

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

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

**Date Report Requested:** 08/25/2009  
**Time Report Requested:** 09:37:47  
**First Dose M/F:** 04/09/03 / 04/10/03  
**Lab:** BAT

F1\_R2\_Rev2

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

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## HISTORICAL CONTROL STUDIES From November 2008 report

### SAME ROUTE

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

### ALL ROUTES

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

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**HISTORICAL CONTROL STUDIES**  
**From November 2008 report**

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

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

Adrenal Cortex  
Adrenal Medulla  
Brain  
Clitoral/Preputial Gland  
Heart  
Islets, Pancreatic  
Kidney  
Liver  
Lung  
Nose  
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  
Skin

Testes  
Thyroid Gland: Follicular Cell

### FEMALE RATS

#### Organ

Mammary Gland

Parathyroid Gland  
Pituitary Gland: Pars Distalis or Unspecified Site  
Skin

Thyroid Gland: C-Cell  
All Organs

#### Morphology

Pheochromocytoma: Benign, Complex, Malignant, NOS  
Alveolar/Bronchiolar Adenoma  
Keratoacanthoma  
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma  
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma  
Adenoma  
Adenoma

#### Morphology

Fibroadenoma  
Fibroma, Fibroadenoma or Adenoma  
Fibroma, Fibroadenoma, Carcinoma, or Adenoma  
Adenoma  
Adenoma  
Fibroma  
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma  
Lipoma  
Adenoma  
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated  
Benign Tumors  
Malignant and Benign Tumors

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Adrenal Cortex</b>			
<b>Adenoma</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/46.01	0/43.06	1/43.38
POLY-3 PERCENT (g)	4.4%	0%	2.3%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	692	---	727 (T)
HC TUMORS SAME ROUTE	1/100 (1%)		
HC TUMORS ALL ROUTES	12/1348 (1%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.373N	P=0.252N	P=0.520N
POLY 1.5	P=0.364N	P=0.243N	P=0.505N
POLY 6	P=0.388N	P=0.265N	P=0.543N
COCH-ARM / FISHERS	P=0.360N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.226N	P=0.090N	P=0.303N
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/N)  
TERMINAL SACRIFICE AT 104 WEEKS

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

---

Adrenal Medulla  
Pheochromocytoma Benign

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**TUMOR RATES**

OVERALL (a)	8/50 (16%)	13/50 (26%)	12/50 (24%)
POLY-3 RATE (b)	8/45.95	13/43.83	12/44.44
POLY-3 PERCENT (g)	17.4%	29.7%	27%
TERMINAL (d)	6/39 (15%)	10/32 (31%)	7/28 (25%)
FIRST INCIDENCE	699	611	608
HC TUMORS SAME ROUTE	16/100 (16%)		
HC TUMORS ALL ROUTES	197/1346 (15%)		

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**STATISTICAL TESTS**

POLY 3	P=0.168	P=0.130	P=0.199
POLY 1.5	P=0.195	P=0.150	P=0.223
POLY 6	P=0.135	P=0.108	P=0.167
COCH-ARM / FISHERS	P=0.199	P=0.163	P=0.227
MAX-ISO-POLY-3	P=0.159	P=0.089	P=0.139
HISTCONT SAME RTE	P=0.216	P=0.125	P=0.197
HISTCONT ALL RTEs	P=0.010**	P=0.053	P=0.097

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Adrenal Medulla</b>			
<b>Pheochromocytoma Malignant</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/45.76	2/43.60	1/43.38
POLY-3 PERCENT (g)	0%	4.6%	2.3%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	---	638	727 (T)
HC TUMORS SAME ROUTE	5/100 (5%)		
HC TUMORS ALL ROUTES	27/1346 (2%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.343	P=0.226	P=0.489
POLY 1.5	P=0.357	P=0.233	P=0.498
POLY 6	P=0.323	P=0.218	P=0.477
COCH-ARM / FISHERS	P=0.360	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.198	P=0.076	P=0.158
HISTCONT SAME RTE	P=0.268	P=0.106	P=0.223
HISTCONT ALL RTEs	P=0.229	P=0.086	P=0.188



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TERMINAL SACRIFICE AT 104 WEEKS**

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

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Adrenal Medulla  
Pheochromocytoma: Benign, Complex, Malignant, NOS

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**TUMOR RATES**

OVERALL (a)	8/50 (16%)	15/50 (30%)	13/50 (26%)
POLY-3 RATE (b)	8/45.95	15/44.37	13/44.44
POLY-3 PERCENT (g)	17.4%	33.8%	29.3%
TERMINAL (d)	6/39 (15%)	10/32 (31%)	8/28 (29%)
FIRST INCIDENCE	699	611	608
HC TUMORS SAME ROUTE	20/100 (20%)		
HC TUMORS ALL ROUTES	225/1346 (17%)		

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**STATISTICAL TESTS**

POLY 3	P=0.117	P=0.059	P=0.138
POLY 1.5	P=0.140	P=0.069	P=0.159
POLY 6	P=0.089	P=0.049*	P=0.112
COCH-ARM / FISHERS	P=0.146	P=0.077	P=0.163
MAX-ISO-POLY-3	P=0.088	P=0.037*	P=0.094
HISTCONT SAME RTE	P=0.119	P=0.051	P=0.132
HISTCONT ALL RTEs	P=0.015*	P=0.040*	P=0.108

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TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Clitoral/Preputial Gland Adenoma			
<hr/>			
<b>TUMOR RATES</b>			
OVERALL (a)	3/50 (6%)	5/50 (10%)	2/50 (4%)
POLY-3 RATE (b)	3/46.04	5/44.14	2/43.39
POLY-3 PERCENT (g)	6.5%	11.3%	4.6%
TERMINAL (d)	2/39 (5%)	2/32 (6%)	1/28 (4%)
FIRST INCIDENCE	653	451	724
HC TUMORS SAME ROUTE	7/100 (7%)		
HC TUMORS ALL ROUTES	50/1345 (4%)		
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<b>STATISTICAL TESTS</b>			
POLY 3	P=0.462N	P=0.333	P=0.527N
POLY 1.5	P=0.431N	P=0.350	P=0.507N
POLY 6	P=0.507N	P=0.312	P=0.556N
COCH-ARM / FISHERS	P=0.421N	P=0.357	P=0.500N
MAX-ISO-POLY-3	P=0.319N	P=0.217	P=0.351N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

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TERMINAL SACRIFICE AT 104 WEEKS**

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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Clitoral/Preputial Gland Carcinoma or Adenoma			
<hr/>			
<b>TUMOR RATES</b>			
OVERALL (a)	4/50 (8%)	5/50 (10%)	2/50 (4%)
POLY-3 RATE (b)	4/46.04	5/44.14	2/43.39
POLY-3 PERCENT (g)	8.7%	11.3%	4.6%
TERMINAL (d)	3/39 (8%)	2/32 (6%)	1/28 (4%)
FIRST INCIDENCE	653	451	724
HC TUMORS SAME ROUTE	9/100 (9%)		
HC TUMORS ALL ROUTES	66/1345 (5%)		
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.319N	P=0.474	P=0.365N
POLY 1.5	P=0.292N	P=0.492	P=0.344N
POLY 6	P=0.360N	P=0.448	P=0.395N
COCH-ARM / FISHERS	P=0.283N	P=0.500	P=0.339N
MAX-ISO-POLY-3	P=0.258N	P=0.341	P=0.229N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Islets, Pancreatic Adenoma</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/46.12	0/43.06	0/43.38
POLY-3 PERCENT (g)	4.3%	0%	0%
TERMINAL (d)	1/39 (3%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	627	---	---
HC TUMORS SAME ROUTE	6/100 (6%)		
HC TUMORS ALL ROUTES	84/1345 (6%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.100N	P=0.253N	P=0.251N
POLY 1.5	P=0.096N	P=0.243N	P=0.241N
POLY 6	P=0.107N	P=0.265N	P=0.266N
COCH-ARM / FISHERS	P=0.095N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.066N	P=0.091N	P=0.089N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Kidney: Renal Tubule Adenoma</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/45.76	0/43.06	2/43.59
POLY-3 PERCENT (g)	2.2%	0%	4.6%
TERMINAL (d)	1/39 (3%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	727 (T)	---	673
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	7/1344 (1%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.357	P=0.512N	P=0.483
POLY 1.5	P=0.360	P=0.505N	P=0.497
POLY 6	P=0.351	P=0.522N	P=0.464
COCH-ARM / FISHERS	P=0.360	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.196	P=0.174N	P=0.271
HISTCONT SAME RTE	P=0.102	(e)	P=0.097
HISTCONT ALL RTEs	P=0.016*	(e)	P=0.013*

