

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

F2_R2

C Number: C20007
Lock Date: 03/27/2007
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.2.0

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SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF KAVA KAVA EXTRACT

MALE RATS

Organ

Bone Marrow
Eye: Iris
Eye: Retina
Intestine Large, Colon
Kidney
Kidney: Pelvis, Transitional Epithelium
Liver

Liver: Bile Duct
Liver: Centrilobular
Liver: Hepatocyte
Lung

Lung: Alveolus
Lymph Node: Mediastinal
Nose
Pancreas: Acinus

Parathyroid Gland
Pituitary Gland: Pars Distalis
Prostate
Prostate: Epithelium
Spleen

Stomach, Forestomach

Morphology

Hyperplasia
Inflammation
Degeneration
Parasite Metazoan
Mineralization
Hyperplasia
Basophilic Focus
Clear Cell Focus
Degeneration Cystic
Hematopoietic Cell Proliferation
Hepatodiaphragmatic Nodule
Mixed Cell Focus
Hyperplasia
Fatty Change
Hypertrophy
Inflammation Granulomatous
Necrosis
Infiltration Cellular Histiocyte
Hyperplasia Lymphoid
Inflammation
Hyperplasia
Metaplasia Hepatocyte
Hyperplasia
Hyperplasia
Inflammation
Hyperplasia
Fibrosis
Thrombosis
Erosion
Inflammation
Mineralization
Ulcer

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SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF KAVA KAVA EXTRACT

Stomach, Forestomach: Epithelium
Testes: Germinal Epithelium
Testes: Interstitial Cell

Hyperplasia
Degeneration
Hyperplasia

FEMALE RATS

Organ

Adrenal Medulla
Brain
Clitoral Gland
Eye: Retina
Heart
Intestine Large, Colon
Kidney
Kidney: Cortex
Kidney: Pelvis
Kidney: Pelvis, Transitional Epithelium
Liver

Liver: Centrilobular
Liver: Hepatocyte
Lymph Node, Mesenteric
Nose

Pancreas: Acinus
Pituitary Gland: Pars Distalis
Spleen

Stomach, Forestomach

Stomach, Forestomach: Epithelium
Thymus
Thyroid Gland: C-Cell
Thyroid Gland: Follicle
Uterus: Endometrium

Morphology

Hyperplasia
Necrosis
Hyperplasia
Degeneration
Cardiomyopathy
Parasite Metazoan
Nephropathy
Cyst
Inflammation
Hyperplasia
Basophilic Focus
Inflammation Chronic
Mixed Cell Focus
Fatty Change
Hypertrophy
Inflammation
Foreign Body
Inflammation
Metaplasia Hepatocyte
Hyperplasia
Fibrosis
Hematopoietic Cell Proliferation
Inflammation
Ulcer
Hyperplasia
Atrophy
Hyperplasia
Cyst
Hyperplasia Cystic

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Adrenal Cortex				
Degeneration Cystic				
LESION RATES				
OVERALL (a)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.34	0/44.61	0/45.55	0/41.46
POLY-3 PERCENT (g)	2.3%	0%	0%	0%
TERMINAL (d)	1/34 (3%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	727 (T)	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.500N	P=0.494N	P=0.490N	P=0.509N
POLY 1.5	P=0.497N	P=0.498N	P=0.492N	P=0.507N
POLY 6	P=0.502N	P=0.490N	P=0.488N	P=0.510N
COCH-ARM / FISHERS	P=0.498N	P=0.495N	P=0.495N	P=0.495N
MAX-ISO-POLY-3	P=0.143N	P=0.157N	P=0.157N	P=0.171N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Adrenal Cortex Hypertrophy				
LESION RATES				
OVERALL (a)	2/49 (4%)	5/50 (10%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	2/43.34	5/44.82	3/45.55	3/42.22
POLY-3 PERCENT (g)	4.6%	11.2%	6.6%	7.1%
TERMINAL (d)	2/34 (6%)	4/35 (11%)	3/34 (9%)	2/31 (7%)
FIRST INCIDENCE	727 (T)	673	727 (T)	454
STATISTICAL TESTS				
POLY 3	P=0.582N	P=0.229	P=0.523	P=0.488
POLY 1.5	P=0.578N	P=0.222	P=0.518	P=0.489
POLY 6	P=0.587N	P=0.240	P=0.527	P=0.487
COCH-ARM / FISHERS	P=0.552N	P=0.226	P=0.510	P=0.510
MAX-ISO-POLY-3	P=0.427	P=0.131	P=0.346	P=0.316

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Adrenal Cortex Necrosis				
LESION RATES				
OVERALL (a)	1/49 (2%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/43.34	1/44.61	1/45.76	1/42.01
POLY-3 PERCENT (g)	2.3%	2.2%	2.2%	2.4%
TERMINAL (d)	1/34 (3%)	1/35 (3%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	727 (T)	727 (T)	673	559
STATISTICAL TESTS				
POLY 3	P=0.658	P=0.754N	P=0.749N	P=0.754
POLY 1.5	P=0.661	P=0.758N	P=0.751N	P=0.754
POLY 6	P=0.654	P=0.749N	P=0.746N	P=0.754
COCH-ARM / FISHERS	P=0.671N	P=0.747N	P=0.747N	P=0.747N
MAX-ISO-POLY-3	P=0.730	P=0.491N	P=0.484N	P=0.490

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Adrenal Cortex: Zona Fasciculata Hyperplasia				
LESION RATES				
OVERALL (a)	8/49 (16%)	6/50 (12%)	9/50 (18%)	13/50 (26%)
POLY-3 RATE (b)	8/43.83	6/44.91	9/46.09	13/44.19
POLY-3 PERCENT (g)	18.3%	13.4%	19.5%	29.4%
TERMINAL (d)	7/34 (21%)	5/35 (14%)	6/34 (18%)	7/31 (23%)
FIRST INCIDENCE	582	646	664	447
STATISTICAL TESTS				
POLY 3	P=0.052	P=0.367N	P=0.546	P=0.163
POLY 1.5	P=0.052	P=0.380N	P=0.535	P=0.156
POLY 6	P=0.053	P=0.351N	P=0.557	P=0.172
COCH-ARM / FISHERS	P=0.061	P=0.371N	P=0.518	P=0.176
MAX-ISO-POLY-3	P=0.084	P=0.266N	P=0.438	P=0.108

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TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Adrenal Medulla Hyperplasia				
LESION RATES				
OVERALL (a)	9/49 (18%)	11/50 (22%)	10/50 (20%)	10/50 (20%)
POLY-3 RATE (b)	9/44.84	11/45.44	10/46.81	10/42.62
POLY-3 PERCENT (g)	20.1%	24.2%	21.4%	23.5%
TERMINAL (d)	5/34 (15%)	6/35 (17%)	6/34 (18%)	6/31 (19%)
FIRST INCIDENCE	545	615	590	589
STATISTICAL TESTS				
POLY 3	P=0.476	P=0.413	P=0.542	P=0.450
POLY 1.5	P=0.493	P=0.403	P=0.533	P=0.461
POLY 6	P=0.458	P=0.428	P=0.547	P=0.441
COCH-ARM / FISHERS	P=0.558	P=0.421	P=0.520	P=0.520
MAX-ISO-POLY-3	P=0.564	P=0.319	P=0.439	P=0.354

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Bone Marrow Hyperplasia				
LESION RATES				
OVERALL (a)	16/49 (33%)	17/50 (34%)	24/50 (48%)	29/50 (58%)
POLY-3 RATE (b)	16/45.46	17/48.23	24/48.54	29/44.64
POLY-3 PERCENT (g)	35.2%	35.3%	49.4%	65%
TERMINAL (d)	9/34 (27%)	7/35 (20%)	13/34 (38%)	19/31 (61%)
FIRST INCIDENCE	511	168	590	451
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.583	P=0.116	P=0.003**
POLY 1.5	P<0.001**	P=0.551	P=0.103	P=0.003**
POLY 6	P<0.001**	P=0.552N	P=0.133	P=0.003**
COCH-ARM / FISHERS	P=0.004**	P=0.528	P=0.088	P=0.010**
MAX-ISO-POLY-3	P=0.002**	P=0.497	P=0.085	P=0.002**

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TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Bone Marrow				
Myelofibrosis				
<hr/>				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.34	0/44.61	0/45.55	0/41.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Brain Hemorrhage				
LESION RATES				
OVERALL (a)	1/49 (2%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/44.01	1/45.00	0/45.55	2/42.23
POLY-3 PERCENT (g)	2.3%	2.2%	0%	4.7%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	1/31 (3%)
FIRST INCIDENCE	504	615	---	447
STATISTICAL TESTS				
POLY 3	P=0.313	P=0.756N	P=0.493N	P=0.486
POLY 1.5	P=0.317	P=0.759N	P=0.494N	P=0.488
POLY 6	P=0.309	P=0.751N	P=0.493N	P=0.483
COCH-ARM / FISHERS	P=0.329	P=0.747N	P=0.495N	P=0.508
MAX-ISO-POLY-3	P=0.268	P=0.493N	P=0.157N	P=0.273

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Brain Necrosis				
LESION RATES				
OVERALL (a)	2/49 (4%)	0/50 (0%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	2/43.84	0/44.61	2/46.00	2/41.67
POLY-3 PERCENT (g)	4.6%	0%	4.4%	4.8%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	1/34 (3%)	1/31 (3%)
FIRST INCIDENCE	629	---	598	673
STATISTICAL TESTS				
POLY 3	P=0.411	P=0.233N	P=0.677N	P=0.676
POLY 1.5	P=0.419	P=0.236N	P=0.680N	P=0.680
POLY 6	P=0.401	P=0.230N	P=0.675N	P=0.671
COCH-ARM / FISHERS	P=0.441	P=0.242N	P=0.684N	P=0.684N
MAX-ISO-POLY-3	P=0.433	P=0.075N	P=0.480N	P=0.479

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Coagulating Gland Inflammation				
LESION RATES				
OVERALL (a)	1/2 (50%)	2/2 (100%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	1/2.00	2/2.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	50%	100%	0%	0%
TERMINAL (d)	0/1 (0%)	2/2 (100%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	545	727 (T)	---	---
STATISTICAL TESTS				
POLY 3	(e)	P=0.500	(e)	(e)
POLY 1.5	(e)	P=0.500	(e)	(e)
POLY 6	(e)	P=0.500	(e)	(e)
COCH-ARM / FISHERS	P=1.000	P=0.500	(e)	(e)
MAX-ISO-POLY-3	(e)	P=0.159	(e)	(e)

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Epididymis Inflammation				
LESION RATES				
OVERALL (a)	1/49 (2%)	4/50 (8%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	1/43.34	4/44.61	3/45.79	2/41.46
POLY-3 PERCENT (g)	2.3%	9%	6.6%	4.8%
TERMINAL (d)	1/34 (3%)	4/35 (11%)	2/34 (6%)	2/31 (7%)
FIRST INCIDENCE	727 (T)	727 (T)	664	727 (T)
STATISTICAL TESTS				
POLY 3	P=0.581N	P=0.187	P=0.325	P=0.485
POLY 1.5	P=0.575N	P=0.182	P=0.320	P=0.487
POLY 6	P=0.588N	P=0.194	P=0.330	P=0.482
COCH-ARM / FISHERS	P=0.544N	P=0.187	P=0.316	P=0.508
MAX-ISO-POLY-3	P=0.318	P=0.091	P=0.173	P=0.272

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Eye: Cornea Inflammation				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/43.34	0/44.61	1/45.97	0/41.46
POLY-3 PERCENT (g)	0%	0%	2.2%	0%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	608	---
STATISTICAL TESTS				
POLY 3	P=0.788N	(e)	P=0.512	(e)
POLY 1.5	P=0.785N	(e)	P=0.509	(e)
POLY 6	P=0.791N	(e)	P=0.515	(e)
COCH-ARM / FISHERS	P=0.778N	(e)	P=0.505	(e)
MAX-ISO-POLY-3	P=0.407	(e)	P=0.172	(e)

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Eye: Iris Inflammation				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/43.34	0/44.61	0/45.55	2/42.28
POLY-3 PERCENT (g)	0%	0%	0%	4.7%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	---	528
STATISTICAL TESTS				
POLY 3	P=0.039*	(e)	(e)	P=0.231
POLY 1.5	P=0.039*	(e)	(e)	P=0.232
POLY 6	P=0.039*	(e)	(e)	P=0.232
COCH-ARM / FISHERS	P=0.043*	(e)	(e)	P=0.253
MAX-ISO-POLY-3	P=0.035*	(e)	(e)	P=0.077

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Eye: Lens				
Cataract				
LESION RATES				
OVERALL (a)	2/49 (4%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/43.34	1/44.61	2/45.55	0/41.46
POLY-3 PERCENT (g)	4.6%	2.2%	4.4%	0%
TERMINAL (d)	2/34 (6%)	1/35 (3%)	2/34 (6%)	0/31 (0%)
FIRST INCIDENCE	727 (T)	727 (T)	727 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.225N	P=0.490N	P=0.676N	P=0.247N
POLY 1.5	P=0.220N	P=0.496N	P=0.680N	P=0.245N
POLY 6	P=0.231N	P=0.482N	P=0.673N	P=0.249N
COCH-ARM / FISHERS	P=0.206N	P=0.492N	P=0.684N	P=0.242N
MAX-ISO-POLY-3	P=0.180N	P=0.273N	P=0.479N	P=0.086N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Eye: Retina Degeneration				
LESION RATES				
OVERALL (a)	6/49 (12%)	6/50 (12%)	10/50 (20%)	16/50 (32%)
POLY-3 RATE (b)	6/43.62	6/44.66	10/45.80	16/41.88
POLY-3 PERCENT (g)	13.8%	13.4%	21.8%	38.2%
TERMINAL (d)	5/34 (15%)	5/35 (14%)	8/34 (24%)	14/31 (45%)
FIRST INCIDENCE	651	714	689	670
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.605N	P=0.235	P=0.008**
POLY 1.5	P=0.002**	P=0.615N	P=0.230	P=0.009**
POLY 6	P<0.001**	P=0.592N	P=0.240	P=0.007**
COCH-ARM / FISHERS	P=0.003**	P=0.606N	P=0.220	P=0.016*
MAX-ISO-POLY-3	P=0.002**	P=0.482N	P=0.164	P=0.004**

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Eye: Retina				
Gliososis				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.34	0/44.61	0/45.55	0/41.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Heart				
Cardiomyopathy				
LESION RATES				
OVERALL (a)	48/49 (98%)	49/50 (98%)	48/50 (96%)	46/50 (92%)
POLY-3 RATE (b)	48/48.33	49/49.95	48/49.79	46/48.00
POLY-3 PERCENT (g)	99.3%	98.1%	96.4%	95.8%
TERMINAL (d)	34/34 (100%)	35/35 (100%)	33/34 (97%)	29/31 (94%)
FIRST INCIDENCE	504	30	454	447
STATISTICAL TESTS				
POLY 3	P=0.263N	P=0.657N	P=0.372N	P=0.320N
POLY 1.5	P=0.306N	P=0.709N	P=0.423N	P=0.384N
POLY 6	P=0.217N	P=0.601N	P=0.339N	P=0.263N
COCH-ARM / FISHERS	P=0.078N	P=0.747	P=0.508N	P=0.187N
MAX-ISO-POLY-3	P=0.220N	P=0.281N	P=0.141N	P=0.125N

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG

Heart: Atrium
Thrombosis

LESION RATES

OVERALL (a)	2/49 (4%)	2/50 (4%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	2/43.69	2/45.27	3/46.02	1/41.61
POLY-3 PERCENT (g)	4.6%	4.4%	6.5%	2.4%
TERMINAL (d)	1/34 (3%)	0/35 (0%)	2/34 (6%)	0/31 (0%)
FIRST INCIDENCE	629	571	590	689

STATISTICAL TESTS

POLY 3	P=0.405N	P=0.681N	P=0.524	P=0.517N
POLY 1.5	P=0.397N	P=0.688N	P=0.518	P=0.513N
POLY 6	P=0.415N	P=0.672N	P=0.528	P=0.521N
COCH-ARM / FISHERS	P=0.368N	P=0.684N	P=0.510	P=0.492N
MAX-ISO-POLY-3	P=0.449N	P=0.485N	P=0.347	P=0.300N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Intestine Large, Colon Parasite Metazoan				
LESION RATES				
OVERALL (a)	7/49 (14%)	2/50 (4%)	5/50 (10%)	2/50 (4%)
POLY-3 RATE (b)	7/43.47	2/44.61	5/46.56	2/41.53
POLY-3 PERCENT (g)	16.1%	4.5%	10.7%	4.8%
TERMINAL (d)	6/34 (18%)	2/35 (6%)	2/34 (6%)	1/31 (3%)
FIRST INCIDENCE	694	727 (T)	608	709
STATISTICAL TESTS				
POLY 3	P=0.172N	P=0.072N	P=0.331N	P=0.089N
POLY 1.5	P=0.165N	P=0.076N	P=0.345N	P=0.087N
POLY 6	P=0.181N	P=0.067N	P=0.316N	P=0.090N
COCH-ARM / FISHERS	P=0.146N	P=0.075N	P=0.365N	P=0.075N
MAX-ISO-POLY-3	P=0.066N	P=0.036N*	P=0.235N	P=0.048N*

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Islets, Pancreatic Hyperplasia				
LESION RATES				
OVERALL (a)	2/49 (4%)	2/50 (4%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	2/43.99	2/44.66	2/46.18	3/41.46
POLY-3 PERCENT (g)	4.6%	4.5%	4.3%	7.2%
TERMINAL (d)	1/34 (3%)	1/35 (3%)	0/34 (0%)	3/31 (10%)
FIRST INCIDENCE	511	714	616	727 (T)
STATISTICAL TESTS				
POLY 3	P=0.364	P=0.689N	P=0.676N	P=0.473
POLY 1.5	P=0.374	P=0.693N	P=0.680N	P=0.480
POLY 6	P=0.354	P=0.683N	P=0.672N	P=0.466
COCH-ARM / FISHERS	P=0.402	P=0.684N	P=0.684N	P=0.510
MAX-ISO-POLY-3	P=0.466	P=0.493N	P=0.479N	P=0.306

