

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
**CAS Number:** 9000-38-8

**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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## HISTORICAL CONTROL STUDIES

From November 2008 report

### SAME ROUTE

- 88105-04 -- Isoeugenol (GAVAGE CORN OIL)
- 99023-04 -- beta-Myrcene (GAVAGE CORN OIL)
- 99020-06 -- Pulegone (GAVAGE CORN OIL)
- 88148-07 -- 3,3',4,4'-Tetrachloroazobenzene (GAVAGE CORN OIL)

### ALL ROUTES

- 99024-08 -- Androstenedione (GAVAGE METHYLCELLULOSE)
- 88138-04 -- Benzophenone (ORAL FEED)
- 99028-06 -- bis(2-Chloroethoxy)methane (SKIN ETHANOL)
- 20011-06 -- 1-Bromopropane (INHALATION AIR)
- 99027-04 -- Chromium picolinate monohydrate (ORAL FEED)
- 05174-06 -- Cresols (ORAL FEED)
- 96011-06 -- Cumene (INHALATION AIR)
- 97003-08 -- 1,2-Dibromo-2,4-dicyanobutane (SKIN ETHANOL)
- 99017-06 -- Diethylamine (INHALATION AIR)
- 93020-08 -- Diisopropylcarbodiimide (SKIN ETHANOL)
- 88004-06 -- Divinylbenzene (INHALATION AIR)
- 88123-07 -- Formamide (GAVAGE WATER)
- 20005-06 -- Ginseng (GAVAGE WATER)
- 99007-06 -- Goldenseal root powder (ORAL FEED)
- 95011-06 -- 5-(Hydroxymethyl)-2-furfural (GAVAGE WATER)
- 88105-04 -- Isoeugenol (GAVAGE CORN OIL)
- 97006-02 -- Methyl isobutyl ketone (INHALATION AIR)
- 91005-08 -- Methylene blue trihydrate (GAVAGE METHYLCELLULOSE)
- 92013-06 -- 4-Methylimidazole (ORAL FEED)
- 88006-04 -- alpha-Methylstyrene (INHALATION AIR)
- 20008-04 -- Milk thistle extract (ORAL FEED)
- 99023-04 -- beta-Myrcene (GAVAGE CORN OIL)
- 97008-06 -- Propargyl alcohol (INHALATION AIR)

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**HISTORICAL CONTROL STUDIES**  
**From November 2008 report**

99020-06 -- Pulegone (GAVAGE CORN OIL)  
20114-06 -- Sodium dichromate dihydrate (VI) (ORAL WATER)  
88148-07 -- 3,3',4,4'-Tetrachloroazobenzene (GAVAGE CORN OIL)  
93025-06 -- Tetralin (INHALATION AIR)  
96019-06 -- Water disinfection byproducts (Bromochloroacetic acid) (ORAL WATER)  
96017-06 -- Water disinfection byproducts (Dibromoacetic acid) (ORAL WATER)  
96015-06 -- Water disinfection byproducts (Dibromoacetonitrile) (ORAL WATER)

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**FOR ALL DOSES THE TUMOR RATES IN THE FOLLOWING TISSUES/ORGANS ARE BASED ON NUMBER OF TISSUES EXAMINED.  
IN OTHER TISSUES/ORGANS RATES ARE BASED ON THE NUMBER OF ANIMALS NECROPSIED.**

Adrenal Cortex  
Adrenal Medulla  
Bone Marrow  
Heart  
Islets, Pancreatic  
Kidney  
Liver  
Lung  
Ovary  
Pituitary Gland  
Spleen  
Testes  
Thyroid Gland

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

**MALE MICE**

**Organ**

Bone Marrow  
Intestine Small: Site Unspecified  
Liver

Stomach, Forestomach

Thyroid Gland: Follicular Cell  
All Organs

**Morphology**

Hemangiosarcoma  
Carcinoma or Adenoma  
Hemangiosarcoma  
Hepatoblastoma  
Hepatocellular Carcinoma or Hepatoblastoma  
Hepatocholangiocarcinoma  
Squamous Cell Carcinoma or Papilloma Squamous  
Squamous Cell Papilloma  
Adenoma  
Hemangiosarcoma  
Hemangiosarcoma or Hemangioma

**FEMALE MICE**

**Organ**

Intestine Small: Site Unspecified

Liver

Ovary  
Skeletal Muscle  
Stomach, Forestomach

All Organs

**Morphology**

Adenoma  
Carcinoma or Adenoma  
Hepatocellular Carcinoma  
Hepatocellular Carcinoma or Hepatoblastoma  
Hepatocellular Carcinoma or Hepatocellular Adenoma  
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma  
Hemangioma  
Rhabdomyosarcoma  
Squamous Cell Carcinoma or Papilloma Squamous  
Squamous Cell Papilloma  
Hemangioma  
Hemangiosarcoma or Hemangioma  
Histiocytic Sarcoma  
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type  
Malignant and Benign Tumors

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Medulla</b>				
<b>Pheochromocytoma Benign</b>				
<b>TUMOR 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	2/44.99	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	---	---	616	---
HC TUMORS SAME ROUTE	1/200 (1%)			
HC TUMORS ALL ROUTES	7/1432 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.607	(e)	P=0.245	(e)
POLY 1.5	P=0.602	(e)	P=0.242	(e)
POLY 6	P=0.613	(e)	P=0.248	(e)
COCH-ARM / FISHERS	P=0.595	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.261	(e)	P=0.083	(e)
HISTCONT SAME RTE	P=0.322	(e)	P=0.085	(e)
HISTCONT ALL RTEs	P=0.302	(e)	P=0.017*	(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>Bone Marrow</b>				
<b>Hemangiosarcoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/43.72	0/42.37	0/44.59	0/44.23
POLY-3 PERCENT (g)	4.6%	0%	0%	0%
TERMINAL (d)	1/34 (3%)	0/33 (0%)	0/34 (0%)	0/36 (0%)
FIRST INCIDENCE	668	---	---	---
HC TUMORS SAME ROUTE	0/200 (0%)			
HC TUMORS ALL ROUTES	11/1441 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.110N	P=0.244N	P=0.233N	P=0.234N
POLY 1.5	P=0.111N	P=0.242N	P=0.234N	P=0.236N
POLY 6	P=0.111N	P=0.244N	P=0.231N	P=0.232N
COCH-ARM / FISHERS	P=0.115N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.032N*	P=0.082N	P=0.076N	P=0.076N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>Bone</b>				
<b>Osteosarcoma</b>				
<b>TUMOR 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	---	---	---	---
HC TUMORS SAME ROUTE	0/200 (0%)			
HC TUMORS ALL ROUTES	3/1449 (0%)			
<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)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)



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**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	5/50 (10%)	5/50 (10%)	3/50 (6%)	6/50 (12%)
POLY-3 RATE (b)	5/43.72	5/43.72	3/44.59	6/45.95
POLY-3 PERCENT (g)	11.4%	11.4%	6.7%	13.1%
TERMINAL (d)	4/34 (12%)	3/33 (9%)	3/34 (9%)	2/36 (6%)
FIRST INCIDENCE	668	437	730 (T)	547
HC TUMORS SAME ROUTE	29/200 (15%)			
HC TUMORS ALL ROUTES	188/1449 (13%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.484	P=0.631	P=0.345N	P=0.535
POLY 1.5	P=0.471	P=0.627	P=0.349N	P=0.519
POLY 6	P=0.502	P=0.623N	P=0.342N	P=0.558
COCH-ARM / FISHERS	P=0.451	P=0.630N	P=0.357N	P=0.500
MAX-ISO-POLY-3	P=0.503	P=0.499	P=0.224N	P=0.408
HISTCONT SAME RTE	P=0.613	P=0.643	P=1.000	P=0.537
HISTCONT ALL RTEs	P=0.588	P=0.630	P=1.000	P=0.518

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	5/50 (10%)	6/50 (12%)	4/50 (8%)	7/50 (14%)
POLY-3 RATE (b)	5/43.72	6/44.53	4/44.59	7/45.95
POLY-3 PERCENT (g)	11.4%	13.5%	9%	15.2%
TERMINAL (d)	4/34 (12%)	3/33 (9%)	4/34 (12%)	3/36 (8%)
FIRST INCIDENCE	668	423	730 (T)	547
HC TUMORS SAME ROUTE	34/200 (17%)			
HC TUMORS ALL ROUTES	229/1449 (16%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.382	P=0.513	P=0.488N	P=0.414
POLY 1.5	P=0.369	P=0.505	P=0.492N	P=0.399
POLY 6	P=0.401	P=0.526	P=0.485N	P=0.438
COCH-ARM / FISHERS	P=0.351	P=0.500	P=0.500N	P=0.380
MAX-ISO-POLY-3	P=0.465	P=0.386	P=0.352N	P=0.304
HISTCONT SAME RTE	P=0.569	P=0.509	P=1.000	P=0.402
HISTCONT ALL RTEs	P=0.544	P=0.490	P=1.000	P=0.380

