

**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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 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
<b>Adrenal Cortex Hypertrophy</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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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 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
<b>Adrenal Cortex</b>				
<b>Vacuolization Cytoplasmic</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	2/50 (4%)	2/50 (4%)	2/50 (4%)	3/50 (6%)
<b>POLY-3 RATE (b)</b>	2/43.49	2/42.37	2/44.59	3/44.23
<b>POLY-3 PERCENT (g)</b>	4.6%	4.7%	4.5%	6.8%
<b>TERMINAL (d)</b>	2/34 (6%)	2/33 (6%)	2/34 (6%)	3/36 (8%)
<b>FIRST INCIDENCE</b>	730 (T)	730 (T)	730 (T)	730 (T)
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.400	P=0.685	P=0.685N	P=0.508
<b>POLY 1.5</b>	P=0.395	P=0.686	P=0.688N	P=0.504
<b>POLY 6</b>	P=0.406	P=0.687	P=0.682N	P=0.514
<b>COCH-ARM / FISHERS</b>	P=0.387	P=0.691N	P=0.691N	P=0.500
<b>MAX-ISO-POLY-3</b>	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
<b>Adrenal Cortex: Subcapsular Hyperplasia</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Adrenal Cortex: Zona Reticularis Hyperplasia</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Adrenal Medulla Hyperplasia</b>				
<b>LESION RATES</b>				
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)	---
<b>STATISTICAL TESTS</b>				
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**

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DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
<b>Bone Marrow Fibrosis</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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

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

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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
<b>Epididymis</b>				
<b>Infiltration Cellular Mononuclear Cell</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Eye: Cornea</b>				
<b>Inflammation Chronic</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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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**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
<b>Harderian Gland Hyperplasia</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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

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
<b>Harderian Gland</b>				
<b>Infiltration Cellular Mononuclear Cell</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	36/50 (72%)	30/50 (60%)	34/50 (68%)	39/50 (78%)
<b>POLY-3 RATE (b)</b>	36/48.48	30/44.95	34/47.17	39/47.87
<b>POLY-3 PERCENT (g)</b>	74.3%	66.8%	72.1%	81.5%
<b>TERMINAL (d)</b>	22/34 (65%)	24/33 (73%)	27/34 (79%)	31/36 (86%)
<b>FIRST INCIDENCE</b>	455	431	494	392
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.152	P=0.280N	P=0.496N	P=0.268
<b>POLY 1.5</b>	P=0.162	P=0.216N	P=0.451N	P=0.302
<b>POLY 6</b>	P=0.122	P=0.376N	P=0.575N	P=0.206
<b>COCH-ARM / FISHERS</b>	P=0.156	P=0.146N	P=0.414N	P=0.322
<b>MAX-ISO-POLY-3</b>	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
<b>Heart</b>				
<b>Cardiomyopathy</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	14/50 (28%)	16/50 (32%)	11/50 (22%)	14/50 (28%)
<b>POLY-3 RATE (b)</b>	14/44.31	16/43.76	11/45.45	14/45.84
<b>POLY-3 PERCENT (g)</b>	31.6%	36.6%	24.2%	30.5%
<b>TERMINAL (d)</b>	10/34 (29%)	10/33 (30%)	8/34 (24%)	10/36 (28%)
<b>FIRST INCIDENCE</b>	648	553	616	574
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.394N	P=0.394	P=0.292N	P=0.548N
<b>POLY 1.5</b>	P=0.414N	P=0.395	P=0.303N	P=0.565N
<b>POLY 6</b>	P=0.373N	P=0.410	P=0.283N	P=0.523N
<b>COCH-ARM / FISHERS</b>	P=0.447N	P=0.414	P=0.322N	P=0.588N
<b>MAX-ISO-POLY-3</b>	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
<b>Heart: Artery</b>				
<b>Infiltration Cellular Mononuclear Cell</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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

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

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Heart: Myocardium  
Mineralization

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**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

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**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

