

TDMS No. 99037 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
alpha/beta Thujone mixture
CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
Time Report Requested: 12:54:37
First Dose M/F: 06/09/03 / 06/09/03
Lab: SRI

Spec. Run excl. high dose

C Number:	C99037B		
Lock Date:	11/20/2006		
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 12.5 MG/KG
	Include 004 12.5 MG/KG	Include 005 25 MG/KG	Include 006 25 MG/KG
Study Gender:	Both		
TDMSE Version:	2.2.0		

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HISTORICAL CONTROL STUDIES From March 2010 report

SAME ROUTE

99024-07 -- Androstenedione (GAVAGE METHYLCELLULOSE)

ALL ROUTES

99024-07 -- Androstenedione (GAVAGE METHYLCELLULOSE)

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)

99017-05 -- Diethylamine (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)

20007-05 -- Kava kava extract (GAVAGE CORN OIL)

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)

99020-05 -- Pulegone (GAVAGE CORN OIL)

99032-03 -- Pyrogallol (SKIN ETHANOL)

20114-07 -- Sodium dichromate dihydrate (VI) (ORAL WATER)

93025-07 -- Tetralin (INHALATION AIR)

88133-07 -- Trimethylolpropane triacrylate (SKIN ACETONE)

96019-05 -- Water disinfection byproducts (Bromochloroacetic 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
Clitoral/Preputial Gland
Heart
Islets, Pancreatic
Lung
Pituitary Gland
Prostate
Testes
Thyroid Gland

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SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF ALPHA/BETA THUJONE MIXTURE

MALE RATS

Organ

Adrenal Medulla

Clitoral/Preputial Gland

Mammary Gland

Skin

Testes

Thyroid Gland: C-Cell

Thyroid Gland: Follicular Cell

FEMALE RATS

Organ

Adrenal Medulla

Lung

Mammary Gland

Pituitary Gland: Pars Distalis or Unspecified Site

Thyroid Gland: C-Cell

All Organs

Morphology

Pheochromocytoma Benign

Pheochromocytoma: Benign, Complex, Malignant, NOS

Carcinoma

Carcinoma or Adenoma

Fibroadenoma

Fibroma, Fibroadenoma or Adenoma

Fibroma, Fibroadenoma, Carcinoma, or Adenoma

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

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

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

Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma

Sarcoma

Adenoma

Adenoma

Adenoma

Morphology

Pheochromocytoma: Benign, Complex, Malignant, NOS

Alveolar/Bronchiolar Adenoma

Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma

Fibroadenoma

Fibroma, Fibroadenoma or Adenoma

Fibroma, Fibroadenoma, Carcinoma, or Adenoma

Adenoma

Carcinoma or Adenoma

Carcinoma or Adenoma

Benign Tumors

Malignant and Benign Tumors

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Adrenal Cortex			
Adenoma			
TUMOR RATES			
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	1/40.82	0/42.35	0/34.40
POLY-3 PERCENT (g)	2.5%	0%	0%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	677	---	---
HC TUMORS SAME ROUTE	3/50 (6%)		
HC TUMORS ALL ROUTES	14/1248 (1%)		
STATISTICAL TESTS			
POLY 3	P=0.298N	P=0.493N	P=0.534N
POLY 1.5	P=0.288N	P=0.494N	P=0.522N
POLY 6	P=0.312N	P=0.494N	P=0.549N
COCH-ARM / FISHERS	P=0.272N	P=0.500N	P=0.505N
MAX-ISO-POLY-3	P=0.208N	P=0.158N	P=0.198N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Adrenal Medulla			
Pheochromocytoma Benign			
TUMOR RATES			
OVERALL (a)	6/50 (12%)	8/50 (16%)	12/49 (24%)
POLY-3 RATE (b)	6/40.67	8/43.31	12/35.83
POLY-3 PERCENT (g)	14.8%	18.5%	33.5%
TERMINAL (d)	5/27 (19%)	5/25 (20%)	6/17 (35%)
FIRST INCIDENCE	716	603	652
HC TUMORS SAME ROUTE	7/50 (14%)		
HC TUMORS ALL ROUTES	177/1245 (14%)		
STATISTICAL TESTS			
POLY 3	P=0.038*	P=0.435	P=0.045*
POLY 1.5	P=0.046*	P=0.422	P=0.058
POLY 6	P=0.030*	P=0.446	P=0.034*
COCH-ARM / FISHERS	P=0.066	P=0.387	P=0.088
MAX-ISO-POLY-3	P=0.040*	P=0.329	P=0.031*
HISTCONT SAME RTE	P=0.069	P=0.480	P=0.055
HISTCONT ALL RTEs	P=0.020*	P=0.414	P=0.032*

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TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG

Adrenal Medulla
Pheochromocytoma: Benign, Complex, Malignant, NOS

TUMOR RATES

OVERALL (a)	6/50 (12%)	8/50 (16%)	13/49 (27%)
POLY-3 RATE (b)	6/40.67	8/43.31	13/35.83
POLY-3 PERCENT (g)	14.8%	18.5%	36.3%
TERMINAL (d)	5/27 (19%)	5/25 (20%)	7/17 (41%)
FIRST INCIDENCE	716	603	652
HC TUMORS SAME ROUTE	8/50 (16%)		
HC TUMORS ALL ROUTES	202/1245 (16%)		

STATISTICAL TESTS

POLY 3	P=0.021*	P=0.435	P=0.025*
POLY 1.5	P=0.026*	P=0.422	P=0.034*
POLY 6	P=0.016*	P=0.446	P=0.017*
COCH-ARM / FISHERS	P=0.041*	P=0.387	P=0.056
MAX-ISO-POLY-3	P=0.021*	P=0.329	P=0.017*
HISTCONT SAME RTE	P=0.038*	P=0.480	P=0.031*
HISTCONT ALL RTEs	P=0.023*	P=0.414	P=0.017*

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TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG

Clitoral/Preputial Gland
Adenoma

TUMOR RATES

OVERALL (a)	2/49 (4%)	1/49 (2%)	4/50 (8%)
POLY-3 RATE (b)	2/40.07	1/41.79	4/35.44
POLY-3 PERCENT (g)	5%	2.4%	11.3%
TERMINAL (d)	1/27 (4%)	0/24 (0%)	2/17 (12%)
FIRST INCIDENCE	615	599	608
HC TUMORS SAME ROUTE	3/50 (6%)		
HC TUMORS ALL ROUTES	49/1246 (4%)		

STATISTICAL TESTS

POLY 3	P=0.221	P=0.485N	P=0.281
POLY 1.5	P=0.230	P=0.488N	P=0.307
POLY 6	P=0.212	P=0.487N	P=0.249
COCH-ARM / FISHERS	P=0.246	P=0.500N	P=0.349
MAX-ISO-POLY-3	P=0.136	P=0.272N	P=0.173
HISTCONT SAME RTE	P=0.217	P=1.000	P=0.275
HISTCONT ALL RTEs	P=0.156	P=1.000	P=0.203

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Clitoral/Preputial Gland Carcinoma			
TUMOR RATES			
OVERALL (a)	1/49 (2%)	0/49 (0%)	5/50 (10%)
POLY-3 RATE (b)	1/39.67	0/41.35	5/36.01
POLY-3 PERCENT (g)	2.5%	0%	13.9%
TERMINAL (d)	1/27 (4%)	0/24 (0%)	3/17 (18%)
FIRST INCIDENCE	729 (T)	---	404
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	18/1246 (1%)		
STATISTICAL TESTS			
POLY 3	P=0.033*	P=0.492N	P=0.079
POLY 1.5	P=0.034*	P=0.493N	P=0.089
POLY 6	P=0.032*	P=0.492N	P=0.066
COCH-ARM / FISHERS	P=0.039*	P=0.500N	P=0.107
MAX-ISO-POLY-3	P=0.011*	P=0.158N	P=0.040*
HISTCONT SAME RTE	P=0.020*	(e)	P=0.070
HISTCONT ALL RTEs	P=0.005**	(e)	P=0.005**

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Clitoral/Preputial Gland Carcinoma or Adenoma			
TUMOR RATES			
OVERALL (a)	3/49 (6%)	1/49 (2%)	9/50 (18%)
POLY-3 RATE (b)	3/40.07	1/41.79	9/36.47
POLY-3 PERCENT (g)	7.5%	2.4%	24.7%
TERMINAL (d)	2/27 (7%)	0/24 (0%)	5/17 (29%)
FIRST INCIDENCE	615	599	404
HC TUMORS SAME ROUTE	3/50 (6%)		
HC TUMORS ALL ROUTES	65/1246 (5%)		
STATISTICAL TESTS			
POLY 3	P=0.018*	P=0.290N	P=0.037*
POLY 1.5	P=0.021*	P=0.293N	P=0.047*
POLY 6	P=0.016*	P=0.290N	P=0.027*
COCH-ARM / FISHERS	P=0.027*	P=0.309N	P=0.065
MAX-ISO-POLY-3	P=0.005**	P=0.147N	P=0.023*
HISTCONT SAME RTE	P=0.008**	P=1.000	P=0.041*
HISTCONT ALL RTEs	P=0.005**	P=1.000	P=0.016*

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Heart			
Schwannoma Benign			
TUMOR RATES			
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/40.62	0/42.35	0/34.98
POLY-3 PERCENT (g)	4.9%	0%	0%
TERMINAL (d)	2/27 (7%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	729 (T)	---	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	3/1248 (0%)		
STATISTICAL TESTS			
POLY 3	P=0.107N	P=0.228N	P=0.271N
POLY 1.5	P=0.102N	P=0.229N	P=0.257N
POLY 6	P=0.113N	P=0.228N	P=0.291N
COCH-ARM / FISHERS	P=0.095N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.088N	P=0.075N	P=0.108N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

