

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

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

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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
Adrenal Cortex			
Adenoma			
TUMOR RATES			
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%)		
STATISTICAL TESTS			
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

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

Adrenal Medulla
Pheochromocytoma Benign

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%)		

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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TERMINAL SACRIFICE AT 104 WEEKS

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

Adrenal Medulla
Pheochromocytoma Malignant

TUMOR RATES

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%)		

STATISTICAL TESTS

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
Clitoral/Preputial Gland Adenoma			
TUMOR RATES			
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%)		
STATISTICAL TESTS			
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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**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
Clitoral/Preputial Gland Carcinoma or Adenoma			
TUMOR RATES			
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%)		
STATISTICAL TESTS			
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
Islets, Pancreatic Adenoma			
TUMOR RATES			
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%)		
STATISTICAL TESTS			
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
Kidney: Renal Tubule Adenoma			
TUMOR RATES			
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%)		
STATISTICAL TESTS			
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
Kidney: Renal Tubule Carcinoma or Adenoma			
TUMOR RATES			
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%)		
STATISTICAL TESTS			
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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**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
Lung			
Alveolar/Bronchiolar Adenoma			
TUMOR RATES			
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%)		
STATISTICAL TESTS			
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*

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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
<hr/>			
Lung			
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma			
<hr/>			
TUMOR RATES			
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%)		
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STATISTICAL TESTS			
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
Mammary Gland Adenoma			
TUMOR RATES	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	4/1349 (0%)		
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)

TDMS No. 99020 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/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
Mammary Gland Carcinoma or Adenoma			
TUMOR RATES	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	12/1349 (1%)		
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)

TDMS No. 99020 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/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
Mammary Gland Fibroadenoma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
Mammary Gland			
Fibroma, Fibroadenoma or Adenoma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
Mammary Gland			
Fibroma, Fibroadenoma, Carcinoma, or Adenoma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva)			
Papilloma Squamous or Papilloma			
TUMOR RATES	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/45.76	1/43.06	2/43.39
POLY-3 PERCENT (g)	0%	2.3%	4.6%
TERMINAL (d)	0/39 (0%)	1/32 (3%)	1/28 (4%)
FIRST INCIDENCE	---	727 (T)	725
HC TUMORS SAME ROUTE	1/100 (1%)		
HC TUMORS ALL ROUTES	7/1349 (1%)		
STATISTICAL TESTS			
POLY 3	P=0.136	P=0.488	P=0.225
POLY 1.5	P=0.141	P=0.495	P=0.235
POLY 6	P=0.128	P=0.478	P=0.213
COCH-ARM / FISHERS	P=0.142	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.104	P=0.158	P=0.076
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
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
Pancreas			
Adenoma			
TUMOR RATES			
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%)		
STATISTICAL TESTS			
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
Parathyroid Gland Adenoma			
TUMOR RATES			
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%)		
STATISTICAL TESTS			
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
Pituitary Gland: Pars Distalis or Unspecified Site Adenoma			
TUMOR RATES			
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%)		
STATISTICAL TESTS			
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
Skin			
Basal Cell Adenoma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
POLY 3	P=0.271	(e)	P=0.489
POLY 1.5	P=0.270	(e)	P=0.498
POLY 6	P=0.272	(e)	P=0.477
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
Skin			
Basal Cell Carcinoma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
Skin			
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma			
TUMOR RATES	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/45.76	2/43.06	1/43.38
POLY-3 PERCENT (g)	0%	4.6%	2.3%
TERMINAL (d)	0/39 (0%)	2/32 (6%)	1/28 (4%)
FIRST INCIDENCE	---	727 (T)	727 (T)
HC TUMORS SAME ROUTE	2/100 (2%)		
HC TUMORS ALL ROUTES	29/1349 (2%)		
STATISTICAL TESTS			
POLY 3	P=0.343	P=0.224	P=0.489
POLY 1.5	P=0.357	P=0.232	P=0.498
POLY 6	P=0.323	P=0.214	P=0.477
COCH-ARM / FISHERS	P=0.360	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.196	P=0.076	P=0.158
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
Skin			
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma			
TUMOR RATES	#	#	#
OVERALL (a)	3/50 (6%)	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%)		
STATISTICAL TESTS			
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
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 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
Skin			
Fibroma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
Skin			
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
Skin			
Keratoacanthoma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
Skin			
Lipoma			
TUMOR RATES	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	2/100 (2%)		
HC TUMORS ALL ROUTES	14/1349 (1%)		
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)