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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
<b>Heart: Valve Inflammation</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Intestine Small, Jejunum: Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
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)	---	---
<b>STATISTICAL TESTS</b>				
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
<b>Islets, Pancreatic Hyperplasia</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Kidney</b>				
<b>Amyloid Deposition</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
<b>POLY-3 RATE (b)</b>	0/43.49	0/42.37	1/44.59	0/44.23
<b>POLY-3 PERCENT (g)</b>	0%	0%	2.2%	0%
<b>TERMINAL (d)</b>	0/34 (0%)	0/33 (0%)	1/34 (3%)	0/36 (0%)
<b>FIRST INCIDENCE</b>	---	---	730 (T)	---
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.702	(e)	P=0.505	(e)
<b>POLY 1.5</b>	P=0.699	(e)	P=0.503	(e)
<b>POLY 6</b>	P=0.707	(e)	P=0.507	(e)
<b>COCH-ARM / FISHERS</b>	P=0.694	(e)	P=0.500	(e)
<b>MAX-ISO-POLY-3</b>	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
<b>Kidney</b>				
<b>Hydronephrosis</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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
<b>Kidney Inflammation</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Kidney</b>				
<b>Metaplasia Osseous</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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
<b>Kidney Mineralization</b>				
<b>LESION RATES</b>				
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	---	---
<b>STATISTICAL TESTS</b>				
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
<b>Kidney</b>				
<b>Nephropathy</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Kidney: Cortex, Medulla Necrosis</b>				
<b>LESION RATES</b>				
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	---	---	---
<b>STATISTICAL TESTS</b>				
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
<b>Kidney: Papilla Necrosis</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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
<b>Kidney: Renal Tubule Cyst</b>				
<b>LESION RATES</b>				
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	---
<b>STATISTICAL TESTS</b>				
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
<b>Kidney: Renal Tubule Hyperplasia</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Kidney: Renal Tubule Mineralization</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Kidney: Renal Tubule Pigmentation Lipofuscin</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Liver</b>				
<b>Angiectasis</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Liver</b>				
<b>Basophilic Focus</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Liver</b>				
<b>Clear Cell Focus</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	18/50 (36%)	18/50 (36%)	19/50 (38%)	21/50 (42%)
<b>POLY-3 RATE (b)</b>	18/44.49	18/43.97	19/44.88	21/45.37
<b>POLY-3 PERCENT (g)</b>	40.5%	40.9%	42.3%	46.3%
<b>TERMINAL (d)</b>	15/34 (44%)	16/33 (49%)	18/34 (53%)	18/36 (50%)
<b>FIRST INCIDENCE</b>	570	423	653	596
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.304	P=0.568	P=0.514	P=0.364
<b>POLY 1.5</b>	P=0.293	P=0.571	P=0.511	P=0.353
<b>POLY 6</b>	P=0.325	P=0.571	P=0.512	P=0.386
<b>COCH-ARM / FISHERS</b>	P=0.277	P=0.582N	P=0.500	P=0.341
<b>MAX-ISO-POLY-3</b>	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
<b>Liver</b>				
<b>Eosinophilic Focus</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Liver</b>				
<b>Fatty Change</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	32/50 (64%)	34/50 (68%)	27/50 (54%)	24/50 (48%)
<b>POLY-3 RATE (b)</b>	32/48.54	34/48.38	27/47.76	24/47.66
<b>POLY-3 PERCENT (g)</b>	65.9%	70.3%	56.5%	50.4%
<b>TERMINAL (d)</b>	22/34 (65%)	22/33 (67%)	18/34 (53%)	17/36 (47%)
<b>FIRST INCIDENCE</b>	369	423	455	392
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.030N*	P=0.404	P=0.227N	P=0.086N
<b>POLY 1.5</b>	P=0.029N*	P=0.398	P=0.220N	P=0.084N
<b>POLY 6</b>	P=0.030N*	P=0.428	P=0.232N	P=0.085N
<b>COCH-ARM / FISHERS</b>	P=0.028N*	P=0.417	P=0.208N	P=0.079N
<b>MAX-ISO-POLY-3</b>	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
<b>Liver</b>				
<b>Hematopoietic Cell Proliferation</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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				
<b>LESION RATES</b>				
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	---
<b>STATISTICAL TESTS</b>				
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
<b>Liver</b>				
<b>Infiltration Cellular Mononuclear Cell</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	49/50 (98%)	47/50 (94%)	47/50 (94%)	48/50 (96%)
<b>POLY-3 RATE (b)</b>	49/49.52	47/49.66	47/49.92	48/49.54
<b>POLY-3 PERCENT (g)</b>	99%	94.6%	94.1%	96.9%
<b>TERMINAL (d)</b>	34/34 (100%)	32/33 (97%)	32/34 (94%)	35/36 (97%)
<b>FIRST INCIDENCE</b>	369	319	455	392
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.469N	P=0.240N	P=0.212N	P=0.493N
<b>POLY 1.5</b>	P=0.474N	P=0.267N	P=0.250N	P=0.496N
<b>POLY 6</b>	P=0.460N	P=0.216N	P=0.171N	P=0.492N
<b>COCH-ARM / FISHERS</b>	P=0.477N	P=0.309N	P=0.309N	P=0.500N
<b>MAX-ISO-POLY-3</b>	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
<b>Liver Mineralization</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Liver</b>				
<b>Mixed Cell Focus</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Liver</b>				
<b>Necrosis</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Liver</b>				
<b>Tension Lipidosis</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Liver: Centrilobular Hypertrophy</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Lung Inflammation</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Lung Mineralization</b>				
<b>LESION RATES</b>				
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	---
<b>STATISTICAL TESTS</b>				
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
<b>Lung: Alveolar Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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
<b>Lung: Alveolus Infiltration Cellular Histiocyte</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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  
 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
<b>Lung: Bronchus Hyperplasia</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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

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
<b>Lymph Node, Mandibular Hyperplasia Lymphoid</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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
<b>Lymph Node, Mesenteric Hyperplasia Lymphoid</b>				
<b>LESION RATES</b>				
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)	---
<b>STATISTICAL TESTS</b>				
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