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TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Islets, Pancreatic Adenoma			
TUMOR RATES			
OVERALL (a)	1/50 (2%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	1/40.62	2/42.35	3/35.18
POLY-3 PERCENT (g)	2.5%	4.7%	8.5%
TERMINAL (d)	1/27 (4%)	2/25 (8%)	2/17 (12%)
FIRST INCIDENCE	729 (T)	729 (T)	677
HC TUMORS SAME ROUTE	4/50 (8%)		
HC TUMORS ALL ROUTES	91/1246 (7%)		
STATISTICAL TESTS			
POLY 3	P=0.190	P=0.515	P=0.255
POLY 1.5	P=0.202	P=0.512	P=0.275
POLY 6	P=0.176	P=0.514	P=0.231
COCH-ARM / FISHERS	P=0.222	P=0.500	P=0.309
MAX-ISO-POLY-3	P=0.190	P=0.296	P=0.136
HISTCONT SAME RTE	P=0.293	P=0.440	P=0.223
HISTCONT ALL RTEs	P=0.221	P=0.371	P=0.161

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Islets, Pancreatic Carcinoma			
TUMOR RATES			
OVERALL (a)	2/50 (4%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/40.83	2/42.35	0/34.98
POLY-3 PERCENT (g)	4.9%	4.7%	0%
TERMINAL (d)	1/27 (4%)	2/25 (8%)	0/17 (0%)
FIRST INCIDENCE	674	729 (T)	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	23/1246 (2%)		
STATISTICAL TESTS			
POLY 3	P=0.227N	P=0.681N	P=0.273N
POLY 1.5	P=0.205N	P=0.683N	P=0.258N
POLY 6	P=0.258N	P=0.684N	P=0.294N
COCH-ARM / FISHERS	P=0.176N	P=0.691N	P=0.247N
MAX-ISO-POLY-3	P=0.200N	P=0.485N	P=0.109N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Islets, Pancreatic Carcinoma or Adenoma			
TUMOR RATES			
OVERALL (a)	3/50 (6%)	4/50 (8%)	3/50 (6%)
POLY-3 RATE (b)	3/40.83	4/42.35	3/35.18
POLY-3 PERCENT (g)	7.4%	9.5%	8.5%
TERMINAL (d)	2/27 (7%)	4/25 (16%)	2/17 (12%)
FIRST INCIDENCE	674	729 (T)	677
HC TUMORS SAME ROUTE	4/50 (8%)		
HC TUMORS ALL ROUTES	114/1246 (9%)		
STATISTICAL TESTS			
POLY 3	P=0.505	P=0.520	P=0.592
POLY 1.5	P=0.534	P=0.517	P=0.621
POLY 6	P=0.468	P=0.516	P=0.554
COCH-ARM / FISHERS	P=0.579	P=0.500	P=0.661N
MAX-ISO-POLY-3	P=0.552	P=0.367	P=0.428
HISTCONT SAME RTE	P=0.711	P=0.528	P=0.596
HISTCONT ALL RTEs	P=0.668	P=0.465	P=0.544

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DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Lung			
Alveolar/Bronchiolar Adenoma			
TUMOR RATES			
OVERALL (a)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/40.67	1/42.35	1/35.26
POLY-3 PERCENT (g)	2.5%	2.4%	2.8%
TERMINAL (d)	0/27 (0%)	1/25 (4%)	0/17 (0%)
FIRST INCIDENCE	716	729 (T)	652
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	30/1248 (2%)		
STATISTICAL TESTS			
POLY 3	P=0.614	P=0.752N	P=0.728
POLY 1.5	P=0.623	P=0.753N	P=0.742
POLY 6	P=0.604	P=0.753N	P=0.711
COCH-ARM / FISHERS	P=0.640	P=0.753N	P=0.753N
MAX-ISO-POLY-3	P=0.616	P=0.488N	P=0.461
HISTCONT SAME RTE	P=0.184	P=0.226	P=0.204
HISTCONT ALL RTEs	P=0.741	P=1.000	P=0.584

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Lung			
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma			
TUMOR RATES			
OVERALL (a)	2/50 (4%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/40.87	1/42.35	2/35.26
POLY-3 PERCENT (g)	4.9%	2.4%	5.7%
TERMINAL (d)	0/27 (0%)	1/25 (4%)	1/17 (6%)
FIRST INCIDENCE	677	729 (T)	652
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	47/1248 (4%)		
STATISTICAL TESTS			
POLY 3	P=0.582	P=0.488N	P=0.640
POLY 1.5	P=0.592	P=0.489N	P=0.662
POLY 6	P=0.570	P=0.490N	P=0.610
COCH-ARM / FISHERS	P=0.610	P=0.500N	P=0.691N
MAX-ISO-POLY-3	P=0.471	P=0.273N	P=0.443
HISTCONT SAME RTE	P=0.188	P=0.430	P=0.201
HISTCONT ALL RTEs	P=0.571	P=1.000	P=0.521

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Mammary Gland Carcinoma			
TUMOR RATES	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/40.62	0/42.35	1/34.98
POLY-3 PERCENT (g)	0%	0%	2.9%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	1/17 (6%)
FIRST INCIDENCE	---	---	729 (T)
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	5/1248 (0%)		
STATISTICAL TESTS			
POLY 3	P=0.281	(e)	P=0.470
POLY 1.5	P=0.275	(e)	P=0.482
POLY 6	P=0.290	(e)	P=0.455
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. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Mammary Gland Carcinoma or Adenoma			
TUMOR RATES	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/40.62	0/42.35	2/34.98
POLY-3 PERCENT (g)	0%	0%	5.7%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	2/17 (12%)
FIRST INCIDENCE	---	---	729 (T)
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	9/1248 (1%)		
STATISTICAL TESTS			
POLY 3	P=0.096	(e)	P=0.205
POLY 1.5	P=0.094	(e)	P=0.218
POLY 6	P=0.099	(e)	P=0.189
COCH-ARM / FISHERS	P=0.095	(e)	P=0.247
MAX-ISO-POLY-3	P=0.051	(e)	P=0.075
HISTCONT SAME RTE	P=0.089	(e)	P=0.129
HISTCONT ALL RTEs	P=0.057	(e)	P=0.048*

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Mammary Gland Fibroadenoma			
TUMOR RATES	#	#	#
OVERALL (a)	3/50 (6%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	3/40.88	0/42.35	3/35.47
POLY-3 PERCENT (g)	7.3%	0%	8.5%
TERMINAL (d)	2/27 (7%)	0/25 (0%)	1/17 (6%)
FIRST INCIDENCE	659	---	615
HC TUMORS SAME ROUTE	2/50 (4%)		
HC TUMORS ALL ROUTES	38/1248 (3%)		
STATISTICAL TESTS			
POLY 3	P=0.590	P=0.112N	P=0.596
POLY 1.5	P=0.592	P=0.113N	P=0.623
POLY 6	P=0.587	P=0.113N	P=0.560
COCH-ARM / FISHERS	P=0.601	P=0.121N	P=0.661N
MAX-ISO-POLY-3	P=0.261	P=0.038N*	P=0.431
HISTCONT SAME RTE	P=0.339	(e)	P=0.166
HISTCONT ALL RTEs	P=0.301	(e)	P=0.228

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Mammary Gland			
Fibroma, Fibroadenoma or Adenoma			
TUMOR RATES	#	#	#
OVERALL (a)	3/50 (6%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	3/40.88	0/42.35	3/35.47
POLY-3 PERCENT (g)	7.3%	0%	8.5%
TERMINAL (d)	2/27 (7%)	0/25 (0%)	1/17 (6%)
FIRST INCIDENCE	659	---	615
HC TUMORS SAME ROUTE	3/50 (6%)		
HC TUMORS ALL ROUTES	44/1248 (4%)		
STATISTICAL TESTS			
POLY 3	P=0.590	P=0.112N	P=0.596
POLY 1.5	P=0.592	P=0.113N	P=0.623
POLY 6	P=0.587	P=0.113N	P=0.560
COCH-ARM / FISHERS	P=0.601	P=0.121N	P=0.661N
MAX-ISO-POLY-3	P=0.261	P=0.038N*	P=0.431
HISTCONT SAME RTE	P=0.386	(e)	P=0.299
HISTCONT ALL RTEs	P=0.308	(e)	P=0.281

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Mammary Gland			
Fibroma, Fibroadenoma, Carcinoma, or Adenoma			
TUMOR RATES	#	#	#
OVERALL (a)	3/50 (6%)	0/50 (0%)	4/50 (8%)
POLY-3 RATE (b)	3/40.88	0/42.35	4/35.47
POLY-3 PERCENT (g)	7.3%	0%	11.3%
TERMINAL (d)	2/27 (7%)	0/25 (0%)	2/17 (12%)
FIRST INCIDENCE	659	---	615
HC TUMORS SAME ROUTE	3/50 (6%)		
HC TUMORS ALL ROUTES	48/1248 (4%)		
STATISTICAL TESTS			
POLY 3	P=0.391	P=0.112N	P=0.422
POLY 1.5	P=0.395	P=0.113N	P=0.454
POLY 6	P=0.388	P=0.113N	P=0.383
COCH-ARM / FISHERS	P=0.406	P=0.121N	P=0.500
MAX-ISO-POLY-3	P=0.130	P=0.038N*	P=0.291
HISTCONT SAME RTE	P=0.208	(e)	P=0.241
HISTCONT ALL RTEs	P=0.148	(e)	P=0.141

TDMS No. 99037 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
alpha/beta Thujone mixture
CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
Time Report Requested: 12:54:37
First Dose M/F: 06/09/03 / 06/09/03
Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG

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

TUMOR RATES

OVERALL (a)	24/50 (48%)	21/50 (42%)	18/50 (36%)
POLY-3 RATE (b)	24/43.71	21/43.41	18/38.70
POLY-3 PERCENT (g)	54.9%	48.4%	46.5%
TERMINAL (d)	14/27 (52%)	15/25 (60%)	6/17 (35%)
FIRST INCIDENCE	356	610	313
HC TUMORS SAME ROUTE	19/50 (38%)		
HC TUMORS ALL ROUTES	580/1243 (47%)		