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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: Site Unspecified Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/43.49	1/42.51	0/44.59	1/44.23
POLY-3 PERCENT (g)	4.6%	2.4%	0%	2.3%
TERMINAL (d)	2/34 (6%)	0/33 (0%)	0/34 (0%)	1/36 (3%)
FIRST INCIDENCE	730 (T)	695	---	730 (T)
HC TUMORS SAME ROUTE	0/200 (0%)			
HC TUMORS ALL ROUTES	9/1449 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.361N	P=0.508N	P=0.231N	P=0.494N
POLY 1.5	P=0.363N	P=0.507N	P=0.234N	P=0.497N
POLY 6	P=0.361N	P=0.505N	P=0.229N	P=0.489N
COCH-ARM / FISHERS	P=0.366N	P=0.500N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.227N	P=0.289N	P=0.076N	P=0.277N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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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>Intestine Small: Site Unspecified Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	3/50 (6%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	3/43.49	1/42.51	0/44.59	1/44.23
POLY-3 PERCENT (g)	6.9%	2.4%	0%	2.3%
TERMINAL (d)	3/34 (9%)	0/33 (0%)	0/34 (0%)	1/36 (3%)
FIRST INCIDENCE	730 (T)	695	---	730 (T)
HC TUMORS SAME ROUTE	2/200 (1%)			
HC TUMORS ALL ROUTES	33/1449 (2%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.194N	P=0.313N	P=0.114N	P=0.299N
POLY 1.5	P=0.196N	P=0.312N	P=0.116N	P=0.302N
POLY 6	P=0.194N	P=0.309N	P=0.112N	P=0.294N
COCH-ARM / FISHERS	P=0.200N	P=0.309N	P=0.121N	P=0.309N
MAX-ISO-POLY-3	P=0.083N	P=0.162N	P=0.038N*	P=0.151N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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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>Kidney: Renal Tubule Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	1/50 (2%)	3/50 (6%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.49	3/42.37	0/44.59	0/44.23
POLY-3 PERCENT (g)	2.3%	7.1%	0%	0%
TERMINAL (d)	1/34 (3%)	3/33 (9%)	0/34 (0%)	0/36 (0%)
FIRST INCIDENCE	730 (T)	730 (T)	---	---
HC TUMORS SAME ROUTE	2/200 (1%)			
HC TUMORS ALL ROUTES	10/1443 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.149N	P=0.296	P=0.495N	P=0.497N
POLY 1.5	P=0.150N	P=0.298	P=0.497N	P=0.498N
POLY 6	P=0.146N	P=0.297	P=0.493N	P=0.494N
COCH-ARM / FISHERS	P=0.153N	P=0.309	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.113N	P=0.150	P=0.158N	P=0.158N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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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>Liver</b>				
<b>Hemangiosarcoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	5/50 (10%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	5/44.48	0/42.37	0/44.59	1/44.97
POLY-3 PERCENT (g)	11.2%	0%	0%	2.2%
TERMINAL (d)	2/34 (6%)	0/33 (0%)	0/34 (0%)	0/36 (0%)
FIRST INCIDENCE	513	---	---	465
HC TUMORS SAME ROUTE	7/200 (4%)			
HC TUMORS ALL ROUTES	38/1447 (3%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.053N	P=0.035N*	P=0.030N*	P=0.098N
POLY 1.5	P=0.055N	P=0.033N*	P=0.030N*	P=0.100N
POLY 6	P=0.052N	P=0.035N*	P=0.030N*	P=0.097N
COCH-ARM / FISHERS	P=0.062N	P=0.028N*	P=0.028N*	P=0.102N
MAX-ISO-POLY-3	P=0.004N**	P=0.013N*	P=0.010N**	P=0.044N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>Hepatoblastoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/50 (0%)	4/50 (8%)	9/50 (18%)	12/50 (24%)
POLY-3 RATE (b)	0/43.49	4/42.67	9/44.79	12/45.48
POLY-3 PERCENT (g)	0%	9.4%	20.1%	26.4%
TERMINAL (d)	0/34 (0%)	2/33 (6%)	8/34 (24%)	8/36 (22%)
FIRST INCIDENCE	---	687	679	582
HC TUMORS SAME ROUTE	10/200 (5%)			
HC TUMORS ALL ROUTES	48/1447 (3%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.057	P=0.002**	P<0.001**
POLY 1.5	P<0.001**	P=0.058	P=0.002**	P<0.001**
POLY 6	P<0.001**	P=0.059	P=0.002**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.059	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.019*	P<0.001**	P<0.001**
HISTCONT SAME RTE	P<0.001**	P=0.021*	P<0.001**	P<0.001**
HISTCONT ALL RTEs	P<0.001**	P=0.019*	P<0.001**	P<0.001**

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>Hepatocellular Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	27/50 (54%)	32/50 (64%)	29/50 (58%)	35/50 (70%)
POLY-3 RATE (b)	27/45.40	32/46.53	29/46.50	35/46.67
POLY-3 PERCENT (g)	59.5%	68.8%	62.4%	75%
TERMINAL (d)	22/34 (65%)	23/33 (70%)	22/34 (65%)	27/36 (75%)
FIRST INCIDENCE	570	431	580	574
HC TUMORS SAME ROUTE	94/200 (47%)			
HC TUMORS ALL ROUTES	733/1447 (51%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.092	P=0.231	P=0.471	P=0.077
POLY 1.5	P=0.089	P=0.216	P=0.452	P=0.073
POLY 6	P=0.103	P=0.262	P=0.494	P=0.091
COCH-ARM / FISHERS	P=0.088	P=0.208	P=0.420	P=0.074
MAX-ISO-POLY-3	P=0.084	P=0.173	P=0.385	P=0.051
HISTCONT SAME RTE	P=0.020*	P=0.073	P=0.132	P=0.052
HISTCONT ALL RTEs	P=0.080	P=0.205	P=0.421	P=0.055



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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>Hepatocellular Carcinoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	20/50 (40%)	18/50 (36%)	26/50 (52%)	20/50 (40%)
POLY-3 RATE (b)	20/46.84	18/44.71	26/48.61	20/45.72
POLY-3 PERCENT (g)	42.7%	40.3%	53.5%	43.8%
TERMINAL (d)	11/34 (32%)	12/33 (36%)	15/34 (44%)	14/36 (39%)
FIRST INCIDENCE	455	431	455	574
HC TUMORS SAME ROUTE	52/200 (26%)			
HC TUMORS ALL ROUTES	415/1447 (29%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.409	P=0.490N	P=0.196	P=0.543
POLY 1.5	P=0.416	P=0.465N	P=0.181	P=0.558
POLY 6	P=0.405	P=0.515N	P=0.215	P=0.530
COCH-ARM / FISHERS	P=0.423	P=0.418N	P=0.158	P=0.581N
MAX-ISO-POLY-3	P=0.392	P=0.406N	P=0.148	P=0.459
HISTCONT SAME RTE	P=0.071	P=0.239	P=0.077	P=0.171
HISTCONT ALL RTEs	P=0.017*	P=0.280	P=0.044*	P=0.186

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>Hepatocellular Carcinoma or Hepatoblastoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	20/50 (40%)	21/50 (42%)	30/50 (60%)	25/50 (50%)
POLY-3 RATE (b)	20/46.84	21/44.87	30/48.61	25/46.92
POLY-3 PERCENT (g)	42.7%	46.8%	61.7%	53.3%
TERMINAL (d)	11/34 (32%)	14/33 (42%)	19/34 (56%)	16/36 (44%)
FIRST INCIDENCE	455	431	455	574
HC TUMORS SAME ROUTE	59/200 (30%)			
HC TUMORS ALL ROUTES	446/1447 (31%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.136	P=0.426	P=0.046*	P=0.205
POLY 1.5	P=0.130	P=0.451	P=0.041*	P=0.205
POLY 6	P=0.151	P=0.405	P=0.052	P=0.213
COCH-ARM / FISHERS	P=0.125	P=0.500	P=0.036*	P=0.211
MAX-ISO-POLY-3	P=0.112	P=0.348	P=0.031*	P=0.150
HISTCONT SAME RTE	P=0.036*	P=0.151	P=0.036*	P=0.087
HISTCONT ALL RTEs	P=0.003**	P=0.197	P=0.026*	P=0.086

