

TDMS No. 20007 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
Time Report Requested: 10:57:30
First Dose M/F: 08/24/04 / 08/23/04
Lab: BAT

F_M3

C Number: C20007
Lock Date: 05/10/2007
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.1.0

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

MALE MICE

Organ

Adrenal Cortex: Subcapsular
Harderian Gland
Kidney

Kidney: Cortex, Medulla
Kidney: Papilla
Kidney: Renal Tubule

Liver

Liver: Centrilobular
Lung
Lymph Node, Mandibular
Pancreas: Acinus
Prostate
Salivary Glands
Seminal Vesicle

Skin
Stomach, Glandular: Epithelium
Thymus
Thyroid Gland
Urinary Bladder

FEMALE MICE

Organ

Morphology

Hyperplasia
Hyperplasia
Hydronephrosis
Mineralization
Nephropathy
Necrosis
Necrosis
Cyst
Hyperplasia
Mineralization
Angiectasis
Eosinophilic Focus
Fatty Change
Mixed Cell Focus
Necrosis
Hypertrophy
Inflammation
Hyperplasia Lymphoid
Hypertrophy
Infiltration Cellular Mononuclear Cell
Infiltration Cellular Mononuclear Cell
Fibrosis
Infiltration Cellular Mononuclear Cell
Inflammation
Ulcer
Hyperplasia
Atrophy
Cyst
Inflammation

Morphology

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

Bone
Brain: Hypothalamus
Islets, Pancreatic
Kidney: Renal Tubule
Liver

Liver: Centrilobular
Lung: Alveolar Epithelium
Nose
Pancreas
Salivary Glands
Spleen
Stomach, Forestomach

Stomach, Forestomach: Epithelium
Stomach, Glandular
Thymus

Uterus
Uterus: Endometrium

Fibrosis
Compression
Hyperplasia
Hyperplasia
Angiectasis
Basophilic Focus
Clear Cell Focus
Eosinophilic Focus
Fatty Change
Infiltration Cellular Mononuclear Cell
Necrosis
Hypertrophy
Hyperplasia
Inflammation Chronic
Inflammation Chronic
Infiltration Cellular Mononuclear Cell
Hematopoietic Cell Proliferation
Erosion
Inflammation Chronic
Ulcer
Hyperplasia
Ulcer
Atrophy
Infiltration Cellular Histiocyte
Inflammation
Hyperplasia Cystic

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Adrenal Cortex Hypertrophy				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/43.67	2/42.37	0/44.59	2/44.80
POLY-3 PERCENT (g)	2.3%	4.7%	0%	4.5%
TERMINAL (d)	0/34 (0%)	2/33 (6%)	0/34 (0%)	1/36 (3%)
FIRST INCIDENCE	683	730 (T)	---	547
STATISTICAL TESTS				
POLY 3	P=0.479	P=0.489	P=0.496N	P=0.509
POLY 1.5	P=0.476	P=0.492	P=0.497N	P=0.505
POLY 6	P=0.485	P=0.490	P=0.495N	P=0.515
COCH-ARM / FISHERS	P=0.469	P=0.500	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.272	P=0.274	P=0.158N	P=0.290

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Adrenal Cortex				
Vacuolization Cytoplasmic				
LESION RATES				
OVERALL (a)	2/50 (4%)	2/50 (4%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	2/43.49	2/42.37	2/44.59	3/44.23
POLY-3 PERCENT (g)	4.6%	4.7%	4.5%	6.8%
TERMINAL (d)	2/34 (6%)	2/33 (6%)	2/34 (6%)	3/36 (8%)
FIRST INCIDENCE	730 (T)	730 (T)	730 (T)	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.400	P=0.685	P=0.685N	P=0.508
POLY 1.5	P=0.395	P=0.686	P=0.688N	P=0.504
POLY 6	P=0.406	P=0.687	P=0.682N	P=0.514
COCH-ARM / FISHERS	P=0.387	P=0.691N	P=0.691N	P=0.500
MAX-ISO-POLY-3	P=0.322	P=0.488	P=0.488N	P=0.330

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Adrenal Cortex: Subcapsular Hyperplasia				
LESION RATES				
OVERALL (a)	44/50 (88%)	45/50 (90%)	48/50 (96%)	49/50 (98%)
POLY-3 RATE (b)	44/49.77	45/48.97	48/49.39	49/49.85
POLY-3 PERCENT (g)	88.4%	91.9%	97.2%	98.3%
TERMINAL (d)	29/34 (85%)	31/33 (94%)	33/34 (97%)	36/36 (100%)
FIRST INCIDENCE	369	319	455	392
STATISTICAL TESTS				
POLY 3	P=0.018*	P=0.401	P=0.090	P=0.052
POLY 1.5	P=0.020*	P=0.443	P=0.104	P=0.054
POLY 6	P=0.017*	P=0.348	P=0.080	P=0.048*
COCH-ARM / FISHERS	P=0.025*	P=0.500	P=0.134	P=0.056
MAX-ISO-POLY-3	P=0.014*	P=0.277	P=0.041*	P=0.020*

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Adrenal Cortex: Zona Reticularis Hyperplasia				
LESION RATES				
OVERALL (a)	5/50 (10%)	3/50 (6%)	2/50 (4%)	4/50 (8%)
POLY-3 RATE (b)	5/43.49	3/42.37	2/44.83	4/44.46
POLY-3 PERCENT (g)	11.5%	7.1%	4.5%	9%
TERMINAL (d)	5/34 (15%)	3/33 (9%)	1/34 (3%)	3/36 (8%)
FIRST INCIDENCE	730 (T)	730 (T)	668	668
STATISTICAL TESTS				
POLY 3	P=0.445N	P=0.370N	P=0.203N	P=0.486N
POLY 1.5	P=0.452N	P=0.368N	P=0.209N	P=0.493N
POLY 6	P=0.438N	P=0.366N	P=0.197N	P=0.474N
COCH-ARM / FISHERS	P=0.463N	P=0.357N	P=0.218N	P=0.500N
MAX-ISO-POLY-3	P=0.206N	P=0.244N	P=0.113N	P=0.349N

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Adrenal Medulla Hyperplasia				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/43.49	0/42.37	1/44.59	0/44.23
POLY-3 PERCENT (g)	2.3%	0%	2.2%	0%
TERMINAL (d)	1/34 (3%)	0/33 (0%)	1/34 (3%)	0/36 (0%)
FIRST INCIDENCE	730 (T)	---	730 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.399N	P=0.505N	P=0.755N	P=0.497N
POLY 1.5	P=0.401N	P=0.504N	P=0.757N	P=0.498N
POLY 6	P=0.397N	P=0.504N	P=0.753N	P=0.494N
COCH-ARM / FISHERS	P=0.405N	P=0.500N	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.158N	P=0.164N	P=0.492N	P=0.158N

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Bone Marrow Fibrosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.49	0/42.37	0/44.59	0/44.23
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/33 (0%)	0/34 (0%)	0/36 (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)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Bone Fibrosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.49	0/42.37	0/44.59	0/44.23
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/33 (0%)	0/34 (0%)	0/36 (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)

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TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG

Brain: Hypothalamus
Compression

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/43.49	0/42.37	1/45.28	0/44.23
POLY-3 PERCENT (g)	0%	0%	2.2%	0%
TERMINAL (d)	0/34 (0%)	0/33 (0%)	0/34 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	494	---

STATISTICAL TESTS

POLY 3	P=0.702	(e)	P=0.508	(e)
POLY 1.5	P=0.699	(e)	P=0.505	(e)
POLY 6	P=0.706	(e)	P=0.511	(e)
COCH-ARM / FISHERS	P=0.694	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.245	(e)	P=0.168	(e)

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Epididymis				
Granuloma Sperm				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	2/43.49	0/42.37	3/44.86	1/44.44
POLY-3 PERCENT (g)	4.6%	0%	6.7%	2.3%
TERMINAL (d)	2/34 (6%)	0/33 (0%)	1/34 (3%)	0/36 (0%)
FIRST INCIDENCE	730 (T)	---	660	673
STATISTICAL TESTS				
POLY 3	P=0.540N	P=0.243N	P=0.514	P=0.492N
POLY 1.5	P=0.546N	P=0.242N	P=0.509	P=0.496N
POLY 6	P=0.534N	P=0.241N	P=0.521	P=0.486N
COCH-ARM / FISHERS	P=0.556N	P=0.247N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.274N	P=0.080N	P=0.337	P=0.275N

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Epididymis				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	29/50 (58%)	22/50 (44%)	33/50 (66%)	28/50 (56%)
POLY-3 RATE (b)	29/44.60	22/43.42	33/45.58	28/47.82
POLY-3 PERCENT (g)	65%	50.7%	72.4%	58.6%
TERMINAL (d)	24/34 (71%)	17/33 (52%)	28/34 (82%)	21/36 (58%)
FIRST INCIDENCE	647	596	653	392
STATISTICAL TESTS				
POLY 3	P=0.483N	P=0.117N	P=0.289	P=0.332N
POLY 1.5	P=0.522	P=0.120N	P=0.283	P=0.396N
POLY 6	P=0.405N	P=0.105N	P=0.293	P=0.267N
COCH-ARM / FISHERS	P=0.386	P=0.115N	P=0.268	P=0.500N
MAX-ISO-POLY-3	P=0.229	P=0.080N	P=0.215	P=0.263N

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Eye: Cornea				
Inflammation Chronic				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/43.49	1/43.15	1/44.59	2/45.04
POLY-3 PERCENT (g)	0%	2.3%	2.2%	4.4%
TERMINAL (d)	0/34 (0%)	0/33 (0%)	1/34 (3%)	0/36 (0%)
FIRST INCIDENCE	---	437	730 (T)	547
STATISTICAL TESTS				
POLY 3	P=0.162	P=0.498	P=0.505	P=0.245
POLY 1.5	P=0.159	P=0.498	P=0.503	P=0.242
POLY 6	P=0.168	P=0.501	P=0.507	P=0.251
COCH-ARM / FISHERS	P=0.153	P=0.500	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.084	P=0.158	P=0.164	P=0.083

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Harderian Gland Hyperplasia				
LESION RATES				
OVERALL (a)	4/50 (8%)	3/50 (6%)	1/50 (2%)	8/50 (16%)
POLY-3 RATE (b)	4/43.97	3/42.99	1/44.59	8/44.23
POLY-3 PERCENT (g)	9.1%	7%	2.2%	18.1%
TERMINAL (d)	3/34 (9%)	1/33 (3%)	1/34 (3%)	8/36 (22%)
FIRST INCIDENCE	587	623	730 (T)	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.079	P=0.512N	P=0.174N	P=0.178
POLY 1.5	P=0.079	P=0.511N	P=0.176N	P=0.178
POLY 6	P=0.079	P=0.506N	P=0.173N	P=0.180
COCH-ARM / FISHERS	P=0.079	P=0.500N	P=0.181N	P=0.178
MAX-ISO-POLY-3	P=0.024*	P=0.358N	P=0.081N	P=0.108

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Harderian Gland				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	36/50 (72%)	30/50 (60%)	34/50 (68%)	39/50 (78%)
POLY-3 RATE (b)	36/48.48	30/44.95	34/47.17	39/47.87
POLY-3 PERCENT (g)	74.3%	66.8%	72.1%	81.5%
TERMINAL (d)	22/34 (65%)	24/33 (73%)	27/34 (79%)	31/36 (86%)
FIRST INCIDENCE	455	431	494	392
STATISTICAL TESTS				
POLY 3	P=0.152	P=0.280N	P=0.496N	P=0.268
POLY 1.5	P=0.162	P=0.216N	P=0.451N	P=0.302
POLY 6	P=0.122	P=0.376N	P=0.575N	P=0.206
COCH-ARM / FISHERS	P=0.156	P=0.146N	P=0.414N	P=0.322
MAX-ISO-POLY-3	P=0.104	P=0.215N	P=0.403N	P=0.193

TDMS No. 20007 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
Time Report Requested: 10:57:30
First Dose M/F: 08/24/04 / 08/23/04
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Heart				
Cardiomyopathy				
LESION RATES				
OVERALL (a)	14/50 (28%)	16/50 (32%)	11/50 (22%)	14/50 (28%)
POLY-3 RATE (b)	14/44.31	16/43.76	11/45.45	14/45.84
POLY-3 PERCENT (g)	31.6%	36.6%	24.2%	30.5%
TERMINAL (d)	10/34 (29%)	10/33 (30%)	8/34 (24%)	10/36 (28%)
FIRST INCIDENCE	648	553	616	574
STATISTICAL TESTS				
POLY 3	P=0.394N	P=0.394	P=0.292N	P=0.548N
POLY 1.5	P=0.414N	P=0.395	P=0.303N	P=0.565N
POLY 6	P=0.373N	P=0.410	P=0.283N	P=0.523N
COCH-ARM / FISHERS	P=0.447N	P=0.414	P=0.322N	P=0.588N
MAX-ISO-POLY-3	P=0.247N	P=0.310	P=0.219N	P=0.455N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Heart: Artery				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	2/50 (4%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/43.49	1/42.37	1/44.88	1/44.32
POLY-3 PERCENT (g)	4.6%	2.4%	2.2%	2.3%
TERMINAL (d)	2/34 (6%)	1/33 (3%)	0/34 (0%)	0/36 (0%)
FIRST INCIDENCE	730 (T)	730 (T)	653	707
STATISTICAL TESTS				
POLY 3	P=0.400N	P=0.509N	P=0.489N	P=0.493N
POLY 1.5	P=0.404N	P=0.507N	P=0.493N	P=0.496N
POLY 6	P=0.397N	P=0.507N	P=0.484N	P=0.488N
COCH-ARM / FISHERS	P=0.409N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.256N	P=0.290N	P=0.274N	P=0.276N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Heart: Myocardium Mineralization				
LESION RATES				
OVERALL (a)	1/50 (2%)	4/50 (8%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/44.01	4/43.28	0/44.59	1/44.68
POLY-3 PERCENT (g)	2.3%	9.2%	0%	2.2%
TERMINAL (d)	0/34 (0%)	0/33 (0%)	0/34 (0%)	0/36 (0%)
FIRST INCIDENCE	570	596	---	595
STATISTICAL TESTS				
POLY 3	P=0.332N	P=0.173	P=0.497N	P=0.757N
POLY 1.5	P=0.334N	P=0.174	P=0.498N	P=0.759N
POLY 6	P=0.327N	P=0.177	P=0.497N	P=0.754N
COCH-ARM / FISHERS	P=0.337N	P=0.181	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.114N	P=0.081	P=0.158N	P=0.494N

TDMS No. 20007 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
Time Report Requested: 10:57:30
First Dose M/F: 08/24/04 / 08/23/04
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG

Heart: Valve
Inflammation

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/43.49	0/42.37	0/44.59	1/44.44
POLY-3 PERCENT (g)	0%	0%	0%	2.3%
TERMINAL (d)	0/34 (0%)	0/33 (0%)	0/34 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	673

STATISTICAL TESTS

POLY 3	P=0.203	(e)	(e)	P=0.504
POLY 1.5	P=0.202	(e)	(e)	P=0.502
POLY 6	P=0.206	(e)	(e)	P=0.508
COCH-ARM / FISHERS	P=0.198	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.082	(e)	(e)	P=0.163

TDMS No. 20007 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
Time Report Requested: 10:57:30
First Dose M/F: 08/24/04 / 08/23/04
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Intestine Small, Jejunum: Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.49	2/42.37	0/44.59	0/44.23
POLY-3 PERCENT (g)	0%	4.7%	0%	0%
TERMINAL (d)	0/34 (0%)	2/33 (6%)	0/34 (0%)	0/36 (0%)
FIRST INCIDENCE	---	730 (T)	---	---
STATISTICAL TESTS				
POLY 3	P=0.404N	P=0.231	(e)	(e)
POLY 1.5	P=0.405N	P=0.232	(e)	(e)
POLY 6	P=0.400N	P=0.232	(e)	(e)
COCH-ARM / FISHERS	P=0.405N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.152N	P=0.075	(e)	(e)

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Islets, Pancreatic Hyperplasia				
LESION RATES				
OVERALL (a)	37/50 (74%)	35/50 (70%)	36/50 (72%)	33/50 (66%)
POLY-3 RATE (b)	37/46.81	35/45.49	36/47.28	33/47.87
POLY-3 PERCENT (g)	79.1%	76.9%	76.1%	68.9%
TERMINAL (d)	28/34 (82%)	27/33 (82%)	27/34 (79%)	23/36 (64%)
FIRST INCIDENCE	455	423	534	547
STATISTICAL TESTS				
POLY 3	P=0.133N	P=0.503N	P=0.462N	P=0.181N
POLY 1.5	P=0.173N	P=0.474N	P=0.475N	P=0.213N
POLY 6	P=0.091N	P=0.514N	P=0.445N	P=0.139N
COCH-ARM / FISHERS	P=0.240N	P=0.412N	P=0.500N	P=0.257N
MAX-ISO-POLY-3	P=0.120N	P=0.397N	P=0.360N	P=0.127N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney				
Amyloid Deposition				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/43.49	0/42.37	1/44.59	0/44.23
POLY-3 PERCENT (g)	0%	0%	2.2%	0%
TERMINAL (d)	0/34 (0%)	0/33 (0%)	1/34 (3%)	0/36 (0%)
FIRST INCIDENCE	---	---	730 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.702	(e)	P=0.505	(e)
POLY 1.5	P=0.699	(e)	P=0.503	(e)
POLY 6	P=0.707	(e)	P=0.507	(e)
COCH-ARM / FISHERS	P=0.694	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.244	(e)	P=0.164	(e)

