

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
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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## SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF ALPHA/BETA THUJONE MIXTURE

### MALE RATS

#### Organ

Adrenal Cortex  
  
Bone Marrow  
Eye  
Islets, Pancreatic  
Kidney  
  
Kidney: Transitional Epithelium  
Liver  
  
Liver: Kupffer Cell  
Lung  
  
Lung: Alveolar Epithelium  
Lymph Node, Mesenteric  
Lymph Node: Mediastinal  
Mammary Gland: Duct  
Nose: Respiratory Epithelium  
Pancreas: Acinus  
Pituitary Gland: Pars Distalis  
Pituitary Gland: Pars Intermedia  
  
Pituitary Gland: Rathke's Cleft  
Prostate  
Skin  
  
Skin: Epidermis  
Spleen

### FEMALE RATS

#### Organ

#### Morphology

Hyperplasia Focal  
Hypertrophy Focal  
Myelofibrosis  
Cataract  
Hyperplasia  
Casts Protein  
Mineralization  
Hyperplasia  
Degeneration Cystic  
Hepatodiaphragmatic Nodule  
Pigmentation  
Infiltration Cellular Histiocyte  
Inflammation Chronic  
Hyperplasia  
Hemorrhage  
Hemorrhage  
Ectasia  
Hyperplasia  
Hyperplasia Focal  
Hyperplasia Focal  
Angiectasis  
Cyst  
Dilatation  
Inflammation Chronic  
Cyst Epithelial Inclusion  
Hyperkeratosis  
Inflammation Chronic  
Hyperplasia  
Pigmentation

#### Morphology

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Adrenal Cortex	Accessory Adrenal Cortical Nodule
	Hyperplasia Focal
	Necrosis
Brain	Necrosis
	Pigmentation
Eye	Cataract
Harderian Gland	Hemorrhage
Heart	Cardiomyopathy
Kidney	Inflammation Chronic
	Mineralization
Liver	Eosinophilic Focus
	Mixed Cell Focus
	Necrosis Focal
Liver: Centrilobular	Necrosis
Lung	Infiltration Cellular Histiocyte
	Inflammation Chronic
Lymph Node: Mediastinal	Hemorrhage
	Hyperplasia Lymphoid
	Pigmentation
Lymph Node: Pancreatic	Hemorrhage
Mammary Gland	Hyperplasia
Mammary Gland: Duct	Ectasia
Mesentery	Accessory Spleen
Pituitary Gland: Pars Distalis	Hyperplasia Focal
Pituitary Gland: Rathke's Cleft	Dilatation
Spleen	Hematopoietic Cell Proliferation
	Necrosis
Thyroid Gland	Degeneration Cystic
Thyroid Gland: C-Cell	Hyperplasia

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS 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 Cortex  
Accessory Adrenal Cortical Nodule

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**LESION RATES**

OVERALL (a)	21/50 (42%)	19/50 (38%)	21/49 (43%)
POLY-3 RATE (b)	21/43.46	19/43.85	21/39.32
POLY-3 PERCENT (g)	48.3%	43.3%	53.4%
TERMINAL (d)	15/27 (56%)	12/25 (48%)	8/17 (47%)
FIRST INCIDENCE	370	603	270

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**STATISTICAL TESTS**

POLY 3	P=0.378	P=0.398N	P=0.402
POLY 1.5	P=0.428	P=0.394N	P=0.459
POLY 6	P=0.328	P=0.415N	P=0.343
COCH-ARM / FISHERS	P=0.507	P=0.419N	P=0.547
MAX-ISO-POLY-3	P=0.349	P=0.318N	P=0.324

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TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Adrenal Cortex Degeneration Fatty</b>			
<b>LESION RATES</b>			
OVERALL (a)	26/50 (52%)	28/50 (56%)	31/49 (63%)
POLY-3 RATE (b)	26/45.47	28/47.00	31/43.32
POLY-3 PERCENT (g)	57.2%	59.6%	71.6%
TERMINAL (d)	12/27 (44%)	11/25 (44%)	9/17 (53%)
FIRST INCIDENCE	367	299	394
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.097	P=0.491	P=0.110
POLY 1.5	P=0.111	P=0.487	P=0.126
POLY 6	P=0.085	P=0.472	P=0.097
COCH-ARM / FISHERS	P=0.152	P=0.421	P=0.176
MAX-ISO-POLY-3	P=0.110	P=0.406	P=0.077

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TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Adrenal Cortex</b>			
<b>Hematopoietic Cell Proliferation</b>			
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<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	2/50 (4%)	0/49 (0%)
POLY-3 RATE (b)	2/41.60	2/43.21	0/34.40
POLY-3 PERCENT (g)	4.8%	4.6%	0%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	367	599	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.237N	P=0.681N	P=0.281N
POLY 1.5	P=0.214N	P=0.683N	P=0.265N
POLY 6	P=0.268N	P=0.679N	P=0.302N
COCH-ARM / FISHERS	P=0.180N	P=0.691N	P=0.253N
MAX-ISO-POLY-3	P=0.210N	P=0.484N	P=0.117N

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TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Adrenal Cortex</b>			
<b>Hyperplasia Focal</b>			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	17/50 (34%)	11/50 (22%)	9/49 (18%)
POLY-3 RATE (b)	17/41.69	11/42.40	9/34.55
POLY-3 PERCENT (g)	40.8%	25.9%	26.1%
TERMINAL (d)	13/27 (48%)	10/25 (40%)	8/17 (47%)
FIRST INCIDENCE	615	716	689
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.089N	P=0.108N	P=0.129N
POLY 1.5	P=0.068N	P=0.110N	P=0.094N
POLY 6	P=0.126N	P=0.116N	P=0.193N
COCH-ARM / FISHERS	P=0.046N*	P=0.133N	P=0.061N
MAX-ISO-POLY-3	P=0.121N	P=0.072N	P=0.102N

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TERMINAL SACRIFICE AT 105 WEEKS**

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DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Adrenal Cortex</b>			
<b>Hypertrophy Focal</b>			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	6/50 (12%)	2/50 (4%)	0/49 (0%)
POLY-3 RATE (b)	6/41.42	2/42.35	0/34.40
POLY-3 PERCENT (g)	14.5%	4.7%	0%
TERMINAL (d)	4/27 (15%)	2/25 (8%)	0/17 (0%)
FIRST INCIDENCE	540	729 (T)	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.011N*	P=0.124N	P=0.027N*
POLY 1.5	P=0.009N**	P=0.125N	P=0.022N*
POLY 6	P=0.013N*	P=0.127N	P=0.035N*
COCH-ARM / FISHERS	P=0.008N**	P=0.134N	P=0.014N*
MAX-ISO-POLY-3	P=0.013N*	P=0.065N	P=0.015N*

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TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Adrenal Cortex Necrosis</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	3/50 (6%)	1/49 (2%)
POLY-3 RATE (b)	2/41.31	3/42.64	1/35.35
POLY-3 PERCENT (g)	4.8%	7%	2.8%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	540	668	270
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.481N	P=0.515	P=0.554N
POLY 1.5	P=0.449N	P=0.513	P=0.534N
POLY 6	P=0.523N	P=0.512	P=0.581N
COCH-ARM / FISHERS	P=0.407N	P=0.500	P=0.508N
MAX-ISO-POLY-3	P=0.396N	P=0.338	P=0.337N

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Adrenal Medulla Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	18/50 (36%)	25/50 (50%)	13/49 (27%)
POLY-3 RATE (b)	18/42.72	25/45.13	13/36.65
POLY-3 PERCENT (g)	42.1%	55.4%	35.5%
TERMINAL (d)	9/27 (33%)	12/25 (48%)	7/17 (41%)
FIRST INCIDENCE	575	556	270
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.378N	P=0.147	P=0.351N
POLY 1.5	P=0.287N	P=0.139	P=0.282N
POLY 6	P=0.523N	P=0.146	P=0.466N
COCH-ARM / FISHERS	P=0.196N	P=0.113	P=0.212N
MAX-ISO-POLY-3	P=0.177N	P=0.107	P=0.282N

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TERMINAL SACRIFICE AT 105 WEEKS**

---

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

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Adrenal Medulla  
Infiltration Cellular Lymphocyte

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**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/49 (0%)
POLY-3 RATE (b)	0/40.62	2/42.35	0/34.59
POLY-3 PERCENT (g)	0%	4.7%	0%
TERMINAL (d)	0/27 (0%)	2/25 (8%)	0/17 (0%)
FIRST INCIDENCE	---	729 (T)	---

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**STATISTICAL TESTS**

POLY 3	P=0.615	P=0.246	(e)
POLY 1.5	P=0.636	P=0.245	(e)
POLY 6	P=0.588	P=0.245	(e)
COCH-ARM / FISHERS	P=0.665	P=0.247	(e)
MAX-ISO-POLY-3	P=0.298	P=0.085	(e)

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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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**Bone Marrow  
Hyperplasia**

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**LESION RATES**

OVERALL (a)	7/50 (14%)	7/50 (14%)	12/50 (24%)
POLY-3 RATE (b)	7/42.59	7/44.10	12/39.19
POLY-3 PERCENT (g)	16.4%	15.9%	30.6%
TERMINAL (d)	4/27 (15%)	1/25 (4%)	5/17 (29%)
FIRST INCIDENCE	367	599	394

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**STATISTICAL TESTS**

POLY 3	P=0.083	P=0.587N	P=0.101
POLY 1.5	P=0.095	P=0.593N	P=0.121
POLY 6	P=0.069	P=0.582N	P=0.079
COCH-ARM / FISHERS	P=0.117	P=0.613N	P=0.154
MAX-ISO-POLY-3	P=0.081	P=0.471N	P=0.069

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TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Bone Marrow Infiltration Cellular Histiocyte</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/40.62	0/42.35	0/34.98
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	---	---	---
<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)

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TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Bone Marrow Myelofibrosis</b>			
<b>LESION RATES</b>			
OVERALL (a)	5/50 (10%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	5/42.46	4/43.44	0/34.98
POLY-3 PERCENT (g)	11.8%	9.2%	0%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	540	626	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.053N	P=0.486N	P=0.050N*
POLY 1.5	P=0.041N*	P=0.486N	P=0.041N*
POLY 6	P=0.073N	P=0.491N	P=0.065N
COCH-ARM / FISHERS	P=0.029N*	P=0.500N	P=0.028N*
MAX-ISO-POLY-3	P=0.051N	P=0.350N	P=0.026N*

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TERMINAL SACRIFICE AT 105 WEEKS**

---

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

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Bone: Femur  
Osteopetrosis

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**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	0/40.62	2/43.08	2/35.28
POLY-3 PERCENT (g)	0%	4.6%	5.7%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	---	626	659

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**STATISTICAL TESTS**

POLY 3	P=0.148	P=0.250	P=0.207
POLY 1.5	P=0.158	P=0.247	P=0.219
POLY 6	P=0.137	P=0.253	P=0.193
COCH-ARM / FISHERS	P=0.176	P=0.247	P=0.247
MAX-ISO-POLY-3	P=0.147	P=0.089	P=0.075

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TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Brain  
Compression

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**LESION RATES**

OVERALL (a)	9/50 (18%)	4/50 (8%)	11/50 (22%)
POLY-3 RATE (b)	9/43.06	4/42.58	11/37.83
POLY-3 PERCENT (g)	20.9%	9.4%	29.1%
TERMINAL (d)	2/27 (7%)	3/25 (12%)	3/17 (18%)
FIRST INCIDENCE	356	668	313

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**STATISTICAL TESTS**

POLY 3	P=0.268	P=0.117N	P=0.276
POLY 1.5	P=0.295	P=0.113N	P=0.323
POLY 6	P=0.239	P=0.127N	P=0.227
COCH-ARM / FISHERS	P=0.341	P=0.117N	P=0.402
MAX-ISO-POLY-3	P=0.092	P=0.068N	P=0.211

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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
<b>Brain Necrosis</b>			
<b>LESION 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)
<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

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Brain Pigmentation</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/40.62	1/42.35	0/34.98
POLY-3 PERCENT (g)	0%	2.4%	0%
TERMINAL (d)	0/27 (0%)	1/25 (4%)	0/17 (0%)
FIRST INCIDENCE	---	729 (T)	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.705	P=0.508	(e)
POLY 1.5	P=0.715	P=0.507	(e)
POLY 6	P=0.691	P=0.508	(e)
COCH-ARM / FISHERS	P=0.731	P=0.500	(e)
MAX-ISO-POLY-3	P=0.402	P=0.169	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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
<b>Esophagus</b>			
<b>Inflammation Acute</b>			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/42.48	0/42.35	0/34.98
POLY-3 PERCENT (g)	4.7%	0%	0%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	163	---	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.111N	P=0.237N	P=0.283N
POLY 1.5	P=0.105N	P=0.237N	P=0.265N
POLY 6	P=0.119N	P=0.239N	P=0.305N
COCH-ARM / FISHERS	P=0.095N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.101N	P=0.076N	P=0.119N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Eye</b>			
<b>Cataract</b>			
<b>LESION RATES</b>			
OVERALL (a)	7/49 (14%)	11/50 (22%)	12/46 (26%)
POLY-3 RATE (b)	7/40.80	11/42.41	12/33.42
POLY-3 PERCENT (g)	17.2%	25.9%	35.9%
TERMINAL (d)	4/27 (15%)	9/25 (36%)	8/17 (47%)
FIRST INCIDENCE	659	716	655
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.045*	P=0.239	P=0.054
POLY 1.5	P=0.063	P=0.245	P=0.076
POLY 6	P=0.029*	P=0.220	P=0.034*
COCH-ARM / FISHERS	P=0.097	P=0.232	P=0.119
MAX-ISO-POLY-3	P=0.059	P=0.168	P=0.041*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Eye Edema			
<b>LESION RATES</b>			
OVERALL (a)	1/49 (2%)	1/50 (2%)	0/46 (0%)
POLY-3 RATE (b)	1/40.34	1/42.35	0/32.85
POLY-3 PERCENT (g)	2.5%	2.4%	0%
TERMINAL (d)	0/27 (0%)	1/25 (4%)	0/17 (0%)
FIRST INCIDENCE	677	729 (T)	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.394N	P=0.750N	P=0.541N
POLY 1.5	P=0.373N	P=0.750N	P=0.529N
POLY 6	P=0.423N	P=0.753N	P=0.556N
COCH-ARM / FISHERS	P=0.343N	P=0.747N	P=0.516N
MAX-ISO-POLY-3	P=0.326N	P=0.486N	P=0.204N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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

---

Eye  
Inflammation Chronic

---

**LESION RATES**

OVERALL (a)	0/49 (0%)	2/50 (4%)	0/46 (0%)
POLY-3 RATE (b)	0/40.14	2/43.12	0/32.85
POLY-3 PERCENT (g)	0%	4.6%	0%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	---	477	---

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**STATISTICAL TESTS**

POLY 3	P=0.609	P=0.253	(e)
POLY 1.5	P=0.629	P=0.251	(e)
POLY 6	P=0.582	P=0.253	(e)
COCH-ARM / FISHERS	P=0.657	P=0.253	(e)
MAX-ISO-POLY-3	P=0.305	P=0.090	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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

---

Eye: Bilateral  
Cataract

---

**LESION RATES**

OVERALL (a)	1/49 (2%)	2/50 (4%)	2/46 (4%)
POLY-3 RATE (b)	1/40.34	2/42.40	2/32.85
POLY-3 PERCENT (g)	2.5%	4.7%	6.1%
TERMINAL (d)	0/27 (0%)	1/25 (4%)	2/17 (12%)
FIRST INCIDENCE	677	716	729 (T)

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**STATISTICAL TESTS**

POLY 3	P=0.328	P=0.517	P=0.429
POLY 1.5	P=0.344	P=0.517	P=0.449
POLY 6	P=0.308	P=0.514	P=0.402
COCH-ARM / FISHERS	P=0.367	P=0.508	P=0.476
MAX-ISO-POLY-3	P=0.347	P=0.298	P=0.240

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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
<b>Eye: Retina Degeneration</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/49 (2%)	2/50 (4%)	0/46 (0%)
POLY-3 RATE (b)	1/40.34	2/42.35	0/32.85
POLY-3 PERCENT (g)	2.5%	4.7%	0%
TERMINAL (d)	0/27 (0%)	2/25 (8%)	0/17 (0%)
FIRST INCIDENCE	677	729 (T)	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.446N	P=0.517	P=0.541N
POLY 1.5	P=0.416N	P=0.517	P=0.529N
POLY 6	P=0.485N	P=0.513	P=0.556N
COCH-ARM / FISHERS	P=0.376N	P=0.508	P=0.516N
MAX-ISO-POLY-3	P=0.266N	P=0.298	P=0.204N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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
<b>Harderian Gland Hemorrhage</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/40.62	0/42.35	0/34.98
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	---	---	---
<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)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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
<b>Harderian Gland Inflammation Chronic</b>			
<b>LESION RATES</b>			
OVERALL (a)	3/50 (6%)	4/50 (8%)	4/50 (8%)
POLY-3 RATE (b)	3/41.14	4/42.46	4/36.58
POLY-3 PERCENT (g)	7.3%	9.4%	10.9%
TERMINAL (d)	2/27 (7%)	3/25 (12%)	0/17 (0%)
FIRST INCIDENCE	570	702	404
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.366	P=0.517	P=0.436
POLY 1.5	P=0.388	P=0.516	P=0.461
POLY 6	P=0.339	P=0.513	P=0.404
COCH-ARM / FISHERS	P=0.424	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.421	P=0.364	P=0.299

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Heart</b>			
<b>Cardiomyopathy</b>			
<b>LESION RATES</b>			
OVERALL (a)	44/50 (88%)	41/50 (82%)	47/50 (94%)
POLY-3 RATE (b)	44/48.22	41/47.12	47/48.19
POLY-3 PERCENT (g)	91.3%	87%	97.5%
TERMINAL (d)	26/27 (96%)	25/25 (100%)	17/17 (100%)
FIRST INCIDENCE	163	299	163
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.139	P=0.354N	P=0.153
POLY 1.5	P=0.151	P=0.320N	P=0.160
POLY 6	P=0.150	P=0.425N	P=0.185
COCH-ARM / FISHERS	P=0.221	P=0.288N	P=0.243
MAX-ISO-POLY-3	P=0.054	P=0.232N	P=0.063

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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

---

Heart  
Thrombosis

---

LESION RATES			
OVERALL (a)	3/50 (6%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	3/41.13	4/43.52	2/35.24
POLY-3 PERCENT (g)	7.3%	9.2%	5.7%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	1/17 (6%)
FIRST INCIDENCE	612	556	659

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STATISTICAL TESTS			
POLY 3	P=0.509N	P=0.531	P=0.570N
POLY 1.5	P=0.472N	P=0.523	P=0.542N
POLY 6	P=0.556N	P=0.535	P=0.607N
COCH-ARM / FISHERS	P=0.417N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.481N	P=0.378	P=0.394N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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
<b>Intestine Large, Colon Edema</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/44 (5%)	1/47 (2%)	1/33 (3%)
POLY-3 RATE (b)	2/38.14	1/40.28	1/26.50
POLY-3 PERCENT (g)	5.2%	2.5%	3.8%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	612	662	631
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.485N	P=0.481N	P=0.625N
POLY 1.5	P=0.477N	P=0.477N	P=0.616N
POLY 6	P=0.494N	P=0.489N	P=0.634N
COCH-ARM / FISHERS	P=0.462N	P=0.475N	P=0.608N
MAX-ISO-POLY-3	P=0.468N	P=0.266N	P=0.401N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Islets, Pancreatic Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	3/50 (6%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	3/40.62	0/42.35	3/35.31
POLY-3 PERCENT (g)	7.4%	0%	8.5%
TERMINAL (d)	3/27 (11%)	0/25 (0%)	2/17 (12%)
FIRST INCIDENCE	729 (T)	---	637
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.590	P=0.111N	P=0.597
POLY 1.5	P=0.593	P=0.112N	P=0.624
POLY 6	P=0.589	P=0.111N	P=0.562
COCH-ARM / FISHERS	P=0.601	P=0.121N	P=0.661N
MAX-ISO-POLY-3	P=0.260	P=0.037N*	P=0.432