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Kidney				
Accumulation, Hyaline Droplet				
LESION RATES				
OVERALL (a)	1/49 (2%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/43.69	0/44.61	1/45.55	2/41.53
POLY-3 PERCENT (g)	2.3%	0%	2.2%	4.8%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	1/34 (3%)	1/31 (3%)
FIRST INCIDENCE	629	---	727 (T)	709
STATISTICAL TESTS				
POLY 3	P=0.222	P=0.496N	P=0.751N	P=0.482
POLY 1.5	P=0.228	P=0.499N	P=0.753N	P=0.486
POLY 6	P=0.216	P=0.493N	P=0.751N	P=0.478
COCH-ARM / FISHERS	P=0.241	P=0.495N	P=0.747N	P=0.508
MAX-ISO-POLY-3	P=0.225	P=0.157N	P=0.487N	P=0.271

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Kidney Infarct				
LESION RATES				
OVERALL (a)	1/49 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/43.34	0/44.61	1/45.55	0/41.46
POLY-3 PERCENT (g)	2.3%	0%	2.2%	0%
TERMINAL (d)	1/34 (3%)	0/35 (0%)	1/34 (3%)	0/31 (0%)
FIRST INCIDENCE	727 (T)	---	727 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.476N	P=0.494N	P=0.750N	P=0.509N
POLY 1.5	P=0.472N	P=0.498N	P=0.752N	P=0.507N
POLY 6	P=0.482N	P=0.490N	P=0.748N	P=0.510N
COCH-ARM / FISHERS	P=0.461N	P=0.495N	P=0.747N	P=0.495N
MAX-ISO-POLY-3	P=0.276N	P=0.157N	P=0.485N	P=0.171N

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Kidney Mineralization				
LESION RATES				
OVERALL (a)	38/49 (78%)	43/50 (86%)	41/50 (82%)	34/50 (68%)
POLY-3 RATE (b)	38/48.07	43/47.78	41/49.32	34/45.59
POLY-3 PERCENT (g)	79.1%	90%	83.1%	74.6%
TERMINAL (d)	26/34 (77%)	31/35 (89%)	27/34 (79%)	24/31 (77%)
FIRST INCIDENCE	504	525	454	451
STATISTICAL TESTS				
POLY 3	P=0.127N	P=0.111	P=0.398	P=0.392N
POLY 1.5	P=0.100N	P=0.107	P=0.392	P=0.351N
POLY 6	P=0.174N	P=0.121	P=0.404	P=0.448N
COCH-ARM / FISHERS	P=0.042N*	P=0.204	P=0.382	P=0.200N
MAX-ISO-POLY-3	P=0.176N	P=0.067	P=0.303	P=0.305N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Kidney				
Nephropathy				
LESION RATES				
OVERALL (a)	46/49 (94%)	47/50 (94%)	48/50 (96%)	48/50 (96%)
POLY-3 RATE (b)	46/48.33	47/48.01	48/50.00	48/48.00
POLY-3 PERCENT (g)	95.2%	97.9%	96%	100%
TERMINAL (d)	32/34 (94%)	34/35 (97%)	32/34 (94%)	31/31 (100%)
FIRST INCIDENCE	504	525	454	447
STATISTICAL TESTS				
POLY 3	P=0.175	P=0.430	P=0.616	P=0.177
POLY 1.5	P=0.151	P=0.404	P=0.569	P=0.151
POLY 6	P=0.197	P=0.475	P=0.659	P=0.215
COCH-ARM / FISHERS	P=0.412	P=0.651	P=0.490	P=0.490
MAX-ISO-POLY-3	P=0.116	P=0.229	P=0.419	P=0.053

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Kidney: Cortex Cyst				
LESION RATES				
OVERALL (a)	1/49 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/43.34	0/44.61	0/45.55	1/41.46
POLY-3 PERCENT (g)	2.3%	0%	0%	2.4%
TERMINAL (d)	1/34 (3%)	0/35 (0%)	0/34 (0%)	1/31 (3%)
FIRST INCIDENCE	727 (T)	---	---	727 (T)
STATISTICAL TESTS				
POLY 3	P=0.524	P=0.494N	P=0.490N	P=0.751
POLY 1.5	P=0.528	P=0.498N	P=0.492N	P=0.753
POLY 6	P=0.518	P=0.490N	P=0.488N	P=0.749
COCH-ARM / FISHERS	P=0.539	P=0.495N	P=0.495N	P=0.747N
MAX-ISO-POLY-3	P=0.398	P=0.157N	P=0.157N	P=0.487

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Kidney: Pelvis Inflammation				
LESION RATES				
OVERALL (a)	1/49 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/43.92	0/44.61	0/45.55	1/41.68
POLY-3 PERCENT (g)	2.3%	0%	0%	2.4%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	545	---	---	670
STATISTICAL TESTS				
POLY 3	P=0.525	P=0.497N	P=0.493N	P=0.749
POLY 1.5	P=0.529	P=0.499N	P=0.494N	P=0.751
POLY 6	P=0.520	P=0.494N	P=0.492N	P=0.747
COCH-ARM / FISHERS	P=0.539	P=0.495N	P=0.495N	P=0.747N
MAX-ISO-POLY-3	P=0.398	P=0.157N	P=0.157N	P=0.485

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Kidney: Pelvis, Transitional Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	0/49 (0%)	1/50 (2%)	1/50 (2%)	15/50 (30%)
POLY-3 RATE (b)	0/43.34	1/44.61	1/45.55	15/42.91
POLY-3 PERCENT (g)	0%	2.2%	2.2%	35%
TERMINAL (d)	0/34 (0%)	1/35 (3%)	1/34 (3%)	9/31 (29%)
FIRST INCIDENCE	---	727 (T)	727 (T)	589
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.506	P=0.510	P<0.001**
POLY 1.5	P<0.001**	P=0.502	P=0.508	P<0.001**
POLY 6	P<0.001**	P=0.510	P=0.512	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.505	P=0.505	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.164	P=0.170	P<0.001**

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Kidney: Renal Tubule Necrosis				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.34	0/44.61	0/45.55	0/41.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Angiectasis				
LESION RATES				
OVERALL (a)	0/49 (0%)	1/50 (2%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/43.34	1/44.61	2/45.55	1/41.46
POLY-3 PERCENT (g)	0%	2.2%	4.4%	2.4%
TERMINAL (d)	0/34 (0%)	1/35 (3%)	2/34 (6%)	1/31 (3%)
FIRST INCIDENCE	---	727 (T)	727 (T)	727 (T)
STATISTICAL TESTS				
POLY 3	P=0.497	P=0.506	P=0.248	P=0.491
POLY 1.5	P=0.503	P=0.502	P=0.246	P=0.493
POLY 6	P=0.490	P=0.510	P=0.250	P=0.490
COCH-ARM / FISHERS	P=0.529	P=0.505	P=0.253	P=0.505
MAX-ISO-POLY-3	P=0.252	P=0.164	P=0.086	P=0.160

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Basophilic Focus				
LESION RATES				
OVERALL (a)	21/49 (43%)	30/50 (60%)	18/50 (36%)	13/50 (26%)
POLY-3 RATE (b)	21/43.92	30/45.47	18/46.05	13/41.74
POLY-3 PERCENT (g)	47.8%	66%	39.1%	31.2%
TERMINAL (d)	20/34 (59%)	25/35 (71%)	15/34 (44%)	11/31 (36%)
FIRST INCIDENCE	545	646	664	673
STATISTICAL TESTS				
POLY 3	P=0.007N**	P=0.057	P=0.264N	P=0.083N
POLY 1.5	P=0.006N**	P=0.050*	P=0.284N	P=0.081N
POLY 6	P=0.007N**	P=0.074	P=0.242N	P=0.082N
COCH-ARM / FISHERS	P=0.004N**	P=0.066	P=0.311N	P=0.060N
MAX-ISO-POLY-3	P=0.011N*	P=0.037*	P=0.203N	P=0.058N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Clear Cell Focus				
LESION RATES				
OVERALL (a)	18/49 (37%)	25/50 (50%)	25/50 (50%)	11/50 (22%)
POLY-3 RATE (b)	18/43.34	25/44.91	25/45.69	11/42.01
POLY-3 PERCENT (g)	41.5%	55.7%	54.7%	26.2%
TERMINAL (d)	18/34 (53%)	24/35 (69%)	24/34 (71%)	10/31 (32%)
FIRST INCIDENCE	727 (T)	646	694	556
STATISTICAL TESTS				
POLY 3	P=0.011N*	P=0.126	P=0.144	P=0.098N
POLY 1.5	P=0.011N*	P=0.113	P=0.138	P=0.101N
POLY 6	P=0.011N*	P=0.147	P=0.147	P=0.093N
COCH-ARM / FISHERS	P=0.008N**	P=0.129	P=0.129	P=0.082N
MAX-ISO-POLY-3	P=0.017N*	P=0.089	P=0.105	P=0.067N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Degeneration Cystic				
LESION RATES				
OVERALL (a)	0/49 (0%)	4/50 (8%)	3/50 (6%)	5/50 (10%)
POLY-3 RATE (b)	0/43.34	4/44.61	3/46.43	5/42.42
POLY-3 PERCENT (g)	0%	9%	6.5%	11.8%
TERMINAL (d)	0/34 (0%)	4/35 (11%)	0/34 (0%)	1/31 (3%)
FIRST INCIDENCE	---	727 (T)	608	556
STATISTICAL TESTS				
POLY 3	P=0.080	P=0.064	P=0.131	P=0.028*
POLY 1.5	P=0.081	P=0.062	P=0.128	P=0.028*
POLY 6	P=0.081	P=0.066	P=0.135	P=0.029*
COCH-ARM / FISHERS	P=0.094	P=0.061	P=0.125	P=0.030*
MAX-ISO-POLY-3	P=0.027*	P=0.022*	P=0.048*	P=0.010**

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Eosinophilic Focus				
LESION RATES				
OVERALL (a)	15/49 (31%)	18/50 (36%)	14/50 (28%)	13/50 (26%)
POLY-3 RATE (b)	15/43.50	18/44.84	14/46.52	13/42.54
POLY-3 PERCENT (g)	34.5%	40.1%	30.1%	30.6%
TERMINAL (d)	14/34 (41%)	17/35 (49%)	10/34 (29%)	10/31 (32%)
FIRST INCIDENCE	686	666	616	556
STATISTICAL TESTS				
POLY 3	P=0.299N	P=0.370	P=0.413N	P=0.437N
POLY 1.5	P=0.294N	P=0.347	P=0.439N	P=0.440N
POLY 6	P=0.301N	P=0.400	P=0.384N	P=0.428N
COCH-ARM / FISHERS	P=0.244N	P=0.361	P=0.474N	P=0.387N
MAX-ISO-POLY-3	P=0.404N	P=0.292	P=0.332N	P=0.349N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Fatty Change Diffuse				
LESION RATES				
OVERALL (a)	11/49 (22%)	8/50 (16%)	12/50 (24%)	8/50 (16%)
POLY-3 RATE (b)	11/46.20	8/45.70	12/46.52	8/42.85
POLY-3 PERCENT (g)	23.8%	17.5%	25.8%	18.7%
TERMINAL (d)	5/34 (15%)	4/35 (11%)	8/34 (24%)	3/31 (10%)
FIRST INCIDENCE	504	525	598	559
STATISTICAL TESTS				
POLY 3	P=0.417N	P=0.313N	P=0.508	P=0.370N
POLY 1.5	P=0.395N	P=0.315N	P=0.514	P=0.353N
POLY 6	P=0.437N	P=0.308N	P=0.499	P=0.385N
COCH-ARM / FISHERS	P=0.329N	P=0.288N	P=0.522	P=0.288N
MAX-ISO-POLY-3	P=0.462N	P=0.231N	P=0.411	P=0.286N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Hematopoietic Cell Proliferation				
LESION RATES				
OVERALL (a)	3/49 (6%)	3/50 (6%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	3/44.15	3/45.25	1/45.55	0/41.46
POLY-3 PERCENT (g)	6.8%	6.6%	2.2%	0%
TERMINAL (d)	1/34 (3%)	0/35 (0%)	1/34 (3%)	0/31 (0%)
FIRST INCIDENCE	511	571	727 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.078N	P=0.651N	P=0.294N	P=0.130N
POLY 1.5	P=0.075N	P=0.658N	P=0.295N	P=0.127N
POLY 6	P=0.081N	P=0.641N	P=0.294N	P=0.133N
COCH-ARM / FISHERS	P=0.068N	P=0.651N	P=0.301N	P=0.117N
MAX-ISO-POLY-3	P=0.100N	P=0.487N	P=0.148N	P=0.048N*

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Hepatodiaphragmatic Nodule				
LESION RATES				
OVERALL (a)	2/49 (4%)	7/50 (14%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	2/43.75	7/44.66	4/45.81	1/41.81
POLY-3 PERCENT (g)	4.6%	15.7%	8.7%	2.4%
TERMINAL (d)	1/34 (3%)	6/35 (17%)	2/34 (6%)	0/31 (0%)
FIRST INCIDENCE	610	714	689	629
STATISTICAL TESTS				
POLY 3	P=0.138N	P=0.083	P=0.358	P=0.516N
POLY 1.5	P=0.135N	P=0.080	P=0.354	P=0.513N
POLY 6	P=0.141N	P=0.086	P=0.362	P=0.519N
COCH-ARM / FISHERS	P=0.117N	P=0.085	P=0.349	P=0.492N
MAX-ISO-POLY-3	P=0.160N	P=0.041*	P=0.221	P=0.298N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Inflammation Chronic				
LESION RATES				
OVERALL (a)	36/49 (73%)	39/50 (78%)	32/50 (64%)	34/50 (68%)
POLY-3 RATE (b)	36/44.82	39/46.00	32/46.96	34/45.25
POLY-3 PERCENT (g)	80.3%	84.8%	68.1%	75.1%
TERMINAL (d)	32/34 (94%)	33/35 (94%)	27/34 (79%)	26/31 (84%)
FIRST INCIDENCE	504	571	598	447
STATISTICAL TESTS				
POLY 3	P=0.249N	P=0.378	P=0.122N	P=0.359N
POLY 1.5	P=0.278N	P=0.323	P=0.159N	P=0.409N
POLY 6	P=0.220N	P=0.486	P=0.082N	P=0.293N
COCH-ARM / FISHERS	P=0.243N	P=0.385	P=0.212N	P=0.353N
MAX-ISO-POLY-3	P=0.151N	P=0.272	P=0.081N	P=0.263N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Mixed Cell Focus				
LESION RATES				
OVERALL (a)	4/49 (8%)	5/50 (10%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	4/44.05	5/44.89	4/46.41	0/41.46
POLY-3 PERCENT (g)	9.1%	11.1%	8.6%	0%
TERMINAL (d)	2/34 (6%)	3/35 (9%)	2/34 (6%)	0/31 (0%)
FIRST INCIDENCE	545	666	598	---
STATISTICAL TESTS				
POLY 3	P=0.041N*	P=0.512	P=0.614N	P=0.068N
POLY 1.5	P=0.039N*	P=0.503	P=0.621N	P=0.066N
POLY 6	P=0.044N*	P=0.523	P=0.608N	P=0.070N
COCH-ARM / FISHERS	P=0.032N*	P=0.513	P=0.631N	P=0.056N
MAX-ISO-POLY-3	P=0.067N	P=0.374	P=0.469N	P=0.026N*

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Necrosis				
LESION RATES				
OVERALL (a)	1/49 (2%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/43.54	2/44.61	0/45.55	1/41.46
POLY-3 PERCENT (g)	2.3%	4.5%	0%	2.4%
TERMINAL (d)	0/34 (0%)	2/35 (6%)	0/34 (0%)	1/31 (3%)
FIRST INCIDENCE	675	727 (T)	---	727 (T)
STATISTICAL TESTS				
POLY 3	P=0.588N	P=0.508	P=0.491N	P=0.750
POLY 1.5	P=0.586N	P=0.503	P=0.493N	P=0.752
POLY 6	P=0.590N	P=0.515	P=0.490N	P=0.747
COCH-ARM / FISHERS	P=0.573N	P=0.508	P=0.495N	P=0.747N
MAX-ISO-POLY-3	P=0.409N	P=0.289	P=0.157N	P=0.486

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Pigmentation Hemosiderin				
LESION RATES				
OVERALL (a)	1/49 (2%)	0/50 (0%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	1/43.69	0/44.61	2/45.66	2/41.78
POLY-3 PERCENT (g)	2.3%	0%	4.4%	4.8%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	1/34 (3%)	1/31 (3%)
FIRST INCIDENCE	629	---	701	640
STATISTICAL TESTS				
POLY 3	P=0.260	P=0.496N	P=0.515	P=0.484
POLY 1.5	P=0.266	P=0.499N	P=0.512	P=0.487
POLY 6	P=0.254	P=0.493N	P=0.517	P=0.482
COCH-ARM / FISHERS	P=0.285	P=0.495N	P=0.508	P=0.508
MAX-ISO-POLY-3	P=0.268	P=0.157N	P=0.296	P=0.272