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney				
Hydronephrosis				
LESION RATES				
OVERALL (a)	6/50 (12%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	6/44.75	1/42.95	0/44.59	1/44.23
POLY-3 PERCENT (g)	13.4%	2.3%	0%	2.3%
TERMINAL (d)	3/34 (9%)	0/33 (0%)	0/34 (0%)	1/36 (3%)
FIRST INCIDENCE	570	546	---	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.022N*	P=0.062N	P=0.015N*	P=0.057N
POLY 1.5	P=0.022N*	P=0.061N	P=0.015N*	P=0.057N
POLY 6	P=0.021N*	P=0.063N	P=0.016N*	P=0.058N
COCH-ARM / FISHERS	P=0.025N*	P=0.056N	P=0.013N*	P=0.056N
MAX-ISO-POLY-3	P=0.002N**	P=0.029N*	P=0.005N**	P=0.024N*

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney Inflammation				
LESION RATES				
OVERALL (a)	2/50 (4%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/43.72	2/42.51	1/44.59	1/44.72
POLY-3 PERCENT (g)	4.6%	4.7%	2.2%	2.2%
TERMINAL (d)	1/34 (3%)	1/33 (3%)	1/34 (3%)	0/36 (0%)
FIRST INCIDENCE	668	693	730 (T)	582
STATISTICAL TESTS				
POLY 3	P=0.329N	P=0.684	P=0.493N	P=0.492N
POLY 1.5	P=0.332N	P=0.686	P=0.495N	P=0.496N
POLY 6	P=0.325N	P=0.686	P=0.492N	P=0.487N
COCH-ARM / FISHERS	P=0.337N	P=0.691N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.270N	P=0.487	P=0.276N	P=0.275N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney				
Metaplasia Osseous				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/43.49	2/42.37	0/44.59	2/44.23
POLY-3 PERCENT (g)	0%	4.7%	0%	4.5%
TERMINAL (d)	0/34 (0%)	2/33 (6%)	0/34 (0%)	2/36 (6%)
FIRST INCIDENCE	---	730 (T)	---	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.251	P=0.231	(e)	P=0.241
POLY 1.5	P=0.249	P=0.232	(e)	P=0.239
POLY 6	P=0.255	P=0.232	(e)	P=0.244
COCH-ARM / FISHERS	P=0.247	P=0.247	(e)	P=0.247
MAX-ISO-POLY-3	P=0.079	P=0.075	(e)	P=0.079

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney Mineralization				
LESION RATES				
OVERALL (a)	3/50 (6%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/44.73	1/42.51	0/44.59	0/44.23
POLY-3 PERCENT (g)	6.7%	2.4%	0%	0%
TERMINAL (d)	1/34 (3%)	0/33 (0%)	0/34 (0%)	0/36 (0%)
FIRST INCIDENCE	369	695	---	---
STATISTICAL TESTS				
POLY 3	P=0.041N*	P=0.324N	P=0.119N	P=0.121N
POLY 1.5	P=0.042N*	P=0.319N	P=0.119N	P=0.120N
POLY 6	P=0.041N*	P=0.324N	P=0.119N	P=0.120N
COCH-ARM / FISHERS	P=0.044N*	P=0.309N	P=0.121N	P=0.121N
MAX-ISO-POLY-3	P=0.016N*	P=0.173N	P=0.038N*	P=0.040N*

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney				
Nephropathy				
LESION RATES				
OVERALL (a)	32/50 (64%)	40/50 (80%)	37/50 (74%)	38/50 (76%)
POLY-3 RATE (b)	32/46.16	40/45.68	37/46.29	38/46.52
POLY-3 PERCENT (g)	69.3%	87.6%	79.9%	81.7%
TERMINAL (d)	25/34 (74%)	33/33 (100%)	30/34 (88%)	31/36 (86%)
FIRST INCIDENCE	513	423	534	392
STATISTICAL TESTS				
POLY 3	P=0.181	P=0.021*	P=0.162	P=0.113
POLY 1.5	P=0.195	P=0.031*	P=0.178	P=0.125
POLY 6	P=0.164	P=0.013*	P=0.139	P=0.101
COCH-ARM / FISHERS	P=0.201	P=0.059	P=0.194	P=0.138
MAX-ISO-POLY-3	P=0.038*	P=0.011*	P=0.107	P=0.071

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney: Cortex, Medulla Necrosis				
LESION RATES				
OVERALL (a)	6/50 (12%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	6/45.43	0/42.37	0/44.59	0/44.23
POLY-3 PERCENT (g)	13.2%	0%	0%	0%
TERMINAL (d)	1/34 (3%)	0/33 (0%)	0/34 (0%)	0/36 (0%)
FIRST INCIDENCE	570	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.002N**	P=0.019N*	P=0.016N*	P=0.017N*
POLY 1.5	P=0.003N**	P=0.018N*	P=0.016N*	P=0.016N*
POLY 6	P=0.002N**	P=0.020N*	P=0.017N*	P=0.017N*
COCH-ARM / FISHERS	P=0.004N**	P=0.013N*	P=0.013N*	P=0.013N*
MAX-ISO-POLY-3	P<0.001N**	P=0.008N**	P=0.005N**	P=0.006N**

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney: Papilla Necrosis				
LESION RATES				
OVERALL (a)	3/50 (6%)	0/50 (0%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	3/43.49	0/42.37	0/44.59	3/44.23
POLY-3 PERCENT (g)	6.9%	0%	0%	6.8%
TERMINAL (d)	3/34 (9%)	0/33 (0%)	0/34 (0%)	3/36 (8%)
FIRST INCIDENCE	730 (T)	---	---	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.455	P=0.123N	P=0.114N	P=0.655N
POLY 1.5	P=0.452	P=0.122N	P=0.116N	P=0.658N
POLY 6	P=0.456	P=0.122N	P=0.112N	P=0.649N
COCH-ARM / FISHERS	P=0.444	P=0.121N	P=0.121N	P=0.661N
MAX-ISO-POLY-3	P=0.117N	P=0.042N*	P=0.038N*	P=0.490N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney: Renal Tubule Cyst				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	0/43.49	0/42.37	3/44.79	0/44.23
POLY-3 PERCENT (g)	0%	0%	6.7%	0%
TERMINAL (d)	0/34 (0%)	0/33 (0%)	2/34 (6%)	0/36 (0%)
FIRST INCIDENCE	---	---	679	---
STATISTICAL TESTS				
POLY 3	P=0.554	(e)	P=0.124	(e)
POLY 1.5	P=0.548	(e)	P=0.122	(e)
POLY 6	P=0.562	(e)	P=0.126	(e)
COCH-ARM / FISHERS	P=0.539	(e)	P=0.121	(e)
MAX-ISO-POLY-3	P=0.109	(e)	P=0.042*	(e)

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney: Renal Tubule Hyperplasia				
LESION RATES				
OVERALL (a)	6/50 (12%)	20/50 (40%)	13/50 (26%)	10/50 (20%)
POLY-3 RATE (b)	6/44.75	20/44.46	13/45.67	10/45.17
POLY-3 PERCENT (g)	13.4%	45%	28.5%	22.1%
TERMINAL (d)	3/34 (9%)	16/33 (49%)	10/34 (29%)	8/36 (22%)
FIRST INCIDENCE	579	431	534	582
STATISTICAL TESTS				
POLY 3	P=0.540N	P<0.001**	P=0.064	P=0.210
POLY 1.5	P=0.545	P<0.001**	P=0.064	P=0.208
POLY 6	P=0.530N	P<0.001**	P=0.064	P=0.213
COCH-ARM / FISHERS	P=0.533	P<0.001**	P=0.062	P=0.207
MAX-ISO-POLY-3	P=0.022*	P<0.001**	P=0.039*	P=0.140

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney: Renal Tubule Mineralization				
LESION RATES				
OVERALL (a)	31/50 (62%)	42/50 (84%)	38/50 (76%)	31/50 (62%)
POLY-3 RATE (b)	31/47.51	42/49.11	38/47.28	31/47.25
POLY-3 PERCENT (g)	65.3%	85.5%	80.4%	65.6%
TERMINAL (d)	22/34 (65%)	28/33 (85%)	28/34 (82%)	23/36 (64%)
FIRST INCIDENCE	369	319	494	547
STATISTICAL TESTS				
POLY 3	P=0.311N	P=0.014*	P=0.068	P=0.572
POLY 1.5	P=0.307N	P=0.012*	P=0.077	P=0.566
POLY 6	P=0.291N	P=0.021*	P=0.065	P=0.576N
COCH-ARM / FISHERS	P=0.281N	P=0.012*	P=0.097	P=0.582N
MAX-ISO-POLY-3	P=0.081	P=0.008**	P=0.042*	P=0.483

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney: Renal Tubule Pigmentation Lipofuscin				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/43.49	0/42.37	1/44.59	2/44.94
POLY-3 PERCENT (g)	2.3%	0%	2.2%	4.5%
TERMINAL (d)	1/34 (3%)	0/33 (0%)	1/34 (3%)	0/36 (0%)
FIRST INCIDENCE	730 (T)	---	730 (T)	582
STATISTICAL TESTS				
POLY 3	P=0.261	P=0.505N	P=0.755N	P=0.511
POLY 1.5	P=0.256	P=0.504N	P=0.757N	P=0.506
POLY 6	P=0.266	P=0.504N	P=0.753N	P=0.520
COCH-ARM / FISHERS	P=0.247	P=0.500N	P=0.753N	P=0.500
MAX-ISO-POLY-3	P=0.154	P=0.164N	P=0.492N	P=0.292

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver				
Angiectasis				
LESION RATES				
OVERALL (a)	3/50 (6%)	6/50 (12%)	7/50 (14%)	10/50 (20%)
POLY-3 RATE (b)	3/43.49	6/43.08	7/44.59	10/44.37
POLY-3 PERCENT (g)	6.9%	13.9%	15.7%	22.5%
TERMINAL (d)	3/34 (9%)	5/33 (15%)	7/34 (21%)	9/36 (25%)
FIRST INCIDENCE	730 (T)	484	730 (T)	692
STATISTICAL TESTS				
POLY 3	P=0.029*	P=0.236	P=0.166	P=0.036*
POLY 1.5	P=0.028*	P=0.236	P=0.164	P=0.036*
POLY 6	P=0.031*	P=0.241	P=0.169	P=0.038*
COCH-ARM / FISHERS	P=0.027*	P=0.243	P=0.159	P=0.036*
MAX-ISO-POLY-3	P=0.020*	P=0.142	P=0.098	P=0.019*

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver				
Basophilic Focus				
LESION RATES				
OVERALL (a)	2/50 (4%)	3/50 (6%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	2/44.51	3/42.67	3/44.77	1/44.37
POLY-3 PERCENT (g)	4.5%	7%	6.7%	2.3%
TERMINAL (d)	0/34 (0%)	1/33 (3%)	2/34 (6%)	0/36 (0%)
FIRST INCIDENCE	570	687	683	692
STATISTICAL TESTS				
POLY 3	P=0.341N	P=0.481	P=0.503	P=0.501N
POLY 1.5	P=0.342N	P=0.486	P=0.502	P=0.501N
POLY 6	P=0.339N	P=0.480	P=0.502	P=0.500N
COCH-ARM / FISHERS	P=0.343N	P=0.500	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.207N	P=0.309	P=0.325	P=0.281N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver				
Clear Cell Focus				
LESION RATES				
OVERALL (a)	18/50 (36%)	18/50 (36%)	19/50 (38%)	21/50 (42%)
POLY-3 RATE (b)	18/44.49	18/43.97	19/44.88	21/45.37
POLY-3 PERCENT (g)	40.5%	40.9%	42.3%	46.3%
TERMINAL (d)	15/34 (44%)	16/33 (49%)	18/34 (53%)	18/36 (50%)
FIRST INCIDENCE	570	423	653	596
STATISTICAL TESTS				
POLY 3	P=0.304	P=0.568	P=0.514	P=0.364
POLY 1.5	P=0.293	P=0.571	P=0.511	P=0.353
POLY 6	P=0.325	P=0.571	P=0.512	P=0.386
COCH-ARM / FISHERS	P=0.277	P=0.582N	P=0.500	P=0.341
MAX-ISO-POLY-3	P=0.287	P=0.479	P=0.426	P=0.288

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver				
Eosinophilic Focus				
LESION RATES				
OVERALL (a)	28/50 (56%)	32/50 (64%)	42/50 (84%)	43/50 (86%)
POLY-3 RATE (b)	28/44.69	32/44.75	42/47.32	43/47.49
POLY-3 PERCENT (g)	62.7%	71.5%	88.8%	90.5%
TERMINAL (d)	23/34 (68%)	25/33 (76%)	31/34 (91%)	34/36 (94%)
FIRST INCIDENCE	617	546	580	392
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.244	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.241	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.273	P=0.002**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.270	P=0.002**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.177	P<0.001**	P<0.001**

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver				
Fatty Change				
LESION RATES				
OVERALL (a)	32/50 (64%)	34/50 (68%)	27/50 (54%)	24/50 (48%)
POLY-3 RATE (b)	32/48.54	34/48.38	27/47.76	24/47.66
POLY-3 PERCENT (g)	65.9%	70.3%	56.5%	50.4%
TERMINAL (d)	22/34 (65%)	22/33 (67%)	18/34 (53%)	17/36 (47%)
FIRST INCIDENCE	369	423	455	392
STATISTICAL TESTS				
POLY 3	P=0.030N*	P=0.404	P=0.227N	P=0.086N
POLY 1.5	P=0.029N*	P=0.398	P=0.220N	P=0.084N
POLY 6	P=0.030N*	P=0.428	P=0.232N	P=0.085N
COCH-ARM / FISHERS	P=0.028N*	P=0.417	P=0.208N	P=0.079N
MAX-ISO-POLY-3	P=0.029N*	P=0.320	P=0.170N	P=0.058N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver				
Hematopoietic Cell Proliferation				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/43.49	2/42.71	0/44.59	1/44.23
POLY-3 PERCENT (g)	2.3%	4.7%	0%	2.3%
TERMINAL (d)	1/34 (3%)	0/33 (0%)	0/34 (0%)	1/36 (3%)
FIRST INCIDENCE	730 (T)	664	---	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.495N	P=0.494	P=0.495N	P=0.757N
POLY 1.5	P=0.497N	P=0.494	P=0.497N	P=0.759N
POLY 6	P=0.493N	P=0.498	P=0.493N	P=0.754N
COCH-ARM / FISHERS	P=0.500N	P=0.500	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.232N	P=0.276	P=0.158N	P=0.494N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver Infarct				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/43.49	1/42.37	2/44.79	0/44.23
POLY-3 PERCENT (g)	0%	2.4%	4.5%	0%
TERMINAL (d)	0/34 (0%)	1/33 (3%)	1/34 (3%)	0/36 (0%)
FIRST INCIDENCE	---	730 (T)	679	---
STATISTICAL TESTS				
POLY 3	P=0.608N	P=0.495	P=0.244	(e)
POLY 1.5	P=0.611N	P=0.496	P=0.241	(e)
POLY 6	P=0.603N	P=0.496	P=0.246	(e)
COCH-ARM / FISHERS	P=0.616N	P=0.500	P=0.247	(e)
MAX-ISO-POLY-3	P=0.205N	P=0.158	P=0.081	(e)

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	49/50 (98%)	47/50 (94%)	47/50 (94%)	48/50 (96%)
POLY-3 RATE (b)	49/49.52	47/49.66	47/49.92	48/49.54
POLY-3 PERCENT (g)	99%	94.6%	94.1%	96.9%
TERMINAL (d)	34/34 (100%)	32/33 (97%)	32/34 (94%)	35/36 (97%)
FIRST INCIDENCE	369	319	455	392
STATISTICAL TESTS				
POLY 3	P=0.469N	P=0.240N	P=0.212N	P=0.493N
POLY 1.5	P=0.474N	P=0.267N	P=0.250N	P=0.496N
POLY 6	P=0.460N	P=0.216N	P=0.171N	P=0.492N
COCH-ARM / FISHERS	P=0.477N	P=0.309N	P=0.309N	P=0.500N
MAX-ISO-POLY-3	P=0.155N	P=0.092N	P=0.085N	P=0.206N