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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
<hr/>			
Kidney			
Casts Protein			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	18/48 (38%)	30/48 (63%)	22/44 (50%)
POLY-3 RATE (b)	18/41.85	30/41.91	22/35.61
POLY-3 PERCENT (g)	43%	71.6%	61.8%
TERMINAL (d)	7/26 (27%)	21/25 (84%)	8/17 (47%)
FIRST INCIDENCE	540	626	450
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.037*	P=0.005**	P=0.072
POLY 1.5	P=0.057	P=0.008**	P=0.094
POLY 6	P=0.025*	P=0.002**	P=0.061
COCH-ARM / FISHERS	P=0.126	P=0.012*	P=0.159
MAX-ISO-POLY-3	P=0.021*	P=0.002**	P=0.054

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Kidney Cyst</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/48 (2%)	3/48 (6%)	0/44 (0%)
POLY-3 RATE (b)	1/39.14	3/40.59	0/31.16
POLY-3 PERCENT (g)	2.6%	7.4%	0%
TERMINAL (d)	1/26 (4%)	3/25 (12%)	0/17 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.489N	P=0.318	P=0.545N
POLY 1.5	P=0.457N	P=0.316	P=0.535N
POLY 6	P=0.526N	P=0.315	P=0.557N
COCH-ARM / FISHERS	P=0.405N	P=0.308	P=0.522N
MAX-ISO-POLY-3	P=0.219N	P=0.167	P=0.208N



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Kidney  
Infarct

---

**LESION RATES**

OVERALL (a)	3/48 (6%)	1/48 (2%)	0/44 (0%)
POLY-3 RATE (b)	3/39.64	1/40.64	0/31.16
POLY-3 PERCENT (g)	7.6%	2.5%	0%
TERMINAL (d)	0/26 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	615	716	---

---

**STATISTICAL TESTS**

POLY 3	P=0.085N	P=0.296N	P=0.166N
POLY 1.5	P=0.078N	P=0.296N	P=0.153N
POLY 6	P=0.094N	P=0.300N	P=0.182N
COCH-ARM / FISHERS	P=0.068N	P=0.308N	P=0.138N
MAX-ISO-POLY-3	P=0.086N	P=0.149N	P=0.076N

---

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

**Kidney  
Inflammation**

---

**LESION RATES**

OVERALL (a)	0/48 (0%)	2/48 (4%)	0/44 (0%)
POLY-3 RATE (b)	0/39.14	2/40.70	0/31.16
POLY-3 PERCENT (g)	0%	4.9%	0%
TERMINAL (d)	0/26 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	---	716	---

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**STATISTICAL TESTS**

POLY 3	P=0.601	P=0.245	(e)
POLY 1.5	P=0.621	P=0.244	(e)
POLY 6	P=0.579	P=0.245	(e)
COCH-ARM / FISHERS	P=0.651	P=0.247	(e)
MAX-ISO-POLY-3	P=0.302	P=0.084	(e)

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Kidney</b>			
<b>Inflammation Chronic</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/48 (0%)	0/48 (0%)	0/44 (0%)
POLY-3 RATE (b)	0/39.14	0/40.59	0/31.16
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/26 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	---	---	---
<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)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Kidney Mineralization</b>			
<b>LESION RATES</b>			
OVERALL (a)	17/48 (35%)	33/48 (69%)	41/44 (93%)
POLY-3 RATE (b)	17/43.45	33/46.45	41/43.72
POLY-3 PERCENT (g)	39.1%	71%	93.8%
TERMINAL (d)	7/26 (27%)	16/25 (64%)	15/17 (88%)
FIRST INCIDENCE	163	299	163
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.002**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Kidney  
Nephropathy

---

**LESION RATES**

OVERALL (a)	45/48 (94%)	44/48 (92%)	41/44 (93%)
POLY-3 RATE (b)	45/46.22	44/45.90	41/42.41
POLY-3 PERCENT (g)	97.4%	95.9%	96.7%
TERMINAL (d)	26/26 (100%)	25/25 (100%)	17/17 (100%)
FIRST INCIDENCE	356	299	163

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**STATISTICAL TESTS**

POLY 3	P=0.555N	P=0.592N	P=0.703N
POLY 1.5	P=0.502N	P=0.481N	P=0.629N
POLY 6	P=0.642N	P=0.831N	P=0.800N
COCH-ARM / FISHERS	P=0.535N	P=0.500N	P=0.619N
MAX-ISO-POLY-3	P=0.493N	P=0.304N	P=0.409N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

**Kidney: Renal Tubule  
Accumulation, Hyaline Droplet**

---

**LESION RATES**

OVERALL (a)	1/48 (2%)	0/48 (0%)	0/44 (0%)
POLY-3 RATE (b)	1/39.34	0/40.59	0/31.16
POLY-3 PERCENT (g)	2.5%	0%	0%
TERMINAL (d)	0/26 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	677	---	---

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**STATISTICAL TESTS**

POLY 3	P=0.305N	P=0.494N	P=0.546N
POLY 1.5	P=0.295N	P=0.494N	P=0.535N
POLY 6	P=0.316N	P=0.496N	P=0.559N
COCH-ARM / FISHERS	P=0.280N	P=0.500N	P=0.522N
MAX-ISO-POLY-3	P=0.221N	P=0.158N	P=0.209N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Kidney: Transitional Epithelium Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/48 (0%)	1/48 (2%)	4/44 (9%)
POLY-3 RATE (b)	0/39.14	1/40.59	4/31.76
POLY-3 PERCENT (g)	0%	2.5%	12.6%
TERMINAL (d)	0/26 (0%)	1/25 (4%)	2/17 (12%)
FIRST INCIDENCE	---	729 (T)	615
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.016*	P=0.507	P=0.036*
POLY 1.5	P=0.017*	P=0.506	P=0.041*
POLY 6	P=0.015*	P=0.506	P=0.032*
COCH-ARM / FISHERS	P=0.020*	P=0.500	P=0.049*
MAX-ISO-POLY-3	P=0.012*	P=0.168	P=0.016*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Liver  
Basophilic Focus

---

LESION RATES			
OVERALL (a)	29/50 (58%)	26/50 (52%)	25/50 (50%)
POLY-3 RATE (b)	29/42.50	26/44.23	25/39.52
POLY-3 PERCENT (g)	68.2%	58.8%	63.3%
TERMINAL (d)	22/27 (82%)	19/25 (76%)	14/17 (82%)
FIRST INCIDENCE	540	599	407

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STATISTICAL TESTS			
POLY 3	P=0.344N	P=0.234N	P=0.398N
POLY 1.5	P=0.301N	P=0.259N	P=0.343N
POLY 6	P=0.403N	P=0.225N	P=0.475N
COCH-ARM / FISHERS	P=0.241N	P=0.344N	P=0.274N
MAX-ISO-POLY-3	P=0.339N	P=0.173N	P=0.312N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Liver</b>			
<b>Clear Cell Focus</b>			
<b>LESION RATES</b>			
OVERALL (a)	19/50 (38%)	23/50 (46%)	11/50 (22%)
POLY-3 RATE (b)	19/41.00	23/43.23	11/34.98
POLY-3 PERCENT (g)	46.4%	53.2%	31.5%
TERMINAL (d)	17/27 (63%)	20/25 (80%)	11/17 (65%)
FIRST INCIDENCE	656	477	729 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.148N	P=0.335	P=0.130N
POLY 1.5	P=0.100N	P=0.324	P=0.095N
POLY 6	P=0.240N	P=0.325	P=0.198N
COCH-ARM / FISHERS	P=0.058N	P=0.272	P=0.063N
MAX-ISO-POLY-3	P=0.085N	P=0.263	P=0.101N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Liver</b>			
<b>Degeneration Cystic</b>			
<b>LESION RATES</b>			
OVERALL (a)	13/50 (26%)	7/50 (14%)	4/50 (8%)
POLY-3 RATE (b)	13/41.62	7/43.24	4/36.27
POLY-3 PERCENT (g)	31.2%	16.2%	11%
TERMINAL (d)	10/27 (37%)	2/25 (8%)	1/17 (6%)
FIRST INCIDENCE	540	626	532
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.016N*	P=0.081N	P=0.027N*
POLY 1.5	P=0.013N*	P=0.086N	P=0.021N*
POLY 6	P=0.021N*	P=0.078N	P=0.037N*
COCH-ARM / FISHERS	P=0.010N**	P=0.105N	P=0.016N*
MAX-ISO-POLY-3	P=0.020N*	P=0.051N	P=0.019N*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Liver</b>			
<b>Eosinophilic Focus</b>			
<b>LESION RATES</b>			
OVERALL (a)	6/50 (12%)	4/50 (8%)	4/50 (8%)
POLY-3 RATE (b)	6/40.99	4/42.79	4/35.32
POLY-3 PERCENT (g)	14.6%	9.4%	11.3%
TERMINAL (d)	4/27 (15%)	3/25 (12%)	3/17 (18%)
FIRST INCIDENCE	659	599	635
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.380N	P=0.341N	P=0.465N
POLY 1.5	P=0.350N	P=0.347N	P=0.426N
POLY 6	P=0.420N	P=0.342N	P=0.519N
COCH-ARM / FISHERS	P=0.303N	P=0.370N	P=0.370N
MAX-ISO-POLY-3	P=0.408N	P=0.233N	P=0.345N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Liver  
Hematopoietic Cell Proliferation

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/40.62	1/42.79	0/34.98
POLY-3 PERCENT (g)	0%	2.3%	0%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	---	599	---

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**STATISTICAL TESTS**

POLY 3	P=0.705	P=0.510	(e)
POLY 1.5	P=0.715	P=0.508	(e)
POLY 6	P=0.691	P=0.511	(e)
COCH-ARM / FISHERS	P=0.731	P=0.500	(e)
MAX-ISO-POLY-3	P=0.403	P=0.172	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Liver</b>			
<b>Hepatodiaphragmatic Nodule</b>			
<b>LESION RATES</b>			
OVERALL (a)	8/50 (16%)	3/50 (6%)	5/50 (10%)
POLY-3 RATE (b)	8/42.13	3/42.82	5/37.68
POLY-3 PERCENT (g)	19%	7%	13.3%
TERMINAL (d)	6/27 (22%)	1/25 (4%)	1/17 (6%)
FIRST INCIDENCE	163	626	270
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.250N	P=0.091N	P=0.349N
POLY 1.5	P=0.234N	P=0.093N	P=0.321N
POLY 6	P=0.270N	P=0.090N	P=0.390N
COCH-ARM / FISHERS	P=0.209N	P=0.100N	P=0.277N
MAX-ISO-POLY-3	P=0.179N	P=0.049N*	P=0.256N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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
<hr/>			
Liver			
Infiltration Cellular Mixed Cell			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	21/50 (42%)	22/50 (44%)	18/50 (36%)
POLY-3 RATE (b)	21/42.51	22/43.34	18/37.84
POLY-3 PERCENT (g)	49.4%	50.8%	47.6%
TERMINAL (d)	16/27 (59%)	18/25 (72%)	12/17 (71%)
FIRST INCIDENCE	540	610	404
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.489N	P=0.537	P=0.525N
POLY 1.5	P=0.410N	P=0.540	P=0.444N
POLY 6	P=0.506	P=0.509	P=0.558
COCH-ARM / FISHERS	P=0.305N	P=0.500	P=0.341N
MAX-ISO-POLY-3	P=0.563N	P=0.447	P=0.435N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<hr/>			
Liver			
Mixed Cell Focus			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	3/50 (6%)	6/50 (12%)	3/50 (6%)
POLY-3 RATE (b)	3/40.62	6/42.35	3/35.51
POLY-3 PERCENT (g)	7.4%	14.2%	8.5%
TERMINAL (d)	3/27 (11%)	6/25 (24%)	1/17 (6%)
FIRST INCIDENCE	729 (T)	729 (T)	637
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.484	P=0.261	P=0.600
POLY 1.5	P=0.518	P=0.259	P=0.625
POLY 6	P=0.442	P=0.258	P=0.568
COCH-ARM / FISHERS	P=0.573	P=0.243	P=0.661N
MAX-ISO-POLY-3	P=0.403	P=0.165	P=0.435

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Liver</b>			
<b>Necrosis Focal</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/40.62	1/43.28	0/34.98
POLY-3 PERCENT (g)	0%	2.3%	0%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	---	299	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.705	P=0.513	(e)
POLY 1.5	P=0.715	P=0.510	(e)
POLY 6	P=0.691	P=0.513	(e)
COCH-ARM / FISHERS	P=0.731	P=0.500	(e)
MAX-ISO-POLY-3	P=0.405	P=0.174	(e)



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Liver: Bile Duct  
Hyperplasia

---

LESION RATES			
OVERALL (a)	41/50 (82%)	45/50 (90%)	40/50 (80%)
POLY-3 RATE (b)	41/45.59	45/47.32	40/46.41
POLY-3 PERCENT (g)	89.9%	95.1%	86.2%
TERMINAL (d)	25/27 (93%)	24/25 (96%)	15/17 (88%)
FIRST INCIDENCE	370	556	270

---

STATISTICAL TESTS			
POLY 3	P=0.311N	P=0.263	P=0.400N
POLY 1.5	P=0.357N	P=0.242	P=0.435N
POLY 6	P=0.287N	P=0.297	P=0.386N
COCH-ARM / FISHERS	P=0.446N	P=0.194	P=0.500N
MAX-ISO-POLY-3	P=0.174N	P=0.143	P=0.275N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Liver: Centrilobular  
Necrosis

---

LESION RATES			
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/40.62	1/42.36	1/35.74
POLY-3 PERCENT (g)	0%	2.4%	2.8%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	---	726	450

---

STATISTICAL TESTS			
POLY 3	P=0.312	P=0.508	P=0.475
POLY 1.5	P=0.320	P=0.507	P=0.485
POLY 6	P=0.302	P=0.508	P=0.461
COCH-ARM / FISHERS	P=0.331	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.268	P=0.169	P=0.158

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Liver: Hepatocyte Vacuolization Cytoplasmic</b>			
<b>LESION RATES</b>			
OVERALL (a)	7/50 (14%)	10/50 (20%)	4/50 (8%)
POLY-3 RATE (b)	7/42.59	10/46.37	4/36.03
POLY-3 PERCENT (g)	16.4%	21.6%	11.1%
TERMINAL (d)	2/27 (7%)	0/25 (0%)	1/17 (6%)
FIRST INCIDENCE	370	299	540
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.371N	P=0.365	P=0.363N
POLY 1.5	P=0.317N	P=0.346	P=0.322N
POLY 6	P=0.438N	P=0.382	P=0.415N
COCH-ARM / FISHERS	P=0.236N	P=0.298	P=0.262N
MAX-ISO-POLY-3	P=0.276N	P=0.278	P=0.266N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Liver: Hepatocyte  
Vacuolization Cytoplasmic Focal

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/40.62	2/42.35	1/34.98
POLY-3 PERCENT (g)	0%	4.7%	2.9%
TERMINAL (d)	0/27 (0%)	2/25 (8%)	1/17 (6%)
FIRST INCIDENCE	---	729 (T)	729 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.314	P=0.246	P=0.470
POLY 1.5	P=0.332	P=0.245	P=0.482
POLY 6	P=0.291	P=0.245	P=0.455
COCH-ARM / FISHERS	P=0.360	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.231	P=0.085	P=0.158

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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

---

Liver: Kupffer Cell  
Pigmentation

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	0/40.62	4/43.00	0/34.98
POLY-3 PERCENT (g)	0%	9.3%	0%
TERMINAL (d)	0/27 (0%)	1/25 (4%)	0/17 (0%)
FIRST INCIDENCE	---	626	---

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**STATISTICAL TESTS**

POLY 3	P=0.533	P=0.067	(e)
POLY 1.5	P=0.571	P=0.066	(e)
POLY 6	P=0.482	P=0.068	(e)
COCH-ARM / FISHERS	P=0.622	P=0.059	(e)
MAX-ISO-POLY-3	P=0.176	P=0.025*	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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
<b>Lung</b>			
<b>Infiltration Cellular Histiocyte</b>			
<b>LESION RATES</b>			
OVERALL (a)	31/50 (62%)	43/50 (86%)	33/50 (66%)
POLY-3 RATE (b)	31/44.32	43/48.82	33/41.79
POLY-3 PERCENT (g)	69.9%	88.1%	79%
TERMINAL (d)	18/27 (67%)	23/25 (92%)	14/17 (82%)
FIRST INCIDENCE	540	299	485
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.154	P=0.021*	P=0.225
POLY 1.5	P=0.216	P=0.014*	P=0.288
POLY 6	P=0.104	P=0.026*	P=0.170
COCH-ARM / FISHERS	P=0.370	P=0.006**	P=0.418
MAX-ISO-POLY-3	P=0.068	P=0.014*	P=0.162

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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
<b>Lung</b>			
<b>Inflammation Chronic</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	6/50 (12%)	2/50 (4%)
POLY-3 RATE (b)	1/40.62	6/42.63	2/35.91
POLY-3 PERCENT (g)	2.5%	14.1%	5.6%
TERMINAL (d)	1/27 (4%)	4/25 (16%)	0/17 (0%)
FIRST INCIDENCE	729 (T)	668	485
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.332	P=0.063	P=0.457
POLY 1.5	P=0.364	P=0.062	P=0.474
POLY 6	P=0.292	P=0.063	P=0.435
COCH-ARM / FISHERS	P=0.417	P=0.056	P=0.500
MAX-ISO-POLY-3	P=0.162	P=0.029*	P=0.257

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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

---

Lung  
Metaplasia Osseous

---

LESION RATES			
OVERALL (a)	2/50 (4%)	5/50 (10%)	6/50 (12%)
POLY-3 RATE (b)	2/41.89	5/42.61	6/36.90
POLY-3 PERCENT (g)	4.8%	11.7%	16.3%
TERMINAL (d)	0/27 (0%)	3/25 (12%)	2/17 (12%)
FIRST INCIDENCE	367	689	313

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STATISTICAL TESTS			
POLY 3	P=0.073	P=0.222	P=0.094
POLY 1.5	P=0.085	P=0.223	P=0.108
POLY 6	P=0.061	P=0.217	P=0.078
COCH-ARM / FISHERS	P=0.107	P=0.218	P=0.134
MAX-ISO-POLY-3	P=0.084	P=0.125	P=0.055

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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
<b>Lung: Alveolar Epithelium Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	11/50 (22%)	17/50 (34%)	19/50 (38%)
POLY-3 RATE (b)	11/41.79	17/44.81	19/38.09
POLY-3 PERCENT (g)	26.3%	37.9%	49.9%
TERMINAL (d)	7/27 (26%)	11/25 (44%)	11/17 (65%)
FIRST INCIDENCE	367	519	485
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.019*	P=0.174	P=0.021*
POLY 1.5	P=0.028*	P=0.160	P=0.033*
POLY 6	P=0.012*	P=0.190	P=0.012*
COCH-ARM / FISHERS	P=0.053	P=0.133	P=0.063
MAX-ISO-POLY-3	P=0.023*	P=0.129	P=0.015*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Lymph Node, Mandibular Hyperplasia Lymphoid</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/2 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/1.80	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/1 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---
<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)

