, NOS**

TUMOR RATES

OVERALL (a)	10/100 (10%)	15/50 (30%)	13/50 (26%)
POLY-3 RATE (b)	10/65.8	15/44.37	13/44.44
POLY-3 PERCENT (g)	15.2%	33.8%	29.3%
TERMINAL (d)	8/41 (20%)	10/32 (31%)	8/28 (29%)
FIRST INCIDENCE	699	611	608
HC TUMORS SAME RTE	20/100 (20%)		
HC TUMORS ALL RTES	209/1196 (18%)		

STATISTICAL TESTS

POLY 3	P=0.051	P=0.015*	P=0.052
POLY 1.5	P=0.022*	P=0.006**	P=0.029*
POLY 6	P=0.100	P=0.033*	P=0.090
COCH-ARM / FISHERS	P=0.005**	P=0.003**	P=0.012*
MAX-ISO-POLY-3	P=0.032*	P=0.009**	P=0.033*
HISTCONT SAME RTE	P=0.042*	P=0.011*	P=0.045*
HISTCONT ALL RTES	P=0.013*	P=0.009**	P=0.035*

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 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Clitoral/Preputial Gland
 Adenoma**

TUMOR RATES

OVERALL (a)	4/100 (4%)	5/50 (10%)	2/50 (4%)
POLY-3 RATE (b)	4/66.57	5/44.14	2/43.39
POLY-3 PERCENT (g)	6%	11.3%	4.6%
TERMINAL (d)	2/41 (5%)	2/32 (6%)	1/28 (4%)
FIRST INCIDENCE	497	451	724
HC TUMORS SAME RTE	7/100 (7%)		
HC TUMORS ALL RTES	43/1193 (4%)		

STATISTICAL TESTS

POLY 3	P=0.498N	P=0.252	P=0.546N
POLY 1.5	P=0.562N	P=0.203	P=0.591N
POLY 6	P=0.446N	P=0.306	P=0.508N
COCH-ARM / FISHERS	P=0.463	P=0.138	P=0.653
MAX-ISO-POLY-3	P=0.347N	P=0.158	P=0.376N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)

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

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

**Clitoral/Preputial Gland
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	5/100 (5%)	5/50 (10%)	2/50 (4%)
POLY-3 RATE (b)	5/66.57	5/44.14	2/43.39
POLY-3 PERCENT (g)	7.5%	11.3%	4.6%
TERMINAL (d)	3/41 (7%)	2/32 (6%)	1/28 (4%)
FIRST INCIDENCE	497	451	724
HC TUMORS SAME RTE	9/100 (9%)		
HC TUMORS ALL RTES	57/1193 (5%)		

STATISTICAL TESTS

POLY 3	P=0.382N	P=0.360	P=0.415N
POLY 1.5	P=0.445N	P=0.298	P=0.463N
POLY 6	P=0.332N	P=0.425	P=0.374N
COCH-ARM / FISHERS	P=0.571	P=0.206	P=0.571N
MAX-ISO-POLY-3	P=0.289N	P=0.247	P=0.274N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)

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

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

**Islets, Pancreatic
 Adenoma**

TUMOR RATES

OVERALL (a)	2/100 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/65.97	0/43.06	0/43.38
POLY-3 PERCENT (g)	3%	0%	0%
TERMINAL (d)	1/41 (2%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	627	---	---
HC TUMORS SAME RTE	6/100 (6%)		
HC TUMORS ALL RTES	73/1194 (6%)		

STATISTICAL TESTS

POLY 3	P=0.179N	P=0.332N	P=0.330N
POLY 1.5	P=0.183N	P=0.357N	P=0.354N
POLY 6	P=0.178N	P=0.309N	P=0.310N
COCH-ARM / FISHERS	P=0.196N	P=0.443N	P=0.443N
MAX-ISO-POLY-3	P=0.127N	P=0.127N	P=0.126N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Kidney: Renal Tubule
 Adenoma**

TUMOR RATES

OVERALL (a)	3/100 (3%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	3/66.11	0/43.06	2/43.59
POLY-3 PERCENT (g)	4.5%	0%	4.6%
TERMINAL (d)	1/41 (2%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	650	---	673
HC TUMORS SAME RTE	0/100 (0%)		
HC TUMORS ALL RTES	5/1190 (0%)		

STATISTICAL TESTS

POLY 3	P=0.605N	P=0.199N	P=0.680
POLY 1.5	P=0.612	P=0.223N	P=0.640
POLY 6	P=0.595N	P=0.179N	P=0.654N
COCH-ARM / FISHERS	P=0.554	P=0.293N	P=0.541
MAX-ISO-POLY-3	P=0.371N	P=0.080N	P=0.494
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Kidney: Renal Tubule
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	3/100 (3%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	3/66.11	1/43.41	2/43.59
POLY-3 PERCENT (g)	4.5%	2.3%	4.6%
TERMINAL (d)	1/41 (2%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	650	632	673
HC TUMORS SAME RTE	0/100 (0%)		
HC TUMORS ALL RTES	7/1190 (1%)		

STATISTICAL TESTS

POLY 3	P=0.607N	P=0.464N	P=0.680
POLY 1.5	P=0.578	P=0.504N	P=0.640
POLY 6	P=0.585N	P=0.425N	P=0.654N
COCH-ARM / FISHERS	P=0.500	P=0.593N	P=0.541
MAX-ISO-POLY-3	P=0.533N	P=0.273N	P=0.494
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 104 WEEKS**

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

Liver
 Hepatocellular Adenoma

TUMOR RATES

OVERALL (a)	2/100 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/66.16	0/43.06	1/43.38
POLY-3 PERCENT (g)	3%	0%	2.3%
TERMINAL (d)	1/41 (2%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	561	---	727 (T)
HC TUMORS SAME RTE	1/100 (1%)		
HC TUMORS ALL RTES	10/1199 (1%)		

STATISTICAL TESTS

POLY 3	P=0.533N	P=0.333N	P=0.649N
POLY 1.5	P=0.543N	P=0.357N	P=0.679N
POLY 6	P=0.528N	P=0.310N	P=0.622N
COCH-ARM / FISHERS	P=0.570N	P=0.443N	P=0.707
MAX-ISO-POLY-3	P=0.352N	P=0.128N	P=0.410N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)

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

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

Lung
Alveolar/Bronchiolar Adenoma

TUMOR RATES

OVERALL (a)	0/100 (0%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	0/65.62	1/43.06	3/43.38
POLY-3 PERCENT (g)	0%	2.3%	6.9%
TERMINAL (d)	0/41 (0%)	1/32 (3%)	3/28 (11%)
FIRST INCIDENCE	---	727 (T)	727 (T)
HC TUMORS SAME RTE	6/100 (6%)		
HC TUMORS ALL RTES	31/1199 (3%)		

STATISTICAL TESTS

POLY 3	P=0.031*	P=0.413	P=0.052
POLY 1.5	P=0.024*	P=0.393	P=0.043*
POLY 6	P=0.037*	P=0.433	P=0.062
COCH-ARM / FISHERS	P=0.017*	P=0.333	P=0.036*
MAX-ISO-POLY-3	P=0.019*	P=0.109	P=0.015*
HISTCONT SAME RTE	P=0.025*	P=0.154	P=0.019*
HISTCONT ALL RTES	P=0.021*	P=0.127	P=0.015*

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**Lung
 Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma**

TUMOR RATES

OVERALL (a)	1/100 (1%)	2/50 (4%)	4/50 (8%)
POLY-3 RATE (b)	1/65.62	2/43.14	4/43.38
POLY-3 PERCENT (g)	1.5%	4.6%	9.2%
TERMINAL (d)	1/41 (2%)	1/32 (3%)	4/28 (14%)
FIRST INCIDENCE	727 (T)	709	727 (T)
HC TUMORS SAME RTE	7/100 (7%)		
HC TUMORS ALL RTES	46/1199 (4%)		

STATISTICAL TESTS

POLY 3	P=0.052	P=0.352	P=0.071
POLY 1.5	P=0.040*	P=0.319	P=0.057
POLY 6	P=0.065	P=0.386	P=0.087
COCH-ARM / FISHERS	P=0.024*	P=0.258	P=0.043*
MAX-ISO-POLY-3	P=0.043*	P=0.169	P=0.029*
HISTCONT SAME RTE	P=0.057	P=0.237	P=0.039*
HISTCONT ALL RTES	P=0.047*	P=0.201	P=0.030*

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**Mammary Gland
 Adenoma**

TUMOR RATES	#	#	#
OVERALL (a)	0/100 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/65.62	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME RTE	0/100 (0%)		
HC TUMORS ALL RTES	5/1199 (0%)		

STATISTICAL TESTS

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

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

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

Date Report Requested: 05/21/2008
Time Report Requested: 09:15:32
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

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

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

Mammary Gland
Carcinoma or Adenoma

TUMOR RATES	#	#	#
OVERALL (a)	0/100 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/65.62	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME RTE	0/100 (0%)		
HC TUMORS ALL RTES	13/1199 (1%)		

STATISTICAL TESTS

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

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**Mammary Gland
 Fibroadenoma**

TUMOR RATES	#	#	#
OVERALL (a)	2/100 (2%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	2/66.43	3/43.17	1/43.64
POLY-3 PERCENT (g)	3%	7%	2.3%
TERMINAL (d)	0/41 (0%)	2/32 (6%)	0/28 (0%)
FIRST INCIDENCE	587	701	659
HC TUMORS SAME RTE	4/100 (4%)		
HC TUMORS ALL RTES	43/1199 (4%)		

STATISTICAL TESTS

POLY 3	P=0.558N	P=0.305	P=0.648N
POLY 1.5	P=0.605N	P=0.267	P=0.678N
POLY 6	P=0.517N	P=0.342	P=0.621N
COCH-ARM / FISHERS	P=0.500	P=0.207	P=0.707
MAX-ISO-POLY-3	P=0.389N	P=0.171	P=0.409N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**Mammary Gland
 Fibroma, Fibroadenoma or Adenoma**

