

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

C Number:	C99037B		
Lock Date:	11/20/2006		
Cage Range:	ALL		
Date Range:	ALL		
Reasons For Removal:	ALL		
Removal Date Range:	ALL		
Treatment Groups:	Include 001 0 MG/KG	Include 002 0 MG/KG	Include 003 12.5 MG/KG
	Include 004 12.5 MG/KG	Include 005 25 MG/KG	Include 006 25 MG/KG
Study Gender:	Both		
TDMSE Version:	2.2.0		

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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

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

FEMALE RATS

Organ

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**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Adrenal Cortex			
Accessory Adrenal Cortical Nodule			
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
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**

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

Adrenal Cortex
Degeneration Fatty

LESION RATES

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

STATISTICAL TESTS

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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**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

Adrenal Cortex
Hematopoietic Cell Proliferation

LESION RATES

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	---

STATISTICAL TESTS

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**

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

Adrenal Cortex
Hyperplasia Focal

LESION RATES

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

STATISTICAL TESTS

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**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Adrenal Cortex			
Hypertrophy Focal			
LESION RATES			
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)	---
STATISTICAL TESTS			
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
Adrenal Cortex Necrosis			
LESION RATES			
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
STATISTICAL TESTS			
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
Adrenal Medulla Hyperplasia			
LESION RATES			
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
STATISTICAL TESTS			
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

Adrenal Medulla
Infiltration Cellular Lymphocyte

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)	---

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**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Bone Marrow Hyperplasia			
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
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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**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
Bone Marrow Infiltration Cellular Histiocyte			
LESION RATES			
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	---	---	---
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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TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Bone Marrow			
Myelofibrosis			
LESION RATES			
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	---
STATISTICAL TESTS			
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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**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

Bone: Femur
Osteopetrosis

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

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			
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
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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TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Brain Necrosis			
LESION RATES			
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/40.62	0/42.35	1/34.98
POLY-3 PERCENT (g)	0%	0%	2.9%
TERMINAL (d)	0/27 (0%)	0/25 (0%)	1/17 (6%)
FIRST INCIDENCE	---	---	729 (T)
STATISTICAL TESTS			
POLY 3	P=0.281	(e)	P=0.470
POLY 1.5	P=0.275	(e)	P=0.482
POLY 6	P=0.290	(e)	P=0.455
COCH-ARM / FISHERS	P=0.269	(e)	P=0.500
MAX-ISO-POLY-3	P=0.151	(e)	P=0.158

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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
Brain Pigmentation			
LESION RATES			
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)	---
STATISTICAL TESTS			
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)

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

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**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
Esophagus			
Inflammation Acute			
LESION RATES			
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	---	---
STATISTICAL TESTS			
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

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

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**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
Cataract

LESION RATES

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

STATISTICAL TESTS

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

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**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			
LESION RATES			
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)	---
STATISTICAL TESTS			
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

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**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
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	---

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)

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

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**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: 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)

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

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

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**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: Retina
Degeneration

LESION RATES

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)	---

STATISTICAL TESTS

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

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

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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
Harderian Gland Hemorrhage			
LESION RATES			
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	---	---	---
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

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**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
Harderian Gland Inflammation Chronic			
LESION RATES			
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
STATISTICAL TESTS			
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

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

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**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

Heart
Cardiomyopathy

LESION RATES

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

STATISTICAL TESTS

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

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**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
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
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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Route: GAVAGE
Species/Strain: RATS/F 344/N

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**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
Intestine Large, Colon Edema			
LESION RATES			
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
STATISTICAL TESTS			
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

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

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**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
Islets, Pancreatic Hyperplasia			
LESION RATES			
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
STATISTICAL TESTS			
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

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 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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**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			
Casts Protein			
LESION RATES			
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
STATISTICAL TESTS			
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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 Species/Strain: RATS/F 344/N

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**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 Cyst			
LESION RATES			
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)	---
STATISTICAL TESTS			
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

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**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
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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
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	---
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
Kidney			
Inflammation Chronic			
LESION RATES			
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	---	---	---
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	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Kidney Mineralization			
LESION RATES			
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
STATISTICAL TESTS			
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
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

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	---	---

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

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: Transitional Epithelium Hyperplasia			
LESION RATES			
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
STATISTICAL TESTS			
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

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

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			
Clear Cell Focus			
LESION RATES			
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)
STATISTICAL TESTS			
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

Liver
Degeneration Cystic

LESION RATES			
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

STATISTICAL TESTS			
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

Liver
Eosinophilic Focus

LESION RATES			
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

STATISTICAL TESTS			
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	---

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)