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Lymph Node, Mesenteric Hemorrhage</b>			
<b>LESION RATES</b>			
OVERALL (a)	4/50 (8%)	2/49 (4%)	10/50 (20%)
POLY-3 RATE (b)	4/41.29	2/41.74	10/38.60
POLY-3 PERCENT (g)	9.7%	4.8%	25.9%
TERMINAL (d)	2/27 (7%)	2/25 (8%)	3/17 (18%)
FIRST INCIDENCE	612	729 (T)	450
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.028*	P=0.331N	P=0.051
POLY 1.5	P=0.030*	P=0.333N	P=0.058
POLY 6	P=0.024*	P=0.335N	P=0.041*
COCH-ARM / FISHERS	P=0.038*	P=0.349N	P=0.074
MAX-ISO-POLY-3	P=0.010**	P=0.198N	P=0.030*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Lymph Node, Mesenteric Hyperplasia Lymphoid</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	2/49 (4%)	4/50 (8%)
POLY-3 RATE (b)	1/40.62	2/41.74	4/36.07
POLY-3 PERCENT (g)	2.5%	4.8%	11.1%
TERMINAL (d)	1/27 (4%)	2/25 (8%)	2/17 (12%)
FIRST INCIDENCE	729 (T)	729 (T)	163
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.099	P=0.510	P=0.143
POLY 1.5	P=0.107	P=0.506	P=0.159
POLY 6	P=0.090	P=0.510	P=0.124
COCH-ARM / FISHERS	P=0.119	P=0.492	P=0.181
MAX-ISO-POLY-3	P=0.093	P=0.292	P=0.073

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Lymph Node, Mesenteric  
Necrosis

---

LESION RATES			
OVERALL (a)	0/50 (0%)	1/49 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/40.62	1/42.11	2/35.64
POLY-3 PERCENT (g)	0%	2.4%	5.6%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	---	626	615

---

STATISTICAL TESTS			
POLY 3	P=0.130	P=0.507	P=0.209
POLY 1.5	P=0.135	P=0.504	P=0.220
POLY 6	P=0.125	P=0.509	P=0.196
COCH-ARM / FISHERS	P=0.143	P=0.495	P=0.247
MAX-ISO-POLY-3	P=0.104	P=0.169	P=0.075

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Lymph Node: Mediastinal Hemorrhage

---

LESION RATES			
OVERALL (a)	2/12 (17%)	0/14 (0%)	0/12 (0%)
POLY-3 RATE (b)	2/10.59	0/10.96	0/10.08
POLY-3 PERCENT (g)	18.9%	0%	0%
TERMINAL (d)	0/3 (0%)	0/4 (0%)	0/5 (0%)
FIRST INCIDENCE	570	---	---

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STATISTICAL TESTS			
POLY 3	P=0.083N	P=0.218N	P=0.238N
POLY 1.5	P=0.082N	P=0.208N	P=0.236N
POLY 6	P=0.082N	P=0.232N	P=0.236N
COCH-ARM / FISHERS	P=0.085N	P=0.203N	P=0.239N
MAX-ISO-POLY-3	P=0.048N*	P=0.066N	P=0.076N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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
<b>Lymph Node: Mediastinal Hyperplasia Lymphoid</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/12 (8%)	1/14 (7%)	3/12 (25%)
POLY-3 RATE (b)	1/10.48	1/11.02	3/10.33
POLY-3 PERCENT (g)	9.5%	9.1%	29.1%
TERMINAL (d)	0/3 (0%)	0/4 (0%)	2/5 (40%)
FIRST INCIDENCE	570	716	663
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.177	P=0.753N	P=0.284
POLY 1.5	P=0.179	P=0.742N	P=0.286
POLY 6	P=0.181	P=0.766	P=0.294
COCH-ARM / FISHERS	P=0.183	P=0.720N	P=0.295
MAX-ISO-POLY-3	P=0.146	P=0.485N	P=0.132

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Lymph Node: Mediastinal  
Pigmentation

---

LESION RATES			
OVERALL (a)	0/12 (0%)	0/14 (0%)	1/12 (8%)
POLY-3 RATE (b)	0/9.96	0/10.96	1/10.08
POLY-3 PERCENT (g)	0%	0%	9.9%
TERMINAL (d)	0/3 (0%)	0/4 (0%)	1/5 (20%)
FIRST INCIDENCE	---	---	729 (T)

---

STATISTICAL TESTS			
POLY 3	P=0.265	(e)	P=0.502
POLY 1.5	P=0.264	(e)	P=0.500
POLY 6	P=0.272	(e)	P=0.512
COCH-ARM / FISHERS	P=0.262	(e)	P=0.500
MAX-ISO-POLY-3	P=0.144	(e)	P=0.160

---



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Lymph Node: Pancreatic Hemorrhage

---

LESION RATES			
OVERALL (a)	1/12 (8%)	0/14 (0%)	0/12 (0%)
POLY-3 RATE (b)	1/9.96	0/10.96	0/10.08
POLY-3 PERCENT (g)	10%	0%	0%
TERMINAL (d)	1/3 (33%)	0/4 (0%)	0/5 (0%)
FIRST INCIDENCE	729 (T)	---	---

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STATISTICAL TESTS			
POLY 3	P=0.263N	P=0.481N	P=0.498N
POLY 1.5	P=0.264N	P=0.476N	P=0.500N
POLY 6	P=0.263N	P=0.485N	P=0.488N
COCH-ARM / FISHERS	P=0.262N	P=0.462N	P=0.500N
MAX-ISO-POLY-3	P=0.140N	P=0.146N	P=0.157N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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 Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/48 (4%)	1/47 (2%)	0/49 (0%)
POLY-3 RATE (b)	2/39.73	1/39.76	0/33.98
POLY-3 PERCENT (g)	5%	2.5%	0%
TERMINAL (d)	1/26 (4%)	0/24 (0%)	0/16 (0%)
FIRST INCIDENCE	570	726	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.178N	P=0.500N	P=0.273N
POLY 1.5	P=0.162N	P=0.499N	P=0.256N
POLY 6	P=0.201N	P=0.504N	P=0.297N
COCH-ARM / FISHERS	P=0.140N	P=0.508N	P=0.242N
MAX-ISO-POLY-3	P=0.155N	P=0.281N	P=0.111N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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 Hyperplasia Focal</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/48 (0%)	0/47 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/39.21	0/39.75	0/33.98
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/26 (0%)	0/24 (0%)	0/16 (0%)
FIRST INCIDENCE	---	---	---
<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)

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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: Duct Ectasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	28/48 (58%)	36/47 (77%)	34/49 (69%)
POLY-3 RATE (b)	28/43.13	36/42.68	34/42.20
POLY-3 PERCENT (g)	64.9%	84.4%	80.6%
TERMINAL (d)	15/26 (58%)	21/24 (88%)	13/16 (81%)
FIRST INCIDENCE	356	556	313
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.042*	P=0.025*	P=0.072
POLY 1.5	P=0.068	P=0.034*	P=0.100
POLY 6	P=0.024*	P=0.016*	P=0.050*
COCH-ARM / FISHERS	P=0.147	P=0.046*	P=0.178
MAX-ISO-POLY-3	P=0.027*	P=0.013*	P=0.045*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Mesentery</b>			
<b>Accessory Spleen</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/11 (0%)	1/10 (10%)	1/11 (9%)
POLY-3 RATE (b)	0/8.83	1/8.74	1/8.27
POLY-3 PERCENT (g)	0%	11.5%	12.1%
TERMINAL (d)	0/6 (0%)	0/4 (0%)	0/5 (0%)
FIRST INCIDENCE	---	610	540
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.321	P=0.498	P=0.487
POLY 1.5	P=0.319	P=0.492	P=0.483
POLY 6	P=0.328	P=0.502	P=0.495
COCH-ARM / FISHERS	P=0.330	P=0.476	P=0.500
MAX-ISO-POLY-3	P=0.270	P=0.160	P=0.156

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Mesentery: Fat  
Necrosis

---

**LESION RATES**

OVERALL (a)	10/11 (91%)	9/10 (90%)	8/11 (73%)
POLY-3 RATE (b)	10/10.59	9/9.61	8/10.41
POLY-3 PERCENT (g)	94.4%	93.7%	76.9%
TERMINAL (d)	6/6 (100%)	4/4 (100%)	3/5 (60%)
FIRST INCIDENCE	540	610	163

---

**STATISTICAL TESTS**

POLY 3	P=0.164N	P=0.854N	P=0.288N
POLY 1.5	P=0.180N	P=0.794N	P=0.293N
POLY 6	P=0.137N	P=0.960N	P=0.274N
COCH-ARM / FISHERS	P=0.189N	P=0.738N	P=0.293N
MAX-ISO-POLY-3	P=0.122N	P=0.467N	P=0.112N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Nose</b>			
<b>Foreign Body</b>			
<b>LESION RATES</b>			
OVERALL (a)	11/50 (22%)	8/50 (16%)	9/50 (18%)
POLY-3 RATE (b)	11/43.07	8/43.44	9/37.78
POLY-3 PERCENT (g)	25.5%	18.4%	23.8%
TERMINAL (d)	6/27 (22%)	4/25 (16%)	1/17 (6%)
FIRST INCIDENCE	163	610	394
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.458N	P=0.294N	P=0.532N
POLY 1.5	P=0.422N	P=0.298N	P=0.487N
POLY 6	P=0.499N	P=0.292N	P=0.584N
COCH-ARM / FISHERS	P=0.350N	P=0.306N	P=0.402N
MAX-ISO-POLY-3	P=0.446N	P=0.212N	P=0.431N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Nose  
Inflammation Chronic

---

**LESION RATES**

OVERALL (a)	13/50 (26%)	15/50 (30%)	13/50 (26%)
POLY-3 RATE (b)	13/42.18	15/43.93	13/39.12
POLY-3 PERCENT (g)	30.8%	34.2%	33.2%
TERMINAL (d)	8/27 (30%)	9/25 (36%)	3/17 (18%)
FIRST INCIDENCE	370	477	394

---

**STATISTICAL TESTS**

POLY 3	P=0.452	P=0.460	P=0.502
POLY 1.5	P=0.484	P=0.450	P=0.533
POLY 6	P=0.419	P=0.461	P=0.468
COCH-ARM / FISHERS	P=0.545	P=0.412	P=0.590N
MAX-ISO-POLY-3	P=0.538	P=0.371	P=0.408

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Nose: Goblet Cell  
Hyperplasia

---

LESION RATES			
OVERALL (a)	2/50 (4%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	2/40.67	1/42.74	3/35.02
POLY-3 PERCENT (g)	4.9%	2.3%	8.6%
TERMINAL (d)	1/27 (4%)	0/25 (0%)	2/17 (12%)
FIRST INCIDENCE	716	617	718

---

STATISTICAL TESTS			
POLY 3	P=0.372	P=0.483N	P=0.432
POLY 1.5	P=0.381	P=0.487N	P=0.460
POLY 6	P=0.362	P=0.481N	P=0.396
COCH-ARM / FISHERS	P=0.399	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.259	P=0.270N	P=0.278

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Nose: Respiratory Epithelium  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	13/50 (26%)	7/50 (14%)	10/50 (20%)
POLY-3 RATE (b)	13/41.51	7/43.86	10/37.47
POLY-3 PERCENT (g)	31.3%	16%	26.7%
TERMINAL (d)	8/27 (30%)	3/25 (12%)	3/17 (18%)
FIRST INCIDENCE	634	477	500

---

**STATISTICAL TESTS**

POLY 3	P=0.329N	P=0.075N	P=0.419N
POLY 1.5	P=0.305N	P=0.082N	P=0.378N
POLY 6	P=0.359N	P=0.072N	P=0.471N
COCH-ARM / FISHERS	P=0.266N	P=0.105N	P=0.318N
MAX-ISO-POLY-3	P=0.215N	P=0.049N*	P=0.332N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Pancreas Atrophy</b>			
<b>LESION RATES</b>			
OVERALL (a)	29/50 (58%)	35/50 (70%)	30/50 (60%)
POLY-3 RATE (b)	29/44.32	35/46.41	30/41.33
POLY-3 PERCENT (g)	65.4%	75.4%	72.6%
TERMINAL (d)	18/27 (67%)	19/25 (76%)	13/17 (77%)
FIRST INCIDENCE	356	477	450
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.253	P=0.198	P=0.307
POLY 1.5	P=0.314	P=0.184	P=0.368
POLY 6	P=0.209	P=0.214	P=0.260
COCH-ARM / FISHERS	P=0.459	P=0.149	P=0.500
MAX-ISO-POLY-3	P=0.262	P=0.143	P=0.234

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Pancreas Cyst</b>			
<b>LESION RATES</b>			
OVERALL (a)	21/50 (42%)	25/50 (50%)	15/50 (30%)
POLY-3 RATE (b)	21/42.74	25/46.23	15/37.57
POLY-3 PERCENT (g)	49.1%	54.1%	39.9%
TERMINAL (d)	13/27 (48%)	13/25 (52%)	7/17 (41%)
FIRST INCIDENCE	540	299	540
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.268N	P=0.398	P=0.269N
POLY 1.5	P=0.207N	P=0.367	P=0.214N
POLY 6	P=0.349N	P=0.411	P=0.344N
COCH-ARM / FISHERS	P=0.131N	P=0.274	P=0.149N
MAX-ISO-POLY-3	P=0.224N	P=0.323	P=0.213N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
alpha/beta Thujone mixture  
CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010  
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Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Pancreas: Acinus  
Hyperplasia Focal

---

**LESION RATES**

OVERALL (a)	8/50 (16%)	1/50 (2%)	6/50 (12%)
POLY-3 RATE (b)	8/40.72	1/42.46	6/34.98
POLY-3 PERCENT (g)	19.6%	2.4%	17.2%
TERMINAL (d)	7/27 (26%)	0/25 (0%)	6/17 (35%)
FIRST INCIDENCE	702	702	729 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.351N	P=0.012N*	P=0.507N
POLY 1.5	P=0.334N	P=0.013N*	P=0.457N
POLY 6	P=0.369N	P=0.012N*	P=0.576N
COCH-ARM / FISHERS	P=0.309N	P=0.015N*	P=0.387N
MAX-ISO-POLY-3	P=0.137N	P=0.005N**	P=0.396N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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 Pigmentation</b>			
<b>LESION RATES</b>			
OVERALL (a)	7/50 (14%)	6/50 (12%)	9/50 (18%)
POLY-3 RATE (b)	7/42.34	6/43.07	9/37.18
POLY-3 PERCENT (g)	16.5%	13.9%	24.2%
TERMINAL (d)	1/27 (4%)	2/25 (8%)	1/17 (6%)
FIRST INCIDENCE	356	626	608
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.256	P=0.487N	P=0.284
POLY 1.5	P=0.283	P=0.486N	P=0.322
POLY 6	P=0.232	P=0.494N	P=0.249
COCH-ARM / FISHERS	P=0.336	P=0.500N	P=0.393
MAX-ISO-POLY-3	P=0.232	P=0.369N	P=0.212

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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

---

Pituitary Gland: Pars Distalis  
Angiectasis

---

**LESION RATES**

OVERALL (a)	2/50 (4%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/40.72	2/42.72	1/35.42
POLY-3 PERCENT (g)	4.9%	4.7%	2.8%
TERMINAL (d)	1/27 (4%)	1/25 (4%)	0/17 (0%)
FIRST INCIDENCE	702	626	598

---

**STATISTICAL TESTS**

POLY 3	P=0.451N	P=0.677N	P=0.549N
POLY 1.5	P=0.427N	P=0.680N	P=0.529N
POLY 6	P=0.482N	P=0.677N	P=0.573N
COCH-ARM / FISHERS	P=0.390N	P=0.691N	P=0.500N
MAX-ISO-POLY-3	P=0.469N	P=0.480N	P=0.332N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Pituitary Gland: Pars Distalis  
Atrophy

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/40.62	1/42.78	1/34.98
POLY-3 PERCENT (g)	0%	2.3%	2.9%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	1/17 (6%)
FIRST INCIDENCE	---	603	729 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.309	P=0.510	P=0.470
POLY 1.5	P=0.318	P=0.508	P=0.482
POLY 6	P=0.299	P=0.511	P=0.455
COCH-ARM / FISHERS	P=0.331	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.268	P=0.172	P=0.158

---



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS 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 Cyst</b>			
<b>LESION RATES</b>			
OVERALL (a)	6/50 (12%)	3/50 (6%)	4/50 (8%)
POLY-3 RATE (b)	6/42.18	3/42.74	4/35.86
POLY-3 PERCENT (g)	14.2%	7%	11.2%
TERMINAL (d)	2/27 (7%)	2/25 (8%)	1/17 (6%)
FIRST INCIDENCE	540	617	485
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.371N	P=0.234N	P=0.475N
POLY 1.5	P=0.341N	P=0.232N	P=0.431N
POLY 6	P=0.410N	P=0.242N	P=0.533N
COCH-ARM / FISHERS	P=0.297N	P=0.243N	P=0.370N
MAX-ISO-POLY-3	P=0.343N	P=0.142N	P=0.354N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS 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 Hyperplasia Focal</b>			
<b>LESION RATES</b>			
OVERALL (a)	16/50 (32%)	13/50 (26%)	3/50 (6%)
POLY-3 RATE (b)	16/42.76	13/45.75	3/36.63
POLY-3 PERCENT (g)	37.4%	28.4%	8.2%
TERMINAL (d)	9/27 (33%)	4/25 (16%)	0/17 (0%)
FIRST INCIDENCE	367	299	485
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.003N**	P=0.248N	P=0.002N**
POLY 1.5	P=0.002N**	P=0.269N	P<0.001N**
POLY 6	P=0.005N**	P=0.234N	P=0.003N**
COCH-ARM / FISHERS	P<0.001N**	P=0.330N	P<0.001N**
MAX-ISO-POLY-3	P=0.003N**	P=0.190N	P<0.001N**

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Pituitary Gland: Pars Intermedia  
Angiectasis

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	0/40.62	4/43.02	1/35.38
POLY-3 PERCENT (g)	0%	9.3%	2.8%
TERMINAL (d)	0/27 (0%)	1/25 (4%)	0/17 (0%)
FIRST INCIDENCE	---	626	612

---

**STATISTICAL TESTS**

POLY 3	P=0.315	P=0.067	P=0.473
POLY 1.5	P=0.344	P=0.066	P=0.483
POLY 6	P=0.280	P=0.068	P=0.459
COCH-ARM / FISHERS	P=0.390	P=0.059	P=0.500
MAX-ISO-POLY-3	P=0.139	P=0.025*	P=0.158

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS 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 Intermedia Cyst</b>			
<b>LESION RATES</b>			
OVERALL (a)	4/50 (8%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	4/41.92	0/42.35	1/34.98
POLY-3 PERCENT (g)	9.5%	0%	2.9%
TERMINAL (d)	1/27 (4%)	0/25 (0%)	1/17 (6%)
FIRST INCIDENCE	540	---	729 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.094N	P=0.058N	P=0.238N
POLY 1.5	P=0.088N	P=0.058N	P=0.212N
POLY 6	P=0.102N	P=0.061N	P=0.275N
COCH-ARM / FISHERS	P=0.082N	P=0.059N	P=0.181N
MAX-ISO-POLY-3	P=0.068N	P=0.019N*	P=0.139N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Pituitary Gland: Pars Intermedia  
Hyperplasia Focal

---

**LESION RATES**

OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/40.62	1/42.79	0/34.98
POLY-3 PERCENT (g)	4.9%	2.3%	0%
TERMINAL (d)	2/27 (7%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	729 (T)	599	---

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**STATISTICAL TESTS**

POLY 3	P=0.173N	P=0.482N	P=0.271N
POLY 1.5	P=0.161N	P=0.486N	P=0.257N
POLY 6	P=0.191N	P=0.480N	P=0.291N
COCH-ARM / FISHERS	P=0.142N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.150N	P=0.270N	P=0.108N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS 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: Rathke's Cleft Dilatation</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	0/40.62	3/42.80	1/35.68
POLY-3 PERCENT (g)	0%	7%	2.8%
TERMINAL (d)	0/27 (0%)	1/25 (4%)	0/17 (0%)
FIRST INCIDENCE	---	662	485
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.321	P=0.128	P=0.474
POLY 1.5	P=0.343	P=0.126	P=0.485
POLY 6	P=0.293	P=0.129	P=0.461
COCH-ARM / FISHERS	P=0.378	P=0.121	P=0.500
MAX-ISO-POLY-3	P=0.177	P=0.046*	P=0.158