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
<b>Mesentery: Fat Necrosis</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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

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
<b>Nose Inflammation</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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
<b>Nose</b>				
<b>Inflammation Chronic</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	9/50 (18%)	8/50 (16%)	7/50 (14%)	5/50 (10%)
<b>POLY-3 RATE (b)</b>	9/43.80	8/42.68	7/46.38	5/45.86
<b>POLY-3 PERCENT (g)</b>	20.6%	18.7%	15.1%	10.9%
<b>TERMINAL (d)</b>	8/34 (24%)	6/33 (18%)	3/34 (9%)	1/36 (3%)
<b>FIRST INCIDENCE</b>	644	687	455	582
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.116N	P=0.524N	P=0.344N	P=0.166N
<b>POLY 1.5</b>	P=0.128N	P=0.519N	P=0.363N	P=0.178N
<b>POLY 6</b>	P=0.102N	P=0.517N	P=0.325N	P=0.149N
<b>COCH-ARM / FISHERS</b>	P=0.146N	P=0.500N	P=0.393N	P=0.194N
<b>MAX-ISO-POLY-3</b>	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
<b>Nose</b>				
Polyp, Inflammatory				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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
<b>Nose: Nasolacrimal Duct Inflammation</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Pancreas</b>				
<b>Inflammation Chronic</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
<b>POLY-3 RATE (b)</b>	0/43.49	0/42.37	1/44.59	0/44.23
<b>POLY-3 PERCENT (g)</b>	0%	0%	2.2%	0%
<b>TERMINAL (d)</b>	0/34 (0%)	0/33 (0%)	1/34 (3%)	0/36 (0%)
<b>FIRST INCIDENCE</b>	---	---	730 (T)	---
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.702	(e)	P=0.505	(e)
<b>POLY 1.5</b>	P=0.699	(e)	P=0.503	(e)
<b>POLY 6</b>	P=0.707	(e)	P=0.507	(e)
<b>COCH-ARM / FISHERS</b>	P=0.694	(e)	P=0.500	(e)
<b>MAX-ISO-POLY-3</b>	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
<b>Pancreas: Acinus Hypertrophy</b>				
<b>LESION RATES</b>				
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)	---	---	---
<b>STATISTICAL TESTS</b>				
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
<b>Peritoneum</b>				
<b>Inflammation Chronic</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/2 (100%)
<b>POLY-3 RATE (b)</b>	0/0.00	0/0.00	0/0.00	2/2.00
<b>POLY-3 PERCENT (g)</b>	0%	0%	0%	100%
<b>TERMINAL (d)</b>	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)
<b>FIRST INCIDENCE</b>	---	---	---	673
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	(e)	(e)	(e)	(e)
<b>POLY 1.5</b>	(e)	(e)	(e)	(e)
<b>POLY 6</b>	(e)	(e)	(e)	(e)
<b>COCH-ARM / FISHERS</b>	(e)	(e)	(e)	(e)
<b>MAX-ISO-POLY-3</b>	(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
<b>Pituitary Gland Cyst</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Pituitary Gland: Pars Distalis Hyperplasia</b>				
<b>LESION RATES</b>				
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)	---
<b>STATISTICAL TESTS</b>				
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
<b>Preputial Gland Cyst</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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
<b>Preputial Gland Inflammation</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Prostate</b>				
<b>Infiltration Cellular Mononuclear Cell</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	29/50 (58%)	31/50 (62%)	38/50 (76%)	29/50 (58%)
<b>POLY-3 RATE (b)</b>	29/44.60	31/44.24	38/47.43	29/47.28
<b>POLY-3 PERCENT (g)</b>	65%	70.1%	80.1%	61.3%
<b>TERMINAL (d)</b>	24/34 (71%)	28/33 (85%)	27/34 (79%)	22/36 (61%)
<b>FIRST INCIDENCE</b>	647	319	455	392
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.352N	P=0.384	P=0.070	P=0.439N
<b>POLY 1.5</b>	P=0.440N	P=0.397	P=0.056	P=0.497N
<b>POLY 6</b>	P=0.252N	P=0.371	P=0.097	P=0.368N
<b>COCH-ARM / FISHERS</b>	P=0.510	P=0.419	P=0.044*	P=0.580N
<b>MAX-ISO-POLY-3</b>	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
<b>Prostate Inflammation</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Salivary Glands</b>				
<b>Infiltration Cellular Mononuclear Cell</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	43/50 (86%)	36/50 (72%)	40/50 (80%)	36/50 (72%)
<b>POLY-3 RATE (b)</b>	43/48.63	36/46.25	40/48.18	36/47.86
<b>POLY-3 PERCENT (g)</b>	88.4%	77.8%	83%	75.2%
<b>TERMINAL (d)</b>	29/34 (85%)	28/33 (85%)	29/34 (85%)	28/36 (78%)
<b>FIRST INCIDENCE</b>	455	423	494	392
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.090N	P=0.123N	P=0.315N	P=0.070N
<b>POLY 1.5</b>	P=0.093N	P=0.094N	P=0.299N	P=0.064N
<b>POLY 6</b>	P=0.097N	P=0.173N	P=0.346N	P=0.087N
<b>COCH-ARM / FISHERS</b>	P=0.120N	P=0.070N	P=0.298N	P=0.070N
<b>MAX-ISO-POLY-3</b>	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
<b>Seminal Vesicle Fibrosis</b>				
<b>LESION RATES</b>				
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)	---	---	---
<b>STATISTICAL TESTS</b>				
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  
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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
<b>Seminal Vesicle Infiltration Cellular Mononuclear Cell</b>				
<b>LESION RATES</b>				
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	---
<b>STATISTICAL TESTS</b>				
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  
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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	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
<b>Seminal Vesicle Inflammation</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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  
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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
<b>Skin</b>				
Cyst Epithelial Inclusion				
<b>LESION RATES</b>				
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	---
<b>STATISTICAL TESTS</b>				
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
<b>Skin</b>				
<b>Ulcer</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Spleen</b>				
<b>Hematopoietic Cell Proliferation</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	16/50 (32%)	19/50 (38%)	21/49 (43%)	15/50 (30%)
<b>POLY-3 RATE (b)</b>	16/45.60	19/45.03	21/47.01	15/47.76
<b>POLY-3 PERCENT (g)</b>	35.1%	42.2%	44.7%	31.4%
<b>TERMINAL (d)</b>	9/34 (27%)	10/33 (30%)	11/34 (32%)	6/36 (17%)
<b>FIRST INCIDENCE</b>	513	484	534	392
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.321N	P=0.315	P=0.232	P=0.437N
<b>POLY 1.5</b>	P=0.352N	P=0.317	P=0.211	P=0.460N
<b>POLY 6</b>	P=0.293N	P=0.329	P=0.262	P=0.413N
<b>COCH-ARM / FISHERS</b>	P=0.415N	P=0.338	P=0.182	P=0.500N
<b>MAX-ISO-POLY-3</b>	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  
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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	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
<b>Spleen</b>				
Hyperplasia Lymphoid				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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  
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 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
<b>Spleen: Lymphoid Follicle Atrophy</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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