TDMS No. 20007 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
Time Report Requested: 10:57:30
First Dose M/F: 08/24/04 / 08/23/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver Mineralization				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/43.97	2/42.54	2/44.59	1/44.72
POLY-3 PERCENT (g)	2.3%	4.7%	4.5%	2.2%
TERMINAL (d)	0/34 (0%)	1/33 (3%)	2/34 (6%)	0/36 (0%)
FIRST INCIDENCE	587	687	730 (T)	582
STATISTICAL TESTS				
POLY 3	P=0.546N	P=0.488	P=0.505	P=0.757N
POLY 1.5	P=0.549N	P=0.491	P=0.504	P=0.758N
POLY 6	P=0.540N	P=0.489	P=0.506	P=0.754N
COCH-ARM / FISHERS	P=0.556N	P=0.500	P=0.500	P=0.753N
MAX-ISO-POLY-3	P=0.340N	P=0.273	P=0.285	P=0.494N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver				
Mixed Cell Focus				
LESION RATES				
OVERALL (a)	15/50 (30%)	28/50 (56%)	15/50 (30%)	12/50 (24%)
POLY-3 RATE (b)	15/43.96	28/44.20	15/45.24	12/44.90
POLY-3 PERCENT (g)	34.1%	63.4%	33.2%	26.7%
TERMINAL (d)	13/34 (38%)	23/33 (70%)	12/34 (35%)	10/36 (28%)
FIRST INCIDENCE	626	484	653	596
STATISTICAL TESTS				
POLY 3	P=0.037N*	P=0.004**	P=0.551N	P=0.298N
POLY 1.5	P=0.043N*	P=0.004**	P=0.564N	P=0.311N
POLY 6	P=0.029N*	P=0.004**	P=0.534N	P=0.278N
COCH-ARM / FISHERS	P=0.060N	P=0.007**	P=0.586N	P=0.326N
MAX-ISO-POLY-3	P=0.014N*	P=0.002**	P=0.460N	P=0.225N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver				
Necrosis				
LESION RATES				
OVERALL (a)	3/50 (6%)	10/50 (20%)	7/50 (14%)	13/50 (26%)
POLY-3 RATE (b)	3/43.72	10/44.22	7/45.92	13/48.00
POLY-3 PERCENT (g)	6.9%	22.6%	15.3%	27.1%
TERMINAL (d)	2/34 (6%)	4/33 (12%)	3/34 (9%)	4/36 (11%)
FIRST INCIDENCE	668	553	455	392
STATISTICAL TESTS				
POLY 3	P=0.021*	P=0.035*	P=0.177	P=0.010**
POLY 1.5	P=0.017*	P=0.034*	P=0.170	P=0.008**
POLY 6	P=0.028*	P=0.040*	P=0.186	P=0.013*
COCH-ARM / FISHERS	P=0.013*	P=0.036*	P=0.159	P=0.006**
MAX-ISO-POLY-3	P=0.007**	P=0.017*	P=0.108	P=0.006**

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver				
Tension Lipidosis				
LESION RATES				
OVERALL (a)	5/50 (10%)	2/50 (4%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	5/44.36	2/42.37	3/45.33	2/44.80
POLY-3 PERCENT (g)	11.3%	4.7%	6.6%	4.5%
TERMINAL (d)	4/34 (12%)	2/33 (6%)	0/34 (0%)	1/36 (3%)
FIRST INCIDENCE	369	730 (T)	623	547
STATISTICAL TESTS				
POLY 3	P=0.197N	P=0.234N	P=0.344N	P=0.212N
POLY 1.5	P=0.203N	P=0.230N	P=0.351N	P=0.215N
POLY 6	P=0.191N	P=0.233N	P=0.334N	P=0.204N
COCH-ARM / FISHERS	P=0.210N	P=0.218N	P=0.357N	P=0.218N
MAX-ISO-POLY-3	P=0.101N	P=0.136N	P=0.223N	P=0.116N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver: Centrilobular Hypertrophy				
LESION RATES				
OVERALL (a)	0/50 (0%)	34/50 (68%)	30/50 (60%)	39/50 (78%)
POLY-3 RATE (b)	0/43.49	34/48.19	30/47.00	39/48.78
POLY-3 PERCENT (g)	0%	70.6%	63.8%	80%
TERMINAL (d)	0/34 (0%)	24/33 (73%)	23/34 (68%)	29/36 (81%)
FIRST INCIDENCE	---	319	455	392
STATISTICAL TESTS				
POLY 3	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	P<0.001**

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Lung Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	0/43.49	2/42.37	3/44.59	2/44.37
POLY-3 PERCENT (g)	0%	4.7%	6.7%	4.5%
TERMINAL (d)	0/34 (0%)	2/33 (6%)	3/34 (9%)	1/36 (3%)
FIRST INCIDENCE	---	730 (T)	730 (T)	692
STATISTICAL TESTS				
POLY 3	P=0.249	P=0.231	P=0.123	P=0.242
POLY 1.5	P=0.244	P=0.232	P=0.122	P=0.240
POLY 6	P=0.257	P=0.232	P=0.124	P=0.245
COCH-ARM / FISHERS	P=0.237	P=0.247	P=0.121	P=0.247
MAX-ISO-POLY-3	P=0.091	P=0.075	P=0.042*	P=0.079

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Lung Mineralization				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/43.49	0/42.37	2/44.77	0/44.23
POLY-3 PERCENT (g)	0%	0%	4.5%	0%
TERMINAL (d)	0/34 (0%)	0/33 (0%)	1/34 (3%)	0/36 (0%)
FIRST INCIDENCE	---	---	683	---
STATISTICAL TESTS				
POLY 3	P=0.607	(e)	P=0.244	(e)
POLY 1.5	P=0.603	(e)	P=0.241	(e)
POLY 6	P=0.614	(e)	P=0.246	(e)
COCH-ARM / FISHERS	P=0.595	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.161	(e)	P=0.081	(e)

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Lung: Alveolar Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	2/50 (4%)	3/50 (6%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/43.49	3/42.37	1/44.59	2/44.23
POLY-3 PERCENT (g)	4.6%	7.1%	2.2%	4.5%
TERMINAL (d)	2/34 (6%)	3/33 (9%)	1/34 (3%)	2/36 (6%)
FIRST INCIDENCE	730 (T)	730 (T)	730 (T)	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.491N	P=0.488	P=0.491N	P=0.688N
POLY 1.5	P=0.494N	P=0.490	P=0.494N	P=0.691N
POLY 6	P=0.486N	P=0.491	P=0.488N	P=0.683N
COCH-ARM / FISHERS	P=0.500N	P=0.500	P=0.500N	P=0.691N
MAX-ISO-POLY-3	P=0.293N	P=0.314	P=0.275N	P=0.492N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Lung: Alveolus Infiltration Cellular Histiocyte				
LESION RATES				
OVERALL (a)	2/50 (4%)	6/50 (12%)	5/50 (10%)	1/50 (2%)
POLY-3 RATE (b)	2/43.72	6/44.08	5/45.02	1/44.23
POLY-3 PERCENT (g)	4.6%	13.6%	11.1%	2.3%
TERMINAL (d)	1/34 (3%)	4/33 (12%)	4/34 (12%)	1/36 (3%)
FIRST INCIDENCE	668	319	605	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.246N	P=0.135	P=0.228	P=0.496N
POLY 1.5	P=0.250N	P=0.134	P=0.224	P=0.498N
POLY 6	P=0.240N	P=0.137	P=0.232	P=0.493N
COCH-ARM / FISHERS	P=0.256N	P=0.134	P=0.218	P=0.500N
MAX-ISO-POLY-3	P=0.095N	P=0.070	P=0.130	P=0.278N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Lung: Bronchus Hyperplasia				
LESION RATES				
OVERALL (a)	2/50 (4%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/43.77	2/42.37	0/44.59	1/44.23
POLY-3 PERCENT (g)	4.6%	4.7%	0%	2.3%
TERMINAL (d)	1/34 (3%)	2/33 (6%)	0/34 (0%)	1/36 (3%)
FIRST INCIDENCE	652	730 (T)	---	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.292N	P=0.682	P=0.233N	P=0.496N
POLY 1.5	P=0.294N	P=0.685	P=0.234N	P=0.498N
POLY 6	P=0.290N	P=0.683	P=0.232N	P=0.493N
COCH-ARM / FISHERS	P=0.296N	P=0.691N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.162N	P=0.485	P=0.075N	P=0.278N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

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 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Lymph Node, Mandibular Hyperplasia Lymphoid				
LESION RATES				
OVERALL (a)	0/50 (0%)	3/50 (6%)	2/50 (4%)	1/49 (2%)
POLY-3 RATE (b)	0/43.49	3/42.62	2/44.59	1/43.72
POLY-3 PERCENT (g)	0%	7%	4.5%	2.3%
TERMINAL (d)	0/34 (0%)	2/33 (6%)	2/34 (6%)	1/36 (3%)
FIRST INCIDENCE	---	664	730 (T)	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.564	P=0.115	P=0.243	P=0.501
POLY 1.5	P=0.557	P=0.115	P=0.241	P=0.499
POLY 6	P=0.575	P=0.116	P=0.245	P=0.505
COCH-ARM / FISHERS	P=0.548	P=0.121	P=0.247	P=0.495
MAX-ISO-POLY-3	P=0.120	P=0.038*	P=0.080	P=0.160

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Lymph Node, Mesenteric Hyperplasia Lymphoid				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/49 (0%)
POLY-3 RATE (b)	0/43.49	1/42.51	2/44.59	0/43.23
POLY-3 PERCENT (g)	0%	2.4%	4.5%	0%
TERMINAL (d)	0/34 (0%)	0/33 (0%)	2/34 (6%)	0/35 (0%)
FIRST INCIDENCE	---	693	730 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.615N	P=0.495	P=0.243	(e)
POLY 1.5	P=0.618N	P=0.496	P=0.241	(e)
POLY 6	P=0.610N	P=0.497	P=0.245	(e)
COCH-ARM / FISHERS	P=0.621N	P=0.500	P=0.247	(e)
MAX-ISO-POLY-3	P=0.205	P=0.158	P=0.080	(e)

TDMS No. 20007 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

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First Dose M/F: 08/24/04 / 08/23/04
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG

Mesentery: Fat
Necrosis

LESION RATES

OVERALL (a)	2/3 (67%)	6/6 (100%)	2/2 (100%)	3/3 (100%)
POLY-3 RATE (b)	2/2.77	6/6.00	2/2.00	3/3.00
POLY-3 PERCENT (g)	72.3%	100%	100%	100%
TERMINAL (d)	2/2 (100%)	4/4 (100%)	2/2 (100%)	3/3 (100%)
FIRST INCIDENCE	730 (T)	596	730 (T)	730 (T)

STATISTICAL TESTS

POLY 3	P=0.443	P=0.472	P=0.666	P=0.600
POLY 1.5	P=0.386	P=0.406	P=0.619	P=0.547
POLY 6	P=0.580	P=0.631	P=0.769	P=0.721
COCH-ARM / FISHERS	P=0.336	P=0.333	P=0.600	P=0.500
MAX-ISO-POLY-3	P=0.059	P=0.098	P=0.232	P=0.168

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

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 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Nose Inflammation				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	1/43.49	1/42.37	4/44.77	1/44.23
POLY-3 PERCENT (g)	2.3%	2.4%	8.9%	2.3%
TERMINAL (d)	1/34 (3%)	1/33 (3%)	3/34 (9%)	1/36 (3%)
FIRST INCIDENCE	730 (T)	730 (T)	683	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.542	P=0.755	P=0.187	P=0.757N
POLY 1.5	P=0.536	P=0.756	P=0.184	P=0.759N
POLY 6	P=0.550	P=0.757	P=0.191	P=0.754N
COCH-ARM / FISHERS	P=0.526	P=0.753N	P=0.181	P=0.753N
MAX-ISO-POLY-3	P=0.215	P=0.491	P=0.091	P=0.494N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Nose				
Inflammation Chronic				
LESION RATES				
OVERALL (a)	9/50 (18%)	8/50 (16%)	7/50 (14%)	5/50 (10%)
POLY-3 RATE (b)	9/43.80	8/42.68	7/46.38	5/45.86
POLY-3 PERCENT (g)	20.6%	18.7%	15.1%	10.9%
TERMINAL (d)	8/34 (24%)	6/33 (18%)	3/34 (9%)	1/36 (3%)
FIRST INCIDENCE	644	687	455	582
STATISTICAL TESTS				
POLY 3	P=0.116N	P=0.524N	P=0.344N	P=0.166N
POLY 1.5	P=0.128N	P=0.519N	P=0.363N	P=0.178N
POLY 6	P=0.102N	P=0.517N	P=0.325N	P=0.149N
COCH-ARM / FISHERS	P=0.146N	P=0.500N	P=0.393N	P=0.194N
MAX-ISO-POLY-3	P=0.112N	P=0.415N	P=0.255N	P=0.108N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Nose				
Polyp, Inflammatory				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/43.49	2/42.54	0/44.59	1/44.23
POLY-3 PERCENT (g)	0%	4.7%	0%	2.3%
TERMINAL (d)	0/34 (0%)	1/33 (3%)	0/34 (0%)	1/36 (3%)
FIRST INCIDENCE	---	687	---	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.544	P=0.232	(e)	P=0.503
POLY 1.5	P=0.542	P=0.233	(e)	P=0.502
POLY 6	P=0.550	P=0.234	(e)	P=0.506
COCH-ARM / FISHERS	P=0.539	P=0.247	(e)	P=0.500
MAX-ISO-POLY-3	P=0.206	P=0.075	(e)	P=0.162

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Nose: Nasolacrimal Duct Inflammation				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	1/43.49	2/43.27	2/45.29	3/45.60
POLY-3 PERCENT (g)	2.3%	4.6%	4.4%	6.6%
TERMINAL (d)	1/34 (3%)	0/33 (0%)	0/34 (0%)	0/36 (0%)
FIRST INCIDENCE	730 (T)	423	580	595
STATISTICAL TESTS				
POLY 3	P=0.253	P=0.498	P=0.514	P=0.322
POLY 1.5	P=0.245	P=0.497	P=0.509	P=0.315
POLY 6	P=0.265	P=0.503	P=0.521	P=0.334
COCH-ARM / FISHERS	P=0.232	P=0.500	P=0.500	P=0.309
MAX-ISO-POLY-3	P=0.172	P=0.279	P=0.295	P=0.172

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Pancreas				
Inflammation Chronic				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/43.49	0/42.37	1/44.59	0/44.23
POLY-3 PERCENT (g)	0%	0%	2.2%	0%
TERMINAL (d)	0/34 (0%)	0/33 (0%)	1/34 (3%)	0/36 (0%)
FIRST INCIDENCE	---	---	730 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.702	(e)	P=0.505	(e)
POLY 1.5	P=0.699	(e)	P=0.503	(e)
POLY 6	P=0.707	(e)	P=0.507	(e)
COCH-ARM / FISHERS	P=0.694	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.244	(e)	P=0.164	(e)

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Pancreas: Acinus Hypertrophy				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/43.49	0/42.37	0/44.59	0/44.23
POLY-3 PERCENT (g)	4.6%	0%	0%	0%
TERMINAL (d)	2/34 (6%)	0/33 (0%)	0/34 (0%)	0/36 (0%)
FIRST INCIDENCE	730 (T)	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.111N	P=0.243N	P=0.231N	P=0.233N
POLY 1.5	P=0.111N	P=0.242N	P=0.234N	P=0.235N
POLY 6	P=0.111N	P=0.241N	P=0.229N	P=0.230N
COCH-ARM / FISHERS	P=0.115N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.021N*	P=0.080N	P=0.075N	P=0.075N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Peritoneum				
Inflammation Chronic				
LESION RATES				
OVERALL (a)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/2 (100%)
POLY-3 RATE (b)	0/0.00	0/0.00	0/0.00	2/2.00
POLY-3 PERCENT (g)	0%	0%	0%	100%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)
FIRST INCIDENCE	---	---	---	673
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 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Pituitary Gland Cyst				
LESION RATES				
OVERALL (a)	1/49 (2%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/42.97	0/42.37	1/44.85	2/44.32
POLY-3 PERCENT (g)	2.3%	0%	2.2%	4.5%
TERMINAL (d)	1/34 (3%)	0/33 (0%)	0/34 (0%)	1/36 (3%)
FIRST INCIDENCE	730 (T)	---	660	707
STATISTICAL TESTS				
POLY 3	P=0.260	P=0.503N	P=0.751N	P=0.511
POLY 1.5	P=0.257	P=0.501N	P=0.753N	P=0.509
POLY 6	P=0.262	P=0.503N	P=0.749N	P=0.515
COCH-ARM / FISHERS	P=0.251	P=0.495N	P=0.747N	P=0.508
MAX-ISO-POLY-3	P=0.151	P=0.163N	P=0.486N	P=0.290