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
Liver			
Hepatodiaphragmatic Nodule			
LESION RATES			
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
STATISTICAL TESTS			
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**

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

Liver
Infiltration Cellular Mixed Cell

LESION RATES

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

STATISTICAL TESTS

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

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/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

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			
Necrosis Focal			
<hr/>			
LESION RATES			
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	---
<hr/>			
STATISTICAL TESTS			
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

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

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

LESION RATES

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

STATISTICAL TESTS

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**

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	---

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)

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

Lung
Infiltration Cellular Histiocyte

LESION RATES			
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

STATISTICAL TESTS			
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

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/>			
Lung Inflammation Chronic			
<hr/>			
LESION RATES			
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
<hr/>			
STATISTICAL TESTS			
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

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
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
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

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
Lung: Alveolar Epithelium Hyperplasia			
LESION RATES			
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
STATISTICAL TESTS			
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*

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, Mandibular Hyperplasia Lymphoid			
LESION RATES			
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	---	---	---
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

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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
Lymph Node, Mesenteric Hemorrhage			
LESION RATES			
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
STATISTICAL TESTS			
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*

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 Hyperplasia Lymphoid			
LESION RATES			
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
STATISTICAL TESTS			
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
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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
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	---	---
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**

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

Lymph Node: Mediastinal
Hyperplasia Lymphoid

LESION RATES

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

STATISTICAL TESTS

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

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
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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

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)	---	---

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

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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
Mammary Gland Hyperplasia			
LESION RATES			
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	---
STATISTICAL TESTS			
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
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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
Mammary Gland Hyperplasia Focal			
LESION RATES			
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	---	---	---
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	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG

Mammary Gland: Duct
Ectasia

LESION RATES

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

STATISTICAL TESTS

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
Mesentery			
Accessory Spleen			
LESION RATES			
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
STATISTICAL TESTS			
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
Nose			
Foreign Body			
LESION RATES			
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
STATISTICAL TESTS			
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

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
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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
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
Pancreas Atrophy			
LESION RATES			
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
STATISTICAL TESTS			
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
 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
Pancreas Cyst			
LESION RATES			
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
STATISTICAL TESTS			
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
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

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

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 Pigmentation			
LESION RATES			
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
STATISTICAL TESTS			
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**

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

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
Pituitary Gland: Pars Distalis Cyst			
LESION RATES			
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
STATISTICAL TESTS			
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

Pituitary Gland: Pars Distalis
Hyperplasia Focal

LESION RATES

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

STATISTICAL TESTS

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
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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
Pituitary Gland: Pars Intermedia Cyst			
LESION RATES			
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)
STATISTICAL TESTS			
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	---

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

Pituitary Gland: Rathke's Cleft
Dilatation

LESION RATES

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

STATISTICAL TESTS

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

Preputial Gland
Hyperplasia

LESION RATES

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)

STATISTICAL TESTS

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

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**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
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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
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

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
Salivary Glands Atrophy			
LESION RATES			
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
STATISTICAL TESTS			
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
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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

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)

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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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
Mineralization

LESION RATES

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	---	---	---

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
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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
Skeletal Muscle Fibrosis			
LESION RATES			
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)	---
STATISTICAL TESTS			
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

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**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			
Cyst Epithelial Inclusion			
LESION RATES			
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
STATISTICAL TESTS			
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

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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

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

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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

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

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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
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
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**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 Fibrosis			
LESION RATES			
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
STATISTICAL TESTS			
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

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**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
Spleen Necrosis			
LESION RATES			
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
STATISTICAL TESTS			
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**

DOSE	Males		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Spleen Pigmentation			
LESION RATES			
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
STATISTICAL TESTS			
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)

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

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 Edema			
LESION RATES			
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
STATISTICAL TESTS			
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
Stomach, Forestomach Ulcer			
LESION RATES			
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
STATISTICAL TESTS			
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
Stomach, Glandular Edema			
LESION RATES			
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
STATISTICAL TESTS			
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

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, Glandular Erosion			
LESION RATES			
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
STATISTICAL TESTS			
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
Stomach, Glandular Ulcer			
LESION RATES			
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
STATISTICAL TESTS			
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
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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

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

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

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

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)	---
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)

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
Thyroid Gland Degeneration Cystic			
LESION RATES			
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
STATISTICAL TESTS			
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
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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
Thyroid Gland			
Ultimobranchial Cyst			
LESION RATES			
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)
STATISTICAL TESTS			
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
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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

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
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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