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Kidney: Renal Tubule Carcinoma or Adenoma</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/45.76	1/43.41	2/43.59
POLY-3 PERCENT (g)	2.2%	2.3%	4.6%
TERMINAL (d)	1/39 (3%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	727 (T)	632	673
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	9/1344 (1%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.368	P=0.749	P=0.483
POLY 1.5	P=0.377	P=0.756	P=0.497
POLY 6	P=0.355	P=0.739	P=0.464
COCH-ARM / FISHERS	P=0.378	P=0.753N	P=0.500
MAX-ISO-POLY-3	P=0.361	P=0.485	P=0.271
HISTCONT SAME RTE	P=0.082	P=0.169	P=0.097
HISTCONT ALL RTEs	P=0.018*	P=0.275	P=0.044*

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Lung</b>			
<b>Alveolar/Bronchiolar Adenoma</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	0/50 (0%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	0/45.76	1/43.06	3/43.38
POLY-3 PERCENT (g)	0%	2.3%	6.9%
TERMINAL (d)	0/39 (0%)	1/32 (3%)	3/28 (11%)
FIRST INCIDENCE	---	727 (T)	727 (T)
HC TUMORS SAME ROUTE	6/100 (6%)		
HC TUMORS ALL ROUTES	34/1349 (3%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.056	P=0.488	P=0.109
POLY 1.5	P=0.059	P=0.495	P=0.117
POLY 6	P=0.052	P=0.478	P=0.099
COCH-ARM / FISHERS	P=0.060	P=0.500	P=0.121
MAX-ISO-POLY-3	P=0.040*	P=0.158	P=0.038*
HISTCONT SAME RTE	P=0.053	P=0.223	P=0.051
HISTCONT ALL RTEs	P=0.043*	P=0.188	P=0.040*

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Lung</b>			
<b>Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	1/50 (2%)	2/50 (4%)	4/50 (8%)
POLY-3 RATE (b)	1/45.76	2/43.14	4/43.38
POLY-3 PERCENT (g)	2.2%	4.6%	9.2%
TERMINAL (d)	1/39 (3%)	1/32 (3%)	4/28 (14%)
FIRST INCIDENCE	727 (T)	709	727 (T)
HC TUMORS SAME ROUTE	7/100 (7%)		
HC TUMORS ALL ROUTES	46/1349 (3%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.108	P=0.479	P=0.163
POLY 1.5	P=0.116	P=0.492	P=0.175
POLY 6	P=0.097	P=0.463	P=0.146
COCH-ARM / FISHERS	P=0.118	P=0.500	P=0.181
MAX-ISO-POLY-3	P=0.100	P=0.269	P=0.080
HISTCONT SAME RTE	P=0.135	P=0.376	P=0.111
HISTCONT ALL RTEs	P=0.112	P=0.334	P=0.090



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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Mammary Gland Adenoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	4/1349 (0%)		
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Mammary Gland Carcinoma or Adenoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	12/1349 (1%)		
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Mammary Gland Fibroadenoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	1/50 (2%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	1/46.11	3/43.17	1/43.64
POLY-3 PERCENT (g)	2.2%	7%	2.3%
TERMINAL (d)	0/39 (0%)	2/32 (6%)	0/28 (0%)
FIRST INCIDENCE	632	701	659
HC TUMORS SAME ROUTE	4/100 (4%)		
HC TUMORS ALL ROUTES	48/1349 (4%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.585	P=0.282	P=0.748
POLY 1.5	P=0.604	P=0.296	P=0.758
POLY 6	P=0.557	P=0.265	P=0.735
COCH-ARM / FISHERS	P=0.610	P=0.309	P=0.753N
MAX-ISO-POLY-3	P=0.385	P=0.146	P=0.484
HISTCONT SAME RTE	P=0.507	P=0.207	P=0.637
HISTCONT ALL RTEs	P=0.461	P=0.173	P=0.612

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Mammary Gland</b>			
<b>Fibroma, Fibroadenoma or Adenoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	1/50 (2%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	1/46.11	3/43.17	1/43.64
POLY-3 PERCENT (g)	2.2%	7%	2.3%
TERMINAL (d)	0/39 (0%)	2/32 (6%)	0/28 (0%)
FIRST INCIDENCE	632	701	659
HC TUMORS SAME ROUTE	4/100 (4%)		
HC TUMORS ALL ROUTES	54/1349 (4%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.585	P=0.282	P=0.748
POLY 1.5	P=0.604	P=0.296	P=0.758
POLY 6	P=0.557	P=0.265	P=0.735
COCH-ARM / FISHERS	P=0.610	P=0.309	P=0.753N
MAX-ISO-POLY-3	P=0.385	P=0.146	P=0.484
HISTCONT SAME RTE	P=0.507	P=0.207	P=0.637
HISTCONT ALL RTEs	P=0.461	P=0.173	P=0.612

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Mammary Gland</b>			
<b>Fibroma, Fibroadenoma, Carcinoma, or Adenoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	1/50 (2%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	1/46.11	3/43.17	1/43.64
POLY-3 PERCENT (g)	2.2%	7%	2.3%
TERMINAL (d)	0/39 (0%)	2/32 (6%)	0/28 (0%)
FIRST INCIDENCE	632	701	659
HC TUMORS SAME ROUTE	4/100 (4%)		
HC TUMORS ALL ROUTES	60/1349 (4%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.585	P=0.282	P=0.748
POLY 1.5	P=0.604	P=0.296	P=0.758
POLY 6	P=0.557	P=0.265	P=0.735
COCH-ARM / FISHERS	P=0.610	P=0.309	P=0.753N
MAX-ISO-POLY-3	P=0.385	P=0.146	P=0.484
HISTCONT SAME RTE	P=0.507	P=0.207	P=0.637
HISTCONT ALL RTEs	P=0.461	P=0.173	P=0.612

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva)</b>			
<b>Papilloma Squamous or Papilloma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/45.76	1/43.06	2/43.39
POLY-3 PERCENT (g)	0%	2.3%	4.6%
TERMINAL (d)	0/39 (0%)	1/32 (3%)	1/28 (4%)
FIRST INCIDENCE	---	727 (T)	725
HC TUMORS SAME ROUTE	1/100 (1%)		
HC TUMORS ALL ROUTES	7/1349 (1%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.136	P=0.488	P=0.225
POLY 1.5	P=0.141	P=0.495	P=0.235
POLY 6	P=0.128	P=0.478	P=0.213
COCH-ARM / FISHERS	P=0.142	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.104	P=0.158	P=0.076
HISTCONT SAME RTE	P=0.141	P=0.223	P=0.106
HISTCONT ALL RTEs	P=0.002**	P=0.143	P=0.011*

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	0/45.76	2/43.06	2/43.39
POLY-3 PERCENT (g)	0%	4.6%	4.6%
TERMINAL (d)	0/39 (0%)	2/32 (6%)	1/28 (4%)
FIRST INCIDENCE	---	727 (T)	725
HC TUMORS SAME ROUTE	2/100 (2%)		
HC TUMORS ALL ROUTES	12/1349 (1%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.164	P=0.224	P=0.225
POLY 1.5	P=0.173	P=0.232	P=0.235
POLY 6	P=0.151	P=0.214	P=0.213
COCH-ARM / FISHERS	P=0.176	P=0.247	P=0.247
MAX-ISO-POLY-3	P=0.146	P=0.076	P=0.076
HISTCONT SAME RTE	P=0.198	P=0.106	P=0.106
HISTCONT ALL RTEs	P=0.005**	P=0.042*	P=0.042*