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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**

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DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
<b>Stomach, Forestomach Erosion</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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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TDMS No. 20007 - 06  
 Test Type: CHRONIC  
 Route: GAVAGE  
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 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
<b>Stomach, Forestomach Inflammation Chronic</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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  
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 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	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
<b>Stomach, Forestomach Necrosis</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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  
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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	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
<b>Stomach, Forestomach Ulcer</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS**

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

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Stomach, Forestomach: Epithelium  
Hyperplasia

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**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

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**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

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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
<b>Stomach, Glandular Infiltration Cellular Mononuclear Cell</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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
<b>Stomach, Glandular Ulcer</b>				
<b>LESION RATES</b>				
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	---	---	---
<b>STATISTICAL TESTS</b>				
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  
 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
<b>Stomach, Glandular: Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
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)	---	---	---
<b>STATISTICAL TESTS</b>				
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
<b>Stomach, Glandular: Glands Ectasia</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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
<b>Testes: Germinal Epithelium Atrophy</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Thymus Hyperplasia</b>				
<b>LESION RATES</b>				
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)	---	---
<b>STATISTICAL TESTS</b>				
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  
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Lab: BAT

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

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

---

Thymus  
Infiltration Cellular Histiocyte

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**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)	---

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**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)

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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	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
<b>Thyroid Gland Cyst</b>				
<b>LESION RATES</b>				
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)	---
<b>STATISTICAL TESTS</b>				
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  
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 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
<b>Tooth Dysplasia</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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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 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
<b>Urethra Inflammation</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Urinary Bladder</b>				
<b>Infiltration Cellular Mononuclear Cell</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	20/50 (40%)	25/50 (50%)	26/50 (52%)	20/50 (40%)
<b>POLY-3 RATE (b)</b>	20/46.84	25/43.84	26/45.66	20/45.15
<b>POLY-3 PERCENT (g)</b>	42.7%	57%	56.9%	44.3%
<b>TERMINAL (d)</b>	11/34 (32%)	19/33 (58%)	22/34 (65%)	16/36 (44%)
<b>FIRST INCIDENCE</b>	369	553	605	596
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.499N	P=0.120	P=0.118	P=0.522
<b>POLY 1.5</b>	P=0.479N	P=0.145	P=0.133	P=0.543
<b>POLY 6</b>	P=0.521N	P=0.106	P=0.101	P=0.505
<b>COCH-ARM / FISHERS</b>	P=0.452N	P=0.211	P=0.158	P=0.581N
<b>MAX-ISO-POLY-3</b>	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  
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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
<b>Urinary Bladder Inflammation</b>				
<b>LESION RATES</b>				
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	---	---
<b>STATISTICAL TESTS</b>				
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  
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 105 WEEKS**

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

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

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**Adrenal Cortex: Subcapsular  
Hyperplasia**