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/>			
LESION RATES			
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/>			
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
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
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
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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
Adrenal Cortex Degeneration Fatty			
LESION RATES			
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
STATISTICAL TESTS			
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

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			
Hematopoietic Cell Proliferation			
<hr/>			
LESION RATES			
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
<hr/>			
STATISTICAL TESTS			
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

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 Hyperplasia Focal			
LESION RATES			
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
STATISTICAL TESTS			
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
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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
Adrenal Cortex			
Hypertrophy Focal			
LESION RATES			
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)
STATISTICAL TESTS			
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

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
Adrenal Cortex Necrosis			
LESION RATES			
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
STATISTICAL TESTS			
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*

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
Adrenal Medulla Hyperplasia			
LESION RATES			
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
STATISTICAL TESTS			
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

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
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	---	---	---
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

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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
Bone Marrow Hyperplasia			
LESION RATES			
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
STATISTICAL TESTS			
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

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
Bone Marrow Infiltration Cellular Histiocyte			
LESION RATES			
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
STATISTICAL TESTS			
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

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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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 Marrow			
Myelofibrosis			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
POLY 3	P=0.683	P=0.492	(e)
POLY 1.5	P=0.698	P=0.493	(e)
POLY 6	P=0.668	P=0.493	(e)
COCH-ARM / FISHERS	P=0.731	P=0.500	(e)
MAX-ISO-POLY-3	P=0.407	P=0.158	(e)

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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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	---

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

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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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
Brain Compression			
LESION RATES			
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
STATISTICAL TESTS			
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

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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 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
Brain Necrosis			
LESION RATES			
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
STATISTICAL TESTS			
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
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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
Brain Pigmentation			
LESION RATES			
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
STATISTICAL TESTS			
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*

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
Clitoral Gland Cyst			
LESION RATES			
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)
STATISTICAL TESTS			
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**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Clitoral Gland Hyperplasia			
LESION RATES			
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
STATISTICAL TESTS			
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

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
Esophagus			
Inflammation Acute			
<hr/>			
LESION RATES			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.55	0/41.70	0/33.30
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	---	---	---
<hr/>			
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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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 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			
LESION RATES			
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)
STATISTICAL TESTS			
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
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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
Eye Edema			
LESION RATES			
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)
STATISTICAL TESTS			
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
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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
<hr/>			
Eye Inflammation Chronic			
<hr/>			
LESION RATES			
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)	---
<hr/>			
STATISTICAL TESTS			
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
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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

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)

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

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
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)
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*

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
Harderian Gland Inflammation Chronic			
LESION RATES			
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
STATISTICAL TESTS			
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

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

Heart
Cardiomyopathy

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

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

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
<hr/>			
Heart Thrombosis			
<hr/>			
LESION RATES			
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.55	0/41.70	0/33.30
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	---	---	---
<hr/>			
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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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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
Intestine Large, Colon Edema			
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)

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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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
Islets, Pancreatic Hyperplasia			
LESION RATES			
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)
STATISTICAL TESTS			
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

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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
Kidney			
Casts Protein			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

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 Cyst			
LESION RATES			
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)	---
STATISTICAL TESTS			
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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 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
Kidney Infarct			
LESION RATES			
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)
STATISTICAL TESTS			
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
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
Kidney Inflammation			
LESION RATES			
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	---	---
STATISTICAL TESTS			
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

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
Kidney			
Inflammation Chronic			
LESION RATES			
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
STATISTICAL TESTS			
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*

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
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

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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 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
Kidney			
Nephropathy			
LESION RATES			
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
STATISTICAL TESTS			
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

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

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

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

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

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: 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)	---

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

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
Liver			
Basophilic Focus			
LESION RATES			
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
STATISTICAL TESTS			
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
Liver			
Clear Cell Focus			
LESION RATES			
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
STATISTICAL TESTS			
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

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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
<hr/>			
Liver Degeneration Cystic			
<hr/>			
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	---	---	---
<hr/>			
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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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 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			
Eosinophilic Focus			
LESION RATES			
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)
STATISTICAL TESTS			
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

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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

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

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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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/>			
Liver			
Hepatodiaphragmatic Nodule			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

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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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

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

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/>			
Liver			
Mixed Cell Focus			
<hr/>			
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
<hr/>			
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

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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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			
Necrosis Focal			
LESION RATES			
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
STATISTICAL TESTS			
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

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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

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

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

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*

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

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
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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

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

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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 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			
Infiltration Cellular Histiocyte			
LESION RATES			
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
STATISTICAL TESTS			
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
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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