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Pituitary Gland: Pars Distalis Hyperplasia				
LESION RATES				
OVERALL (a)	1/49 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/42.97	0/42.37	1/44.59	0/44.23
POLY-3 PERCENT (g)	2.3%	0%	2.2%	0%
TERMINAL (d)	1/34 (3%)	0/33 (0%)	1/34 (3%)	0/36 (0%)
FIRST INCIDENCE	730 (T)	---	730 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.395N	P=0.503N	P=0.752N	P=0.494N
POLY 1.5	P=0.397N	P=0.501N	P=0.753N	P=0.495N
POLY 6	P=0.394N	P=0.503N	P=0.752N	P=0.492N
COCH-ARM / FISHERS	P=0.402N	P=0.495N	P=0.747N	P=0.495N
MAX-ISO-POLY-3	P=0.156N	P=0.163N	P=0.488N	P=0.157N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Preputial Gland Cyst				
LESION RATES				
OVERALL (a)	4/50 (8%)	5/50 (10%)	5/50 (10%)	3/50 (6%)
POLY-3 RATE (b)	4/44.25	5/42.51	5/45.35	3/44.23
POLY-3 PERCENT (g)	9%	11.8%	11%	6.8%
TERMINAL (d)	3/34 (9%)	4/33 (12%)	4/34 (12%)	3/36 (8%)
FIRST INCIDENCE	455	695	455	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.374N	P=0.475	P=0.515	P=0.500N
POLY 1.5	P=0.377N	P=0.481	P=0.510	P=0.501N
POLY 6	P=0.368N	P=0.477	P=0.521	P=0.496N
COCH-ARM / FISHERS	P=0.382N	P=0.500	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.272N	P=0.340	P=0.377	P=0.346N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Preputial Gland Inflammation				
LESION RATES				
OVERALL (a)	10/50 (20%)	4/50 (8%)	9/50 (18%)	13/50 (26%)
POLY-3 RATE (b)	10/44.49	4/42.37	9/45.54	13/45.55
POLY-3 PERCENT (g)	22.5%	9.4%	19.8%	28.5%
TERMINAL (d)	6/34 (18%)	4/33 (12%)	6/34 (18%)	11/36 (31%)
FIRST INCIDENCE	647	730 (T)	494	465
STATISTICAL TESTS				
POLY 3	P=0.124	P=0.085N	P=0.477N	P=0.338
POLY 1.5	P=0.118	P=0.081N	P=0.484N	P=0.331
POLY 6	P=0.129	P=0.088N	P=0.476N	P=0.343
COCH-ARM / FISHERS	P=0.107	P=0.074N	P=0.500N	P=0.318
MAX-ISO-POLY-3	P=0.070	P=0.051N	P=0.376N	P=0.256

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Prostate				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	29/50 (58%)	31/50 (62%)	38/50 (76%)	29/50 (58%)
POLY-3 RATE (b)	29/44.60	31/44.24	38/47.43	29/47.28
POLY-3 PERCENT (g)	65%	70.1%	80.1%	61.3%
TERMINAL (d)	24/34 (71%)	28/33 (85%)	27/34 (79%)	22/36 (61%)
FIRST INCIDENCE	647	319	455	392
STATISTICAL TESTS				
POLY 3	P=0.352N	P=0.384	P=0.070	P=0.439N
POLY 1.5	P=0.440N	P=0.397	P=0.056	P=0.497N
POLY 6	P=0.252N	P=0.371	P=0.097	P=0.368N
COCH-ARM / FISHERS	P=0.510	P=0.419	P=0.044*	P=0.580N
MAX-ISO-POLY-3	P=0.131N	P=0.296	P=0.047*	P=0.355N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Prostate Inflammation				
LESION RATES				
OVERALL (a)	4/50 (8%)	9/50 (18%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	4/45.12	9/45.00	4/45.55	2/44.94
POLY-3 PERCENT (g)	8.9%	20%	8.8%	4.5%
TERMINAL (d)	0/34 (0%)	1/33 (3%)	1/34 (3%)	0/36 (0%)
FIRST INCIDENCE	570	546	616	582
STATISTICAL TESTS				
POLY 3	P=0.116N	P=0.113	P=0.638N	P=0.339N
POLY 1.5	P=0.116N	P=0.112	P=0.639N	P=0.338N
POLY 6	P=0.116N	P=0.120	P=0.638N	P=0.338N
COCH-ARM / FISHERS	P=0.119N	P=0.117	P=0.643N	P=0.339N
MAX-ISO-POLY-3	P=0.060N	P=0.065	P=0.493N	P=0.201N

TDMS No. 20007 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
Time Report Requested: 10:57:30
First Dose M/F: 08/24/04 / 08/23/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Salivary Glands				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	43/50 (86%)	36/50 (72%)	40/50 (80%)	36/50 (72%)
POLY-3 RATE (b)	43/48.63	36/46.25	40/48.18	36/47.86
POLY-3 PERCENT (g)	88.4%	77.8%	83%	75.2%
TERMINAL (d)	29/34 (85%)	28/33 (85%)	29/34 (85%)	28/36 (78%)
FIRST INCIDENCE	455	423	494	392
STATISTICAL TESTS				
POLY 3	P=0.090N	P=0.123N	P=0.315N	P=0.070N
POLY 1.5	P=0.093N	P=0.094N	P=0.299N	P=0.064N
POLY 6	P=0.097N	P=0.173N	P=0.346N	P=0.087N
COCH-ARM / FISHERS	P=0.120N	P=0.070N	P=0.298N	P=0.070N
MAX-ISO-POLY-3	P=0.042N*	P=0.078N	P=0.218N	P=0.041N*

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Seminal Vesicle Fibrosis				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/43.49	0/42.37	0/44.59	0/44.23
POLY-3 PERCENT (g)	4.6%	0%	0%	0%
TERMINAL (d)	2/34 (6%)	0/33 (0%)	0/34 (0%)	0/36 (0%)
FIRST INCIDENCE	730 (T)	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.111N	P=0.243N	P=0.231N	P=0.233N
POLY 1.5	P=0.111N	P=0.242N	P=0.234N	P=0.235N
POLY 6	P=0.111N	P=0.241N	P=0.229N	P=0.230N
COCH-ARM / FISHERS	P=0.115N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.021N*	P=0.080N	P=0.075N	P=0.075N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Seminal Vesicle Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	4/50 (8%)	4/50 (8%)	6/50 (12%)	0/50 (0%)
POLY-3 RATE (b)	4/43.99	4/42.93	6/44.85	0/44.23
POLY-3 PERCENT (g)	9.1%	9.3%	13.4%	0%
TERMINAL (d)	3/34 (9%)	3/33 (9%)	5/34 (15%)	0/36 (0%)
FIRST INCIDENCE	579	553	660	---
STATISTICAL TESTS				
POLY 3	P=0.074N	P=0.630	P=0.381	P=0.059N
POLY 1.5	P=0.076N	P=0.632	P=0.378	P=0.060N
POLY 6	P=0.072N	P=0.634	P=0.386	P=0.058N
COCH-ARM / FISHERS	P=0.080N	P=0.643N	P=0.370	P=0.059N
MAX-ISO-POLY-3	P=0.032N*	P=0.484	P=0.264	P=0.019N*

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Seminal Vesicle Inflammation				
LESION RATES				
OVERALL (a)	6/50 (12%)	5/50 (10%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	6/44.09	5/44.77	0/44.59	2/44.94
POLY-3 PERCENT (g)	13.6%	11.2%	0%	4.5%
TERMINAL (d)	4/34 (12%)	0/33 (0%)	0/34 (0%)	0/36 (0%)
FIRST INCIDENCE	626	484	---	582
STATISTICAL TESTS				
POLY 3	P=0.041N*	P=0.489N	P=0.014N*	P=0.126N
POLY 1.5	P=0.042N*	P=0.498N	P=0.015N*	P=0.129N
POLY 6	P=0.041N*	P=0.472N	P=0.014N*	P=0.121N
COCH-ARM / FISHERS	P=0.045N*	P=0.500N	P=0.013N*	P=0.134N
MAX-ISO-POLY-3	P=0.019N*	P=0.363N	P=0.004N**	P=0.066N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Skin				
Cyst Epithelial Inclusion				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/43.49	0/42.37	2/44.60	0/44.23
POLY-3 PERCENT (g)	0%	0%	4.5%	0%
TERMINAL (d)	0/34 (0%)	0/33 (0%)	1/34 (3%)	0/36 (0%)
FIRST INCIDENCE	---	---	729	---
STATISTICAL TESTS				
POLY 3	P=0.607	(e)	P=0.243	(e)
POLY 1.5	P=0.603	(e)	P=0.241	(e)
POLY 6	P=0.614	(e)	P=0.245	(e)
COCH-ARM / FISHERS	P=0.595	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.161	(e)	P=0.080	(e)

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Skin				
Ulcer				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	9/50 (18%)	4/50 (8%)
POLY-3 RATE (b)	1/43.49	1/42.62	9/45.41	4/44.37
POLY-3 PERCENT (g)	2.3%	2.4%	19.8%	9%
TERMINAL (d)	1/34 (3%)	0/33 (0%)	5/34 (15%)	3/36 (8%)
FIRST INCIDENCE	730 (T)	664	616	692
STATISTICAL TESTS				
POLY 3	P=0.083	P=0.756	P=0.010**	P=0.184
POLY 1.5	P=0.080	P=0.757	P=0.009**	P=0.182
POLY 6	P=0.088	P=0.759	P=0.010**	P=0.189
COCH-ARM / FISHERS	P=0.080	P=0.753N	P=0.008**	P=0.181
MAX-ISO-POLY-3	P=0.019*	P=0.493	P=0.004**	P=0.088

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Spleen				
Hematopoietic Cell Proliferation				
LESION RATES				
OVERALL (a)	16/50 (32%)	19/50 (38%)	21/49 (43%)	15/50 (30%)
POLY-3 RATE (b)	16/45.60	19/45.03	21/47.01	15/47.76
POLY-3 PERCENT (g)	35.1%	42.2%	44.7%	31.4%
TERMINAL (d)	9/34 (27%)	10/33 (30%)	11/34 (32%)	6/36 (17%)
FIRST INCIDENCE	513	484	534	392
STATISTICAL TESTS				
POLY 3	P=0.321N	P=0.315	P=0.232	P=0.437N
POLY 1.5	P=0.352N	P=0.317	P=0.211	P=0.460N
POLY 6	P=0.293N	P=0.329	P=0.262	P=0.413N
COCH-ARM / FISHERS	P=0.415N	P=0.338	P=0.182	P=0.500N
MAX-ISO-POLY-3	P=0.182N	P=0.244	P=0.177	P=0.354N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Spleen				
Hyperplasia Lymphoid				
LESION RATES				
OVERALL (a)	3/50 (6%)	3/50 (6%)	2/49 (4%)	3/50 (6%)
POLY-3 RATE (b)	3/43.49	3/42.37	2/43.97	3/44.23
POLY-3 PERCENT (g)	6.9%	7.1%	4.6%	6.8%
TERMINAL (d)	3/34 (9%)	3/33 (9%)	2/34 (6%)	3/36 (8%)
FIRST INCIDENCE	730 (T)	730 (T)	730 (T)	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.550N	P=0.651	P=0.495N	P=0.655N
POLY 1.5	P=0.555N	P=0.653	P=0.500N	P=0.658N
POLY 6	P=0.544N	P=0.654	P=0.489N	P=0.649N
COCH-ARM / FISHERS	P=0.563N	P=0.661N	P=0.510N	P=0.661N
MAX-ISO-POLY-3	P=0.399N	P=0.485	P=0.319N	P=0.490N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Spleen: Lymphoid Follicle Atrophy				
LESION RATES				
OVERALL (a)	6/50 (12%)	5/50 (10%)	3/49 (6%)	6/50 (12%)
POLY-3 RATE (b)	6/45.12	5/44.54	3/44.23	6/46.01
POLY-3 PERCENT (g)	13.3%	11.2%	6.8%	13%
TERMINAL (d)	2/34 (6%)	0/33 (0%)	1/34 (3%)	2/36 (6%)
FIRST INCIDENCE	570	319	683	547
STATISTICAL TESTS				
POLY 3	P=0.551N	P=0.509N	P=0.251N	P=0.607N
POLY 1.5	P=0.556N	P=0.507N	P=0.251N	P=0.613N
POLY 6	P=0.545N	P=0.506N	P=0.253N	P=0.598N
COCH-ARM / FISHERS	P=0.562	P=0.500N	P=0.254N	P=0.620N
MAX-ISO-POLY-3	P=0.307N	P=0.381N	P=0.154N	P=0.484N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Stomach, Forestomach Erosion				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.49	0/42.37	0/44.59	0/44.23
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/33 (0%)	0/34 (0%)	0/36 (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 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Stomach, Forestomach Inflammation Chronic				
LESION RATES				
OVERALL (a)	19/50 (38%)	22/50 (44%)	24/50 (48%)	24/50 (48%)
POLY-3 RATE (b)	19/45.27	22/45.64	24/47.65	24/46.51
POLY-3 PERCENT (g)	42%	48.2%	50.4%	51.6%
TERMINAL (d)	13/34 (38%)	14/33 (42%)	16/34 (47%)	18/36 (50%)
FIRST INCIDENCE	587	319	494	392
STATISTICAL TESTS				
POLY 3	P=0.219	P=0.348	P=0.272	P=0.235
POLY 1.5	P=0.210	P=0.342	P=0.248	P=0.226
POLY 6	P=0.226	P=0.367	P=0.296	P=0.243
COCH-ARM / FISHERS	P=0.187	P=0.342	P=0.210	P=0.210
MAX-ISO-POLY-3	P=0.180	P=0.274	P=0.212	P=0.178

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Stomach, Forestomach Necrosis				
LESION RATES				
OVERALL (a)	8/50 (16%)	11/50 (22%)	12/50 (24%)	10/50 (20%)
POLY-3 RATE (b)	8/44.79	11/43.12	12/46.99	10/45.45
POLY-3 PERCENT (g)	17.9%	25.5%	25.5%	22%
TERMINAL (d)	4/34 (12%)	9/33 (27%)	6/34 (18%)	6/36 (17%)
FIRST INCIDENCE	587	546	494	582
STATISTICAL TESTS				
POLY 3	P=0.428	P=0.270	P=0.262	P=0.410
POLY 1.5	P=0.416	P=0.281	P=0.249	P=0.405
POLY 6	P=0.442	P=0.264	P=0.275	P=0.418
COCH-ARM / FISHERS	P=0.395	P=0.306	P=0.227	P=0.398
MAX-ISO-POLY-3	P=0.232	P=0.195	P=0.192	P=0.312

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Stomach, Forestomach Ulcer				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.49	0/42.37	0/44.59	0/44.23
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/33 (0%)	0/34 (0%)	0/36 (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 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
Time Report Requested: 10:57:30
First Dose M/F: 08/24/04 / 08/23/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Stomach, Forestomach: Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	18/50 (36%)	22/50 (44%)	25/50 (50%)	22/50 (44%)
POLY-3 RATE (b)	18/45.27	22/45.64	25/47.65	22/45.18
POLY-3 PERCENT (g)	39.8%	48.2%	52.5%	48.7%
TERMINAL (d)	12/34 (35%)	14/33 (42%)	17/34 (50%)	18/36 (50%)
FIRST INCIDENCE	587	319	494	582
STATISTICAL TESTS				
POLY 3	P=0.248	P=0.273	P=0.151	P=0.257
POLY 1.5	P=0.254	P=0.268	P=0.136	P=0.263
POLY 6	P=0.239	P=0.288	P=0.167	P=0.252
COCH-ARM / FISHERS	P=0.258	P=0.270	P=0.113	P=0.270
MAX-ISO-POLY-3	P=0.149	P=0.207	P=0.112	P=0.193