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver: Bile Duct Hyperplasia				
LESION RATES				
OVERALL (a)	32/49 (65%)	39/50 (78%)	40/50 (80%)	34/50 (68%)
POLY-3 RATE (b)	32/46.31	39/46.13	40/48.37	34/45.34
POLY-3 PERCENT (g)	69.1%	84.6%	82.7%	75%
TERMINAL (d)	24/34 (71%)	30/35 (86%)	29/34 (85%)	22/31 (71%)
FIRST INCIDENCE	504	615	590	447
STATISTICAL TESTS				
POLY 3	P=0.514N	P=0.056	P=0.087	P=0.343
POLY 1.5	P=0.508N	P=0.059	P=0.081	P=0.346
POLY 6	P=0.510N	P=0.057	P=0.094	P=0.351
COCH-ARM / FISHERS	P=0.379N	P=0.119	P=0.078	P=0.472
MAX-ISO-POLY-3	P=0.135	P=0.033*	P=0.056	P=0.263

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver: Centrilobular Fatty Change				
LESION RATES				
OVERALL (a)	1/49 (2%)	7/50 (14%)	4/50 (8%)	21/50 (42%)
POLY-3 RATE (b)	1/43.50	7/44.61	4/45.95	21/42.62
POLY-3 PERCENT (g)	2.3%	15.7%	8.7%	49.3%
TERMINAL (d)	0/34 (0%)	7/35 (20%)	3/34 (9%)	19/31 (61%)
FIRST INCIDENCE	686	727 (T)	616	528
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.032*	P=0.195	P<0.001**
POLY 1.5	P<0.001**	P=0.031*	P=0.192	P<0.001**
POLY 6	P<0.001**	P=0.034*	P=0.199	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.032*	P=0.187	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.013*	P=0.098	P<0.001**

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver: Centrilobular Necrosis				
LESION RATES				
OVERALL (a)	0/49 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/43.34	2/45.12	0/45.55	1/41.68
POLY-3 PERCENT (g)	0%	4.4%	0%	2.4%
TERMINAL (d)	0/34 (0%)	1/35 (3%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	571	---	670
STATISTICAL TESTS				
POLY 3	P=0.604	P=0.246	(e)	P=0.492
POLY 1.5	P=0.604	P=0.241	(e)	P=0.493
POLY 6	P=0.604	P=0.253	(e)	P=0.492
COCH-ARM / FISHERS	P=0.620	P=0.253	(e)	P=0.505
MAX-ISO-POLY-3	P=0.335	P=0.083	(e)	P=0.160

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver: Hepatocyte Hypertrophy				
LESION RATES				
OVERALL (a)	0/49 (0%)	2/50 (4%)	2/50 (4%)	22/50 (44%)
POLY-3 RATE (b)	0/43.34	2/44.61	2/45.55	22/44.64
POLY-3 PERCENT (g)	0%	4.5%	4.4%	49.3%
TERMINAL (d)	0/34 (0%)	2/35 (6%)	2/34 (6%)	15/31 (48%)
FIRST INCIDENCE	---	727 (T)	727 (T)	30
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.243	P=0.248	P<0.001**
POLY 1.5	P<0.001**	P=0.240	P=0.246	P<0.001**
POLY 6	P<0.001**	P=0.248	P=0.250	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.253	P=0.253	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.081	P=0.086	P<0.001**

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver: Oval Cell Hyperplasia				
LESION RATES				
OVERALL (a)	0/49 (0%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/43.34	2/45.06	1/45.55	1/41.46
POLY-3 PERCENT (g)	0%	4.4%	2.2%	2.4%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	1/34 (3%)	1/31 (3%)
FIRST INCIDENCE	---	615	727 (T)	727 (T)
STATISTICAL TESTS				
POLY 3	P=0.604	P=0.246	P=0.510	P=0.491
POLY 1.5	P=0.608	P=0.241	P=0.508	P=0.493
POLY 6	P=0.600	P=0.252	P=0.512	P=0.490
COCH-ARM / FISHERS	P=0.630	P=0.253	P=0.505	P=0.505
MAX-ISO-POLY-3	P=0.302	P=0.083	P=0.170	P=0.160

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lung				
Inflammation Chronic				
LESION RATES				
OVERALL (a)	6/49 (12%)	3/50 (6%)	9/50 (18%)	9/50 (18%)
POLY-3 RATE (b)	6/44.59	3/44.71	9/46.00	9/42.01
POLY-3 PERCENT (g)	13.5%	6.7%	19.6%	21.4%
TERMINAL (d)	3/34 (9%)	1/35 (3%)	6/34 (18%)	6/31 (19%)
FIRST INCIDENCE	582	714	664	670
STATISTICAL TESTS				
POLY 3	P=0.090	P=0.240N	P=0.309	P=0.244
POLY 1.5	P=0.099	P=0.244N	P=0.308	P=0.255
POLY 6	P=0.083	P=0.237N	P=0.307	P=0.233
COCH-ARM / FISHERS	P=0.127	P=0.233N	P=0.303	P=0.303
MAX-ISO-POLY-3	P=0.127	P=0.146N	P=0.220	P=0.173

TDMS No. 20007 - 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 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lung				
Inflammation Granulomatous				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	0/43.34	0/44.61	0/45.55	3/41.69
POLY-3 PERCENT (g)	0%	0%	0%	7.2%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	2/31 (7%)
FIRST INCIDENCE	---	---	---	665
STATISTICAL TESTS				
POLY 3	P=0.007**	(e)	(e)	P=0.111
POLY 1.5	P=0.007**	(e)	(e)	P=0.113
POLY 6	P=0.007**	(e)	(e)	P=0.111
COCH-ARM / FISHERS	P=0.009**	(e)	(e)	P=0.125
MAX-ISO-POLY-3	P=0.010**	(e)	(e)	P=0.038*

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lung Necrosis				
LESION RATES				
OVERALL (a)	2/49 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/43.84	0/44.61	0/45.55	0/41.46
POLY-3 PERCENT (g)	4.6%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	629	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.262N	P=0.233N	P=0.229N	P=0.250N
POLY 1.5	P=0.259N	P=0.236N	P=0.230N	P=0.247N
POLY 6	P=0.264N	P=0.230N	P=0.229N	P=0.254N
COCH-ARM / FISHERS	P=0.260N	P=0.242N	P=0.242N	P=0.242N
MAX-ISO-POLY-3	P=0.045N*	P=0.075N	P=0.075N	P=0.089N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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Kava kava extract
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lung: Alveolar Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	19/49 (39%)	13/50 (26%)	20/50 (40%)	15/50 (30%)
POLY-3 RATE (b)	19/44.71	13/44.79	20/46.58	15/42.35
POLY-3 PERCENT (g)	42.5%	29%	42.9%	35.4%
TERMINAL (d)	16/34 (47%)	12/35 (34%)	15/34 (44%)	13/31 (42%)
FIRST INCIDENCE	504	679	608	454
STATISTICAL TESTS				
POLY 3	P=0.470N	P=0.131N	P=0.567	P=0.322N
POLY 1.5	P=0.443N	P=0.139N	P=0.552	P=0.308N
POLY 6	P=0.504N	P=0.119N	P=0.586N	P=0.339N
COCH-ARM / FISHERS	P=0.362N	P=0.126N	P=0.532	P=0.240N
MAX-ISO-POLY-3	P=0.411N	P=0.090N	P=0.482	P=0.254N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lung: Alveolar Epithelium Hypertrophy				
LESION RATES				
OVERALL (a)	2/49 (4%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/43.75	0/44.61	2/45.90	1/41.46
POLY-3 PERCENT (g)	4.6%	0%	4.4%	2.4%
TERMINAL (d)	1/34 (3%)	0/35 (0%)	0/34 (0%)	1/31 (3%)
FIRST INCIDENCE	610	---	664	727 (T)
STATISTICAL TESTS				
POLY 3	P=0.613N	P=0.233N	P=0.677N	P=0.519N
POLY 1.5	P=0.605N	P=0.236N	P=0.680N	P=0.514N
POLY 6	P=0.622N	P=0.229N	P=0.674N	P=0.524N
COCH-ARM / FISHERS	P=0.588N	P=0.242N	P=0.684N	P=0.492N
MAX-ISO-POLY-3	P=0.438N	P=0.075N	P=0.480N	P=0.302N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lung: Alveolar Epithelium Metaplasia				
LESION RATES				
OVERALL (a)	1/49 (2%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/43.34	1/44.61	2/46.07	0/41.46
POLY-3 PERCENT (g)	2.3%	2.2%	4.3%	0%
TERMINAL (d)	1/34 (3%)	1/35 (3%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	727 (T)	727 (T)	608	---
STATISTICAL TESTS				
POLY 3	P=0.346N	P=0.754N	P=0.521	P=0.509N
POLY 1.5	P=0.341N	P=0.758N	P=0.516	P=0.507N
POLY 6	P=0.352N	P=0.749N	P=0.527	P=0.510N
COCH-ARM / FISHERS	P=0.322N	P=0.747N	P=0.508	P=0.495N
MAX-ISO-POLY-3	P=0.308N	P=0.491N	P=0.303	P=0.171N

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

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First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lung: Alveolus Infiltration Cellular Histiocyte				
LESION RATES				
OVERALL (a)	8/49 (16%)	3/50 (6%)	11/50 (22%)	9/50 (18%)
POLY-3 RATE (b)	8/43.47	3/44.79	11/45.66	9/41.83
POLY-3 PERCENT (g)	18.4%	6.7%	24.1%	21.5%
TERMINAL (d)	7/34 (21%)	2/35 (6%)	10/34 (29%)	7/31 (23%)
FIRST INCIDENCE	694	679	701	670
STATISTICAL TESTS				
POLY 3	P=0.192	P=0.088N	P=0.346	P=0.465
POLY 1.5	P=0.206	P=0.094N	P=0.337	P=0.470
POLY 6	P=0.179	P=0.081N	P=0.351	P=0.462
COCH-ARM / FISHERS	P=0.250	P=0.094N	P=0.323	P=0.518
MAX-ISO-POLY-3	P=0.178	P=0.048N*	P=0.260	P=0.362

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lymph Node, Mesenteric Atrophy				
LESION RATES				
OVERALL (a)	2/49 (4%)	2/50 (4%)	0/50 (0%)	5/50 (10%)
POLY-3 RATE (b)	2/43.50	2/44.82	0/45.55	5/42.09
POLY-3 PERCENT (g)	4.6%	4.5%	0%	11.9%
TERMINAL (d)	1/34 (3%)	1/35 (3%)	0/34 (0%)	2/31 (7%)
FIRST INCIDENCE	686	673	---	629
STATISTICAL TESTS				
POLY 3	P=0.061	P=0.683N	P=0.227N	P=0.202
POLY 1.5	P=0.063	P=0.690N	P=0.229N	P=0.204
POLY 6	P=0.060	P=0.675N	P=0.226N	P=0.202
COCH-ARM / FISHERS	P=0.071	P=0.684N	P=0.242N	P=0.226
MAX-ISO-POLY-3	P=0.055	P=0.487N	P=0.075N	P=0.114

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lymph Node, Mesenteric Inflammation				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.34	0/44.61	0/45.55	0/41.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lymph Node: Mediastinal Hyperplasia Lymphoid				
LESION RATES				
OVERALL (a)	3/4 (75%)	0/3 (0%)	0/2 (0%)	1/5 (20%)
POLY-3 RATE (b)	3/4.00	0/2.55	0/1.59	1/4.82
POLY-3 PERCENT (g)	75%	0%	0%	20.8%
TERMINAL (d)	3/4 (75%)	0/1 (0%)	0/1 (0%)	1/4 (25%)
FIRST INCIDENCE	727 (T)	---	---	727 (T)
STATISTICAL TESTS				
POLY 3	P=0.245N	P=0.097N	P=0.246N	P=0.162N
POLY 1.5	P=0.269N	P=0.078N	P=0.203N	P=0.157N
POLY 6	P=0.215N	P=0.135N	P=0.316N	P=0.173N
COCH-ARM / FISHERS	P=0.326N	P=0.114N	P=0.200N	P=0.167N
MAX-ISO-POLY-3	P=0.017N*	P=0.023N*	P=0.089N	P=0.050N*

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

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 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Mammary Gland Hyperplasia				
LESION RATES				
OVERALL (a)	1/48 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.01	0/44.61	0/45.55	0/41.46
POLY-3 PERCENT (g)	2.3%	0%	0%	0%
TERMINAL (d)	1/34 (3%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	727 (T)	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.495N	P=0.493N	P=0.489N	P=0.507N
POLY 1.5	P=0.494N	P=0.495N	P=0.490N	P=0.505N
POLY 6	P=0.497N	P=0.489N	P=0.488N	P=0.510N
COCH-ARM / FISHERS	P=0.496N	P=0.490N	P=0.490N	P=0.490N
MAX-ISO-POLY-3	P=0.141N	P=0.156N	P=0.156N	P=0.170N

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

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Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Mesentery: Fat Necrosis				
LESION RATES				
OVERALL (a)	4/6 (67%)	7/8 (88%)	6/7 (86%)	5/6 (83%)
POLY-3 RATE (b)	4/5.52	7/7.49	6/6.54	5/6.00
POLY-3 PERCENT (g)	72.5%	93.5%	91.8%	83.3%
TERMINAL (d)	2/2 (100%)	4/4 (100%)	4/4 (100%)	4/5 (80%)
FIRST INCIDENCE	504	615	598	559
STATISTICAL TESTS				
POLY 3	P=0.713N	P=0.383	P=0.447	P=0.603
POLY 1.5	P=0.640	P=0.382	P=0.440	P=0.552
POLY 6	P=0.627N	P=0.427	P=0.494	P=0.699
COCH-ARM / FISHERS	P=0.554	P=0.385	P=0.437	P=0.500
MAX-ISO-POLY-3	P=0.305	P=0.136	P=0.174	P=0.337

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Nose				
Foreign Body				
LESION RATES				
OVERALL (a)	1/49 (2%)	4/50 (8%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/44.01	4/44.61	1/45.55	2/41.67
POLY-3 PERCENT (g)	2.3%	9%	2.2%	4.8%
TERMINAL (d)	0/34 (0%)	4/35 (11%)	1/34 (3%)	1/31 (3%)
FIRST INCIDENCE	504	727 (T)	727 (T)	673
STATISTICAL TESTS				
POLY 3	P=0.617N	P=0.182	P=0.753N	P=0.481
POLY 1.5	P=0.612N	P=0.179	P=0.754N	P=0.485
POLY 6	P=0.620N	P=0.187	P=0.753N	P=0.478
COCH-ARM / FISHERS	P=0.586N	P=0.187	P=0.747N	P=0.508
MAX-ISO-POLY-3	P=0.419	P=0.086	P=0.489N	P=0.271

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Nose Inflammation				
LESION RATES				
OVERALL (a)	18/49 (37%)	14/50 (28%)	10/50 (20%)	18/50 (36%)
POLY-3 RATE (b)	18/45.50	14/45.68	10/46.16	18/44.90
POLY-3 PERCENT (g)	39.6%	30.7%	21.7%	40.1%
TERMINAL (d)	13/34 (38%)	10/35 (29%)	7/34 (21%)	10/31 (32%)
FIRST INCIDENCE	504	571	630	447
STATISTICAL TESTS				
POLY 3	P=0.317	P=0.250N	P=0.048N*	P=0.565
POLY 1.5	P=0.318	P=0.260N	P=0.049N*	P=0.559
POLY 6	P=0.317	P=0.238N	P=0.050N*	P=0.573
COCH-ARM / FISHERS	P=0.354	P=0.238N	P=0.052N	P=0.553N
MAX-ISO-POLY-3	P=0.274	P=0.186N	P=0.029N*	P=0.478

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Nose: Olfactory Epithelium Metaplasia				
LESION RATES				
OVERALL (a)	2/49 (4%)	1/50 (2%)	3/50 (6%)	5/50 (10%)
POLY-3 RATE (b)	2/43.34	1/44.61	3/45.55	5/43.20
POLY-3 PERCENT (g)	4.6%	2.2%	6.6%	11.6%
TERMINAL (d)	2/34 (6%)	1/35 (3%)	3/34 (9%)	1/31 (3%)
FIRST INCIDENCE	727 (T)	727 (T)	727 (T)	528
STATISTICAL TESTS				
POLY 3	P=0.072	P=0.490N	P=0.523	P=0.214
POLY 1.5	P=0.072	P=0.496N	P=0.518	P=0.211
POLY 6	P=0.072	P=0.482N	P=0.527	P=0.220
COCH-ARM / FISHERS	P=0.079	P=0.492N	P=0.510	P=0.226
MAX-ISO-POLY-3	P=0.097	P=0.273N	P=0.346	P=0.119

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Nose: Respiratory Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	1/49 (2%)	3/50 (6%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	1/43.34	3/44.87	1/45.55	4/41.93
POLY-3 PERCENT (g)	2.3%	6.7%	2.2%	9.5%
TERMINAL (d)	1/34 (3%)	1/35 (3%)	1/34 (3%)	3/31 (10%)
FIRST INCIDENCE	727 (T)	679	727 (T)	589
STATISTICAL TESTS				
POLY 3	P=0.154	P=0.318	P=0.750N	P=0.168
POLY 1.5	P=0.156	P=0.310	P=0.752N	P=0.170
POLY 6	P=0.151	P=0.328	P=0.748N	P=0.167
COCH-ARM / FISHERS	P=0.172	P=0.316	P=0.747N	P=0.187
MAX-ISO-POLY-3	P=0.115	P=0.166	P=0.485N	P=0.081

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Pancreas Atrophy				
LESION RATES				
OVERALL (a)	16/49 (33%)	13/50 (26%)	18/50 (36%)	18/50 (36%)
POLY-3 RATE (b)	16/44.94	13/45.20	18/46.76	18/43.12
POLY-3 PERCENT (g)	35.6%	28.8%	38.5%	41.8%
TERMINAL (d)	11/34 (32%)	11/35 (31%)	13/34 (38%)	11/31 (36%)
FIRST INCIDENCE	582	571	608	559
STATISTICAL TESTS				
POLY 3	P=0.202	P=0.319N	P=0.472	P=0.354
POLY 1.5	P=0.217	P=0.328N	P=0.463	P=0.365
POLY 6	P=0.193	P=0.312N	P=0.476	P=0.347
COCH-ARM / FISHERS	P=0.283	P=0.306N	P=0.445	P=0.445
MAX-ISO-POLY-3	P=0.295	P=0.244N	P=0.387	P=0.281