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
Kava kava extract  
CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>Hepatocellular Carcinoma or Hepatocellular Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	38/50 (76%)	39/50 (78%)	38/50 (76%)	40/50 (80%)
POLY-3 RATE (b)	38/48.23	39/47.18	38/48.90	40/46.67
POLY-3 PERCENT (g)	78.8%	82.7%	77.7%	85.7%
TERMINAL (d)	26/34 (77%)	28/33 (85%)	25/34 (74%)	32/36 (89%)
FIRST INCIDENCE	455	431	455	574
HC TUMORS SAME ROUTE	124/200 (62%)			
HC TUMORS ALL ROUTES	961/1447 (66%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.266	P=0.410	P=0.548N	P=0.261
POLY 1.5	P=0.311	P=0.441	P=0.561N	P=0.317
POLY 6	P=0.223	P=0.380	P=0.537N	P=0.208
COCH-ARM / FISHERS	P=0.376	P=0.500	P=0.592N	P=0.405
MAX-ISO-POLY-3	P=0.307	P=0.313	P=0.448N	P=0.182
HISTCONT SAME RTE	P=0.037*	P=0.115	P=0.176	P=0.092
HISTCONT ALL RTEs	P=0.085	P=0.256	P=0.366	P=0.201

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	38/50 (76%)	39/50 (78%)	40/50 (80%)	42/50 (84%)
POLY-3 RATE (b)	38/48.23	39/47.18	40/48.90	42/47.38
POLY-3 PERCENT (g)	78.8%	82.7%	81.8%	88.7%
TERMINAL (d)	26/34 (77%)	28/33 (85%)	27/34 (79%)	32/36 (89%)
FIRST INCIDENCE	455	431	455	574
HC TUMORS SAME ROUTE	127/200 (64%)			
HC TUMORS ALL ROUTES	972/1447 (67%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.125	P=0.410	P=0.452	P=0.142
POLY 1.5	P=0.143	P=0.441	P=0.438	P=0.169
POLY 6	P=0.114	P=0.380	P=0.464	P=0.126
COCH-ARM / FISHERS	P=0.179	P=0.500	P=0.405	P=0.227
MAX-ISO-POLY-3	P=0.149	P=0.313	P=0.351	P=0.089
HISTCONT SAME RTE	P=0.021*	P=0.116	P=0.118	P=0.074
HISTCONT ALL RTEs	P=0.054	P=0.280	P=0.288	P=0.101

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 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 PRIMARY TUMORS 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>Hepatocholangiocarcinoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	4/50 (8%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	4/44.38	0/42.37	0/44.59	1/44.23
POLY-3 PERCENT (g)	9%	0%	0%	2.3%
TERMINAL (d)	1/34 (3%)	0/33 (0%)	0/34 (0%)	1/36 (3%)
FIRST INCIDENCE	587	---	---	730 (T)
HC TUMORS SAME ROUTE	3/200 (2%)			
HC TUMORS ALL ROUTES	12/1447 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.116N	P=0.066N	P=0.059N	P=0.179N
POLY 1.5	P=0.118N	P=0.064N	P=0.060N	P=0.179N
POLY 6	P=0.115N	P=0.067N	P=0.060N	P=0.179N
COCH-ARM / FISHERS	P=0.125N	P=0.059N	P=0.059N	P=0.181N
MAX-ISO-POLY-3	P=0.013N*	P=0.024N*	P=0.019N*	P=0.084N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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</b>				
<b>Alveolar/Bronchiolar Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	9/50 (18%)	7/50 (14%)	8/50 (16%)	9/50 (18%)
POLY-3 RATE (b)	9/44.31	7/42.37	8/45.84	9/44.74
POLY-3 PERCENT (g)	20.3%	16.5%	17.5%	20.1%
TERMINAL (d)	7/34 (21%)	7/33 (21%)	4/34 (12%)	8/36 (22%)
FIRST INCIDENCE	570	730 (T)	455	574
HC TUMORS SAME ROUTE	25/200 (13%)			
HC TUMORS ALL ROUTES	238/1448 (16%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.515	P=0.430N	P=0.469N	P=0.595N
POLY 1.5	P=0.506	P=0.419N	P=0.480N	P=0.598N
POLY 6	P=0.527	P=0.435N	P=0.458N	P=0.588N
COCH-ARM / FISHERS	P=0.487	P=0.393N	P=0.500N	P=0.602N
MAX-ISO-POLY-3	P=0.613N	P=0.328N	P=0.366N	P=0.490N
HISTCONT SAME RTE	P=0.113	P=0.415	P=0.320	P=0.180
HISTCONT ALL RTEs	P=0.738	P=1.000	P=1.000	P=0.523

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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</b>				
<b>Alveolar/Bronchiolar Carcinoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	2/50 (4%)	6/50 (12%)	6/50 (12%)	1/50 (2%)
POLY-3 RATE (b)	2/43.67	6/43.99	6/44.59	1/44.23
POLY-3 PERCENT (g)	4.6%	13.6%	13.5%	2.3%
TERMINAL (d)	1/34 (3%)	3/33 (9%)	6/34 (18%)	1/36 (3%)
FIRST INCIDENCE	683	319	730 (T)	730 (T)
HC TUMORS SAME ROUTE	13/200 (7%)			
HC TUMORS ALL ROUTES	163/1448 (11%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.266N	P=0.134	P=0.139	P=0.496N
POLY 1.5	P=0.270N	P=0.133	P=0.137	P=0.498N
POLY 6	P=0.259N	P=0.139	P=0.140	P=0.492N
COCH-ARM / FISHERS	P=0.278N	P=0.134	P=0.134	P=0.500N
MAX-ISO-POLY-3	P=0.127N	P=0.070	P=0.074	P=0.278N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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</b>				
<b>Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	11/50 (22%)	13/50 (26%)	13/50 (26%)	10/50 (20%)
POLY-3 RATE (b)	11/44.49	13/43.99	13/45.84	10/44.74
POLY-3 PERCENT (g)	24.7%	29.6%	28.4%	22.4%
TERMINAL (d)	8/34 (24%)	10/33 (30%)	9/34 (27%)	9/36 (25%)
FIRST INCIDENCE	570	319	455	574
HC TUMORS SAME ROUTE	36/200 (18%)			
HC TUMORS ALL ROUTES	384/1448 (27%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.384N	P=0.393	P=0.439	P=0.494N
POLY 1.5	P=0.389N	P=0.397	P=0.429	P=0.497N
POLY 6	P=0.377N	P=0.395	P=0.448	P=0.490N
COCH-ARM / FISHERS	P=0.400N	P=0.408	P=0.408	P=0.500N
MAX-ISO-POLY-3	P=0.464N	P=0.305	P=0.349	P=0.394N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)