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Stomach, Glandular Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/43.49	0/42.37	2/44.59	1/44.23
POLY-3 PERCENT (g)	4.6%	0%	4.5%	2.3%
TERMINAL (d)	2/34 (6%)	0/33 (0%)	2/34 (6%)	1/36 (3%)
FIRST INCIDENCE	730 (T)	---	730 (T)	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.519N	P=0.243N	P=0.685N	P=0.494N
POLY 1.5	P=0.523N	P=0.242N	P=0.688N	P=0.497N
POLY 6	P=0.516N	P=0.241N	P=0.682N	P=0.489N
COCH-ARM / FISHERS	P=0.531N	P=0.247N	P=0.691N	P=0.500N
MAX-ISO-POLY-3	P=0.257N	P=0.080N	P=0.488N	P=0.277N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Stomach, Glandular Ulcer				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.97	0/42.37	0/44.59	0/44.23
POLY-3 PERCENT (g)	2.3%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/33 (0%)	0/34 (0%)	0/36 (0%)
FIRST INCIDENCE	587	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.302N	P=0.507N	P=0.497N	P=0.499N
POLY 1.5	P=0.303N	P=0.505N	P=0.498N	P=0.499N
POLY 6	P=0.303N	P=0.508N	P=0.497N	P=0.497N
COCH-ARM / FISHERS	P=0.306N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.078N	P=0.167N	P=0.158N	P=0.158N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
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 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Stomach, Glandular: Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/43.49	0/42.37	0/44.59	0/44.23
POLY-3 PERCENT (g)	4.6%	0%	0%	0%
TERMINAL (d)	2/34 (6%)	0/33 (0%)	0/34 (0%)	0/36 (0%)
FIRST INCIDENCE	730 (T)	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.111N	P=0.243N	P=0.231N	P=0.233N
POLY 1.5	P=0.111N	P=0.242N	P=0.234N	P=0.235N
POLY 6	P=0.111N	P=0.241N	P=0.229N	P=0.230N
COCH-ARM / FISHERS	P=0.115N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.021N*	P=0.080N	P=0.075N	P=0.075N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Stomach, Glandular: Glands Ectasia				
LESION RATES				
OVERALL (a)	2/50 (4%)	1/50 (2%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	2/43.67	1/42.51	2/44.59	2/44.23
POLY-3 PERCENT (g)	4.6%	2.4%	4.5%	4.5%
TERMINAL (d)	1/34 (3%)	0/33 (0%)	2/34 (6%)	2/36 (6%)
FIRST INCIDENCE	683	695	730 (T)	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.537	P=0.509N	P=0.687N	P=0.690N
POLY 1.5	P=0.533	P=0.508N	P=0.689N	P=0.691N
POLY 6	P=0.541	P=0.508N	P=0.685N	P=0.686N
COCH-ARM / FISHERS	P=0.526	P=0.500N	P=0.691N	P=0.691N
MAX-ISO-POLY-3	P=0.400	P=0.290N	P=0.490N	P=0.494N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Testes: Germinal Epithelium Atrophy				
LESION RATES				
OVERALL (a)	2/50 (4%)	4/50 (8%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/43.49	4/42.37	1/44.85	1/44.23
POLY-3 PERCENT (g)	4.6%	9.4%	2.2%	2.3%
TERMINAL (d)	2/34 (6%)	4/33 (12%)	0/34 (0%)	1/36 (3%)
FIRST INCIDENCE	730 (T)	730 (T)	660	730 (T)
STATISTICAL TESTS				
POLY 3	P=0.225N	P=0.325	P=0.489N	P=0.494N
POLY 1.5	P=0.228N	P=0.327	P=0.493N	P=0.497N
POLY 6	P=0.220N	P=0.327	P=0.484N	P=0.489N
COCH-ARM / FISHERS	P=0.232N	P=0.339	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.145N	P=0.193	P=0.274N	P=0.277N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Thymus Atrophy				
LESION RATES				
OVERALL (a)	41/48 (85%)	41/47 (87%)	46/47 (98%)	43/49 (88%)
POLY-3 RATE (b)	41/46.82	41/43.47	46/47.00	43/46.66
POLY-3 PERCENT (g)	87.6%	94.3%	97.9%	92.2%
TERMINAL (d)	28/33 (85%)	31/32 (97%)	32/33 (97%)	34/36 (94%)
FIRST INCIDENCE	455	319	455	465
STATISTICAL TESTS				
POLY 3	P=0.276	P=0.212	P=0.058	P=0.341
POLY 1.5	P=0.318	P=0.325	P=0.046*	P=0.405
POLY 6	P=0.218	P=0.133	P=0.070	P=0.267
COCH-ARM / FISHERS	P=0.358	P=0.517	P=0.032*	P=0.484
MAX-ISO-POLY-3	P=0.063	P=0.123	P=0.024*	P=0.221

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Thymus Hyperplasia				
LESION RATES				
OVERALL (a)	1/48 (2%)	1/47 (2%)	0/47 (0%)	0/49 (0%)
POLY-3 RATE (b)	1/41.79	1/39.92	0/41.78	0/43.72
POLY-3 PERCENT (g)	2.4%	2.5%	0%	0%
TERMINAL (d)	1/33 (3%)	1/32 (3%)	0/33 (0%)	0/36 (0%)
FIRST INCIDENCE	730 (T)	730 (T)	---	---
STATISTICAL TESTS				
POLY 3	P=0.232N	P=0.751	P=0.500N	P=0.491N
POLY 1.5	P=0.232N	P=0.751	P=0.501N	P=0.493N
POLY 6	P=0.231N	P=0.753	P=0.499N	P=0.488N
COCH-ARM / FISHERS	P=0.233N	P=0.747	P=0.505N	P=0.495N
MAX-ISO-POLY-3	P=0.153N	P=0.485	P=0.159N	P=0.157N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Thymus				
Infiltration Cellular Histiocyte				
LESION RATES				
OVERALL (a)	0/48 (0%)	0/47 (0%)	2/47 (4%)	0/49 (0%)
POLY-3 RATE (b)	0/41.79	0/39.92	2/41.78	0/43.72
POLY-3 PERCENT (g)	0%	0%	4.8%	0%
TERMINAL (d)	0/33 (0%)	0/32 (0%)	2/33 (6%)	0/36 (0%)
FIRST INCIDENCE	---	---	730 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.617	(e)	P=0.237	(e)
POLY 1.5	P=0.610	(e)	P=0.235	(e)
POLY 6	P=0.625	(e)	P=0.238	(e)
COCH-ARM / FISHERS	P=0.600	(e)	P=0.242	(e)
MAX-ISO-POLY-3	P=0.161	(e)	P=0.076	(e)

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Thyroid Gland Cyst				
LESION RATES				
OVERALL (a)	4/50 (8%)	0/50 (0%)	1/49 (2%)	0/50 (0%)
POLY-3 RATE (b)	4/44.62	0/42.37	1/43.59	0/44.23
POLY-3 PERCENT (g)	9%	0%	2.3%	0%
TERMINAL (d)	1/34 (3%)	0/33 (0%)	1/33 (3%)	0/36 (0%)
FIRST INCIDENCE	570	---	730 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.035N*	P=0.067N	P=0.185N	P=0.061N
POLY 1.5	P=0.036N*	P=0.065N	P=0.185N	P=0.061N
POLY 6	P=0.034N*	P=0.068N	P=0.188N	P=0.061N
COCH-ARM / FISHERS	P=0.040N*	P=0.059N	P=0.187N	P=0.059N
MAX-ISO-POLY-3	P=0.005N**	P=0.024N*	P=0.088N	P=0.020N*

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Tooth Dysplasia				
LESION RATES				
OVERALL (a)	33/33 (100%)	32/32 (100%)	27/27 (100%)	21/21 (100%)
POLY-3 RATE (b)	33/33.00	32/32.00	27/27.00	21/21.00
POLY-3 PERCENT (g)	100%	100%	100%	100%
TERMINAL (d)	25/25 (100%)	24/24 (100%)	20/20 (100%)	20/20 (100%)
FIRST INCIDENCE	570	553	494	707
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 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Urethra Inflammation				
LESION RATES				
OVERALL (a)	2/2 (100%)	4/4 (100%)	0/0 (0%)	1/1 (100%)
POLY-3 RATE (b)	2/2.00	4/4.00	0/0.00	1/1.00
POLY-3 PERCENT (g)	100%	100%	0%	100%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	570	546	---	582
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 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Urinary Bladder				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	20/50 (40%)	25/50 (50%)	26/50 (52%)	20/50 (40%)
POLY-3 RATE (b)	20/46.84	25/43.84	26/45.66	20/45.15
POLY-3 PERCENT (g)	42.7%	57%	56.9%	44.3%
TERMINAL (d)	11/34 (32%)	19/33 (58%)	22/34 (65%)	16/36 (44%)
FIRST INCIDENCE	369	553	605	596
STATISTICAL TESTS				
POLY 3	P=0.499N	P=0.120	P=0.118	P=0.522
POLY 1.5	P=0.479N	P=0.145	P=0.133	P=0.543
POLY 6	P=0.521N	P=0.106	P=0.101	P=0.505
COCH-ARM / FISHERS	P=0.452N	P=0.211	P=0.158	P=0.581N
MAX-ISO-POLY-3	P=0.166	P=0.088	P=0.083	P=0.437

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Urinary Bladder Inflammation				
LESION RATES				
OVERALL (a)	4/50 (8%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	4/44.75	2/43.04	0/44.59	0/44.23
POLY-3 PERCENT (g)	8.9%	4.7%	0%	0%
TERMINAL (d)	1/34 (3%)	0/33 (0%)	0/34 (0%)	0/36 (0%)
FIRST INCIDENCE	570	546	---	---
STATISTICAL TESTS				
POLY 3	P=0.016N*	P=0.355N	P=0.060N	P=0.062N
POLY 1.5	P=0.016N*	P=0.350N	P=0.060N	P=0.061N
POLY 6	P=0.016N*	P=0.356N	P=0.061N	P=0.062N
COCH-ARM / FISHERS	P=0.018N*	P=0.339N	P=0.059N	P=0.059N
MAX-ISO-POLY-3	P=0.010N**	P=0.218N	P=0.019N*	P=0.020N*

TDMS No. 20007 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
Time Report Requested: 10:57:30
First Dose M/F: 08/24/04 / 08/23/04
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Adrenal Cortex Hypertrophy				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.80	0/46.04	0/47.88	0/45.33
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	0/37 (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 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Adrenal Cortex				
Vacuolization Cytoplasmic				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	1/45.21	0/46.04	4/47.88	0/45.33
POLY-3 PERCENT (g)	2.2%	0%	8.4%	0%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	4/45 (9%)	0/37 (0%)
FIRST INCIDENCE	610	---	729 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.535N	P=0.496N	P=0.197	P=0.499N
POLY 1.5	P=0.536N	P=0.497N	P=0.190	P=0.500N
POLY 6	P=0.536N	P=0.496N	P=0.204	P=0.500N
COCH-ARM / FISHERS	P=0.531N	P=0.500N	P=0.181	P=0.500N
MAX-ISO-POLY-3	P=0.145N	P=0.158N	P=0.100	P=0.158N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Adrenal Cortex: Subcapsular Hyperplasia				
LESION RATES				
OVERALL (a)	49/50 (98%)	50/50 (100%)	50/50 (100%)	50/50 (100%)
POLY-3 RATE (b)	49/49.84	50/50.00	50/50.00	50/50.00
POLY-3 PERCENT (g)	98.3%	100%	100%	100%
TERMINAL (d)	38/38 (100%)	34/34 (100%)	45/45 (100%)	37/37 (100%)
FIRST INCIDENCE	394	372	534	148
STATISTICAL TESTS				
POLY 3	P=0.353	P=0.574	P=0.574	P=0.574
POLY 1.5	P=0.328	P=0.536	P=0.536	P=0.536
POLY 6	P=0.412	P=0.660	P=0.660	P=0.660
COCH-ARM / FISHERS	P=0.306	P=0.500	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.078	P=0.159	P=0.159	P=0.159

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Adrenal Cortex: Zona Reticularis Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.80	0/46.04	0/47.88	1/45.33
POLY-3 PERCENT (g)	0%	0%	0%	2.2%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	1/37 (3%)
FIRST INCIDENCE	---	---	---	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.199	(e)	(e)	P=0.502
POLY 1.5	P=0.199	(e)	(e)	P=0.501
POLY 6	P=0.200	(e)	(e)	P=0.504
COCH-ARM / FISHERS	P=0.198	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.080	(e)	(e)	P=0.161

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Adrenal Medulla Hyperplasia				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	1/44.80	0/46.04	2/47.88	2/45.33
POLY-3 PERCENT (g)	2.2%	0%	4.2%	4.4%
TERMINAL (d)	1/38 (3%)	0/34 (0%)	2/45 (4%)	2/37 (5%)
FIRST INCIDENCE	729 (T)	---	729 (T)	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.246	P=0.495N	P=0.523	P=0.504
POLY 1.5	P=0.245	P=0.496N	P=0.514	P=0.501
POLY 6	P=0.247	P=0.493N	P=0.533	P=0.506
COCH-ARM / FISHERS	P=0.245	P=0.500N	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.172	P=0.158N	P=0.305	P=0.284

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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Date Report Requested: 04/13/2009
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 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Bone Marrow Fibrosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/44.80	2/46.04	1/47.88	1/45.33
POLY-3 PERCENT (g)	0%	4.3%	2.1%	2.2%
TERMINAL (d)	0/38 (0%)	2/34 (6%)	1/45 (2%)	1/37 (3%)
FIRST INCIDENCE	---	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.507	P=0.243	P=0.513	P=0.502
POLY 1.5	P=0.503	P=0.241	P=0.508	P=0.501
POLY 6	P=0.510	P=0.244	P=0.519	P=0.504
COCH-ARM / FISHERS	P=0.500	P=0.247	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.180	P=0.081	P=0.175	P=0.161

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
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 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Bone Fibrosis				
LESION RATES				
OVERALL (a)	15/50 (30%)	8/50 (16%)	7/50 (14%)	9/50 (18%)
POLY-3 RATE (b)	15/46.07	8/46.08	7/47.88	9/45.91
POLY-3 PERCENT (g)	32.6%	17.4%	14.6%	19.6%
TERMINAL (d)	11/38 (29%)	7/34 (21%)	7/45 (16%)	8/37 (22%)
FIRST INCIDENCE	523	718	729 (T)	548
STATISTICAL TESTS				
POLY 3	P=0.126N	P=0.072N	P=0.033N*	P=0.118N
POLY 1.5	P=0.130N	P=0.072N	P=0.037N*	P=0.120N
POLY 6	P=0.124N	P=0.075N	P=0.030N*	P=0.119N
COCH-ARM / FISHERS	P=0.132N	P=0.077N	P=0.045N*	P=0.121N
MAX-ISO-POLY-3	P=0.034N*	P=0.044N*	P=0.020N*	P=0.077N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Brain: Hypothalamus Compression				
LESION RATES				
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.97	0/46.04	0/47.88	0/45.33
POLY-3 PERCENT (g)	4.5%	0%	0%	0%
TERMINAL (d)	1/38 (3%)	0/34 (0%)	0/45 (0%)	0/37 (0%)
FIRST INCIDENCE	684	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.114N	P=0.232N	P=0.224N	P=0.235N
POLY 1.5	P=0.114N	P=0.234N	P=0.229N	P=0.237N
POLY 6	P=0.113N	P=0.231N	P=0.218N	P=0.235N
COCH-ARM / FISHERS	P=0.115N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.021N*	P=0.075N	P=0.075N	P=0.075N

TDMS No. 20007 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
Time Report Requested: 10:57:30
First Dose M/F: 08/24/04 / 08/23/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG

Eye: Cornea
Inflammation Chronic

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.80	0/46.04	0/47.88	0/45.33
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	0/37 (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 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Harderian Gland Hyperplasia				
LESION RATES				
OVERALL (a)	3/50 (6%)	4/49 (8%)	5/50 (10%)	5/50 (10%)
POLY-3 RATE (b)	3/44.80	4/45.91	5/47.88	5/46.14
POLY-3 PERCENT (g)	6.7%	8.7%	10.4%	10.8%
TERMINAL (d)	3/38 (8%)	4/34 (12%)	5/45 (11%)	3/37 (8%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	548
STATISTICAL TESTS				
POLY 3	P=0.307	P=0.513	P=0.394	P=0.373
POLY 1.5	P=0.299	P=0.506	P=0.380	P=0.364
POLY 6	P=0.317	P=0.518	P=0.410	P=0.381
COCH-ARM / FISHERS	P=0.293	P=0.489	P=0.357	P=0.357
MAX-ISO-POLY-3	P=0.254	P=0.360	P=0.268	P=0.247