TUMOR RATES	#	#	#
OVERALL (a)	2/100 (2%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	2/66.43	3/43.17	1/43.64
POLY-3 PERCENT (g)	3%	7%	2.3%
TERMINAL (d)	0/41 (0%)	2/32 (6%)	0/28 (0%)
FIRST INCIDENCE	587	701	659
HC TUMORS SAME RTE	4/100 (4%)		
HC TUMORS ALL RTES	49/1199 (4%)		

STATISTICAL TESTS

POLY 3	P=0.558N	P=0.305	P=0.648N
POLY 1.5	P=0.605N	P=0.267	P=0.678N
POLY 6	P=0.517N	P=0.342	P=0.621N
COCH-ARM / FISHERS	P=0.500	P=0.207	P=0.707
MAX-ISO-POLY-3	P=0.389N	P=0.171	P=0.409N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

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

TUMOR RATES	#	#	#
OVERALL (a)	2/100 (2%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	2/66.43	3/43.17	1/43.64
POLY-3 PERCENT (g)	3%	7%	2.3%
TERMINAL (d)	0/41 (0%)	2/32 (6%)	0/28 (0%)
FIRST INCIDENCE	587	701	659
HC TUMORS SAME RTE	4/100 (4%)		
HC TUMORS ALL RTES	55/1199 (5%)		

STATISTICAL TESTS

POLY 3	P=0.558N	P=0.305	P=0.648N
POLY 1.5	P=0.605N	P=0.267	P=0.678N
POLY 6	P=0.517N	P=0.342	P=0.621N
COCH-ARM / FISHERS	P=0.500	P=0.207	P=0.707
MAX-ISO-POLY-3	P=0.389N	P=0.171	P=0.409N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva)
 Papilloma Squamous or Papilloma**

TUMOR RATES	#	#	#
OVERALL (a)	0/100 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/65.62	1/43.06	2/43.39
POLY-3 PERCENT (g)	0%	2.3%	4.6%
TERMINAL (d)	0/41 (0%)	1/32 (3%)	1/28 (4%)
FIRST INCIDENCE	---	727 (T)	725
HC TUMORS SAME RTE	1/100 (1%)		
HC TUMORS ALL RTES	5/1199 (0%)		

STATISTICAL TESTS

POLY 3	P=0.096	P=0.413	P=0.144
POLY 1.5	P=0.080	P=0.393	P=0.128
POLY 6	P=0.111	P=0.433	P=0.160
COCH-ARM / FISHERS	P=0.057	P=0.333	P=0.110
MAX-ISO-POLY-3	P=0.065	P=0.109	P=0.039*
HISTCONT SAME RTE	P=0.088	P=0.154	P=0.053
HISTCONT ALL RTES	P<0.001**	P=0.109	P=0.008**

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva)
 Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma**

TUMOR RATES	#	#	#
OVERALL (a)	0/100 (0%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	0/65.62	2/43.06	2/43.39
POLY-3 PERCENT (g)	0%	4.6%	4.6%
TERMINAL (d)	0/41 (0%)	2/32 (6%)	1/28 (4%)
FIRST INCIDENCE	---	727 (T)	725
HC TUMORS SAME RTE	2/100 (2%)		
HC TUMORS ALL RTES	8/1199 (1%)		

STATISTICAL TESTS

POLY 3	P=0.121	P=0.143	P=0.144
POLY 1.5	P=0.097	P=0.126	P=0.128
POLY 6	P=0.146	P=0.161	P=0.160
COCH-ARM / FISHERS	P=0.064	P=0.110	P=0.110
MAX-ISO-POLY-3	P=0.101	P=0.039*	P=0.039*
HISTCONT SAME RTE	P=0.137	P=0.053	P=0.053
HISTCONT ALL RTES	P=0.002**	P=0.019*	P=0.019*

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**Pancreas
 Adenoma**

TUMOR RATES

OVERALL (a)	2/100 (2%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	2/65.62	3/43.06	0/43.38
POLY-3 PERCENT (g)	3.1%	7%	0%
TERMINAL (d)	2/41 (5%)	3/32 (9%)	0/28 (0%)
FIRST INCIDENCE	727 (T)	727 (T)	---
HC TUMORS SAME RTE	8/100 (8%)		
HC TUMORS ALL RTES	21/1191 (2%)		

STATISTICAL TESTS

POLY 3	P=0.307N	P=0.309	P=0.329N
POLY 1.5	P=0.353N	P=0.269	P=0.353N
POLY 6	P=0.269N	P=0.350	P=0.307N
COCH-ARM / FISHERS	P=0.446N	P=0.207	P=0.443N
MAX-ISO-POLY-3	P=0.135N	P=0.173	P=0.124N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**Parathyroid Gland
 Adenoma**

TUMOR RATES

OVERALL (a)	1/97 (1%)	0/44 (0%)	0/45 (0%)
POLY-3 RATE (b)	1/64.12	0/37.96	0/38.65
POLY-3 PERCENT (g)	1.6%	0%	0%
TERMINAL (d)	1/40 (3%)	0/28 (0%)	0/25 (0%)
FIRST INCIDENCE	727 (T)	---	---
HC TUMORS SAME RTE	1/92 (1%)		
HC TUMORS ALL RTES	5/1139 (0%)		

STATISTICAL TESTS

POLY 3	P=0.391N	P=0.608N	P=0.604N
POLY 1.5	P=0.391N	P=0.627N	P=0.622N
POLY 6	P=0.394N	P=0.588N	P=0.589N
COCH-ARM / FISHERS	P=0.395N	P=0.688N	P=0.683N
MAX-ISO-POLY-3	P=0.269N	P=0.227N	P=0.225N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

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

TUMOR RATES

OVERALL (a)	12/100 (12%)	14/50 (28%)	17/50 (34%)
POLY-3 RATE (b)	12/66.04	14/44.18	17/45.21
POLY-3 PERCENT (g)	18.2%	31.7%	37.6%
TERMINAL (d)	10/41 (24%)	10/32 (31%)	10/28 (36%)
FIRST INCIDENCE	650	580	594
HC TUMORS SAME RTE	25/100 (25%)		
HC TUMORS ALL RTES	541/1192 (45%)		

STATISTICAL TESTS

POLY 3	P=0.014*	P=0.069	P=0.014*
POLY 1.5	P=0.005**	P=0.037*	P=0.005**
POLY 6	P=0.034*	P=0.124	P=0.032*
COCH-ARM / FISHERS	P<0.001**	P=0.015*	P=0.002**
MAX-ISO-POLY-3	P=0.014*	P=0.046*	P=0.008**
HISTCONT SAME RTE	P=0.018*	P=0.064	P=0.010**
HISTCONT ALL RTES	P=0.015*	P=0.050*	P=0.008**

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**Skin
 Basal Cell Adenoma**

TUMOR RATES	#	#	#
OVERALL (a)	1/100 (1%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/65.82	0/43.06	1/43.38
POLY-3 PERCENT (g)	1.5%	0%	2.3%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	673	---	727 (T)
HC TUMORS SAME RTE	0/100 (0%)		
HC TUMORS ALL RTES	12/1199 (1%)		

STATISTICAL TESTS

POLY 3	P=0.567	P=0.587N	P=0.670
POLY 1.5	P=0.545	P=0.607N	P=0.646
POLY 6	P=0.585	P=0.568N	P=0.690
COCH-ARM / FISHERS	P=0.500	P=0.667N	P=0.557
MAX-ISO-POLY-3	P=0.380	P=0.211N	P=0.382
HISTCONT SAME RTE	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**Skin
 Basal Cell Carcinoma**

TUMOR RATES	#	#	#
OVERALL (a)	0/100 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/65.62	2/43.06	0/43.38
POLY-3 PERCENT (g)	0%	4.6%	0%
TERMINAL (d)	0/41 (0%)	2/32 (6%)	0/28 (0%)
FIRST INCIDENCE	---	727 (T)	---
HC TUMORS SAME RTE	2/100 (2%)		
HC TUMORS ALL RTES	6/1199 (1%)		

STATISTICAL TESTS

POLY 3	P=0.656	P=0.143	(e)
POLY 1.5	P=0.601	P=0.126	(e)
POLY 6	P=0.687N	P=0.161	(e)
COCH-ARM / FISHERS	P=0.500	P=0.110	(e)
MAX-ISO-POLY-3	P=0.215	P=0.039*	(e)
HISTCONT SAME RTE	P=0.290	P=0.053	(e)
HISTCONT ALL RTES	P=0.250	P=0.022*	(e)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

Skin
 Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma

TUMOR RATES	#	#	#
OVERALL (a)	1/100 (1%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/65.82	2/43.06	1/43.38
POLY-3 PERCENT (g)	1.5%	4.6%	2.3%
TERMINAL (d)	0/41 (0%)	2/32 (6%)	1/28 (4%)
FIRST INCIDENCE	673	727 (T)	727 (T)
HC TUMORS SAME RTE	2/100 (2%)		
HC TUMORS ALL RTES	25/1199 (2%)		

STATISTICAL TESTS

POLY 3	P=0.522	P=0.350	P=0.670
POLY 1.5	P=0.472	P=0.318	P=0.646
POLY 6	P=0.565	P=0.382	P=0.690
COCH-ARM / FISHERS	P=0.380	P=0.258	P=0.557
MAX-ISO-POLY-3	P=0.380	P=0.168	P=0.382
HISTCONT SAME RTE	P=0.471	P=0.201	P=0.522
HISTCONT ALL RTES	P=0.454	P=0.200	P=0.485

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

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)	5/100 (5%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	5/65.82	3/43.06	2/43.5
POLY-3 PERCENT (g)	7.6%	7%	4.6%
TERMINAL (d)	4/41 (10%)	3/32 (9%)	1/28 (4%)
FIRST INCIDENCE	673	727 (T)	697
HC TUMORS SAME RTE	11/100 (11%)		
HC TUMORS ALL RTES	112/1199 (9%)		

STATISTICAL TESTS

POLY 3	P=0.348N	P=0.602N	P=0.407N
POLY 1.5	P=0.398N	P=0.643	P=0.459N
POLY 6	P=0.308N	P=0.548N	P=0.363N
COCH-ARM / FISHERS	P=0.500N	P=0.535	P=0.571N
MAX-ISO-POLY-3	P=0.381N	P=0.450N	P=0.267N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**Skin
 Fibroma**