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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 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 PRIMARY TUMORS 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 or Unspecified Site Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/49 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/42.97	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	---
HC TUMORS SAME ROUTE	0/198 (0%)			
HC TUMORS ALL ROUTES	6/1417 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.702	(e)	P=0.510	(e)
POLY 1.5	P=0.700	(e)	P=0.508	(e)
POLY 6	P=0.705	(e)	P=0.512	(e)
COCH-ARM / FISHERS	P=0.697	(e)	P=0.505	(e)
MAX-ISO-POLY-3	P=0.399	(e)	P=0.170	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>Skeletal Muscle</b>				
<b>Rhabdomyosarcoma</b>				
<b>TUMOR 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	---	---	---	---
HC TUMORS SAME ROUTE	1/200 (1%)			
HC TUMORS ALL ROUTES	2/1449 (0%)			
<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)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>Hemangiosarcoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	2/50 (4%)	1/50 (2%)	2/49 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/44.14	1/42.95	2/44.43	0/44.23
POLY-3 PERCENT (g)	4.5%	2.3%	4.5%	0%
TERMINAL (d)	1/34 (3%)	0/33 (0%)	0/34 (0%)	0/36 (0%)
FIRST INCIDENCE	513	546	668	---
HC TUMORS SAME ROUTE	5/199 (3%)			
HC TUMORS ALL ROUTES	36/1437 (3%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.197N	P=0.510N	P=0.692N	P=0.237N
POLY 1.5	P=0.199N	P=0.508N	P=0.692	P=0.237N
POLY 6	P=0.196N	P=0.507N	P=0.686N	P=0.235N
COCH-ARM / FISHERS	P=0.201N	P=0.500N	P=0.684	P=0.247N
MAX-ISO-POLY-3	P=0.160N	P=0.291N	P=0.496N	P=0.076N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Squamous Cell Carcinoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.49	0/42.37	0/44.59	0/44.23
POLY-3 PERCENT (g)	2.3%	0%	0%	0%
TERMINAL (d)	1/34 (3%)	0/33 (0%)	0/34 (0%)	0/36 (0%)
FIRST INCIDENCE	730 (T)	---	---	---
HC TUMORS SAME ROUTE	1/200 (1%)			
HC TUMORS ALL ROUTES	6/1449 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.304N	P=0.505N	P=0.495N	P=0.497N
POLY 1.5	P=0.304N	P=0.504N	P=0.497N	P=0.498N
POLY 6	P=0.305N	P=0.504N	P=0.493N	P=0.494N
COCH-ARM / FISHERS	P=0.306N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.124N	P=0.165N	P=0.158N	P=0.158N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Squamous Cell Carcinoma or Papilloma Squamous</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	9/50 (18%)	3/50 (6%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	9/44.54	3/42.37	0/44.59	2/44.23
POLY-3 PERCENT (g)	20.2%	7.1%	0%	4.5%
TERMINAL (d)	5/34 (15%)	3/33 (9%)	0/34 (0%)	2/36 (6%)
FIRST INCIDENCE	648	730 (T)	---	730 (T)
HC TUMORS SAME ROUTE	2/200 (1%)			
HC TUMORS ALL ROUTES	19/1449 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.007N**	P=0.070N	P=0.002N**	P=0.025N*
POLY 1.5	P=0.007N**	P=0.067N	P=0.002N**	P=0.025N*
POLY 6	P=0.007N**	P=0.073N	P=0.002N**	P=0.025N*
COCH-ARM / FISHERS	P=0.010N**	P=0.061N	P<0.001N**	P=0.026N*
MAX-ISO-POLY-3	P<0.001N**	P=0.040N*	P<0.001N**	P=0.011N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Squamous Cell Papilloma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	8/50 (16%)	3/50 (6%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	8/44.54	3/42.37	0/44.59	2/44.23
POLY-3 PERCENT (g)	18%	7.1%	0%	4.5%
TERMINAL (d)	4/34 (12%)	3/33 (9%)	0/34 (0%)	2/36 (6%)
FIRST INCIDENCE	648	730 (T)	---	730 (T)
HC TUMORS SAME ROUTE	1/200 (1%)			
HC TUMORS ALL ROUTES	14/1449 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.015N*	P=0.113N	P=0.003N**	P=0.045N*
POLY 1.5	P=0.015N*	P=0.109N	P=0.004N**	P=0.045N*
POLY 6	P=0.015N*	P=0.117N	P=0.004N**	P=0.046N*
COCH-ARM / FISHERS	P=0.019N*	P=0.100N	P=0.003N**	P=0.046N*
MAX-ISO-POLY-3	P=0.003N**	P=0.067N	P<0.001N**	P=0.022N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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: Follicular Cell Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/43.49	0/42.37	0/43.59	2/44.80
POLY-3 PERCENT (g)	0%	0%	0%	4.5%
TERMINAL (d)	0/34 (0%)	0/33 (0%)	0/33 (0%)	1/36 (3%)
FIRST INCIDENCE	---	---	---	547
HC TUMORS SAME ROUTE	0/200 (0%)			
HC TUMORS ALL ROUTES	19/1441 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.048*	(e)	(e)	P=0.244
POLY 1.5	P=0.047*	(e)	(e)	P=0.241
POLY 6	P=0.049*	(e)	(e)	P=0.248
COCH-ARM / FISHERS	P=0.047*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.038*	(e)	(e)	P=0.082
HISTCONT SAME RTE	P=0.038*	(e)	(e)	P=0.047*
HISTCONT ALL RTEs	P=0.043*	(e)	(e)	P=0.093

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>All Organs</b>				
<b>Hemangioma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/43.49	1/42.37	0/44.59	0/44.23
POLY-3 PERCENT (g)	4.6%	2.4%	0%	0%
TERMINAL (d)	2/34 (6%)	1/33 (3%)	0/34 (0%)	0/36 (0%)
FIRST INCIDENCE	730 (T)	730 (T)	---	---
HC TUMORS SAME ROUTE	0/200 (0%)			
HC TUMORS ALL ROUTES	14/1449 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.098N	P=0.509N	P=0.231N	P=0.233N
POLY 1.5	P=0.099N	P=0.507N	P=0.234N	P=0.235N
POLY 6	P=0.098N	P=0.507N	P=0.229N	P=0.230N
COCH-ARM / FISHERS	P=0.101N	P=0.500N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.077N	P=0.291N	P=0.076N	P=0.076N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)



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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>All Organs</b>				
<b>Hemangiosarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	6/50 (12%)	2/50 (4%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	6/44.48	2/43.41	4/45.43	1/44.97
POLY-3 PERCENT (g)	13.5%	4.6%	8.8%	2.2%
TERMINAL (d)	3/34 (9%)	0/33 (0%)	1/34 (3%)	0/36 (0%)
FIRST INCIDENCE	513	546	623	465
HC TUMORS SAME ROUTE	16/200 (8%)			
HC TUMORS ALL ROUTES	98/1449 (7%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.060N	P=0.140N	P=0.356N	P=0.054N
POLY 1.5	P=0.062N	P=0.139N	P=0.361N	P=0.055N
POLY 6	P=0.059N	P=0.137N	P=0.349N	P=0.052N
COCH-ARM / FISHERS	P=0.066N	P=0.134N	P=0.370N	P=0.056N
MAX-ISO-POLY-3	P=0.030N*	P=0.075N	P=0.244N	P=0.023N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>All Organs</b>				
<b>Hemangiosarcoma or Hemangioma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	8/50 (16%)	3/50 (6%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	8/44.48	3/43.41	4/45.43	1/44.97
POLY-3 PERCENT (g)	18%	6.9%	8.8%	2.2%
TERMINAL (d)	5/34 (15%)	1/33 (3%)	1/34 (3%)	0/36 (0%)
FIRST INCIDENCE	513	546	623	465
HC TUMORS SAME ROUTE	16/200 (8%)			
HC TUMORS ALL ROUTES	110/1449 (8%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.014N*	P=0.105N	P=0.165N	P=0.015N*
POLY 1.5	P=0.015N*	P=0.104N	P=0.170N	P=0.015N*
POLY 6	P=0.014N*	P=0.102N	P=0.159N	P=0.014N*
COCH-ARM / FISHERS	P=0.017N*	P=0.100N	P=0.178N	P=0.015N*
MAX-ISO-POLY-3	P=0.006N**	P=0.059N	P=0.102N	P=0.006N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>All Organs</b>				
<b>Histiocytic Sarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/43.49	1/42.46	1/44.59	1/44.68
POLY-3 PERCENT (g)	0%	2.4%	2.2%	2.2%
TERMINAL (d)	0/34 (0%)	0/33 (0%)	1/34 (3%)	0/36 (0%)
FIRST INCIDENCE	---	707	730 (T)	595
HC TUMORS SAME ROUTE	0/200 (0%)			
HC TUMORS ALL ROUTES	8/1449 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.397	P=0.495	P=0.505	P=0.505
POLY 1.5	P=0.392	P=0.496	P=0.503	P=0.503
POLY 6	P=0.405	P=0.497	P=0.507	P=0.510
COCH-ARM / FISHERS	P=0.384	P=0.500	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.338	P=0.158	P=0.165	P=0.165
HISTCONT SAME RTE	P=0.122	P=0.054	P=0.049*	P=0.049*
HISTCONT ALL RTEs	P=0.075	P=0.150	P=0.154	P=0.154