TDMS No. 20007 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
Time Report Requested: 10:57:30
First Dose M/F: 08/24/04 / 08/23/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Harderian Gland Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	38/50 (76%)	42/49 (86%)	42/50 (84%)	38/50 (76%)
POLY-3 RATE (b)	38/46.64	42/48.29	42/49.44	38/47.49
POLY-3 PERCENT (g)	81.5%	87%	85%	80%
TERMINAL (d)	32/38 (84%)	31/34 (91%)	38/45 (84%)	30/37 (81%)
FIRST INCIDENCE	544	521	534	548
STATISTICAL TESTS				
POLY 3	P=0.382N	P=0.318	P=0.425	P=0.534N
POLY 1.5	P=0.413N	P=0.254	P=0.343	P=0.571N
POLY 6	P=0.362N	P=0.381	P=0.511	P=0.507N
COCH-ARM / FISHERS	P=0.423N	P=0.166	P=0.227	P=0.592N
MAX-ISO-POLY-3	P=0.277N	P=0.226	P=0.322	P=0.425N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Heart				
Cardiomyopathy				
LESION RATES				
OVERALL (a)	2/50 (4%)	1/50 (2%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	2/44.80	1/46.04	4/48.77	1/45.33
POLY-3 PERCENT (g)	4.5%	2.2%	8.2%	2.2%
TERMINAL (d)	2/38 (5%)	1/34 (3%)	2/45 (4%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	554	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.498N	P=0.490N	P=0.377	P=0.496N
POLY 1.5	P=0.501N	P=0.494N	P=0.362	P=0.499N
POLY 6	P=0.496N	P=0.489N	P=0.396	P=0.494N
COCH-ARM / FISHERS	P=0.500N	P=0.500N	P=0.339	P=0.500N
MAX-ISO-POLY-3	P=0.260N	P=0.274N	P=0.241	P=0.278N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Heart: Artery				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	1/50 (2%)	4/50 (8%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	1/44.80	4/46.06	3/47.88	0/45.33
POLY-3 PERCENT (g)	2.2%	8.7%	6.3%	0%
TERMINAL (d)	1/38 (3%)	3/34 (9%)	3/45 (7%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	724	729 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.224N	P=0.187	P=0.330	P=0.498N
POLY 1.5	P=0.228N	P=0.184	P=0.320	P=0.499N
POLY 6	P=0.221N	P=0.189	P=0.340	P=0.496N
COCH-ARM / FISHERS	P=0.232N	P=0.181	P=0.309	P=0.500N
MAX-ISO-POLY-3	P=0.092N	P=0.091	P=0.179	P=0.158N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Heart: Myocardium Mineralization				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.80	2/46.30	0/47.88	1/45.35
POLY-3 PERCENT (g)	0%	4.3%	0%	2.2%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	0/37 (0%)
FIRST INCIDENCE	---	666	---	725
STATISTICAL TESTS				
POLY 3	P=0.548	P=0.245	(e)	P=0.502
POLY 1.5	P=0.543	P=0.242	(e)	P=0.501
POLY 6	P=0.551	P=0.247	(e)	P=0.504
COCH-ARM / FISHERS	P=0.539	P=0.247	(e)	P=0.500
MAX-ISO-POLY-3	P=0.207	P=0.082	(e)	P=0.161

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Heart: Valve Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.80	2/46.93	0/47.88	0/45.33
POLY-3 PERCENT (g)	0%	4.3%	0%	0%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	0/37 (0%)
FIRST INCIDENCE	---	372	---	---
STATISTICAL TESTS				
POLY 3	P=0.392N	P=0.248	(e)	(e)
POLY 1.5	P=0.397N	P=0.244	(e)	(e)
POLY 6	P=0.387N	P=0.250	(e)	(e)
COCH-ARM / FISHERS	P=0.405N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.161N	P=0.085	(e)	(e)

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Intestine Small, Jejunum: Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.80	0/46.04	0/47.88	1/45.53
POLY-3 PERCENT (g)	0%	0%	0%	2.2%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	678
STATISTICAL TESTS				
POLY 3	P=0.200	(e)	(e)	P=0.503
POLY 1.5	P=0.199	(e)	(e)	P=0.501
POLY 6	P=0.201	(e)	(e)	P=0.505
COCH-ARM / FISHERS	P=0.198	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.081	(e)	(e)	P=0.162

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Islets, Pancreatic Hyperplasia				
LESION RATES				
OVERALL (a)	4/50 (8%)	4/50 (8%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	4/44.80	4/47.21	1/48.21	0/45.33
POLY-3 PERCENT (g)	8.9%	8.5%	2.1%	0%
TERMINAL (d)	4/38 (11%)	2/34 (6%)	0/45 (0%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	521	638	---
STATISTICAL TESTS				
POLY 3	P=0.020N*	P=0.614N	P=0.157N	P=0.059N
POLY 1.5	P=0.021N*	P=0.625N	P=0.166N	P=0.060N
POLY 6	P=0.020N*	P=0.605N	P=0.148N	P=0.058N
COCH-ARM / FISHERS	P=0.022N*	P=0.643N	P=0.181N	P=0.059N
MAX-ISO-POLY-3	P=0.020N*	P=0.468N	P=0.078N	P=0.019N*

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney				
Amyloid Deposition				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/44.80	2/46.04	2/47.88	1/45.33
POLY-3 PERCENT (g)	2.2%	4.3%	4.2%	2.2%
TERMINAL (d)	1/38 (3%)	2/34 (6%)	2/45 (4%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.550N	P=0.510	P=0.523	P=0.758N
POLY 1.5	P=0.553N	P=0.506	P=0.514	P=0.760N
POLY 6	P=0.547N	P=0.511	P=0.533	P=0.757N
COCH-ARM / FISHERS	P=0.556N	P=0.500	P=0.500	P=0.753N
MAX-ISO-POLY-3	P=0.355N	P=0.290	P=0.305	P=0.495N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney				
Hydronephrosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.80	1/46.04	0/47.88	0/45.33
POLY-3 PERCENT (g)	0%	2.2%	0%	0%
TERMINAL (d)	0/38 (0%)	1/34 (3%)	0/45 (0%)	0/37 (0%)
FIRST INCIDENCE	---	729 (T)	---	---
STATISTICAL TESTS				
POLY 3	P=0.559N	P=0.505	(e)	(e)
POLY 1.5	P=0.562N	P=0.504	(e)	(e)
POLY 6	P=0.557N	P=0.507	(e)	(e)
COCH-ARM / FISHERS	P=0.567N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.242N	P=0.165	(e)	(e)

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney Inflammation				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/44.80	1/46.12	0/47.88	1/45.33
POLY-3 PERCENT (g)	2.2%	2.2%	0%	2.2%
TERMINAL (d)	1/38 (3%)	0/34 (0%)	0/45 (0%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	708	---	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.611N	P=0.754N	P=0.487N	P=0.758N
POLY 1.5	P=0.613N	P=0.756N	P=0.492N	P=0.760N
POLY 6	P=0.609N	P=0.753N	P=0.481N	P=0.757N
COCH-ARM / FISHERS	P=0.616N	P=0.753N	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.333N	P=0.490N	P=0.158N	P=0.495N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney				
Metaplasia Osseous				
LESION RATES				
OVERALL (a)	3/50 (6%)	1/50 (2%)	1/50 (2%)	5/50 (10%)
POLY-3 RATE (b)	3/44.80	1/46.04	1/47.88	5/45.33
POLY-3 PERCENT (g)	6.7%	2.2%	2.1%	11%
TERMINAL (d)	3/38 (8%)	1/34 (3%)	1/45 (2%)	5/37 (14%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.162	P=0.295N	P=0.282N	P=0.363
POLY 1.5	P=0.161	P=0.299N	P=0.291N	P=0.359
POLY 6	P=0.163	P=0.293N	P=0.272N	P=0.366
COCH-ARM / FISHERS	P=0.162	P=0.309N	P=0.309N	P=0.357
MAX-ISO-POLY-3	P=0.062	P=0.150N	P=0.146N	P=0.237

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney Mineralization				
LESION RATES				
OVERALL (a)	12/50 (24%)	20/50 (40%)	7/50 (14%)	13/50 (26%)
POLY-3 RATE (b)	12/44.91	20/46.76	7/47.88	13/46.66
POLY-3 PERCENT (g)	26.7%	42.8%	14.6%	27.9%
TERMINAL (d)	11/38 (29%)	15/34 (44%)	7/45 (16%)	8/37 (22%)
FIRST INCIDENCE	701	666	729 (T)	523
STATISTICAL TESTS				
POLY 3	P=0.284N	P=0.079	P=0.117N	P=0.545
POLY 1.5	P=0.305N	P=0.073	P=0.130N	P=0.522
POLY 6	P=0.262N	P=0.086	P=0.104N	P=0.568
COCH-ARM / FISHERS	P=0.331N	P=0.066	P=0.154N	P=0.500
MAX-ISO-POLY-3	P=0.072N	P=0.054	P=0.079N	P=0.450

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney				
Nephropathy				
LESION RATES				
OVERALL (a)	21/50 (42%)	25/50 (50%)	26/50 (52%)	20/50 (40%)
POLY-3 RATE (b)	21/45.54	25/46.71	26/48.44	20/47.40
POLY-3 PERCENT (g)	46.1%	53.5%	53.7%	42.2%
TERMINAL (d)	19/38 (50%)	20/34 (59%)	25/45 (56%)	14/37 (38%)
FIRST INCIDENCE	523	669	554	523
STATISTICAL TESTS				
POLY 3	P=0.306N	P=0.305	P=0.298	P=0.432N
POLY 1.5	P=0.346N	P=0.293	P=0.263	P=0.467N
POLY 6	P=0.263N	P=0.320	P=0.342	P=0.393N
COCH-ARM / FISHERS	P=0.387N	P=0.274	P=0.212	P=0.500N
MAX-ISO-POLY-3	P=0.197N	P=0.238	P=0.237	P=0.352N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney: Cortex, Medulla Necrosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.80	0/46.04	0/47.88	0/45.33
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	0/37 (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 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney: Papilla Necrosis				
LESION RATES				
OVERALL (a)	1/50 (2%)	3/50 (6%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	1/44.80	3/46.29	1/47.88	3/45.61
POLY-3 PERCENT (g)	2.2%	6.5%	2.1%	6.6%
TERMINAL (d)	1/38 (3%)	1/34 (3%)	1/45 (2%)	2/37 (5%)
FIRST INCIDENCE	729 (T)	669	729 (T)	654
STATISTICAL TESTS				
POLY 3	P=0.322	P=0.317	P=0.746N	P=0.312
POLY 1.5	P=0.317	P=0.313	P=0.751N	P=0.308
POLY 6	P=0.327	P=0.321	P=0.739N	P=0.315
COCH-ARM / FISHERS	P=0.313	P=0.309	P=0.753N	P=0.309
MAX-ISO-POLY-3	P=0.160	P=0.166	P=0.479N	P=0.160

TDMS No. 20007 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
Time Report Requested: 10:57:30
First Dose M/F: 08/24/04 / 08/23/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney: Renal Tubule Cyst				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.80	0/46.04	0/47.88	0/45.33
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	0/37 (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 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney: Renal Tubule Hyperplasia				
LESION RATES				
OVERALL (a)	3/50 (6%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	3/45.43	1/46.04	2/47.88	0/45.33
POLY-3 PERCENT (g)	6.6%	2.2%	4.2%	0%
TERMINAL (d)	2/38 (5%)	1/34 (3%)	2/45 (4%)	0/37 (0%)
FIRST INCIDENCE	523	729 (T)	729 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.104N	P=0.300N	P=0.476N	P=0.119N
POLY 1.5	P=0.105N	P=0.302N	P=0.485N	P=0.120N
POLY 6	P=0.103N	P=0.300N	P=0.466N	P=0.119N
COCH-ARM / FISHERS	P=0.104N	P=0.309N	P=0.500N	P=0.121N
MAX-ISO-POLY-3	P=0.039N*	P=0.152N	P=0.306N	P=0.038N*

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney: Renal Tubule Mineralization				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.80	0/46.04	0/47.88	0/45.33
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	0/37 (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 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney: Renal Tubule Pigmentation Lipofuscin				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.80	0/46.04	0/47.88	0/45.33
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	0/37 (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 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver				
Angiectasis				
LESION RATES				
OVERALL (a)	3/50 (6%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	3/44.80	0/46.04	2/47.88	0/45.33
POLY-3 PERCENT (g)	6.7%	0%	4.2%	0%
TERMINAL (d)	3/38 (8%)	0/34 (0%)	2/45 (4%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.125N	P=0.114N	P=0.470N	P=0.116N
POLY 1.5	P=0.125N	P=0.116N	P=0.481N	P=0.118N
POLY 6	P=0.124N	P=0.113N	P=0.457N	P=0.115N
COCH-ARM / FISHERS	P=0.125N	P=0.121N	P=0.500N	P=0.121N
MAX-ISO-POLY-3	P=0.026N*	P=0.038N*	P=0.302N	P=0.038N*

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver				
Basophilic Focus				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	0/44.80	1/46.15	4/47.88	1/45.53
POLY-3 PERCENT (g)	0%	2.2%	8.4%	2.2%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	4/45 (9%)	0/37 (0%)
FIRST INCIDENCE	---	701	729 (T)	678
STATISTICAL TESTS				
POLY 3	P=0.340	P=0.506	P=0.069	P=0.503
POLY 1.5	P=0.336	P=0.504	P=0.066	P=0.501
POLY 6	P=0.344	P=0.508	P=0.074	P=0.505
COCH-ARM / FISHERS	P=0.337	P=0.500	P=0.059	P=0.500
MAX-ISO-POLY-3	P=0.078	P=0.165	P=0.026*	P=0.162

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver				
Clear Cell Focus				
LESION RATES				
OVERALL (a)	3/50 (6%)	0/50 (0%)	1/50 (2%)	5/50 (10%)
POLY-3 RATE (b)	3/44.80	0/46.04	1/47.88	5/45.33
POLY-3 PERCENT (g)	6.7%	0%	2.1%	11%
TERMINAL (d)	3/38 (8%)	0/34 (0%)	1/45 (2%)	5/37 (14%)
FIRST INCIDENCE	729 (T)	---	729 (T)	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.111	P=0.114N	P=0.282N	P=0.363
POLY 1.5	P=0.110	P=0.116N	P=0.291N	P=0.359
POLY 6	P=0.111	P=0.113N	P=0.272N	P=0.366
COCH-ARM / FISHERS	P=0.113	P=0.121N	P=0.309N	P=0.357
MAX-ISO-POLY-3	P=0.037*	P=0.038N*	P=0.146N	P=0.237

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver				
Eosinophilic Focus				
LESION RATES				
OVERALL (a)	9/50 (18%)	7/50 (14%)	16/50 (32%)	26/50 (52%)
POLY-3 RATE (b)	9/45.43	7/46.14	16/48.43	26/46.58
POLY-3 PERCENT (g)	19.8%	15.2%	33%	55.8%
TERMINAL (d)	8/38 (21%)	5/34 (15%)	15/45 (33%)	22/37 (60%)
FIRST INCIDENCE	523	715	556	548
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.379N	P=0.111	P<0.001**
POLY 1.5	P<0.001**	P=0.384N	P=0.099	P<0.001**
POLY 6	P<0.001**	P=0.377N	P=0.127	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.393N	P=0.083	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.282N	P=0.078	P<0.001**

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver				
Fatty Change				
LESION RATES				
OVERALL (a)	39/50 (78%)	33/50 (66%)	42/50 (84%)	23/50 (46%)
POLY-3 RATE (b)	39/49.20	33/47.83	42/49.44	23/45.85
POLY-3 PERCENT (g)	79.3%	69%	85%	50.2%
TERMINAL (d)	29/38 (76%)	26/34 (77%)	38/45 (84%)	19/37 (51%)
FIRST INCIDENCE	394	565	534	654
STATISTICAL TESTS				
POLY 3	P=0.002N**	P=0.173N	P=0.317	P=0.002N**
POLY 1.5	P=0.002N**	P=0.157N	P=0.312	P<0.001N**
POLY 6	P=0.004N**	P=0.195N	P=0.325	P=0.003N**
COCH-ARM / FISHERS	P<0.001N**	P=0.133N	P=0.306	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.122N	P=0.229	P<0.001N**

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver				
Hematopoietic Cell Proliferation				
LESION RATES				
OVERALL (a)	1/50 (2%)	4/50 (8%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	1/44.80	4/46.39	4/47.88	1/45.33
POLY-3 PERCENT (g)	2.2%	8.6%	8.4%	2.2%
TERMINAL (d)	1/38 (3%)	2/34 (6%)	4/45 (9%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	669	729 (T)	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.449N	P=0.189	P=0.200	P=0.758N
POLY 1.5	P=0.454N	P=0.186	P=0.192	P=0.760N
POLY 6	P=0.445N	P=0.193	P=0.209	P=0.757N
COCH-ARM / FISHERS	P=0.456N	P=0.181	P=0.181	P=0.753N
MAX-ISO-POLY-3	P=0.189N	P=0.093	P=0.103	P=0.495N

TDMS No. 20007 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
Time Report Requested: 10:57:30
First Dose M/F: 08/24/04 / 08/23/04
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver Infarct				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.80	0/46.04	0/47.88	0/45.33
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	0/37 (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 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	45/50 (90%)	47/50 (94%)	49/50 (98%)	44/50 (88%)
POLY-3 RATE (b)	45/47.81	47/49.05	49/49.44	44/49.08
POLY-3 PERCENT (g)	94.1%	95.8%	99.1%	89.7%
TERMINAL (d)	38/38 (100%)	34/34 (100%)	45/45 (100%)	36/37 (97%)
FIRST INCIDENCE	394	372	534	148
STATISTICAL TESTS				
POLY 3	P=0.162N	P=0.541	P=0.150	P=0.315N
POLY 1.5	P=0.247N	P=0.444	P=0.119	P=0.396N
POLY 6	P=0.082N	P=0.714	P=0.264	P=0.220N
COCH-ARM / FISHERS	P=0.375N	P=0.357	P=0.102	P=0.500N
MAX-ISO-POLY-3	P=0.049N*	P=0.326	P=0.041*	P=0.188N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