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Pancreas Inflammation				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/43.34	0/44.61	2/45.65	1/41.46
POLY-3 PERCENT (g)	0%	0%	4.4%	2.4%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	1/34 (3%)	1/31 (3%)
FIRST INCIDENCE	---	---	702	727 (T)
STATISTICAL TESTS				
POLY 3	P=0.356	(e)	P=0.249	P=0.491
POLY 1.5	P=0.363	(e)	P=0.246	P=0.493
POLY 6	P=0.348	(e)	P=0.251	P=0.490
COCH-ARM / FISHERS	P=0.386	(e)	P=0.253	P=0.505
MAX-ISO-POLY-3	P=0.196	(e)	P=0.086	P=0.160

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Pancreas: Acinus Hyperplasia				
LESION RATES				
OVERALL (a)	6/49 (12%)	9/50 (18%)	9/50 (18%)	2/50 (4%)
POLY-3 RATE (b)	6/43.50	9/44.61	9/46.14	2/41.81
POLY-3 PERCENT (g)	13.8%	20.2%	19.5%	4.8%
TERMINAL (d)	5/34 (15%)	9/35 (26%)	7/34 (21%)	1/31 (3%)
FIRST INCIDENCE	686	727 (T)	630	629
STATISTICAL TESTS				
POLY 3	P=0.056N	P=0.304	P=0.330	P=0.145N
POLY 1.5	P=0.053N	P=0.294	P=0.319	P=0.144N
POLY 6	P=0.058N	P=0.317	P=0.341	P=0.146N
COCH-ARM / FISHERS	P=0.043N*	P=0.303	P=0.303	P=0.128N
MAX-ISO-POLY-3	P=0.079N	P=0.215	P=0.241	P=0.081N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Pancreas: Acinus Metaplasia Hepatocyte				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	6/50 (12%)
POLY-3 RATE (b)	0/43.34	0/44.61	0/45.55	6/41.65
POLY-3 PERCENT (g)	0%	0%	0%	14.4%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	5/31 (16%)
FIRST INCIDENCE	---	---	---	679
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	(e)	P=0.013*
POLY 1.5	P<0.001**	(e)	(e)	P=0.013*
POLY 6	P<0.001**	(e)	(e)	P=0.013*
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.014*
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P=0.005**

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Parathyroid Gland Hyperplasia				
LESION RATES				
OVERALL (a)	1/49 (2%)	0/50 (0%)	1/48 (2%)	10/50 (20%)
POLY-3 RATE (b)	1/44.01	0/44.61	1/43.87	10/42.56
POLY-3 PERCENT (g)	2.3%	0%	2.3%	23.5%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/33 (0%)	6/31 (19%)
FIRST INCIDENCE	504	---	701	559
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.497N	P=0.760	P=0.003**
POLY 1.5	P<0.001**	P=0.500N	P=0.758	P=0.003**
POLY 6	P<0.001**	P=0.494N	P=0.760N	P=0.003**
COCH-ARM / FISHERS	P<0.001**	P=0.495N	P=0.747	P=0.004**
MAX-ISO-POLY-3	P<0.001**	P=0.157N	P=0.498	P<0.001**

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Pituitary Gland: Pars Distalis Angiectasis				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/43.34	0/44.61	1/45.55	0/41.46
POLY-3 PERCENT (g)	0%	0%	2.2%	0%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	1/34 (3%)	0/31 (0%)
FIRST INCIDENCE	---	---	727 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.788N	(e)	P=0.510	(e)
POLY 1.5	P=0.785N	(e)	P=0.508	(e)
POLY 6	P=0.791N	(e)	P=0.512	(e)
COCH-ARM / FISHERS	P=0.778N	(e)	P=0.505	(e)
MAX-ISO-POLY-3	P=0.405	(e)	P=0.170	(e)

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Pituitary Gland: Pars Distalis Hyperplasia				
LESION RATES				
OVERALL (a)	17/49 (35%)	20/50 (40%)	21/50 (42%)	11/50 (22%)
POLY-3 RATE (b)	17/44.07	20/46.75	21/46.59	11/43.66
POLY-3 PERCENT (g)	38.6%	42.8%	45.1%	25.2%
TERMINAL (d)	13/34 (38%)	11/35 (31%)	17/34 (50%)	6/31 (19%)
FIRST INCIDENCE	629	571	608	454
STATISTICAL TESTS				
POLY 3	P=0.052N	P=0.423	P=0.338	P=0.130N
POLY 1.5	P=0.051N	P=0.377	P=0.321	P=0.136N
POLY 6	P=0.057N	P=0.489	P=0.353	P=0.124N
COCH-ARM / FISHERS	P=0.039N*	P=0.368	P=0.295	P=0.119N
MAX-ISO-POLY-3	P=0.083N	P=0.344	P=0.269	P=0.089N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Preputial Gland Inflammation				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	1/49 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/43.34	0/44.61	1/44.70	2/42.01
POLY-3 PERCENT (g)	0%	0%	2.2%	4.8%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	1/34 (3%)	1/31 (3%)
FIRST INCIDENCE	---	---	727 (T)	559
STATISTICAL TESTS				
POLY 3	P=0.084	(e)	P=0.506	P=0.230
POLY 1.5	P=0.085	(e)	P=0.504	P=0.231
POLY 6	P=0.082	(e)	P=0.508	P=0.230
COCH-ARM / FISHERS	P=0.092	(e)	P=0.500	P=0.253
MAX-ISO-POLY-3	P=0.081	(e)	P=0.166	P=0.077

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Prostate Inflammation				
LESION RATES				
OVERALL (a)	28/49 (57%)	24/50 (48%)	21/50 (42%)	16/50 (32%)
POLY-3 RATE (b)	28/47.77	24/45.93	21/46.35	16/44.64
POLY-3 PERCENT (g)	58.6%	52.3%	45.3%	35.8%
TERMINAL (d)	18/34 (53%)	20/35 (57%)	15/34 (44%)	7/31 (23%)
FIRST INCIDENCE	504	525	664	447
STATISTICAL TESTS				
POLY 3	P=0.019N*	P=0.340N	P=0.135N	P=0.021N*
POLY 1.5	P=0.017N*	P=0.320N	P=0.117N	P=0.018N*
POLY 6	P=0.019N*	P=0.365N	P=0.164N	P=0.023N*
COCH-ARM / FISHERS	P=0.011N*	P=0.239N	P=0.096N	P=0.010N**
MAX-ISO-POLY-3	P=0.025N*	P=0.272N	P=0.099N	P=0.015N*

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Prostate: Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	9/49 (18%)	8/50 (16%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	9/43.47	8/45.27	2/45.70	3/41.46
POLY-3 PERCENT (g)	20.7%	17.7%	4.4%	7.2%
TERMINAL (d)	8/34 (24%)	6/35 (17%)	1/34 (3%)	3/31 (10%)
FIRST INCIDENCE	694	571	689	727 (T)
STATISTICAL TESTS				
POLY 3	P=0.051N	P=0.463N	P=0.019N*	P=0.069N
POLY 1.5	P=0.048N*	P=0.484N	P=0.021N*	P=0.067N
POLY 6	P=0.054N	P=0.437N	P=0.018N*	P=0.070N
COCH-ARM / FISHERS	P=0.042N*	P=0.482N	P=0.023N*	P=0.056N
MAX-ISO-POLY-3	P=0.035N*	P=0.360N	P=0.009N**	P=0.040N*

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Seminal Vesicle Inflammation				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/43.34	0/44.61	1/45.79	2/41.75
POLY-3 PERCENT (g)	0%	0%	2.2%	4.8%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	664	670
STATISTICAL TESTS				
POLY 3	P=0.082	(e)	P=0.511	P=0.229
POLY 1.5	P=0.084	(e)	P=0.508	P=0.230
POLY 6	P=0.081	(e)	P=0.514	P=0.228
COCH-ARM / FISHERS	P=0.091	(e)	P=0.505	P=0.253
MAX-ISO-POLY-3	P=0.081	(e)	P=0.171	P=0.077

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Skin Inflammation				
LESION RATES				
OVERALL (a)	0/49 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/43.34	2/44.61	0/45.55	1/41.46
POLY-3 PERCENT (g)	0%	4.5%	0%	2.4%
TERMINAL (d)	0/34 (0%)	2/35 (6%)	0/34 (0%)	1/31 (3%)
FIRST INCIDENCE	---	727 (T)	---	727 (T)
STATISTICAL TESTS				
POLY 3	P=0.601	P=0.243	(e)	P=0.491
POLY 1.5	P=0.603	P=0.240	(e)	P=0.493
POLY 6	P=0.600	P=0.248	(e)	P=0.490
COCH-ARM / FISHERS	P=0.620	P=0.253	(e)	P=0.505
MAX-ISO-POLY-3	P=0.335	P=0.081	(e)	P=0.160

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Spleen Fibrosis				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/43.34	0/44.61	0/45.55	2/41.82
POLY-3 PERCENT (g)	0%	0%	0%	4.8%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	---	673
STATISTICAL TESTS				
POLY 3	P=0.038*	(e)	(e)	P=0.229
POLY 1.5	P=0.039*	(e)	(e)	P=0.230
POLY 6	P=0.038*	(e)	(e)	P=0.229
COCH-ARM / FISHERS	P=0.043*	(e)	(e)	P=0.253
MAX-ISO-POLY-3	P=0.035*	(e)	(e)	P=0.077

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Spleen				
Hematopoietic Cell Proliferation				
LESION RATES				
OVERALL (a)	10/49 (20%)	10/50 (20%)	7/50 (14%)	5/50 (10%)
POLY-3 RATE (b)	10/45.09	10/47.69	7/46.67	5/43.82
POLY-3 PERCENT (g)	22.2%	21%	15%	11.4%
TERMINAL (d)	5/34 (15%)	2/35 (6%)	2/34 (6%)	1/31 (3%)
FIRST INCIDENCE	504	168	616	447
STATISTICAL TESTS				
POLY 3	P=0.107N	P=0.544N	P=0.269N	P=0.141N
POLY 1.5	P=0.102N	P=0.566N	P=0.275N	P=0.140N
POLY 6	P=0.116N	P=0.516N	P=0.263N	P=0.144N
COCH-ARM / FISHERS	P=0.083N	P=0.579N	P=0.282N	P=0.122N
MAX-ISO-POLY-3	P=0.158N	P=0.444N	P=0.191N	P=0.091N

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG

Spleen
Pigmentation Hemosiderin

LESION RATES

OVERALL (a)	31/49 (63%)	32/50 (64%)	35/50 (70%)	32/50 (64%)
POLY-3 RATE (b)	31/46.89	32/45.08	35/48.36	32/46.15
POLY-3 PERCENT (g)	66.1%	71%	72.4%	69.3%
TERMINAL (d)	24/34 (71%)	29/35 (83%)	25/34 (74%)	21/31 (68%)
FIRST INCIDENCE	504	666	454	447

STATISTICAL TESTS

POLY 3	P=0.510	P=0.387	P=0.326	P=0.455
POLY 1.5	P=0.486	P=0.418	P=0.319	P=0.446
POLY 6	P=0.555	P=0.359	P=0.340	P=0.483
COCH-ARM / FISHERS	P=0.549N	P=0.553	P=0.310	P=0.553
MAX-ISO-POLY-3	P=0.488	P=0.306	P=0.252	P=0.368

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Spleen Thrombosis				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/43.34	0/44.61	0/45.55	2/41.46
POLY-3 PERCENT (g)	0%	0%	0%	4.8%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	2/31 (7%)
FIRST INCIDENCE	---	---	---	727 (T)
STATISTICAL TESTS				
POLY 3	P=0.038*	(e)	(e)	P=0.227
POLY 1.5	P=0.039*	(e)	(e)	P=0.229
POLY 6	P=0.037*	(e)	(e)	P=0.225
COCH-ARM / FISHERS	P=0.043*	(e)	(e)	P=0.253
MAX-ISO-POLY-3	P=0.035*	(e)	(e)	P=0.077

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Spleen: Lymphoid Follicle Atrophy				
LESION RATES				
OVERALL (a)	2/49 (4%)	2/50 (4%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/44.41	2/45.18	2/46.01	1/42.08
POLY-3 PERCENT (g)	4.5%	4.4%	4.4%	2.4%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	504	571	630	528
STATISTICAL TESTS				
POLY 3	P=0.410N	P=0.688N	P=0.681N	P=0.519N
POLY 1.5	P=0.403N	P=0.692N	P=0.683N	P=0.514N
POLY 6	P=0.417N	P=0.682N	P=0.680N	P=0.524N
COCH-ARM / FISHERS	P=0.379N	P=0.684N	P=0.684N	P=0.492N
MAX-ISO-POLY-3	P=0.502N	P=0.492N	P=0.485N	P=0.302N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Stomach, Forestomach Erosion				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	0/43.34	0/44.61	1/45.95	4/42.21
POLY-3 PERCENT (g)	0%	0%	2.2%	9.5%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	2/31 (7%)
FIRST INCIDENCE	---	---	616	559
STATISTICAL TESTS				
POLY 3	P=0.004**	(e)	P=0.512	P=0.057
POLY 1.5	P=0.004**	(e)	P=0.509	P=0.057
POLY 6	P=0.004**	(e)	P=0.515	P=0.057
COCH-ARM / FISHERS	P=0.006**	(e)	P=0.505	P=0.061
MAX-ISO-POLY-3	P=0.007**	(e)	P=0.172	P=0.020*

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Stomach, Forestomach Inflammation				
LESION RATES				
OVERALL (a)	8/49 (16%)	4/50 (8%)	9/50 (18%)	22/50 (44%)
POLY-3 RATE (b)	8/46.37	4/45.68	9/47.00	22/44.31
POLY-3 PERCENT (g)	17.3%	8.8%	19.2%	49.7%
TERMINAL (d)	1/34 (3%)	1/35 (3%)	3/34 (9%)	11/31 (36%)
FIRST INCIDENCE	504	525	590	559
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.184N	P=0.512	P<0.001**
POLY 1.5	P<0.001**	P=0.184N	P=0.514	P<0.001**
POLY 6	P<0.001**	P=0.183N	P=0.510	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.168N	P=0.518	P=0.002**
MAX-ISO-POLY-3	P<0.001**	P=0.116N	P=0.405	P<0.001**

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Stomach, Forestomach Mineralization				
LESION RATES				
OVERALL (a)	0/49 (0%)	2/50 (4%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	0/43.34	2/44.91	1/45.69	3/41.74
POLY-3 PERCENT (g)	0%	4.5%	2.2%	7.2%
TERMINAL (d)	0/34 (0%)	1/35 (3%)	0/34 (0%)	1/31 (3%)
FIRST INCIDENCE	---	646	694	689
STATISTICAL TESTS				
POLY 3	P=0.120	P=0.245	P=0.511	P=0.112
POLY 1.5	P=0.123	P=0.240	P=0.508	P=0.113
POLY 6	P=0.119	P=0.251	P=0.513	P=0.111
COCH-ARM / FISHERS	P=0.135	P=0.253	P=0.505	P=0.125
MAX-ISO-POLY-3	P=0.063	P=0.082	P=0.170	P=0.038*

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Stomach, Forestomach Ulcer				
LESION RATES				
OVERALL (a)	4/49 (8%)	0/50 (0%)	6/50 (12%)	13/50 (26%)
POLY-3 RATE (b)	4/44.89	0/44.61	6/46.61	13/43.34
POLY-3 PERCENT (g)	8.9%	0%	12.9%	30%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	1/34 (3%)	5/31 (16%)
FIRST INCIDENCE	504	---	590	589
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.061N	P=0.393	P=0.011*
POLY 1.5	P<0.001**	P=0.061N	P=0.389	P=0.011*
POLY 6	P<0.001**	P=0.060N	P=0.397	P=0.011*
COCH-ARM / FISHERS	P<0.001**	P=0.056N	P=0.383	P=0.017*
MAX-ISO-POLY-3	P<0.001**	P=0.020N*	P=0.276	P=0.006**

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Stomach, Forestomach: Epithelium Dysplasia				
LESION RATES				
OVERALL (a)	1/49 (2%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/43.50	0/44.61	2/46.02	1/41.46
POLY-3 PERCENT (g)	2.3%	0%	4.4%	2.4%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	1/34 (3%)	1/31 (3%)
FIRST INCIDENCE	686	---	590	727 (T)
STATISTICAL TESTS				
POLY 3	P=0.549	P=0.495N	P=0.520	P=0.750
POLY 1.5	P=0.558	P=0.498N	P=0.515	P=0.752
POLY 6	P=0.539	P=0.491N	P=0.524	P=0.748
COCH-ARM / FISHERS	P=0.580	P=0.495N	P=0.508	P=0.747N
MAX-ISO-POLY-3	P=0.404	P=0.157N	P=0.301	P=0.486

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Stomach, Forestomach: Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	6/49 (12%)	4/50 (8%)	11/50 (22%)	27/50 (54%)
POLY-3 RATE (b)	6/45.55	4/45.68	11/47.24	27/45.78
POLY-3 PERCENT (g)	13.2%	8.8%	23.3%	59%
TERMINAL (d)	1/34 (3%)	1/35 (3%)	4/34 (12%)	14/31 (45%)
FIRST INCIDENCE	504	525	590	447
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.368N	P=0.160	P<0.001**
POLY 1.5	P<0.001**	P=0.372N	P=0.157	P<0.001**
POLY 6	P<0.001**	P=0.362N	P=0.165	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.357N	P=0.154	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.252N	P=0.106	P<0.001**