TUMOR RATES	#	#	#
OVERALL (a)	3/100 (3%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	3/65.62	2/43.49	3/44.55
POLY-3 PERCENT (g)	4.6%	4.6%	6.7%
TERMINAL (d)	3/41 (7%)	1/32 (3%)	1/28 (4%)
FIRST INCIDENCE	727 (T)	605	455
HC TUMORS SAME RTE	8/100 (8%)		
HC TUMORS ALL RTES	121/1199 (10%)		

STATISTICAL TESTS

POLY 3	P=0.403	P=0.682	P=0.474
POLY 1.5	P=0.350	P=0.638	P=0.421
POLY 6	P=0.451	P=0.642N	P=0.524
COCH-ARM / FISHERS	P=0.257	P=0.541	P=0.317
MAX-ISO-POLY-3	P=0.430	P=0.496	P=0.311
HISTCONT SAME RTE	P=0.561	P=0.651	P=0.431
HISTCONT ALL RTES	P=0.520	P=0.627	P=0.390

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

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

TUMOR RATES	#	#	#
OVERALL (a)	4/100 (4%)	2/50 (4%)	4/50 (8%)
POLY-3 RATE (b)	4/66.16	2/43.49	4/44.66
POLY-3 PERCENT (g)	6.1%	4.6%	9%
TERMINAL (d)	3/41 (7%)	1/32 (3%)	1/28 (4%)
FIRST INCIDENCE	561	605	455
HC TUMORS SAME RTE	11/100 (11%)		
HC TUMORS ALL RTES	146/1199 (12%)		

STATISTICAL TESTS

POLY 3	P=0.355	P=0.542N	P=0.416
POLY 1.5	P=0.305	P=0.592N	P=0.357
POLY 6	P=0.401	P=0.492N	P=0.472
COCH-ARM / FISHERS	P=0.217	P=0.653	P=0.254
MAX-ISO-POLY-3	P=0.329	P=0.372N	P=0.280
HISTCONT SAME RTE	P=0.438	P=1.000	P=0.390
HISTCONT ALL RTES	P=0.392	P=1.000	P=0.350

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**Skin
 Keratoacanthoma**

TUMOR RATES	#	#	#
OVERALL (a)	3/100 (3%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	3/65.62	0/43.06	1/43.5
POLY-3 PERCENT (g)	4.6%	0%	2.3%
TERMINAL (d)	3/41 (7%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	727 (T)	---	697
HC TUMORS SAME RTE	9/100 (9%)		
HC TUMORS ALL RTES	71/1199 (6%)		

STATISTICAL TESTS

POLY 3	P=0.334N	P=0.198N	P=0.460N
POLY 1.5	P=0.347N	P=0.223N	P=0.499N
POLY 6	P=0.326N	P=0.176N	P=0.424N
COCH-ARM / FISHERS	P=0.380N	P=0.293N	P=0.593N
MAX-ISO-POLY-3	P=0.200N	P=0.078N	P=0.270N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**Skin
 Lipoma**

TUMOR RATES	#	#	#
OVERALL (a)	0/100 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/65.62	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME RTE	2/100 (2%)		
HC TUMORS ALL RTES	11/1199 (1%)		

STATISTICAL TESTS

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

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**Skin
 Schwannoma Malignant**

TUMOR RATES	#	#	#
OVERALL (a)	3/100 (3%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	3/66.15	2/43.28	1/43.7
POLY-3 PERCENT (g)	4.5%	4.6%	2.3%
TERMINAL (d)	0/41 (0%)	1/32 (3%)	0/28 (0%)
FIRST INCIDENCE	627	672	641
HC TUMORS SAME RTE	0/100 (0%)		
HC TUMORS ALL RTES	7/1199 (1%)		

STATISTICAL TESTS

POLY 3	P=0.383N	P=0.676	P=0.461N
POLY 1.5	P=0.421N	P=0.636	P=0.500N
POLY 6	P=0.352N	P=0.652N	P=0.428N
COCH-ARM / FISHERS	P=0.500N	P=0.541	P=0.593N
MAX-ISO-POLY-3	P=0.388N	P=0.491	P=0.271N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
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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)
 TERMINAL SACRIFICE AT 104 WEEKS**

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

Skin
 Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma

TUMOR RATES	#	#	#
OVERALL (a)	0/100 (0%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	0/65.62	3/43.06	0/43.38
POLY-3 PERCENT (g)	0%	7%	0%
TERMINAL (d)	0/41 (0%)	3/32 (9%)	0/28 (0%)
FIRST INCIDENCE	---	727 (T)	---
HC TUMORS SAME RTE	2/100 (2%)		
HC TUMORS ALL RTES	9/1199 (1%)		

STATISTICAL TESTS

POLY 3	P=0.616	P=0.051	(e)
POLY 1.5	P=0.549	P=0.042*	(e)
POLY 6	P=0.652N	P=0.062	(e)
COCH-ARM / FISHERS	P=0.430	P=0.036*	(e)
MAX-ISO-POLY-3	P=0.142	P=0.015*	(e)
HISTCONT SAME RTE	P=0.193	P=0.019*	(e)
HISTCONT ALL RTES	P=0.163	P=0.007**	(e)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

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

TUMOR RATES	#	#	#
OVERALL (a)	4/100 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	4/65.62	1/43.06	1/43.5
POLY-3 PERCENT (g)	6.1%	2.3%	2.3%
TERMINAL (d)	4/41 (10%)	1/32 (3%)	0/28 (0%)
FIRST INCIDENCE	727 (T)	727 (T)	697
HC TUMORS SAME RTE	9/100 (9%)		
HC TUMORS ALL RTES	91/1199 (8%)		

STATISTICAL TESTS

POLY 3	P=0.230N	P=0.322N	P=0.318N
POLY 1.5	P=0.254N	P=0.364N	P=0.358N
POLY 6	P=0.212N	P=0.283N	P=0.282N
COCH-ARM / FISHERS	P=0.309N	P=0.459N	P=0.459N
MAX-ISO-POLY-3	P=0.231N	P=0.181N	P=0.177N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
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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)
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Skin
 Squamous Cell Papilloma, Papilloma, or Keratoacanthoma**

TUMOR RATES	#	#	#
OVERALL (a)	4/100 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	4/65.62	0/43.06	1/43.5
POLY-3 PERCENT (g)	6.1%	0%	2.3%
TERMINAL (d)	4/41 (10%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	727 (T)	---	697
HC TUMORS SAME RTE	9/100 (9%)		
HC TUMORS ALL RTES	87/1199 (7%)		

STATISTICAL TESTS

POLY 3	P=0.201N	P=0.121N	P=0.318N
POLY 1.5	P=0.214N	P=0.143N	P=0.358N
POLY 6	P=0.194N	P=0.103N	P=0.282N
COCH-ARM / FISHERS	P=0.247N	P=0.194N	P=0.459N
MAX-ISO-POLY-3	P=0.113N	P=0.049N*	P=0.177N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
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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)
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Spleen
 Hemangiosarcoma**

TUMOR RATES

OVERALL (a)	0/100 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/65.62	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME RTE	1/100 (1%)		
HC TUMORS ALL RTES	4/1192 (0%)		

STATISTICAL TESTS

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

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**Testes
 Adenoma**

TUMOR RATES

OVERALL (a)	90/99 (91%)	45/50 (90%)	43/50 (86%)
POLY-3 RATE (b)	90/91.8	45/48.16	43/48.48
POLY-3 PERCENT (g)	98%	93.5%	88.7%
TERMINAL (d)	41/41 (100%)	29/32 (91%)	26/28 (93%)
FIRST INCIDENCE	360	451	455
HC TUMORS SAME RTE	93/100 (93%)		
HC TUMORS ALL RTES	1035/1199 (86%)		

STATISTICAL TESTS

POLY 3	P=0.009N**	P=0.150N	P=0.011N*
POLY 1.5	P=0.021N*	P=0.256N	P=0.028N*
POLY 6	P=0.008N**	P=0.091N	P=0.009N**
COCH-ARM / FISHERS	P=0.229N	P=0.536N	P=0.259N
MAX-ISO-POLY-3	P=0.012N*	P=0.082N	P=0.008N**
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**Thyroid Gland: C-Cell
 Adenoma**

TUMOR RATES

OVERALL (a)	9/97 (9%)	7/50 (14%)	4/44 (9%)
POLY-3 RATE (b)	9/66.07	7/43.49	4/39.18
POLY-3 PERCENT (g)	13.6%	16.1%	10.2%
TERMINAL (d)	4/41 (10%)	6/32 (19%)	2/28 (7%)
FIRST INCIDENCE	388	605	594
HC TUMORS SAME RTE	21/100 (21%)		
HC TUMORS ALL RTES	151/1185 (13%)		

STATISTICAL TESTS

POLY 3	P=0.387N	P=0.466	P=0.415N
POLY 1.5	P=0.467N	P=0.392	P=0.485N
POLY 6	P=0.318N	P=0.536	P=0.351N
COCH-ARM / FISHERS	P=0.494	P=0.273	P=0.625
MAX-ISO-POLY-3	P=0.377N	P=0.361	P=0.307N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
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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)
 TERMINAL SACRIFICE AT 104 WEEKS**

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

**Thyroid Gland: Follicular Cell
 Adenoma**

TUMOR RATES

OVERALL (a)	1/97 (1%)	4/50 (8%)	2/44 (5%)
POLY-3 RATE (b)	1/64.82	4/43.41	2/38.62
POLY-3 PERCENT (g)	1.5%	9.2%	5.2%
TERMINAL (d)	0/41 (0%)	3/32 (9%)	2/28 (7%)
FIRST INCIDENCE	605	632	727 (T)
HC TUMORS SAME RTE	2/100 (2%)		
HC TUMORS ALL RTES	15/1185 (1%)		