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<b>LESION RATES</b>				
<b>OVERALL (a)</b>	49/50 (98%)	50/50 (100%)	50/50 (100%)	50/50 (100%)
<b>POLY-3 RATE (b)</b>	49/49.84	50/50.00	50/50.00	50/50.00
<b>POLY-3 PERCENT (g)</b>	98.3%	100%	100%	100%
<b>TERMINAL (d)</b>	38/38 (100%)	34/34 (100%)	45/45 (100%)	37/37 (100%)
<b>FIRST INCIDENCE</b>	394	372	534	148

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<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.353	P=0.574	P=0.574	P=0.574
<b>POLY 1.5</b>	P=0.328	P=0.536	P=0.536	P=0.536
<b>POLY 6</b>	P=0.412	P=0.660	P=0.660	P=0.660
<b>COCH-ARM / FISHERS</b>	P=0.306	P=0.500	P=0.500	P=0.500
<b>MAX-ISO-POLY-3</b>	P=0.078	P=0.159	P=0.159	P=0.159

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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: Zona Reticularis  
Hyperplasia

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**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)

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**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

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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
<b>Adrenal Medulla Hyperplasia</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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  
 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
<b>Bone Marrow Fibrosis</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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  
 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
<b>Bone Fibrosis</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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  
 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
<b>Brain: Hypothalamus Compression</b>				
<b>LESION RATES</b>				
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	---	---	---
<b>STATISTICAL TESTS</b>				
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**

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

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Eye: Cornea  
Inflammation Chronic

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**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	---	---	---	---

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**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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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
<b>Harderian Gland Hyperplasia</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Harderian Gland Infiltration Cellular Mononuclear Cell</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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  
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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
<b>Heart</b>				
<b>Cardiomyopathy</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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
<b>Heart: Artery</b>				
<b>Infiltration Cellular Mononuclear Cell</b>				
<b>LESION RATES</b>				
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)	---
<b>STATISTICAL TESTS</b>				
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
<b>Heart: Myocardium Mineralization</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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  
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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
<b>Heart: Valve Inflammation</b>				
<b>LESION RATES</b>				
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	---	---
<b>STATISTICAL TESTS</b>				
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
<b>Intestine Small, Jejunum: Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Islets, Pancreatic Hyperplasia</b>				
<b>LESION RATES</b>				
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	---
<b>STATISTICAL TESTS</b>				
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
<b>Kidney</b>				
<b>Amyloid Deposition</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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
<b>Kidney</b>				
<b>Hydronephrosis</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
<b>POLY-3 RATE (b)</b>	0/44.80	1/46.04	0/47.88	0/45.33
<b>POLY-3 PERCENT (g)</b>	0%	2.2%	0%	0%
<b>TERMINAL (d)</b>	0/38 (0%)	1/34 (3%)	0/45 (0%)	0/37 (0%)
<b>FIRST INCIDENCE</b>	---	729 (T)	---	---
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.559N	P=0.505	(e)	(e)
<b>POLY 1.5</b>	P=0.562N	P=0.504	(e)	(e)
<b>POLY 6</b>	P=0.557N	P=0.507	(e)	(e)
<b>COCH-ARM / FISHERS</b>	P=0.567N	P=0.500	(e)	(e)
<b>MAX-ISO-POLY-3</b>	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
<b>Kidney Inflammation</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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
<b>Kidney</b>				
<b>Metaplasia Osseous</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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
<b>Kidney Mineralization</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Kidney</b>				
<b>Nephropathy</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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**

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

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**Kidney: Cortex, Medulla  
Necrosis**

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**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	---	---	---	---

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**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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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
<b>Kidney: Papilla Necrosis</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Kidney: Renal Tubule Cyst</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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
<b>Kidney: Renal Tubule Hyperplasia</b>				
<b>LESION RATES</b>				
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)	---
<b>STATISTICAL TESTS</b>				
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
<b>Kidney: Renal Tubule Mineralization</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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**

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

---

Kidney: Renal Tubule  
Pigmentation Lipofuscin

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**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	---	---	---	---