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 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver				
Mineralization				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.80	0/46.04	0/47.88	0/45.33
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	0/37 (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 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver				
Mixed Cell Focus				
LESION RATES				
OVERALL (a)	12/50 (24%)	13/50 (26%)	14/50 (28%)	7/50 (14%)
POLY-3 RATE (b)	12/44.91	13/46.51	14/48.21	7/45.61
POLY-3 PERCENT (g)	26.7%	28%	29%	15.4%
TERMINAL (d)	11/38 (29%)	10/34 (29%)	13/45 (29%)	6/37 (16%)
FIRST INCIDENCE	701	666	638	654
STATISTICAL TESTS				
POLY 3	P=0.106N	P=0.541	P=0.493	P=0.141N
POLY 1.5	P=0.112N	P=0.525	P=0.461	P=0.148N
POLY 6	P=0.101N	P=0.555	P=0.530	P=0.135N
COCH-ARM / FISHERS	P=0.116N	P=0.500	P=0.410	P=0.154N
MAX-ISO-POLY-3	P=0.086N	P=0.446	P=0.403	P=0.092N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver				
Necrosis				
LESION RATES				
OVERALL (a)	5/50 (10%)	4/50 (8%)	5/50 (10%)	1/50 (2%)
POLY-3 RATE (b)	5/45.23	4/46.41	5/47.88	1/45.33
POLY-3 PERCENT (g)	11.1%	8.6%	10.4%	2.2%
TERMINAL (d)	3/38 (8%)	1/34 (3%)	5/45 (11%)	1/37 (3%)
FIRST INCIDENCE	639	669	729 (T)	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.094N	P=0.484N	P=0.594N	P=0.101N
POLY 1.5	P=0.095N	P=0.489N	P=0.607N	P=0.102N
POLY 6	P=0.094N	P=0.481N	P=0.580N	P=0.101N
COCH-ARM / FISHERS	P=0.094N	P=0.500N	P=0.630N	P=0.102N
MAX-ISO-POLY-3	P=0.063N	P=0.348N	P=0.461N	P=0.044N*

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
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 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver				
Tension Lipidosis				
LESION RATES				
OVERALL (a)	3/50 (6%)	8/50 (16%)	7/50 (14%)	4/50 (8%)
POLY-3 RATE (b)	3/44.91	8/46.86	7/47.88	4/45.33
POLY-3 PERCENT (g)	6.7%	17.1%	14.6%	8.8%
TERMINAL (d)	2/38 (5%)	6/34 (18%)	7/45 (16%)	4/37 (11%)
FIRST INCIDENCE	701	521	729 (T)	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.523N	P=0.112	P=0.185	P=0.505
POLY 1.5	P=0.529N	P=0.107	P=0.175	P=0.501
POLY 6	P=0.520N	P=0.116	P=0.197	P=0.507
COCH-ARM / FISHERS	P=0.530N	P=0.100	P=0.159	P=0.500
MAX-ISO-POLY-3	P=0.160	P=0.065	P=0.115	P=0.351

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
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 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Liver: Centrilobular Hypertrophy				
LESION RATES				
OVERALL (a)	0/50 (0%)	20/50 (40%)	48/50 (96%)	49/50 (98%)
POLY-3 RATE (b)	0/44.80	20/46.14	48/49.93	49/49.98
POLY-3 PERCENT (g)	0%	43.4%	96.1%	98%
TERMINAL (d)	0/38 (0%)	18/34 (53%)	44/45 (98%)	37/37 (100%)
FIRST INCIDENCE	---	715	534	148
STATISTICAL TESTS				
POLY 3	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	P<0.001**

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Lung Inflammation				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/44.80	0/46.04	2/47.88	0/45.33
POLY-3 PERCENT (g)	2.2%	0%	4.2%	0%
TERMINAL (d)	1/38 (3%)	0/34 (0%)	2/45 (4%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.462N	P=0.495N	P=0.523	P=0.498N
POLY 1.5	P=0.463N	P=0.496N	P=0.514	P=0.499N
POLY 6	P=0.461N	P=0.493N	P=0.533	P=0.496N
COCH-ARM / FISHERS	P=0.461N	P=0.500N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.204N	P=0.158N	P=0.305	P=0.158N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Lung Mineralization				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.80	1/46.12	0/47.88	0/45.33
POLY-3 PERCENT (g)	0%	2.2%	0%	0%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	0/37 (0%)
FIRST INCIDENCE	---	708	---	---
STATISTICAL TESTS				
POLY 3	P=0.559N	P=0.506	(e)	(e)
POLY 1.5	P=0.562N	P=0.504	(e)	(e)
POLY 6	P=0.556N	P=0.507	(e)	(e)
COCH-ARM / FISHERS	P=0.567N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.242N	P=0.165	(e)	(e)

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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Date Report Requested: 04/13/2009
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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Lung: Alveolar Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	3/50 (6%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	3/44.80	1/46.04	0/47.88	1/45.33
POLY-3 PERCENT (g)	6.7%	2.2%	0%	2.2%
TERMINAL (d)	3/38 (8%)	1/34 (3%)	0/45 (0%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	---	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.198N	P=0.295N	P=0.107N	P=0.301N
POLY 1.5	P=0.199N	P=0.299N	P=0.112N	P=0.304N
POLY 6	P=0.196N	P=0.293N	P=0.103N	P=0.299N
COCH-ARM / FISHERS	P=0.200N	P=0.309N	P=0.121N	P=0.309N
MAX-ISO-POLY-3	P=0.052N	P=0.150N	P=0.038N*	P=0.152N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Lung: Alveolus Infiltration Cellular Histiocyte				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.80	1/46.04	0/47.88	1/45.33
POLY-3 PERCENT (g)	0%	2.2%	0%	2.2%
TERMINAL (d)	0/38 (0%)	1/34 (3%)	0/45 (0%)	1/37 (3%)
FIRST INCIDENCE	---	729 (T)	---	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.410	P=0.505	(e)	P=0.502
POLY 1.5	P=0.408	P=0.504	(e)	P=0.501
POLY 6	P=0.413	P=0.507	(e)	P=0.504
COCH-ARM / FISHERS	P=0.405	P=0.500	(e)	P=0.500
MAX-ISO-POLY-3	P=0.161	P=0.165	(e)	P=0.161

TDMS No. 20007 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Lung: Bronchus Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.80	0/46.04	0/47.88	0/45.33
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	0/37 (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 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Lymph Node, Mandibular Hyperplasia Lymphoid				
LESION RATES				
OVERALL (a)	4/48 (8%)	4/49 (8%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	4/43.40	4/45.91	4/47.88	2/45.33
POLY-3 PERCENT (g)	9.2%	8.7%	8.4%	4.4%
TERMINAL (d)	4/38 (11%)	4/34 (12%)	4/45 (9%)	2/37 (5%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.240N	P=0.612N	P=0.588N	P=0.317N
POLY 1.5	P=0.241N	P=0.618N	P=0.600N	P=0.319N
POLY 6	P=0.239N	P=0.612N	P=0.576N	P=0.317N
COCH-ARM / FISHERS	P=0.238N	P=0.631N	P=0.619N	P=0.319N
MAX-ISO-POLY-3	P=0.204N	P=0.466N	P=0.442N	P=0.187N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Lymph Node, Mesenteric Hyperplasia Lymphoid				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.80	0/46.04	0/47.88	1/45.33
POLY-3 PERCENT (g)	0%	0%	0%	2.2%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	1/37 (3%)
FIRST INCIDENCE	---	---	---	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.199	(e)	(e)	P=0.502
POLY 1.5	P=0.199	(e)	(e)	P=0.501
POLY 6	P=0.200	(e)	(e)	P=0.504
COCH-ARM / FISHERS	P=0.198	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.080	(e)	(e)	P=0.161

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Mesentery: Fat Necrosis				
LESION RATES				
OVERALL (a)	8/8 (100%)	10/10 (100%)	5/5 (100%)	6/6 (100%)
POLY-3 RATE (b)	8/8.00	10/10.00	5/5.00	6/6.00
POLY-3 PERCENT (g)	100%	100%	100%	100%
TERMINAL (d)	6/6 (100%)	5/5 (100%)	5/5 (100%)	4/4 (100%)
FIRST INCIDENCE	610	565	729 (T)	548
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 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Nose Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.80	0/46.04	0/47.88	1/45.61
POLY-3 PERCENT (g)	0%	0%	0%	2.2%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	654
STATISTICAL TESTS				
POLY 3	P=0.200	(e)	(e)	P=0.504
POLY 1.5	P=0.199	(e)	(e)	P=0.501
POLY 6	P=0.201	(e)	(e)	P=0.506
COCH-ARM / FISHERS	P=0.198	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.081	(e)	(e)	P=0.163

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Nose				
Inflammation Chronic				
LESION RATES				
OVERALL (a)	4/50 (8%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	4/45.34	2/47.18	0/47.88	0/45.33
POLY-3 PERCENT (g)	8.8%	4.2%	0%	0%
TERMINAL (d)	3/38 (8%)	0/34 (0%)	0/45 (0%)	0/37 (0%)
FIRST INCIDENCE	560	521	---	---
STATISTICAL TESTS				
POLY 3	P=0.017N*	P=0.319N	P=0.054N	P=0.060N
POLY 1.5	P=0.017N*	P=0.326N	P=0.056N	P=0.061N
POLY 6	P=0.017N*	P=0.314N	P=0.051N	P=0.060N
COCH-ARM / FISHERS	P=0.018N*	P=0.339N	P=0.059N	P=0.059N
MAX-ISO-POLY-3	P=0.009N**	P=0.191N	P=0.019N*	P=0.019N*

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Nose				
Polyp, Inflammatory				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.80	0/46.04	0/47.88	0/45.33
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	0/37 (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 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Nose: Nasolacrimal Duct Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.80	0/46.04	1/48.44	0/45.33
POLY-3 PERCENT (g)	0%	0%	2.1%	0%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	554	---
STATISTICAL TESTS				
POLY 3	P=0.692	(e)	P=0.516	(e)
POLY 1.5	P=0.691	(e)	P=0.510	(e)
POLY 6	P=0.692	(e)	P=0.522	(e)
COCH-ARM / FISHERS	P=0.694	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.249	(e)	P=0.177	(e)

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Ovary				
Angiectasis				
LESION RATES				
OVERALL (a)	1/49 (2%)	1/50 (2%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/43.80	1/46.04	2/47.88	1/45.33
POLY-3 PERCENT (g)	2.3%	2.2%	4.2%	2.2%
TERMINAL (d)	1/37 (3%)	1/34 (3%)	2/45 (4%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.598	P=0.749N	P=0.531	P=0.753N
POLY 1.5	P=0.595	P=0.752N	P=0.522	P=0.755N
POLY 6	P=0.600	P=0.748N	P=0.541	P=0.752N
COCH-ARM / FISHERS	P=0.596	P=0.747N	P=0.508	P=0.747N
MAX-ISO-POLY-3	P=0.388	P=0.484N	P=0.312	P=0.489N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Ovary Cyst				
LESION RATES				
OVERALL (a)	4/49 (8%)	10/50 (20%)	6/50 (12%)	4/50 (8%)
POLY-3 RATE (b)	4/43.80	10/46.39	6/48.21	4/45.33
POLY-3 PERCENT (g)	9.1%	21.6%	12.5%	8.8%
TERMINAL (d)	4/37 (11%)	8/34 (24%)	5/45 (11%)	4/37 (11%)
FIRST INCIDENCE	729 (T)	669	638	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.303N	P=0.089	P=0.431	P=0.624N
POLY 1.5	P=0.311N	P=0.085	P=0.412	P=0.629N
POLY 6	P=0.295N	P=0.093	P=0.454	P=0.621N
COCH-ARM / FISHERS	P=0.318N	P=0.080	P=0.383	P=0.631N
MAX-ISO-POLY-3	P=0.179N	P=0.054	P=0.312	P=0.478N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
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 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Ovary Thrombosis				
LESION RATES				
OVERALL (a)	0/49 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/43.80	1/46.04	2/48.43	0/45.33
POLY-3 PERCENT (g)	0%	2.2%	4.1%	0%
TERMINAL (d)	0/37 (0%)	1/34 (3%)	1/45 (2%)	0/37 (0%)
FIRST INCIDENCE	---	729 (T)	556	---
STATISTICAL TESTS				
POLY 3	P=0.608N	P=0.510	P=0.260	(e)
POLY 1.5	P=0.611N	P=0.508	P=0.253	(e)
POLY 6	P=0.605N	P=0.511	P=0.269	(e)
COCH-ARM / FISHERS	P=0.612N	P=0.505	P=0.253	(e)
MAX-ISO-POLY-3	P=0.215N	P=0.169	P=0.096	(e)

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Pancreas				
Inflammation Chronic				
LESION RATES				
OVERALL (a)	2/49 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.38	0/46.04	0/47.88	0/45.33
POLY-3 PERCENT (g)	4.5%	0%	0%	0%
TERMINAL (d)	2/38 (5%)	0/34 (0%)	0/45 (0%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.111N	P=0.229N	P=0.221N	P=0.232N
POLY 1.5	P=0.111N	P=0.230N	P=0.225N	P=0.233N
POLY 6	P=0.110N	P=0.229N	P=0.216N	P=0.232N
COCH-ARM / FISHERS	P=0.113N	P=0.242N	P=0.242N	P=0.242N
MAX-ISO-POLY-3	P=0.021N*	P=0.074N	P=0.074N	P=0.074N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Pancreas: Acinus Hypertrophy				
LESION RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.38	0/46.04	0/47.88	1/45.33
POLY-3 PERCENT (g)	0%	0%	0%	2.2%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	1/37 (3%)
FIRST INCIDENCE	---	---	---	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.200	(e)	(e)	P=0.504
POLY 1.5	P=0.199	(e)	(e)	P=0.504
POLY 6	P=0.200	(e)	(e)	P=0.504
COCH-ARM / FISHERS	P=0.200	(e)	(e)	P=0.505
MAX-ISO-POLY-3	P=0.080	(e)	(e)	P=0.162

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Peritoneum				
Inflammation Chronic				
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 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
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 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Pituitary Gland Cyst				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	2/49 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/44.80	1/46.04	2/46.88	1/45.33
POLY-3 PERCENT (g)	2.2%	2.2%	4.3%	2.2%
TERMINAL (d)	1/38 (3%)	1/34 (3%)	2/44 (5%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.591	P=0.755N	P=0.516	P=0.758N
POLY 1.5	P=0.589	P=0.757N	P=0.507	P=0.760N
POLY 6	P=0.593	P=0.753N	P=0.526	P=0.757N
COCH-ARM / FISHERS	P=0.590	P=0.753N	P=0.492	P=0.753N
MAX-ISO-POLY-3	P=0.380	P=0.491N	P=0.297	P=0.495N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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Date Report Requested: 04/13/2009
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 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Pituitary Gland: Pars Distalis Hyperplasia				
LESION RATES				
OVERALL (a)	4/50 (8%)	4/50 (8%)	7/49 (14%)	5/50 (10%)
POLY-3 RATE (b)	4/44.80	4/46.04	7/46.88	5/45.33
POLY-3 PERCENT (g)	8.9%	8.7%	14.9%	11%
TERMINAL (d)	4/38 (11%)	4/34 (12%)	7/44 (16%)	5/37 (14%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.379	P=0.628N	P=0.288	P=0.507
POLY 1.5	P=0.374	P=0.633N	P=0.273	P=0.502
POLY 6	P=0.383	P=0.625N	P=0.305	P=0.511
COCH-ARM / FISHERS	P=0.374	P=0.643N	P=0.251	P=0.500
MAX-ISO-POLY-3	P=0.265	P=0.482N	P=0.195	P=0.369

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Salivary Glands				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	34/49 (69%)	33/49 (67%)	31/50 (62%)	26/50 (52%)
POLY-3 RATE (b)	34/47.14	33/48.07	31/48.81	26/46.37
POLY-3 PERCENT (g)	72.1%	68.7%	63.5%	56.1%
TERMINAL (d)	27/38 (71%)	25/34 (74%)	29/45 (64%)	21/37 (57%)
FIRST INCIDENCE	421	521	534	548
STATISTICAL TESTS				
POLY 3	P=0.051N	P=0.441N	P=0.245N	P=0.075N
POLY 1.5	P=0.045N*	P=0.456N	P=0.258N	P=0.069N
POLY 6	P=0.058N	P=0.443N	P=0.235N	P=0.086N
COCH-ARM / FISHERS	P=0.033N*	P=0.500N	P=0.287N	P=0.059N
MAX-ISO-POLY-3	P=0.050N*	P=0.352N	P=0.184N	P=0.050N*