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Preputial Gland Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/49 (4%)	0/49 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/39.67	0/41.35	1/34.98
POLY-3 PERCENT (g)	5%	0%	2.9%
TERMINAL (d)	2/27 (7%)	0/24 (0%)	1/17 (6%)
FIRST INCIDENCE	729 (T)	---	729 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.381N	P=0.228N	P=0.544N
POLY 1.5	P=0.371N	P=0.229N	P=0.523N
POLY 6	P=0.392N	P=0.228N	P=0.571N
COCH-ARM / FISHERS	P=0.355N	P=0.247N	P=0.492N
MAX-ISO-POLY-3	P=0.246N	P=0.075N	P=0.328N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Preputial Gland  
Inflammation Chronic

---

**LESION RATES**

OVERALL (a)	13/49 (27%)	19/49 (39%)	18/50 (36%)
POLY-3 RATE (b)	13/42.67	19/43.25	18/39.70
POLY-3 PERCENT (g)	30.5%	43.9%	45.3%
TERMINAL (d)	4/27 (15%)	9/24 (38%)	3/17 (18%)
FIRST INCIDENCE	540	610	485

---

**STATISTICAL TESTS**

POLY 3	P=0.096	P=0.139	P=0.118
POLY 1.5	P=0.123	P=0.147	P=0.147
POLY 6	P=0.075	P=0.124	P=0.096
COCH-ARM / FISHERS	P=0.188	P=0.141	P=0.212
MAX-ISO-POLY-3	P=0.124	P=0.096	P=0.087

---



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Prostate  
Inflammation Chronic

---

**LESION RATES**

OVERALL (a)	32/50 (64%)	20/50 (40%)	23/50 (46%)
POLY-3 RATE (b)	32/46.34	20/43.56	23/39.92
POLY-3 PERCENT (g)	69.1%	45.9%	57.6%
TERMINAL (d)	17/27 (63%)	13/25 (52%)	9/17 (53%)
FIRST INCIDENCE	356	617	313

---

**STATISTICAL TESTS**

POLY 3	P=0.120N	P=0.017N*	P=0.181N
POLY 1.5	P=0.081N	P=0.013N*	P=0.114N
POLY 6	P=0.182N	P=0.029N*	P=0.280N
COCH-ARM / FISHERS	P=0.045N*	P=0.014N*	P=0.054N
MAX-ISO-POLY-3	P=0.073N	P=0.012N*	P=0.143N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Prostate: Epithelium  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	23/50 (46%)	17/50 (34%)	18/50 (36%)
POLY-3 RATE (b)	23/45.48	17/43.58	18/39.14
POLY-3 PERCENT (g)	50.6%	39%	46%
TERMINAL (d)	10/27 (37%)	11/25 (44%)	6/17 (35%)
FIRST INCIDENCE	356	519	313

---

**STATISTICAL TESTS**

POLY 3	P=0.344N	P=0.184N	P=0.419N
POLY 1.5	P=0.272N	P=0.162N	P=0.328N
POLY 6	P=0.437N	P=0.231N	P=0.527N
COCH-ARM / FISHERS	P=0.178N	P=0.154N	P=0.208N
MAX-ISO-POLY-3	P=0.329N	P=0.136N	P=0.344N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Salivary Glands Atrophy</b>			
<b>LESION RATES</b>			
OVERALL (a)	7/50 (14%)	4/50 (8%)	9/50 (18%)
POLY-3 RATE (b)	7/41.65	4/42.95	9/35.33
POLY-3 PERCENT (g)	16.8%	9.3%	25.5%
TERMINAL (d)	4/27 (15%)	1/25 (4%)	8/17 (47%)
FIRST INCIDENCE	570	599	631
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.252	P=0.241N	P=0.257
POLY 1.5	P=0.280	P=0.244N	P=0.311
POLY 6	P=0.220	P=0.244N	P=0.193
COCH-ARM / FISHERS	P=0.330	P=0.262N	P=0.393
MAX-ISO-POLY-3	P=0.124	P=0.156N	P=0.193

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Salivary Glands  
Inflammation Chronic

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/40.62	2/42.40	0/34.98
POLY-3 PERCENT (g)	0%	4.7%	0%
TERMINAL (d)	0/27 (0%)	1/25 (4%)	0/17 (0%)
FIRST INCIDENCE	---	716	---

---

**STATISTICAL TESTS**

POLY 3	P=0.616	P=0.247	(e)
POLY 1.5	P=0.638	P=0.245	(e)
POLY 6	P=0.586	P=0.246	(e)
COCH-ARM / FISHERS	P=0.669	P=0.247	(e)
MAX-ISO-POLY-3	P=0.298	P=0.085	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Salivary Glands</b>			
<b>Mineralization</b>			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/40.62	0/42.35	0/34.98
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	---	---	---
<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)

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Skeletal Muscle Fibrosis</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/2 (0%)	2/4 (50%)	0/2 (0%)
POLY-3 RATE (b)	0/1.49	2/2.89	0/1.28
POLY-3 PERCENT (g)	0%	69.3%	0%
TERMINAL (d)	0/1 (0%)	2/2 (100%)	0/0 (0%)
FIRST INCIDENCE	---	729 (T)	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.700	P=0.342	(e)
POLY 1.5	P=0.707	P=0.361	(e)
POLY 6	P=0.678	P=0.324	(e)
COCH-ARM / FISHERS	P=0.718	P=0.400	(e)
MAX-ISO-POLY-3	P=0.283	P=0.090	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS 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>			
Cyst Epithelial Inclusion			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	2/50 (4%)	4/50 (8%)
POLY-3 RATE (b)	0/40.62	2/42.35	4/36.07
POLY-3 PERCENT (g)	0%	4.7%	11.1%
TERMINAL (d)	0/27 (0%)	2/25 (8%)	2/17 (12%)
FIRST INCIDENCE	---	729 (T)	450
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.028*	P=0.246	P=0.046*
POLY 1.5	P=0.031*	P=0.245	P=0.051
POLY 6	P=0.025*	P=0.245	P=0.039*
COCH-ARM / FISHERS	P=0.037*	P=0.247	P=0.059
MAX-ISO-POLY-3	P=0.025*	P=0.085	P=0.018*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Skin  
Hyperkeratosis

---

**LESION RATES**

OVERALL (a)	1/50 (2%)	3/50 (6%)	5/50 (10%)
POLY-3 RATE (b)	1/40.62	3/42.91	5/35.02
POLY-3 PERCENT (g)	2.5%	7%	14.3%
TERMINAL (d)	1/27 (4%)	2/25 (8%)	4/17 (24%)
FIRST INCIDENCE	729 (T)	556	718

---

**STATISTICAL TESTS**

POLY 3	P=0.050*	P=0.325	P=0.069
POLY 1.5	P=0.057	P=0.320	P=0.081
POLY 6	P=0.043*	P=0.326	P=0.056
COCH-ARM / FISHERS	P=0.070	P=0.309	P=0.102
MAX-ISO-POLY-3	P=0.050*	P=0.174	P=0.037*

---



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Skin  
Inflammation Chronic

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	4/50 (8%)
POLY-3 RATE (b)	0/40.62	0/42.35	4/35.02
POLY-3 PERCENT (g)	0%	0%	11.4%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	3/17 (18%)
FIRST INCIDENCE	---	---	718

---

**STATISTICAL TESTS**

POLY 3	P=0.012*	(e)	P=0.043*
POLY 1.5	P=0.013*	(e)	P=0.049*
POLY 6	P=0.013*	(e)	P=0.035*
COCH-ARM / FISHERS	P=0.015*	(e)	P=0.059
MAX-ISO-POLY-3	P=0.007**	(e)	P=0.018*

---

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Skin: Epidermis  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	0/40.62	1/42.35	3/34.98
POLY-3 PERCENT (g)	0%	2.4%	8.6%
TERMINAL (d)	0/27 (0%)	1/25 (4%)	3/17 (18%)
FIRST INCIDENCE	---	729 (T)	729 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.051	P=0.508	P=0.093
POLY 1.5	P=0.054	P=0.507	P=0.103
POLY 6	P=0.048*	P=0.508	P=0.082
COCH-ARM / FISHERS	P=0.060	P=0.500	P=0.121
MAX-ISO-POLY-3	P=0.039*	P=0.169	P=0.037*

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Spleen Fibrosis</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	3/50 (6%)	1/49 (2%)
POLY-3 RATE (b)	2/41.26	3/42.81	1/34.48
POLY-3 PERCENT (g)	4.9%	7%	2.9%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	540	626	706
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.493N	P=0.517	P=0.562N
POLY 1.5	P=0.459N	P=0.514	P=0.540N
POLY 6	P=0.536N	P=0.516	P=0.590N
COCH-ARM / FISHERS	P=0.407N	P=0.500	P=0.508N
MAX-ISO-POLY-3	P=0.408N	P=0.341	P=0.346N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Spleen  
Hematopoietic Cell Proliferation

---

**LESION RATES**

OVERALL (a)	6/50 (12%)	7/50 (14%)	1/49 (2%)
POLY-3 RATE (b)	6/42.79	7/44.53	1/35.00
POLY-3 PERCENT (g)	14%	15.7%	2.9%
TERMINAL (d)	1/27 (4%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	367	477	532

---

**STATISTICAL TESTS**

POLY 3	P=0.121N	P=0.531	P=0.094N
POLY 1.5	P=0.095N	P=0.524	P=0.079N
POLY 6	P=0.159N	P=0.534	P=0.117N
COCH-ARM / FISHERS	P=0.065N	P=0.500	P=0.059N
MAX-ISO-POLY-3	P=0.093N	P=0.412	P=0.058N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<hr/>			
Spleen			
Necrosis			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/49 (4%)
POLY-3 RATE (b)	0/40.62	1/42.36	2/34.92
POLY-3 PERCENT (g)	0%	2.4%	5.7%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	---	726	655
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.126	P=0.508	P=0.204
POLY 1.5	P=0.130	P=0.507	P=0.215
POLY 6	P=0.122	P=0.508	P=0.193
COCH-ARM / FISHERS	P=0.138	P=0.500	P=0.242
MAX-ISO-POLY-3	P=0.101	P=0.169	P=0.074

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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
<b>Spleen Pigmentation</b>			
<b>LESION RATES</b>			
OVERALL (a)	19/50 (38%)	24/50 (48%)	30/49 (61%)
POLY-3 RATE (b)	19/44.96	24/44.51	30/44.11
POLY-3 PERCENT (g)	42.3%	53.9%	68%
TERMINAL (d)	11/27 (41%)	16/25 (64%)	12/17 (71%)
FIRST INCIDENCE	163	299	163
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.007**	P=0.180	P=0.009**
POLY 1.5	P=0.009**	P=0.198	P=0.011*
POLY 6	P=0.005**	P=0.147	P=0.007**
COCH-ARM / FISHERS	P=0.014*	P=0.210	P=0.017*
MAX-ISO-POLY-3	P=0.007**	P=0.130	P=0.005**

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Spleen: Lymphoid Follicle Atrophy

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	2/49 (4%)
POLY-3 RATE (b)	0/40.62	1/42.40	2/35.16
POLY-3 PERCENT (g)	0%	2.4%	5.7%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	---	716	608

---

**STATISTICAL TESTS**

POLY 3	P=0.127	P=0.509	P=0.206
POLY 1.5	P=0.131	P=0.507	P=0.216
POLY 6	P=0.122	P=0.508	P=0.195
COCH-ARM / FISHERS	P=0.138	P=0.500	P=0.242
MAX-ISO-POLY-3	P=0.101	P=0.169	P=0.074

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Spleen: Lymphoid Follicle  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	10/50 (20%)	12/50 (24%)	8/49 (16%)
POLY-3 RATE (b)	10/41.52	12/43.78	8/34.38
POLY-3 PERCENT (g)	24.1%	27.4%	23.3%
TERMINAL (d)	7/27 (26%)	7/25 (28%)	8/17 (47%)
FIRST INCIDENCE	540	599	729 (T)

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**STATISTICAL TESTS**

POLY 3	P=0.546N	P=0.459	P=0.574N
POLY 1.5	P=0.475N	P=0.446	P=0.508N
POLY 6	P=0.487	P=0.467	P=0.556
COCH-ARM / FISHERS	P=0.372N	P=0.405	P=0.416N
MAX-ISO-POLY-3	P=0.558N	P=0.365	P=0.468N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Stomach, Forestomach Edema</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	2/41.37	4/43.46	1/35.13
POLY-3 PERCENT (g)	4.8%	9.2%	2.9%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	612	477	689
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.510N	P=0.360	P=0.557N
POLY 1.5	P=0.467N	P=0.356	P=0.533N
POLY 6	P=0.565N	P=0.359	P=0.587N
COCH-ARM / FISHERS	P=0.406N	P=0.339	P=0.500N
MAX-ISO-POLY-3	P=0.334N	P=0.223	P=0.341N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Stomach, Forestomach Ulcer</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	1/40.96	3/43.56	2/35.24
POLY-3 PERCENT (g)	2.4%	6.9%	5.7%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	634	477	689
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.339	P=0.327	P=0.448
POLY 1.5	P=0.362	P=0.322	P=0.469
POLY 6	P=0.312	P=0.329	P=0.421
COCH-ARM / FISHERS	P=0.399	P=0.309	P=0.500
MAX-ISO-POLY-3	P=0.336	P=0.177	P=0.252

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Stomach, Forestomach: Epithelium  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	9/50 (18%)	12/50 (24%)	13/50 (26%)
POLY-3 RATE (b)	9/43.90	12/45.63	13/38.49
POLY-3 PERCENT (g)	20.5%	26.3%	33.8%
TERMINAL (d)	0/27 (0%)	1/25 (4%)	3/17 (18%)
FIRST INCIDENCE	367	477	313

---

**STATISTICAL TESTS**

POLY 3	P=0.114	P=0.345	P=0.132
POLY 1.5	P=0.143	P=0.339	P=0.168
POLY 6	P=0.087	P=0.345	P=0.097
COCH-ARM / FISHERS	P=0.202	P=0.312	P=0.235
MAX-ISO-POLY-3	P=0.142	P=0.263	P=0.098

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Stomach, Glandular Edema</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/49 (2%)
POLY-3 RATE (b)	0/40.62	2/42.49	1/34.33
POLY-3 PERCENT (g)	0%	4.7%	2.9%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	---	708	689
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.310	P=0.247	P=0.467
POLY 1.5	P=0.327	P=0.245	P=0.478
POLY 6	P=0.289	P=0.247	P=0.452
COCH-ARM / FISHERS	P=0.355	P=0.247	P=0.495
MAX-ISO-POLY-3	P=0.233	P=0.085	P=0.157

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Stomach, Glandular Erosion</b>			
<b>LESION RATES</b>			
OVERALL (a)	3/50 (6%)	6/50 (12%)	6/49 (12%)
POLY-3 RATE (b)	3/41.83	6/43.63	6/35.84
POLY-3 PERCENT (g)	7.2%	13.8%	16.7%
TERMINAL (d)	1/27 (4%)	1/25 (4%)	2/17 (12%)
FIRST INCIDENCE	367	603	485
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.136	P=0.262	P=0.169
POLY 1.5	P=0.155	P=0.257	P=0.192
POLY 6	P=0.116	P=0.265	P=0.145
COCH-ARM / FISHERS	P=0.193	P=0.243	P=0.233
MAX-ISO-POLY-3	P=0.167	P=0.166	P=0.109

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Stomach, Glandular Ulcer</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	5/50 (10%)	2/49 (4%)
POLY-3 RATE (b)	2/41.26	5/43.74	2/34.48
POLY-3 PERCENT (g)	4.9%	11.4%	5.8%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	0/17 (0%)
FIRST INCIDENCE	540	519	659
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.479	P=0.239	P=0.628
POLY 1.5	P=0.516	P=0.234	P=0.652
POLY 6	P=0.435	P=0.243	P=0.598
COCH-ARM / FISHERS	P=0.574	P=0.218	P=0.684
MAX-ISO-POLY-3	P=0.380	P=0.142	P=0.431

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Testes: Germinal Epithelium  
Atrophy

---

**LESION RATES**

OVERALL (a)	5/50 (10%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	5/40.92	2/42.46	3/35.35
POLY-3 PERCENT (g)	12.2%	4.7%	8.5%
TERMINAL (d)	3/27 (11%)	1/25 (4%)	1/17 (6%)
FIRST INCIDENCE	677	702	637

---

**STATISTICAL TESTS**

POLY 3	P=0.325N	P=0.200N	P=0.438N
POLY 1.5	P=0.305N	P=0.203N	P=0.405N
POLY 6	P=0.351N	P=0.201N	P=0.483N
COCH-ARM / FISHERS	P=0.274N	P=0.218N	P=0.357N
MAX-ISO-POLY-3	P=0.283N	P=0.112N	P=0.311N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Testes: Interstitial Cell  
Hyperplasia

---

LESION RATES			
OVERALL (a)	9/50 (18%)	5/50 (10%)	6/50 (12%)
POLY-3 RATE (b)	9/42.92	5/44.22	6/38.33
POLY-3 PERCENT (g)	21%	11.3%	15.7%
TERMINAL (d)	3/27 (11%)	1/25 (4%)	0/17 (0%)
FIRST INCIDENCE	370	299	394

---

STATISTICAL TESTS			
POLY 3	P=0.288N	P=0.174N	P=0.371N
POLY 1.5	P=0.265N	P=0.175N	P=0.336N
POLY 6	P=0.320N	P=0.179N	P=0.419N
COCH-ARM / FISHERS	P=0.231N	P=0.194N	P=0.288N
MAX-ISO-POLY-3	P=0.264N	P=0.112N	P=0.280N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Thymus  
Cyst

---

LESION RATES			
OVERALL (a)	0/44 (0%)	1/45 (2%)	0/45 (0%)
POLY-3 RATE (b)	0/36.61	1/37.97	0/31.51
POLY-3 PERCENT (g)	0%	2.6%	0%
TERMINAL (d)	0/26 (0%)	1/24 (4%)	0/15 (0%)
FIRST INCIDENCE	---	729 (T)	---

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STATISTICAL TESTS			
POLY 3	P=0.704	P=0.507	(e)
POLY 1.5	P=0.716	P=0.508	(e)
POLY 6	P=0.687	P=0.505	(e)
COCH-ARM / FISHERS	P=0.728N	P=0.506	(e)
MAX-ISO-POLY-3	P=0.402	P=0.166	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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
<b>Thyroid Gland Degeneration Cystic</b>			
<b>LESION RATES</b>			
OVERALL (a)	7/46 (15%)	6/48 (13%)	4/42 (10%)
POLY-3 RATE (b)	7/38.17	6/41.24	4/31.76
POLY-3 PERCENT (g)	18.3%	14.6%	12.6%
TERMINAL (d)	4/26 (15%)	2/25 (8%)	2/17 (12%)
FIRST INCIDENCE	634	677	652
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.311N	P=0.440N	P=0.372N
POLY 1.5	P=0.289N	P=0.442N	P=0.347N
POLY 6	P=0.346N	P=0.447N	P=0.412N
COCH-ARM / FISHERS	P=0.259N	P=0.467N	P=0.316N
MAX-ISO-POLY-3	P=0.377N	P=0.329N	P=0.270N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS 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</b>			
<b>Ultimobranchial Cyst</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/46 (4%)	2/48 (4%)	1/42 (2%)
POLY-3 RATE (b)	2/37.67	2/40.80	1/31.39
POLY-3 PERCENT (g)	5.3%	4.9%	3.2%
TERMINAL (d)	2/26 (8%)	2/25 (8%)	1/17 (6%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.460N	P=0.666N	P=0.564N
POLY 1.5	P=0.443N	P=0.667N	P=0.550N
POLY 6	P=0.485N	P=0.670N	P=0.584N
COCH-ARM / FISHERS	P=0.421N	P=0.675N	P=0.534N
MAX-ISO-POLY-3	P=0.482N	P=0.467N	P=0.344N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Thyroid Gland: C-Cell  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	2/46 (4%)	7/48 (15%)	2/42 (5%)
POLY-3 RATE (b)	2/38.27	7/41.78	2/31.59
POLY-3 PERCENT (g)	5.2%	16.8%	6.3%
TERMINAL (d)	1/26 (4%)	4/25 (16%)	1/17 (6%)
FIRST INCIDENCE	540	610	677