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Stomach, Glandular Inflammation				
LESION RATES				
OVERALL (a)	2/49 (4%)	3/50 (6%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	2/43.97	3/45.06	3/46.36	3/41.81
POLY-3 PERCENT (g)	4.6%	6.7%	6.5%	7.2%
TERMINAL (d)	0/34 (0%)	1/35 (3%)	0/34 (0%)	1/31 (3%)
FIRST INCIDENCE	629	615	590	670
STATISTICAL TESTS				
POLY 3	P=0.462	P=0.511	P=0.524	P=0.477
POLY 1.5	P=0.472	P=0.504	P=0.518	P=0.482
POLY 6	P=0.451	P=0.519	P=0.529	P=0.472
COCH-ARM / FISHERS	P=0.506	P=0.510	P=0.510	P=0.510
MAX-ISO-POLY-3	P=0.504	P=0.334	P=0.348	P=0.308

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Stomach, Glandular: Epithelium Necrosis				
LESION RATES				
OVERALL (a)	2/49 (4%)	1/50 (2%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	2/43.69	1/45.12	2/46.00	3/41.59
POLY-3 PERCENT (g)	4.6%	2.2%	4.4%	7.2%
TERMINAL (d)	1/34 (3%)	0/35 (0%)	0/34 (0%)	2/31 (7%)
FIRST INCIDENCE	629	571	664	694
STATISTICAL TESTS				
POLY 3	P=0.278	P=0.489N	P=0.675N	P=0.478
POLY 1.5	P=0.287	P=0.495N	P=0.680N	P=0.482
POLY 6	P=0.269	P=0.481N	P=0.672N	P=0.472
COCH-ARM / FISHERS	P=0.310	P=0.492N	P=0.684N	P=0.510
MAX-ISO-POLY-3	P=0.340	P=0.273N	P=0.478N	P=0.309

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Testes: Germinal Epithelium Degeneration				
LESION RATES				
OVERALL (a)	3/49 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/44.29	0/44.61	0/45.55	0/41.46
POLY-3 PERCENT (g)	6.8%	0%	0%	0%
TERMINAL (d)	1/34 (3%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	504	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.146N	P=0.117N	P=0.114N	P=0.131N
POLY 1.5	P=0.144N	P=0.119N	P=0.114N	P=0.128N
POLY 6	P=0.148N	P=0.115N	P=0.114N	P=0.134N
COCH-ARM / FISHERS	P=0.147N	P=0.117N	P=0.117N	P=0.117N
MAX-ISO-POLY-3	P=0.015N*	P=0.038N*	P=0.037N*	P=0.049N*

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Testes: Interstitial Cell Hyperplasia				
LESION RATES				
OVERALL (a)	17/49 (35%)	15/50 (30%)	10/50 (20%)	4/50 (8%)
POLY-3 RATE (b)	17/46.01	15/46.20	10/47.03	4/44.06
POLY-3 PERCENT (g)	37%	32.5%	21.3%	9.1%
TERMINAL (d)	11/34 (32%)	9/35 (26%)	4/34 (12%)	0/31 (0%)
FIRST INCIDENCE	504	525	608	447
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.408N	P=0.073N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.419N	P=0.075N	P<0.001N**
POLY 6	P<0.001N**	P=0.390N	P=0.071N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.388N	P=0.078N	P<0.001N**
MAX-ISO-POLY-3	P=0.002N**	P=0.326N	P=0.046N*	P<0.001N**

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Thymus Atrophy				
LESION RATES				
OVERALL (a)	47/48 (98%)	49/50 (98%)	49/50 (98%)	46/50 (92%)
POLY-3 RATE (b)	47/48.00	49/49.00	49/49.79	46/47.79
POLY-3 PERCENT (g)	97.9%	100%	98.4%	96.3%
TERMINAL (d)	33/34 (97%)	35/35 (100%)	34/34 (100%)	30/31 (97%)
FIRST INCIDENCE	504	168	454	447
STATISTICAL TESTS				
POLY 3	P=0.269N	P=0.496	P=0.724	P=0.549N
POLY 1.5	P=0.251N	P=0.499	P=0.738	P=0.523N
POLY 6	P=0.304N	P=0.496	P=0.694	P=0.592N
COCH-ARM / FISHERS	P=0.060N	P=0.742	P=0.742	P=0.194N
MAX-ISO-POLY-3	P=0.251N	P=0.156	P=0.424	P=0.312N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Thyroid Gland: C-Cell Hyperplasia				
LESION RATES				
OVERALL (a)	8/49 (16%)	12/50 (24%)	12/50 (24%)	7/50 (14%)
POLY-3 RATE (b)	8/43.47	12/44.66	12/46.12	7/42.12
POLY-3 PERCENT (g)	18.4%	26.9%	26%	16.6%
TERMINAL (d)	7/34 (21%)	11/35 (31%)	10/34 (29%)	4/31 (13%)
FIRST INCIDENCE	694	714	608	665
STATISTICAL TESTS				
POLY 3	P=0.289N	P=0.243	P=0.270	P=0.527N
POLY 1.5	P=0.282N	P=0.232	P=0.259	P=0.525N
POLY 6	P=0.291N	P=0.258	P=0.281	P=0.524N
COCH-ARM / FISHERS	P=0.237N	P=0.242	P=0.242	P=0.483N
MAX-ISO-POLY-3	P=0.354N	P=0.173	P=0.199	P=0.414N

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG

Thyroid Gland: Follicle
Cyst

LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.34	0/44.61	0/45.55	0/41.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Thyroid Gland: Follicular Cell Hyperplasia				
LESION RATES				
OVERALL (a)	0/49 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/43.34	2/44.61	0/45.55	1/41.46
POLY-3 PERCENT (g)	0%	4.5%	0%	2.4%
TERMINAL (d)	0/34 (0%)	2/35 (6%)	0/34 (0%)	1/31 (3%)
FIRST INCIDENCE	---	727 (T)	---	727 (T)
STATISTICAL TESTS				
POLY 3	P=0.601	P=0.243	(e)	P=0.491
POLY 1.5	P=0.603	P=0.240	(e)	P=0.493
POLY 6	P=0.600	P=0.248	(e)	P=0.490
COCH-ARM / FISHERS	P=0.620	P=0.253	(e)	P=0.505
MAX-ISO-POLY-3	P=0.335	P=0.081	(e)	P=0.160

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Tooth Malformation				
LESION RATES				
OVERALL (a)	10/10 (100%)	6/6 (100%)	9/9 (100%)	11/11 (100%)
POLY-3 RATE (b)	10/10.00	6/6.00	9/9.00	11/11.00
POLY-3 PERCENT (g)	100%	100%	100%	100%
TERMINAL (d)	10/10 (100%)	4/4 (100%)	5/5 (100%)	7/7 (100%)
FIRST INCIDENCE	727 (T)	525	590	589
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Urinary Bladder Inflammation				
LESION RATES				
OVERALL (a)	2/49 (4%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/43.92	0/44.61	1/45.79	2/42.32
POLY-3 PERCENT (g)	4.6%	0%	2.2%	4.7%
TERMINAL (d)	1/34 (3%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	545	---	664	559
STATISTICAL TESTS				
POLY 3	P=0.394	P=0.234N	P=0.485N	P=0.681
POLY 1.5	P=0.398	P=0.236N	P=0.488N	P=0.682
POLY 6	P=0.389	P=0.230N	P=0.483N	P=0.681
COCH-ARM / FISHERS	P=0.412	P=0.242N	P=0.492N	P=0.684N
MAX-ISO-POLY-3	P=0.405	P=0.075N	P=0.271N	P=0.485

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Adrenal Cortex Degeneration Cystic				
LESION RATES				
OVERALL (a)	3/50 (6%)	6/50 (12%)	7/50 (14%)	6/50 (12%)
POLY-3 RATE (b)	3/44.11	6/44.49	7/40.88	6/41.90
POLY-3 PERCENT (g)	6.8%	13.5%	17.1%	14.3%
TERMINAL (d)	2/34 (6%)	5/34 (15%)	3/24 (13%)	4/34 (12%)
FIRST INCIDENCE	701	705	647	629
STATISTICAL TESTS				
POLY 3	P=0.308	P=0.246	P=0.126	P=0.216
POLY 1.5	P=0.312	P=0.242	P=0.141	P=0.218
POLY 6	P=0.319	P=0.247	P=0.108	P=0.222
COCH-ARM / FISHERS	P=0.353	P=0.243	P=0.159	P=0.243
MAX-ISO-POLY-3	P=0.185	P=0.150	P=0.076	P=0.133

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Adrenal Cortex Hypertrophy				
LESION RATES				
OVERALL (a)	2/50 (4%)	3/50 (6%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	2/44.00	3/44.99	1/40.19	3/41.67
POLY-3 PERCENT (g)	4.6%	6.7%	2.5%	7.2%
TERMINAL (d)	2/34 (6%)	1/34 (3%)	1/24 (4%)	2/34 (6%)
FIRST INCIDENCE	728 (T)	615	728 (T)	688
STATISTICAL TESTS				
POLY 3	P=0.440	P=0.510	P=0.532N	P=0.475
POLY 1.5	P=0.442	P=0.503	P=0.516N	P=0.477
POLY 6	P=0.446	P=0.517	P=0.555N	P=0.481
COCH-ARM / FISHERS	P=0.465	P=0.500	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.476	P=0.334	P=0.315N	P=0.306

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Adrenal Cortex Necrosis				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/44.14	0/44.40	1/40.51	2/42.73
POLY-3 PERCENT (g)	4.5%	0%	2.5%	4.7%
TERMINAL (d)	1/34 (3%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	692	---	639	380
STATISTICAL TESTS				
POLY 3	P=0.397	P=0.236N	P=0.530N	P=0.682
POLY 1.5	P=0.397	P=0.238N	P=0.516N	P=0.681
POLY 6	P=0.403	P=0.235N	P=0.552N	P=0.689
COCH-ARM / FISHERS	P=0.408	P=0.247N	P=0.500N	P=0.691N
MAX-ISO-POLY-3	P=0.411	P=0.076N	P=0.313N	P=0.486

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Adrenal Cortex: Zona Fasciculata Hyperplasia				
LESION RATES				
OVERALL (a)	6/50 (12%)	6/50 (12%)	4/50 (8%)	9/50 (18%)
POLY-3 RATE (b)	6/44.00	6/44.51	4/40.51	9/41.55
POLY-3 PERCENT (g)	13.6%	13.5%	9.9%	21.7%
TERMINAL (d)	6/34 (18%)	5/34 (15%)	3/24 (13%)	8/34 (24%)
FIRST INCIDENCE	728 (T)	701	639	721
STATISTICAL TESTS				
POLY 3	P=0.145	P=0.613N	P=0.422N	P=0.245
POLY 1.5	P=0.149	P=0.620N	P=0.397N	P=0.249
POLY 6	P=0.149	P=0.609N	P=0.461N	P=0.251
COCH-ARM / FISHERS	P=0.176	P=0.620N	P=0.370N	P=0.288
MAX-ISO-POLY-3	P=0.193	P=0.491N	P=0.304N	P=0.172

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Adrenal Medulla Hyperplasia				
LESION RATES				
OVERALL (a)	3/50 (6%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	3/45.23	0/44.40	1/40.19	1/41.67
POLY-3 PERCENT (g)	6.6%	0%	2.5%	2.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/24 (4%)	0/34 (0%)
FIRST INCIDENCE	450	---	728 (T)	688
STATISTICAL TESTS				
POLY 3	P=0.466N	P=0.122N	P=0.349N	P=0.335N
POLY 1.5	P=0.465N	P=0.122N	P=0.328N	P=0.330N
POLY 6	P=0.462N	P=0.123N	P=0.379N	P=0.335N
COCH-ARM / FISHERS	P=0.454N	P=0.121N	P=0.309N	P=0.309N
MAX-ISO-POLY-3	P=0.143N	P=0.040N*	P=0.198N	P=0.185N

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Bone Marrow Hyperplasia				
LESION RATES				
OVERALL (a)	26/50 (52%)	27/50 (54%)	19/50 (38%)	23/50 (46%)
POLY-3 RATE (b)	26/47.27	27/47.01	19/43.27	23/44.15
POLY-3 PERCENT (g)	55%	57.4%	43.9%	52.1%
TERMINAL (d)	16/34 (47%)	17/34 (50%)	8/24 (33%)	14/34 (41%)
FIRST INCIDENCE	450	605	518	380
STATISTICAL TESTS				
POLY 3	P=0.404N	P=0.488	P=0.196N	P=0.473N
POLY 1.5	P=0.386N	P=0.475	P=0.154N	P=0.455N
POLY 6	P=0.391N	P=0.505	P=0.259N	P=0.460N
COCH-ARM / FISHERS	P=0.293N	P=0.500	P=0.114N	P=0.345N
MAX-ISO-POLY-3	P=0.361N	P=0.404	P=0.152N	P=0.392N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Bone Marrow				
Myelofibrosis				
LESION RATES				
OVERALL (a)	2/50 (4%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/44.76	1/44.51	1/40.28	1/42.06
POLY-3 PERCENT (g)	4.5%	2.3%	2.5%	2.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	506	701	705	559
STATISTICAL TESTS				
POLY 3	P=0.514N	P=0.502N	P=0.537N	P=0.522N
POLY 1.5	P=0.513N	P=0.503N	P=0.520N	P=0.520N
POLY 6	P=0.509N	P=0.502N	P=0.561N	P=0.519N
COCH-ARM / FISHERS	P=0.500N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.461N	P=0.282N	P=0.320N	P=0.304N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Brain Hemorrhage				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	2/45.02	2/41.04	0/41.52
POLY-3 PERCENT (g)	0%	4.4%	4.9%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	605	579	---
STATISTICAL TESTS				
POLY 3	P=0.396N	P=0.242	P=0.222	(e)
POLY 1.5	P=0.394N	P=0.239	P=0.229	(e)
POLY 6	P=0.392N	P=0.245	P=0.211	(e)
COCH-ARM / FISHERS	P=0.373N	P=0.247	P=0.247	(e)
MAX-ISO-POLY-3	P=0.286	P=0.081	P=0.075	(e)

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Brain Necrosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	3/50 (6%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	3/45.05	2/40.54	0/41.52
POLY-3 PERCENT (g)	0%	6.7%	4.9%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/24 (4%)	0/34 (0%)
FIRST INCIDENCE	---	605	629	---
STATISTICAL TESTS				
POLY 3	P=0.300N	P=0.123	P=0.219	(e)
POLY 1.5	P=0.299N	P=0.120	P=0.228	(e)
POLY 6	P=0.295N	P=0.125	P=0.207	(e)
COCH-ARM / FISHERS	P=0.281N	P=0.121	P=0.247	(e)
MAX-ISO-POLY-3	P=0.237	P=0.041*	P=0.075	(e)

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Clitoral Gland Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	3/49 (6%)	5/50 (10%)	1/49 (2%)
POLY-3 RATE (b)	0/44.00	3/43.80	5/40.37	1/41.37
POLY-3 PERCENT (g)	0%	6.9%	12.4%	2.4%
TERMINAL (d)	0/34 (0%)	3/34 (9%)	4/24 (17%)	1/34 (3%)
FIRST INCIDENCE	---	728 (T)	681	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.537N	P=0.118	P=0.024*	P=0.488
POLY 1.5	P=0.535N	P=0.116	P=0.027*	P=0.488
POLY 6	P=0.530N	P=0.119	P=0.019*	P=0.490
COCH-ARM / FISHERS	P=0.506N	P=0.117	P=0.028*	P=0.495
MAX-ISO-POLY-3	P=0.109	P=0.038*	P=0.009**	P=0.157

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Clitoral Gland Inflammation				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/49 (4%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	1/44.00	2/44.14	0/40.19	0/41.37
POLY-3 PERCENT (g)	2.3%	4.5%	0%	0%
TERMINAL (d)	1/34 (3%)	1/34 (3%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	728 (T)	632	---	---
STATISTICAL TESTS				
POLY 3	P=0.232N	P=0.501	P=0.518N	P=0.512N
POLY 1.5	P=0.234N	P=0.496	P=0.509N	P=0.512N
POLY 6	P=0.228N	P=0.507	P=0.531N	P=0.510N
COCH-ARM / FISHERS	P=0.230N	P=0.492	P=0.500N	P=0.505N
MAX-ISO-POLY-3	P=0.198N	P=0.283	P=0.180N	P=0.173N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Coagulating Gland Inflammation				
LESION RATES				
OVERALL (a)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/0.00	0/0.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Eye: Cornea Inflammation				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	1/44.00	0/44.40	2/40.89	2/41.52
POLY-3 PERCENT (g)	2.3%	0%	4.9%	4.8%
TERMINAL (d)	1/34 (3%)	0/34 (0%)	0/24 (0%)	2/34 (6%)
FIRST INCIDENCE	728 (T)	---	532	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.257	P=0.498N	P=0.474	P=0.480
POLY 1.5	P=0.261	P=0.500N	P=0.487	P=0.481
POLY 6	P=0.259	P=0.497N	P=0.455	P=0.483
COCH-ARM / FISHERS	P=0.281	P=0.500N	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.262	P=0.158N	P=0.266	P=0.269

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
<hr/>				
Eye: Iris Inflammation				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Eye: Lens				
Cataract				
LESION RATES				
OVERALL (a)	2/50 (4%)	3/50 (6%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	2/44.24	3/44.62	1/40.47	3/41.52
POLY-3 PERCENT (g)	4.5%	6.7%	2.5%	7.2%
TERMINAL (d)	1/34 (3%)	2/34 (6%)	0/24 (0%)	3/34 (9%)
FIRST INCIDENCE	664	670	652	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.438	P=0.504	P=0.531N	P=0.471
POLY 1.5	P=0.441	P=0.500	P=0.516N	P=0.474
POLY 6	P=0.441	P=0.506	P=0.553N	P=0.474
COCH-ARM / FISHERS	P=0.465	P=0.500	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.472	P=0.328	P=0.314N	P=0.303