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Skin				
Cyst Epithelial Inclusion				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.80	0/46.04	0/47.88	0/45.33
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	0/37 (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 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Skin				
Ulcer				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.80	1/46.27	0/47.88	0/45.33
POLY-3 PERCENT (g)	2.2%	2.2%	0%	0%
TERMINAL (d)	1/38 (3%)	0/34 (0%)	0/45 (0%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	669	---	---
STATISTICAL TESTS				
POLY 3	P=0.233N	P=0.753N	P=0.487N	P=0.498N
POLY 1.5	P=0.234N	P=0.756N	P=0.492N	P=0.499N
POLY 6	P=0.231N	P=0.751N	P=0.481N	P=0.496N
COCH-ARM / FISHERS	P=0.236N	P=0.753N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.158N	P=0.489N	P=0.158N	P=0.158N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Spleen				
Hematopoietic Cell Proliferation				
LESION RATES				
OVERALL (a)	26/49 (53%)	24/48 (50%)	20/50 (40%)	10/49 (20%)
POLY-3 RATE (b)	26/46.54	24/45.26	20/49.04	10/45.99
POLY-3 PERCENT (g)	55.9%	53%	40.8%	21.7%
TERMINAL (d)	21/38 (55%)	18/34 (53%)	18/45 (40%)	4/37 (11%)
FIRST INCIDENCE	421	666	534	548
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.475N	P=0.100N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.469N	P=0.112N	P<0.001N**
POLY 6	P<0.001N**	P=0.484N	P=0.090N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.461N	P=0.135N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.391N	P=0.072N	P<0.001N**

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
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 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Spleen				
Hyperplasia Lymphoid				
LESION RATES				
OVERALL (a)	7/49 (14%)	6/48 (13%)	6/50 (12%)	5/49 (10%)
POLY-3 RATE (b)	7/44.49	6/44.63	6/48.76	5/44.35
POLY-3 PERCENT (g)	15.7%	13.4%	12.3%	11.3%
TERMINAL (d)	6/38 (16%)	6/34 (18%)	4/45 (9%)	5/37 (14%)
FIRST INCIDENCE	701	729 (T)	556	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.324N	P=0.498N	P=0.430N	P=0.381N
POLY 1.5	P=0.326N	P=0.504N	P=0.451N	P=0.382N
POLY 6	P=0.323N	P=0.494N	P=0.406N	P=0.382N
COCH-ARM / FISHERS	P=0.323N	P=0.516N	P=0.484N	P=0.380N
MAX-ISO-POLY-3	P=0.271N	P=0.379N	P=0.323N	P=0.270N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Spleen: Lymphoid Follicle Atrophy				
LESION RATES				
OVERALL (a)	4/49 (8%)	2/48 (4%)	4/50 (8%)	2/49 (4%)
POLY-3 RATE (b)	4/46.25	2/45.05	4/48.51	2/44.80
POLY-3 PERCENT (g)	8.7%	4.4%	8.3%	4.5%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	2/45 (4%)	0/37 (0%)
FIRST INCIDENCE	523	666	554	654
STATISTICAL TESTS				
POLY 3	P=0.352N	P=0.349N	P=0.616N	P=0.352N
POLY 1.5	P=0.349N	P=0.348N	P=0.621N	P=0.348N
POLY 6	P=0.357N	P=0.353N	P=0.612N	P=0.359N
COCH-ARM / FISHERS	P=0.339N	P=0.349N	P=0.631N	P=0.339N
MAX-ISO-POLY-3	P=0.215N	P=0.211N	P=0.470N	P=0.215N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Stomach, Forestomach Erosion				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	14/50 (28%)	11/50 (22%)
POLY-3 RATE (b)	0/44.80	1/46.04	14/49.06	11/46.50
POLY-3 PERCENT (g)	0%	2.2%	28.5%	23.7%
TERMINAL (d)	0/38 (0%)	1/34 (3%)	11/45 (24%)	8/37 (22%)
FIRST INCIDENCE	---	729 (T)	554	523
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.505	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.504	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.507	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.165	P<0.001**	P<0.001**

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Stomach, Forestomach Inflammation Chronic				
LESION RATES				
OVERALL (a)	3/50 (6%)	6/50 (12%)	21/50 (42%)	22/50 (44%)
POLY-3 RATE (b)	3/45.30	6/47.04	21/49.06	22/47.52
POLY-3 PERCENT (g)	6.6%	12.8%	42.8%	46.3%
TERMINAL (d)	1/38 (3%)	2/34 (6%)	18/45 (40%)	16/37 (43%)
FIRST INCIDENCE	639	565	554	523
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.261	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.254	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.267	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.243	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.165	P<0.001**	P<0.001**

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Stomach, Forestomach Necrosis				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.80	0/46.04	0/47.88	0/45.33
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	0/37 (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 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Stomach, Forestomach Ulcer				
LESION RATES				
OVERALL (a)	0/50 (0%)	2/50 (4%)	3/50 (6%)	6/50 (12%)
POLY-3 RATE (b)	0/44.80	2/46.28	3/47.88	6/46.36
POLY-3 PERCENT (g)	0%	4.3%	6.3%	12.9%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	3/45 (7%)	3/37 (8%)
FIRST INCIDENCE	---	681	729 (T)	548
STATISTICAL TESTS				
POLY 3	P=0.007**	P=0.245	P=0.131	P=0.017*
POLY 1.5	P=0.007**	P=0.242	P=0.127	P=0.016*
POLY 6	P=0.008**	P=0.247	P=0.137	P=0.018*
COCH-ARM / FISHERS	P=0.007**	P=0.247	P=0.121	P=0.013*
MAX-ISO-POLY-3	P=0.005**	P=0.082	P=0.049*	P=0.006**

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Stomach, Forestomach: Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	3/50 (6%)	6/50 (12%)	23/50 (46%)	24/50 (48%)
POLY-3 RATE (b)	3/45.41	6/46.51	23/49.06	24/47.52
POLY-3 PERCENT (g)	6.6%	12.9%	46.9%	50.5%
TERMINAL (d)	0/38 (0%)	3/34 (9%)	20/45 (44%)	18/37 (49%)
FIRST INCIDENCE	639	669	554	523
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.254	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.250	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.255	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.243	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.158	P<0.001**	P<0.001**

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Stomach, Glandular Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/44.80	1/46.04	0/47.88	1/45.84
POLY-3 PERCENT (g)	4.5%	2.2%	0%	2.2%
TERMINAL (d)	2/38 (5%)	1/34 (3%)	0/45 (0%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---	576
STATISTICAL TESTS				
POLY 3	P=0.363N	P=0.490N	P=0.223N	P=0.492N
POLY 1.5	P=0.365N	P=0.494N	P=0.228N	P=0.496N
POLY 6	P=0.361N	P=0.489N	P=0.217N	P=0.488N
COCH-ARM / FISHERS	P=0.366N	P=0.500N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.138N	P=0.274N	P=0.075N	P=0.275N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Stomach, Glandular Ulcer				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/44.80	0/46.04	0/47.88	2/46.24
POLY-3 PERCENT (g)	0%	0%	0%	4.3%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	523
STATISTICAL TESTS				
POLY 3	P=0.046*	(e)	(e)	P=0.244
POLY 1.5	P=0.046*	(e)	(e)	P=0.241
POLY 6	P=0.047*	(e)	(e)	P=0.248
COCH-ARM / FISHERS	P=0.046*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.025*	(e)	(e)	P=0.082

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Stomach, Glandular: Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/44.80	0/46.04	1/47.88	2/45.33
POLY-3 PERCENT (g)	0%	0%	2.1%	4.4%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	1/45 (2%)	2/37 (5%)
FIRST INCIDENCE	---	---	729 (T)	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.070	(e)	P=0.513	P=0.240
POLY 1.5	P=0.070	(e)	P=0.508	P=0.238
POLY 6	P=0.071	(e)	P=0.519	P=0.241
COCH-ARM / FISHERS	P=0.070	(e)	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.052	(e)	P=0.175	P=0.078

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Stomach, Glandular: Glands Ectasia				
LESION RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/44.80	1/46.04	2/47.88	0/45.33
POLY-3 PERCENT (g)	2.2%	2.2%	4.2%	0%
TERMINAL (d)	1/38 (3%)	1/34 (3%)	2/45 (4%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.364N	P=0.755N	P=0.523	P=0.498N
POLY 1.5	P=0.367N	P=0.757N	P=0.514	P=0.499N
POLY 6	P=0.362N	P=0.753N	P=0.533	P=0.496N
COCH-ARM / FISHERS	P=0.366N	P=0.753N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.179N	P=0.491N	P=0.305	P=0.158N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Thymus Atrophy				
LESION RATES				
OVERALL (a)	39/50 (78%)	44/50 (88%)	46/49 (94%)	40/47 (85%)
POLY-3 RATE (b)	39/47.44	44/48.78	46/48.39	40/45.50
POLY-3 PERCENT (g)	82.2%	90.2%	95.1%	87.9%
TERMINAL (d)	31/38 (82%)	32/34 (94%)	42/44 (96%)	31/36 (86%)
FIRST INCIDENCE	523	521	554	523
STATISTICAL TESTS				
POLY 3	P=0.271	P=0.191	P=0.040*	P=0.312
POLY 1.5	P=0.229	P=0.168	P=0.031*	P=0.272
POLY 6	P=0.315	P=0.210	P=0.051	P=0.353
COCH-ARM / FISHERS	P=0.228	P=0.143	P=0.022*	P=0.262
MAX-ISO-POLY-3	P=0.069	P=0.121	P=0.019*	P=0.216

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Thymus Hyperplasia				
LESION RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/49 (4%)	1/47 (2%)
POLY-3 RATE (b)	1/44.80	0/46.04	2/46.88	1/42.79
POLY-3 PERCENT (g)	2.2%	0%	4.3%	2.3%
TERMINAL (d)	1/38 (3%)	0/34 (0%)	2/44 (5%)	1/36 (3%)
FIRST INCIDENCE	729 (T)	---	729 (T)	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.481	P=0.495N	P=0.516	P=0.751
POLY 1.5	P=0.479	P=0.496N	P=0.507	P=0.748
POLY 6	P=0.485	P=0.493N	P=0.526	P=0.753
COCH-ARM / FISHERS	P=0.480	P=0.500N	P=0.492	P=0.737
MAX-ISO-POLY-3	P=0.242	P=0.158N	P=0.297	P=0.485

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Thymus				
Infiltration Cellular Histiocyte				
LESION RATES				
OVERALL (a)	5/50 (10%)	0/50 (0%)	0/49 (0%)	2/47 (4%)
POLY-3 RATE (b)	5/44.80	0/46.04	0/46.88	2/42.79
POLY-3 PERCENT (g)	11.2%	0%	0%	4.7%
TERMINAL (d)	5/38 (13%)	0/34 (0%)	0/44 (0%)	2/36 (6%)
FIRST INCIDENCE	729 (T)	---	---	729 (T)
STATISTICAL TESTS				
POLY 3	P=0.211N	P=0.028N*	P=0.027N*	P=0.235N
POLY 1.5	P=0.212N	P=0.029N*	P=0.029N*	P=0.240N
POLY 6	P=0.210N	P=0.028N*	P=0.025N*	P=0.229N
COCH-ARM / FISHERS	P=0.216N	P=0.028N*	P=0.030N*	P=0.244N
MAX-ISO-POLY-3	P=0.010N**	P=0.010N**	P=0.010N**	P=0.133N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Thyroid Gland Cyst				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.80	1/46.27	0/47.88	0/45.33
POLY-3 PERCENT (g)	0%	2.2%	0%	0%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	0/37 (0%)
FIRST INCIDENCE	---	669	---	---
STATISTICAL TESTS				
POLY 3	P=0.559N	P=0.506	(e)	(e)
POLY 1.5	P=0.562N	P=0.504	(e)	(e)
POLY 6	P=0.556N	P=0.508	(e)	(e)
COCH-ARM / FISHERS	P=0.567N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.243N	P=0.166	(e)	(e)

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Tooth Dysplasia				
LESION RATES				
OVERALL (a)	1/1 (100%)	1/1 (100%)	2/2 (100%)	2/2 (100%)
POLY-3 RATE (b)	1/1.00	1/1.00	2/2.00	2/2.00
POLY-3 PERCENT (g)	100%	100%	100%	100%
TERMINAL (d)	1/1 (100%)	0/0 (0%)	2/2 (100%)	2/2 (100%)
FIRST INCIDENCE	729 (T)	711	729 (T)	729 (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 - 06
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
Time Report Requested: 10:57:30
First Dose M/F: 08/24/04 / 08/23/04
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Urethra 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 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Urinary Bladder				
Infiltration Cellular Mononuclear Cell				
LESION RATES				
OVERALL (a)	34/50 (68%)	34/48 (71%)	40/50 (80%)	34/50 (68%)
POLY-3 RATE (b)	34/46.37	34/45.99	40/48.51	34/47.04
POLY-3 PERCENT (g)	73.3%	73.9%	82.5%	72.3%
TERMINAL (d)	29/38 (76%)	27/34 (79%)	38/45 (84%)	27/37 (73%)
FIRST INCIDENCE	523	669	554	576
STATISTICAL TESTS				
POLY 3	P=0.536N	P=0.569	P=0.196	P=0.549N
POLY 1.5	P=0.526	P=0.534	P=0.167	P=0.578N
POLY 6	P=0.498N	P=0.599N	P=0.231	P=0.514N
COCH-ARM / FISHERS	P=0.524	P=0.466	P=0.127	P=0.585N
MAX-ISO-POLY-3	P=0.307N	P=0.471	P=0.137	P=0.452N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 04/13/2009
 Time Report Requested: 10:57:30
 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Urinary Bladder Inflammation				
LESION RATES				
OVERALL (a)	0/50 (0%)	1/48 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.80	1/44.99	0/47.88	0/45.33
POLY-3 PERCENT (g)	0%	2.2%	0%	0%
TERMINAL (d)	0/38 (0%)	1/34 (3%)	0/45 (0%)	0/37 (0%)
FIRST INCIDENCE	---	729 (T)	---	---
STATISTICAL TESTS				
POLY 3	P=0.555N	P=0.501	(e)	(e)
POLY 1.5	P=0.559N	P=0.498	(e)	(e)
POLY 6	P=0.552N	P=0.503	(e)	(e)
COCH-ARM / FISHERS	P=0.565N	P=0.490	(e)	(e)
MAX-ISO-POLY-3	P=0.240N	P=0.161	(e)	(e)

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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 First Dose M/F: 08/24/04 / 08/23/04
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Uterus Inflammation				
LESION RATES				
OVERALL (a)	3/50 (6%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/44.91	1/46.04	0/47.88	0/45.33
POLY-3 PERCENT (g)	6.7%	2.2%	0%	0%
TERMINAL (d)	2/38 (5%)	1/34 (3%)	0/45 (0%)	0/37 (0%)
FIRST INCIDENCE	700	729 (T)	---	---
STATISTICAL TESTS				
POLY 3	P=0.042N*	P=0.296N	P=0.108N	P=0.117N
POLY 1.5	P=0.043N*	P=0.300N	P=0.112N	P=0.118N
POLY 6	P=0.042N*	P=0.295N	P=0.103N	P=0.116N
COCH-ARM / FISHERS	P=0.044N*	P=0.309N	P=0.121N	P=0.121N
MAX-ISO-POLY-3	P=0.015N*	P=0.150N	P=0.038N*	P=0.038N*

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Uterus				
Metaplasia				
LESION RATES				
OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.80	2/46.04	0/47.88	0/45.33
POLY-3 PERCENT (g)	2.2%	4.3%	0%	0%
TERMINAL (d)	1/38 (3%)	2/34 (6%)	0/45 (0%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---	---
STATISTICAL TESTS				
POLY 3	P=0.183N	P=0.510	P=0.487N	P=0.498N
POLY 1.5	P=0.185N	P=0.506	P=0.492N	P=0.499N
POLY 6	P=0.181N	P=0.511	P=0.481N	P=0.496N
COCH-ARM / FISHERS	P=0.188N	P=0.500	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.111N	P=0.290	P=0.158N	P=0.158N

TDMS No. 20007 - 06
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Uterus: Endometrium Hyperplasia Cystic				
LESION RATES				
OVERALL (a)	42/50 (84%)	44/50 (88%)	42/50 (84%)	36/50 (72%)
POLY-3 RATE (b)	42/47.84	44/47.88	42/49.00	36/48.06
POLY-3 PERCENT (g)	87.8%	91.9%	85.7%	74.9%
TERMINAL (d)	36/38 (95%)	33/34 (97%)	40/45 (89%)	27/37 (73%)
FIRST INCIDENCE	394	565	554	548
STATISTICAL TESTS				
POLY 3	P=0.018N*	P=0.361	P=0.500N	P=0.079N
POLY 1.5	P=0.029N*	P=0.356	P=0.549N	P=0.102N
POLY 6	P=0.009N**	P=0.405	P=0.429N	P=0.052N
COCH-ARM / FISHERS	P=0.041N*	P=0.387	P=0.607N	P=0.114N
MAX-ISO-POLY-3	P=0.016N*	P=0.234	P=0.376N	P=0.046N*

TDMS No. 20007 - 06
Test Type: CHRONIC
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Species/Strain: MICE/B6C3F1

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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 ***