STATISTICAL TESTS

POLY 3	P=0.243	P=0.074	P=0.317
POLY 1.5	P=0.194	P=0.059	P=0.288
POLY 6	P=0.295	P=0.091	P=0.346
COCH-ARM / FISHERS	P=0.124	P=0.046*	P=0.230
MAX-ISO-POLY-3	P=0.138	P=0.031*	P=0.148
HISTCONT SAME RTE	P=0.187	P=0.041*	P=0.189
HISTCONT ALL RTES	P=0.005**	P=0.006**	P=0.079

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**Tongue
 Squamous Cell Papilloma**

TUMOR RATES	#	#	#
OVERALL (a)	0/100 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/65.62	1/43.06	2/43.39
POLY-3 PERCENT (g)	0%	2.3%	4.6%
TERMINAL (d)	0/41 (0%)	1/32 (3%)	1/28 (4%)
FIRST INCIDENCE	---	727 (T)	725
HC TUMORS SAME RTE	0/100 (0%)		
HC TUMORS ALL RTES	4/1199 (0%)		

STATISTICAL TESTS

POLY 3	P=0.096	P=0.413	P=0.144
POLY 1.5	P=0.080	P=0.393	P=0.128
POLY 6	P=0.111	P=0.433	P=0.160
COCH-ARM / FISHERS	P=0.057	P=0.333	P=0.110
MAX-ISO-POLY-3	P=0.065	P=0.109	P=0.039*
HISTCONT SAME RTE	P=0.088	P=0.129	P=0.053
HISTCONT ALL RTES	P<0.001**	P=0.078	P=0.005**

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**Urinary Bladder
 Carcinoma**

TUMOR RATES

OVERALL (a)	0/99 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/65.46	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME RTE	0/100 (0%)		
HC TUMORS ALL RTES	1/1194 (0%)		

STATISTICAL TESTS

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

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**Urinary Bladder
 Carcinoma or Papilloma**

TUMOR RATES

OVERALL (a)	0/99 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/65.46	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME RTE	1/100 (1%)		
HC TUMORS ALL RTES	4/1194 (0%)		

STATISTICAL TESTS

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

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

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

Date Report Requested: 05/21/2008
Time Report Requested: 09:15:32
First Dose M/F: 04/09/03 / 04/10/03
Lab: BAT

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

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

Urinary Bladder
Papilloma

TUMOR RATES

OVERALL (a)	0/99 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/65.46	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME RTE	1/100 (1%)		
HC TUMORS ALL RTEs	3/1194 (0%)		

STATISTICAL TESTS

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

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**All Organs
 Hemangiosarcoma**

TUMOR RATES	#	#	#
OVERALL (a)	0/100 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/65.62	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/41 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME RTE	1/100 (1%)		
HC TUMORS ALL RTES	6/1199 (1%)		

STATISTICAL TESTS

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

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

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

TUMOR RATES	#	#	#
OVERALL (a)	4/100 (4%)	6/50 (12%)	6/50 (12%)
POLY-3 RATE (b)	4/66.05	6/44.1	6/44.69
POLY-3 PERCENT (g)	6.1%	13.6%	13.4%
TERMINAL (d)	2/41 (5%)	4/32 (13%)	1/28 (4%)
FIRST INCIDENCE	627	199	598
HC TUMORS SAME RTE	19/100 (19%)		
HC TUMORS ALL RTES	465/1199 (39%)		

STATISTICAL TESTS

POLY 3	P=0.136	P=0.147	P=0.153
POLY 1.5	P=0.092	P=0.111	P=0.114
POLY 6	P=0.190	P=0.188	P=0.199
COCH-ARM / FISHERS	P=0.042*	P=0.070	P=0.070
MAX-ISO-POLY-3	P=0.145	P=0.087	P=0.090
HISTCONT SAME RTE	P=0.197	P=0.122	P=0.125
HISTCONT ALL RTES	P=0.166	P=0.100	P=0.102

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**All Organs
 Mesothelioma: Benign**

TUMOR RATES	#	#	#
OVERALL (a)	0/100 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/65.62	2/43.06	1/43.38
POLY-3 PERCENT (g)	0%	4.6%	2.3%
TERMINAL (d)	0/41 (0%)	2/32 (6%)	1/28 (4%)
FIRST INCIDENCE	---	727 (T)	727 (T)
HC TUMORS SAME RTE	0/100 (0%)		
HC TUMORS ALL RTES	1/1199 (0%)		

STATISTICAL TESTS

POLY 3	P=0.305	P=0.143	P=0.415
POLY 1.5	P=0.260	P=0.126	P=0.396
POLY 6	P=0.350	P=0.161	P=0.432
COCH-ARM / FISHERS	P=0.190	P=0.110	P=0.333
MAX-ISO-POLY-3	P=0.147	P=0.039*	P=0.109
HISTCONT SAME RTE	P=0.199	P=0.053	P=0.128
HISTCONT ALL RTES	P<0.001**	P<0.001**	P=0.006**

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**All Organs
 Mesothelioma: Benign, Malignant, NOS**

TUMOR RATES	#	#	#
OVERALL (a)	3/100 (3%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	3/65.93	2/43.06	2/43.38
POLY-3 PERCENT (g)	4.6%	4.6%	4.6%
TERMINAL (d)	1/41 (2%)	2/32 (6%)	2/28 (7%)
FIRST INCIDENCE	673	727 (T)	727 (T)
HC TUMORS SAME RTE	5/100 (5%)		
HC TUMORS ALL RTES	35/1199 (3%)		

STATISTICAL TESTS

POLY 3	P=0.598	P=0.676	P=0.679
POLY 1.5	P=0.549	P=0.635	P=0.640
POLY 6	P=0.579N	P=0.654N	P=0.656N
COCH-ARM / FISHERS	P=0.454	P=0.541	P=0.541
MAX-ISO-POLY-3	P=0.657	P=0.490	P=0.493
HISTCONT SAME RTE	P=0.798	P=0.644	P=0.648
HISTCONT ALL RTES	P=0.540	P=0.447	P=0.450

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**All Organs
 Mesothelioma: Malignant**

TUMOR RATES	#	#	#
OVERALL (a)	3/100 (3%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	3/65.93	0/43.06	1/43.38
POLY-3 PERCENT (g)	4.6%	0%	2.3%
TERMINAL (d)	1/41 (2%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	673	---	727 (T)
HC TUMORS SAME RTE	5/100 (5%)		
HC TUMORS ALL RTES	34/1199 (3%)		

STATISTICAL TESTS

POLY 3	P=0.335N	P=0.199N	P=0.463N
POLY 1.5	P=0.348N	P=0.223N	P=0.501N
POLY 6	P=0.327N	P=0.178N	P=0.430N
COCH-ARM / FISHERS	P=0.380N	P=0.293N	P=0.593N
MAX-ISO-POLY-3	P=0.203N	P=0.079N	P=0.273N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**All Organs
 Benign Tumors**

TUMOR RATES	#	#	#
OVERALL (a)	91/100 (91%)	48/50 (96%)	48/50 (96%)
POLY-3 RATE (b)	91/92.09	48/48.16	48/49.16
POLY-3 PERCENT (g)	98.8%	99.7%	97.6%
TERMINAL (d)	41/41 (100%)	32/32 (100%)	28/28 (100%)
FIRST INCIDENCE	360	451	455
HC TUMORS SAME RTE	98/100 (98%)		
HC TUMORS ALL RTES	1166/1199 (97%)		

STATISTICAL TESTS

POLY 3	P=0.449N	P=0.860	P=0.600N
POLY 1.5	P=0.593	P=0.420	P=0.756
POLY 6	P=0.255N	P=1.000	P=0.479N
COCH-ARM / FISHERS	P=0.130	P=0.224	P=0.224
MAX-ISO-POLY-3	P=0.230N	P=0.129	P=0.249N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**All Organs
 Malignant Tumors**

TUMOR RATES	#	#	#
OVERALL (a)	13/100 (13%)	16/50 (32%)	14/50 (28%)
POLY-3 RATE (b)	13/67.99	16/45.42	14/46.45
POLY-3 PERCENT (g)	19.1%	35.2%	30.1%
TERMINAL (d)	5/41 (12%)	9/32 (28%)	4/28 (14%)
FIRST INCIDENCE	394	199	465
HC TUMORS SAME RTE	52/100 (52%)		
HC TUMORS ALL RTES	686/1199 (57%)		

STATISTICAL TESTS

POLY 3	P=0.108	P=0.036*	P=0.117
POLY 1.5	P=0.050*	P=0.017*	P=0.065
POLY 6	P=0.199	P=0.068	P=0.193
COCH-ARM / FISHERS	P=0.010**	P=0.006**	P=0.023*
MAX-ISO-POLY-3	P=0.071	P=0.024*	P=0.080
HISTCONT SAME RTE	P=0.096	P=0.031*	P=0.112
HISTCONT ALL RTES	P=0.079	P=0.025*	P=0.091

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

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

**All Organs
 Malignant and Benign Tumors**

TUMOR RATES	#	#	#
OVERALL (a)	92/100 (92%)	49/50 (98%)	49/50 (98%)
POLY-3 RATE (b)	92/92.93	49/49.14	49/49.25
POLY-3 PERCENT (g)	99%	99.7%	99.5%
TERMINAL (d)	41/41 (100%)	32/32 (100%)	28/28 (100%)
FIRST INCIDENCE	360	199	455
HC TUMORS SAME RTE	100/100 (100%)		
HC TUMORS ALL RTES	1195/1199 (100%)		

STATISTICAL TESTS

POLY 3	P=0.628	P=0.913	P=0.938
POLY 1.5	P=0.263	P=0.441	P=0.508
POLY 6	P=1.000	P=1.000	P=1.000
COCH-ARM / FISHERS	P=0.059	P=0.135	P=0.135
MAX-ISO-POLY-3	P=0.263	P=0.146	P=0.258
HISTCONT SAME RTE	P=0.355	P=0.207	P=0.361
HISTCONT ALL RTES	P=0.310	P=0.174	P=0.320

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Adrenal Cortex
 Adenoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.4	0/22.06
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	17/1098 (2%)			

STATISTICAL TESTS

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

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Adrenal Medulla
 Pheochromocytoma Benign**