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**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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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
<b>Liver</b>				
<b>Angiectasis</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	3/50 (6%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
<b>POLY-3 RATE (b)</b>	3/44.80	0/46.04	2/47.88	0/45.33
<b>POLY-3 PERCENT (g)</b>	6.7%	0%	4.2%	0%
<b>TERMINAL (d)</b>	3/38 (8%)	0/34 (0%)	2/45 (4%)	0/37 (0%)
<b>FIRST INCIDENCE</b>	729 (T)	---	729 (T)	---
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.125N	P=0.114N	P=0.470N	P=0.116N
<b>POLY 1.5</b>	P=0.125N	P=0.116N	P=0.481N	P=0.118N
<b>POLY 6</b>	P=0.124N	P=0.113N	P=0.457N	P=0.115N
<b>COCH-ARM / FISHERS</b>	P=0.125N	P=0.121N	P=0.500N	P=0.121N
<b>MAX-ISO-POLY-3</b>	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
<b>Liver</b>				
<b>Basophilic Focus</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Liver</b>				
<b>Clear Cell Focus</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	3/50 (6%)	0/50 (0%)	1/50 (2%)	5/50 (10%)
<b>POLY-3 RATE (b)</b>	3/44.80	0/46.04	1/47.88	5/45.33
<b>POLY-3 PERCENT (g)</b>	6.7%	0%	2.1%	11%
<b>TERMINAL (d)</b>	3/38 (8%)	0/34 (0%)	1/45 (2%)	5/37 (14%)
<b>FIRST INCIDENCE</b>	729 (T)	---	729 (T)	729 (T)
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.111	P=0.114N	P=0.282N	P=0.363
<b>POLY 1.5</b>	P=0.110	P=0.116N	P=0.291N	P=0.359
<b>POLY 6</b>	P=0.111	P=0.113N	P=0.272N	P=0.366
<b>COCH-ARM / FISHERS</b>	P=0.113	P=0.121N	P=0.309N	P=0.357
<b>MAX-ISO-POLY-3</b>	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
<b>Liver</b>				
<b>Eosinophilic Focus</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	9/50 (18%)	7/50 (14%)	16/50 (32%)	26/50 (52%)
<b>POLY-3 RATE (b)</b>	9/45.43	7/46.14	16/48.43	26/46.58
<b>POLY-3 PERCENT (g)</b>	19.8%	15.2%	33%	55.8%
<b>TERMINAL (d)</b>	8/38 (21%)	5/34 (15%)	15/45 (33%)	22/37 (60%)
<b>FIRST INCIDENCE</b>	523	715	556	548
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P<0.001**	P=0.379N	P=0.111	P<0.001**
<b>POLY 1.5</b>	P<0.001**	P=0.384N	P=0.099	P<0.001**
<b>POLY 6</b>	P<0.001**	P=0.377N	P=0.127	P<0.001**
<b>COCH-ARM / FISHERS</b>	P<0.001**	P=0.393N	P=0.083	P<0.001**
<b>MAX-ISO-POLY-3</b>	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
<b>Liver</b>				
<b>Fatty Change</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	39/50 (78%)	33/50 (66%)	42/50 (84%)	23/50 (46%)
<b>POLY-3 RATE (b)</b>	39/49.20	33/47.83	42/49.44	23/45.85
<b>POLY-3 PERCENT (g)</b>	79.3%	69%	85%	50.2%
<b>TERMINAL (d)</b>	29/38 (76%)	26/34 (77%)	38/45 (84%)	19/37 (51%)
<b>FIRST INCIDENCE</b>	394	565	534	654
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.002N**	P=0.173N	P=0.317	P=0.002N**
<b>POLY 1.5</b>	P=0.002N**	P=0.157N	P=0.312	P<0.001N**
<b>POLY 6</b>	P=0.004N**	P=0.195N	P=0.325	P=0.003N**
<b>COCH-ARM / FISHERS</b>	P<0.001N**	P=0.133N	P=0.306	P<0.001N**
<b>MAX-ISO-POLY-3</b>	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
<b>Liver</b>				
<b>Hematopoietic Cell Proliferation</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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  
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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
Liver Infarct				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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
<b>Liver</b>				
<b>Infiltration Cellular Mononuclear Cell</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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  
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 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
<b>Liver</b>				
<b>Mineralization</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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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 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
<b>Liver</b>				
<b>Mixed Cell Focus</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	12/50 (24%)	13/50 (26%)	14/50 (28%)	7/50 (14%)
<b>POLY-3 RATE (b)</b>	12/44.91	13/46.51	14/48.21	7/45.61
<b>POLY-3 PERCENT (g)</b>	26.7%	28%	29%	15.4%
<b>TERMINAL (d)</b>	11/38 (29%)	10/34 (29%)	13/45 (29%)	6/37 (16%)
<b>FIRST INCIDENCE</b>	701	666	638	654
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.106N	P=0.541	P=0.493	P=0.141N
<b>POLY 1.5</b>	P=0.112N	P=0.525	P=0.461	P=0.148N
<b>POLY 6</b>	P=0.101N	P=0.555	P=0.530	P=0.135N
<b>COCH-ARM / FISHERS</b>	P=0.116N	P=0.500	P=0.410	P=0.154N
<b>MAX-ISO-POLY-3</b>	P=0.086N	P=0.446	P=0.403	P=0.092N

TDMS No. 20007 - 06  
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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
<b>Liver</b>				
<b>Necrosis</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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  
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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
<b>Liver</b>				
<b>Tension Lipidosis</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	3/50 (6%)	8/50 (16%)	7/50 (14%)	4/50 (8%)
<b>POLY-3 RATE (b)</b>	3/44.91	8/46.86	7/47.88	4/45.33
<b>POLY-3 PERCENT (g)</b>	6.7%	17.1%	14.6%	8.8%
<b>TERMINAL (d)</b>	2/38 (5%)	6/34 (18%)	7/45 (16%)	4/37 (11%)
<b>FIRST INCIDENCE</b>	701	521	729 (T)	729 (T)
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.523N	P=0.112	P=0.185	P=0.505
<b>POLY 1.5</b>	P=0.529N	P=0.107	P=0.175	P=0.501
<b>POLY 6</b>	P=0.520N	P=0.116	P=0.197	P=0.507
<b>COCH-ARM / FISHERS</b>	P=0.530N	P=0.100	P=0.159	P=0.500
<b>MAX-ISO-POLY-3</b>	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  
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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
<b>Liver: Centrilobular Hypertrophy</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
<b>Lung Inflammation</b>				
<b>LESION RATES</b>				
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)	---
<b>STATISTICAL TESTS</b>				
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**