---

**STATISTICAL TESTS**

POLY 3	P=0.453	P=0.099	P=0.624
POLY 1.5	P=0.485	P=0.098	P=0.640
POLY 6	P=0.408	P=0.098	P=0.600
COCH-ARM / FISHERS	P=0.528	P=0.090	P=0.657
MAX-ISO-POLY-3	P=0.254	P=0.055	P=0.426

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Thyroid Gland: Follicular Cell  
Hyperplasia Focal

---

**LESION RATES**

OVERALL (a)	0/46 (0%)	2/48 (4%)	1/42 (2%)
POLY-3 RATE (b)	0/37.67	2/40.80	1/31.43
POLY-3 PERCENT (g)	0%	4.9%	3.2%
TERMINAL (d)	0/26 (0%)	2/25 (8%)	0/17 (0%)
FIRST INCIDENCE	---	729 (T)	718

---

**STATISTICAL TESTS**

POLY 3	P=0.308	P=0.255	P=0.464
POLY 1.5	P=0.320	P=0.254	P=0.472
POLY 6	P=0.292	P=0.252	P=0.453
COCH-ARM / FISHERS	P=0.335	P=0.258	P=0.477
MAX-ISO-POLY-3	P=0.231	P=0.091	P=0.152

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<hr/>			
Tongue			
Hyperplasia			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/0 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/0.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---
<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)

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Adrenal Cortex  
Accessory Adrenal Cortical Nodule

---

**LESION RATES**

OVERALL (a)	7/47 (15%)	12/49 (24%)	13/46 (28%)
POLY-3 RATE (b)	7/42.33	12/43.32	13/33.91
POLY-3 PERCENT (g)	16.5%	27.7%	38.3%
TERMINAL (d)	7/35 (20%)	8/33 (24%)	8/19 (42%)
FIRST INCIDENCE	729 (T)	422	183

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**STATISTICAL TESTS**

POLY 3	P=0.023*	P=0.161	P=0.027*
POLY 1.5	P=0.035*	P=0.163	P=0.043*
POLY 6	P=0.016*	P=0.164	P=0.018*
COCH-ARM / FISHERS	P=0.078	P=0.178	P=0.094
MAX-ISO-POLY-3	P=0.029*	P=0.105	P=0.023*

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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>Adrenal Cortex Degeneration Fatty</b>			
<b>LESION RATES</b>			
OVERALL (a)	23/47 (49%)	18/49 (37%)	19/46 (41%)
POLY-3 RATE (b)	23/44.01	18/43.71	19/33.94
POLY-3 PERCENT (g)	52.3%	41.2%	56%
TERMINAL (d)	17/35 (49%)	13/33 (39%)	13/19 (68%)
FIRST INCIDENCE	545	452	494
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.506	P=0.202N	P=0.461
POLY 1.5	P=0.483N	P=0.189N	P=0.575N
POLY 6	P=0.407	P=0.217N	P=0.328
COCH-ARM / FISHERS	P=0.259N	P=0.158N	P=0.298N
MAX-ISO-POLY-3	P=0.327	P=0.149N	P=0.382

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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>Hematopoietic Cell Proliferation</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/47 (2%)	2/49 (4%)	4/46 (9%)
POLY-3 RATE (b)	1/42.53	2/42.84	4/32.99
POLY-3 PERCENT (g)	2.4%	4.7%	12.1%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	677	508	579
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.080	P=0.503	P=0.111
POLY 1.5	P=0.088	P=0.505	P=0.128
POLY 6	P=0.075	P=0.501	P=0.099
COCH-ARM / FISHERS	P=0.111	P=0.516	P=0.174
MAX-ISO-POLY-3	P=0.079	P=0.284	P=0.065

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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>Hyperplasia Focal</b>			
<b>LESION RATES</b>			
OVERALL (a)	22/47 (47%)	14/49 (29%)	9/46 (20%)
POLY-3 RATE (b)	22/42.33	14/41.55	9/32.04
POLY-3 PERCENT (g)	52%	33.7%	28.1%
TERMINAL (d)	22/35 (63%)	13/33 (39%)	6/19 (32%)
FIRST INCIDENCE	729 (T)	721	652
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.017N*	P=0.065N	P=0.030N*
POLY 1.5	P=0.010N**	P=0.062N	P=0.016N*
POLY 6	P=0.027N*	P=0.066N	P=0.050N*
COCH-ARM / FISHERS	P=0.003N**	P=0.051N	P=0.005N**
MAX-ISO-POLY-3	P=0.022N*	P=0.044N*	P=0.029N*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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>Adrenal Cortex</b>			
<b>Hypertrophy Focal</b>			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	7/47 (15%)	6/49 (12%)	2/46 (4%)
POLY-3 RATE (b)	7/42.33	6/41.67	2/31.39
POLY-3 PERCENT (g)	16.5%	14.4%	6.4%
TERMINAL (d)	7/35 (20%)	5/33 (15%)	2/19 (11%)
FIRST INCIDENCE	729 (T)	689	729 (T)
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.162N	P=0.512N	P=0.173N
POLY 1.5	P=0.124N	P=0.501N	P=0.137N
POLY 6	P=0.204N	P=0.520N	P=0.213N
COCH-ARM / FISHERS	P=0.069N	P=0.467N	P=0.084N
MAX-ISO-POLY-3	P=0.188N	P=0.393N	P=0.126N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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 Necrosis</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/47 (4%)	1/49 (2%)	6/46 (13%)
POLY-3 RATE (b)	2/42.88	1/42.11	6/34.98
POLY-3 PERCENT (g)	4.7%	2.4%	17.2%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	1/19 (5%)
FIRST INCIDENCE	652	540	257
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.048*	P=0.506N	P=0.076
POLY 1.5	P=0.052	P=0.500N	P=0.090
POLY 6	P=0.045*	P=0.512N	P=0.063
COCH-ARM / FISHERS	P=0.065	P=0.484N	P=0.127
MAX-ISO-POLY-3	P=0.024*	P=0.289N	P=0.048*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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 Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	7/48 (15%)	5/50 (10%)	3/48 (6%)
POLY-3 RATE (b)	7/44.27	5/41.70	3/31.94
POLY-3 PERCENT (g)	15.8%	12%	9.4%
TERMINAL (d)	4/35 (11%)	5/33 (15%)	1/19 (5%)
FIRST INCIDENCE	452	729 (T)	652
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.262N	P=0.421N	P=0.322N
POLY 1.5	P=0.209N	P=0.399N	P=0.261N
POLY 6	P=0.316N	P=0.443N	P=0.382N
COCH-ARM / FISHERS	P=0.120N	P=0.351N	P=0.158N
MAX-ISO-POLY-3	P=0.338N	P=0.313N	P=0.244N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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

---

Adrenal Medulla  
Infiltration Cellular Lymphocyte

---

**LESION RATES**

OVERALL (a)	0/48 (0%)	0/50 (0%)	0/48 (0%)
POLY-3 RATE (b)	0/42.65	0/41.70	0/31.54
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	---	---	---

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**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)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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>Bone Marrow Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	4/50 (8%)	6/50 (12%)	6/50 (12%)
POLY-3 RATE (b)	4/44.32	6/45.78	6/36.27
POLY-3 PERCENT (g)	9%	13.1%	16.5%
TERMINAL (d)	2/35 (6%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	547	422	494
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.209	P=0.390	P=0.251
POLY 1.5	P=0.233	P=0.377	P=0.281
POLY 6	P=0.196	P=0.405	P=0.231
COCH-ARM / FISHERS	P=0.314	P=0.370	P=0.370
MAX-ISO-POLY-3	P=0.259	P=0.273	P=0.178

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Bone Marrow Infiltration Cellular Histiocyte</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/43.55	1/42.36	2/34.29
POLY-3 PERCENT (g)	2.3%	2.4%	5.8%
TERMINAL (d)	1/35 (3%)	0/33 (0%)	1/19 (5%)
FIRST INCIDENCE	729 (T)	508	179
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.337	P=0.755	P=0.418
POLY 1.5	P=0.348	P=0.755	P=0.445
POLY 6	P=0.329	P=0.756	P=0.393
COCH-ARM / FISHERS	P=0.378	P=0.753N	P=0.500
MAX-ISO-POLY-3	P=0.315	P=0.491	P=0.239

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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>Bone Marrow</b>			
<b>Myelofibrosis</b>			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/43.55	1/41.86	0/33.30
POLY-3 PERCENT (g)	0%	2.4%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	---	688	---
<hr/>			
<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)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Bone: Femur  
Osteopetrosis

---

**LESION RATES**

OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/43.83	1/42.46	0/33.30
POLY-3 PERCENT (g)	2.3%	2.4%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	652	452	---

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**STATISTICAL TESTS**

POLY 3	P=0.432N	P=0.754	P=0.554N
POLY 1.5	P=0.398N	P=0.755	P=0.537N
POLY 6	P=0.464N	P=0.754	P=0.570N
COCH-ARM / FISHERS	P=0.331N	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.351N	P=0.490	P=0.224N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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>Brain Compression</b>			
<b>LESION RATES</b>			
OVERALL (a)	9/50 (18%)	10/50 (20%)	6/50 (12%)
POLY-3 RATE (b)	9/45.86	10/43.14	6/34.72
POLY-3 PERCENT (g)	19.6%	23.2%	17.3%
TERMINAL (d)	3/35 (9%)	5/33 (15%)	1/19 (5%)
FIRST INCIDENCE	499	508	513
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.503N	P=0.441	P=0.508N
POLY 1.5	P=0.419N	P=0.456	P=0.434N
POLY 6	P=0.553	P=0.429	P=0.576N
COCH-ARM / FISHERS	P=0.251N	P=0.500	P=0.288N
MAX-ISO-POLY-3	P=0.481N	P=0.345	P=0.406N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Brain Necrosis</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	0/43.55	0/41.70	3/34.10
POLY-3 PERCENT (g)	0%	0%	8.8%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	1/19 (5%)
FIRST INCIDENCE	---	---	431
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.034*	(e)	P=0.081
POLY 1.5	P=0.034*	(e)	P=0.091
POLY 6	P=0.035*	(e)	P=0.072
COCH-ARM / FISHERS	P=0.037*	(e)	P=0.121
MAX-ISO-POLY-3	P=0.018*	(e)	P=0.037*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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>Brain Pigmentation</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	3/50 (6%)	5/50 (10%)
POLY-3 RATE (b)	1/43.90	3/41.85	5/36.81
POLY-3 PERCENT (g)	2.3%	7.2%	13.6%
TERMINAL (d)	0/35 (0%)	2/33 (6%)	1/19 (5%)
FIRST INCIDENCE	631	689	183
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.046*	P=0.288	P=0.066
POLY 1.5	P=0.053	P=0.292	P=0.077
POLY 6	P=0.040*	P=0.287	P=0.056
COCH-ARM / FISHERS	P=0.070	P=0.309	P=0.102
MAX-ISO-POLY-3	P=0.050*	P=0.147	P=0.037*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Clitoral Gland Cyst</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/44.04	0/41.70	1/33.30
POLY-3 PERCENT (g)	4.5%	0%	3%
TERMINAL (d)	1/35 (3%)	0/33 (0%)	1/19 (5%)
FIRST INCIDENCE	579	---	729 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.412N	P=0.249N	P=0.595N
POLY 1.5	P=0.397N	P=0.247N	P=0.565N
POLY 6	P=0.424N	P=0.251N	P=0.623N
COCH-ARM / FISHERS	P=0.360N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.310N	P=0.088N	P=0.381N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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 Gland Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	9/50 (18%)	7/50 (14%)	11/50 (22%)
POLY-3 RATE (b)	9/44.10	7/41.96	11/35.98
POLY-3 PERCENT (g)	20.4%	16.7%	30.6%
TERMINAL (d)	7/35 (20%)	6/33 (18%)	4/19 (21%)
FIRST INCIDENCE	631	660	494
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.212	P=0.434N	P=0.217
POLY 1.5	P=0.245	P=0.425N	P=0.264
POLY 6	P=0.189	P=0.438N	P=0.185
COCH-ARM / FISHERS	P=0.348	P=0.393N	P=0.402
MAX-ISO-POLY-3	P=0.170	P=0.332N	P=0.171

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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>Esophagus</b>			
<b>Inflammation Acute</b>			
<hr/>			
<b>LESION 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	---	---	---
<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)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Eye Cataract			
<b>LESION RATES</b>			
OVERALL (a)	0/44 (0%)	5/47 (11%)	3/41 (7%)
POLY-3 RATE (b)	0/40.71	5/40.66	3/28.47
POLY-3 PERCENT (g)	0%	12.3%	10.5%
TERMINAL (d)	0/35 (0%)	3/33 (9%)	3/19 (16%)
FIRST INCIDENCE	---	689	729 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.048*	P=0.030*	P=0.066
POLY 1.5	P=0.064	P=0.031*	P=0.077
POLY 6	P=0.036*	P=0.029*	P=0.057
COCH-ARM / FISHERS	P=0.111	P=0.033*	P=0.108
MAX-ISO-POLY-3	P=0.064	P=0.010**	P=0.033*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Eye Edema			
<b>LESION RATES</b>			
OVERALL (a)	0/44 (0%)	2/47 (4%)	2/41 (5%)
POLY-3 RATE (b)	0/40.71	2/40.63	2/28.47
POLY-3 PERCENT (g)	0%	4.9%	7%
TERMINAL (d)	0/35 (0%)	1/33 (3%)	2/19 (11%)
FIRST INCIDENCE	---	688	729 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.111	P=0.236	P=0.166
POLY 1.5	P=0.124	P=0.240	P=0.183
POLY 6	P=0.100	P=0.234	P=0.152
COCH-ARM / FISHERS	P=0.157	P=0.264	P=0.230
MAX-ISO-POLY-3	P=0.134	P=0.079	P=0.070

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Eye</b>			
<b>Inflammation Chronic</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/44 (2%)	1/47 (2%)	0/41 (0%)
POLY-3 RATE (b)	1/40.97	1/40.47	0/28.47
POLY-3 PERCENT (g)	2.4%	2.5%	0%
TERMINAL (d)	0/35 (0%)	1/33 (3%)	0/19 (0%)
FIRST INCIDENCE	659	729 (T)	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.448N	P=0.758	P=0.571N
POLY 1.5	P=0.412N	P=0.758N	P=0.552N
POLY 6	P=0.484N	P=0.753	P=0.588N
COCH-ARM / FISHERS	P=0.343N	P=0.736N	P=0.518N
MAX-ISO-POLY-3	P=0.369N	P=0.496	P=0.240N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Eye: Bilateral  
Cataract

---

**LESION RATES**

OVERALL (a)	0/44 (0%)	0/47 (0%)	1/41 (2%)
POLY-3 RATE (b)	0/40.71	0/40.47	1/28.47
POLY-3 PERCENT (g)	0%	0%	3.5%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	1/19 (5%)
FIRST INCIDENCE	---	---	729 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.279	(e)	P=0.430
POLY 1.5	P=0.269	(e)	P=0.448
POLY 6	P=0.292	(e)	P=0.413
COCH-ARM / FISHERS	P=0.257	(e)	P=0.482
MAX-ISO-POLY-3	P=0.139	(e)	P=0.153

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Eye: Retina  
Degeneration

---

**LESION RATES**

OVERALL (a)	0/44 (0%)	1/47 (2%)	2/41 (5%)
POLY-3 RATE (b)	0/40.71	1/40.47	2/28.47
POLY-3 PERCENT (g)	0%	2.5%	7%
TERMINAL (d)	0/35 (0%)	1/33 (3%)	2/19 (11%)
FIRST INCIDENCE	---	729 (T)	729 (T)

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**STATISTICAL TESTS**

POLY 3	P=0.105	P=0.499	P=0.166
POLY 1.5	P=0.111	P=0.503	P=0.183
POLY 6	P=0.101	P=0.496	P=0.152
COCH-ARM / FISHERS	P=0.127	P=0.516	P=0.230
MAX-ISO-POLY-3	P=0.093	P=0.163	P=0.070

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Harderian Gland  
Hemorrhage

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	4/49 (8%)
POLY-3 RATE (b)	0/43.55	0/41.70	4/32.30
POLY-3 PERCENT (g)	0%	0%	12.4%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	4/18 (22%)
FIRST INCIDENCE	---	---	729 (T)

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**STATISTICAL TESTS**

POLY 3	P=0.012*	(e)	P=0.031*
POLY 1.5	P=0.012*	(e)	P=0.038*
POLY 6	P=0.012*	(e)	P=0.025*
COCH-ARM / FISHERS	P=0.014*	(e)	P=0.056
MAX-ISO-POLY-3	P=0.006**	(e)	P=0.017*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Harderian Gland Inflammation Chronic</b>			
<b>LESION RATES</b>			
OVERALL (a)	9/50 (18%)	11/50 (22%)	9/49 (18%)
POLY-3 RATE (b)	9/43.80	11/42.63	9/35.55
POLY-3 PERCENT (g)	20.6%	25.8%	25.3%
TERMINAL (d)	8/35 (23%)	8/33 (24%)	4/18 (22%)
FIRST INCIDENCE	662	568	390
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.348	P=0.373	P=0.408
POLY 1.5	P=0.396	P=0.375	P=0.458
POLY 6	P=0.313	P=0.382	P=0.367
COCH-ARM / FISHERS	P=0.531	P=0.402	P=0.584
MAX-ISO-POLY-3	P=0.441	P=0.284	P=0.323

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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

---

Heart  
Cardiomyopathy

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**LESION RATES**

OVERALL (a)	40/50 (80%)	30/50 (60%)	30/50 (60%)
POLY-3 RATE (b)	40/48.59	30/42.99	30/41.43
POLY-3 PERCENT (g)	82.3%	69.8%	72.4%
TERMINAL (d)	29/35 (83%)	27/33 (82%)	11/19 (58%)
FIRST INCIDENCE	452	540	257

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**STATISTICAL TESTS**

POLY 3	P=0.136N	P=0.109N	P=0.182N
POLY 1.5	P=0.085N	P=0.066N	P=0.113N
POLY 6	P=0.170N	P=0.172N	P=0.224N
COCH-ARM / FISHERS	P=0.022N*	P=0.024N*	P=0.024N*
MAX-ISO-POLY-3	P=0.156N	P=0.079N	P=0.138N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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/>			
Heart Thrombosis			
<hr/>			
<b>LESION 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	---	---	---
<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)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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

---

Intestine Large, Colon  
Edema

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**LESION RATES**

OVERALL (a)	0/41 (0%)	0/43 (0%)	0/33 (0%)
POLY-3 RATE (b)	0/38.75	0/38.98	0/26.73
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	---	---	---