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>All Organs</b>				
<b>Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	2/50 (4%)	3/50 (6%)	1/50 (2%)	6/50 (12%)
POLY-3 RATE (b)	2/43.49	3/42.37	1/44.59	6/44.83
POLY-3 PERCENT (g)	4.6%	7.1%	2.2%	13.4%
TERMINAL (d)	2/34 (6%)	3/33 (9%)	1/34 (3%)	4/36 (11%)
FIRST INCIDENCE	730 (T)	730 (T)	730 (T)	596
HC TUMORS SAME ROUTE	3/200 (2%)			
HC TUMORS ALL ROUTES	49/1449 (3%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.085	P=0.488	P=0.491N	P=0.142
POLY 1.5	P=0.082	P=0.490	P=0.494N	P=0.138
POLY 6	P=0.088	P=0.491	P=0.488N	P=0.150
COCH-ARM / FISHERS	P=0.079	P=0.500	P=0.500N	P=0.134
MAX-ISO-POLY-3	P=0.081	P=0.315	P=0.275N	P=0.077
HISTCONT SAME RTE	P=0.027*	P=0.082	P=0.520	P=0.044*
HISTCONT ALL RTEs	P=0.013*	P=0.266	P=1.000	P=0.020*

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>All Organs</b>				
<b>Osteosarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.36	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	369	---	---	---
HC TUMORS SAME ROUTE	0/200 (0%)			
HC TUMORS ALL ROUTES	3/1449 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.301N	P=0.509N	P=0.499N	P=0.501N
POLY 1.5	P=0.302N	P=0.507N	P=0.500N	P=0.501N
POLY 6	P=0.302N	P=0.509N	P=0.498N	P=0.499N
COCH-ARM / FISHERS	P=0.306N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.125N	P=0.170N	P=0.158N	P=0.159N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>All Organs</b>				
<b>Osteosarcoma or Osteoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.36	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	369	---	---	---
HC TUMORS SAME ROUTE	0/200 (0%)			
HC TUMORS ALL ROUTES	3/1449 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.301N	P=0.509N	P=0.499N	P=0.501N
POLY 1.5	P=0.302N	P=0.507N	P=0.500N	P=0.501N
POLY 6	P=0.302N	P=0.509N	P=0.498N	P=0.499N
COCH-ARM / FISHERS	P=0.306N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.125N	P=0.170N	P=0.158N	P=0.159N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>All Organs</b>				
<b>Benign Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
<b>OVERALL (a)</b>	34/50 (68%)	38/50 (76%)	35/50 (70%)	37/50 (74%)
<b>POLY-3 RATE (b)</b>	34/45.94	38/46.53	35/48.35	37/47.25
<b>POLY-3 PERCENT (g)</b>	74%	81.7%	72.4%	78.3%
<b>TERMINAL (d)</b>	27/34 (79%)	29/33 (88%)	24/34 (71%)	28/36 (78%)
<b>FIRST INCIDENCE</b>	570	431	455	547
<b>HC TUMORS SAME ROUTE</b>	126/200 (63%)			
<b>HC TUMORS ALL ROUTES</b>	971/1449 (67%)			
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.471	P=0.251	P=0.522N	P=0.400
<b>POLY 1.5</b>	P=0.430	P=0.244	P=0.578N	P=0.366
<b>POLY 6</b>	P=0.531	P=0.264	P=0.465N	P=0.454
<b>COCH-ARM / FISHERS</b>	P=0.375	P=0.252	P=0.500	P=0.330
<b>MAX-ISO-POLY-3</b>	P=0.493	P=0.176	P=0.427N	P=0.308
<b>HISTCONT SAME RTE</b>	P=0.123	P=0.086	P=0.300	P=0.120
<b>HISTCONT ALL RTEs</b>	P=0.400	P=0.211	P=0.569	P=0.385

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>All Organs</b>				
<b>Malignant Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	32/50 (64%)	27/50 (54%)	36/50 (72%)	32/50 (64%)
POLY-3 RATE (b)	32/48.61	27/47.63	36/48.84	32/48.58
POLY-3 PERCENT (g)	65.8%	56.7%	73.7%	65.9%
TERMINAL (d)	19/34 (56%)	16/33 (49%)	24/34 (71%)	20/36 (56%)
FIRST INCIDENCE	369	319	455	465
HC TUMORS SAME ROUTE	97/200 (49%)			
HC TUMORS ALL ROUTES	759/1449 (52%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.369	P=0.236N	P=0.264	P=0.583
POLY 1.5	P=0.356	P=0.225N	P=0.261	P=0.576
POLY 6	P=0.400	P=0.251N	P=0.269	P=0.567N
COCH-ARM / FISHERS	P=0.355	P=0.208N	P=0.260	P=0.582N
MAX-ISO-POLY-3	P=0.299	P=0.179N	P=0.197	P=0.498
HISTCONT SAME RTE	P=0.106	P=0.446	P=0.128	P=0.223
HISTCONT ALL RTEs	P=0.077	P=0.537	P=0.115	P=0.259



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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>All Organs</b>				
<b>Malignant and Benign Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	47/50 (94%)	46/50 (92%)	47/50 (94%)	47/50 (94%)
POLY-3 RATE (b)	47/50.00	46/49.36	47/50.00	47/49.16
POLY-3 PERCENT (g)	94%	93.2%	94%	95.6%
TERMINAL (d)	31/34 (91%)	32/33 (97%)	31/34 (91%)	34/36 (94%)
FIRST INCIDENCE	369	319	455	465
HC TUMORS SAME ROUTE	165/200 (83%)			
HC TUMORS ALL ROUTES	1251/1449 (86%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.410	P=0.600N	P=0.662	P=0.536
POLY 1.5	P=0.436	P=0.551N	P=0.662	P=0.576
POLY 6	P=0.413	P=0.661	P=0.662	P=0.513
COCH-ARM / FISHERS	P=0.519	P=0.500N	P=0.661N	P=0.661N
MAX-ISO-POLY-3	P=0.528	P=0.431N	P=1.000	P=0.358
HISTCONT SAME RTE	P=0.064	P=0.200	P=0.177	P=0.147
HISTCONT ALL RTEs	P=0.149	P=0.364	P=0.328	P=0.272

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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</b>				
<b>Pheochromocytoma Benign</b>				
<b>TUMOR 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)
HC TUMORS SAME ROUTE	1/196 (1%)			
HC TUMORS ALL ROUTES	15/1488 (1%)			
<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=0.260	P=0.165	(e)	P=0.162
HISTCONT SAME RTE	P=0.310	P=0.201	(e)	P=0.200
HISTCONT ALL RTEs	P=0.300	P=0.197	(e)	P=0.192

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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</b>				
<b>Hemangiosarcoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.80	2/46.06	0/47.88	0/45.33
POLY-3 PERCENT (g)	0%	4.3%	0%	0%
TERMINAL (d)	0/38 (0%)	1/34 (3%)	0/45 (0%)	0/37 (0%)
FIRST INCIDENCE	---	724	---	---
HC TUMORS SAME ROUTE	1/197 (1%)			
HC TUMORS ALL ROUTES	8/1492 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.394N	P=0.243	(e)	(e)
POLY 1.5	P=0.399N	P=0.241	(e)	(e)
POLY 6	P=0.391N	P=0.245	(e)	(e)
COCH-ARM / FISHERS	P=0.405N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.257N	P=0.082	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTEs	(h)	(h)	(e)	(e)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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</b>				
<b>Osteosarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.80	2/46.36	0/47.88	1/45.91
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	---	548
HC TUMORS SAME ROUTE	1/198 (1%)			
HC TUMORS ALL ROUTES	7/1498 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.552	P=0.245	(e)	P=0.505
POLY 1.5	P=0.546	P=0.242	(e)	P=0.502
POLY 6	P=0.557	P=0.247	(e)	P=0.507
COCH-ARM / FISHERS	P=0.539	P=0.247	(e)	P=0.500
MAX-ISO-POLY-3	P=0.341	P=0.083	(e)	P=0.165
HISTCONT SAME RTE	P=0.421	P=0.085	(e)	P=0.206
HISTCONT ALL RTEs	P=0.246	P=0.015*	(e)	P=0.169

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	5/50 (10%)	5/50 (10%)	2/50 (4%)	6/50 (12%)
POLY-3 RATE (b)	5/45.72	5/46.06	2/47.88	6/45.91
POLY-3 PERCENT (g)	10.9%	10.9%	4.2%	13.1%
TERMINAL (d)	3/38 (8%)	4/34 (12%)	2/45 (4%)	5/37 (14%)
FIRST INCIDENCE	421	723	729 (T)	548
HC TUMORS SAME ROUTE	28/198 (14%)			
HC TUMORS ALL ROUTES	160/1498 (11%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.473	P=0.626N	P=0.198N	P=0.503
POLY 1.5	P=0.468	P=0.627N	P=0.205N	P=0.499
POLY 6	P=0.478	P=0.626N	P=0.190N	P=0.506
COCH-ARM / FISHERS	P=0.467	P=0.630N	P=0.218N	P=0.500
MAX-ISO-POLY-3	P=0.383	P=0.494N	P=0.112N	P=0.376
HISTCONT SAME RTE	P=0.473	P=1.000	P=1.000	P=0.498
HISTCONT ALL RTEs	P=0.446	P=1.000	P=1.000	P=0.477