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Pancreas</b>			
<b>Adenoma</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	2/50 (4%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	2/45.76	3/43.06	0/43.38
POLY-3 PERCENT (g)	4.4%	7%	0%
TERMINAL (d)	2/39 (5%)	3/32 (9%)	0/28 (0%)
FIRST INCIDENCE	727 (T)	727 (T)	---
HC TUMORS SAME ROUTE	8/100 (8%)		
HC TUMORS ALL ROUTES	22/1344 (2%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.223N	P=0.472	P=0.249N
POLY 1.5	P=0.206N	P=0.489	P=0.240N
POLY 6	P=0.250N	P=0.450	P=0.263N
COCH-ARM / FISHERS	P=0.202N	P=0.500	P=0.247N
MAX-ISO-POLY-3	P=0.117N	P=0.305	P=0.088N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Parathyroid Gland Adenoma</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	1/49 (2%)	0/44 (0%)	0/45 (0%)
POLY-3 RATE (b)	1/44.76	0/37.96	0/38.65
POLY-3 PERCENT (g)	2.2%	0%	0%
TERMINAL (d)	1/38 (3%)	0/28 (0%)	0/25 (0%)
FIRST INCIDENCE	727 (T)	---	---
HC TUMORS SAME ROUTE	1/92 (1%)		
HC TUMORS ALL ROUTES	5/1285 (0%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.295N	P=0.533N	P=0.529N
POLY 1.5	P=0.287N	P=0.526N	P=0.520N
POLY 6	P=0.307N	P=0.542N	P=0.542N
COCH-ARM / FISHERS	P=0.283N	P=0.527N	P=0.521N
MAX-ISO-POLY-3	P=0.198N	P=0.192N	P=0.189N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Pituitary Gland: Pars Distalis or Unspecified Site Adenoma</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	11/50 (22%)	14/50 (28%)	17/50 (34%)
POLY-3 RATE (b)	11/45.90	14/44.18	17/45.21
POLY-3 PERCENT (g)	24%	31.7%	37.6%
TERMINAL (d)	10/39 (26%)	10/32 (31%)	10/28 (36%)
FIRST INCIDENCE	692	580	594
HC TUMORS SAME ROUTE	25/100 (25%)		
HC TUMORS ALL ROUTES	624/1344 (46%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.095	P=0.280	P=0.116
POLY 1.5	P=0.111	P=0.308	P=0.134
POLY 6	P=0.077	P=0.247	P=0.096
COCH-ARM / FISHERS	P=0.110	P=0.322	P=0.133
MAX-ISO-POLY-3	P=0.107	P=0.211	P=0.079
HISTCONT SAME RTE	P=0.145	P=0.296	P=0.110
HISTCONT ALL RTEs	P=0.121	P=0.257	P=0.090

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Skin</b>			
<b>Basal Cell Adenoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/45.76	0/43.06	1/43.38
POLY-3 PERCENT (g)	0%	0%	2.3%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	---	---	727 (T)
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	13/1349 (1%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.271	(e)	P=0.489
POLY 1.5	P=0.270	(e)	P=0.498
POLY 6	P=0.272	(e)	P=0.477
COCH-ARM / FISHERS	P=0.269	(e)	P=0.500
MAX-ISO-POLY-3	P=0.151	(e)	P=0.158
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Skin</b>			
<b>Basal Cell Carcinoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	2/43.06	0/43.38
POLY-3 PERCENT (g)	0%	4.6%	0%
TERMINAL (d)	0/39 (0%)	2/32 (6%)	0/28 (0%)
FIRST INCIDENCE	---	727 (T)	---
HC TUMORS SAME ROUTE	2/100 (2%)		
HC TUMORS ALL ROUTES	10/1349 (1%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.651	P=0.224	(e)
POLY 1.5	P=0.665	P=0.232	(e)
POLY 6	P=0.630	P=0.214	(e)
COCH-ARM / FISHERS	P=0.669	P=0.247	(e)
MAX-ISO-POLY-3	P=0.264	P=0.076	(e)
HISTCONT SAME RTE	P=0.356	P=0.106	(e)
HISTCONT ALL RTEs	P=0.311	P=0.078	(e)

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Skin</b>			
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/45.76	2/43.06	1/43.38
POLY-3 PERCENT (g)	0%	4.6%	2.3%
TERMINAL (d)	0/39 (0%)	2/32 (6%)	1/28 (4%)
FIRST INCIDENCE	---	727 (T)	727 (T)
HC TUMORS SAME ROUTE	2/100 (2%)		
HC TUMORS ALL ROUTES	29/1349 (2%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.343	P=0.224	P=0.489
POLY 1.5	P=0.357	P=0.232	P=0.498
POLY 6	P=0.323	P=0.214	P=0.477
COCH-ARM / FISHERS	P=0.360	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.196	P=0.076	P=0.158
HISTCONT SAME RTE	P=0.265	P=0.106	P=0.223
HISTCONT ALL RTEs	P=0.227	P=0.086	P=0.188

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Skin</b>			
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	3/50 (6%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	3/45.76	3/43.06	2/43.50
POLY-3 PERCENT (g)	6.6%	7%	4.6%
TERMINAL (d)	3/39 (8%)	3/32 (9%)	1/28 (4%)
FIRST INCIDENCE	727 (T)	727 (T)	697
HC TUMORS SAME ROUTE	11/100 (11%)		
HC TUMORS ALL ROUTES	123/1349 (9%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.440N	P=0.634	P=0.523N
POLY 1.5	P=0.418N	P=0.651	P=0.505N
POLY 6	P=0.471N	P=0.611	P=0.549N
COCH-ARM / FISHERS	P=0.412N	P=0.661N	P=0.500N
MAX-ISO-POLY-3	P=0.466N	P=0.469	P=0.348N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Skin</b>			
<b>Fibroma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	3/50 (6%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	3/45.76	2/43.49	3/44.55
POLY-3 PERCENT (g)	6.6%	4.6%	6.7%
TERMINAL (d)	3/39 (8%)	1/32 (3%)	1/28 (4%)
FIRST INCIDENCE	727 (T)	605	455
HC TUMORS SAME ROUTE	8/100 (8%)		
HC TUMORS ALL ROUTES	124/1349 (9%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.578	P=0.523N	P=0.650
POLY 1.5	P=0.586N	P=0.508N	P=0.660N
POLY 6	P=0.559	P=0.542N	P=0.628
COCH-ARM / FISHERS	P=0.588	P=0.500N	P=0.661N
MAX-ISO-POLY-3	P=0.560	P=0.348N	P=0.486
HISTCONT SAME RTE	P=0.704	P=1.000	P=0.639
HISTCONT ALL RTEs	P=0.676	P=1.000	P=0.614

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Skin</b>			
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	3/50 (6%)	2/50 (4%)	4/50 (8%)
POLY-3 RATE (b)	3/45.76	2/43.49	4/44.66
POLY-3 PERCENT (g)	6.6%	4.6%	9%
TERMINAL (d)	3/39 (8%)	1/32 (3%)	1/28 (4%)
FIRST INCIDENCE	727 (T)	605	455
HC TUMORS SAME ROUTE	11/100 (11%)		
HC TUMORS ALL ROUTES	154/1349 (11%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.407	P=0.523N	P=0.487
POLY 1.5	P=0.419	P=0.508N	P=0.503
POLY 6	P=0.389	P=0.542N	P=0.462
COCH-ARM / FISHERS	P=0.417	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.369	P=0.348N	P=0.337
HISTCONT SAME RTE	P=0.486	P=1.000	P=0.464
HISTCONT ALL RTEs	P=0.440	P=1.000	P=0.424



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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Skin</b>			
<b>Keratoacanthoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	3/50 (6%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	3/45.76	0/43.06	1/43.50
POLY-3 PERCENT (g)	6.6%	0%	2.3%
TERMINAL (d)	3/39 (8%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	727 (T)	---	697
HC TUMORS SAME ROUTE	9/100 (9%)		
HC TUMORS ALL ROUTES	73/1349 (5%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.183N	P=0.130N	P=0.324N
POLY 1.5	P=0.177N	P=0.123N	P=0.309N
POLY 6	P=0.193N	P=0.139N	P=0.345N
COCH-ARM / FISHERS	P=0.176N	P=0.121N	P=0.309N
MAX-ISO-POLY-3	P=0.097N	P=0.047N*	P=0.173N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Skin</b>			
<b>Lipoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	2/100 (2%)		
HC TUMORS ALL ROUTES	14/1349 (1%)		
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Skin</b>			
<b>Schwannoma Malignant</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	3/50 (6%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	3/46.30	2/43.28	1/43.70
POLY-3 PERCENT (g)	6.5%	4.6%	2.3%
TERMINAL (d)	0/39 (0%)	1/32 (3%)	0/28 (0%)
FIRST INCIDENCE	627	672	641
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	8/1349 (1%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.243N	P=0.531N	P=0.326N
POLY 1.5	P=0.228N	P=0.512N	P=0.311N
POLY 6	P=0.267N	P=0.554N	P=0.350N
COCH-ARM / FISHERS	P=0.222N	P=0.500N	P=0.309N
MAX-ISO-POLY-3	P=0.245N	P=0.356N	P=0.176N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Skin</b>			
<b>Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	3/43.06	0/43.38
POLY-3 PERCENT (g)	0%	7%	0%
TERMINAL (d)	0/39 (0%)	3/32 (9%)	0/28 (0%)
FIRST INCIDENCE	---	727 (T)	---
HC TUMORS SAME ROUTE	2/100 (2%)		
HC TUMORS ALL ROUTES	17/1349 (1%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.616	P=0.108	(e)
POLY 1.5	P=0.635	P=0.115	(e)
POLY 6	P=0.587	P=0.100	(e)
COCH-ARM / FISHERS	P=0.640	P=0.121	(e)
MAX-ISO-POLY-3	P=0.191	P=0.038*	(e)
HISTCONT SAME RTE	P=0.259	P=0.051	(e)
HISTCONT ALL RTEs	P=0.221	P=0.030*	(e)