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Eye: Retina Degeneration				
LESION RATES				
OVERALL (a)	5/50 (10%)	5/50 (10%)	5/50 (10%)	12/50 (24%)
POLY-3 RATE (b)	5/44.24	5/45.05	5/40.65	12/41.81
POLY-3 PERCENT (g)	11.3%	11.1%	12.3%	28.7%
TERMINAL (d)	4/34 (12%)	3/34 (9%)	2/24 (8%)	10/34 (29%)
FIRST INCIDENCE	664	605	652	688
STATISTICAL TESTS				
POLY 3	P=0.008**	P=0.619N	P=0.577	P=0.037*
POLY 1.5	P=0.008**	P=0.627N	P=0.602	P=0.039*
POLY 6	P=0.008**	P=0.613N	P=0.538	P=0.039*
COCH-ARM / FISHERS	P=0.013*	P=0.630N	P=0.630N	P=0.054
MAX-ISO-POLY-3	P=0.013*	P=0.487N	P=0.444	P=0.023*

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Eye: Retina				
Gliososis				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	1/44.00	0/44.40	3/40.27	1/41.52
POLY-3 PERCENT (g)	2.3%	0%	7.5%	2.4%
TERMINAL (d)	1/34 (3%)	0/34 (0%)	2/24 (8%)	1/34 (3%)
FIRST INCIDENCE	728 (T)	---	708	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.557	P=0.498N	P=0.274	P=0.748
POLY 1.5	P=0.563	P=0.500N	P=0.289	P=0.749
POLY 6	P=0.560	P=0.497N	P=0.252	P=0.750
COCH-ARM / FISHERS	P=0.592	P=0.500N	P=0.309	P=0.753N
MAX-ISO-POLY-3	P=0.257	P=0.158N	P=0.143	P=0.483

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
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 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Heart				
Cardiomyopathy				
LESION RATES				
OVERALL (a)	42/50 (84%)	45/50 (90%)	45/50 (90%)	47/50 (94%)
POLY-3 RATE (b)	42/46.05	45/47.22	45/47.17	47/47.15
POLY-3 PERCENT (g)	91.2%	95.3%	95.4%	99.7%
TERMINAL (d)	33/34 (97%)	34/34 (100%)	24/24 (100%)	34/34 (100%)
FIRST INCIDENCE	615	558	518	194
STATISTICAL TESTS				
POLY 3	P=0.043*	P=0.336	P=0.322	P=0.040*
POLY 1.5	P=0.044*	P=0.257	P=0.296	P=0.033*
POLY 6	P=0.069	P=0.429	P=0.363	P=0.084
COCH-ARM / FISHERS	P=0.119	P=0.277	P=0.277	P=0.100
MAX-ISO-POLY-3	P=0.019*	P=0.189	P=0.175	P=0.010**

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG

Heart: Atrium
Thrombosis

LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.00	1/44.51	0/40.19	1/41.67
POLY-3 PERCENT (g)	0%	2.3%	0%	2.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	701	---	688

STATISTICAL TESTS				
POLY 3	P=0.451	P=0.502	(e)	P=0.489
POLY 1.5	P=0.451	P=0.500	(e)	P=0.490
POLY 6	P=0.455	P=0.504	(e)	P=0.492
COCH-ARM / FISHERS	P=0.464	P=0.500	(e)	P=0.500
MAX-ISO-POLY-3	P=0.257	P=0.161	(e)	P=0.158

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Intestine Large, Colon				
Parasite Metazoan				
LESION RATES				
OVERALL (a)	3/50 (6%)	1/50 (2%)	8/50 (16%)	6/50 (12%)
POLY-3 RATE (b)	3/44.40	1/44.40	8/42.87	6/42.24
POLY-3 PERCENT (g)	6.8%	2.3%	18.7%	14.2%
TERMINAL (d)	2/34 (6%)	1/34 (3%)	3/24 (13%)	4/34 (12%)
FIRST INCIDENCE	615	728 (T)	98	489
STATISTICAL TESTS				
POLY 3	P=0.095	P=0.305N	P=0.086	P=0.217
POLY 1.5	P=0.098	P=0.307N	P=0.095	P=0.219
POLY 6	P=0.099	P=0.305N	P=0.073	P=0.221
COCH-ARM / FISHERS	P=0.121	P=0.309N	P=0.100	P=0.243
MAX-ISO-POLY-3	P=0.058	P=0.154N	P=0.048*	P=0.134

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Islets, Pancreatic Hyperplasia				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	1/44.14	0/44.40	3/40.49	1/41.52
POLY-3 PERCENT (g)	2.3%	0%	7.4%	2.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/24 (4%)	1/34 (3%)
FIRST INCIDENCE	692	---	672	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.557	P=0.499N	P=0.275	P=0.747
POLY 1.5	P=0.563	P=0.500N	P=0.289	P=0.748
POLY 6	P=0.559	P=0.498N	P=0.254	P=0.749
COCH-ARM / FISHERS	P=0.592	P=0.500N	P=0.309	P=0.753N
MAX-ISO-POLY-3	P=0.258	P=0.158N	P=0.143	P=0.482

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Kidney				
Accumulation, Hyaline Droplet				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/44.00	2/45.09	1/40.19	1/41.52
POLY-3 PERCENT (g)	0%	4.4%	2.5%	2.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/24 (4%)	1/34 (3%)
FIRST INCIDENCE	---	631	728 (T)	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.604	P=0.243	P=0.482	P=0.488
POLY 1.5	P=0.606	P=0.239	P=0.491	P=0.489
POLY 6	P=0.608	P=0.246	P=0.469	P=0.490
COCH-ARM / FISHERS	P=0.627	P=0.247	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.285	P=0.081	P=0.158	P=0.158

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Kidney Infarct				
LESION RATES				
OVERALL (a)	2/50 (4%)	3/50 (6%)	4/50 (8%)	3/50 (6%)
POLY-3 RATE (b)	2/44.00	3/44.40	4/41.07	3/41.52
POLY-3 PERCENT (g)	4.6%	6.8%	9.7%	7.2%
TERMINAL (d)	2/34 (6%)	3/34 (9%)	2/24 (8%)	3/34 (9%)
FIRST INCIDENCE	728 (T)	728 (T)	518	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.475	P=0.504	P=0.305	P=0.474
POLY 1.5	P=0.480	P=0.500	P=0.321	P=0.476
POLY 6	P=0.481	P=0.506	P=0.282	P=0.478
COCH-ARM / FISHERS	P=0.515	P=0.500	P=0.339	P=0.500
MAX-ISO-POLY-3	P=0.398	P=0.328	P=0.184	P=0.305

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Kidney Mineralization				
LESION RATES				
OVERALL (a)	43/50 (86%)	43/50 (86%)	45/50 (90%)	46/50 (92%)
POLY-3 RATE (b)	43/48.86	43/47.41	45/49.37	46/48.47
POLY-3 PERCENT (g)	88%	90.7%	91.2%	94.9%
TERMINAL (d)	29/34 (85%)	31/34 (91%)	21/24 (88%)	32/34 (94%)
FIRST INCIDENCE	450	558	98	111
STATISTICAL TESTS				
POLY 3	P=0.171	P=0.461	P=0.427	P=0.192
POLY 1.5	P=0.197	P=0.487	P=0.454	P=0.223
POLY 6	P=0.159	P=0.425	P=0.388	P=0.174
COCH-ARM / FISHERS	P=0.197	P=0.613N	P=0.380	P=0.262
MAX-ISO-POLY-3	P=0.177	P=0.334	P=0.303	P=0.108

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Kidney				
Nephropathy				
LESION RATES				
OVERALL (a)	34/50 (68%)	35/50 (70%)	37/50 (74%)	43/50 (86%)
POLY-3 RATE (b)	34/45.98	35/46.59	37/46.71	43/44.94
POLY-3 PERCENT (g)	74%	75.1%	79.2%	95.7%
TERMINAL (d)	26/34 (77%)	27/34 (79%)	19/24 (79%)	34/34 (100%)
FIRST INCIDENCE	510	605	518	194
STATISTICAL TESTS				
POLY 3	P=0.002**	P=0.545	P=0.357	P=0.002**
POLY 1.5	P=0.003**	P=0.506	P=0.347	P=0.003**
POLY 6	P=0.002**	P=0.579	P=0.370	P=0.002**
COCH-ARM / FISHERS	P=0.017*	P=0.500	P=0.330	P=0.028*
MAX-ISO-POLY-3	P=0.003**	P=0.446	P=0.269	P<0.001**

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Kidney: Cortex Cyst				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.38	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	4.5%	0%	0%	0%
TERMINAL (d)	1/34 (3%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	621	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.261N	P=0.237N	P=0.260N	P=0.252N
POLY 1.5	P=0.261N	P=0.238N	P=0.249N	P=0.250N
POLY 6	P=0.258N	P=0.237N	P=0.277N	P=0.251N
COCH-ARM / FISHERS	P=0.262N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.047N*	P=0.076N	P=0.097N	P=0.090N

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Kidney: Pelvis Inflammation				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	5/50 (10%)	4/50 (8%)
POLY-3 RATE (b)	1/44.00	1/44.40	5/40.43	4/41.52
POLY-3 PERCENT (g)	2.3%	2.3%	12.4%	9.6%
TERMINAL (d)	1/34 (3%)	1/34 (3%)	4/24 (17%)	4/34 (12%)
FIRST INCIDENCE	728 (T)	728 (T)	664	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.108	P=0.759N	P=0.082	P=0.161
POLY 1.5	P=0.112	P=0.761	P=0.091	P=0.163
POLY 6	P=0.110	P=0.758N	P=0.070	P=0.163
COCH-ARM / FISHERS	P=0.133	P=0.753N	P=0.102	P=0.181
MAX-ISO-POLY-3	P=0.087	P=0.497N	P=0.040*	P=0.079

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Kidney: Pelvis, Transitional Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	4/50 (8%)	6/50 (12%)
POLY-3 RATE (b)	0/44.00	0/44.40	4/40.43	6/41.55
POLY-3 PERCENT (g)	0%	0%	9.9%	14.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	3/24 (13%)	5/34 (15%)
FIRST INCIDENCE	---	---	664	721
STATISTICAL TESTS				
POLY 3	P=0.002**	(e)	P=0.050*	P=0.012*
POLY 1.5	P=0.002**	(e)	P=0.055	P=0.013*
POLY 6	P=0.002**	(e)	P=0.043*	P=0.013*
COCH-ARM / FISHERS	P=0.003**	(e)	P=0.059	P=0.013*
MAX-ISO-POLY-3	P=0.002**	(e)	P=0.019*	P=0.004**

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Kidney: Renal Tubule Necrosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/44.00	0/44.40	1/40.97	2/43.35
POLY-3 PERCENT (g)	0%	0%	2.4%	4.6%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	439	140
STATISTICAL TESTS				
POLY 3	P=0.087	(e)	P=0.486	P=0.234
POLY 1.5	P=0.087	(e)	P=0.493	P=0.233
POLY 6	P=0.088	(e)	P=0.474	P=0.237
COCH-ARM / FISHERS	P=0.090	(e)	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.080	(e)	P=0.158	P=0.076

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Angiectasis				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	1/44.00	2/44.40	0/40.19	3/41.52
POLY-3 PERCENT (g)	2.3%	4.5%	0%	7.2%
TERMINAL (d)	1/34 (3%)	2/34 (6%)	0/24 (0%)	3/34 (9%)
FIRST INCIDENCE	728 (T)	728 (T)	---	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.200	P=0.503	P=0.518N	P=0.284
POLY 1.5	P=0.201	P=0.500	P=0.509N	P=0.286
POLY 6	P=0.203	P=0.505	P=0.531N	P=0.288
COCH-ARM / FISHERS	P=0.213	P=0.500	P=0.500N	P=0.309
MAX-ISO-POLY-3	P=0.184	P=0.284	P=0.180N	P=0.146

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Basophilic Focus				
LESION RATES				
OVERALL (a)	44/50 (88%)	42/50 (84%)	41/50 (82%)	11/50 (22%)
POLY-3 RATE (b)	44/46.81	42/46.66	41/46.58	11/42.21
POLY-3 PERCENT (g)	94%	90%	88%	26.1%
TERMINAL (d)	34/34 (100%)	33/34 (97%)	22/24 (92%)	7/34 (21%)
FIRST INCIDENCE	450	558	519	664
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.357N	P=0.233N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.402N	P=0.244N	P<0.001N**
POLY 6	P<0.001N**	P=0.332N	P=0.229N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.387N	P=0.288N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.214N	P=0.129N	P<0.001N**

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Clear Cell Focus				
LESION RATES				
OVERALL (a)	12/50 (24%)	14/50 (28%)	11/50 (22%)	8/50 (16%)
POLY-3 RATE (b)	12/44.11	14/44.72	11/40.19	8/41.52
POLY-3 PERCENT (g)	27.2%	31.3%	27.4%	19.3%
TERMINAL (d)	11/34 (32%)	13/34 (38%)	11/24 (46%)	8/34 (24%)
FIRST INCIDENCE	701	639	728 (T)	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.155N	P=0.424	P=0.590	P=0.270N
POLY 1.5	P=0.152N	P=0.412	P=0.554N	P=0.267N
POLY 6	P=0.145N	P=0.433	P=0.514	P=0.262N
COCH-ARM / FISHERS	P=0.121N	P=0.410	P=0.500N	P=0.227N
MAX-ISO-POLY-3	P=0.248N	P=0.336	P=0.493	P=0.200N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Degeneration Cystic				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	1/41.67
POLY-3 PERCENT (g)	0%	0%	0%	2.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	---	688
STATISTICAL TESTS				
POLY 3	P=0.212	(e)	(e)	P=0.489
POLY 1.5	P=0.213	(e)	(e)	P=0.490
POLY 6	P=0.213	(e)	(e)	P=0.492
COCH-ARM / FISHERS	P=0.221	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.126	(e)	(e)	P=0.158

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Eosinophilic Focus				
LESION RATES				
OVERALL (a)	23/50 (46%)	31/50 (62%)	24/50 (48%)	23/50 (46%)
POLY-3 RATE (b)	23/44.00	31/45.66	24/42.29	23/41.52
POLY-3 PERCENT (g)	52.3%	67.9%	56.8%	55.4%
TERMINAL (d)	23/34 (68%)	27/34 (79%)	17/24 (71%)	23/34 (68%)
FIRST INCIDENCE	728 (T)	615	532	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.402N	P=0.089	P=0.418	P=0.470
POLY 1.5	P=0.379N	P=0.077	P=0.459	P=0.480
POLY 6	P=0.391N	P=0.106	P=0.358	P=0.491
COCH-ARM / FISHERS	P=0.269N	P=0.080	P=0.500	P=0.579N
MAX-ISO-POLY-3	P=0.369	P=0.061	P=0.335	P=0.385

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Fatty Change Diffuse				
LESION RATES				
OVERALL (a)	9/50 (18%)	10/50 (20%)	10/50 (20%)	11/50 (22%)
POLY-3 RATE (b)	9/45.64	10/45.96	10/42.10	11/41.67
POLY-3 PERCENT (g)	19.7%	21.8%	23.8%	26.4%
TERMINAL (d)	4/34 (12%)	4/34 (12%)	4/24 (17%)	10/34 (29%)
FIRST INCIDENCE	450	605	532	688
STATISTICAL TESTS				
POLY 3	P=0.285	P=0.507	P=0.421	P=0.314
POLY 1.5	P=0.307	P=0.497	P=0.457	P=0.331
POLY 6	P=0.274	P=0.515	P=0.372	P=0.306
COCH-ARM / FISHERS	P=0.384	P=0.500	P=0.500	P=0.402
MAX-ISO-POLY-3	P=0.389	P=0.403	P=0.330	P=0.240

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Hematopoietic Cell Proliferation				
LESION RATES				
OVERALL (a)	1/50 (2%)	3/50 (6%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.40	3/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	2.3%	6.8%	0%	0%
TERMINAL (d)	0/34 (0%)	3/34 (9%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	615	728 (T)	---	---
STATISTICAL TESTS				
POLY 3	P=0.171N	P=0.305	P=0.520N	P=0.513N
POLY 1.5	P=0.172N	P=0.304	P=0.510N	P=0.512N
POLY 6	P=0.169N	P=0.304	P=0.534N	P=0.513N
COCH-ARM / FISHERS	P=0.166N	P=0.309	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.144N	P=0.154	P=0.183N	P=0.175N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Hepatodiaphragmatic Nodule				
LESION RATES				
OVERALL (a)	5/50 (10%)	6/50 (12%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	5/44.14	6/44.72	1/40.47	2/41.52
POLY-3 PERCENT (g)	11.3%	13.4%	2.5%	4.8%
TERMINAL (d)	4/34 (12%)	5/34 (15%)	0/24 (0%)	2/34 (6%)
FIRST INCIDENCE	693	639	653	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.132N	P=0.509	P=0.122N	P=0.241N
POLY 1.5	P=0.132N	P=0.502	P=0.112N	P=0.239N
POLY 6	P=0.128N	P=0.514	P=0.139N	P=0.237N
COCH-ARM / FISHERS	P=0.121N	P=0.500	P=0.102N	P=0.218N
MAX-ISO-POLY-3	P=0.122N	P=0.383	P=0.063N	P=0.143N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Inflammation Chronic				
LESION RATES				
OVERALL (a)	43/50 (86%)	40/50 (80%)	38/50 (76%)	35/50 (70%)
POLY-3 RATE (b)	43/47.47	40/47.55	38/46.20	35/45.07
POLY-3 PERCENT (g)	90.6%	84.1%	82.3%	77.7%
TERMINAL (d)	32/34 (94%)	31/34 (91%)	22/24 (92%)	28/34 (82%)
FIRST INCIDENCE	450	51	98	194
STATISTICAL TESTS				
POLY 3	P=0.080N	P=0.250N	P=0.168N	P=0.067N
POLY 1.5	P=0.077N	P=0.259N	P=0.131N	P=0.061N
POLY 6	P=0.067N	P=0.263N	P=0.255N	P=0.067N
COCH-ARM / FISHERS	P=0.046N*	P=0.298N	P=0.154N	P=0.045N*
MAX-ISO-POLY-3	P=0.065N	P=0.158N	P=0.101N	P=0.039N*