TDMS No. 99020 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/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
Skin			
Schwannoma Malignant			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
Skin			
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
Skin			
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
Skin			
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
<hr/>			
Spleen			
Hemangiosarcoma			
<hr/>			
TUMOR RATES			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.76	0/43.06	0/43.38
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/39 (0%)	0/32 (0%)	0/28 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	1/100 (1%)		
HC TUMORS ALL ROUTES	3/1346 (0%)		
<hr/>			
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
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
Testes			
Adenoma			
TUMOR RATES			
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%)		
STATISTICAL TESTS			
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**

DOSE	Males		
	0 MG/KG	18.75 MG/KG	37.5 MG/KG
Thyroid Gland: C-Cell Adenoma			
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%)		
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)

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

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

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

TDMS No. 99020 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/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
All Organs			
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
All Organs			
Mesothelioma: Benign			
TUMOR RATES	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/45.76	2/43.06	1/43.38
POLY-3 PERCENT (g)	0%	4.6%	2.3%
TERMINAL (d)	0/39 (0%)	2/32 (6%)	1/28 (4%)
FIRST INCIDENCE	---	727 (T)	727 (T)
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	1/1349 (0%)		
STATISTICAL TESTS			
POLY 3	P=0.343	P=0.224	P=0.489
POLY 1.5	P=0.357	P=0.232	P=0.498
POLY 6	P=0.323	P=0.214	P=0.477
COCH-ARM / FISHERS	P=0.360	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.196	P=0.076	P=0.158
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
All Organs			
Mesothelioma: Benign, Malignant, NOS			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
All Organs			
Mesothelioma: Malignant			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
All Organs			
Benign Tumors			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
All Organs			
Malignant Tumors			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
All Organs			
Malignant and Benign Tumors			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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**

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
Adrenal Cortex			
Adenoma			
<hr/>			
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	24/1296 (2%)		
<hr/>			
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
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
Adrenal Medulla			
Pheochromocytoma Benign			
TUMOR RATES			
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%)		
STATISTICAL TESTS			
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
<hr/>			
Adrenal Medulla			
Pheochromocytoma Malignant			
<hr/>			
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	8/1288 (1%)		
<hr/>			
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
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
Adrenal Medulla			
Pheochromocytoma: Benign, Complex, Malignant, NOS			
TUMOR RATES			
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%)		
STATISTICAL TESTS			
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
Clitoral/Preputial Gland Adenoma			
TUMOR RATES			
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%)		
STATISTICAL TESTS			
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
Clitoral/Preputial Gland Carcinoma or Adenoma			
TUMOR RATES			
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%)		
STATISTICAL TESTS			
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
Islets, Pancreatic Adenoma			
TUMOR RATES			
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%)		
STATISTICAL TESTS			
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
Kidney: Renal Tubule 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	1/1290 (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)

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)

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
Lung			
Alveolar/Bronchiolar Adenoma			
TUMOR RATES			
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%)		
STATISTICAL TESTS			
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
Lung			
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma			
TUMOR RATES			
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%)		
STATISTICAL TESTS			
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
Mammary Gland Adenoma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
Mammary Gland Carcinoma or Adenoma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
Mammary Gland Fibroadenoma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
Mammary Gland			
Fibroma, Fibroadenoma or Adenoma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
Mammary Gland			
Fibroma, Fibroadenoma, Carcinoma, or Adenoma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva)			
Papilloma Squamous or Papilloma			
TUMOR RATES	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)
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%)		
STATISTICAL TESTS			
POLY 3	P=0.368	P=0.514	P=0.520
POLY 1.5	P=0.353	P=0.507	P=0.512
POLY 6	P=0.389	P=0.523	P=0.532
COCH-ARM / FISHERS	P=0.331	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.298	P=0.176	P=0.183
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
Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva) Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma			
TUMOR RATES	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)
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%)		
STATISTICAL TESTS			
POLY 3	P=0.368	P=0.514	P=0.520
POLY 1.5	P=0.353	P=0.507	P=0.512
POLY 6	P=0.389	P=0.523	P=0.532
COCH-ARM / FISHERS	P=0.331	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.298	P=0.176	P=0.183
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
<hr/>			
Pancreas Adenoma			
<hr/>			
TUMOR RATES			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/42.78	0/45.81	0/46.50
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	0/100 (0%)		
HC TUMORS ALL ROUTES	1/1291 (0%)		
<hr/>			
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
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
Parathyroid Gland Adenoma			
TUMOR RATES			
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%)		
STATISTICAL TESTS			
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
Pituitary Gland: Pars Distalis or Unspecified Site Adenoma			
TUMOR RATES			
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%)		
STATISTICAL TESTS			
POLY 3	P<0.001N**	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P<0.001N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.002N**	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
Skin			
Basal Cell Adenoma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
POLY 3	P=0.104	(e)	P=0.261
POLY 1.5	P=0.100	(e)	P=0.251
POLY 6	P=0.109	(e)	P=0.274
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
Skin			
Basal Cell 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	1/1300 (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)