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Skin</b>			
<b>Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	3/45.76	1/43.06	1/43.50
POLY-3 PERCENT (g)	6.6%	2.3%	2.3%
TERMINAL (d)	3/39 (8%)	1/32 (3%)	0/28 (0%)
FIRST INCIDENCE	727 (T)	727 (T)	697
HC TUMORS SAME ROUTE	9/100 (9%)		
HC TUMORS ALL ROUTES	98/1349 (7%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.215N	P=0.327N	P=0.324N
POLY 1.5	P=0.205N	P=0.314N	P=0.309N
POLY 6	P=0.231N	P=0.345N	P=0.345N
COCH-ARM / FISHERS	P=0.202N	P=0.309N	P=0.309N
MAX-ISO-POLY-3	P=0.211N	P=0.177N	P=0.173N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Skin</b>			
<b>Squamous Cell Papilloma, Papilloma, or Keratoacanthoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	3/50 (6%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	3/45.76	0/43.06	1/43.50
POLY-3 PERCENT (g)	6.6%	0%	2.3%
TERMINAL (d)	3/39 (8%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	727 (T)	---	697
HC TUMORS SAME ROUTE	9/100 (9%)		
HC TUMORS ALL ROUTES	90/1349 (7%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.183N	P=0.130N	P=0.324N
POLY 1.5	P=0.177N	P=0.123N	P=0.309N
POLY 6	P=0.193N	P=0.139N	P=0.345N
COCH-ARM / FISHERS	P=0.176N	P=0.121N	P=0.309N
MAX-ISO-POLY-3	P=0.097N	P=0.047N*	P=0.173N
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/N

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:37:47  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
Spleen			
Hemangiosarcoma			
<hr/>			
<b>TUMOR RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	1/100 (1%)		
HC TUMORS ALL ROUTES	3/1346 (0%)		
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Testes</b>			
<b>Adenoma</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	46/50 (92%)	45/50 (90%)	43/50 (86%)
POLY-3 RATE (b)	46/47.05	45/48.16	43/48.48
POLY-3 PERCENT (g)	97.8%	93.5%	88.7%
TERMINAL (d)	39/39 (100%)	29/32 (91%)	26/28 (93%)
FIRST INCIDENCE	627	451	455
HC TUMORS SAME ROUTE	93/100 (93%)		
HC TUMORS ALL ROUTES	1124/1349 (83%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.049N*	P=0.290N	P=0.071N
POLY 1.5	P=0.048N*	P=0.295N	P=0.072N
POLY 6	P=0.060N	P=0.260N	P=0.080N
COCH-ARM / FISHERS	P=0.209N	P=0.500N	P=0.262N
MAX-ISO-POLY-3	P=0.042N*	P=0.143N	P=0.030N*
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/N

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:37:47  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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

---

Thyroid Gland: C-Cell  
Adenoma

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**TUMOR RATES**

OVERALL (a)	8/50 (16%)	7/50 (14%)	4/44 (9%)
POLY-3 RATE (b)	8/46.59	7/43.49	4/39.18
POLY-3 PERCENT (g)	17.2%	16.1%	10.2%
TERMINAL (d)	4/39 (10%)	6/32 (19%)	2/28 (7%)
FIRST INCIDENCE	627	605	594
HC TUMORS SAME ROUTE	21/100 (21%)		
HC TUMORS ALL ROUTES	164/1342 (12%)		

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**STATISTICAL TESTS**

POLY 3	P=0.232N	P=0.558N	P=0.271N
POLY 1.5	P=0.210N	P=0.523N	P=0.249N
POLY 6	P=0.265N	P=0.602N	P=0.301N
COCH-ARM / FISHERS	P=0.204N	P=0.500N	P=0.246N
MAX-ISO-POLY-3	P=0.270N	P=0.446N	P=0.191N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:37:47  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

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

---

Thyroid Gland: Follicular Cell  
Adenoma

---

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	4/50 (8%)	2/44 (5%)
POLY-3 RATE (b)	0/45.76	4/43.41	2/38.62
POLY-3 PERCENT (g)	0%	9.2%	5.2%
TERMINAL (d)	0/39 (0%)	3/32 (9%)	2/28 (7%)
FIRST INCIDENCE	---	632	727 (T)
HC TUMORS SAME ROUTE	2/100 (2%)		
HC TUMORS ALL ROUTES	16/1342 (1%)		

---

**STATISTICAL TESTS**

POLY 3	P=0.166	P=0.054	P=0.200
POLY 1.5	P=0.179	P=0.058	P=0.207
POLY 6	P=0.150	P=0.049*	P=0.191
COCH-ARM / FISHERS	P=0.183	P=0.059	P=0.216
MAX-ISO-POLY-3	P=0.086	P=0.019*	P=0.069
HISTCONT SAME RTE	P=0.117	P=0.025*	P=0.096
HISTCONT ALL RTEs	P=0.009**	P=0.010**	P=0.077

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>Tongue</b>			
<b>Squamous Cell Papilloma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/45.76	1/43.06	2/43.39
POLY-3 PERCENT (g)	0%	2.3%	4.6%
TERMINAL (d)	0/39 (0%)	1/32 (3%)	1/28 (4%)
FIRST INCIDENCE	---	727 (T)	725
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	6/1349 (0%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.136	P=0.488	P=0.225
POLY 1.5	P=0.141	P=0.495	P=0.235
POLY 6	P=0.128	P=0.478	P=0.213
COCH-ARM / FISHERS	P=0.142	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.104	P=0.158	P=0.076
HISTCONT SAME RTE	P=0.112	P=0.120	P=0.106
HISTCONT ALL RTEs	P<0.001**	P=0.116	P=0.008**

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:37:47  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<hr/>			
All Organs			
Hemangiosarcoma			
<hr/>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	1/100 (1%)		
HC TUMORS ALL ROUTES	7/1349 (1%)		
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>All Organs</b>			
<b>Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	4/50 (8%)	6/50 (12%)	6/50 (12%)
POLY-3 RATE (b)	4/46.20	6/44.10	6/44.69
POLY-3 PERCENT (g)	8.7%	13.6%	13.4%
TERMINAL (d)	2/39 (5%)	4/32 (13%)	1/28 (4%)
FIRST INCIDENCE	627	199	598
HC TUMORS SAME ROUTE	19/100 (19%)		
HC TUMORS ALL ROUTES	549/1349 (41%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.292	P=0.340	P=0.349
POLY 1.5	P=0.313	P=0.364	P=0.369
POLY 6	P=0.265	P=0.309	P=0.323
COCH-ARM / FISHERS	P=0.314	P=0.370	P=0.370
MAX-ISO-POLY-3	P=0.335	P=0.234	P=0.239
HISTCONT SAME RTE	P=0.445	P=0.328	P=0.335
HISTCONT ALL RTEs	P=0.399	P=0.286	P=0.294

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>All Organs</b>			
<b>Mesothelioma: Benign</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/45.76	2/43.06	1/43.38
POLY-3 PERCENT (g)	0%	4.6%	2.3%
TERMINAL (d)	0/39 (0%)	2/32 (6%)	1/28 (4%)
FIRST INCIDENCE	---	727 (T)	727 (T)
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	1/1349 (0%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.343	P=0.224	P=0.489
POLY 1.5	P=0.357	P=0.232	P=0.498
POLY 6	P=0.323	P=0.214	P=0.477
COCH-ARM / FISHERS	P=0.360	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.196	P=0.076	P=0.158
HISTCONT SAME RTE	P=0.232	P=0.106	P=0.119
HISTCONT ALL RTEs	P<0.001**	P<0.001**	P=0.004**