STATISTICAL TESTS

POLY 3	P=0.250N	P=0.342N	P=0.290N
POLY 1.5	P=0.198N	P=0.327N	P=0.229N
POLY 6	P=0.317N	P=0.386N	P=0.365N
COCH-ARM / FISHERS	P=0.133N	P=0.344N	P=0.156N
MAX-ISO-POLY-3	P=0.324N	P=0.267N	P=0.231N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Pituitary Gland: Pars Distalis or Unspecified Site Carcinoma or Adenoma			
TUMOR RATES			
OVERALL (a)	24/50 (48%)	21/50 (42%)	18/50 (36%)
POLY-3 RATE (b)	24/43.71	21/43.41	18/38.70
POLY-3 PERCENT (g)	54.9%	48.4%	46.5%
TERMINAL (d)	14/27 (52%)	15/25 (60%)	6/17 (35%)
FIRST INCIDENCE	356	610	313
HC TUMORS SAME ROUTE	19/50 (38%)		
HC TUMORS ALL ROUTES	581/1243 (47%)		
STATISTICAL TESTS			
POLY 3	P=0.250N	P=0.342N	P=0.290N
POLY 1.5	P=0.198N	P=0.327N	P=0.229N
POLY 6	P=0.317N	P=0.386N	P=0.365N
COCH-ARM / FISHERS	P=0.133N	P=0.344N	P=0.156N
MAX-ISO-POLY-3	P=0.324N	P=0.267N	P=0.231N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Prostate Adenoma			
TUMOR RATES			
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/40.62	0/42.35	0/34.98
POLY-3 PERCENT (g)	4.9%	0%	0%
TERMINAL (d)	2/27 (7%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	729 (T)	---	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	4/1247 (0%)		
STATISTICAL TESTS			
POLY 3	P=0.107N	P=0.228N	P=0.271N
POLY 1.5	P=0.102N	P=0.229N	P=0.257N
POLY 6	P=0.113N	P=0.228N	P=0.291N
COCH-ARM / FISHERS	P=0.095N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.088N	P=0.075N	P=0.108N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Basal Cell Adenoma			
TUMOR RATES	#	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/40.72	2/42.35	0/34.98
POLY-3 PERCENT (g)	2.5%	4.7%	0%
TERMINAL (d)	0/27 (0%)	2/25 (8%)	0/17 (0%)
FIRST INCIDENCE	702	729 (T)	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	14/1248 (1%)		
STATISTICAL TESTS			
POLY 3	P=0.435N	P=0.514	P=0.530N
POLY 1.5	P=0.404N	P=0.512	P=0.518N
POLY 6	P=0.477N	P=0.512	P=0.546N
COCH-ARM / FISHERS	P=0.360N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.256N	P=0.295	P=0.195N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma			
TUMOR RATES	#	#	#
OVERALL (a)	3/50 (6%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	3/40.72	2/42.35	0/34.98
POLY-3 PERCENT (g)	7.4%	4.7%	0%
TERMINAL (d)	2/27 (7%)	2/25 (8%)	0/17 (0%)
FIRST INCIDENCE	702	729 (T)	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	18/1248 (1%)		
STATISTICAL TESTS			
POLY 3	P=0.110N	P=0.482N	P=0.147N
POLY 1.5	P=0.098N	P=0.485N	P=0.135N
POLY 6	P=0.128N	P=0.484N	P=0.165N
COCH-ARM / FISHERS	P=0.082N	P=0.500N	P=0.121N
MAX-ISO-POLY-3	P=0.101N	P=0.311N	P=0.063N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma			
TUMOR RATES	#	#	#
OVERALL (a)	4/50 (8%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	4/40.72	3/42.35	0/34.98
POLY-3 PERCENT (g)	9.8%	7.1%	0%
TERMINAL (d)	3/27 (11%)	3/25 (12%)	0/17 (0%)
FIRST INCIDENCE	702	729 (T)	---
HC TUMORS SAME ROUTE	1/50 (2%)		
HC TUMORS ALL ROUTES	28/1248 (2%)		
STATISTICAL TESTS			
POLY 3	P=0.071N	P=0.479N	P=0.081N
POLY 1.5	P=0.061N	P=0.482N	P=0.072N
POLY 6	P=0.087N	P=0.481N	P=0.095N
COCH-ARM / FISHERS	P=0.049N*	P=0.500N	P=0.059N
MAX-ISO-POLY-3	P=0.066N	P=0.330N	P=0.037N*
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 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)	9/50 (18%)	7/50 (14%)	2/50 (4%)
POLY-3 RATE (b)	9/40.72	7/43.82	2/34.98
POLY-3 PERCENT (g)	22.1%	16%	5.7%
TERMINAL (d)	8/27 (30%)	3/25 (12%)	2/17 (12%)
FIRST INCIDENCE	702	599	729 (T)
HC TUMORS SAME ROUTE	5/50 (10%)		
HC TUMORS ALL ROUTES	103/1248 (8%)		
STATISTICAL TESTS			
POLY 3	P=0.040N*	P=0.330N	P=0.043N*
POLY 1.5	P=0.031N*	P=0.349N	P=0.035N*
POLY 6	P=0.052N	P=0.311N	P=0.057N
COCH-ARM / FISHERS	P=0.023N*	P=0.393N	P=0.026N*
MAX-ISO-POLY-3	P=0.045N*	P=0.244N	P=0.028N*
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Fibroma			
TUMOR RATES	#	#	#
OVERALL (a)	11/50 (22%)	12/50 (24%)	6/50 (12%)
POLY-3 RATE (b)	11/41.77	12/43.82	6/35.83
POLY-3 PERCENT (g)	26.3%	27.4%	16.8%
TERMINAL (d)	7/27 (26%)	5/25 (20%)	4/17 (24%)
FIRST INCIDENCE	540	610	540
HC TUMORS SAME ROUTE	5/50 (10%)		
HC TUMORS ALL ROUTES	102/1248 (8%)		
STATISTICAL TESTS			
POLY 3	P=0.223N	P=0.554	P=0.228N
POLY 1.5	P=0.180N	P=0.541	P=0.189N
POLY 6	P=0.286N	P=0.562	P=0.285N
COCH-ARM / FISHERS	P=0.127N	P=0.500	P=0.143N
MAX-ISO-POLY-3	P=0.237N	P=0.456	P=0.171N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma			
TUMOR RATES	#	#	#
OVERALL (a)	16/50 (32%)	13/50 (26%)	8/50 (16%)
POLY-3 RATE (b)	16/42.84	13/43.87	8/36.18
POLY-3 PERCENT (g)	37.4%	29.6%	22.1%
TERMINAL (d)	10/27 (37%)	5/25 (20%)	5/17 (29%)
FIRST INCIDENCE	367	610	540
HC TUMORS SAME ROUTE	6/50 (12%)		
HC TUMORS ALL ROUTES	127/1248 (10%)		
STATISTICAL TESTS			
POLY 3	P=0.091N	P=0.295N	P=0.107N
POLY 1.5	P=0.068N	P=0.302N	P=0.079N
POLY 6	P=0.127N	P=0.292N	P=0.152N
COCH-ARM / FISHERS	P=0.041N*	P=0.330N	P=0.050N*
MAX-ISO-POLY-3	P=0.121N	P=0.224N	P=0.084N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Fibrosarcoma			
TUMOR RATES	#	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	3/41.49	1/42.40	2/35.33
POLY-3 PERCENT (g)	7.2%	2.4%	5.7%
TERMINAL (d)	2/27 (7%)	0/25 (0%)	1/17 (6%)
FIRST INCIDENCE	367	716	631
HC TUMORS SAME ROUTE	1/50 (2%)		
HC TUMORS ALL ROUTES	14/1248 (1%)		
STATISTICAL TESTS			
POLY 3	P=0.450N	P=0.297N	P=0.573N
POLY 1.5	P=0.431N	P=0.298N	P=0.545N
POLY 6	P=0.471N	P=0.298N	P=0.606N
COCH-ARM / FISHERS	P=0.399N	P=0.309N	P=0.500N
MAX-ISO-POLY-3	P=0.378N	P=0.150N	P=0.397N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma			
TUMOR RATES	#	#	#
OVERALL (a)	6/50 (12%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	6/41.69	1/42.40	2/35.33
POLY-3 PERCENT (g)	14.4%	2.4%	5.7%
TERMINAL (d)	4/27 (15%)	0/25 (0%)	1/17 (6%)
FIRST INCIDENCE	367	716	631
HC TUMORS SAME ROUTE	1/50 (2%)		
HC TUMORS ALL ROUTES	25/1248 (2%)		
STATISTICAL TESTS			
POLY 3	P=0.087N	P=0.052N	P=0.191N
POLY 1.5	P=0.080N	P=0.053N	P=0.167N
POLY 6	P=0.096N	P=0.053N	P=0.224N
COCH-ARM / FISHERS	P=0.070N	P=0.056N	P=0.134N
MAX-ISO-POLY-3	P=0.074N	P=0.022N*	P=0.124N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Keratoacanthoma			
TUMOR RATES	#	#	#
OVERALL (a)	5/50 (10%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	5/40.62	3/43.41	2/34.98
POLY-3 PERCENT (g)	12.3%	6.9%	5.7%
TERMINAL (d)	5/27 (19%)	0/25 (0%)	2/17 (12%)
FIRST INCIDENCE	729 (T)	599	729 (T)
HC TUMORS SAME ROUTE	3/50 (6%)		
HC TUMORS ALL ROUTES	62/1248 (5%)		
STATISTICAL TESTS			
POLY 3	P=0.206N	P=0.319N	P=0.279N
POLY 1.5	P=0.187N	P=0.330N	P=0.252N
POLY 6	P=0.230N	P=0.310N	P=0.317N
COCH-ARM / FISHERS	P=0.158N	P=0.357N	P=0.218N
MAX-ISO-POLY-3	P=0.245N	P=0.208N	P=0.180N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Sarcoma			
TUMOR RATES	#	#	#
OVERALL (a)	3/50 (6%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/40.82	0/42.35	0/34.98
POLY-3 PERCENT (g)	7.4%	0%	0%
TERMINAL (d)	2/27 (7%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	677	---	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	6/1248 (1%)		
STATISTICAL TESTS			
POLY 3	P=0.041N*	P=0.112N	P=0.148N
POLY 1.5	P=0.039N*	P=0.113N	P=0.135N
POLY 6	P=0.045N*	P=0.112N	P=0.166N
COCH-ARM / FISHERS	P=0.037N*	P=0.121N	P=0.121N
MAX-ISO-POLY-3	P=0.041N*	P=0.037N*	P=0.063N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma			
TUMOR RATES	#	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/40.62	2/42.76	0/34.98
POLY-3 PERCENT (g)	2.5%	4.7%	0%
TERMINAL (d)	1/27 (4%)	1/25 (4%)	0/17 (0%)
FIRST INCIDENCE	729 (T)	610	---
HC TUMORS SAME ROUTE	1/50 (2%)		
HC TUMORS ALL ROUTES	16/1248 (1%)		
STATISTICAL TESTS			
POLY 3	P=0.434N	P=0.518	P=0.530N
POLY 1.5	P=0.403N	P=0.514	P=0.518N
POLY 6	P=0.475N	P=0.520	P=0.545N
COCH-ARM / FISHERS	P=0.360N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.257N	P=0.300	P=0.194N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma			
TUMOR RATES	#	#	#
OVERALL (a)	5/50 (10%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	5/40.62	4/43.82	2/34.98
POLY-3 PERCENT (g)	12.3%	9.1%	5.7%
TERMINAL (d)	5/27 (19%)	0/25 (0%)	2/17 (12%)
FIRST INCIDENCE	729 (T)	599	729 (T)
HC TUMORS SAME ROUTE	4/50 (8%)		
HC TUMORS ALL ROUTES	78/1248 (6%)		
STATISTICAL TESTS			
POLY 3	P=0.227N	P=0.452N	P=0.279N
POLY 1.5	P=0.203N	P=0.467N	P=0.252N
POLY 6	P=0.258N	P=0.437N	P=0.317N
COCH-ARM / FISHERS	P=0.169N	P=0.500N	P=0.218N
MAX-ISO-POLY-3	P=0.259N	P=0.325N	P=0.180N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Trichoepithelioma			
TUMOR RATES	#	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/40.62	0/42.35	0/34.98
POLY-3 PERCENT (g)	4.9%	0%	0%
TERMINAL (d)	2/27 (7%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	729 (T)	---	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	4/1248 (0%)		
STATISTICAL TESTS			
POLY 3	P=0.107N	P=0.228N	P=0.271N
POLY 1.5	P=0.102N	P=0.229N	P=0.257N
POLY 6	P=0.113N	P=0.228N	P=0.291N
COCH-ARM / FISHERS	P=0.095N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.088N	P=0.075N	P=0.108N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Testes			
Adenoma			
TUMOR RATES			
OVERALL (a)	35/50 (70%)	44/50 (88%)	40/50 (80%)
POLY-3 RATE (b)	35/43.96	44/48.02	40/42.97
POLY-3 PERCENT (g)	79.6%	91.6%	93.1%
TERMINAL (d)	24/27 (89%)	24/25 (96%)	17/17 (100%)
FIRST INCIDENCE	540	477	450
HC TUMORS SAME ROUTE	42/50 (84%)		
HC TUMORS ALL ROUTES	1018/1248 (82%)		
STATISTICAL TESTS			
POLY 3	P=0.022*	P=0.068	P=0.040*
POLY 1.5	P=0.040*	P=0.046*	P=0.068
POLY 6	P=0.014*	P=0.102	P=0.027*
COCH-ARM / FISHERS	P=0.133	P=0.024*	P=0.178
MAX-ISO-POLY-3	P=0.019*	P=0.040*	P=0.018*
HISTCONT SAME RTE	P=0.035*	P=0.070	P=0.033*
HISTCONT ALL RTES	P=0.021*	P=0.043*	P=0.019*