TUMOR RATES

OVERALL (a)	3/50 (6%)	1/50 (2%)	2/50 (4%)	0/49 (0%)
POLY-3 RATE (b)	3/42.78	1/45.81	2/47.5	0/22.06
POLY-3 PERCENT (g)	7%	2.2%	4.2%	0%
TERMINAL (d)	3/31 (10%)	1/37 (3%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	702	---
HC TUMORS SAME RTE	3/100 (3%)			
HC TUMORS ALL RTES	27/1091 (3%)			

STATISTICAL TESTS

POLY 3	P=0.210N	P=0.281N	P=0.452N	P=0.278N
POLY 1.5	P=0.157N	P=0.293N	P=0.472N	P=0.197N
POLY 6	P=0.284N	P=0.267N	P=0.426N	P=0.422N
COCH-ARM / FISHERS	P=0.106N	P=0.309N	P=0.500N	P=0.125N
MAX-ISO-POLY-3	P=0.290N	P=0.145N	P=0.292N	P=0.179N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Adrenal Medulla
 Pheochromocytoma Malignant**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.4	0/22.06
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	8/1091 (1%)			

STATISTICAL TESTS

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

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Adrenal Medulla
 Pheochromocytoma: Benign, Complex, Malignant, NOS**

TUMOR RATES

OVERALL (a)	3/50 (6%)	1/50 (2%)	2/50 (4%)	0/49 (0%)
POLY-3 RATE (b)	3/42.78	1/45.81	2/47.5	0/22.06
POLY-3 PERCENT (g)	7%	2.2%	4.2%	0%
TERMINAL (d)	3/31 (10%)	1/37 (3%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	702	---
HC TUMORS SAME RTE	3/100 (3%)			
HC TUMORS ALL RTES	36/1091 (3%)			

STATISTICAL TESTS

POLY 3	P=0.210N	P=0.281N	P=0.452N	P=0.278N
POLY 1.5	P=0.157N	P=0.293N	P=0.472N	P=0.197N
POLY 6	P=0.284N	P=0.267N	P=0.426N	P=0.422N
COCH-ARM / FISHERS	P=0.106N	P=0.309N	P=0.500N	P=0.125N
MAX-ISO-POLY-3	P=0.290N	P=0.145N	P=0.292N	P=0.179N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Clitoral/Preputial Gland
 Adenoma**

TUMOR RATES

OVERALL (a)	3/50 (6%)	3/50 (6%)	3/50 (6%)	1/49 (2%)
POLY-3 RATE (b)	3/43.62	3/45.81	3/47.4	1/22.45
POLY-3 PERCENT (g)	6.9%	6.6%	6.3%	4.5%
TERMINAL (d)	1/31 (3%)	3/37 (8%)	3/38 (8%)	0/0 (0%)
FIRST INCIDENCE	495	728 (T)	728 (T)	617
HC TUMORS SAME RTE	10/98 (10%)			
HC TUMORS ALL RTEs	104/1096 (10%)			

STATISTICAL TESTS

POLY 3	P=0.451N	P=0.640N	P=0.623N	P=0.555N
POLY 1.5	P=0.353N	P=0.651N	P=0.639N	P=0.444N
POLY 6	P=0.543N	P=0.626N	P=0.601N	P=0.655
COCH-ARM / FISHERS	P=0.228N	P=0.661N	P=0.661N	P=0.316N
MAX-ISO-POLY-3	P=0.624N	P=0.475N	P=0.459N	P=0.387N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Clitoral/Preputial Gland
 Carcinoma or Adenoma**

TUMOR RATES

OVERALL (a)	3/50 (6%)	3/50 (6%)	3/50 (6%)	1/49 (2%)
POLY-3 RATE (b)	3/43.62	3/45.81	3/47.4	1/22.45
POLY-3 PERCENT (g)	6.9%	6.6%	6.3%	4.5%
TERMINAL (d)	1/31 (3%)	3/37 (8%)	3/38 (8%)	0/0 (0%)
FIRST INCIDENCE	495	728 (T)	728 (T)	617
HC TUMORS SAME RTE	12/98 (12%)			
HC TUMORS ALL RTEs	133/1096 (12%)			

STATISTICAL TESTS

POLY 3	P=0.451N	P=0.640N	P=0.623N	P=0.555N
POLY 1.5	P=0.353N	P=0.651N	P=0.639N	P=0.444N
POLY 6	P=0.543N	P=0.626N	P=0.601N	P=0.655
COCH-ARM / FISHERS	P=0.228N	P=0.661N	P=0.661N	P=0.316N
MAX-ISO-POLY-3	P=0.624N	P=0.475N	P=0.459N	P=0.387N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Islets, Pancreatic
 Adenoma**

TUMOR RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	0/49 (0%)	0/46 (0%)
POLY-3 RATE (b)	1/42.78	1/45.81	0/46.5	0/20.85
POLY-3 PERCENT (g)	2.3%	2.2%	0%	0%
TERMINAL (d)	1/31 (3%)	1/37 (3%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	---	---
HC TUMORS SAME RTE	1/100 (1%)			
HC TUMORS ALL RTES	21/1092 (2%)			

STATISTICAL TESTS

POLY 3	P=0.246N	P=0.745N	P=0.483N	P=0.630N
POLY 1.5	P=0.235N	P=0.753N	P=0.492N	P=0.582N
POLY 6	P=0.268N	P=0.736N	P=0.472N	P=0.690N
COCH-ARM / FISHERS	P=0.247N	P=0.753N	P=0.505N	P=0.521N
MAX-ISO-POLY-3	P=0.398N	P=0.480N	P=0.160N	P=0.309N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Kidney: Renal Tubule
 Adenoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/49 (2%)
POLY-3 RATE (b)	0/42.78	0/45.81	1/47.4	1/22.52
POLY-3 PERCENT (g)	0%	0%	2.1%	4.4%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	---	---	728 (T)	593
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	1/1093 (0%)			

STATISTICAL TESTS

POLY 3	P=0.129	(e)	P=0.520	P=0.382
POLY 1.5	P=0.148	(e)	P=0.512	P=0.431
POLY 6	P=0.153	(e)	P=0.532	P=0.319
COCH-ARM / FISHERS	P=0.231	(e)	P=0.500	P=0.495
MAX-ISO-POLY-3	P=0.207	(e)	P=0.183	P=0.155
HISTCONT SAME RTE	P=0.170	(e)	P=0.102	P=0.210
HISTCONT ALL RTES	P=0.003**	(e)	P=0.007**	P=0.021*

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

Kidney: Renal Tubule
 Carcinoma or Adenoma

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/49 (2%)
POLY-3 RATE (b)	0/42.78	0/45.81	1/47.4	1/22.52
POLY-3 PERCENT (g)	0%	0%	2.1%	4.4%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	---	---	728 (T)	593
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	1/1093 (0%)			

STATISTICAL TESTS

POLY 3	P=0.129	(e)	P=0.520	P=0.382
POLY 1.5	P=0.148	(e)	P=0.512	P=0.431
POLY 6	P=0.153	(e)	P=0.532	P=0.319
COCH-ARM / FISHERS	P=0.231	(e)	P=0.500	P=0.495
MAX-ISO-POLY-3	P=0.207	(e)	P=0.183	P=0.155
HISTCONT SAME RTE	P=0.170	(e)	P=0.102	P=0.210
HISTCONT ALL RTES	P=0.003**	(e)	P=0.007**	P=0.021*

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

Liver
 Hepatocellular Adenoma

TUMOR RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	1/50 (2%)	3/47 (6%)
POLY-3 RATE (b)	1/42.78	1/45.81	1/47.4	3/22.77
POLY-3 PERCENT (g)	2.3%	2.2%	2.1%	13.2%
TERMINAL (d)	1/31 (3%)	1/37 (3%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	728 (T)	470
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	14/1099 (1%)			

STATISTICAL TESTS

POLY 3	P=0.111	P=0.745N	P=0.737N	P=0.132
POLY 1.5	P=0.107	P=0.753N	P=0.747N	P=0.188
POLY 6	P=0.181	P=0.736N	P=0.724N	P=0.077
COCH-ARM / FISHERS	P=0.147	P=0.753N	P=0.753N	P=0.285
MAX-ISO-POLY-3	P=0.102	P=0.480N	P=0.471N	P=0.095
HISTCONT SAME RTE	P=0.139	P=0.171	P=0.170	P=0.134
HISTCONT ALL RTES	P=0.117	P=0.543	P=0.549	P=0.110

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

Lung
 Alveolar/Bronchiolar Adenoma

TUMOR RATES

OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/43.27	1/45.81	0/47.4	0/22.19
POLY-3 PERCENT (g)	4.6%	2.2%	0%	0%
TERMINAL (d)	1/31 (3%)	1/37 (3%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	581	728 (T)	---	---
HC TUMORS SAME RTE	5/100 (5%)			
HC TUMORS ALL RTES	24/1099 (2%)			

STATISTICAL TESTS

POLY 3	P=0.098N	P=0.480N	P=0.217N	P=0.404N
POLY 1.5	P=0.096N	P=0.490N	P=0.225N	P=0.324N
POLY 6	P=0.097N	P=0.469N	P=0.207N	P=0.524N
COCH-ARM / FISHERS	P=0.101N	P=0.500N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.155N	P=0.269N	P=0.076N	P=0.231N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Lung
 Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma**

TUMOR RATES

OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/43.27	1/45.81	0/47.4	0/22.19
POLY-3 PERCENT (g)	4.6%	2.2%	0%	0%
TERMINAL (d)	1/31 (3%)	1/37 (3%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	581	728 (T)	---	---
HC TUMORS SAME RTE	5/100 (5%)			
HC TUMORS ALL RTES	29/1099 (3%)			

STATISTICAL TESTS

POLY 3	P=0.098N	P=0.480N	P=0.217N	P=0.404N
POLY 1.5	P=0.096N	P=0.490N	P=0.225N	P=0.324N
POLY 6	P=0.097N	P=0.469N	P=0.207N	P=0.524N
COCH-ARM / FISHERS	P=0.101N	P=0.500N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.155N	P=0.269N	P=0.076N	P=0.231N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Mammary Gland
 Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/43.03	0/45.81	0/47.4	0/22.19
POLY-3 PERCENT (g)	4.7%	0%	0%	0%
TERMINAL (d)	1/31 (3%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	659	---	---	---
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	15/1100 (1%)			