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>All Organs</b>			
<b>Mesothelioma: Benign, Malignant, NOS</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	2/50 (4%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	2/45.88	2/43.06	2/43.38
POLY-3 PERCENT (g)	4.4%	4.6%	4.6%
TERMINAL (d)	1/39 (3%)	2/32 (6%)	2/28 (7%)
FIRST INCIDENCE	699	727 (T)	727 (T)
HC TUMORS SAME ROUTE	5/100 (5%)		
HC TUMORS ALL ROUTES	35/1349 (3%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.580	P=0.671	P=0.674
POLY 1.5	P=0.595	P=0.685	P=0.689
POLY 6	P=0.557	P=0.652	P=0.651
COCH-ARM / FISHERS	P=0.601	P=0.691N	P=0.691N
MAX-ISO-POLY-3	P=0.638	P=0.474	P=0.477
HISTCONT SAME RTE	P=0.782	P=0.627	P=0.630
HISTCONT ALL RTEs	P=0.424	P=0.393	P=0.397

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>All Organs</b>			
<b>Mesothelioma: Malignant</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/45.88	0/43.06	1/43.38
POLY-3 PERCENT (g)	4.4%	0%	2.3%
TERMINAL (d)	1/39 (3%)	0/32 (0%)	1/28 (4%)
FIRST INCIDENCE	699	---	727 (T)
HC TUMORS SAME ROUTE	5/100 (5%)		
HC TUMORS ALL ROUTES	34/1349 (3%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.373N	P=0.252N	P=0.519N
POLY 1.5	P=0.364N	P=0.243N	P=0.505N
POLY 6	P=0.386N	P=0.263N	P=0.541N
COCH-ARM / FISHERS	P=0.360N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.224N	P=0.090N	P=0.302N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>All Organs</b>			
<b>Benign Tumors</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	47/50 (94%)	48/50 (96%)	48/50 (96%)
POLY-3 RATE (b)	47/47.18	48/48.16	48/49.16
POLY-3 PERCENT (g)	99.6%	99.7%	97.6%
TERMINAL (d)	39/39 (100%)	32/32 (100%)	28/28 (100%)
FIRST INCIDENCE	627	451	455
HC TUMORS SAME ROUTE	98/100 (98%)		
HC TUMORS ALL ROUTES	1308/1349 (97%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.284N	P=1.000	P=0.521N
POLY 1.5	P=0.318N	P=0.944N	P=0.510N
POLY 6	P=0.307N	P=1.000	P=0.575N
COCH-ARM / FISHERS	P=0.406	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.162N	P=0.449	P=0.168N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>All Organs</b>			
<b>Malignant Tumors</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	10/50 (20%)	16/50 (32%)	14/50 (28%)
POLY-3 RATE (b)	10/46.55	16/45.42	14/46.45
POLY-3 PERCENT (g)	21.5%	35.2%	30.1%
TERMINAL (d)	5/39 (13%)	9/32 (28%)	4/28 (14%)
FIRST INCIDENCE	627	199	465
HC TUMORS SAME ROUTE	52/100 (52%)		
HC TUMORS ALL ROUTES	788/1349 (58%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.208	P=0.108	P=0.237
POLY 1.5	P=0.228	P=0.125	P=0.255
POLY 6	P=0.181	P=0.088	P=0.213
COCH-ARM / FISHERS	P=0.214	P=0.127	P=0.241
MAX-ISO-POLY-3	P=0.159	P=0.072	P=0.171
HISTCONT SAME RTE	P=0.216	P=0.101	P=0.240
HISTCONT ALL RTEs	P=0.183	P=0.082	P=0.205

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
<b>All Organs</b>			
<b>Malignant and Benign Tumors</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	47/50 (94%)	49/50 (98%)	49/50 (98%)
POLY-3 RATE (b)	47/47.18	49/49.14	49/49.25
POLY-3 PERCENT (g)	99.6%	99.7%	99.5%
TERMINAL (d)	39/39 (100%)	32/32 (100%)	28/28 (100%)
FIRST INCIDENCE	627	199	455
HC TUMORS SAME ROUTE	100/100 (100%)		
HC TUMORS ALL ROUTES	1343/1349 (100%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.948N	P=1.000	P=0.999N
POLY 1.5	P=0.776N	P=0.945	P=0.927N
POLY 6	P=1.000N	P=1.000	P=1.000N
COCH-ARM / FISHERS	P=0.202	P=0.309	P=0.309
MAX-ISO-POLY-3	P=0.528N	P=0.410	P=0.429N
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/N

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:37:47  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Adrenal Cortex			
Adenoma			
<hr/>			
<b>TUMOR RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	24/1296 (2%)		
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Adrenal Medulla</b>			
<b>Pheochromocytoma Benign</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	3/50 (6%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	3/42.78	1/45.81	2/47.50
POLY-3 PERCENT (g)	7%	2.2%	4.2%
TERMINAL (d)	3/31 (10%)	1/37 (3%)	1/38 (3%)
FIRST INCIDENCE	728 (T)	728 (T)	702
HC TUMORS SAME ROUTE	3/100 (3%)		
HC TUMORS ALL ROUTES	33/1288 (3%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.375N	P=0.281N	P=0.452N
POLY 1.5	P=0.385N	P=0.293N	P=0.472N
POLY 6	P=0.362N	P=0.267N	P=0.426N
COCH-ARM / FISHERS	P=0.399N	P=0.309N	P=0.500N
MAX-ISO-POLY-3	P=0.285N	P=0.145N	P=0.292N
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/N

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:37:47  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Adrenal Medulla</b>			
<b>Pheochromocytoma Malignant</b>			
<hr/>			
<b>TUMOR RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	8/1288 (1%)		
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Adrenal Medulla</b>			
<b>Pheochromocytoma: Benign, Complex, Malignant, NOS</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	3/50 (6%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	3/42.78	1/45.81	2/47.50
POLY-3 PERCENT (g)	7%	2.2%	4.2%
TERMINAL (d)	3/31 (10%)	1/37 (3%)	1/38 (3%)
FIRST INCIDENCE	728 (T)	728 (T)	702
HC TUMORS SAME ROUTE	3/100 (3%)		
HC TUMORS ALL ROUTES	45/1288 (4%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.375N	P=0.281N	P=0.452N
POLY 1.5	P=0.385N	P=0.293N	P=0.472N
POLY 6	P=0.362N	P=0.267N	P=0.426N
COCH-ARM / FISHERS	P=0.399N	P=0.309N	P=0.500N
MAX-ISO-POLY-3	P=0.285N	P=0.145N	P=0.292N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Clitoral/Preputial Gland Adenoma</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	3/50 (6%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	3/43.62	3/45.81	3/47.40
POLY-3 PERCENT (g)	6.9%	6.6%	6.3%
TERMINAL (d)	1/31 (3%)	3/37 (8%)	3/38 (8%)
FIRST INCIDENCE	495	728 (T)	728 (T)
HC TUMORS SAME ROUTE	10/98 (10%)		
HC TUMORS ALL ROUTES	122/1297 (9%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.545N	P=0.640N	P=0.623N
POLY 1.5	P=0.561N	P=0.651N	P=0.639N
POLY 6	P=0.525N	P=0.626N	P=0.601N
COCH-ARM / FISHERS	P=0.583	P=0.661N	P=0.661N
MAX-ISO-POLY-3	P=0.619N	P=0.475N	P=0.459N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Clitoral/Preputial Gland Carcinoma or Adenoma</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	3/50 (6%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	3/43.62	3/45.81	3/47.40
POLY-3 PERCENT (g)	6.9%	6.6%	6.3%
TERMINAL (d)	1/31 (3%)	3/37 (8%)	3/38 (8%)
FIRST INCIDENCE	495	728 (T)	728 (T)
HC TUMORS SAME ROUTE	12/98 (12%)		
HC TUMORS ALL ROUTES	158/1297 (12%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.545N	P=0.640N	P=0.623N
POLY 1.5	P=0.561N	P=0.651N	P=0.639N
POLY 6	P=0.525N	P=0.626N	P=0.601N
COCH-ARM / FISHERS	P=0.583	P=0.661N	P=0.661N
MAX-ISO-POLY-3	P=0.619N	P=0.475N	P=0.459N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Islets, Pancreatic Adenoma</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/49 (0%)
POLY-3 RATE (b)	1/42.78	1/45.81	0/46.50
POLY-3 PERCENT (g)	2.3%	2.2%	0%
TERMINAL (d)	1/31 (3%)	1/37 (3%)	0/38 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	---
HC TUMORS SAME ROUTE	1/100 (1%)		
HC TUMORS ALL ROUTES	20/1290 (2%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.318N	P=0.745N	P=0.483N
POLY 1.5	P=0.325N	P=0.753N	P=0.492N
POLY 6	P=0.308N	P=0.736N	P=0.472N
COCH-ARM / FISHERS	P=0.335N	P=0.753N	P=0.505N
MAX-ISO-POLY-3	P=0.270N	P=0.480N	P=0.160N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Kidney: Renal Tubule Adenoma</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.78	0/45.81	1/47.40
POLY-3 PERCENT (g)	0%	0%	2.1%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)
FIRST INCIDENCE	---	---	728 (T)
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	1/1290 (0%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.288	(e)	P=0.520
POLY 1.5	P=0.280	(e)	P=0.512
POLY 6	P=0.298	(e)	P=0.532
COCH-ARM / FISHERS	P=0.269	(e)	P=0.500
MAX-ISO-POLY-3	P=0.186	(e)	P=0.183
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/N