---

**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)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
alpha/beta Thujone mixture  
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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 NON-NEOPLASTIC LESIONS 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 Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/49 (2%)	0/49 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/43.12	0/41.14	1/33.30
POLY-3 PERCENT (g)	2.3%	0%	3%
TERMINAL (d)	1/35 (3%)	0/33 (0%)	1/19 (5%)
FIRST INCIDENCE	729 (T)	---	729 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.673	P=0.509N	P=0.699
POLY 1.5	P=0.670	P=0.508N	P=0.722
POLY 6	P=0.679	P=0.510N	P=0.678
COCH-ARM / FISHERS	P=0.664N	P=0.500N	P=0.747N
MAX-ISO-POLY-3	P=0.417	P=0.170N	P=0.434

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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>Kidney</b>			
<b>Casts Protein</b>			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	14/44 (32%)	8/45 (18%)	12/40 (30%)
POLY-3 RATE (b)	14/41.28	8/39.57	12/28.54
POLY-3 PERCENT (g)	33.9%	20.2%	42%
TERMINAL (d)	11/35 (31%)	5/33 (15%)	7/19 (37%)
FIRST INCIDENCE	579	689	431
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.426	P=0.127N	P=0.333
POLY 1.5	P=0.483	P=0.119N	P=0.425
POLY 6	P=0.391	P=0.133N	P=0.277
COCH-ARM / FISHERS	P=0.456N	P=0.098N	P=0.523N
MAX-ISO-POLY-3	P=0.180	P=0.088N	P=0.277

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Kidney Cyst</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/44 (2%)	1/45 (2%)	0/40 (0%)
POLY-3 RATE (b)	1/40.81	1/39.23	0/26.10
POLY-3 PERCENT (g)	2.5%	2.6%	0%
TERMINAL (d)	0/35 (0%)	1/33 (3%)	0/19 (0%)
FIRST INCIDENCE	566	729 (T)	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.477N	P=0.752	P=0.586N
POLY 1.5	P=0.437N	P=0.755	P=0.566N
POLY 6	P=0.510N	P=0.750	P=0.601N
COCH-ARM / FISHERS	P=0.349N	P=0.747N	P=0.524N
MAX-ISO-POLY-3	P=0.388N	P=0.488	P=0.257N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
alpha/beta Thujone mixture  
CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010  
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Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Kidney Infarct</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/44 (5%)	1/45 (2%)	1/40 (3%)
POLY-3 RATE (b)	2/40.48	1/39.23	1/26.10
POLY-3 PERCENT (g)	4.9%	2.6%	3.8%
TERMINAL (d)	1/35 (3%)	1/33 (3%)	1/19 (5%)
FIRST INCIDENCE	677	729 (T)	729 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.512N	P=0.511N	P=0.646N
POLY 1.5	P=0.481N	P=0.507N	P=0.612N
POLY 6	P=0.534N	P=0.514N	P=0.671N
COCH-ARM / FISHERS	P=0.406N	P=0.491N	P=0.536N
MAX-ISO-POLY-3	P=0.516N	P=0.293N	P=0.429N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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>Kidney Inflammation</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/44 (2%)	0/45 (0%)	0/40 (0%)
POLY-3 RATE (b)	1/40.48	0/39.23	0/26.10
POLY-3 PERCENT (g)	2.5%	0%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	677	---	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.340N	P=0.506N	P=0.584N
POLY 1.5	P=0.321N	P=0.504N	P=0.565N
POLY 6	P=0.356N	P=0.508N	P=0.600N
COCH-ARM / FISHERS	P=0.280N	P=0.494N	P=0.524N
MAX-ISO-POLY-3	P=0.288N	P=0.168N	P=0.255N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
alpha/beta Thujone mixture  
CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010  
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Kidney</b>			
<b>Inflammation Chronic</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/44 (0%)	1/45 (2%)	3/40 (8%)
POLY-3 RATE (b)	0/40.28	1/39.23	3/27.76
POLY-3 PERCENT (g)	0%	2.6%	10.8%
TERMINAL (d)	0/35 (0%)	1/33 (3%)	1/19 (5%)
FIRST INCIDENCE	---	729 (T)	183
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.038*	P=0.495	P=0.064
POLY 1.5	P=0.040*	P=0.497	P=0.074
POLY 6	P=0.037*	P=0.494	P=0.058
COCH-ARM / FISHERS	P=0.049*	P=0.506	P=0.104
MAX-ISO-POLY-3	P=0.032*	P=0.160	P=0.032*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
alpha/beta Thujone mixture  
CAS Number: THUJONEMIXAB

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

**Kidney  
Mineralization**

---

**LESION RATES**

OVERALL (a)	16/44 (36%)	24/45 (53%)	17/40 (43%)
POLY-3 RATE (b)	16/41.69	24/42.28	17/31.18
POLY-3 PERCENT (g)	38.4%	56.8%	54.5%
TERMINAL (d)	13/35 (37%)	17/33 (52%)	8/19 (42%)
FIRST INCIDENCE	452	452	179

---

**STATISTICAL TESTS**

POLY 3	P=0.081	P=0.068	P=0.128
POLY 1.5	P=0.119	P=0.066	P=0.177
POLY 6	P=0.068	P=0.075	P=0.110
COCH-ARM / FISHERS	P=0.309	P=0.081	P=0.363
MAX-ISO-POLY-3	P=0.110	P=0.043*	P=0.108

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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>Kidney</b>			
<b>Nephropathy</b>			
<b>LESION RATES</b>			
OVERALL (a)	33/44 (75%)	36/45 (80%)	26/40 (65%)
POLY-3 RATE (b)	33/43.06	36/42.00	26/30.74
POLY-3 PERCENT (g)	76.6%	85.7%	84.6%
TERMINAL (d)	26/35 (74%)	28/33 (85%)	18/19 (95%)
FIRST INCIDENCE	452	452	338
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.195	P=0.209	P=0.287
POLY 1.5	P=0.398	P=0.243	P=0.503
POLY 6	P=0.097	P=0.189	P=0.159
COCH-ARM / FISHERS	P=0.189N	P=0.378	P=0.223N
MAX-ISO-POLY-3	P=0.272	P=0.141	P=0.223

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
alpha/beta Thujone mixture  
CAS Number: THUJONEMIXAB

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Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

**Kidney: Renal Tubule  
Accumulation, Hyaline Droplet**

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**LESION RATES**

OVERALL (a)	2/44 (5%)	5/45 (11%)	4/40 (10%)
POLY-3 RATE (b)	2/40.63	5/39.39	4/26.55
POLY-3 PERCENT (g)	4.9%	12.7%	15.1%
TERMINAL (d)	1/35 (3%)	4/33 (12%)	2/19 (11%)
FIRST INCIDENCE	631	689	617

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**STATISTICAL TESTS**

POLY 3	P=0.119	P=0.202	P=0.169
POLY 1.5	P=0.147	P=0.207	P=0.202
POLY 6	P=0.102	P=0.200	P=0.148
COCH-ARM / FISHERS	P=0.236	P=0.226	P=0.293
MAX-ISO-POLY-3	P=0.164	P=0.114	P=0.118

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS 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

---

Kidney: Transitional Epithelium  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	2/44 (5%)	1/45 (2%)	0/40 (0%)
POLY-3 RATE (b)	2/40.48	1/39.23	0/26.10
POLY-3 PERCENT (g)	4.9%	2.6%	0%
TERMINAL (d)	1/35 (3%)	1/33 (3%)	0/19 (0%)
FIRST INCIDENCE	677	729 (T)	---

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**STATISTICAL TESTS**

POLY 3	P=0.236N	P=0.511N	P=0.344N
POLY 1.5	P=0.209N	P=0.507N	P=0.316N
POLY 6	P=0.259N	P=0.514N	P=0.367N
COCH-ARM / FISHERS	P=0.154N	P=0.491N	P=0.271N
MAX-ISO-POLY-3	P=0.237N	P=0.293N	P=0.173N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 alpha/beta Thujone mixture  
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010  
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Liver</b>			
<b>Basophilic Focus</b>			
<b>LESION RATES</b>			
OVERALL (a)	46/50 (92%)	46/50 (92%)	40/49 (82%)
POLY-3 RATE (b)	46/48.93	46/47.61	40/43.72
POLY-3 PERCENT (g)	94%	96.6%	91.5%
TERMINAL (d)	34/35 (97%)	32/33 (97%)	18/19 (95%)
FIRST INCIDENCE	452	412	179
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.401N	P=0.443	P=0.472N
POLY 1.5	P=0.280N	P=0.468	P=0.350N
POLY 6	P=0.457N	P=0.480	P=0.535N
COCH-ARM / FISHERS	P=0.072N	P=0.643N	P=0.109N
MAX-ISO-POLY-3	P=0.286N	P=0.251	P=0.311N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Liver</b>			
<b>Clear Cell Focus</b>			
<b>LESION RATES</b>			
OVERALL (a)	17/50 (34%)	21/50 (42%)	11/49 (22%)
POLY-3 RATE (b)	17/44.00	21/42.47	11/33.60
POLY-3 PERCENT (g)	38.6%	49.4%	32.7%
TERMINAL (d)	15/35 (43%)	19/33 (58%)	9/19 (47%)
FIRST INCIDENCE	662	568	579
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.438N	P=0.209	P=0.383N
POLY 1.5	P=0.324N	P=0.220	P=0.295N
POLY 6	P=0.544N	P=0.206	P=0.471N
COCH-ARM / FISHERS	P=0.134N	P=0.268	P=0.146N
MAX-ISO-POLY-3	P=0.262N	P=0.155	P=0.316N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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/>			
Liver Degeneration Cystic			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/43.55	0/41.70	0/32.98
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	---	---	---
<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)

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Liver</b>			
<b>Eosinophilic Focus</b>			
<b>LESION RATES</b>			
OVERALL (a)	8/50 (16%)	2/50 (4%)	2/49 (4%)
POLY-3 RATE (b)	8/44.25	2/41.70	2/32.98
POLY-3 PERCENT (g)	18.1%	4.8%	6.1%
TERMINAL (d)	5/35 (14%)	2/33 (6%)	2/19 (11%)
FIRST INCIDENCE	631	729 (T)	729 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.042N*	P=0.055N	P=0.115N
POLY 1.5	P=0.034N*	P=0.052N	P=0.089N
POLY 6	P=0.050N*	P=0.057N	P=0.146N
COCH-ARM / FISHERS	P=0.023N*	P=0.046N*	P=0.049N*
MAX-ISO-POLY-3	P=0.055N	P=0.029N*	P=0.087N



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Liver  
Hematopoietic Cell Proliferation

---

**LESION RATES**

OVERALL (a)	1/50 (2%)	1/50 (2%)	4/49 (8%)
POLY-3 RATE (b)	1/43.74	1/42.36	4/35.15
POLY-3 PERCENT (g)	2.3%	2.4%	11.4%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	677	508	485

---

**STATISTICAL TESTS**

POLY 3	P=0.079	P=0.754	P=0.119
POLY 1.5	P=0.083	P=0.754	P=0.133
POLY 6	P=0.076	P=0.754	P=0.110
COCH-ARM / FISHERS	P=0.097	P=0.753N	P=0.175
MAX-ISO-POLY-3	P=0.064	P=0.490	P=0.067

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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/>			
Liver			
Hepatodiaphragmatic Nodule			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	5/50 (10%)	8/50 (16%)	6/49 (12%)
POLY-3 RATE (b)	5/44.87	8/42.29	6/35.57
POLY-3 PERCENT (g)	11.1%	18.9%	16.9%
TERMINAL (d)	3/35 (9%)	6/33 (18%)	1/19 (5%)
FIRST INCIDENCE	462	603	275
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.266	P=0.237	P=0.341
POLY 1.5	P=0.311	P=0.246	P=0.384
POLY 6	P=0.231	P=0.234	P=0.304
COCH-ARM / FISHERS	P=0.425	P=0.277	P=0.486
MAX-ISO-POLY-3	P=0.316	P=0.162	P=0.254

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Liver  
Infiltration Cellular Mixed Cell

---

LESION RATES			
OVERALL (a)	30/50 (60%)	30/50 (60%)	32/49 (65%)
POLY-3 RATE (b)	30/45.89	30/44.43	32/42.84
POLY-3 PERCENT (g)	65.4%	67.5%	74.7%
TERMINAL (d)	24/35 (69%)	23/33 (70%)	17/19 (90%)
FIRST INCIDENCE	452	508	179

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STATISTICAL TESTS			
POLY 3	P=0.195	P=0.503	P=0.223
POLY 1.5	P=0.231	P=0.511	P=0.263
POLY 6	P=0.164	P=0.516	P=0.186
COCH-ARM / FISHERS	P=0.331	P=0.581N	P=0.368
MAX-ISO-POLY-3	P=0.233	P=0.411	P=0.164

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Liver  
Mixed Cell Focus

---

LESION RATES			
OVERALL (a)	10/50 (20%)	4/50 (8%)	4/49 (8%)
POLY-3 RATE (b)	10/44.04	4/42.26	4/34.24
POLY-3 PERCENT (g)	22.7%	9.5%	11.7%
TERMINAL (d)	9/35 (26%)	2/33 (6%)	1/19 (5%)
FIRST INCIDENCE	579	568	500

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STATISTICAL TESTS			
POLY 3	P=0.090N	P=0.082N	P=0.169N
POLY 1.5	P=0.076N	P=0.081N	P=0.137N
POLY 6	P=0.101N	P=0.081N	P=0.198N
COCH-ARM / FISHERS	P=0.049N*	P=0.074N	P=0.080N
MAX-ISO-POLY-3	P=0.123N	P=0.049N*	P=0.130N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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/>			
Liver			
Necrosis Focal			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	1/50 (2%)	5/49 (10%)
POLY-3 RATE (b)	1/44.04	1/41.70	5/35.65
POLY-3 PERCENT (g)	2.3%	2.4%	14%
TERMINAL (d)	0/35 (0%)	1/33 (3%)	1/19 (5%)
FIRST INCIDENCE	579	729 (T)	257
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.034*	P=0.749	P=0.060
POLY 1.5	P=0.037*	P=0.751	P=0.070
POLY 6	P=0.032*	P=0.747	P=0.053
COCH-ARM / FISHERS	P=0.046*	P=0.753N	P=0.098
MAX-ISO-POLY-3	P=0.027*	P=0.484	P=0.035*

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Liver: Bile Duct  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	4/50 (8%)	2/50 (4%)	7/49 (14%)
POLY-3 RATE (b)	4/44.13	2/41.70	7/33.42
POLY-3 PERCENT (g)	9.1%	4.8%	20.9%
TERMINAL (d)	3/35 (9%)	2/33 (6%)	4/19 (21%)
FIRST INCIDENCE	545	729 (T)	652

---

**STATISTICAL TESTS**

POLY 3	P=0.121	P=0.363N	P=0.126
POLY 1.5	P=0.135	P=0.357N	P=0.159
POLY 6	P=0.112	P=0.367N	P=0.102
COCH-ARM / FISHERS	P=0.178	P=0.339N	P=0.251
MAX-ISO-POLY-3	P=0.058	P=0.227N	P=0.095

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Liver: Centrilobular  
Necrosis

---

LESION RATES			
OVERALL (a)	0/50 (0%)	0/50 (0%)	3/49 (6%)
POLY-3 RATE (b)	0/43.55	0/41.70	3/34.04
POLY-3 PERCENT (g)	0%	0%	8.8%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	---	---	449

---

STATISTICAL TESTS			
POLY 3	P=0.033*	(e)	P=0.080
POLY 1.5	P=0.033*	(e)	P=0.090
POLY 6	P=0.033*	(e)	P=0.073
COCH-ARM / FISHERS	P=0.036*	(e)	P=0.117
MAX-ISO-POLY-3	P=0.018*	(e)	P=0.036*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Liver: Hepatocyte  
Vacuolization Cytoplasmic

---

**LESION RATES**

OVERALL (a)	5/50 (10%)	4/50 (8%)	3/49 (6%)
POLY-3 RATE (b)	5/45.11	4/43.70	3/33.72
POLY-3 PERCENT (g)	11.1%	9.2%	8.9%
TERMINAL (d)	1/35 (3%)	0/33 (0%)	1/19 (5%)
FIRST INCIDENCE	545	422	494

---

**STATISTICAL TESTS**

POLY 3	P=0.449N	P=0.520N	P=0.523N
POLY 1.5	P=0.402N	P=0.517N	P=0.472N
POLY 6	P=0.492N	P=0.521N	P=0.571N
COCH-ARM / FISHERS	P=0.300N	P=0.500N	P=0.369N
MAX-ISO-POLY-3	P=0.535N	P=0.383N	P=0.390N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Liver: Hepatocyte  
Vacuolization Cytoplasmic Focal

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/43.55	0/41.70	0/32.98
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	---	---	---

---

**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)

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Liver: Kupffer Cell  
Pigmentation

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	1/49 (2%)
POLY-3 RATE (b)	0/43.55	1/42.29	1/33.03
POLY-3 PERCENT (g)	0%	2.4%	3%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	---	540	716

---

**STATISTICAL TESTS**

POLY 3	P=0.289	P=0.494	P=0.446
POLY 1.5	P=0.299	P=0.495	P=0.461
POLY 6	P=0.281	P=0.495	P=0.432
COCH-ARM / FISHERS	P=0.327	P=0.500	P=0.495
MAX-ISO-POLY-3	P=0.266	P=0.158	P=0.157

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS 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>Infiltration Cellular Histiocyte</b>			
<b>LESION RATES</b>			
OVERALL (a)	46/50 (92%)	43/50 (86%)	36/50 (72%)
POLY-3 RATE (b)	46/47.81	43/46.64	36/41.90
POLY-3 PERCENT (g)	96.2%	92.2%	85.9%
TERMINAL (d)	35/35 (100%)	31/33 (94%)	17/19 (90%)
FIRST INCIDENCE	452	412	275
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.036N*	P=0.318N	P=0.051N
POLY 1.5	P=0.021N*	P=0.328N	P=0.031N*
POLY 6	P=0.049N*	P=0.292N	P=0.070N
COCH-ARM / FISHERS	P=0.005N**	P=0.262N	P=0.009N**
MAX-ISO-POLY-3	P=0.035N*	P=0.162N	P=0.025N*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Lung  
Inflammation Chronic

---

LESION RATES			
OVERALL (a)	10/50 (20%)	3/50 (6%)	5/50 (10%)
POLY-3 RATE (b)	10/44.43	3/41.70	5/33.36
POLY-3 PERCENT (g)	22.5%	7.2%	15%
TERMINAL (d)	7/35 (20%)	3/33 (9%)	4/19 (21%)
FIRST INCIDENCE	631	729 (T)	714

---

STATISTICAL TESTS			
POLY 3	P=0.152N	P=0.044N*	P=0.297N
POLY 1.5	P=0.127N	P=0.041N*	P=0.232N
POLY 6	P=0.178N	P=0.046N*	P=0.369N
COCH-ARM / FISHERS	P=0.083N	P=0.036N*	P=0.131N
MAX-ISO-POLY-3	P=0.144N	P=0.025N*	P=0.235N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS 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>Metaplasia Osseous</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/43.55	1/41.70	2/33.77
POLY-3 PERCENT (g)	0%	2.4%	5.9%
TERMINAL (d)	0/35 (0%)	1/33 (3%)	0/19 (0%)
FIRST INCIDENCE	---	729 (T)	652
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.118	P=0.491	P=0.186
POLY 1.5	P=0.124	P=0.493	P=0.200
POLY 6	P=0.114	P=0.491	P=0.174
COCH-ARM / FISHERS	P=0.142	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.103	P=0.158	P=0.075