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Thyroid Gland: C-Cell Adenoma			
TUMOR RATES			
OVERALL (a)	6/46 (13%)	1/48 (2%)	5/42 (12%)
POLY-3 RATE (b)	6/37.67	1/41.43	5/32.41
POLY-3 PERCENT (g)	15.9%	2.4%	15.4%
TERMINAL (d)	6/26 (23%)	0/25 (0%)	2/17 (12%)
FIRST INCIDENCE	729 (T)	519	608
HC TUMORS SAME ROUTE	3/50 (6%)		
HC TUMORS ALL ROUTES	163/1244 (13%)		
STATISTICAL TESTS			
POLY 3	P=0.494N	P=0.040N*	P=0.607N
POLY 1.5	P=0.488N	P=0.042N*	P=0.589N
POLY 6	P=0.503N	P=0.040N*	P=0.630N
COCH-ARM / FISHERS	P=0.478N	P=0.049N*	P=0.565N
MAX-ISO-POLY-3	P=0.223N	P=0.019N*	P=0.477N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Thyroid Gland: C-Cell Carcinoma			
TUMOR RATES			
OVERALL (a)	0/46 (0%)	1/48 (2%)	0/42 (0%)
POLY-3 RATE (b)	0/37.67	1/40.80	0/31.39
POLY-3 PERCENT (g)	0%	2.5%	0%
TERMINAL (d)	0/26 (0%)	1/25 (4%)	0/17 (0%)
FIRST INCIDENCE	---	729 (T)	---
HC TUMORS SAME ROUTE	1/50 (2%)		
HC TUMORS ALL ROUTES	32/1244 (3%)		
STATISTICAL TESTS			
POLY 3	P=0.706	P=0.516	(e)
POLY 1.5	P=0.712	P=0.515	(e)
POLY 6	P=0.696	P=0.514	(e)
COCH-ARM / FISHERS	P=0.722	P=0.511	(e)
MAX-ISO-POLY-3	P=0.402	P=0.175	(e)
HISTCONT SAME RTE	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Thyroid Gland: C-Cell Carcinoma or Adenoma			
TUMOR RATES			
OVERALL (a)	6/46 (13%)	2/48 (4%)	5/42 (12%)
POLY-3 RATE (b)	6/37.67	2/41.43	5/32.41
POLY-3 PERCENT (g)	15.9%	4.8%	15.4%
TERMINAL (d)	6/26 (23%)	1/25 (4%)	2/17 (12%)
FIRST INCIDENCE	729 (T)	519	608
HC TUMORS SAME ROUTE	4/50 (8%)		
HC TUMORS ALL ROUTES	192/1244 (15%)		
STATISTICAL TESTS			
POLY 3	P=0.505N	P=0.102N	P=0.607N
POLY 1.5	P=0.496N	P=0.106N	P=0.589N
POLY 6	P=0.516N	P=0.101N	P=0.630N
COCH-ARM / FISHERS	P=0.483N	P=0.120N	P=0.565N
MAX-ISO-POLY-3	P=0.299N	P=0.055N	P=0.477N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

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 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Thyroid Gland: Follicular Cell Adenoma			
TUMOR RATES			
OVERALL (a)	0/46 (0%)	0/48 (0%)	2/42 (5%)
POLY-3 RATE (b)	0/37.67	0/40.80	2/31.81
POLY-3 PERCENT (g)	0%	0%	6.3%
TERMINAL (d)	0/26 (0%)	0/25 (0%)	1/17 (6%)
FIRST INCIDENCE	---	---	608
HC TUMORS SAME ROUTE	3/50 (6%)		
HC TUMORS ALL ROUTES	12/1244 (1%)		
STATISTICAL TESTS			
POLY 3	P=0.083	(e)	P=0.200
POLY 1.5	P=0.083	(e)	P=0.207
POLY 6	P=0.084	(e)	P=0.190
COCH-ARM / FISHERS	P=0.084	(e)	P=0.225
MAX-ISO-POLY-3	P=0.044*	(e)	P=0.070
HISTCONT SAME RTE	P=0.076	(e)	P=0.120
HISTCONT ALL RTEs	P=0.048*	(e)	P=0.078

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
All Organs			
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated			
TUMOR RATES	#	#	#
OVERALL (a)	22/50 (44%)	18/50 (36%)	18/50 (36%)
POLY-3 RATE (b)	22/44.08	18/45.39	18/38.76
POLY-3 PERCENT (g)	49.9%	39.7%	46.4%
TERMINAL (d)	10/27 (37%)	7/25 (28%)	5/17 (29%)
FIRST INCIDENCE	540	519	485
HC TUMORS SAME ROUTE	26/50 (52%)		
HC TUMORS ALL ROUTES	480/1248 (39%)		
STATISTICAL TESTS			
POLY 3	P=0.392N	P=0.220N	P=0.462N
POLY 1.5	P=0.328N	P=0.226N	P=0.380N
POLY 6	P=0.469N	P=0.228N	P=0.559N
COCH-ARM / FISHERS	P=0.236N	P=0.270N	P=0.270N
MAX-ISO-POLY-3	P=0.377N	P=0.165N	P=0.380N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
All Organs			
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type			
TUMOR RATES	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/40.62	2/43.46	1/35.13
POLY-3 PERCENT (g)	0%	4.6%	2.9%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	---	477	689
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	3/1248 (0%)		
STATISTICAL TESTS			
POLY 3	P=0.316	P=0.252	P=0.471
POLY 1.5	P=0.333	P=0.248	P=0.483
POLY 6	P=0.295	P=0.255	P=0.456
COCH-ARM / FISHERS	P=0.360	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.236	P=0.091	P=0.158
HISTCONT SAME RTE	P=0.340	P=0.153	P=0.224
HISTCONT ALL RTEs	P=0.003**	P=0.002**	P=0.042*