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:37:47  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

---

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

---

Kidney: Renal Tubule  
Carcinoma or Adenoma

---

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.78	0/45.81	1/47.40
POLY-3 PERCENT (g)	0%	0%	2.1%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)
FIRST INCIDENCE	---	---	728 (T)
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	2/1290 (0%)		

---

**STATISTICAL TESTS**

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

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Lung</b>			
<b>Alveolar/Bronchiolar Adenoma</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/43.27	1/45.81	0/47.40
POLY-3 PERCENT (g)	4.6%	2.2%	0%
TERMINAL (d)	1/31 (3%)	1/37 (3%)	0/38 (0%)
FIRST INCIDENCE	581	728 (T)	---
HC TUMORS SAME ROUTE	5/100 (5%)		
HC TUMORS ALL ROUTES	26/1300 (2%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.132N	P=0.480N	P=0.217N
POLY 1.5	P=0.136N	P=0.490N	P=0.225N
POLY 6	P=0.127N	P=0.469N	P=0.207N
COCH-ARM / FISHERS	P=0.142N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.104N	P=0.269N	P=0.076N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Lung</b>			
<b>Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/43.27	1/45.81	0/47.40
POLY-3 PERCENT (g)	4.6%	2.2%	0%
TERMINAL (d)	1/31 (3%)	1/37 (3%)	0/38 (0%)
FIRST INCIDENCE	581	728 (T)	---
HC TUMORS SAME ROUTE	5/100 (5%)		
HC TUMORS ALL ROUTES	32/1300 (3%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.132N	P=0.480N	P=0.217N
POLY 1.5	P=0.136N	P=0.490N	P=0.225N
POLY 6	P=0.127N	P=0.469N	P=0.207N
COCH-ARM / FISHERS	P=0.142N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.104N	P=0.269N	P=0.076N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Mammary Gland Adenoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/43.03	0/45.81	0/47.40
POLY-3 PERCENT (g)	4.7%	0%	0%
TERMINAL (d)	1/31 (3%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	659	---	---
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	17/1300 (1%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.094N	P=0.223N	P=0.216N
POLY 1.5	P=0.094N	P=0.230N	P=0.225N
POLY 6	P=0.094N	P=0.216N	P=0.206N
COCH-ARM / FISHERS	P=0.095N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.052N	P=0.076N	P=0.076N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Mammary Gland Carcinoma or Adenoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/43.03	1/46.10	0/47.40
POLY-3 PERCENT (g)	4.7%	2.2%	0%
TERMINAL (d)	1/31 (3%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	659	650	---
HC TUMORS SAME ROUTE	4/100 (4%)		
HC TUMORS ALL ROUTES	84/1300 (7%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.132N	P=0.476N	P=0.216N
POLY 1.5	P=0.136N	P=0.488N	P=0.225N
POLY 6	P=0.126N	P=0.462N	P=0.206N
COCH-ARM / FISHERS	P=0.142N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.104N	P=0.267N	P=0.076N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Mammary Gland Fibroadenoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	21/50 (42%)	27/50 (54%)	8/50 (16%)
POLY-3 RATE (b)	21/44.49	27/46.69	8/47.40
POLY-3 PERCENT (g)	47.2%	57.8%	16.9%
TERMINAL (d)	14/31 (45%)	23/37 (62%)	8/38 (21%)
FIRST INCIDENCE	604	573	728 (T)
HC TUMORS SAME ROUTE	43/100 (43%)		
HC TUMORS ALL ROUTES	676/1300 (52%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001N**	P=0.206	P<0.001N**
POLY 1.5	P<0.001N**	P=0.180	P=0.002N**
POLY 6	P<0.001N**	P=0.232	P<0.001N**
COCH-ARM / FISHERS	P=0.005N**	P=0.158	P=0.004N**
MAX-ISO-POLY-3	P<0.001N**	P=0.156	P<0.001N**
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Mammary Gland</b>			
<b>Fibroma, Fibroadenoma or Adenoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	22/50 (44%)	27/50 (54%)	8/50 (16%)
POLY-3 RATE (b)	22/44.75	27/46.69	8/47.40
POLY-3 PERCENT (g)	49.2%	57.8%	16.9%
TERMINAL (d)	14/31 (45%)	23/37 (62%)	8/38 (21%)
FIRST INCIDENCE	604	573	728 (T)
HC TUMORS SAME ROUTE	43/100 (43%)		
HC TUMORS ALL ROUTES	685/1300 (53%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001N**	P=0.264	P<0.001N**
POLY 1.5	P<0.001N**	P=0.236	P<0.001N**
POLY 6	P<0.001N**	P=0.288	P<0.001N**
COCH-ARM / FISHERS	P=0.003N**	P=0.212	P=0.002N**
MAX-ISO-POLY-3	P<0.001N**	P=0.205	P<0.001N**
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Mammary Gland</b>			
<b>Fibroma, Fibroadenoma, Carcinoma, or Adenoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	22/50 (44%)	28/50 (56%)	8/50 (16%)
POLY-3 RATE (b)	22/44.75	28/46.97	8/47.40
POLY-3 PERCENT (g)	49.2%	59.6%	16.9%
TERMINAL (d)	14/31 (45%)	23/37 (62%)	8/38 (21%)
FIRST INCIDENCE	604	573	728 (T)
HC TUMORS SAME ROUTE	45/100 (45%)		
HC TUMORS ALL ROUTES	720/1300 (55%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001N**	P=0.210	P<0.001N**
POLY 1.5	P<0.001N**	P=0.182	P<0.001N**
POLY 6	P<0.001N**	P=0.238	P<0.001N**
COCH-ARM / FISHERS	P=0.003N**	P=0.159	P=0.002N**
MAX-ISO-POLY-3	P<0.001N**	P=0.159	P<0.001N**
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva)</b>			
<b>Papilloma Squamous or Papilloma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/42.78	1/45.96	1/47.40
POLY-3 PERCENT (g)	0%	2.2%	2.1%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)
FIRST INCIDENCE	---	689	728 (T)
HC TUMORS SAME ROUTE	1/100 (1%)		
HC TUMORS ALL ROUTES	8/1300 (1%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.368	P=0.514	P=0.520
POLY 1.5	P=0.353	P=0.507	P=0.512
POLY 6	P=0.389	P=0.523	P=0.532
COCH-ARM / FISHERS	P=0.331	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.298	P=0.176	P=0.183
HISTCONT SAME RTE	P=0.399	P=0.248	P=0.258
HISTCONT ALL RTEs	P=0.217	P=0.211	P=0.221

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/42.78	1/45.96	1/47.40
POLY-3 PERCENT (g)	0%	2.2%	2.1%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)
FIRST INCIDENCE	---	689	728 (T)
HC TUMORS SAME ROUTE	2/100 (2%)		
HC TUMORS ALL ROUTES	13/1300 (1%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.368	P=0.514	P=0.520
POLY 1.5	P=0.353	P=0.507	P=0.512
POLY 6	P=0.389	P=0.523	P=0.532
COCH-ARM / FISHERS	P=0.331	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.298	P=0.176	P=0.183
HISTCONT SAME RTE	P=0.399	P=0.248	P=0.258
HISTCONT ALL RTEs	P=0.352	P=0.211	P=0.221