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	5/50 (10%)	5/50 (10%)	2/50 (4%)	6/50 (12%)
POLY-3 RATE (b)	5/45.72	5/46.06	2/47.88	6/45.91
POLY-3 PERCENT (g)	10.9%	10.9%	4.2%	13.1%
TERMINAL (d)	3/38 (8%)	4/34 (12%)	2/45 (4%)	5/37 (14%)
FIRST INCIDENCE	421	723	729 (T)	548
HC TUMORS SAME ROUTE	30/198 (15%)			
HC TUMORS ALL ROUTES	197/1498 (13%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.473	P=0.626N	P=0.198N	P=0.503
POLY 1.5	P=0.468	P=0.627N	P=0.205N	P=0.499
POLY 6	P=0.478	P=0.626N	P=0.190N	P=0.506
COCH-ARM / FISHERS	P=0.467	P=0.630N	P=0.218N	P=0.500
MAX-ISO-POLY-3	P=0.383	P=0.494N	P=0.112N	P=0.376
HISTCONT SAME RTE	P=0.473	P=1.000	P=1.000	P=0.498
HISTCONT ALL RTEs	P=0.446	P=1.000	P=1.000	P=0.477

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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: Site Unspecified Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.80	0/46.04	0/47.88	0/45.33
POLY-3 PERCENT (g)	4.5%	0%	0%	0%
TERMINAL (d)	2/38 (5%)	0/34 (0%)	0/45 (0%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	---	---	---
HC TUMORS SAME ROUTE	0/198 (0%)			
HC TUMORS ALL ROUTES	3/1498 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.114N	P=0.231N	P=0.223N	P=0.234N
POLY 1.5	P=0.114N	P=0.233N	P=0.228N	P=0.236N
POLY 6	P=0.114N	P=0.230N	P=0.217N	P=0.233N
COCH-ARM / FISHERS	P=0.115N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.032N*	P=0.076N	P=0.076N	P=0.076N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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: Site Unspecified Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.80	0/46.04	0/47.88	0/45.33
POLY-3 PERCENT (g)	4.5%	0%	0%	0%
TERMINAL (d)	2/38 (5%)	0/34 (0%)	0/45 (0%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	---	---	---
HC TUMORS SAME ROUTE	1/198 (1%)			
HC TUMORS ALL ROUTES	8/1498 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.114N	P=0.231N	P=0.223N	P=0.234N
POLY 1.5	P=0.114N	P=0.233N	P=0.228N	P=0.236N
POLY 6	P=0.114N	P=0.230N	P=0.217N	P=0.233N
COCH-ARM / FISHERS	P=0.115N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.032N*	P=0.076N	P=0.076N	P=0.076N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)



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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Adenoma</b>				
<b>TUMOR 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	---	---	---	---
HC TUMORS SAME ROUTE	1/195 (1%)			
HC TUMORS ALL ROUTES	1/1488 (0%)			
<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)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>Hemangiosarcoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/44.80	1/46.04	1/47.88	0/45.33
POLY-3 PERCENT (g)	2.2%	2.2%	2.1%	0%
TERMINAL (d)	1/38 (3%)	1/34 (3%)	1/45 (2%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	---
HC TUMORS SAME ROUTE	0/197 (0%)			
HC TUMORS ALL ROUTES	13/1494 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.310N	P=0.755N	P=0.746N	P=0.498N
POLY 1.5	P=0.312N	P=0.757N	P=0.751N	P=0.499N
POLY 6	P=0.308N	P=0.753N	P=0.739N	P=0.496N
COCH-ARM / FISHERS	P=0.311N	P=0.753N	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.335N	P=0.491N	P=0.481N	P=0.158N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>Hepatoblastoma</b>				
<b>TUMOR 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	1/47.88	0/45.33
POLY-3 PERCENT (g)	0%	0%	2.1%	0%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	1/45 (2%)	0/37 (0%)
FIRST INCIDENCE	---	---	729 (T)	---
HC TUMORS SAME ROUTE	0/197 (0%)			
HC TUMORS ALL ROUTES	4/1494 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.692	(e)	P=0.513	(e)
POLY 1.5	P=0.691	(e)	P=0.508	(e)
POLY 6	P=0.693	(e)	P=0.519	(e)
COCH-ARM / FISHERS	P=0.694	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.401	(e)	P=0.175	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>Hepatocellular Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	8/50 (16%)	11/50 (22%)	14/50 (28%)	5/50 (10%)
POLY-3 RATE (b)	8/45.34	11/46.34	14/47.88	5/45.33
POLY-3 PERCENT (g)	17.6%	23.7%	29.2%	11%
TERMINAL (d)	7/38 (18%)	9/34 (27%)	14/45 (31%)	5/37 (14%)
FIRST INCIDENCE	560	669	729 (T)	729 (T)
HC TUMORS SAME ROUTE	33/197 (17%)			
HC TUMORS ALL ROUTES	396/1494 (27%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.212N	P=0.322	P=0.141	P=0.275N
POLY 1.5	P=0.215N	P=0.317	P=0.130	P=0.278N
POLY 6	P=0.212N	P=0.326	P=0.154	P=0.275N
COCH-ARM / FISHERS	P=0.214N	P=0.306	P=0.114	P=0.277N
MAX-ISO-POLY-3	P=0.108N	P=0.239	P=0.099	P=0.185N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>Hepatocellular Carcinoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	3/50 (6%)	13/50 (26%)	8/50 (16%)	8/50 (16%)
POLY-3 RATE (b)	3/44.80	13/46.32	8/48.55	8/46.40
POLY-3 PERCENT (g)	6.7%	28.1%	16.5%	17.2%
TERMINAL (d)	3/38 (8%)	9/34 (27%)	6/45 (13%)	3/37 (8%)
FIRST INCIDENCE	729 (T)	701	534	604
HC TUMORS SAME ROUTE	11/197 (6%)			
HC TUMORS ALL ROUTES	137/1494 (9%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.337	P=0.007**	P=0.126	P=0.109
POLY 1.5	P=0.317	P=0.006**	P=0.115	P=0.104
POLY 6	P=0.363	P=0.007**	P=0.140	P=0.117
COCH-ARM / FISHERS	P=0.301	P=0.006**	P=0.100	P=0.100
MAX-ISO-POLY-3	P=0.066	P=0.003**	P=0.079	P=0.063
HISTCONT SAME RTE	P=0.080	P=0.003**	P=0.079	P=0.078
HISTCONT ALL RTEs	P=0.074	P=0.003**	P=0.089	P=0.070

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>Hepatocellular Carcinoma or Hepatoblastoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	3/50 (6%)	13/50 (26%)	9/50 (18%)	8/50 (16%)
POLY-3 RATE (b)	3/44.80	13/46.32	9/48.55	8/46.40
POLY-3 PERCENT (g)	6.7%	28.1%	18.5%	17.2%
TERMINAL (d)	3/38 (8%)	9/34 (27%)	7/45 (16%)	3/37 (8%)
FIRST INCIDENCE	729 (T)	701	534	604
HC TUMORS SAME ROUTE	11/197 (6%)			
HC TUMORS ALL ROUTES	140/1494 (9%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.328	P=0.007**	P=0.080	P=0.109
POLY 1.5	P=0.308	P=0.006**	P=0.072	P=0.104
POLY 6	P=0.354	P=0.007**	P=0.090	P=0.117
COCH-ARM / FISHERS	P=0.292	P=0.006**	P=0.061	P=0.100
MAX-ISO-POLY-3	P=0.057	P=0.003**	P=0.049*	P=0.063
HISTCONT SAME RTE	P=0.069	P=0.003**	P=0.059	P=0.078
HISTCONT ALL RTEs	P=0.064	P=0.003**	P=0.053	P=0.070