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
All Organs			
Mesothelioma: Benign, Malignant, NOS			
TUMOR RATES	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/40.72	1/42.36	2/35.31
POLY-3 PERCENT (g)	4.9%	2.4%	5.7%
TERMINAL (d)	1/27 (4%)	0/25 (0%)	1/17 (6%)
FIRST INCIDENCE	704	726	637
HC TUMORS SAME ROUTE	1/50 (2%)		
HC TUMORS ALL ROUTES	30/1248 (2%)		
STATISTICAL TESTS			
POLY 3	P=0.583	P=0.486N	P=0.642
POLY 1.5	P=0.592	P=0.488N	P=0.663
POLY 6	P=0.572	P=0.488N	P=0.614
COCH-ARM / FISHERS	P=0.610	P=0.500N	P=0.691N
MAX-ISO-POLY-3	P=0.473	P=0.272N	P=0.444
HISTCONT SAME RTE	P=0.252	P=1.000	P=0.181
HISTCONT ALL RTEs	P=0.405	P=1.000	P=0.308

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
All Organs			
Mesothelioma: Malignant			
TUMOR RATES	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/40.72	1/42.36	2/35.31
POLY-3 PERCENT (g)	4.9%	2.4%	5.7%
TERMINAL (d)	1/27 (4%)	0/25 (0%)	1/17 (6%)
FIRST INCIDENCE	704	726	637
HC TUMORS SAME ROUTE	1/50 (2%)		
HC TUMORS ALL ROUTES	29/1248 (2%)		
STATISTICAL TESTS			
POLY 3	P=0.583	P=0.486N	P=0.642
POLY 1.5	P=0.592	P=0.488N	P=0.663
POLY 6	P=0.572	P=0.488N	P=0.614
COCH-ARM / FISHERS	P=0.610	P=0.500N	P=0.691N
MAX-ISO-POLY-3	P=0.473	P=0.272N	P=0.444
HISTCONT SAME RTE	P=0.252	P=1.000	P=0.181
HISTCONT ALL RTEs	P=0.402	P=1.000	P=0.305

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
All Organs			
Benign Tumors			
TUMOR RATES	#	#	#
OVERALL (a)	44/50 (88%)	47/50 (94%)	44/50 (88%)
POLY-3 RATE (b)	44/46.56	47/48.41	44/44.89
POLY-3 PERCENT (g)	94.5%	97.1%	98%
TERMINAL (d)	26/27 (96%)	25/25 (100%)	17/17 (100%)
FIRST INCIDENCE	356	477	313
HC TUMORS SAME ROUTE	47/50 (94%)		
HC TUMORS ALL ROUTES	1204/1248 (97%)		
STATISTICAL TESTS			
POLY 3	P=0.219	P=0.445	P=0.336
POLY 1.5	P=0.342	P=0.375	P=0.453
POLY 6	P=0.162	P=0.505	P=0.286
COCH-ARM / FISHERS	P=0.566	P=0.243	P=0.620N
MAX-ISO-POLY-3	P=0.187	P=0.239	P=0.137
HISTCONT SAME RTE	P=0.289	P=0.365	P=0.224
HISTCONT ALL RTEs	P=0.217	P=0.294	P=0.162

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
All Organs			
Malignant Tumors			
TUMOR RATES	#	#	#
OVERALL (a)	31/50 (62%)	31/50 (62%)	33/50 (66%)
POLY-3 RATE (b)	31/45.37	31/48.38	33/43.11
POLY-3 PERCENT (g)	68.3%	64.1%	76.6%
TERMINAL (d)	16/27 (59%)	12/25 (48%)	11/17 (65%)
FIRST INCIDENCE	367	299	404
HC TUMORS SAME ROUTE	34/50 (68%)		
HC TUMORS ALL ROUTES	690/1248 (55%)		
STATISTICAL TESTS			
POLY 3	P=0.243	P=0.413N	P=0.257
POLY 1.5	P=0.283	P=0.453N	P=0.307
POLY 6	P=0.208	P=0.394N	P=0.214
COCH-ARM / FISHERS	P=0.378	P=0.582N	P=0.418
MAX-ISO-POLY-3	P=0.203	P=0.333N	P=0.190
HISTCONT SAME RTE	P=0.298	P=1.000	P=0.300
HISTCONT ALL RTEs	P=0.132	P=0.454	P=0.200

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
All Organs			
Malignant and Benign Tumors			
TUMOR RATES	#	#	#
OVERALL (a)	48/50 (96%)	50/50 (100%)	47/50 (94%)
POLY-3 RATE (b)	48/48.14	50/50.00	47/47.22
POLY-3 PERCENT (g)	99.7%	100%	99.5%
TERMINAL (d)	27/27 (100%)	25/25 (100%)	17/17 (100%)
FIRST INCIDENCE	356	299	313
HC TUMORS SAME ROUTE	49/50 (98%)		
HC TUMORS ALL ROUTES	1238/1248 (99%)		
STATISTICAL TESTS			
POLY 3	P=0.993N	P=1.000	P=1.000N
POLY 1.5	P=0.686N	P=0.917	P=0.883N
POLY 6	P=1.000N	P=1.000	P=1.000N
COCH-ARM / FISHERS	P=0.390N	P=0.247	P=0.500N
MAX-ISO-POLY-3	P=0.269N	P=0.142	P=0.353N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Adrenal Cortex			
Adenoma			
TUMOR RATES			
OVERALL (a)	1/47 (2%)	2/49 (4%)	0/46 (0%)
POLY-3 RATE (b)	1/42.33	2/41.52	0/31.39
POLY-3 PERCENT (g)	2.4%	4.8%	0%
TERMINAL (d)	1/35 (3%)	2/33 (6%)	0/19 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	23/1198 (2%)		
STATISTICAL TESTS			
POLY 3	P=0.501N	P=0.493	P=0.558N
POLY 1.5	P=0.454N	P=0.499	P=0.540N
POLY 6	P=0.548N	P=0.489	P=0.576N
COCH-ARM / FISHERS	P=0.365N	P=0.516	P=0.505N
MAX-ISO-POLY-3	P=0.290N	P=0.279	P=0.228N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Adrenal Medulla			
Pheochromocytoma Benign			
TUMOR RATES			
OVERALL (a)	2/48 (4%)	0/50 (0%)	0/48 (0%)
POLY-3 RATE (b)	2/42.65	0/41.70	0/31.54
POLY-3 PERCENT (g)	4.7%	0%	0%
TERMINAL (d)	2/35 (6%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	729 (T)	---	---
HC TUMORS SAME ROUTE	3/50 (6%)		
HC TUMORS ALL ROUTES	30/1190 (3%)		
STATISTICAL TESTS			
POLY 3	P=0.120N	P=0.242N	P=0.310N
POLY 1.5	P=0.111N	P=0.238N	P=0.285N
POLY 6	P=0.129N	P=0.244N	P=0.334N
COCH-ARM / FISHERS	P=0.094N	P=0.237N	P=0.247N
MAX-ISO-POLY-3	P=0.131N	P=0.083N	P=0.145N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Adrenal Medulla			
Pheochromocytoma: Benign, Complex, Malignant, NOS			
TUMOR RATES			
OVERALL (a)	3/48 (6%)	0/50 (0%)	1/48 (2%)
POLY-3 RATE (b)	3/42.65	0/41.70	1/31.54
POLY-3 PERCENT (g)	7%	0%	3.2%
TERMINAL (d)	3/35 (9%)	0/33 (0%)	1/19 (5%)
FIRST INCIDENCE	729 (T)	---	729 (T)
HC TUMORS SAME ROUTE	4/50 (8%)		
HC TUMORS ALL ROUTES	41/1190 (3%)		
STATISTICAL TESTS			
POLY 3	P=0.214N	P=0.122N	P=0.420N
POLY 1.5	P=0.201N	P=0.120N	P=0.381N
POLY 6	P=0.224N	P=0.124N	P=0.456N
COCH-ARM / FISHERS	P=0.174N	P=0.114N	P=0.308N
MAX-ISO-POLY-3	P=0.180N	P=0.042N*	P=0.267N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Clitoral/Preputial Gland Adenoma			
TUMOR RATES			
OVERALL (a)	12/50 (24%)	10/50 (20%)	6/50 (12%)
POLY-3 RATE (b)	12/44.00	10/41.73	6/34.85
POLY-3 PERCENT (g)	27.3%	24%	17.2%
TERMINAL (d)	10/35 (29%)	9/33 (27%)	3/19 (16%)
FIRST INCIDENCE	662	721	513
HC TUMORS SAME ROUTE	12/50 (24%)		
HC TUMORS ALL ROUTES	107/1197 (9%)		
STATISTICAL TESTS			
POLY 3	P=0.194N	P=0.459N	P=0.217N
POLY 1.5	P=0.152N	P=0.446N	P=0.173N
POLY 6	P=0.233N	P=0.468N	P=0.259N
COCH-ARM / FISHERS	P=0.079N	P=0.405N	P=0.096N
MAX-ISO-POLY-3	P=0.245N	P=0.365N	P=0.172N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Clitoral/Preputial Gland Carcinoma			
TUMOR RATES			
OVERALL (a)	2/50 (4%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	2/43.55	1/41.70	3/34.21
POLY-3 PERCENT (g)	4.6%	2.4%	8.8%
TERMINAL (d)	2/35 (6%)	1/33 (3%)	0/19 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	500
HC TUMORS SAME ROUTE	1/50 (2%)		
HC TUMORS ALL ROUTES	38/1197 (3%)		
STATISTICAL TESTS			
POLY 3	P=0.350	P=0.515N	P=0.392
POLY 1.5	P=0.363	P=0.512N	P=0.424
POLY 6	P=0.343	P=0.515N	P=0.365
COCH-ARM / FISHERS	P=0.399	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.249	P=0.297N	P=0.256
HISTCONT SAME RTE	P=0.199	P=0.626	P=0.188
HISTCONT ALL RTEs	P=0.293	P=1.000	P=0.317