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Pancreas</b>			
<b>Adenoma</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/46.50
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	1/1291 (0%)		
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Parathyroid Gland Adenoma</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	2/46 (4%)	0/47 (0%)	0/49 (0%)
POLY-3 RATE (b)	2/38.78	0/42.87	0/47.20
POLY-3 PERCENT (g)	5.2%	0%	0%
TERMINAL (d)	2/27 (7%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	728 (T)	---	---
HC TUMORS SAME ROUTE	0/94 (0%)		
HC TUMORS ALL ROUTES	0/1221 (0%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.088N	P=0.215N	P=0.196N
POLY 1.5	P=0.088N	P=0.223N	P=0.207N
POLY 6	P=0.088N	P=0.205N	P=0.183N
COCH-ARM / FISHERS	P=0.090N	P=0.242N	P=0.232N
MAX-ISO-POLY-3	P=0.049N*	P=0.074N	P=0.072N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Pituitary Gland: Pars Distalis or Unspecified Site Adenoma</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	27/50 (54%)	12/50 (24%)	9/50 (18%)
POLY-3 RATE (b)	27/46.04	12/46.53	9/47.50
POLY-3 PERCENT (g)	58.6%	25.8%	19%
TERMINAL (d)	17/31 (55%)	9/37 (24%)	8/38 (21%)
FIRST INCIDENCE	495	600	702
HC TUMORS SAME ROUTE	50/100 (50%)		
HC TUMORS ALL ROUTES	713/1294 (55%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001N**	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P<0.001N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.002N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P<0.001N**	P<0.001N**
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Skin</b>			
<b>Basal Cell Adenoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/42.78	0/45.81	2/47.40
POLY-3 PERCENT (g)	0%	0%	4.2%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	2/38 (5%)
FIRST INCIDENCE	---	---	728 (T)
HC TUMORS SAME ROUTE	1/100 (1%)		
HC TUMORS ALL ROUTES	3/1300 (0%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.104	(e)	P=0.261
POLY 1.5	P=0.100	(e)	P=0.251
POLY 6	P=0.109	(e)	P=0.274
COCH-ARM / FISHERS	P=0.095	(e)	P=0.247
MAX-ISO-POLY-3	P=0.076	(e)	P=0.098
HISTCONT SAME RTE	P=0.103	(e)	P=0.138
HISTCONT ALL RTEs	P=0.002**	(e)	P=0.002**

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Skin</b>			
<b>Basal Cell Carcinoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	1/1300 (0%)		
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Skin</b>			
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/42.78	0/45.81	2/47.40
POLY-3 PERCENT (g)	0%	0%	4.2%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	2/38 (5%)
FIRST INCIDENCE	---	---	728 (T)
HC TUMORS SAME ROUTE	1/100 (1%)		
HC TUMORS ALL ROUTES	9/1300 (1%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.104	(e)	P=0.261
POLY 1.5	P=0.100	(e)	P=0.251
POLY 6	P=0.109	(e)	P=0.274
COCH-ARM / FISHERS	P=0.095	(e)	P=0.247
MAX-ISO-POLY-3	P=0.076	(e)	P=0.098
HISTCONT SAME RTE	P=0.103	(e)	P=0.138
HISTCONT ALL RTEs	P=0.055	(e)	P=0.044*

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Skin</b>			
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/42.78	0/45.81	2/47.40
POLY-3 PERCENT (g)	2.3%	0%	4.2%
TERMINAL (d)	1/31 (3%)	0/37 (0%)	2/38 (5%)
FIRST INCIDENCE	728 (T)	---	728 (T)
HC TUMORS SAME ROUTE	1/100 (1%)		
HC TUMORS ALL ROUTES	25/1300 (2%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.381	P=0.486N	P=0.536
POLY 1.5	P=0.373	P=0.493N	P=0.521
POLY 6	P=0.392	P=0.478N	P=0.555
COCH-ARM / FISHERS	P=0.360	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.241	P=0.158N	P=0.319
HISTCONT SAME RTE	P=0.145	(e)	P=0.133
HISTCONT ALL RTEs	P=0.282	(e)	P=0.329

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Skin</b>			
<b>Fibroma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	3/43.20	1/46.09	0/47.40
POLY-3 PERCENT (g)	7%	2.2%	0%
TERMINAL (d)	2/31 (7%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	607	652	---
HC TUMORS SAME ROUTE	2/100 (2%)		
HC TUMORS ALL ROUTES	23/1300 (2%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.054N	P=0.282N	P=0.103N
POLY 1.5	P=0.056N	P=0.293N	P=0.109N
POLY 6	P=0.051N	P=0.269N	P=0.095N
COCH-ARM / FISHERS	P=0.060N	P=0.309N	P=0.121N
MAX-ISO-POLY-3	P=0.040N*	P=0.146N	P=0.038N*
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Skin</b>			
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	3/43.20	1/46.09	0/47.40
POLY-3 PERCENT (g)	7%	2.2%	0%
TERMINAL (d)	2/31 (7%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	607	652	---
HC TUMORS SAME ROUTE	3/100 (3%)		
HC TUMORS ALL ROUTES	31/1300 (2%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.054N	P=0.282N	P=0.103N
POLY 1.5	P=0.056N	P=0.293N	P=0.109N
POLY 6	P=0.051N	P=0.269N	P=0.095N
COCH-ARM / FISHERS	P=0.060N	P=0.309N	P=0.121N
MAX-ISO-POLY-3	P=0.040N*	P=0.146N	P=0.038N*
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Skin</b>			
<b>Keratoacanthoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	10/1300 (1%)		
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Skin</b>			
<b>Lipoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	3/45.81	0/47.40
POLY-3 PERCENT (g)	0%	6.6%	0%
TERMINAL (d)	0/31 (0%)	3/37 (8%)	0/38 (0%)
FIRST INCIDENCE	---	728 (T)	---
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	0/1300 (0%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.591N	P=0.131	(e)
POLY 1.5	P=0.612N	P=0.125	(e)
POLY 6	P=0.563N	P=0.139	(e)
COCH-ARM / FISHERS	P=0.640	P=0.121	(e)
MAX-ISO-POLY-3	P=0.205N	P=0.049*	(e)
HISTCONT SAME RTE	(h)	(h)	(e)
HISTCONT ALL RTEs	(h)	(h)	(e)



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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:37:47  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<hr/>			
Skin			
Schwannoma Malignant			
<hr/>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	3/1300 (0%)		
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)

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

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:37:47  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 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%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	4/1300 (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)

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Skin</b>			
<b>Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/42.78	0/45.81	0/47.40
POLY-3 PERCENT (g)	2.3%	0%	0%
TERMINAL (d)	1/31 (3%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	728 (T)	---	---
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	17/1300 (1%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.274N	P=0.486N	P=0.480N
POLY 1.5	P=0.272N	P=0.493N	P=0.488N
POLY 6	P=0.277N	P=0.478N	P=0.468N
COCH-ARM / FISHERS	P=0.269N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.151N	P=0.158N	P=0.158N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Skin</b>			
<b>Squamous Cell Papilloma, Papilloma, or Keratoacanthoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/42.78	0/45.81	0/47.40
POLY-3 PERCENT (g)	2.3%	0%	0%
TERMINAL (d)	1/31 (3%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	728 (T)	---	---
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	14/1300 (1%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.274N	P=0.486N	P=0.480N
POLY 1.5	P=0.272N	P=0.493N	P=0.488N
POLY 6	P=0.277N	P=0.478N	P=0.468N
COCH-ARM / FISHERS	P=0.269N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.151N	P=0.158N	P=0.158N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Spleen</b>			
<b>Hemangiosarcoma</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/43.41	0/45.81	0/47.40
POLY-3 PERCENT (g)	4.6%	0%	0%
TERMINAL (d)	1/31 (3%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	519	---	---
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	1/1293 (0%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.094N	P=0.225N	P=0.218N
POLY 1.5	P=0.094N	P=0.231N	P=0.226N
POLY 6	P=0.093N	P=0.218N	P=0.208N
COCH-ARM / FISHERS	P=0.095N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.052N	P=0.076N	P=0.076N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Thyroid Gland: C-Cell Adenoma</b>			
<b>TUMOR RATES</b>			
OVERALL (a)	8/50 (16%)	6/50 (12%)	3/50 (6%)
POLY-3 RATE (b)	8/42.78	6/45.81	3/47.50
POLY-3 PERCENT (g)	18.7%	13.1%	6.3%
TERMINAL (d)	8/31 (26%)	6/37 (16%)	2/38 (5%)
FIRST INCIDENCE	728 (T)	728 (T)	702
HC TUMORS SAME ROUTE	12/100 (12%)		
HC TUMORS ALL ROUTES	128/1288 (10%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.053N	P=0.334N	P=0.069N
POLY 1.5	P=0.062N	P=0.359N	P=0.081N
POLY 6	P=0.042N*	P=0.303N	P=0.055N
COCH-ARM / FISHERS	P=0.078N	P=0.387N	P=0.100N
MAX-ISO-POLY-3	P=0.060N	P=0.243N	P=0.042N*
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/N