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
<b>Lung Mineralization</b>				
<b>LESION RATES</b>				
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	---	---
<b>STATISTICAL TESTS</b>				
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  
 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
<b>Lung: Alveolar Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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

**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
<b>Lung: Alveolus Infiltration Cellular Histiocyte</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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

**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
<b>Lung: Bronchus Hyperplasia</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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
<b>Lymph Node, Mandibular Hyperplasia Lymphoid</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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**

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
<b>Lymph Node, Mesenteric Hyperplasia Lymphoid</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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  
 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
<b>Mesentery: Fat Necrosis</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Nose Inflammation</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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  
 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
<b>Nose</b>				
<b>Inflammation Chronic</b>				
<b>LESION RATES</b>				
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	---	---
<b>STATISTICAL TESTS</b>				
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  
 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
<b>Nose</b>				
Polyp, Inflammatory				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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
<b>Nose: Nasolacrimal Duct Inflammation</b>				
<b>LESION RATES</b>				
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	---
<b>STATISTICAL TESTS</b>				
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
<b>Ovary</b>				
<b>Angiectasis</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	1/49 (2%)	1/50 (2%)	2/50 (4%)	1/50 (2%)
<b>POLY-3 RATE (b)</b>	1/43.80	1/46.04	2/47.88	1/45.33
<b>POLY-3 PERCENT (g)</b>	2.3%	2.2%	4.2%	2.2%
<b>TERMINAL (d)</b>	1/37 (3%)	1/34 (3%)	2/45 (4%)	1/37 (3%)
<b>FIRST INCIDENCE</b>	729 (T)	729 (T)	729 (T)	729 (T)
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.598	P=0.749N	P=0.531	P=0.753N
<b>POLY 1.5</b>	P=0.595	P=0.752N	P=0.522	P=0.755N
<b>POLY 6</b>	P=0.600	P=0.748N	P=0.541	P=0.752N
<b>COCH-ARM / FISHERS</b>	P=0.596	P=0.747N	P=0.508	P=0.747N
<b>MAX-ISO-POLY-3</b>	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
<b>Ovary Cyst</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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  
 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
<b>Ovary Thrombosis</b>				
<b>LESION RATES</b>				
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	---
<b>STATISTICAL TESTS</b>				
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
<b>Pancreas</b>				
<b>Inflammation Chronic</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	2/49 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>POLY-3 RATE (b)</b>	2/44.38	0/46.04	0/47.88	0/45.33
<b>POLY-3 PERCENT (g)</b>	4.5%	0%	0%	0%
<b>TERMINAL (d)</b>	2/38 (5%)	0/34 (0%)	0/45 (0%)	0/37 (0%)
<b>FIRST INCIDENCE</b>	729 (T)	---	---	---
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.111N	P=0.229N	P=0.221N	P=0.232N
<b>POLY 1.5</b>	P=0.111N	P=0.230N	P=0.225N	P=0.233N
<b>POLY 6</b>	P=0.110N	P=0.229N	P=0.216N	P=0.232N
<b>COCH-ARM / FISHERS</b>	P=0.113N	P=0.242N	P=0.242N	P=0.242N
<b>MAX-ISO-POLY-3</b>	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
<b>Pancreas: Acinus Hypertrophy</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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
<b>Peritoneum</b>				
<b>Inflammation Chronic</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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
<b>Pituitary Gland Cyst</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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  
 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
<b>Pituitary Gland: Pars Distalis Hyperplasia</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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**