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>Hepatocellular Carcinoma or Hepatocellular Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	10/50 (20%)	21/50 (42%)	20/50 (40%)	13/50 (26%)
POLY-3 RATE (b)	10/45.34	21/46.55	20/48.55	13/46.40
POLY-3 PERCENT (g)	22.1%	45.1%	41.2%	28%
TERMINAL (d)	9/38 (24%)	16/34 (47%)	18/45 (40%)	8/37 (22%)
FIRST INCIDENCE	560	669	534	604
HC TUMORS SAME ROUTE	41/197 (21%)			
HC TUMORS ALL ROUTES	481/1494 (32%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.542	P=0.015*	P=0.036*	P=0.338
POLY 1.5	P=0.516	P=0.014*	P=0.031*	P=0.325
POLY 6	P=0.512N	P=0.015*	P=0.044*	P=0.355
COCH-ARM / FISHERS	P=0.500	P=0.015*	P=0.024*	P=0.318
MAX-ISO-POLY-3	P=0.082	P=0.009**	P=0.025*	P=0.258
HISTCONT SAME RTE	P=0.100	P=0.009**	P=0.028*	P=0.340
HISTCONT ALL RTEs	P=0.093	P=0.009**	P=0.026*	P=0.319

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	10/50 (20%)	21/50 (42%)	20/50 (40%)	13/50 (26%)
POLY-3 RATE (b)	10/45.34	21/46.55	20/48.55	13/46.40
POLY-3 PERCENT (g)	22.1%	45.1%	41.2%	28%
TERMINAL (d)	9/38 (24%)	16/34 (47%)	18/45 (40%)	8/37 (22%)
FIRST INCIDENCE	560	669	534	604
HC TUMORS SAME ROUTE	41/197 (21%)			
HC TUMORS ALL ROUTES	482/1494 (32%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.542	P=0.015*	P=0.036*	P=0.338
POLY 1.5	P=0.516	P=0.014*	P=0.031*	P=0.325
POLY 6	P=0.512N	P=0.015*	P=0.044*	P=0.355
COCH-ARM / FISHERS	P=0.500	P=0.015*	P=0.024*	P=0.318
MAX-ISO-POLY-3	P=0.082	P=0.009**	P=0.025*	P=0.258
HISTCONT SAME RTE	P=0.100	P=0.009**	P=0.028*	P=0.340
HISTCONT ALL RTEs	P=0.093	P=0.009**	P=0.026*	P=0.319



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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>Hepatocholangiocarcinoma</b>				
<b>TUMOR 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	---	---	---	---
HC TUMORS SAME ROUTE	0/197 (0%)			
HC TUMORS ALL ROUTES	2/1494 (0%)			
<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)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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</b>				
<b>Alveolar/Bronchiolar Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	2/50 (4%)	4/50 (8%)	5/50 (10%)	2/50 (4%)
POLY-3 RATE (b)	2/44.97	4/46.20	5/48.44	2/45.33
POLY-3 PERCENT (g)	4.5%	8.7%	10.3%	4.4%
TERMINAL (d)	1/38 (3%)	1/34 (3%)	4/45 (9%)	2/37 (5%)
FIRST INCIDENCE	684	708	554	729 (T)
HC TUMORS SAME ROUTE	12/196 (6%)			
HC TUMORS ALL ROUTES	72/1496 (5%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.514N	P=0.350	P=0.248	P=0.691N
POLY 1.5	P=0.519N	P=0.346	P=0.236	P=0.693N
POLY 6	P=0.512N	P=0.352	P=0.261	P=0.690N
COCH-ARM / FISHERS	P=0.519N	P=0.339	P=0.218	P=0.691N
MAX-ISO-POLY-3	P=0.424N	P=0.213	P=0.150	P=0.496N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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</b>				
<b>Alveolar/Bronchiolar Carcinoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	2/50 (4%)	1/50 (2%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	2/45.29	1/46.04	3/47.88	2/45.53
POLY-3 PERCENT (g)	4.4%	2.2%	6.3%	4.4%
TERMINAL (d)	1/38 (3%)	1/34 (3%)	3/45 (7%)	1/37 (3%)
FIRST INCIDENCE	581	729 (T)	729 (T)	678
HC TUMORS SAME ROUTE	4/196 (2%)			
HC TUMORS ALL ROUTES	59/1496 (4%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.500	P=0.494N	P=0.525	P=0.692N
POLY 1.5	P=0.498	P=0.496N	P=0.516	P=0.694
POLY 6	P=0.502	P=0.495N	P=0.535	P=0.691N
COCH-ARM / FISHERS	P=0.500	P=0.500N	P=0.500	P=0.691N
MAX-ISO-POLY-3	P=0.506	P=0.277N	P=0.350	P=0.497N
HISTCONT SAME RTE	P=0.317	P=1.000	P=0.157	P=0.327
HISTCONT ALL RTEs	P=0.592	P=1.000	P=0.436	P=0.627

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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</b>				
<b>Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	4/50 (8%)	5/50 (10%)	8/50 (16%)	4/50 (8%)
POLY-3 RATE (b)	4/45.46	5/46.20	8/48.44	4/45.53
POLY-3 PERCENT (g)	8.8%	10.8%	16.5%	8.8%
TERMINAL (d)	2/38 (5%)	2/34 (6%)	7/45 (16%)	3/37 (8%)
FIRST INCIDENCE	581	708	554	678
HC TUMORS SAME ROUTE	16/196 (8%)			
HC TUMORS ALL ROUTES	127/1496 (9%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.546	P=0.510	P=0.210	P=0.642N
POLY 1.5	P=0.543	P=0.507	P=0.198	P=0.642
POLY 6	P=0.547	P=0.510	P=0.223	P=0.643N
COCH-ARM / FISHERS	P=0.547	P=0.500	P=0.178	P=0.643N
MAX-ISO-POLY-3	P=0.446	P=0.373	P=0.139	P=0.498N
HISTCONT SAME RTE	P=0.426	P=0.388	P=0.090	P=1.000
HISTCONT ALL RTEs	P=0.521	P=0.473	P=0.127	P=1.000

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>Cystadenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	5/49 (10%)	9/50 (18%)	9/50 (18%)	4/50 (8%)
POLY-3 RATE (b)	5/43.97	9/46.16	9/48.49	4/45.33
POLY-3 PERCENT (g)	11.4%	19.5%	18.6%	8.8%
TERMINAL (d)	4/37 (11%)	8/34 (24%)	8/45 (18%)	4/37 (11%)
FIRST INCIDENCE	684	697	534	729 (T)
HC TUMORS SAME ROUTE	8/196 (4%)			
HC TUMORS ALL ROUTES	67/1468 (5%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.302N	P=0.220	P=0.252	P=0.481N
POLY 1.5	P=0.309N	P=0.215	P=0.233	P=0.485N
POLY 6	P=0.298N	P=0.222	P=0.272	P=0.479N
COCH-ARM / FISHERS	P=0.313N	P=0.205	P=0.205	P=0.487N
MAX-ISO-POLY-3	P=0.250N	P=0.148	P=0.179	P=0.346N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>Hemangioma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/49 (0%)	3/50 (6%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/43.80	3/46.04	1/47.88	0/45.33
POLY-3 PERCENT (g)	0%	6.5%	2.1%	0%
TERMINAL (d)	0/37 (0%)	3/34 (9%)	1/45 (2%)	0/37 (0%)
FIRST INCIDENCE	---	729 (T)	729 (T)	---
HC TUMORS SAME ROUTE	2/196 (1%)			
HC TUMORS ALL ROUTES	2/1468 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.350N	P=0.128	P=0.518	(e)
POLY 1.5	P=0.355N	P=0.126	P=0.513	(e)
POLY 6	P=0.345N	P=0.129	P=0.524	(e)
COCH-ARM / FISHERS	P=0.362N	P=0.125	P=0.505	(e)
MAX-ISO-POLY-3	P=0.233N	P=0.045*	P=0.179	(e)
HISTCONT SAME RTE	(h)	(h)	(h)	(e)
HISTCONT ALL RTEs	(h)	(h)	(h)	(e)