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
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 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Clitoral/Preputial Gland Carcinoma or Adenoma			
TUMOR RATES			
OVERALL (a)	14/50 (28%)	10/50 (20%)	9/50 (18%)
POLY-3 RATE (b)	14/44.00	10/41.73	9/35.75
POLY-3 PERCENT (g)	31.8%	24%	25.2%
TERMINAL (d)	12/35 (34%)	9/33 (27%)	3/19 (16%)
FIRST INCIDENCE	662	721	500
HC TUMORS SAME ROUTE	13/50 (26%)		
HC TUMORS ALL ROUTES	144/1197 (12%)		
STATISTICAL TESTS			
POLY 3	P=0.278N	P=0.283N	P=0.344N
POLY 1.5	P=0.234N	P=0.274N	P=0.288N
POLY 6	P=0.312N	P=0.290N	P=0.388N
COCH-ARM / FISHERS	P=0.139N	P=0.241N	P=0.171N
MAX-ISO-POLY-3	P=0.357N	P=0.214N	P=0.277N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
alpha/beta Thujone mixture
CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
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First Dose M/F: 06/09/03 / 06/09/03
Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Heart			
Schwannoma Benign			
TUMOR RATES			
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/43.55	0/41.70	2/33.35
POLY-3 PERCENT (g)	0%	0%	6%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	1/19 (5%)
FIRST INCIDENCE	---	---	716
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	3/1200 (0%)		
STATISTICAL TESTS			
POLY 3	P=0.097	(e)	P=0.183
POLY 1.5	P=0.094	(e)	P=0.199
POLY 6	P=0.101	(e)	P=0.170
COCH-ARM / FISHERS	P=0.095	(e)	P=0.247
MAX-ISO-POLY-3	P=0.051	(e)	P=0.075
HISTCONT SAME RTE	P=0.089	(e)	P=0.128
HISTCONT ALL RTEs	P=0.006**	(e)	P=0.006**

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Islets, Pancreatic Adenoma			
TUMOR RATES			
OVERALL (a)	1/49 (2%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.12	0/41.14	0/33.30
POLY-3 PERCENT (g)	2.3%	0%	0%
TERMINAL (d)	1/35 (3%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	729 (T)	---	---
HC TUMORS SAME ROUTE	1/50 (2%)		
HC TUMORS ALL ROUTES	26/1195 (2%)		
STATISTICAL TESTS			
POLY 3	P=0.317N	P=0.509N	P=0.551N
POLY 1.5	P=0.300N	P=0.508N	P=0.533N
POLY 6	P=0.332N	P=0.510N	P=0.567N
COCH-ARM / FISHERS	P=0.267N	P=0.500N	P=0.495N
MAX-ISO-POLY-3	P=0.242N	P=0.170N	P=0.221N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
alpha/beta Thujone mixture
CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
Time Report Requested: 12:54:37
First Dose M/F: 06/09/03 / 06/09/03
Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Islets, Pancreatic Carcinoma			
TUMOR RATES			
OVERALL (a)	0/49 (0%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.12	0/41.14	0/33.30
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	1/50 (2%)		
HC TUMORS ALL ROUTES	4/1195 (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. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Islets, Pancreatic Carcinoma or Adenoma			
TUMOR RATES			
OVERALL (a)	1/49 (2%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.12	0/41.14	0/33.30
POLY-3 PERCENT (g)	2.3%	0%	0%
TERMINAL (d)	1/35 (3%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	729 (T)	---	---
HC TUMORS SAME ROUTE	2/50 (4%)		
HC TUMORS ALL ROUTES	30/1195 (3%)		
STATISTICAL TESTS			
POLY 3	P=0.317N	P=0.509N	P=0.551N
POLY 1.5	P=0.300N	P=0.508N	P=0.533N
POLY 6	P=0.332N	P=0.510N	P=0.567N
COCH-ARM / FISHERS	P=0.267N	P=0.500N	P=0.495N
MAX-ISO-POLY-3	P=0.242N	P=0.170N	P=0.221N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Lung			
Alveolar/Bronchiolar Adenoma			
TUMOR RATES			
OVERALL (a)	0/50 (0%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	0/43.55	3/41.70	0/33.30
POLY-3 PERCENT (g)	0%	7.2%	0%
TERMINAL (d)	0/35 (0%)	3/33 (9%)	0/19 (0%)
FIRST INCIDENCE	---	729 (T)	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	22/1200 (2%)		
STATISTICAL TESTS			
POLY 3	P=0.507	P=0.111	(e)
POLY 1.5	P=0.551	P=0.112	(e)
POLY 6	P=0.464	P=0.110	(e)
COCH-ARM / FISHERS	P=0.640	P=0.121	(e)
MAX-ISO-POLY-3	P=0.233	P=0.038*	(e)
HISTCONT SAME RTE	P=0.350	P=0.066	(e)
HISTCONT ALL RTEs	P=0.272	P=0.040*	(e)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Lung			
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma			
TUMOR RATES			
OVERALL (a)	0/50 (0%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	0/43.55	3/41.70	1/33.99
POLY-3 PERCENT (g)	0%	7.2%	2.9%
TERMINAL (d)	0/35 (0%)	3/33 (9%)	0/19 (0%)
FIRST INCIDENCE	---	729 (T)	494
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	27/1200 (2%)		
STATISTICAL TESTS			
POLY 3	P=0.273	P=0.111	P=0.451
POLY 1.5	P=0.304	P=0.112	P=0.466
POLY 6	P=0.247	P=0.110	P=0.438
COCH-ARM / FISHERS	P=0.378	P=0.121	P=0.500
MAX-ISO-POLY-3	P=0.181	P=0.038*	P=0.158
HISTCONT SAME RTE	P=0.280	P=0.066	P=0.249
HISTCONT ALL RTEs	P=0.209	P=0.040*	P=0.188