STATISTICAL TESTS

POLY 3	P=0.083N	P=0.223N	P=0.216N	P=0.403N
POLY 1.5	P=0.090N	P=0.230N	P=0.225N	P=0.323N
POLY 6	P=0.074N	P=0.216N	P=0.206N	P=0.523N
COCH-ARM / FISHERS	P=0.115N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.130N	P=0.076N	P=0.076N	P=0.230N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Mammary Gland
 Carcinoma or Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/43.03	1/46.1	0/47.4	0/22.19
POLY-3 PERCENT (g)	4.7%	2.2%	0%	0%
TERMINAL (d)	1/31 (3%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	659	650	---	---
HC TUMORS SAME RTE	4/100 (4%)			
HC TUMORS ALL RTES	75/1100 (7%)			

STATISTICAL TESTS

POLY 3	P=0.098N	P=0.476N	P=0.216N	P=0.403N
POLY 1.5	P=0.096N	P=0.488N	P=0.225N	P=0.323N
POLY 6	P=0.097N	P=0.462N	P=0.206N	P=0.523N
COCH-ARM / FISHERS	P=0.101N	P=0.500N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.155N	P=0.267N	P=0.076N	P=0.230N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Mammary Gland
 Fibroadenoma**

TUMOR RATES

	#	#	#	#
OVERALL (a)	21/50 (42%)	27/50 (54%)	8/50 (16%)	0/50 (0%)
POLY-3 RATE (b)	21/44.49	27/46.69	8/47.4	0/22.19
POLY-3 PERCENT (g)	47.2%	57.8%	16.9%	0%
TERMINAL (d)	14/31 (45%)	23/37 (62%)	8/38 (21%)	0/0 (0%)
FIRST INCIDENCE	604	573	728 (T)	---
HC TUMORS SAME RTE	43/100 (43%)			
HC TUMORS ALL RTEs	574/1100 (52%)			

STATISTICAL TESTS

POLY 3	P<0.001N**	P=0.206	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.180	P=0.002N**	P<0.001N**
POLY 6	P<0.001N**	P=0.232	P<0.001N**	P=0.015N*
COCH-ARM / FISHERS	P<0.001N**	P=0.158	P=0.004N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.156	P<0.001N**	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Mammary Gland
 Fibroma, Fibroadenoma or Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	22/50 (44%)	27/50 (54%)	8/50 (16%)	0/50 (0%)
POLY-3 RATE (b)	22/44.75	27/46.69	8/47.4	0/22.19
POLY-3 PERCENT (g)	49.2%	57.8%	16.9%	0%
TERMINAL (d)	14/31 (45%)	23/37 (62%)	8/38 (21%)	0/0 (0%)
FIRST INCIDENCE	604	573	728 (T)	---
HC TUMORS SAME RTE	43/100 (43%)			
HC TUMORS ALL RTEs	583/1100 (53%)			

STATISTICAL TESTS

POLY 3	P<0.001N**	P=0.264	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.236	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P=0.288	P<0.001N**	P=0.013N*
COCH-ARM / FISHERS	P<0.001N**	P=0.212	P=0.002N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.205	P<0.001N**	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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

TUMOR RATES	#	#	#	#
OVERALL (a)	22/50 (44%)	28/50 (56%)	8/50 (16%)	0/50 (0%)
POLY-3 RATE (b)	22/44.75	28/46.97	8/47.4	0/22.19
POLY-3 PERCENT (g)	49.2%	59.6%	16.9%	0%
TERMINAL (d)	14/31 (45%)	23/37 (62%)	8/38 (21%)	0/0 (0%)
FIRST INCIDENCE	604	573	728 (T)	---
HC TUMORS SAME RTE	45/100 (45%)			
HC TUMORS ALL RTES	619/1100 (56%)			

STATISTICAL TESTS

POLY 3	P<0.001N**	P=0.210	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.182	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P=0.238	P<0.001N**	P=0.013N*
COCH-ARM / FISHERS	P<0.001N**	P=0.159	P=0.002N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.159	P<0.001N**	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva)
 Papilloma Squamous or Papilloma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	1/45.96	1/47.4	0/22.19
POLY-3 PERCENT (g)	0%	2.2%	2.1%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	---	689	728 (T)	---
HC TUMORS SAME RTE	1/100 (1%)			
HC TUMORS ALL RTES	6/1100 (1%)			

STATISTICAL TESTS

POLY 3	P=0.516	P=0.514	P=0.520	(e)
POLY 1.5	P=0.606	P=0.507	P=0.512	(e)
POLY 6	P=0.437	P=0.523	P=0.532	(e)
COCH-ARM / FISHERS	P=0.595N	P=0.500	P=0.500	(e)
MAX-ISO-POLY-3	P=0.553	P=0.176	P=0.183	(e)
HISTCONT SAME RTE	P=0.686	P=0.248	P=0.258	(e)
HISTCONT ALL RTES	P=0.448	P=0.211	P=0.221	(e)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva)
 Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	1/45.96	1/47.4	0/22.19
POLY-3 PERCENT (g)	0%	2.2%	2.1%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	---	689	728 (T)	---
HC TUMORS SAME RTE	2/100 (2%)			
HC TUMORS ALL RTES	10/1100 (1%)			

STATISTICAL TESTS

POLY 3	P=0.516	P=0.514	P=0.520	(e)
POLY 1.5	P=0.606	P=0.507	P=0.512	(e)
POLY 6	P=0.437	P=0.523	P=0.532	(e)
COCH-ARM / FISHERS	P=0.595N	P=0.500	P=0.500	(e)
MAX-ISO-POLY-3	P=0.553	P=0.176	P=0.183	(e)
HISTCONT SAME RTE	P=0.686	P=0.248	P=0.258	(e)
HISTCONT ALL RTES	P=0.651	P=0.211	P=0.221	(e)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Pancreas
 Adenoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)	1/46 (2%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/46.5	1/21.24
POLY-3 PERCENT (g)	0%	0%	0%	4.7%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	617
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	3/1093 (0%)			

STATISTICAL TESTS

POLY 3	P=0.191	(e)	(e)	P=0.372
POLY 1.5	P=0.153	(e)	(e)	P=0.419
POLY 6	P=0.351	(e)	(e)	P=0.313
COCH-ARM / FISHERS	P=0.187	(e)	(e)	P=0.479
MAX-ISO-POLY-3	P=0.112	(e)	(e)	P=0.151
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Parathyroid Gland
 Adenoma**

TUMOR RATES

OVERALL (a)	2/46 (4%)	0/47 (0%)	0/49 (0%)	0/49 (0%)
POLY-3 RATE (b)	2/38.78	0/42.87	0/47.2	0/22.06
POLY-3 PERCENT (g)	5.2%	0%	0%	0%
TERMINAL (d)	2/27 (7%)	0/35 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	---	---	---
HC TUMORS SAME RTE	0/94 (0%)			
HC TUMORS ALL RTES	0/1032 (0%)			

STATISTICAL TESTS

POLY 3	P=0.078N	P=0.215N	P=0.196N	P=0.378N
POLY 1.5	P=0.086N	P=0.223N	P=0.207N	P=0.302N
POLY 6	P=0.069N	P=0.205N	P=0.183N	P=0.501N
COCH-ARM / FISHERS	P=0.108N	P=0.242N	P=0.232N	P=0.232N
MAX-ISO-POLY-3	P=0.122N	P=0.074N	P=0.072N	P=0.211N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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

TUMOR RATES

OVERALL (a)	27/50 (54%)	12/50 (24%)	9/50 (18%)	3/50 (6%)
POLY-3 RATE (b)	27/46.04	12/46.53	9/47.5	3/23.5
POLY-3 PERCENT (g)	58.6%	25.8%	19%	12.8%
TERMINAL (d)	17/31 (55%)	9/37 (24%)	8/38 (21%)	0/0 (0%)
FIRST INCIDENCE	495	600	702	470
HC TUMORS SAME RTE	50/100 (50%)			
HC TUMORS ALL RTES	613/1093 (56%)			

STATISTICAL TESTS

POLY 3	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P<0.001N**	P<0.001N**	P=0.034N*
COCH-ARM / FISHERS	P<0.001N**	P=0.002N**	P<0.001N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Skin
 Basal Cell Adenoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	2/47.4	0/22.19
POLY-3 PERCENT (g)	0%	0%	4.2%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	2/38 (5%)	0/0 (0%)
FIRST INCIDENCE	---	---	728 (T)	---
HC TUMORS SAME RTE	1/100 (1%)			
HC TUMORS ALL RTES	3/1100 (0%)			

STATISTICAL TESTS

POLY 3	P=0.239	(e)	P=0.261	(e)
POLY 1.5	P=0.364	(e)	P=0.251	(e)
POLY 6	P=0.134	(e)	P=0.274	(e)
COCH-ARM / FISHERS	P=0.595	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.386	(e)	P=0.098	(e)
HISTCONT SAME RTE	P=0.500	(e)	P=0.138	(e)
HISTCONT ALL RTES	P=0.038*	(e)	P=0.004**	(e)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Skin
 Basal Cell Carcinoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.4	0/22.19
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	3/1100 (0%)			

STATISTICAL TESTS

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

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

Skin
 Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	2/47.4	0/22.19
POLY-3 PERCENT (g)	0%	0%	4.2%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	2/38 (5%)	0/0 (0%)
FIRST INCIDENCE	---	---	728 (T)	---
HC TUMORS SAME RTE	1/100 (1%)			
HC TUMORS ALL RTES	12/1100 (1%)			