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
<b>Salivary Glands</b>				
<b>Infiltration Cellular Mononuclear Cell</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	34/49 (69%)	33/49 (67%)	31/50 (62%)	26/50 (52%)
<b>POLY-3 RATE (b)</b>	34/47.14	33/48.07	31/48.81	26/46.37
<b>POLY-3 PERCENT (g)</b>	72.1%	68.7%	63.5%	56.1%
<b>TERMINAL (d)</b>	27/38 (71%)	25/34 (74%)	29/45 (64%)	21/37 (57%)
<b>FIRST INCIDENCE</b>	421	521	534	548
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.051N	P=0.441N	P=0.245N	P=0.075N
<b>POLY 1.5</b>	P=0.045N*	P=0.456N	P=0.258N	P=0.069N
<b>POLY 6</b>	P=0.058N	P=0.443N	P=0.235N	P=0.086N
<b>COCH-ARM / FISHERS</b>	P=0.033N*	P=0.500N	P=0.287N	P=0.059N
<b>MAX-ISO-POLY-3</b>	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  
 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
<b>Skin</b>				
Cyst Epithelial Inclusion				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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
<b>Skin</b>				
<b>Ulcer</b>				
<b>LESION RATES</b>				
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	---	---
<b>STATISTICAL TESTS</b>				
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
<b>Spleen</b>				
<b>Hematopoietic Cell Proliferation</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	26/49 (53%)	24/48 (50%)	20/50 (40%)	10/49 (20%)
<b>POLY-3 RATE (b)</b>	26/46.54	24/45.26	20/49.04	10/45.99
<b>POLY-3 PERCENT (g)</b>	55.9%	53%	40.8%	21.7%
<b>TERMINAL (d)</b>	21/38 (55%)	18/34 (53%)	18/45 (40%)	4/37 (11%)
<b>FIRST INCIDENCE</b>	421	666	534	548
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P<0.001N**	P=0.475N	P=0.100N	P<0.001N**
<b>POLY 1.5</b>	P<0.001N**	P=0.469N	P=0.112N	P<0.001N**
<b>POLY 6</b>	P<0.001N**	P=0.484N	P=0.090N	P<0.001N**
<b>COCH-ARM / FISHERS</b>	P<0.001N**	P=0.461N	P=0.135N	P<0.001N**
<b>MAX-ISO-POLY-3</b>	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  
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
<b>Spleen</b>				
<b>Hyperplasia Lymphoid</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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  
 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
<b>Spleen: Lymphoid Follicle Atrophy</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Stomach, Forestomach Erosion</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Stomach, Forestomach Inflammation Chronic</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Stomach, Forestomach Necrosis</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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
<b>Stomach, Forestomach Ulcer</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Stomach, Forestomach: Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Stomach, Glandular Infiltration Cellular Mononuclear Cell</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Stomach, Glandular Ulcer</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Stomach, Glandular: Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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
<b>Stomach, Glandular: Glands Ectasia</b>				
<b>LESION RATES</b>				
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)	---
<b>STATISTICAL TESTS</b>				
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
<b>Thymus Atrophy</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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
<b>Thymus Hyperplasia</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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
<b>Thymus</b>				
<b>Infiltration Cellular Histiocyte</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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
<b>Thyroid Gland Cyst</b>				
<b>LESION RATES</b>				
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	---	---
<b>STATISTICAL TESTS</b>				
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
<b>Tooth Dysplasia</b>				
<b>LESION RATES</b>				
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)
<b>STATISTICAL TESTS</b>				
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**

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DOSE	Females			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
<b>Urethra Inflammation</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
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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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
<b>Urinary Bladder</b>				
<b>Infiltration Cellular Mononuclear Cell</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	34/50 (68%)	34/48 (71%)	40/50 (80%)	34/50 (68%)
<b>POLY-3 RATE (b)</b>	34/46.37	34/45.99	40/48.51	34/47.04
<b>POLY-3 PERCENT (g)</b>	73.3%	73.9%	82.5%	72.3%
<b>TERMINAL (d)</b>	29/38 (76%)	27/34 (79%)	38/45 (84%)	27/37 (73%)
<b>FIRST INCIDENCE</b>	523	669	554	576
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.536N	P=0.569	P=0.196	P=0.549N
<b>POLY 1.5</b>	P=0.526	P=0.534	P=0.167	P=0.578N
<b>POLY 6</b>	P=0.498N	P=0.599N	P=0.231	P=0.514N
<b>COCH-ARM / FISHERS</b>	P=0.524	P=0.466	P=0.127	P=0.585N
<b>MAX-ISO-POLY-3</b>	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
<b>Urinary Bladder Inflammation</b>				
<b>LESION RATES</b>				
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)	---	---
<b>STATISTICAL TESTS</b>				
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  
 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
<b>Uterus Inflammation</b>				
<b>LESION RATES</b>				
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)	---	---
<b>STATISTICAL TESTS</b>				
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  
 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
<b>Uterus</b>				
<b>Metaplasia</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
<b>POLY-3 RATE (b)</b>	1/44.80	2/46.04	0/47.88	0/45.33
<b>POLY-3 PERCENT (g)</b>	2.2%	4.3%	0%	0%
<b>TERMINAL (d)</b>	1/38 (3%)	2/34 (6%)	0/45 (0%)	0/37 (0%)
<b>FIRST INCIDENCE</b>	729 (T)	729 (T)	---	---
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.183N	P=0.510	P=0.487N	P=0.498N
<b>POLY 1.5</b>	P=0.185N	P=0.506	P=0.492N	P=0.499N
<b>POLY 6</b>	P=0.181N	P=0.511	P=0.481N	P=0.496N
<b>COCH-ARM / FISHERS</b>	P=0.188N	P=0.500	P=0.500N	P=0.500N
<b>MAX-ISO-POLY-3</b>	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**

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
<b>Uterus: Endometrium Hyperplasia Cystic</b>				
<b>LESION RATES</b>				
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
<b>STATISTICAL TESTS</b>				
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  
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  
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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 \*\*\*