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Mammary Gland Carcinoma			
TUMOR RATES	#	#	#
OVERALL (a)	2/50 (4%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	2/44.04	3/42.36	1/33.49
POLY-3 PERCENT (g)	4.5%	7.1%	3%
TERMINAL (d)	1/35 (3%)	2/33 (6%)	0/19 (0%)
FIRST INCIDENCE	579	508	681
HC TUMORS SAME ROUTE	2/50 (4%)		
HC TUMORS ALL ROUTES	63/1200 (5%)		
STATISTICAL TESTS			
POLY 3	P=0.549N	P=0.482	P=0.593N
POLY 1.5	P=0.501N	P=0.485	P=0.564N
POLY 6	P=0.591N	P=0.482	P=0.620N
COCH-ARM / FISHERS	P=0.399N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.437N	P=0.311	P=0.379N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Mammary Gland Carcinoma or Adenoma			
TUMOR RATES	#	#	#
OVERALL (a)	3/50 (6%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	3/44.31	4/43.17	1/33.49
POLY-3 PERCENT (g)	6.8%	9.3%	3%
TERMINAL (d)	1/35 (3%)	2/33 (6%)	0/19 (0%)
FIRST INCIDENCE	579	422	681
HC TUMORS SAME ROUTE	3/50 (6%)		
HC TUMORS ALL ROUTES	87/1200 (7%)		
STATISTICAL TESTS			
POLY 3	P=0.409N	P=0.486	P=0.411N
POLY 1.5	P=0.356N	P=0.487	P=0.376N
POLY 6	P=0.460N	P=0.485	P=0.445N
COCH-ARM / FISHERS	P=0.252N	P=0.500	P=0.309N
MAX-ISO-POLY-3	P=0.316N	P=0.336	P=0.259N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Mammary Gland Fibroadenoma			
TUMOR RATES	#	#	#
OVERALL (a)	26/50 (52%)	28/50 (56%)	15/50 (30%)
POLY-3 RATE (b)	26/44.03	28/44.65	15/34.99
POLY-3 PERCENT (g)	59.1%	62.7%	42.9%
TERMINAL (d)	24/35 (69%)	20/33 (61%)	9/19 (47%)
FIRST INCIDENCE	652	508	547
HC TUMORS SAME ROUTE	35/50 (70%)		
HC TUMORS ALL ROUTES	629/1200 (52%)		
STATISTICAL TESTS			
POLY 3	P=0.126N	P=0.445	P=0.107N
POLY 1.5	P=0.076N	P=0.408	P=0.067N
POLY 6	P=0.168N	P=0.523	P=0.145N
COCH-ARM / FISHERS	P=0.018N*	P=0.421	P=0.021N*
MAX-ISO-POLY-3	P=0.098N	P=0.358	P=0.091N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Mammary Gland			
Fibroma, Fibroadenoma or Adenoma			
TUMOR RATES	#	#	#
OVERALL (a)	28/50 (56%)	29/50 (58%)	15/50 (30%)
POLY-3 RATE (b)	28/44.29	29/45.45	15/34.99
POLY-3 PERCENT (g)	63.2%	63.8%	42.9%
TERMINAL (d)	25/35 (71%)	20/33 (61%)	9/19 (47%)
FIRST INCIDENCE	652	422	547
HC TUMORS SAME ROUTE	36/50 (72%)		
HC TUMORS ALL ROUTES	642/1200 (54%)		
STATISTICAL TESTS			
POLY 3	P=0.061N	P=0.566	P=0.050N*
POLY 1.5	P=0.033N*	P=0.514	P=0.028N*
POLY 6	P=0.090N	P=0.534N	P=0.075N
COCH-ARM / FISHERS	P=0.006N**	P=0.500	P=0.007N**
MAX-ISO-POLY-3	P=0.061N	P=0.476	P=0.044N*
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Mammary Gland			
Fibroma, Fibroadenoma, Carcinoma, or Adenoma			
TUMOR RATES	#	#	#
OVERALL (a)	30/50 (60%)	30/50 (60%)	16/50 (32%)
POLY-3 RATE (b)	30/44.79	30/46.12	16/35.18
POLY-3 PERCENT (g)	67%	65.1%	45.5%
TERMINAL (d)	26/35 (74%)	20/33 (61%)	9/19 (47%)
FIRST INCIDENCE	579	422	547
HC TUMORS SAME ROUTE	37/50 (74%)		
HC TUMORS ALL ROUTES	672/1200 (56%)		
STATISTICAL TESTS			
POLY 3	P=0.045N*	P=0.511N	P=0.037N*
POLY 1.5	P=0.022N*	P=0.565N	P=0.019N*
POLY 6	P=0.068N	P=0.427N	P=0.060N
COCH-ARM / FISHERS	P=0.003N**	P=0.581N	P=0.004N**
MAX-ISO-POLY-3	P=0.050N*	P=0.420N	P=0.034N*
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Pituitary Gland: Pars Distalis or Unspecified Site Adenoma			
TUMOR RATES			
OVERALL (a)	25/50 (50%)	25/49 (51%)	15/49 (31%)
POLY-3 RATE (b)	25/46.67	25/43.29	15/34.62
POLY-3 PERCENT (g)	53.6%	57.8%	43.3%
TERMINAL (d)	17/35 (49%)	19/33 (58%)	8/19 (42%)
FIRST INCIDENCE	499	508	485
HC TUMORS SAME ROUTE	19/50 (38%)		
HC TUMORS ALL ROUTES	657/1197 (55%)		
STATISTICAL TESTS			
POLY 3	P=0.270N	P=0.425	P=0.245N
POLY 1.5	P=0.153N	P=0.469	P=0.145N
POLY 6	P=0.408N	P=0.383	P=0.366N
COCH-ARM / FISHERS	P=0.033N*	P=0.540	P=0.039N*
MAX-ISO-POLY-3	P=0.235N	P=0.346	P=0.209N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Pituitary Gland: Pars Distalis or Unspecified Site Carcinoma or Adenoma			
TUMOR RATES			
OVERALL (a)	26/50 (52%)	25/49 (51%)	15/49 (31%)
POLY-3 RATE (b)	26/46.67	25/43.29	15/34.62
POLY-3 PERCENT (g)	55.7%	57.8%	43.3%
TERMINAL (d)	18/35 (51%)	19/33 (58%)	8/19 (42%)
FIRST INCIDENCE	499	508	485
HC TUMORS SAME ROUTE	19/50 (38%)		
HC TUMORS ALL ROUTES	670/1197 (56%)		
STATISTICAL TESTS			
POLY 3	P=0.203N	P=0.507	P=0.188N
POLY 1.5	P=0.109N	P=0.550	P=0.104N
POLY 6	P=0.327N	P=0.465	P=0.298N
COCH-ARM / FISHERS	P=0.021N*	P=0.541N	P=0.025N*
MAX-ISO-POLY-3	P=0.204N	P=0.422	P=0.163N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Basal Cell Adenoma			
TUMOR RATES	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/43.55	1/41.70	0/33.30
POLY-3 PERCENT (g)	2.3%	2.4%	0%
TERMINAL (d)	1/35 (3%)	1/33 (3%)	0/19 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	4/1200 (0%)		
STATISTICAL TESTS			
POLY 3	P=0.429N	P=0.751	P=0.553N
POLY 1.5	P=0.397N	P=0.753	P=0.536N
POLY 6	P=0.460N	P=0.751	P=0.568N
COCH-ARM / FISHERS	P=0.331N	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.347N	P=0.487	P=0.223N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma			
TUMOR RATES	#	#	#
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/43.55	1/41.70	0/33.30
POLY-3 PERCENT (g)	2.3%	2.4%	0%
TERMINAL (d)	1/35 (3%)	1/33 (3%)	0/19 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	7/1200 (1%)		
STATISTICAL TESTS			
POLY 3	P=0.429N	P=0.751	P=0.553N
POLY 1.5	P=0.397N	P=0.753	P=0.536N
POLY 6	P=0.460N	P=0.751	P=0.568N
COCH-ARM / FISHERS	P=0.331N	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.347N	P=0.487	P=0.223N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma			
TUMOR RATES	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/43.80	1/41.70	0/33.30
POLY-3 PERCENT (g)	4.6%	2.4%	0%
TERMINAL (d)	1/35 (3%)	1/33 (3%)	0/19 (0%)
FIRST INCIDENCE	662	729 (T)	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	8/1200 (1%)		
STATISTICAL TESTS			
POLY 3	P=0.205N	P=0.517N	P=0.303N
POLY 1.5	P=0.183N	P=0.513N	P=0.281N
POLY 6	P=0.227N	P=0.519N	P=0.325N
COCH-ARM / FISHERS	P=0.142N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.193N	P=0.299N	P=0.138N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 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)	2/50 (4%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/43.80	2/41.85	0/33.30
POLY-3 PERCENT (g)	4.6%	4.8%	0%
TERMINAL (d)	1/35 (3%)	1/33 (3%)	0/19 (0%)
FIRST INCIDENCE	662	689	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	19/1200 (2%)		
STATISTICAL TESTS			
POLY 3	P=0.274N	P=0.678	P=0.303N
POLY 1.5	P=0.239N	P=0.681	P=0.281N
POLY 6	P=0.309N	P=0.677	P=0.325N
COCH-ARM / FISHERS	P=0.176N	P=0.691N	P=0.247N
MAX-ISO-POLY-3	P=0.233N	P=0.481	P=0.138N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
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 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Fibroma			
TUMOR RATES	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/43.83	1/42.29	1/33.72
POLY-3 PERCENT (g)	4.6%	2.4%	3%
TERMINAL (d)	1/35 (3%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	652	540	607
HC TUMORS SAME ROUTE	3/50 (6%)		
HC TUMORS ALL ROUTES	23/1200 (2%)		
STATISTICAL TESTS			
POLY 3	P=0.463N	P=0.512N	P=0.590N
POLY 1.5	P=0.438N	P=0.511N	P=0.562N
POLY 6	P=0.485N	P=0.512N	P=0.614N
COCH-ARM / FISHERS	P=0.378N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.473N	P=0.294N	P=0.375N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma			
TUMOR RATES	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/43.83	1/42.29	1/33.72
POLY-3 PERCENT (g)	4.6%	2.4%	3%
TERMINAL (d)	1/35 (3%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	652	540	607
HC TUMORS SAME ROUTE	3/50 (6%)		
HC TUMORS ALL ROUTES	29/1200 (2%)		
STATISTICAL TESTS			
POLY 3	P=0.463N	P=0.512N	P=0.590N
POLY 1.5	P=0.438N	P=0.511N	P=0.562N
POLY 6	P=0.485N	P=0.512N	P=0.614N
COCH-ARM / FISHERS	P=0.378N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.473N	P=0.294N	P=0.375N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

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 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Fibrosarcoma			
TUMOR RATES	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.55	0/41.70	0/33.30
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	4/1200 (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. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

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 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma			
TUMOR RATES	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.55	0/41.70	0/33.30
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	7/1200 (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. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
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 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Keratoacanthoma			
TUMOR RATES	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/43.55	1/41.85	0/33.30
POLY-3 PERCENT (g)	0%	2.4%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	---	689	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	7/1200 (1%)		
STATISTICAL TESTS			
POLY 3	P=0.683	P=0.492	(e)
POLY 1.5	P=0.698	P=0.493	(e)
POLY 6	P=0.668	P=0.493	(e)
COCH-ARM / FISHERS	P=0.731	P=0.500	(e)
MAX-ISO-POLY-3	P=0.407	P=0.158	(e)
HISTCONT SAME RTE	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

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 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Sarcoma			
TUMOR RATES	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.55	0/41.70	0/33.30
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	2/1200 (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. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

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 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma			
TUMOR RATES	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.80	0/41.70	0/33.30
POLY-3 PERCENT (g)	2.3%	0%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	662	---	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	4/1200 (0%)		
STATISTICAL TESTS			
POLY 3	P=0.318N	P=0.510N	P=0.554N
POLY 1.5	P=0.302N	P=0.508N	P=0.537N
POLY 6	P=0.334N	P=0.511N	P=0.570N
COCH-ARM / FISHERS	P=0.269N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.245N	P=0.171N	P=0.224N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

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 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma			
TUMOR RATES	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/43.55	1/41.85	0/33.30
POLY-3 PERCENT (g)	0%	2.4%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	---	689	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	12/1200 (1%)		
STATISTICAL TESTS			
POLY 3	P=0.683	P=0.492	(e)
POLY 1.5	P=0.698	P=0.493	(e)
POLY 6	P=0.668	P=0.493	(e)
COCH-ARM / FISHERS	P=0.731	P=0.500	(e)
MAX-ISO-POLY-3	P=0.407	P=0.158	(e)
HISTCONT SAME RTE	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

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 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Skin			
Trichoepithelioma			
TUMOR RATES	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.55	0/41.70	0/33.30
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	3/1200 (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. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