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
Lung			
Metaplasia Osseous			
LESION RATES			
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
STATISTICAL TESTS			
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
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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
Lung: Alveolar Epithelium Hyperplasia			
LESION RATES			
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
STATISTICAL TESTS			
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

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
Lymph Node, Mandibular Hyperplasia Lymphoid			
LESION RATES			
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)	---
STATISTICAL TESTS			
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
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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
Lymph Node, Mesenteric Hemorrhage			
LESION RATES			
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
STATISTICAL TESTS			
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
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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
Lymph Node, Mesenteric Hyperplasia Lymphoid			
LESION RATES			
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
STATISTICAL TESTS			
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

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

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

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

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
Lymph Node: Mediastinal Hemorrhage			
LESION RATES			
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
STATISTICAL TESTS			
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

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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
Lymph Node: Mediastinal Hyperplasia Lymphoid			
LESION RATES			
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
STATISTICAL TESTS			
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

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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
Lymph Node: Mediastinal Pigmentation			
LESION RATES			
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
STATISTICAL TESTS			
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

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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
Lymph Node: Pancreatic Hemorrhage			
LESION RATES			
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
STATISTICAL TESTS			
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
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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
Mammary Gland Hyperplasia			
LESION RATES			
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
STATISTICAL TESTS			
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

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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
Mammary Gland Hyperplasia Focal			
LESION RATES			
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	---
STATISTICAL TESTS			
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

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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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

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

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
Mesentery			
Accessory Spleen			
LESION RATES			
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
STATISTICAL TESTS			
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
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

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

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

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
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

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

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			
Inflammation Chronic			
LESION RATES			
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
STATISTICAL TESTS			
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	---	---

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

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			
LESION RATES			
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)
STATISTICAL TESTS			
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**

DOSE	Females		
	0 MG/KG	12.5 MG/KG	25 MG/KG
Pancreas			
Atrophy			
LESION RATES			
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
STATISTICAL TESTS			
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

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
Pancreas Cyst			
LESION RATES			
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
STATISTICAL TESTS			
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

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

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

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

**STATISTICAL ANALYSIS OF 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

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

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
Cyst

LESION RATES

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

STATISTICAL TESTS

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

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

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)	---	---

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

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 Cyst			
LESION RATES			
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
STATISTICAL TESTS			
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

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	---	---	---

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

Pituitary Gland: Rathke's Cleft
Dilatation

LESION RATES

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

STATISTICAL TESTS

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**

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
Skeletal Muscle Fibrosis			
LESION RATES			
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	---	---	---
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
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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

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

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			
Inflammation Chronic			
LESION RATES			
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.55	0/41.70	0/33.30
POLY-3 PERCENT (g)	2.3%	0%	0%
TERMINAL (d)	1/35 (3%)	0/33 (0%)	0/19 (0%)
FIRST INCIDENCE	729 (T)	---	---
STATISTICAL TESTS			
POLY 3	P=0.317N	P=0.509N	P=0.553N
POLY 1.5	P=0.302N	P=0.507N	P=0.536N
POLY 6	P=0.332N	P=0.509N	P=0.568N
COCH-ARM / FISHERS	P=0.269N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.243N	P=0.169N	P=0.223N

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: Epidermis
Hyperplasia

LESION RATES

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)	---

STATISTICAL TESTS

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
<hr/>			
Spleen Fibrosis			
<hr/>			
LESION RATES			
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	---	---
<hr/>			
STATISTICAL TESTS			
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

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/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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
Spleen Pigmentation			
LESION RATES			
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
STATISTICAL TESTS			
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

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
Stomach, Forestomach Edema			
LESION RATES			
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	---
STATISTICAL TESTS			
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

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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
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

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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

Stomach, Forestomach: Epithelium
Hyperplasia

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

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

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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**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, Glandular Edema			
LESION RATES			
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	---	---
STATISTICAL TESTS			
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

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
Stomach, Glandular Erosion			
LESION RATES			
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)
STATISTICAL TESTS			
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

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
Stomach, Glandular Ulcer			
LESION RATES			
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
STATISTICAL TESTS			
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
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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

Thymus
Cyst

LESION RATES			
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)	---

STATISTICAL TESTS			
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

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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
Thyroid Gland Degeneration Cystic			
LESION RATES			
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
STATISTICAL TESTS			
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*

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
Thyroid Gland			
Ultimobranchial Cyst			
LESION RATES			
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
STATISTICAL TESTS			
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

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

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

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

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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**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

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
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	---
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)

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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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
Uterus			
Hyperplasia Cystic			
<hr/>			
LESION RATES			
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/>			
STATISTICAL TESTS			
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

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

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