STATISTICAL TESTS

POLY 3	P=0.239	(e)	P=0.261	(e)
POLY 1.5	P=0.364	(e)	P=0.251	(e)
POLY 6	P=0.134	(e)	P=0.274	(e)
COCH-ARM / FISHERS	P=0.595	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.386	(e)	P=0.098	(e)
HISTCONT SAME RTE	P=0.500	(e)	P=0.138	(e)
HISTCONT ALL RTES	P=0.452	(e)	P=0.113	(e)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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%)	0/50 (0%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	1/42.78	0/45.81	2/47.4	2/22.91
POLY-3 PERCENT (g)	2.3%	0%	4.2%	8.7%
TERMINAL (d)	1/31 (3%)	0/37 (0%)	2/38 (5%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	---	728 (T)	586
HC TUMORS SAME RTE	1/100 (1%)			
HC TUMORS ALL RTES	24/1100 (2%)			

STATISTICAL TESTS

POLY 3	P=0.132	P=0.486N	P=0.536	P=0.304
POLY 1.5	P=0.153	P=0.493N	P=0.521	P=0.386
POLY 6	P=0.156	P=0.478N	P=0.555	P=0.208
COCH-ARM / FISHERS	P=0.245	P=0.500N	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.212	P=0.158N	P=0.319	P=0.193
HISTCONT SAME RTE	P=0.173	(e)	P=0.133	P=0.212
HISTCONT ALL RTES	P=0.244	(e)	P=0.385	P=0.235

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Skin
 Fibroma**

TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/43.2	1/46.09	0/47.4	0/22.19
POLY-3 PERCENT (g)	7%	2.2%	0%	0%
TERMINAL (d)	2/31 (7%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	607	652	---	---
HC TUMORS SAME RTE	2/100 (2%)			
HC TUMORS ALL RTES	19/1100 (2%)			

STATISTICAL TESTS

POLY 3	P=0.040N*	P=0.282N	P=0.103N	P=0.279N
POLY 1.5	P=0.041N*	P=0.293N	P=0.109N	P=0.196N
POLY 6	P=0.035N*	P=0.269N	P=0.095N	P=0.426N
COCH-ARM / FISHERS	P=0.044N*	P=0.309N	P=0.121N	P=0.121N
MAX-ISO-POLY-3	P=0.061N	P=0.146N	P=0.038N*	P=0.181N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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

TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/43.2	1/46.09	0/47.4	0/22.19
POLY-3 PERCENT (g)	7%	2.2%	0%	0%
TERMINAL (d)	2/31 (7%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	607	652	---	---
HC TUMORS SAME RTE	3/100 (3%)			
HC TUMORS ALL RTES	25/1100 (2%)			

STATISTICAL TESTS

POLY 3	P=0.040N*	P=0.282N	P=0.103N	P=0.279N
POLY 1.5	P=0.041N*	P=0.293N	P=0.109N	P=0.196N
POLY 6	P=0.035N*	P=0.269N	P=0.095N	P=0.426N
COCH-ARM / FISHERS	P=0.044N*	P=0.309N	P=0.121N	P=0.121N
MAX-ISO-POLY-3	P=0.061N	P=0.146N	P=0.038N*	P=0.181N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Skin
 Keratoacanthoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.4	1/22.67
POLY-3 PERCENT (g)	0%	0%	0%	4.4%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	586
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	8/1100 (1%)			

STATISTICAL TESTS

POLY 3	P=0.199	(e)	(e)	P=0.384
POLY 1.5	P=0.161	(e)	(e)	P=0.434
POLY 6	P=0.362	(e)	(e)	P=0.320
COCH-ARM / FISHERS	P=0.198	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.123	(e)	(e)	P=0.157
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Skin
 Lipoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	3/50 (6%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	3/45.81	0/47.4	0/22.19
POLY-3 PERCENT (g)	0%	6.6%	0%	0%
TERMINAL (d)	0/31 (0%)	3/37 (8%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	728 (T)	---	---
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	1/1100 (0%)			

STATISTICAL TESTS

POLY 3	P=0.418N	P=0.131	(e)	(e)
POLY 1.5	P=0.357N	P=0.125	(e)	(e)
POLY 6	P=0.501N	P=0.139	(e)	(e)
COCH-ARM / FISHERS	P=0.311N	P=0.121	(e)	(e)
MAX-ISO-POLY-3	P=0.427N	P=0.049*	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTES	(h)	(h)	(e)	(e)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Skin
 Schwannoma Malignant**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.4	0/22.19
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	3/1100 (0%)			

STATISTICAL TESTS

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

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

Skin
 Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.4	0/22.19
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	4/1100 (0%)			

STATISTICAL TESTS

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

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/42.78	0/45.81	0/47.4	2/22.91
POLY-3 PERCENT (g)	2.3%	0%	0%	8.7%
TERMINAL (d)	1/31 (3%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	---	---	586
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	12/1100 (1%)			

STATISTICAL TESTS

POLY 3	P=0.281	P=0.486N	P=0.480N	P=0.304
POLY 1.5	P=0.225	P=0.493N	P=0.488N	P=0.386
POLY 6	P=0.481	P=0.478N	P=0.468N	P=0.208
COCH-ARM / FISHERS	P=0.246	P=0.500N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.101	P=0.158N	P=0.158N	P=0.193
HISTCONT SAME RTE	P=0.137	(e)	(e)	P=0.191
HISTCONT ALL RTES	P=0.115	(e)	(e)	P=0.097

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Skin
 Squamous Cell Papilloma, Papilloma, or Keratoacanthoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/42.78	0/45.81	0/47.4	2/22.91
POLY-3 PERCENT (g)	2.3%	0%	0%	8.7%
TERMINAL (d)	1/31 (3%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	---	---	586
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	11/1100 (1%)			

STATISTICAL TESTS

POLY 3	P=0.281	P=0.486N	P=0.480N	P=0.304
POLY 1.5	P=0.225	P=0.493N	P=0.488N	P=0.386
POLY 6	P=0.481	P=0.478N	P=0.468N	P=0.208
COCH-ARM / FISHERS	P=0.246	P=0.500N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.101	P=0.158N	P=0.158N	P=0.193
HISTCONT SAME RTE	P=0.137	(e)	(e)	P=0.191
HISTCONT ALL RTES	P=0.115	(e)	(e)	P=0.094

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Spleen
 Hemangiosarcoma**

TUMOR RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/46 (0%)
POLY-3 RATE (b)	2/43.41	0/45.81	0/47.4	0/20.85
POLY-3 PERCENT (g)	4.6%	0%	0%	0%
TERMINAL (d)	1/31 (3%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	519	---	---	---
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	1/1094 (0%)			

STATISTICAL TESTS

POLY 3	P=0.084N	P=0.225N	P=0.218N	P=0.419N
POLY 1.5	P=0.093N	P=0.231N	P=0.226N	P=0.342N
POLY 6	P=0.076N	P=0.218N	P=0.208N	P=0.533N
COCH-ARM / FISHERS	P=0.120N	P=0.247N	P=0.247N	P=0.269N
MAX-ISO-POLY-3	P=0.133N	P=0.076N	P=0.076N	P=0.242N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Thyroid Gland: C-Cell
 Adenoma**

TUMOR RATES

OVERALL (a)	8/50 (16%)	6/50 (12%)	3/50 (6%)	0/49 (0%)
POLY-3 RATE (b)	8/42.78	6/45.81	3/47.5	0/22.06
POLY-3 PERCENT (g)	18.7%	13.1%	6.3%	0%
TERMINAL (d)	8/31 (26%)	6/37 (16%)	2/38 (5%)	0/0 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	702	---
HC TUMORS SAME RTE	12/100 (12%)			
HC TUMORS ALL RTEs	124/1086 (11%)			

STATISTICAL TESTS

POLY 3	P=0.011N*	P=0.334N	P=0.069N	P=0.050N*
POLY 1.5	P=0.006N**	P=0.359N	P=0.081N	P=0.017N*
POLY 6	P=0.017N*	P=0.303N	P=0.055N	P=0.177N
COCH-ARM / FISHERS	P=0.002N**	P=0.387N	P=0.100N	P=0.003N**
MAX-ISO-POLY-3	P=0.017N*	P=0.243N	P=0.042N*	P=0.053N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Thyroid Gland: Follicular Cell
 Adenoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.4	0/22.06
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	5/1086 (1%)			

STATISTICAL TESTS

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

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Tongue
 Squamous Cell Papilloma**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	1/45.96	1/47.4	0/22.19
POLY-3 PERCENT (g)	0%	2.2%	2.1%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	---	689	728 (T)	---
HC TUMORS SAME RTE	1/100 (1%)			
HC TUMORS ALL RTES	5/1100 (1%)			

STATISTICAL TESTS

POLY 3	P=0.516	P=0.514	P=0.520	(e)
POLY 1.5	P=0.606	P=0.507	P=0.512	(e)
POLY 6	P=0.437	P=0.523	P=0.532	(e)
COCH-ARM / FISHERS	P=0.595N	P=0.500	P=0.500	(e)
MAX-ISO-POLY-3	P=0.553	P=0.176	P=0.183	(e)
HISTCONT SAME RTE	P=0.686	P=0.248	P=0.258	(e)
HISTCONT ALL RTES	P=0.372	P=0.187	P=0.190	(e)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Urinary Bladder
 Carcinoma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	2/47 (4%)
POLY-3 RATE (b)	0/42.78	0/44.81	0/47.4	2/22.7
POLY-3 PERCENT (g)	0%	0%	0%	8.8%
TERMINAL (d)	0/31 (0%)	0/36 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	390
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	0/1096 (0%)			

STATISTICAL TESTS

POLY 3	P=0.049*	(e)	(e)	P=0.129
POLY 1.5	P=0.035*	(e)	(e)	P=0.165
POLY 6	P=0.132	(e)	(e)	P=0.092
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.232
MAX-ISO-POLY-3	P=0.028*	(e)	(e)	P=0.070
HISTCONT SAME RTE	P=0.038*	(e)	(e)	P=0.097
HISTCONT ALL RTES	P=0.005**	(e)	(e)	P=0.004**

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Urinary Bladder
 Carcinoma or Papilloma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/49 (0%)	1/50 (2%)	5/47 (11%)
POLY-3 RATE (b)	0/42.78	0/44.81	1/47.4	5/24.04
POLY-3 PERCENT (g)	0%	0%	2.1%	20.8%
TERMINAL (d)	0/31 (0%)	0/36 (0%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	---	---	728 (T)	390
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	2/1096 (0%)			

