

**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

<b>C Number:</b>	C99037B		
<b>Lock Date:</b>	11/20/2006		
<b>Cage Range:</b>	ALL		
<b>Date Range:</b>	ALL		
<b>Reasons For Removal:</b>	ALL		
<b>Removal Date Range:</b>	ALL		
<b>Treatment Groups:</b>	Include 001 0 MG/KG	Include 002 0 MG/KG	Include 003 12.5 MG/KG
	Include 004 12.5 MG/KG	Include 005 25 MG/KG	Include 006 25 MG/KG
<b>Study Gender:</b>	Both		
<b>TDMSE Version:</b>	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
<b>Adrenal Cortex</b>			
<b>Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Adrenal Medulla</b>			
<b>Pheochromocytoma Benign</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

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

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Adrenal Medulla  
Pheochromocytoma: Benign, Complex, Malignant, NOS

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**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%)		

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**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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**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
<b>Clitoral/Preputial Gland Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Clitoral/Preputial Gland Carcinoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Clitoral/Preputial Gland Carcinoma or Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Heart</b>			
<b>Schwannoma Benign</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Islets, Pancreatic Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Islets, Pancreatic Carcinoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Islets, Pancreatic Carcinoma or Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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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 CAS Number: THUJONEMIXAB

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 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
<b>Lung</b>			
<b>Alveolar/Bronchiolar Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Lung</b>			
<b>Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Mammary Gland Carcinoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Mammary Gland Carcinoma or Adenoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Mammary Gland Fibroadenoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Mammary Gland Fibroma, Fibroadenoma or Adenoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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  
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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
<b>Mammary Gland</b>			
<b>Fibroma, Fibroadenoma, Carcinoma, or Adenoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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  
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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
<b>Pituitary Gland: Pars Distalis or Unspecified Site Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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  
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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
<b>Pituitary Gland: Pars Distalis or Unspecified Site Carcinoma or Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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  
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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
<b>Prostate Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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

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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
<b>Skin</b>			
<b>Basal Cell Adenoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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  
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 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
<b>Skin</b>			
<b>Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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  
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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
<b>Skin</b>			
<b>Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Skin</b>			
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Skin</b>			
<b>Fibroma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Skin</b>			
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Skin</b>			
<b>Fibrosarcoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Skin</b>			
<b>Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Skin</b>			
<b>Keratoacanthoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Skin</b>			
<b>Sarcoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Skin</b>			
<b>Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Skin</b>			
<b>Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Skin</b>			
<b>Trichoepithelioma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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**

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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*

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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
<b>Thyroid Gland: C-Cell Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Thyroid Gland: C-Cell Carcinoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Thyroid Gland: C-Cell Carcinoma or Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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

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
<b>Thyroid Gland: Follicular Cell Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>All Organs</b>			
<b>Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>All Organs</b>			
<b>Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>All Organs</b>			
<b>Mesothelioma: Benign, Malignant, NOS</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>All Organs</b>			
<b>Mesothelioma: Malignant</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>All Organs</b>			
<b>Benign Tumors</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>All Organs</b>			
<b>Malignant Tumors</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>All Organs</b>			
<b>Malignant and Benign Tumors</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Adrenal Cortex</b>			
<b>Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Adrenal Medulla</b>			
<b>Pheochromocytoma Benign</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Adrenal Medulla</b>			
<b>Pheochromocytoma: Benign, Complex, Malignant, NOS</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Clitoral/Preputial Gland Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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**

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DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Clitoral/Preputial Gland Carcinoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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

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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
<b>Clitoral/Preputial Gland Carcinoma or Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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

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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
<b>Heart</b>			
<b>Schwannoma Benign</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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

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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
<b>Islets, Pancreatic Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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  
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CAS Number: THUJONEMIXAB

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First Dose M/F: 06/09/03 / 06/09/03  
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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<hr/>			
Islets, Pancreatic Carcinoma			
<hr/>			
<b>TUMOR RATES</b>			
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%)		
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)

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TDMS No. 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
<b>Islets, Pancreatic Carcinoma or Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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  
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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
<b>Lung</b>			
<b>Alveolar/Bronchiolar Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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

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 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
<b>Lung</b>			
<b>Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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

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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
<b>Mammary Gland Carcinoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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

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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
<b>Mammary Gland Carcinoma or Adenoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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  
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 Route: GAVAGE  
 Species/Strain: RATS/F 344/N

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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
<b>Mammary Gland Fibroadenoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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  
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 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
<b>Mammary Gland</b>			
<b>Fibroma, Fibroadenoma or Adenoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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

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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
<b>Mammary Gland</b>			
<b>Fibroma, Fibroadenoma, Carcinoma, or Adenoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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  
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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
<b>Pituitary Gland: Pars Distalis or Unspecified Site Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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  
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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
<b>Pituitary Gland: Pars Distalis or Unspecified Site Carcinoma or Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Skin</b>			
<b>Basal Cell Adenoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Skin</b>			
<b>Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Skin</b>			
<b>Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Skin</b>			
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma			
<b>TUMOR RATES</b>	#	#	#
OVERALL (a)	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%)		
<b>STATISTICAL TESTS</b>			
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  
 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
<b>Skin</b>			
<b>Fibroma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Skin</b>			
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Skin</b>			
<b>Fibrosarcoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)

TDMS No. 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**

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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  
 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
<b>Skin</b>			
<b>Keratoacanthoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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

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
<b>Skin</b>			
<b>Sarcoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)

TDMS No. 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
<b>Skin</b>			
<b>Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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

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
<b>Skin</b>			
<b>Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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

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
<b>Skin</b>			
<b>Trichoepithelioma</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)

TDMS No. 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
<b>Thyroid Gland: C-Cell Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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  
 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
<b>Thyroid Gland: C-Cell Carcinoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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  
 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
<b>Thyroid Gland: C-Cell Carcinoma or Adenoma</b>			
<b>TUMOR RATES</b>			
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%)		
<b>STATISTICAL TESTS</b>			
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

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: 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  
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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
<b>Uterus</b>			
<b>Polyp Stromal</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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
<b>Uterus</b>			
<b>Sarcoma Stromal or Polyp Stromal</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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

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
<b>All Organs</b>			
<b>Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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

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
<b>All Organs</b>			
<b>Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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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 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
<b>All Organs</b>			
<b>Mesothelioma: Benign, Malignant, NOS</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)

TDMS No. 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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 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
<b>All Organs</b>			
<b>Mesothelioma: Malignant</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)

TDMS No. 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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 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
<b>All Organs</b>			
<b>Benign Tumors</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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  
 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
<b>All Organs</b>			
<b>Malignant Tumors</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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  
 alpha/beta Thujone mixture  
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010  
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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
<b>All Organs</b>			
<b>Malignant and Benign Tumors</b>			
<b>TUMOR RATES</b>	#	#	#
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%)		
<b>STATISTICAL TESTS</b>			
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  
Route: GAVAGE  
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 \*\*\*