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 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Thyroid Gland: C-Cell Adenoma			
TUMOR RATES			
OVERALL (a)	4/42 (10%)	1/46 (2%)	1/44 (2%)
POLY-3 RATE (b)	4/39.37	1/40.20	1/28.59
POLY-3 PERCENT (g)	10.2%	2.5%	3.5%
TERMINAL (d)	3/35 (9%)	1/33 (3%)	1/19 (5%)
FIRST INCIDENCE	689	729 (T)	729 (T)
HC TUMORS SAME ROUTE	4/50 (8%)		
HC TUMORS ALL ROUTES	122/1191 (10%)		
STATISTICAL TESTS			
POLY 3	P=0.146N	P=0.171N	P=0.291N
POLY 1.5	P=0.126N	P=0.165N	P=0.244N
POLY 6	P=0.165N	P=0.178N	P=0.339N
COCH-ARM / FISHERS	P=0.090N	P=0.153N	P=0.166N
MAX-ISO-POLY-3	P=0.198N	P=0.081N	P=0.192N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
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 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Thyroid Gland: C-Cell Carcinoma			
TUMOR RATES			
OVERALL (a)	3/42 (7%)	1/46 (2%)	0/44 (0%)
POLY-3 RATE (b)	3/39.22	1/40.20	0/28.59
POLY-3 PERCENT (g)	7.7%	2.5%	0%
TERMINAL (d)	3/35 (9%)	1/33 (3%)	0/19 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	13/1191 (1%)		
STATISTICAL TESTS			
POLY 3	P=0.095N	P=0.296N	P=0.186N
POLY 1.5	P=0.079N	P=0.289N	P=0.157N
POLY 6	P=0.112N	P=0.302N	P=0.216N
COCH-ARM / FISHERS	P=0.054N	P=0.274N	P=0.112N
MAX-ISO-POLY-3	P=0.117N	P=0.149N	P=0.100N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
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 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Thyroid Gland: C-Cell Carcinoma or Adenoma			
TUMOR RATES			
OVERALL (a)	7/42 (17%)	2/46 (4%)	1/44 (2%)
POLY-3 RATE (b)	7/39.37	2/40.20	1/28.59
POLY-3 PERCENT (g)	17.8%	5%	3.5%
TERMINAL (d)	6/35 (17%)	2/33 (6%)	1/19 (5%)
FIRST INCIDENCE	689	729 (T)	729 (T)
HC TUMORS SAME ROUTE	4/50 (8%)		
HC TUMORS ALL ROUTES	134/1191 (11%)		
STATISTICAL TESTS			
POLY 3	P=0.025N*	P=0.072N	P=0.081N
POLY 1.5	P=0.019N*	P=0.067N	P=0.056N
POLY 6	P=0.033N*	P=0.076N	P=0.113N
COCH-ARM / FISHERS	P=0.011N*	P=0.059N	P=0.025N*
MAX-ISO-POLY-3	P=0.033N*	P=0.036N*	P=0.062N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
alpha/beta Thujone mixture
CAS Number: THUJONEMIXAB

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First Dose M/F: 06/09/03 / 06/09/03
Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG

Thyroid Gland: Follicular Cell
Adenoma

TUMOR RATES

OVERALL (a)	0/42 (0%)	0/46 (0%)	0/44 (0%)
POLY-3 RATE (b)	0/39.22	0/40.20	0/28.59
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	5/1191 (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. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Uterus			
Polyp Stromal			
TUMOR RATES	#	#	#
OVERALL (a)	17/50 (34%)	18/50 (36%)	12/50 (24%)
POLY-3 RATE (b)	17/46.18	18/44.11	12/37.71
POLY-3 PERCENT (g)	36.8%	40.8%	31.8%
TERMINAL (d)	12/35 (34%)	14/33 (42%)	3/19 (16%)
FIRST INCIDENCE	462	412	338
HC TUMORS SAME ROUTE	9/50 (18%)		
HC TUMORS ALL ROUTES	202/1200 (17%)		
STATISTICAL TESTS			
POLY 3	P=0.399N	P=0.431	P=0.403N
POLY 1.5	P=0.321N	P=0.448	P=0.332N
POLY 6	P=0.466N	P=0.418	P=0.464N
COCH-ARM / FISHERS	P=0.166N	P=0.500	P=0.189N
MAX-ISO-POLY-3	P=0.384N	P=0.350	P=0.331N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
 Time Report Requested: 12:54:37
 First Dose M/F: 06/09/03 / 06/09/03
 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Uterus			
Sarcoma Stromal or Polyp Stromal			
TUMOR RATES	#	#	#
OVERALL (a)	17/50 (34%)	18/50 (36%)	13/50 (26%)
POLY-3 RATE (b)	17/46.18	18/44.11	13/38.42
POLY-3 PERCENT (g)	36.8%	40.8%	33.8%
TERMINAL (d)	12/35 (34%)	14/33 (42%)	3/19 (16%)
FIRST INCIDENCE	462	412	338
HC TUMORS SAME ROUTE	9/50 (18%)		
HC TUMORS ALL ROUTES	207/1200 (17%)		
STATISTICAL TESTS			
POLY 3	P=0.464N	P=0.431	P=0.478N
POLY 1.5	P=0.392N	P=0.448	P=0.410N
POLY 6	P=0.523N	P=0.418	P=0.533N
COCH-ARM / FISHERS	P=0.227N	P=0.500	P=0.257N
MAX-ISO-POLY-3	P=0.462N	P=0.350	P=0.395N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

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 Lab: SRI

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
All Organs			
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated			
TUMOR RATES	#	#	#
OVERALL (a)	10/50 (20%)	5/50 (10%)	5/50 (10%)
POLY-3 RATE (b)	10/44.87	5/42.11	5/33.75
POLY-3 PERCENT (g)	22.3%	11.9%	14.8%
TERMINAL (d)	6/35 (17%)	3/33 (9%)	2/19 (11%)
FIRST INCIDENCE	545	663	652
HC TUMORS SAME ROUTE	5/50 (10%)		
HC TUMORS ALL ROUTES	253/1200 (21%)		
STATISTICAL TESTS			
POLY 3	P=0.194N	P=0.158N	P=0.296N
POLY 1.5	P=0.157N	P=0.151N	P=0.233N
POLY 6	P=0.232N	P=0.163N	P=0.362N
COCH-ARM / FISHERS	P=0.093N	P=0.131N	P=0.131N
MAX-ISO-POLY-3	P=0.247N	P=0.105N	P=0.234N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
All Organs			
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type			
TUMOR RATES	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.55	0/41.70	0/33.30
POLY-3 PERCENT (g)	2.3%	0%	0%
TERMINAL (d)	1/35 (3%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	729 (T)	---	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	2/1200 (0%)		
STATISTICAL TESTS			
POLY 3	P=0.317N	P=0.509N	P=0.553N
POLY 1.5	P=0.302N	P=0.507N	P=0.536N
POLY 6	P=0.332N	P=0.509N	P=0.568N
COCH-ARM / FISHERS	P=0.269N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.243N	P=0.169N	P=0.223N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
alpha/beta Thujone mixture
CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG

All Organs
Mesothelioma: Benign, Malignant, NOS

TUMOR RATES	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.55	0/41.70	0/33.30
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	5/1200 (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. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
All Organs			
Mesothelioma: Malignant			
TUMOR RATES	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.55	0/41.70	0/33.30
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	---	---	---
HC TUMORS SAME ROUTE	0/50 (0%)		
HC TUMORS ALL ROUTES	4/1200 (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. 99037 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 alpha/beta Thujone mixture
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
All Organs			
Benign Tumors			
TUMOR RATES	#	#	#
OVERALL (a)	46/50 (92%)	46/50 (92%)	35/50 (70%)
POLY-3 RATE (b)	46/48.46	46/48.24	35/41.97
POLY-3 PERCENT (g)	94.9%	95.4%	83.4%
TERMINAL (d)	34/35 (97%)	31/33 (94%)	15/19 (79%)
FIRST INCIDENCE	462	412	338
HC TUMORS SAME ROUTE	44/50 (88%)		
HC TUMORS ALL ROUTES	1037/1200 (86%)		
STATISTICAL TESTS			
POLY 3	P=0.036N*	P=0.658	P=0.056N
POLY 1.5	P=0.015N*	P=0.603	P=0.028N*
POLY 6	P=0.053N	P=0.673N	P=0.077N
COCH-ARM / FISHERS	P=0.002N**	P=0.643N	P=0.005N**
MAX-ISO-POLY-3	P=0.028N*	P=0.458	P=0.033N*
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 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 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
All Organs			
Malignant Tumors			
TUMOR RATES	#	#	#
OVERALL (a)	20/50 (40%)	12/50 (24%)	14/50 (28%)
POLY-3 RATE (b)	20/46.92	12/44.06	14/37.30
POLY-3 PERCENT (g)	42.6%	27.2%	37.5%
TERMINAL (d)	12/35 (34%)	7/33 (21%)	3/19 (16%)
FIRST INCIDENCE	452	452	485
HC TUMORS SAME ROUTE	10/50 (20%)		
HC TUMORS ALL ROUTES	426/1200 (36%)		
STATISTICAL TESTS			
POLY 3	P=0.289N	P=0.091N	P=0.402N
POLY 1.5	P=0.230N	P=0.084N	P=0.313N
POLY 6	P=0.336N	P=0.099N	P=0.473N
COCH-ARM / FISHERS	P=0.116N	P=0.066N	P=0.146N
MAX-ISO-POLY-3	P=0.253N	P=0.066N	P=0.335N
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 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 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
All Organs			
Malignant and Benign Tumors			
TUMOR RATES	#	#	#
OVERALL (a)	49/50 (98%)	48/50 (96%)	39/50 (78%)
POLY-3 RATE (b)	49/50.00	48/49.01	39/43.62
POLY-3 PERCENT (g)	98%	98%	89.4%
TERMINAL (d)	34/35 (97%)	32/33 (97%)	16/19 (84%)
FIRST INCIDENCE	452	412	338
HC TUMORS SAME ROUTE	46/50 (92%)		
HC TUMORS ALL ROUTES	1126/1200 (94%)		
STATISTICAL TESTS			
POLY 3	P=0.047N*	P=0.755N	P=0.085N
POLY 1.5	P=0.012N*	P=0.739N	P=0.030N*
POLY 6	P=0.080N	P=0.756N	P=0.129N
COCH-ARM / FISHERS	P<0.001N**	P=0.500N	P=0.002N**
MAX-ISO-POLY-3	P=0.036N*	P=0.492N	P=0.042N*
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)

TDMS No. 99037 - 05
Test Type: CHRONIC
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Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
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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 ***