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Mixed Cell Focus				
LESION RATES				
OVERALL (a)	15/50 (30%)	10/50 (20%)	9/50 (18%)	3/50 (6%)
POLY-3 RATE (b)	15/44.70	10/44.72	9/41.66	3/41.52
POLY-3 PERCENT (g)	33.6%	22.4%	21.6%	7.2%
TERMINAL (d)	12/34 (35%)	9/34 (27%)	4/24 (17%)	3/34 (9%)
FIRST INCIDENCE	621	639	532	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.004N**	P=0.171N	P=0.156N	P=0.002N**
POLY 1.5	P=0.004N**	P=0.177N	P=0.137N	P=0.002N**
POLY 6	P=0.003N**	P=0.170N	P=0.191N	P=0.002N**
COCH-ARM / FISHERS	P=0.003N**	P=0.178N	P=0.121N	P=0.002N**
MAX-ISO-POLY-3	P=0.003N**	P=0.117N	P=0.113N	P<0.001N**

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Necrosis				
LESION RATES				
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.14	1/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	4.5%	2.3%	0%	0%
TERMINAL (d)	1/34 (3%)	1/34 (3%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	692	728 (T)	---	---
STATISTICAL TESTS				
POLY 3	P=0.189N	P=0.498N	P=0.258N	P=0.251N
POLY 1.5	P=0.189N	P=0.501N	P=0.248N	P=0.250N
POLY 6	P=0.187N	P=0.497N	P=0.275N	P=0.249N
COCH-ARM / FISHERS	P=0.186N	P=0.500N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.097N	P=0.279N	P=0.096N	P=0.089N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver				
Pigmentation Hemosiderin				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/44.00	0/44.40	1/40.58	1/41.76
POLY-3 PERCENT (g)	2.3%	0%	2.5%	2.4%
TERMINAL (d)	1/34 (3%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	728 (T)	---	618	664
STATISTICAL TESTS				
POLY 3	P=0.539	P=0.498N	P=0.743	P=0.749
POLY 1.5	P=0.542	P=0.500N	P=0.751	P=0.749
POLY 6	P=0.543	P=0.497N	P=0.729	P=0.753
COCH-ARM / FISHERS	P=0.559	P=0.500N	P=0.753N	P=0.753N
MAX-ISO-POLY-3	P=0.523	P=0.158N	P=0.477	P=0.485

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver: Bile Duct Hyperplasia				
LESION RATES				
OVERALL (a)	12/50 (24%)	15/50 (30%)	10/50 (20%)	10/50 (20%)
POLY-3 RATE (b)	12/45.91	15/45.75	10/41.15	10/43.19
POLY-3 PERCENT (g)	26.1%	32.8%	24.3%	23.2%
TERMINAL (d)	7/34 (21%)	8/34 (24%)	5/24 (21%)	6/34 (18%)
FIRST INCIDENCE	506	605	632	380
STATISTICAL TESTS				
POLY 3	P=0.298N	P=0.320	P=0.520N	P=0.468N
POLY 1.5	P=0.292N	P=0.315	P=0.467N	P=0.460N
POLY 6	P=0.290N	P=0.324	P=0.592N	P=0.464N
COCH-ARM / FISHERS	P=0.247N	P=0.326	P=0.405N	P=0.405N
MAX-ISO-POLY-3	P=0.413N	P=0.244	P=0.424N	P=0.375N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver: Centrilobular Fatty Change				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	2/41.52
POLY-3 PERCENT (g)	0%	0%	0%	4.8%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	2/34 (6%)
FIRST INCIDENCE	---	---	---	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.038*	(e)	(e)	P=0.224
POLY 1.5	P=0.038*	(e)	(e)	P=0.225
POLY 6	P=0.038*	(e)	(e)	P=0.226
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.034*	(e)	(e)	P=0.076

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver: Centrilobular Necrosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.00	1/44.40	0/40.19	1/41.65
POLY-3 PERCENT (g)	0%	2.3%	0%	2.4%
TERMINAL (d)	0/34 (0%)	1/34 (3%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	728 (T)	---	694
STATISTICAL TESTS				
POLY 3	P=0.451	P=0.502	(e)	P=0.489
POLY 1.5	P=0.451	P=0.500	(e)	P=0.490
POLY 6	P=0.455	P=0.503	(e)	P=0.492
COCH-ARM / FISHERS	P=0.464	P=0.500	(e)	P=0.500
MAX-ISO-POLY-3	P=0.257	P=0.161	(e)	P=0.158

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver: Hepatocyte Hypertrophy				
LESION RATES				
OVERALL (a)	5/50 (10%)	2/50 (4%)	3/50 (6%)	33/50 (66%)
POLY-3 RATE (b)	5/44.24	2/44.40	3/40.27	33/41.81
POLY-3 PERCENT (g)	11.3%	4.5%	7.5%	78.9%
TERMINAL (d)	3/34 (9%)	2/34 (6%)	2/24 (8%)	31/34 (91%)
FIRST INCIDENCE	693	728 (T)	708	688
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.214N	P=0.409N	P<0.001**
POLY 1.5	P<0.001**	P=0.217N	P=0.384N	P<0.001**
POLY 6	P<0.001**	P=0.214N	P=0.449N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.218N	P=0.357N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.118N	P=0.283N	P<0.001**

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Liver: Oval Cell Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	2/44.83	2/40.37	0/41.52
POLY-3 PERCENT (g)	0%	4.5%	5%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	605	705	---
STATISTICAL TESTS				
POLY 3	P=0.396N	P=0.241	P=0.218	(e)
POLY 1.5	P=0.394N	P=0.238	P=0.227	(e)
POLY 6	P=0.391N	P=0.244	P=0.205	(e)
COCH-ARM / FISHERS	P=0.373N	P=0.247	P=0.247	(e)
MAX-ISO-POLY-3	P=0.283	P=0.080	P=0.075	(e)

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lung Inflammation Chronic				
LESION RATES				
OVERALL (a)	4/50 (8%)	5/50 (10%)	2/50 (4%)	7/50 (14%)
POLY-3 RATE (b)	4/44.14	5/44.83	2/40.34	7/41.76
POLY-3 PERCENT (g)	9.1%	11.2%	5%	16.8%
TERMINAL (d)	3/34 (9%)	3/34 (9%)	1/24 (4%)	6/34 (18%)
FIRST INCIDENCE	693	605	688	664
STATISTICAL TESTS				
POLY 3	P=0.155	P=0.510	P=0.379N	P=0.229
POLY 1.5	P=0.158	P=0.502	P=0.359N	P=0.231
POLY 6	P=0.160	P=0.515	P=0.411N	P=0.234
COCH-ARM / FISHERS	P=0.179	P=0.500	P=0.339N	P=0.262
MAX-ISO-POLY-3	P=0.181	P=0.372	P=0.243N	P=0.149

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lung				
Inflammation Granulomatous				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
<hr/>				
Lung Necrosis				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lung: Alveolar Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	11/50 (22%)	14/50 (28%)	6/50 (12%)	7/50 (14%)
POLY-3 RATE (b)	11/44.09	14/45.47	6/40.19	7/41.67
POLY-3 PERCENT (g)	25%	30.8%	14.9%	16.8%
TERMINAL (d)	10/34 (29%)	9/34 (27%)	6/24 (25%)	6/34 (18%)
FIRST INCIDENCE	705	632	728 (T)	688
STATISTICAL TESTS				
POLY 3	P=0.124N	P=0.352	P=0.190N	P=0.254N
POLY 1.5	P=0.122N	P=0.332	P=0.166N	P=0.253N
POLY 6	P=0.117N	P=0.375	P=0.234N	P=0.244N
COCH-ARM / FISHERS	P=0.102N	P=0.322	P=0.143N	P=0.218N
MAX-ISO-POLY-3	P=0.153N	P=0.272	P=0.135N	P=0.184N

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lung: Alveolar Epithelium Hypertrophy				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.00	1/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	2.3%	2.3%	0%	0%
TERMINAL (d)	1/34 (3%)	1/34 (3%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	---	---
STATISTICAL TESTS				
POLY 3	P=0.328N	P=0.759N	P=0.518N	P=0.512N
POLY 1.5	P=0.329N	P=0.761	P=0.509N	P=0.511N
POLY 6	P=0.325N	P=0.758N	P=0.531N	P=0.510N
COCH-ARM / FISHERS	P=0.325N	P=0.753N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.280N	P=0.497N	P=0.180N	P=0.173N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lung: Alveolar Epithelium Metaplasia				
LESION RATES				
OVERALL (a)	2/50 (4%)	3/50 (6%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.14	3/44.62	0/40.19	0/41.52
POLY-3 PERCENT (g)	4.5%	6.7%	0%	0%
TERMINAL (d)	1/34 (3%)	2/34 (6%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	693	670	---	---
STATISTICAL TESTS				
POLY 3	P=0.104N	P=0.505	P=0.258N	P=0.251N
POLY 1.5	P=0.105N	P=0.500	P=0.248N	P=0.250N
POLY 6	P=0.102N	P=0.508	P=0.275N	P=0.249N
COCH-ARM / FISHERS	P=0.101N	P=0.500	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.106N	P=0.329	P=0.096N	P=0.089N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lung: Alveolus Infiltration Cellular Histiocyte				
LESION RATES				
OVERALL (a)	12/50 (24%)	17/50 (34%)	12/50 (24%)	16/50 (32%)
POLY-3 RATE (b)	12/44.32	17/45.55	12/41.38	16/42.24
POLY-3 PERCENT (g)	27.1%	37.3%	29%	37.9%
TERMINAL (d)	10/34 (29%)	13/34 (38%)	7/24 (29%)	14/34 (41%)
FIRST INCIDENCE	669	558	628	489
STATISTICAL TESTS				
POLY 3	P=0.269	P=0.207	P=0.517	P=0.198
POLY 1.5	P=0.278	P=0.194	P=0.553	P=0.202
POLY 6	P=0.276	P=0.218	P=0.463	P=0.204
COCH-ARM / FISHERS	P=0.344	P=0.189	P=0.592N	P=0.252
MAX-ISO-POLY-3	P=0.238	P=0.151	P=0.422	P=0.145

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lymph Node, Mesenteric Atrophy				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/44.14	1/44.40	1/40.40	0/41.52
POLY-3 PERCENT (g)	2.3%	2.3%	2.5%	0%
TERMINAL (d)	0/34 (0%)	1/34 (3%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	693	728 (T)	672	---
STATISTICAL TESTS				
POLY 3	P=0.342N	P=0.759N	P=0.741	P=0.512N
POLY 1.5	P=0.340N	P=0.760	P=0.750	P=0.511N
POLY 6	P=0.339N	P=0.759N	P=0.726	P=0.511N
COCH-ARM / FISHERS	P=0.327N	P=0.753N	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.349N	P=0.498N	P=0.475	P=0.174N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lymph Node, Mesenteric Inflammation				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.00	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	4.6%	0%	0%	0%
TERMINAL (d)	2/34 (6%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	728 (T)	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.262N	P=0.235N	P=0.258N	P=0.250N
POLY 1.5	P=0.262N	P=0.237N	P=0.248N	P=0.249N
POLY 6	P=0.260N	P=0.234N	P=0.274N	P=0.248N
COCH-ARM / FISHERS	P=0.262N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.045N*	P=0.076N	P=0.095N	P=0.089N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lymph Node: Mediastinal Hyperplasia Lymphoid				
LESION RATES				
OVERALL (a)	0/1 (0%)	0/3 (0%)	0/3 (0%)	0/2 (0%)
POLY-3 RATE (b)	0/0.34	0/2.01	0/1.91	0/2.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/2 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Mammary Gland Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	2/40.51	0/41.52
POLY-3 PERCENT (g)	0%	0%	4.9%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/24 (4%)	0/34 (0%)
FIRST INCIDENCE	---	---	639	---
STATISTICAL TESTS				
POLY 3	P=0.698N	(e)	P=0.219	(e)
POLY 1.5	P=0.694N	(e)	P=0.228	(e)
POLY 6	P=0.696N	(e)	P=0.207	(e)
COCH-ARM / FISHERS	P=0.675N	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.249	(e)	P=0.075	(e)

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Mesentery: Fat Necrosis				
LESION RATES				
OVERALL (a)	10/10 (100%)	9/9 (100%)	7/7 (100%)	9/9 (100%)
POLY-3 RATE (b)	10/10.00	9/9.00	7/7.00	9/9.00
POLY-3 PERCENT (g)	100%	100%	100%	100%
TERMINAL (d)	5/5 (100%)	7/7 (100%)	4/4 (100%)	6/6 (100%)
FIRST INCIDENCE	506	558	532	616
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Nose				
Foreign Body				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.00	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	4.6%	0%	0%	0%
TERMINAL (d)	2/34 (6%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	728 (T)	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.262N	P=0.235N	P=0.258N	P=0.250N
POLY 1.5	P=0.262N	P=0.237N	P=0.248N	P=0.249N
POLY 6	P=0.260N	P=0.234N	P=0.274N	P=0.248N
COCH-ARM / FISHERS	P=0.262N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.045N*	P=0.076N	P=0.095N	P=0.089N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Nose Inflammation				
LESION RATES				
OVERALL (a)	8/50 (16%)	2/50 (4%)	9/50 (18%)	8/50 (16%)
POLY-3 RATE (b)	8/44.58	2/44.75	9/41.70	8/42.21
POLY-3 PERCENT (g)	18%	4.5%	21.6%	19%
TERMINAL (d)	5/34 (15%)	1/34 (3%)	5/24 (21%)	7/34 (21%)
FIRST INCIDENCE	621	632	539	489
STATISTICAL TESTS				
POLY 3	P=0.232	P=0.044N*	P=0.439	P=0.562
POLY 1.5	P=0.239	P=0.045N*	P=0.469	P=0.565
POLY 6	P=0.235	P=0.043N*	P=0.394	P=0.567
COCH-ARM / FISHERS	P=0.280	P=0.046N*	P=0.500	P=0.607N
MAX-ISO-POLY-3	P=0.204	P=0.021N*	P=0.340	P=0.452

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Nose: Olfactory Epithelium Metaplasia				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/44.00	0/44.40	1/40.19	0/41.52
POLY-3 PERCENT (g)	2.3%	0%	2.5%	0%
TERMINAL (d)	1/34 (3%)	0/34 (0%)	1/24 (4%)	0/34 (0%)
FIRST INCIDENCE	728 (T)	---	728 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.476N	P=0.498N	P=0.740	P=0.512N
POLY 1.5	P=0.474N	P=0.500N	P=0.750	P=0.511N
POLY 6	P=0.475N	P=0.497N	P=0.725	P=0.510N
COCH-ARM / FISHERS	P=0.464N	P=0.500N	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.280N	P=0.158N	P=0.474	P=0.173N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Nose: Respiratory Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	1/40.37	0/41.52
POLY-3 PERCENT (g)	0%	0%	2.5%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	681	---
STATISTICAL TESTS				
POLY 3	P=0.789N	(e)	P=0.483	(e)
POLY 1.5	P=0.787N	(e)	P=0.491	(e)
POLY 6	P=0.788N	(e)	P=0.471	(e)
COCH-ARM / FISHERS	P=0.779N	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.384	(e)	P=0.158	(e)

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Ovary Cyst				
LESION RATES				
OVERALL (a)	8/50 (16%)	9/50 (18%)	6/50 (12%)	5/50 (10%)
POLY-3 RATE (b)	8/44.33	9/44.56	6/40.92	5/41.92
POLY-3 PERCENT (g)	18.1%	20.2%	14.7%	11.9%
TERMINAL (d)	6/34 (18%)	8/34 (24%)	4/24 (17%)	3/34 (9%)
FIRST INCIDENCE	664	688	618	664
STATISTICAL TESTS				
POLY 3	P=0.210N	P=0.505	P=0.449N	P=0.312N
POLY 1.5	P=0.209N	P=0.498	P=0.419N	P=0.310N
POLY 6	P=0.198N	P=0.506	P=0.496N	P=0.303N
COCH-ARM / FISHERS	P=0.181N	P=0.500	P=0.387N	P=0.277N
MAX-ISO-POLY-3	P=0.308N	P=0.397	P=0.342N	P=0.221N

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Pancreas				
Atrophy				
LESION RATES				
OVERALL (a)	13/50 (26%)	10/50 (20%)	16/50 (32%)	17/50 (34%)
POLY-3 RATE (b)	13/45.52	10/45.76	16/42.46	17/42.92
POLY-3 PERCENT (g)	28.6%	21.9%	37.7%	39.6%
TERMINAL (d)	10/34 (29%)	6/34 (18%)	10/24 (42%)	14/34 (41%)
FIRST INCIDENCE	450	631	519	489
STATISTICAL TESTS				
POLY 3	P=0.077	P=0.310N	P=0.246	P=0.190
POLY 1.5	P=0.084	P=0.321N	P=0.282	P=0.196
POLY 6	P=0.079	P=0.295N	P=0.199	P=0.199
COCH-ARM / FISHERS	P=0.125	P=0.318N	P=0.330	P=0.257
MAX-ISO-POLY-3	P=0.123	P=0.231N	P=0.188	P=0.142