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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>Lung: Alveolar Epithelium Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	23/50 (46%)	25/50 (50%)	17/50 (34%)
POLY-3 RATE (b)	23/43.70	25/43.49	17/37.05
POLY-3 PERCENT (g)	52.6%	57.5%	45.9%
TERMINAL (d)	22/35 (63%)	21/33 (64%)	9/19 (47%)
FIRST INCIDENCE	689	412	488
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.344N	P=0.402	P=0.348N
POLY 1.5	P=0.285N	P=0.393	P=0.292N
POLY 6	P=0.368N	P=0.430	P=0.373N
COCH-ARM / FISHERS	P=0.134N	P=0.421	P=0.154N
MAX-ISO-POLY-3	P=0.307N	P=0.320	P=0.284N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Lymph Node, Mandibular Hyperplasia Lymphoid</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/1 (100%)	4/4 (100%)	0/1 (0%)
POLY-3 RATE (b)	1/1.00	4/4.00	0/0.58
POLY-3 PERCENT (g)	100%	100%	0%
TERMINAL (d)	1/1 (100%)	4/4 (100%)	0/0 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.171N	(e)	(e)
POLY 1.5	P=0.171N	(e)	(e)
POLY 6	P=0.171N	(e)	(e)
COCH-ARM / FISHERS	P=0.171N	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Lymph Node, Mesenteric Hemorrhage</b>			
<b>LESION RATES</b>			
OVERALL (a)	8/50 (16%)	9/50 (18%)	6/47 (13%)
POLY-3 RATE (b)	8/44.71	9/42.23	6/32.13
POLY-3 PERCENT (g)	17.9%	21.3%	18.7%
TERMINAL (d)	5/35 (14%)	8/33 (24%)	3/18 (17%)
FIRST INCIDENCE	566	568	494
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.502	P=0.448	P=0.582
POLY 1.5	P=0.554N	P=0.461	P=0.583N
POLY 6	P=0.445	P=0.437	P=0.525
COCH-ARM / FISHERS	P=0.387N	P=0.500	P=0.436N
MAX-ISO-POLY-3	P=0.565	P=0.347	P=0.469



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Lymph Node, Mesenteric Hyperplasia Lymphoid</b>			
<b>LESION RATES</b>			
OVERALL (a)	4/50 (8%)	5/50 (10%)	4/47 (9%)
POLY-3 RATE (b)	4/44.65	5/41.98	4/31.48
POLY-3 PERCENT (g)	9%	11.9%	12.7%
TERMINAL (d)	1/35 (3%)	3/33 (9%)	2/18 (11%)
FIRST INCIDENCE	566	663	513
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.370	P=0.461	P=0.444
POLY 1.5	P=0.419	P=0.471	P=0.497
POLY 6	P=0.330	P=0.454	P=0.396
COCH-ARM / FISHERS	P=0.533	P=0.500	P=0.607
MAX-ISO-POLY-3	P=0.459	P=0.332	P=0.327

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Lymph Node, Mesenteric  
Necrosis

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/47 (2%)
POLY-3 RATE (b)	0/43.55	0/41.70	1/31.50
POLY-3 PERCENT (g)	0%	0%	3.2%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/18 (0%)
FIRST INCIDENCE	---	---	257

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**STATISTICAL TESTS**

POLY 3	P=0.280	(e)	P=0.436
POLY 1.5	P=0.271	(e)	P=0.453
POLY 6	P=0.292	(e)	P=0.421
COCH-ARM / FISHERS	P=0.260	(e)	P=0.485
MAX-ISO-POLY-3	P=0.144	(e)	P=0.154

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Lymph Node: Mediastinal Hemorrhage</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/7 (0%)	2/8 (25%)	2/6 (33%)
POLY-3 RATE (b)	0/5.93	2/5.50	2/5.10
POLY-3 PERCENT (g)	0%	36.4%	39.2%
TERMINAL (d)	0/4 (0%)	0/2 (0%)	0/1 (0%)
FIRST INCIDENCE	---	508	494
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.102	P=0.192	P=0.170
POLY 1.5	P=0.109	P=0.215	P=0.174
POLY 6	P=0.093	P=0.173	P=0.163
COCH-ARM / FISHERS	P=0.116	P=0.267	P=0.192
MAX-ISO-POLY-3	P=0.080	P=0.058	P=0.042*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Lymph Node: Mediastinal Hyperplasia Lymphoid</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/7 (0%)	6/8 (75%)	3/6 (50%)
POLY-3 RATE (b)	0/5.93	6/7.34	3/5.60
POLY-3 PERCENT (g)	0%	81.8%	53.6%
TERMINAL (d)	0/4 (0%)	1/2 (50%)	0/1 (0%)
FIRST INCIDENCE	---	422	494
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.030*	P<0.001**	P=0.053
POLY 1.5	P=0.026*	P<0.001**	P=0.050*
POLY 6	P=0.039*	P<0.001**	P=0.057
COCH-ARM / FISHERS	P=0.050*	P=0.006**	P=0.070
MAX-ISO-POLY-3	P=0.002**	P<0.001**	P=0.009**

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Lymph Node: Mediastinal Pigmentation</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/7 (0%)	5/8 (63%)	1/6 (17%)
POLY-3 RATE (b)	0/5.93	5/6.60	1/4.51
POLY-3 PERCENT (g)	0%	75.8%	22.2%
TERMINAL (d)	0/4 (0%)	1/2 (50%)	0/1 (0%)
FIRST INCIDENCE	---	508	579
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.178	P<0.001**	P=0.444
POLY 1.5	P=0.223	P=0.002**	P=0.455
POLY 6	P=0.126	P<0.001**	P=0.428
COCH-ARM / FISHERS	P=0.314	P=0.019*	P=0.462
MAX-ISO-POLY-3	P=0.025*	P<0.001**	P=0.141

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Lymph Node: Pancreatic Hemorrhage</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/7 (0%)	1/8 (13%)	2/6 (33%)
POLY-3 RATE (b)	0/5.93	1/4.68	2/4.82
POLY-3 PERCENT (g)	0%	21.4%	41.5%
TERMINAL (d)	0/4 (0%)	1/2 (50%)	0/1 (0%)
FIRST INCIDENCE	---	729 (T)	494
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.074	P=0.452	P=0.155
POLY 1.5	P=0.084	P=0.484	P=0.166
POLY 6	P=0.059	P=0.414	P=0.138
COCH-ARM / FISHERS	P=0.096	P=0.533	P=0.192
MAX-ISO-POLY-3	P=0.051	P=0.158	P=0.040*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS 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 Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	19/50 (38%)	21/50 (42%)	10/50 (20%)
POLY-3 RATE (b)	19/45.82	21/44.65	10/35.11
POLY-3 PERCENT (g)	41.5%	47%	28.5%
TERMINAL (d)	13/35 (37%)	13/33 (39%)	5/19 (26%)
FIRST INCIDENCE	499	452	500
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.204N	P=0.373	P=0.165N
POLY 1.5	P=0.127N	P=0.378	P=0.108N
POLY 6	P=0.290N	P=0.378	P=0.233N
COCH-ARM / FISHERS	P=0.036N*	P=0.419	P=0.038N*
MAX-ISO-POLY-3	P=0.143N	P=0.298	P=0.141N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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>Mammary Gland Hyperplasia Focal</b>			
<b>LESION RATES</b>			
OVERALL (a)	3/50 (6%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	3/43.55	1/41.96	0/33.30
POLY-3 PERCENT (g)	6.9%	2.4%	0%
TERMINAL (d)	3/35 (9%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	729 (T)	660	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.093N	P=0.318N	P=0.174N
POLY 1.5	P=0.081N	P=0.317N	P=0.155N
POLY 6	P=0.104N	P=0.316N	P=0.194N
COCH-ARM / FISHERS	P=0.060N	P=0.309N	P=0.121N
MAX-ISO-POLY-3	P=0.103N	P=0.168N	P=0.088N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

**Mammary Gland: Duct  
Ectasia**

---

**LESION RATES**

OVERALL (a)	47/50 (94%)	45/50 (90%)	39/50 (78%)
POLY-3 RATE (b)	47/49.04	45/46.79	39/41.17
POLY-3 PERCENT (g)	95.8%	96.2%	94.7%
TERMINAL (d)	34/35 (97%)	32/33 (97%)	19/19 (100%)
FIRST INCIDENCE	462	452	485

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**STATISTICAL TESTS**

POLY 3	P=0.522N	P=0.688	P=0.617N
POLY 1.5	P=0.202N	P=0.644N	P=0.267N
POLY 6	P=0.545	P=0.653	P=0.671
COCH-ARM / FISHERS	P=0.012N*	P=0.357N	P=0.020N*
MAX-ISO-POLY-3	P=0.510N	P=0.462	P=0.388N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 alpha/beta Thujone mixture  
 CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010  
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Mesentery</b>			
<b>Accessory Spleen</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/13 (0%)	1/11 (9%)	2/9 (22%)
POLY-3 RATE (b)	0/11.42	1/10.18	2/5.78
POLY-3 PERCENT (g)	0%	9.8%	34.6%
TERMINAL (d)	0/8 (0%)	0/8 (0%)	1/4 (25%)
FIRST INCIDENCE	---	689	179
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.067	P=0.477	P=0.091
POLY 1.5	P=0.068	P=0.471	P=0.103
POLY 6	P=0.070	P=0.489	P=0.088
COCH-ARM / FISHERS	P=0.081	P=0.458	P=0.156
MAX-ISO-POLY-3	P=0.059	P=0.146	P=0.038*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Mesentery: Fat  
Necrosis

---

**LESION RATES**

OVERALL (a)	13/13 (100%)	10/11 (91%)	8/9 (89%)
POLY-3 RATE (b)	13/13.00	10/10.84	8/8.02
POLY-3 PERCENT (g)	100%	92.2%	99.8%
TERMINAL (d)	8/8 (100%)	8/8 (100%)	4/4 (100%)
FIRST INCIDENCE	579	508	183

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**STATISTICAL TESTS**

POLY 3	P=0.693N	P=0.538N	P=1.000N
POLY 1.5	P=0.612N	P=0.501N	P=1.000N
POLY 6	P=0.747N	P=0.620N	P=1.000N
COCH-ARM / FISHERS	P=0.251N	P=0.458N	P=0.409N
MAX-ISO-POLY-3	P=0.389N	P=0.148N	P=0.143N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Nose  
Foreign Body

---

**LESION RATES**

OVERALL (a)	7/50 (14%)	5/50 (10%)	3/50 (6%)
POLY-3 RATE (b)	7/44.10	5/41.70	3/33.42
POLY-3 PERCENT (g)	15.9%	12%	9%
TERMINAL (d)	5/35 (14%)	5/33 (15%)	2/19 (11%)
FIRST INCIDENCE	631	729 (T)	699

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**STATISTICAL TESTS**

POLY 3	P=0.239N	P=0.418N	P=0.293N
POLY 1.5	P=0.197N	P=0.409N	P=0.244N
POLY 6	P=0.282N	P=0.426N	P=0.344N
COCH-ARM / FISHERS	P=0.122N	P=0.380N	P=0.159N
MAX-ISO-POLY-3	P=0.304N	P=0.307N	P=0.218N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Nose</b>			
<b>Inflammation Chronic</b>			
<b>LESION RATES</b>			
OVERALL (a)	11/50 (22%)	11/50 (22%)	9/50 (18%)
POLY-3 RATE (b)	11/44.73	11/42.99	9/34.21
POLY-3 PERCENT (g)	24.6%	25.6%	26.3%
TERMINAL (d)	7/35 (20%)	8/33 (24%)	7/19 (37%)
FIRST INCIDENCE	623	540	431
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.489	P=0.555	P=0.534
POLY 1.5	P=0.540N	P=0.562	P=0.580N
POLY 6	P=0.413	P=0.552	P=0.445
COCH-ARM / FISHERS	P=0.356N	P=0.595N	P=0.402N
MAX-ISO-POLY-3	P=0.595	P=0.457	P=0.438

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Nose: Goblet Cell  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.90	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	631	---	---

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**STATISTICAL TESTS**

POLY 3	P=0.319N	P=0.510N	P=0.554N
POLY 1.5	P=0.303N	P=0.508N	P=0.537N
POLY 6	P=0.335N	P=0.512N	P=0.570N
COCH-ARM / FISHERS	P=0.269N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.246N	P=0.171N	P=0.224N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Nose: Respiratory Epithelium  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	5/50 (10%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	5/44.04	4/41.70	2/33.30
POLY-3 PERCENT (g)	11.4%	9.6%	6%
TERMINAL (d)	4/35 (11%)	4/33 (12%)	2/19 (11%)
FIRST INCIDENCE	579	729 (T)	729 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.295N	P=0.534N	P=0.344N
POLY 1.5	P=0.251N	P=0.526N	P=0.299N
POLY 6	P=0.339N	P=0.539N	P=0.388N
COCH-ARM / FISHERS	P=0.169N	P=0.500N	P=0.218N
MAX-ISO-POLY-3	P=0.342N	P=0.396N	P=0.241N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Ovary Cyst			
<b>LESION RATES</b>			
OVERALL (a)	3/50 (6%)	6/50 (12%)	3/50 (6%)
POLY-3 RATE (b)	3/43.74	6/43.77	3/33.30
POLY-3 PERCENT (g)	6.9%	13.7%	9%
TERMINAL (d)	2/35 (6%)	3/33 (9%)	3/19 (16%)
FIRST INCIDENCE	677	412	729 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.395	P=0.241	P=0.531
POLY 1.5	P=0.449	P=0.238	P=0.575
POLY 6	P=0.348	P=0.247	P=0.489
COCH-ARM / FISHERS	P=0.573	P=0.243	P=0.661N
MAX-ISO-POLY-3	P=0.383	P=0.146	P=0.380



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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>Pancreas</b>			
<b>Atrophy</b>			
<b>LESION RATES</b>			
OVERALL (a)	25/49 (51%)	24/49 (49%)	23/50 (46%)
POLY-3 RATE (b)	25/45.43	24/43.72	23/38.76
POLY-3 PERCENT (g)	55%	54.9%	59.3%
TERMINAL (d)	19/35 (54%)	19/33 (58%)	12/19 (63%)
FIRST INCIDENCE	452	412	257
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.399	P=0.581N	P=0.428
POLY 1.5	P=0.511	P=0.565N	P=0.548
POLY 6	P=0.299	P=0.587	P=0.312
COCH-ARM / FISHERS	P=0.345N	P=0.500N	P=0.383N
MAX-ISO-POLY-3	P=0.485	P=0.494N	P=0.351

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Pancreas Cyst</b>			
<b>LESION RATES</b>			
OVERALL (a)	14/49 (29%)	11/49 (22%)	9/50 (18%)
POLY-3 RATE (b)	14/44.30	11/42.74	9/36.09
POLY-3 PERCENT (g)	31.6%	25.7%	24.9%
TERMINAL (d)	11/35 (31%)	8/33 (24%)	4/19 (21%)
FIRST INCIDENCE	452	452	351
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.288N	P=0.356N	P=0.342N
POLY 1.5	P=0.234N	P=0.353N	P=0.277N
POLY 6	P=0.336N	P=0.351N	P=0.403N
COCH-ARM / FISHERS	P=0.129N	P=0.322N	P=0.157N
MAX-ISO-POLY-3	P=0.385N	P=0.276N	P=0.276N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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

---

Pancreas: Acinus  
Hyperplasia Focal

---

**LESION RATES**

OVERALL (a)	2/49 (4%)	1/49 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/43.12	1/41.14	2/33.30
POLY-3 PERCENT (g)	4.6%	2.4%	6%
TERMINAL (d)	2/35 (6%)	1/33 (3%)	2/19 (11%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.561	P=0.516N	P=0.597
POLY 1.5	P=0.576	P=0.513N	P=0.632
POLY 6	P=0.550	P=0.517N	P=0.563
COCH-ARM / FISHERS	P=0.602N	P=0.500N	P=0.684N
MAX-ISO-POLY-3	P=0.451	P=0.298N	P=0.407

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Pituitary Gland  
Pigmentation

---

**LESION RATES**

OVERALL (a)	5/50 (10%)	5/49 (10%)	9/49 (18%)
POLY-3 RATE (b)	5/44.08	5/43.30	9/34.68
POLY-3 PERCENT (g)	11.3%	11.6%	26%
TERMINAL (d)	3/35 (9%)	1/33 (3%)	4/19 (21%)
FIRST INCIDENCE	623	508	351

---

**STATISTICAL TESTS**

POLY 3	P=0.076	P=0.619	P=0.083
POLY 1.5	P=0.091	P=0.616	P=0.108
POLY 6	P=0.066	P=0.627	P=0.064
COCH-ARM / FISHERS	P=0.138	P=0.617	P=0.183
MAX-ISO-POLY-3	P=0.078	P=0.487	P=0.064

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Pituitary Gland: Pars Distalis  
Angiectasis

---

**LESION RATES**

OVERALL (a)	9/50 (18%)	4/49 (8%)	5/49 (10%)
POLY-3 RATE (b)	9/45.37	4/42.35	5/34.10
POLY-3 PERCENT (g)	19.8%	9.4%	14.7%
TERMINAL (d)	5/35 (14%)	3/33 (9%)	1/19 (5%)
FIRST INCIDENCE	452	508	351

---

**STATISTICAL TESTS**

POLY 3	P=0.258N	P=0.142N	P=0.384N
POLY 1.5	P=0.221N	P=0.136N	P=0.321N
POLY 6	P=0.291N	P=0.147N	P=0.443N
COCH-ARM / FISHERS	P=0.149N	P=0.125N	P=0.205N
MAX-ISO-POLY-3	P=0.269N	P=0.091N	P=0.301N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Pituitary Gland: Pars Distalis  
Atrophy

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/49 (0%)	2/49 (4%)
POLY-3 RATE (b)	0/43.55	0/41.69	2/33.29
POLY-3 PERCENT (g)	0%	0%	6%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	1/19 (5%)
FIRST INCIDENCE	---	---	183

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**STATISTICAL TESTS**

POLY 3	P=0.095	(e)	P=0.183
POLY 1.5	P=0.093	(e)	P=0.198
POLY 6	P=0.099	(e)	P=0.169
COCH-ARM / FISHERS	P=0.094	(e)	P=0.242
MAX-ISO-POLY-3	P=0.051	(e)	P=0.074

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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 Cyst</b>			
<b>LESION RATES</b>			
OVERALL (a)	18/50 (36%)	20/49 (41%)	17/49 (35%)
POLY-3 RATE (b)	18/45.17	20/44.64	17/38.73
POLY-3 PERCENT (g)	39.9%	44.8%	43.9%
TERMINAL (d)	14/35 (40%)	15/33 (46%)	5/19 (26%)
FIRST INCIDENCE	545	422	257
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.389	P=0.396	P=0.439
POLY 1.5	P=0.435	P=0.392	P=0.486
POLY 6	P=0.369	P=0.404	P=0.418
COCH-ARM / FISHERS	P=0.489N	P=0.387	P=0.530N
MAX-ISO-POLY-3	P=0.480	P=0.316	P=0.361

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Pituitary Gland: Pars Distalis  
Hyperplasia Focal

---

**LESION RATES**

OVERALL (a)	5/50 (10%)	13/49 (27%)	6/49 (12%)
POLY-3 RATE (b)	5/43.55	13/43.37	6/34.80
POLY-3 PERCENT (g)	11.5%	30%	17.2%
TERMINAL (d)	5/35 (14%)	10/33 (30%)	1/19 (5%)
FIRST INCIDENCE	729 (T)	452	431

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**STATISTICAL TESTS**

POLY 3	P=0.224	P=0.028*	P=0.346
POLY 1.5	P=0.274	P=0.028*	P=0.384
POLY 6	P=0.191	P=0.030*	P=0.318
COCH-ARM / FISHERS	P=0.428	P=0.030*	P=0.486
MAX-ISO-POLY-3	P=0.140	P=0.015*	P=0.257

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Pituitary Gland: Pars Intermedia  
Angiectasis

---

**LESION RATES**

OVERALL (a)	2/50 (4%)	0/49 (0%)	0/49 (0%)
POLY-3 RATE (b)	2/43.55	0/41.69	0/32.31
POLY-3 PERCENT (g)	4.6%	0%	0%
TERMINAL (d)	2/35 (6%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	729 (T)	---	---