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:37:47  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

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

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

---

Thyroid Gland: Follicular Cell  
Adenoma

---

**TUMOR RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	6/1288 (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)

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Tongue</b>			
<b>Squamous Cell Papilloma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/42.78	1/45.96	1/47.40
POLY-3 PERCENT (g)	0%	2.2%	2.1%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)
FIRST INCIDENCE	---	689	728 (T)
HC TUMORS SAME ROUTE	1/100 (1%)		
HC TUMORS ALL ROUTES	6/1300 (1%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.368	P=0.514	P=0.520
POLY 1.5	P=0.353	P=0.507	P=0.512
POLY 6	P=0.389	P=0.523	P=0.532
COCH-ARM / FISHERS	P=0.331	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.298	P=0.176	P=0.183
HISTCONT SAME RTE	P=0.399	P=0.248	P=0.258
HISTCONT ALL RTEs	P=0.133	P=0.179	P=0.182



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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>Uterus</b>			
<b>Polyp Stromal</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	5/50 (10%)	2/50 (4%)	5/50 (10%)
POLY-3 RATE (b)	5/42.91	2/46.10	5/47.50
POLY-3 PERCENT (g)	11.7%	4.3%	10.5%
TERMINAL (d)	4/31 (13%)	1/37 (3%)	4/38 (11%)
FIRST INCIDENCE	693	650	702
HC TUMORS SAME ROUTE	16/100 (16%)		
HC TUMORS ALL ROUTES	236/1300 (18%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.534N	P=0.188N	P=0.565N
POLY 1.5	P=0.550N	P=0.201N	P=0.592N
POLY 6	P=0.514N	P=0.172N	P=0.529N
COCH-ARM / FISHERS	P=0.573	P=0.218N	P=0.630N
MAX-ISO-POLY-3	P=0.354N	P=0.107N	P=0.434N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>All Organs</b>			
<b>Hemangiosarcoma</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/43.41	0/45.81	0/47.40
POLY-3 PERCENT (g)	4.6%	0%	0%
TERMINAL (d)	1/31 (3%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	519	---	---
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	4/1300 (0%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.094N	P=0.225N	P=0.218N
POLY 1.5	P=0.094N	P=0.231N	P=0.226N
POLY 6	P=0.093N	P=0.218N	P=0.208N
COCH-ARM / FISHERS	P=0.095N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.052N	P=0.076N	P=0.076N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>All Organs</b>			
<b>Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	4/50 (8%)	4/50 (8%)	11/50 (22%)
POLY-3 RATE (b)	4/42.99	4/47.01	11/48.80
POLY-3 PERCENT (g)	9.3%	8.5%	22.5%
TERMINAL (d)	3/31 (10%)	0/37 (0%)	4/38 (11%)
FIRST INCIDENCE	672	561	428
HC TUMORS SAME ROUTE	13/100 (13%)		
HC TUMORS ALL ROUTES	293/1300 (23%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.038*	P=0.593N	P=0.076
POLY 1.5	P=0.032*	P=0.617N	P=0.061
POLY 6	P=0.047*	P=0.563N	P=0.098
COCH-ARM / FISHERS	P=0.025*	P=0.643N	P=0.045*
MAX-ISO-POLY-3	P=0.048*	P=0.449N	P=0.052
HISTCONT SAME RTE	P=0.063	P=1.000	P=0.072
HISTCONT ALL RTEs	P=0.052	P=1.000	P=0.057

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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>All Organs</b>			
<b>Mesothelioma: Benign</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/47.40
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	1/1300 (0%)		
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>All Organs</b>			
<b>Mesothelioma: Benign, Malignant, NOS</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.27	0/45.81	0/47.40
POLY-3 PERCENT (g)	2.3%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	581	---	---
HC TUMORS SAME ROUTE	1/100 (1%)		
HC TUMORS ALL ROUTES	4/1300 (0%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.274N	P=0.489N	P=0.482N
POLY 1.5	P=0.272N	P=0.494N	P=0.489N
POLY 6	P=0.276N	P=0.482N	P=0.472N
COCH-ARM / FISHERS	P=0.269N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.151N	P=0.158N	P=0.158N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>All Organs</b>			
<b>Mesothelioma: Malignant</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.27	0/45.81	0/47.40
POLY-3 PERCENT (g)	2.3%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	581	---	---
HC TUMORS SAME ROUTE	1/100 (1%)		
HC TUMORS ALL ROUTES	3/1300 (0%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.274N	P=0.489N	P=0.482N
POLY 1.5	P=0.272N	P=0.494N	P=0.489N
POLY 6	P=0.276N	P=0.482N	P=0.472N
COCH-ARM / FISHERS	P=0.269N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.151N	P=0.158N	P=0.158N
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>All Organs</b>			
<b>Benign Tumors</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	42/50 (84%)	39/50 (78%)	27/50 (54%)
POLY-3 RATE (b)	42/47.50	39/48.13	27/47.89
POLY-3 PERCENT (g)	88.4%	81%	56.4%
TERMINAL (d)	27/31 (87%)	29/37 (78%)	22/38 (58%)
FIRST INCIDENCE	495	573	702
HC TUMORS SAME ROUTE	81/100 (81%)		
HC TUMORS ALL ROUTES	1133/1300 (87%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001N**	P=0.229N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.270N	P<0.001N**
POLY 6	P<0.001N**	P=0.199N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.306N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.151N	P<0.001N**
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/N

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>All Organs</b>			
<b>Malignant Tumors</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	8/50 (16%)	6/50 (12%)	14/50 (28%)
POLY-3 RATE (b)	8/44.72	6/47.30	14/49.49
POLY-3 PERCENT (g)	17.9%	12.7%	28.3%
TERMINAL (d)	4/31 (13%)	1/37 (3%)	6/38 (16%)
FIRST INCIDENCE	519	561	428
HC TUMORS SAME ROUTE	29/100 (29%)		
HC TUMORS ALL ROUTES	485/1300 (37%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.111	P=0.344N	P=0.172
POLY 1.5	P=0.097	P=0.365N	P=0.147
POLY 6	P=0.131	P=0.316N	P=0.208
COCH-ARM / FISHERS	P=0.079	P=0.387N	P=0.114
MAX-ISO-POLY-3	P=0.086	P=0.251N	P=0.128
HISTCONT SAME RTE	P=0.116	P=1.000	P=0.181
HISTCONT ALL RTEs	P=0.096	P=1.000	P=0.150



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

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

Date Report Requested: 08/25/2009  
 Time Report Requested: 09:37:47  
 First Dose M/F: 04/09/03 / 04/10/03  
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
<b>All Organs</b>			
<b>Malignant and Benign Tumors</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	44/50 (88%)	41/50 (82%)	38/50 (76%)
POLY-3 RATE (b)	44/48.74	41/49.00	38/49.77
POLY-3 PERCENT (g)	90.3%	83.7%	76.4%
TERMINAL (d)	27/31 (87%)	29/37 (78%)	27/38 (71%)
FIRST INCIDENCE	495	561	428
HC TUMORS SAME ROUTE	91/100 (91%)		
HC TUMORS ALL ROUTES	1225/1300 (94%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.041N*	P=0.250N	P=0.053N
POLY 1.5	P=0.048N*	P=0.279N	P=0.062N
POLY 6	P=0.037N*	P=0.224N	P=0.048N*
COCH-ARM / FISHERS	P=0.076N	P=0.288N	P=0.096N
MAX-ISO-POLY-3	P=0.041N*	P=0.166N	P=0.031N*
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/N

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

Date Report Requested: 08/25/2009  
Time Report Requested: 09:37:47  
First Dose M/F: 04/09/03 / 04/10/03  
Lab: BAT

## LEGEND

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