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
Skin			
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma			
TUMOR RATES	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)
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%)		
STATISTICAL TESTS			
POLY 3	P=0.104	(e)	P=0.261
POLY 1.5	P=0.100	(e)	P=0.251
POLY 6	P=0.109	(e)	P=0.274
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
Skin			
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma			
TUMOR RATES	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)
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%)		
STATISTICAL TESTS			
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
Skin			
Fibroma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
Skin			
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
Skin			
Keratoacanthoma			
<hr/>			
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	10/1300 (1%)		
<hr/>			
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
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
Skin			
Lipoma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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**

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
Skin			
Schwannoma Malignant			
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	3/1300 (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)

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

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)

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
Skin			
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
Skin			
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
Spleen			
Hemangiosarcoma			
TUMOR RATES			
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%)		
STATISTICAL TESTS			
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
Thyroid Gland: C-Cell Adenoma			
TUMOR RATES			
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%)		
STATISTICAL TESTS			
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

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)

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
Tongue			
Squamous Cell Papilloma			
TUMOR RATES	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/42.78	1/45.96	1/47.40
POLY-3 PERCENT (g)	0%	2.2%	2.1%
TERMINAL (d)	0/31 (0%)	0/37 (0%)	1/38 (3%)
FIRST INCIDENCE	---	689	728 (T)
HC TUMORS SAME ROUTE	1/100 (1%)		
HC TUMORS ALL ROUTES	6/1300 (1%)		
STATISTICAL TESTS			
POLY 3	P=0.368	P=0.514	P=0.520
POLY 1.5	P=0.353	P=0.507	P=0.512
POLY 6	P=0.389	P=0.523	P=0.532
COCH-ARM / FISHERS	P=0.331	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.298	P=0.176	P=0.183
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
Uterus			
Polyp Stromal			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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

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 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
All Organs			
Hemangiosarcoma			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
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 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
All Organs			
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
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 Species/Strain: RATS/F 344/N

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
All Organs			
Mesothelioma: Benign			
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	1/1300 (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)

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

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

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

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
All Organs			
Mesothelioma: Benign, Malignant, NOS			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
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 First Dose M/F: 04/09/03 / 04/10/03
 Lab: BAT

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
All Organs			
Mesothelioma: Malignant			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
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**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
All Organs			
Benign Tumors			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
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**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
All Organs			
Malignant Tumors			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
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 Species/Strain: RATS/F 344/N

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

DOSE	Females		
	0 MG/KG	37.5 MG/KG	75.0 MG/KG
All Organs			
Malignant and Benign Tumors			
TUMOR RATES	#	#	#
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%)		
STATISTICAL TESTS			
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
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LEGEND

- (a) Number of tumor-bearing animals/number of animals examined at site.
- (b) Number of tumor-bearing animals/Poly-3 number
- (d) Observed incidence at terminal kill.
- (e) Value of Statistic cannot be computed.
- (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
- (g) Poly-3 adjusted lifetime tumor incidence.
- (h) Value of Historical Controls statistic is only calculated when Poly-3 trend is positive and when there is more than one tumor in the treatment groups.
- (I) Interim sacrifice
- (T) Terminal sacrifice
- # Tumor rates based on numbers of animals necropsied.
- * To the right of any statistical result, indicates significance at ($P \leq 0.05$).
- ** To the right of any statistical result, indicates significance at ($P \leq 0.01$).
- N Indicates a negative trend for all tests
The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

*** END OF REPORT ***