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**STATISTICAL TESTS**

POLY 3	P=0.123N	P=0.247N	P=0.309N
POLY 1.5	P=0.114N	P=0.245N	P=0.286N
POLY 6	P=0.130N	P=0.247N	P=0.331N
COCH-ARM / FISHERS	P=0.098N	P=0.253N	P=0.253N
MAX-ISO-POLY-3	P=0.131N	P=0.084N	P=0.143N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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 Intermedia Cyst</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/50 (2%)	2/49 (4%)	2/49 (4%)
POLY-3 RATE (b)	1/44.29	2/41.69	2/33.00
POLY-3 PERCENT (g)	2.3%	4.8%	6.1%
TERMINAL (d)	0/35 (0%)	2/33 (6%)	1/19 (5%)
FIRST INCIDENCE	462	729 (T)	494
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.304	P=0.479	P=0.400
POLY 1.5	P=0.327	P=0.483	P=0.429
POLY 6	P=0.285	P=0.477	P=0.374
COCH-ARM / FISHERS	P=0.383	P=0.492	P=0.492
MAX-ISO-POLY-3	P=0.337	P=0.268	P=0.230

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Pituitary Gland: Pars Intermedia  
Hyperplasia Focal

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/49 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/43.55	0/41.69	0/32.31
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	---	---	---

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**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)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS 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: Rathke's Cleft Dilatation</b>			
<b>LESION RATES</b>			
OVERALL (a)	7/50 (14%)	1/49 (2%)	13/49 (27%)
POLY-3 RATE (b)	7/45.95	1/41.69	13/38.16
POLY-3 PERCENT (g)	15.2%	2.4%	34.1%
TERMINAL (d)	2/35 (6%)	1/33 (3%)	4/19 (21%)
FIRST INCIDENCE	452	729 (T)	179
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.028*	P=0.041N*	P=0.037*
POLY 1.5	P=0.034*	P=0.038N*	P=0.053
POLY 6	P=0.024*	P=0.045N*	P=0.026*
COCH-ARM / FISHERS	P=0.052	P=0.032N*	P=0.096
MAX-ISO-POLY-3	P=0.002**	P=0.022N*	P=0.029*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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

---

Salivary Glands  
Atrophy

---

**LESION RATES**

OVERALL (a)	9/50 (18%)	10/50 (20%)	5/50 (10%)
POLY-3 RATE (b)	9/44.12	10/41.95	5/33.88
POLY-3 PERCENT (g)	20.4%	23.8%	14.8%
TERMINAL (d)	8/35 (23%)	9/33 (27%)	3/19 (16%)
FIRST INCIDENCE	547	663	616

---

**STATISTICAL TESTS**

POLY 3	P=0.375N	P=0.450	P=0.367N
POLY 1.5	P=0.303N	P=0.461	P=0.306N
POLY 6	P=0.439N	P=0.448	P=0.422N
COCH-ARM / FISHERS	P=0.170N	P=0.500	P=0.194N
MAX-ISO-POLY-3	P=0.339N	P=0.352	P=0.287N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Salivary Glands  
Inflammation Chronic

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/43.55	1/41.70	0/33.30
POLY-3 PERCENT (g)	0%	2.4%	0%
TERMINAL (d)	0/35 (0%)	1/33 (3%)	0/19 (0%)
FIRST INCIDENCE	---	729 (T)	---

---

**STATISTICAL TESTS**

POLY 3	P=0.683	P=0.491	(e)
POLY 1.5	P=0.698	P=0.493	(e)
POLY 6	P=0.668	P=0.491	(e)
COCH-ARM / FISHERS	P=0.731	P=0.500	(e)
MAX-ISO-POLY-3	P=0.406	P=0.158	(e)

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Salivary Glands  
Mineralization

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/43.55	2/41.95	0/33.30
POLY-3 PERCENT (g)	0%	4.8%	0%
TERMINAL (d)	0/35 (0%)	1/33 (3%)	0/19 (0%)
FIRST INCIDENCE	---	663	---

---

**STATISTICAL TESTS**

POLY 3	P=0.571	P=0.229	(e)
POLY 1.5	P=0.604	P=0.230	(e)
POLY 6	P=0.540	P=0.229	(e)
COCH-ARM / FISHERS	P=0.669	P=0.247	(e)
MAX-ISO-POLY-3	P=0.305	P=0.076	(e)

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Skeletal Muscle Fibrosis</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/0 (0%)	0/0 (0%)	0/1 (0%)
POLY-3 RATE (b)	0/0.00	0/0.00	0/0.61
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---
<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)

---



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Skin  
Cyst Epithelial Inclusion

---

LESION RATES			
OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/43.55	0/41.70	1/33.30
POLY-3 PERCENT (g)	4.6%	0%	3%
TERMINAL (d)	2/35 (6%)	0/33 (0%)	1/19 (5%)
FIRST INCIDENCE	729 (T)	---	729 (T)

---

STATISTICAL TESTS			
POLY 3	P=0.409N	P=0.247N	P=0.592N
POLY 1.5	P=0.395N	P=0.245N	P=0.563N
POLY 6	P=0.420N	P=0.247N	P=0.618N
COCH-ARM / FISHERS	P=0.360N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.305N	P=0.085N	P=0.377N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Skin  
Hyperkeratosis

---

**LESION RATES**

OVERALL (a)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/43.55	1/41.70	1/33.30
POLY-3 PERCENT (g)	2.3%	2.4%	3%
TERMINAL (d)	1/35 (3%)	1/33 (3%)	1/19 (5%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.590	P=0.751	P=0.697
POLY 1.5	P=0.604	P=0.753	P=0.719
POLY 6	P=0.580	P=0.751	P=0.677
COCH-ARM / FISHERS	P=0.640	P=0.753N	P=0.753N
MAX-ISO-POLY-3	P=0.586	P=0.487	P=0.432

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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>Inflammation Chronic</b>			
<b>LESION 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)	---	---
<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

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Skin: Epidermis Hyperplasia</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/43.55	1/41.70	0/33.30
POLY-3 PERCENT (g)	4.6%	2.4%	0%
TERMINAL (d)	2/35 (6%)	1/33 (3%)	0/19 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.203N	P=0.515N	P=0.301N
POLY 1.5	P=0.182N	P=0.512N	P=0.280N
POLY 6	P=0.224N	P=0.515N	P=0.322N
COCH-ARM / FISHERS	P=0.142N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.191N	P=0.297N	P=0.136N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Spleen Fibrosis</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/48 (2%)	0/49 (0%)	0/48 (0%)
POLY-3 RATE (b)	1/42.92	0/41.50	0/31.54
POLY-3 PERCENT (g)	2.3%	0%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	659	---	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.323N	P=0.507N	P=0.560N
POLY 1.5	P=0.305N	P=0.504N	P=0.541N
POLY 6	P=0.341N	P=0.509N	P=0.578N
COCH-ARM / FISHERS	P=0.269N	P=0.495N	P=0.500N
MAX-ISO-POLY-3	P=0.255N	P=0.168N	P=0.231N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Spleen  
Hematopoietic Cell Proliferation

---

**LESION RATES**

OVERALL (a)	21/48 (44%)	31/49 (63%)	21/48 (44%)
POLY-3 RATE (b)	21/43.58	31/46.61	21/36.75
POLY-3 PERCENT (g)	48.2%	66.5%	57.2%
TERMINAL (d)	18/35 (51%)	22/33 (67%)	9/19 (47%)
FIRST INCIDENCE	623	127	485

---

**STATISTICAL TESTS**

POLY 3	P=0.194	P=0.055	P=0.279
POLY 1.5	P=0.263	P=0.048*	P=0.350
POLY 6	P=0.169	P=0.065	P=0.249
COCH-ARM / FISHERS	P=0.541	P=0.042*	P=0.581N
MAX-ISO-POLY-3	P=0.162	P=0.039*	P=0.226

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<hr/>			
Spleen Necrosis			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/48 (0%)	1/49 (2%)	3/48 (6%)
POLY-3 RATE (b)	0/42.65	1/42.10	3/34.06
POLY-3 PERCENT (g)	0%	2.4%	8.8%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	---	540	257
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.047*	P=0.497	P=0.083
POLY 1.5	P=0.050*	P=0.498	P=0.093
POLY 6	P=0.045*	P=0.497	P=0.075
COCH-ARM / FISHERS	P=0.060	P=0.505	P=0.121
MAX-ISO-POLY-3	P=0.038*	P=0.160	P=0.037*

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Spleen Pigmentation</b>			
<b>LESION RATES</b>			
OVERALL (a)	39/48 (81%)	40/49 (82%)	39/48 (81%)
POLY-3 RATE (b)	39/46.47	40/46.89	39/46.08
POLY-3 PERCENT (g)	83.9%	85.3%	84.6%
TERMINAL (d)	31/35 (89%)	28/33 (85%)	17/19 (90%)
FIRST INCIDENCE	452	127	179
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.520	P=0.542	P=0.580
POLY 1.5	P=0.534	P=0.550	P=0.589
POLY 6	P=0.504	P=0.564	P=0.569
COCH-ARM / FISHERS	P=0.552	P=0.584	P=0.603N
MAX-ISO-POLY-3	P=0.596	P=0.421	P=0.459

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Spleen: Lymphoid Follicle Atrophy

---

LESION RATES			
OVERALL (a)	2/48 (4%)	3/49 (6%)	2/48 (4%)
POLY-3 RATE (b)	2/43.26	3/42.32	2/33.29
POLY-3 PERCENT (g)	4.6%	7.1%	6%
TERMINAL (d)	0/35 (0%)	2/33 (6%)	0/19 (0%)
FIRST INCIDENCE	631	412	257

---

STATISTICAL TESTS			
POLY 3	P=0.483	P=0.490	P=0.596
POLY 1.5	P=0.519	P=0.495	P=0.630
POLY 6	P=0.449	P=0.484	P=0.561
COCH-ARM / FISHERS	P=0.594	P=0.510	P=0.692N
MAX-ISO-POLY-3	P=0.516	P=0.317	P=0.405

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Spleen: Lymphoid Follicle  
Hyperplasia

---

LESION RATES			
OVERALL (a)	3/48 (6%)	3/49 (6%)	2/48 (4%)
POLY-3 RATE (b)	3/43.35	3/42.17	2/32.73
POLY-3 PERCENT (g)	6.9%	7.1%	6.1%
TERMINAL (d)	1/35 (3%)	2/33 (6%)	0/19 (0%)
FIRST INCIDENCE	579	508	494

---

STATISTICAL TESTS			
POLY 3	P=0.556N	P=0.650	P=0.625N
POLY 1.5	P=0.512N	P=0.655	P=0.586N
POLY 6	P=0.595N	P=0.644	P=0.658N
COCH-ARM / FISHERS	P=0.412N	P=0.651N	P=0.500N
MAX-ISO-POLY-3	P=0.603N	P=0.486	P=0.450N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Stomach, Forestomach Edema</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/44.13	1/42.46	0/33.30
POLY-3 PERCENT (g)	4.5%	2.4%	0%
TERMINAL (d)	1/35 (3%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	545	452	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.206N	P=0.513N	P=0.305N
POLY 1.5	P=0.184N	P=0.511N	P=0.282N
POLY 6	P=0.229N	P=0.514N	P=0.327N
COCH-ARM / FISHERS	P=0.142N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.196N	P=0.295N	P=0.140N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Stomach, Forestomach  
Ulcer

---

**LESION RATES**

OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/44.13	2/42.62	0/33.30
POLY-3 PERCENT (g)	2.3%	4.7%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	545	452	---

---

**STATISTICAL TESTS**

POLY 3	P=0.500N	P=0.488	P=0.555N
POLY 1.5	P=0.453N	P=0.490	P=0.537N
POLY 6	P=0.545N	P=0.489	P=0.571N
COCH-ARM / FISHERS	P=0.360N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.287N	P=0.273	P=0.225N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Stomach, Forestomach: Epithelium  
Hyperplasia

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**LESION RATES**

OVERALL (a)	7/50 (14%)	8/50 (16%)	2/50 (4%)
POLY-3 RATE (b)	7/45.41	8/45.55	2/34.67
POLY-3 PERCENT (g)	15.4%	17.6%	5.8%
TERMINAL (d)	2/35 (6%)	1/33 (3%)	0/19 (0%)
FIRST INCIDENCE	462	422	494

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**STATISTICAL TESTS**

POLY 3	P=0.198N	P=0.503	P=0.163N
POLY 1.5	P=0.152N	P=0.495	P=0.131N
POLY 6	P=0.248N	P=0.515	P=0.198N
COCH-ARM / FISHERS	P=0.078N	P=0.500	P=0.080N
MAX-ISO-POLY-3	P=0.161N	P=0.390	P=0.117N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Stomach, Glandular Edema</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/48 (2%)	0/47 (0%)	0/48 (0%)
POLY-3 RATE (b)	1/42.94	0/40.48	0/31.54
POLY-3 PERCENT (g)	2.3%	0%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	652	---	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.326N	P=0.512N	P=0.560N
POLY 1.5	P=0.307N	P=0.510N	P=0.541N
POLY 6	P=0.344N	P=0.512N	P=0.578N
COCH-ARM / FISHERS	P=0.270N	P=0.505N	P=0.500N
MAX-ISO-POLY-3	P=0.257N	P=0.172N	P=0.231N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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>Stomach, Glandular Erosion</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/48 (2%)	1/47 (2%)	1/48 (2%)
POLY-3 RATE (b)	1/42.85	1/40.64	1/31.54
POLY-3 PERCENT (g)	2.3%	2.5%	3.2%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	1/19 (5%)
FIRST INCIDENCE	677	688	729 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.584	P=0.749	P=0.688
POLY 1.5	P=0.600	P=0.750	P=0.713
POLY 6	P=0.573	P=0.750	P=0.662
COCH-ARM / FISHERS	P=0.639	P=0.747	P=0.753N
MAX-ISO-POLY-3	P=0.577	P=0.485	P=0.424

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Stomach, Glandular Ulcer</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/48 (2%)	0/47 (0%)	3/48 (6%)
POLY-3 RATE (b)	1/42.94	0/40.48	3/32.76
POLY-3 PERCENT (g)	2.3%	0%	9.2%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	652	---	607
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.167	P=0.512N	P=0.217
POLY 1.5	P=0.167	P=0.510N	P=0.242
POLY 6	P=0.169	P=0.512N	P=0.198
COCH-ARM / FISHERS	P=0.177	P=0.505N	P=0.308
MAX-ISO-POLY-3	P=0.069	P=0.172N	P=0.125



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
<b>Thymus Cyst</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/48 (0%)	2/45 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/42.13	2/38.29	0/33.30
POLY-3 PERCENT (g)	0%	5.2%	0%
TERMINAL (d)	0/34 (0%)	2/30 (7%)	0/19 (0%)
FIRST INCIDENCE	---	729 (T)	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.573	P=0.216	(e)
POLY 1.5	P=0.608	P=0.218	(e)
POLY 6	P=0.540	P=0.215	(e)
COCH-ARM / FISHERS	P=0.658N	P=0.231	(e)
MAX-ISO-POLY-3	P=0.296	P=0.072	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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>Thyroid Gland Degeneration Cystic</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/42 (2%)	2/46 (4%)	5/44 (11%)
POLY-3 RATE (b)	1/39.72	2/40.23	5/30.73
POLY-3 PERCENT (g)	2.5%	5%	16.3%
TERMINAL (d)	0/35 (0%)	1/33 (3%)	1/19 (5%)
FIRST INCIDENCE	579	721	500
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.037*	P=0.504	P=0.053
POLY 1.5	P=0.043*	P=0.513	P=0.067
POLY 6	P=0.033*	P=0.496	P=0.044*
COCH-ARM / FISHERS	P=0.063	P=0.534	P=0.112
MAX-ISO-POLY-3	P=0.036*	P=0.287	P=0.035*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS 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</b>			
<b>Ultimobranchial Cyst</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/42 (5%)	1/46 (2%)	3/44 (7%)
POLY-3 RATE (b)	2/39.22	1/40.20	3/30.22
POLY-3 PERCENT (g)	5.1%	2.5%	9.9%
TERMINAL (d)	2/35 (6%)	1/33 (3%)	1/19 (5%)
FIRST INCIDENCE	729 (T)	729 (T)	179
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.359	P=0.491N	P=0.384
POLY 1.5	P=0.375	P=0.485N	P=0.429
POLY 6	P=0.348	P=0.498N	P=0.343
COCH-ARM / FISHERS	P=0.416	P=0.466N	P=0.522
MAX-ISO-POLY-3	P=0.238	P=0.275N	P=0.253

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Thyroid Gland: C-Cell  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	1/42 (2%)	11/46 (24%)	2/44 (5%)
POLY-3 RATE (b)	1/39.22	11/41.02	2/28.64
POLY-3 PERCENT (g)	2.6%	26.8%	7%
TERMINAL (d)	1/35 (3%)	9/33 (27%)	1/19 (5%)
FIRST INCIDENCE	729 (T)	508	716

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**STATISTICAL TESTS**

POLY 3	P=0.140	P=0.002**	P=0.393
POLY 1.5	P=0.224	P=0.002**	P=0.433
POLY 6	P=0.084	P=0.002**	P=0.358
COCH-ARM / FISHERS	P=0.460	P=0.003**	P=0.518
MAX-ISO-POLY-3	P=0.060	P<0.001**	P=0.231

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
alpha/beta Thujone mixture  
CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010  
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Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS 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  
Hyperplasia Focal

---

**LESION RATES**

OVERALL (a)	0/42 (0%)	1/46 (2%)	1/44 (2%)
POLY-3 RATE (b)	0/39.22	1/40.46	1/29.08
POLY-3 PERCENT (g)	0%	2.5%	3.4%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	---	660	579

---

**STATISTICAL TESTS**

POLY 3	P=0.290	P=0.506	P=0.442
POLY 1.5	P=0.304	P=0.509	P=0.463
POLY 6	P=0.280	P=0.503	P=0.423
COCH-ARM / FISHERS	P=0.339	P=0.523	P=0.512
MAX-ISO-POLY-3	P=0.268	P=0.164	P=0.161

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
alpha/beta Thujone mixture  
CAS Number: THUJONEMIXAB

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Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 105 WEEKS**

---

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

---

Tongue  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	1/1 (100%)	2/3 (67%)	0/0 (0%)
POLY-3 RATE (b)	1/1.00	2/2.41	0/0.00
POLY-3 PERCENT (g)	100%	83.1%	0%
TERMINAL (d)	1/1 (100%)	1/1 (100%)	0/0 (0%)
FIRST INCIDENCE	729 (T)	721	---

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**STATISTICAL TESTS**

POLY 3	(e)	P=0.944N	(e)
POLY 1.5	(e)	P=0.822N	(e)
POLY 6	(e)	P=1.000N	(e)
COCH-ARM / FISHERS	P=0.748N	P=0.750N	(e)
MAX-ISO-POLY-3	(e)	P=0.332N	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
alpha/beta Thujone mixture  
CAS Number: THUJONEMIXAB

Date Report Requested: 09/09/2010  
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS 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>Hyperplasia Cystic</b>			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	22/50 (44%)	17/50 (34%)	19/49 (39%)
POLY-3 RATE (b)	22/44.68	17/43.87	19/37.75
POLY-3 PERCENT (g)	49.2%	38.8%	50.3%
TERMINAL (d)	18/35 (51%)	10/33 (30%)	10/19 (53%)
FIRST INCIDENCE	547	452	179
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.541N	P=0.214N	P=0.550
POLY 1.5	P=0.482N	P=0.221N	P=0.552N
POLY 6	P=0.515	P=0.199N	P=0.494
COCH-ARM / FISHERS	P=0.332N	P=0.206N	P=0.373N
MAX-ISO-POLY-3	P=0.412	P=0.159N	P=0.462

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
alpha/beta Thujone mixture  
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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.  
(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 \*\*\*