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Pancreas				
Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	1/41.52
POLY-3 PERCENT (g)	0%	0%	0%	2.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	1/34 (3%)
FIRST INCIDENCE	---	---	---	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.211	(e)	(e)	P=0.488
POLY 1.5	P=0.213	(e)	(e)	P=0.489
POLY 6	P=0.212	(e)	(e)	P=0.490
COCH-ARM / FISHERS	P=0.221	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.126	(e)	(e)	P=0.158

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Pancreas: Acinus Hyperplasia				
LESION RATES				
OVERALL (a)	1/50 (2%)	3/50 (6%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.00	3/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	2.3%	6.8%	0%	0%
TERMINAL (d)	1/34 (3%)	3/34 (9%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	---	---
STATISTICAL TESTS				
POLY 3	P=0.170N	P=0.308	P=0.518N	P=0.512N
POLY 1.5	P=0.171N	P=0.305	P=0.509N	P=0.511N
POLY 6	P=0.166N	P=0.310	P=0.531N	P=0.510N
COCH-ARM / FISHERS	P=0.166N	P=0.309	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.143N	P=0.157	P=0.180N	P=0.173N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Pancreas: Acinus Metaplasia Hepatocyte				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	4/50 (8%)
POLY-3 RATE (b)	0/44.00	1/44.40	0/40.19	4/41.83
POLY-3 PERCENT (g)	0%	2.3%	0%	9.6%
TERMINAL (d)	0/34 (0%)	1/34 (3%)	0/24 (0%)	2/34 (6%)
FIRST INCIDENCE	---	728 (T)	---	687
STATISTICAL TESTS				
POLY 3	P=0.008**	P=0.502	(e)	P=0.054
POLY 1.5	P=0.008**	P=0.500	(e)	P=0.054
POLY 6	P=0.009**	P=0.503	(e)	P=0.056
COCH-ARM / FISHERS	P=0.010**	P=0.500	(e)	P=0.059
MAX-ISO-POLY-3	P=0.008**	P=0.161	(e)	P=0.019*

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Parathyroid Gland Hyperplasia				
LESION RATES				
OVERALL (a)	0/44 (0%)	0/47 (0%)	0/44 (0%)	0/47 (0%)
POLY-3 RATE (b)	0/38.47	0/41.49	0/36.06	0/39.92
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/32 (0%)	0/24 (0%)	0/33 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Pituitary Gland: Pars Distalis Angiectasis				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/44.00	1/44.40	1/40.19	2/41.52
POLY-3 PERCENT (g)	2.3%	2.3%	2.5%	4.8%
TERMINAL (d)	1/34 (3%)	0/34 (0%)	1/24 (4%)	2/34 (6%)
FIRST INCIDENCE	728 (T)	727	728 (T)	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.343	P=0.759N	P=0.740	P=0.480
POLY 1.5	P=0.346	P=0.761	P=0.750	P=0.481
POLY 6	P=0.347	P=0.758N	P=0.725	P=0.483
COCH-ARM / FISHERS	P=0.364	P=0.753N	P=0.753N	P=0.500
MAX-ISO-POLY-3	P=0.404	P=0.497N	P=0.474	P=0.269

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Pituitary Gland: Pars Distalis Hyperplasia				
LESION RATES				
OVERALL (a)	11/50 (22%)	20/50 (40%)	16/50 (32%)	23/50 (46%)
POLY-3 RATE (b)	11/45.96	20/45.49	16/42.99	23/43.72
POLY-3 PERCENT (g)	23.9%	44%	37.2%	52.6%
TERMINAL (d)	8/34 (24%)	15/34 (44%)	10/24 (42%)	17/34 (50%)
FIRST INCIDENCE	506	632	439	399
STATISTICAL TESTS				
POLY 3	P=0.014*	P=0.033*	P=0.126	P=0.004**
POLY 1.5	P=0.016*	P=0.033*	P=0.151	P=0.004**
POLY 6	P=0.015*	P=0.033*	P=0.095	P=0.004**
COCH-ARM / FISHERS	P=0.030*	P=0.041*	P=0.184	P=0.010**
MAX-ISO-POLY-3	P=0.005**	P=0.020*	P=0.091	P=0.002**

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Skin Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Spleen Fibrosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	3/50 (6%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/44.00	3/45.18	0/40.19	2/41.79
POLY-3 PERCENT (g)	0%	6.6%	0%	4.8%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	605	---	664
STATISTICAL TESTS				
POLY 3	P=0.394	P=0.123	(e)	P=0.226
POLY 1.5	P=0.392	P=0.120	(e)	P=0.226
POLY 6	P=0.402	P=0.126	(e)	P=0.229
COCH-ARM / FISHERS	P=0.408	P=0.121	(e)	P=0.247
MAX-ISO-POLY-3	P=0.160	P=0.042*	(e)	P=0.076

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Spleen				
Hematopoietic Cell Proliferation				
LESION RATES				
OVERALL (a)	19/50 (38%)	18/50 (36%)	17/50 (34%)	7/50 (14%)
POLY-3 RATE (b)	19/45.60	18/45.65	17/43.26	7/42.04
POLY-3 PERCENT (g)	41.7%	39.4%	39.3%	16.7%
TERMINAL (d)	14/34 (41%)	13/34 (38%)	8/24 (33%)	5/34 (15%)
FIRST INCIDENCE	450	615	532	616
STATISTICAL TESTS				
POLY 3	P=0.004N**	P=0.498N	P=0.496N	P=0.008N**
POLY 1.5	P=0.004N**	P=0.510N	P=0.459N	P=0.008N**
POLY 6	P=0.004N**	P=0.489N	P=0.548N	P=0.008N**
COCH-ARM / FISHERS	P=0.003N**	P=0.500N	P=0.418N	P=0.006N**
MAX-ISO-POLY-3	P=0.007N**	P=0.412N	P=0.410N	P=0.005N**

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Spleen Pigmentation Hemosiderin				
LESION RATES				
OVERALL (a)	37/50 (74%)	37/50 (74%)	41/50 (82%)	42/50 (84%)
POLY-3 RATE (b)	37/45.64	37/46.20	41/48.57	42/48.99
POLY-3 PERCENT (g)	81.1%	80.1%	84.4%	85.7%
TERMINAL (d)	29/34 (85%)	30/34 (88%)	19/24 (79%)	28/34 (82%)
FIRST INCIDENCE	621	558	98	111
STATISTICAL TESTS				
POLY 3	P=0.283	P=0.560N	P=0.435	P=0.365
POLY 1.5	P=0.226	P=0.593N	P=0.376	P=0.288
POLY 6	P=0.383	P=0.551N	P=0.493	P=0.470
COCH-ARM / FISHERS	P=0.117	P=0.590N	P=0.235	P=0.163
MAX-ISO-POLY-3	P=0.407	P=0.449N	P=0.331	P=0.271

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
<hr/>				
Spleen Thrombosis				
<hr/>				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Spleen: Lymphoid Follicle Atrophy				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	1/44.00	1/44.56	4/41.62	2/43.35
POLY-3 PERCENT (g)	2.3%	2.2%	9.6%	4.6%
TERMINAL (d)	1/34 (3%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	728 (T)	688	439	140
STATISTICAL TESTS				
POLY 3	P=0.431	P=0.758N	P=0.161	P=0.495
POLY 1.5	P=0.432	P=0.760N	P=0.170	P=0.493
POLY 6	P=0.438	P=0.756N	P=0.149	P=0.500
COCH-ARM / FISHERS	P=0.445	P=0.753N	P=0.181	P=0.500
MAX-ISO-POLY-3	P=0.233	P=0.496N	P=0.079	P=0.277

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Stomach, Forestomach Erosion				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	1/44.75	2/40.63	0/41.52
POLY-3 PERCENT (g)	0%	2.2%	4.9%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	631	652	---
STATISTICAL TESTS				
POLY 3	P=0.524N	P=0.503	P=0.220	(e)
POLY 1.5	P=0.521N	P=0.501	P=0.228	(e)
POLY 6	P=0.521N	P=0.505	P=0.208	(e)
COCH-ARM / FISHERS	P=0.500N	P=0.500	P=0.247	(e)
MAX-ISO-POLY-3	P=0.329	P=0.163	P=0.075	(e)

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Stomach, Forestomach Inflammation				
LESION RATES				
OVERALL (a)	5/50 (10%)	7/50 (14%)	7/50 (14%)	13/50 (26%)
POLY-3 RATE (b)	5/46.44	7/45.23	7/41.82	13/44.73
POLY-3 PERCENT (g)	10.8%	15.5%	16.7%	29.1%
TERMINAL (d)	1/34 (3%)	3/34 (9%)	1/24 (4%)	9/34 (27%)
FIRST INCIDENCE	450	631	579	111
STATISTICAL TESTS				
POLY 3	P=0.014*	P=0.361	P=0.307	P=0.025*
POLY 1.5	P=0.015*	P=0.363	P=0.338	P=0.027*
POLY 6	P=0.013*	P=0.358	P=0.271	P=0.023*
COCH-ARM / FISHERS	P=0.018*	P=0.380	P=0.380	P=0.033*
MAX-ISO-POLY-3	P=0.018*	P=0.256	P=0.220	P=0.014*

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Stomach, Forestomach Mineralization				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Stomach, Forestomach Ulcer				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	3/50 (6%)	7/50 (14%)
POLY-3 RATE (b)	1/44.76	1/44.40	3/40.90	7/42.75
POLY-3 PERCENT (g)	2.2%	2.3%	7.3%	16.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/24 (4%)	5/34 (15%)
FIRST INCIDENCE	450	727	579	140
STATISTICAL TESTS				
POLY 3	P=0.003**	P=0.759	P=0.273	P=0.025*
POLY 1.5	P=0.003**	P=0.758	P=0.288	P=0.026*
POLY 6	P=0.003**	P=0.759	P=0.254	P=0.026*
COCH-ARM / FISHERS	P=0.004**	P=0.753N	P=0.309	P=0.030*
MAX-ISO-POLY-3	P=0.005**	P=0.497	P=0.143	P=0.011*

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Stomach, Forestomach: Epithelium Dysplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Stomach, Forestomach: Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	5/50 (10%)	6/50 (12%)	8/50 (16%)	19/50 (38%)
POLY-3 RATE (b)	5/46.57	6/45.30	8/41.82	19/43.90
POLY-3 PERCENT (g)	10.7%	13.3%	19.1%	43.3%
TERMINAL (d)	0/34 (0%)	2/34 (6%)	2/24 (8%)	15/34 (44%)
FIRST INCIDENCE	450	631	579	111
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.481	P=0.209	P<0.001**
POLY 1.5	P<0.001**	P=0.483	P=0.237	P<0.001**
POLY 6	P<0.001**	P=0.477	P=0.176	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500	P=0.277	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.357	P=0.145	P<0.001**

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
Time Report Requested: 09:10:56
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Stomach, Glandular Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	2/44.75	0/40.19	0/41.52
POLY-3 PERCENT (g)	0%	4.5%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	631	---	---
STATISTICAL TESTS				
POLY 3	P=0.395N	P=0.241	(e)	(e)
POLY 1.5	P=0.397N	P=0.238	(e)	(e)
POLY 6	P=0.389N	P=0.243	(e)	(e)
COCH-ARM / FISHERS	P=0.392N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.280N	P=0.080	(e)	(e)

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Stomach, Glandular: Epithelium Necrosis				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.64	1/44.75	0/40.19	0/41.52
POLY-3 PERCENT (g)	2.2%	2.2%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	519	631	---	---
STATISTICAL TESTS				
POLY 3	P=0.329N	P=0.760N	P=0.521N	P=0.514N
POLY 1.5	P=0.329N	P=0.760	P=0.511N	P=0.512N
POLY 6	P=0.327N	P=0.759N	P=0.535N	P=0.514N
COCH-ARM / FISHERS	P=0.325N	P=0.753N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.286N	P=0.499N	P=0.184N	P=0.176N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Thymus Atrophy				
LESION RATES				
OVERALL (a)	48/50 (96%)	43/50 (86%)	47/49 (96%)	45/48 (94%)
POLY-3 RATE (b)	48/48.34	43/46.91	47/47.65	45/45.92
POLY-3 PERCENT (g)	99.3%	91.7%	98.6%	98%
TERMINAL (d)	34/34 (100%)	33/34 (97%)	23/23 (100%)	33/33 (100%)
FIRST INCIDENCE	450	558	439	140
STATISTICAL TESTS				
POLY 3	P=0.435	P=0.068N	P=0.825N	P=0.663N
POLY 1.5	P=0.432	P=0.074N	P=0.765N	P=0.616N
POLY 6	P=0.515	P=0.077N	P=0.945N	P=0.674N
COCH-ARM / FISHERS	P=0.454	P=0.080N	P=0.684N	P=0.480N
MAX-ISO-POLY-3	P=0.253N	P=0.022N*	P=0.336N	P=0.262N

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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Date Report Requested: 09/21/2010
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 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Thyroid Gland: C-Cell Hyperplasia				
LESION RATES				
OVERALL (a)	15/50 (30%)	15/50 (30%)	6/50 (12%)	4/50 (8%)
POLY-3 RATE (b)	15/44.52	15/45.00	6/40.89	4/41.52
POLY-3 PERCENT (g)	33.7%	33.3%	14.7%	9.6%
TERMINAL (d)	12/34 (35%)	11/34 (32%)	4/24 (17%)	4/34 (12%)
FIRST INCIDENCE	664	632	629	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.002N**	P=0.575N	P=0.034N*	P=0.006N**
POLY 1.5	P=0.002N**	P=0.586N	P=0.028N*	P=0.006N**
POLY 6	P=0.002N**	P=0.569N	P=0.047N*	P=0.006N**
COCH-ARM / FISHERS	P=0.002N**	P=0.586N	P=0.024N*	P=0.005N**
MAX-ISO-POLY-3	P=0.004N**	P=0.485N	P=0.023N*	P=0.003N**

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Thyroid Gland: Follicle Cyst				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	2/41.65
POLY-3 PERCENT (g)	0%	0%	0%	4.8%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	1/34 (3%)
FIRST INCIDENCE	---	---	---	694
STATISTICAL TESTS				
POLY 3	P=0.038*	(e)	(e)	P=0.225
POLY 1.5	P=0.038*	(e)	(e)	P=0.226
POLY 6	P=0.039*	(e)	(e)	P=0.228
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.034*	(e)	(e)	P=0.076

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/21/2010
 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Thyroid Gland: Follicular Cell Hyperplasia				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	4/50 (8%)	4/50 (8%)
POLY-3 RATE (b)	1/44.00	1/44.59	4/40.40	4/41.67
POLY-3 PERCENT (g)	2.3%	2.2%	9.9%	9.6%
TERMINAL (d)	1/34 (3%)	0/34 (0%)	3/24 (13%)	3/34 (9%)
FIRST INCIDENCE	728 (T)	678	672	688
STATISTICAL TESTS				
POLY 3	P=0.095	P=0.758N	P=0.153	P=0.162
POLY 1.5	P=0.098	P=0.760N	P=0.165	P=0.163
POLY 6	P=0.097	P=0.756N	P=0.136	P=0.166
COCH-ARM / FISHERS	P=0.114	P=0.753N	P=0.181	P=0.181
MAX-ISO-POLY-3	P=0.120	P=0.495N	P=0.077	P=0.079

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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Date Report Requested: 09/21/2010
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 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Tooth Malformation				
LESION RATES				
OVERALL (a)	5/5 (100%)	3/3 (100%)	4/4 (100%)	2/2 (100%)
POLY-3 RATE (b)	5/5.00	3/3.00	4/4.00	2/2.00
POLY-3 PERCENT (g)	100%	100%	100%	100%
TERMINAL (d)	5/5 (100%)	2/2 (100%)	1/1 (100%)	2/2 (100%)
FIRST INCIDENCE	728 (T)	678	629	728 (T)
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Urinary Bladder Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20007 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

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 Time Report Requested: 09:10:56
 First Dose M/F: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Uterus Hemorrhage				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.00	2/44.40	0/40.19	1/41.52
POLY-3 PERCENT (g)	0%	4.5%	0%	2.4%
TERMINAL (d)	0/34 (0%)	2/34 (6%)	0/24 (0%)	1/34 (3%)
FIRST INCIDENCE	---	728 (T)	---	728 (T)
STATISTICAL TESTS				
POLY 3	P=0.603	P=0.239	(e)	P=0.488
POLY 1.5	P=0.603	P=0.237	(e)	P=0.489
POLY 6	P=0.607	P=0.240	(e)	P=0.490
COCH-ARM / FISHERS	P=0.617	P=0.247	(e)	P=0.500
MAX-ISO-POLY-3	P=0.334	P=0.078	(e)	P=0.158

TDMS No. 20007 - 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: 08/18/04 / 08/19/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Uterus: Endometrium Hyperplasia Cystic				
LESION RATES				
OVERALL (a)	5/50 (10%)	5/50 (10%)	6/50 (12%)	10/50 (20%)
POLY-3 RATE (b)	5/44.14	5/44.40	6/41.37	10/41.68
POLY-3 PERCENT (g)	11.3%	11.3%	14.5%	24%
TERMINAL (d)	4/34 (12%)	5/34 (15%)	3/24 (13%)	9/34 (27%)
FIRST INCIDENCE	692	728 (T)	439	687
STATISTICAL TESTS				
POLY 3	P=0.045*	P=0.627N	P=0.454	P=0.102
POLY 1.5	P=0.048*	P=0.629	P=0.478	P=0.105
POLY 6	P=0.047*	P=0.626N	P=0.417	P=0.105
COCH-ARM / FISHERS	P=0.062	P=0.630N	P=0.500	P=0.131
MAX-ISO-POLY-3	P=0.073	P=0.495N	P=0.335	P=0.065

TDMS No. 20007 - 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 ***