STATISTICAL TESTS

POLY 3	P<0.001**	(e)	P=0.520	P=0.005**
POLY 1.5	P<0.001**	(e)	P=0.512	P=0.011*
POLY 6	P=0.003**	(e)	P=0.532	P=0.002**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.500	P=0.024*
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.183	P=0.007**
HISTCONT SAME RTE	P<0.001**	(e)	P=0.102	P=0.008**
HISTCONT ALL RTES	P<0.001**	(e)	P=0.026*	P=0.003**

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Urinary Bladder
 Papilloma**

TUMOR RATES

OVERALL (a)	0/50 (0%)	0/49 (0%)	1/50 (2%)	3/47 (6%)
POLY-3 RATE (b)	0/42.78	0/44.81	1/47.4	3/22.63
POLY-3 PERCENT (g)	0%	0%	2.1%	13.3%
TERMINAL (d)	0/31 (0%)	0/36 (0%)	1/38 (3%)	0/0 (0%)
FIRST INCIDENCE	---	---	728 (T)	578
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	2/1096 (0%)			

STATISTICAL TESTS

POLY 3	P=0.012*	(e)	P=0.520	P=0.044*
POLY 1.5	P=0.010**	(e)	P=0.512	P=0.065
POLY 6	P=0.028*	(e)	P=0.532	P=0.026*
COCH-ARM / FISHERS	P=0.017*	(e)	P=0.500	P=0.110
MAX-ISO-POLY-3	P=0.017*	(e)	P=0.183	P=0.033*
HISTCONT SAME RTE	P=0.023*	(e)	P=0.102	P=0.044*
HISTCONT ALL RTES	P=0.004**	(e)	P=0.026*	P=0.006**

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**Uterus
 Polyp Stromal**

TUMOR RATES	#	#	#	#
OVERALL (a)	5/50 (10%)	2/50 (4%)	5/50 (10%)	2/50 (4%)
POLY-3 RATE (b)	5/42.91	2/46.1	5/47.5	2/23.21
POLY-3 PERCENT (g)	11.7%	4.3%	10.5%	8.6%
TERMINAL (d)	4/31 (13%)	1/37 (3%)	4/38 (11%)	0/0 (0%)
FIRST INCIDENCE	693	650	702	538
HC TUMORS SAME RTE	16/100 (16%)			
HC TUMORS ALL RTES	203/1100 (19%)			

STATISTICAL TESTS

POLY 3	P=0.520N	P=0.188N	P=0.565N	P=0.513N
POLY 1.5	P=0.413N	P=0.201N	P=0.592N	P=0.370N
POLY 6	P=0.540	P=0.172N	P=0.529N	P=0.573
COCH-ARM / FISHERS	P=0.256N	P=0.218N	P=0.630N	P=0.218N
MAX-ISO-POLY-3	P=0.565N	P=0.107N	P=0.434N	P=0.387N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**All Organs
 Hemangiosarcoma**

TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/43.41	0/45.81	0/47.4	0/22.19
POLY-3 PERCENT (g)	4.6%	0%	0%	0%
TERMINAL (d)	1/31 (3%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	519	---	---	---
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	4/1100 (0%)			

STATISTICAL TESTS

POLY 3	P=0.083N	P=0.225N	P=0.218N	P=0.405N
POLY 1.5	P=0.090N	P=0.231N	P=0.226N	P=0.325N
POLY 6	P=0.074N	P=0.218N	P=0.208N	P=0.524N
COCH-ARM / FISHERS	P=0.115N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.130N	P=0.076N	P=0.076N	P=0.232N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

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

TUMOR RATES	#	#	#	#
OVERALL (a)	4/50 (8%)	4/50 (8%)	11/50 (22%)	9/50 (18%)
POLY-3 RATE (b)	4/42.99	4/47.01	11/48.8	9/26.54
POLY-3 PERCENT (g)	9.3%	8.5%	22.5%	33.9%
TERMINAL (d)	3/31 (10%)	0/37 (0%)	4/38 (11%)	0/0 (0%)
FIRST INCIDENCE	672	561	428	450
HC TUMORS SAME RTE	13/100 (13%)			
HC TUMORS ALL RTES	265/1100 (24%)			

STATISTICAL TESTS

POLY 3	P=0.003**	P=0.593N	P=0.076	P=0.014*
POLY 1.5	P=0.009**	P=0.617N	P=0.061	P=0.038*
POLY 6	P<0.001**	P=0.563N	P=0.098	P=0.002**
COCH-ARM / FISHERS	P=0.049*	P=0.643N	P=0.045*	P=0.117
MAX-ISO-POLY-3	P=0.005**	P=0.449N	P=0.052	P=0.018*
HISTCONT SAME RTE	P=0.006**	P=1.000	P=0.072	P=0.024*
HISTCONT ALL RTES	P=0.005**	P=1.000	P=0.057	P=0.019*

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**All Organs
 Mesothelioma: Benign**

TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.4	0/22.19
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME RTE	0/100 (0%)			
HC TUMORS ALL RTES	1/1100 (0%)			

STATISTICAL TESTS

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

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**All Organs
 Mesothelioma: Benign, Malignant, NOS**

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.27	0/45.81	0/47.4	0/22.19
POLY-3 PERCENT (g)	2.3%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	581	---	---	---
HC TUMORS SAME RTE	1/100 (1%)			
HC TUMORS ALL RTES	4/1100 (0%)			

STATISTICAL TESTS

POLY 3	P=0.239N	P=0.489N	P=0.482N	P=0.621N
POLY 1.5	P=0.245N	P=0.494N	P=0.489N	P=0.569N
POLY 6	P=0.248N	P=0.482N	P=0.472N	P=0.685N
COCH-ARM / FISHERS	P=0.306N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.378N	P=0.158N	P=0.158N	P=0.303N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

All Organs
 Mesothelioma: Malignant

TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.27	0/45.81	0/47.4	0/22.19
POLY-3 PERCENT (g)	2.3%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)	0/0 (0%)
FIRST INCIDENCE	581	---	---	---
HC TUMORS SAME RTE	1/100 (1%)			
HC TUMORS ALL RTES	3/1100 (0%)			

STATISTICAL TESTS

POLY 3	P=0.239N	P=0.489N	P=0.482N	P=0.621N
POLY 1.5	P=0.245N	P=0.494N	P=0.489N	P=0.569N
POLY 6	P=0.248N	P=0.482N	P=0.472N	P=0.685N
COCH-ARM / FISHERS	P=0.306N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.378N	P=0.158N	P=0.158N	P=0.303N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**All Organs
 Benign Tumors**

TUMOR RATES

	#	#	#	#
OVERALL (a)	42/50 (84%)	39/50 (78%)	27/50 (54%)	12/50 (24%)
POLY-3 RATE (b)	42/47.5	39/48.13	27/47.89	12/27.35
POLY-3 PERCENT (g)	88.4%	81%	56.4%	43.9%
TERMINAL (d)	27/31 (87%)	29/37 (78%)	22/38 (58%)	0/0 (0%)
FIRST INCIDENCE	495	573	702	470
HC TUMORS SAME RTE	81/100 (81%)			
HC TUMORS ALL RTES	966/1100 (88%)			

STATISTICAL TESTS

POLY 3	P<0.001N**	P=0.229N	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.270N	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P=0.199N	P<0.001N**	P=0.004N**
COCH-ARM / FISHERS	P<0.001N**	P=0.306N	P<0.001N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.151N	P<0.001N**	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

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

Date Report Requested: 05/21/2008
 Time Report Requested: 09:15:32
 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**All Organs
 Malignant Tumors**

TUMOR RATES	#	#	#	#
OVERALL (a)	8/50 (16%)	6/50 (12%)	14/50 (28%)	11/50 (22%)
POLY-3 RATE (b)	8/44.72	6/47.3	14/49.49	11/27.95
POLY-3 PERCENT (g)	17.9%	12.7%	28.3%	39.4%
TERMINAL (d)	4/31 (13%)	1/37 (3%)	6/38 (16%)	0/0 (0%)
FIRST INCIDENCE	519	561	428	390
HC TUMORS SAME RTE	29/100 (29%)			
HC TUMORS ALL RTES	428/1100 (39%)			

STATISTICAL TESTS

POLY 3	P=0.012*	P=0.344N	P=0.172	P=0.042*
POLY 1.5	P=0.033*	P=0.365N	P=0.147	P=0.115
POLY 6	P=0.005**	P=0.316N	P=0.208	P=0.007**
COCH-ARM / FISHERS	P=0.146	P=0.387N	P=0.114	P=0.306
MAX-ISO-POLY-3	P=0.018*	P=0.251N	P=0.128	P=0.048*
HISTCONT SAME RTE	P=0.023*	P=1.000	P=0.181	P=0.065
HISTCONT ALL RTES	P=0.019*	P=1.000	P=0.151	P=0.053

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

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

Date Report Requested: 05/21/2008
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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)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG

**All Organs
 Malignant and Benign Tumors**

TUMOR RATES	#	#	#	#
OVERALL (a)	44/50 (88%)	41/50 (82%)	38/50 (76%)	20/50 (40%)
POLY-3 RATE (b)	44/48.74	41/49	38/49.77	20/32.27
POLY-3 PERCENT (g)	90.3%	83.7%	76.4%	62%
TERMINAL (d)	27/31 (87%)	29/37 (78%)	27/38 (71%)	0/0 (0%)
FIRST INCIDENCE	495	561	428	390
HC TUMORS SAME RTE	91/100 (91%)			
HC TUMORS ALL RTES	1039/1100 (95%)			

STATISTICAL TESTS

POLY 3	P<0.001N**	P=0.250N	P=0.053N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.279N	P=0.062N	P<0.001N**
POLY 6	P=0.028N*	P=0.224N	P=0.048N*	P=0.059N
COCH-ARM / FISHERS	P<0.001N**	P=0.288N	P=0.096N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.166N	P=0.031N*	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTES	(h)	(h)	(h)	(h)

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

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
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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 ***