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 or Unspecified Site Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	2/50 (4%)	1/50 (2%)	1/49 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/44.80	1/46.04	1/46.88	0/45.33
POLY-3 PERCENT (g)	4.5%	2.2%	2.1%	0%
TERMINAL (d)	2/38 (5%)	1/34 (3%)	1/44 (2%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	---
HC TUMORS SAME ROUTE	8/195 (4%)			
HC TUMORS ALL ROUTES	104/1464 (7%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.153N	P=0.490N	P=0.484N	P=0.234N
POLY 1.5	P=0.154N	P=0.494N	P=0.493N	P=0.236N
POLY 6	P=0.152N	P=0.489N	P=0.474N	P=0.233N
COCH-ARM / FISHERS	P=0.154N	P=0.500N	P=0.508N	P=0.247N
MAX-ISO-POLY-3	P=0.122N	P=0.275N	P=0.273N	P=0.076N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>Skeletal Muscle</b>				
<b>Rhabdomyosarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	3/50 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/45.12	0/46.04	0/47.88	0/45.33
POLY-3 PERCENT (g)	6.7%	0%	0%	0%
TERMINAL (d)	2/38 (5%)	0/34 (0%)	0/45 (0%)	0/37 (0%)
FIRST INCIDENCE	639	---	---	---
HC TUMORS SAME ROUTE	2/198 (1%)			
HC TUMORS ALL ROUTES	3/1498 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.045N*	P=0.115N	P=0.109N	P=0.118N
POLY 1.5	P=0.045N*	P=0.116N	P=0.112N	P=0.119N
POLY 6	P=0.044N*	P=0.115N	P=0.105N	P=0.118N
COCH-ARM / FISHERS	P=0.047N*	P=0.121N	P=0.121N	P=0.121N
MAX-ISO-POLY-3	P=0.009N**	P=0.038N*	P=0.038N*	P=0.038N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)



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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>Hemangiosarcoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/49 (0%)	0/48 (0%)	1/50 (2%)	0/49 (0%)
POLY-3 RATE (b)	0/44.38	0/44.63	1/47.88	0/44.35
POLY-3 PERCENT (g)	0%	0%	2.1%	0%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	1/45 (2%)	0/37 (0%)
FIRST INCIDENCE	---	---	729 (T)	---
HC TUMORS SAME ROUTE	2/195 (1%)			
HC TUMORS ALL ROUTES	27/1478 (2%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.689	(e)	P=0.515	(e)
POLY 1.5	P=0.690	(e)	P=0.511	(e)
POLY 6	P=0.687	(e)	P=0.520	(e)
COCH-ARM / FISHERS	P=0.696	(e)	P=0.505	(e)
MAX-ISO-POLY-3	P=0.401	(e)	P=0.176	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Squamous Cell Carcinoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.80	0/46.04	2/47.88	0/45.33
POLY-3 PERCENT (g)	0%	0%	4.2%	0%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	2/45 (4%)	0/37 (0%)
FIRST INCIDENCE	---	---	729 (T)	---
HC TUMORS SAME ROUTE	0/198 (0%)			
HC TUMORS ALL ROUTES	3/1498 (0%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.594	(e)	P=0.252	(e)
POLY 1.5	P=0.592	(e)	P=0.247	(e)
POLY 6	P=0.594	(e)	P=0.259	(e)
COCH-ARM / FISHERS	P=0.595	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.267	(e)	P=0.091	(e)
HISTCONT SAME RTE	P=0.309	(e)	P=0.041*	(e)
HISTCONT ALL RTEs	P=0.129	(e)	P<0.001**	(e)

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Squamous Cell Carcinoma or Papilloma Squamous</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	3/50 (6%)	3/50 (6%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	3/44.80	3/46.04	4/47.88	0/45.33
POLY-3 PERCENT (g)	6.7%	6.5%	8.4%	0%
TERMINAL (d)	3/38 (8%)	3/34 (9%)	4/45 (9%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	---
HC TUMORS SAME ROUTE	6/198 (3%)			
HC TUMORS ALL ROUTES	27/1498 (2%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.111N	P=0.650N	P=0.536	P=0.116N
POLY 1.5	P=0.113N	P=0.654N	P=0.522	P=0.118N
POLY 6	P=0.109N	P=0.647N	P=0.552	P=0.115N
COCH-ARM / FISHERS	P=0.114N	P=0.661N	P=0.500	P=0.121N
MAX-ISO-POLY-3	P=0.107N	P=0.486N	P=0.384	P=0.038N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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 Squamous Cell Papilloma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	3/50 (6%)	3/50 (6%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	3/44.80	3/46.04	2/47.88	0/45.33
POLY-3 PERCENT (g)	6.7%	6.5%	4.2%	0%
TERMINAL (d)	3/38 (8%)	3/34 (9%)	2/45 (4%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	---
HC TUMORS SAME ROUTE	6/198 (3%)			
HC TUMORS ALL ROUTES	24/1498 (2%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.070N	P=0.650N	P=0.470N	P=0.116N
POLY 1.5	P=0.071N	P=0.654N	P=0.481N	P=0.118N
POLY 6	P=0.068N	P=0.647N	P=0.457N	P=0.115N
COCH-ARM / FISHERS	P=0.072N	P=0.661N	P=0.500N	P=0.121N
MAX-ISO-POLY-3	P=0.098N	P=0.486N	P=0.303N	P=0.038N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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: Follicular Cell Adenoma</b>				
<b>TUMOR 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	---	---	---	---
HC TUMORS SAME ROUTE	2/196 (1%)			
HC TUMORS ALL ROUTES	25/1483 (2%)			
<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)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>Polyp Stromal</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	2/44.80	0/46.04	0/47.88	2/45.33
POLY-3 PERCENT (g)	4.5%	0%	0%	4.4%
TERMINAL (d)	2/38 (5%)	0/34 (0%)	0/45 (0%)	2/37 (5%)
FIRST INCIDENCE	729 (T)	---	---	729 (T)
HC TUMORS SAME ROUTE	0/198 (0%)			
HC TUMORS ALL ROUTES	39/1498 (3%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.500	P=0.231N	P=0.223N	P=0.690N
POLY 1.5	P=0.499	P=0.233N	P=0.228N	P=0.692N
POLY 6	P=0.501	P=0.230N	P=0.217N	P=0.688N
COCH-ARM / FISHERS	P=0.500	P=0.247N	P=0.247N	P=0.691N
MAX-ISO-POLY-3	P=0.267N	P=0.076N	P=0.076N	P=0.494N
HISTCONT SAME RTE	P=0.130	(e)	(e)	P=0.113
HISTCONT ALL RTEs	P=0.318	(e)	(e)	P=0.443

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>All Organs</b>				
<b>Hemangioma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	3/50 (6%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	0/44.80	3/46.04	3/47.88	2/45.56
POLY-3 PERCENT (g)	0%	6.5%	6.3%	4.4%
TERMINAL (d)	0/38 (0%)	3/34 (9%)	3/45 (7%)	1/37 (3%)
FIRST INCIDENCE	---	729 (T)	729 (T)	669
HC TUMORS SAME ROUTE	4/198 (2%)			
HC TUMORS ALL ROUTES	21/1498 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.322	P=0.124	P=0.131	P=0.241
POLY 1.5	P=0.316	P=0.122	P=0.127	P=0.239
POLY 6	P=0.328	P=0.124	P=0.137	P=0.243
COCH-ARM / FISHERS	P=0.313	P=0.121	P=0.121	P=0.247
MAX-ISO-POLY-3	P=0.150	P=0.042*	P=0.049*	P=0.080
HISTCONT SAME RTE	P=0.185	P=0.050*	P=0.059	P=0.099
HISTCONT ALL RTEs	P=0.017*	P=0.039*	P=0.040*	P=0.090

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>All Organs</b>				
<b>Hemangiosarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/44.80	2/46.06	1/47.88	1/45.33
POLY-3 PERCENT (g)	2.2%	4.3%	2.1%	2.2%
TERMINAL (d)	1/38 (3%)	1/34 (3%)	1/45 (2%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	724	729 (T)	729 (T)
HC TUMORS SAME ROUTE	5/198 (3%)			
HC TUMORS ALL ROUTES	68/1498 (5%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.524N	P=0.510	P=0.746N	P=0.758N
POLY 1.5	P=0.527N	P=0.506	P=0.751N	P=0.760N
POLY 6	P=0.521N	P=0.512	P=0.739N	P=0.757N
COCH-ARM / FISHERS	P=0.531N	P=0.500	P=0.753N	P=0.753N
MAX-ISO-POLY-3	P=0.583N	P=0.291	P=0.481N	P=0.496N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)



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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>All Organs</b>				
<b>Hemangiosarcoma or Hemangioma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	1/50 (2%)	5/50 (10%)	4/50 (8%)	3/50 (6%)
POLY-3 RATE (b)	1/44.80	5/46.06	4/47.88	3/45.56
POLY-3 PERCENT (g)	2.2%	10.9%	8.4%	6.6%
TERMINAL (d)	1/38 (3%)	4/34 (12%)	4/45 (9%)	2/37 (5%)
FIRST INCIDENCE	729 (T)	724	729 (T)	669
HC TUMORS SAME ROUTE	9/198 (5%)			
HC TUMORS ALL ROUTES	89/1498 (6%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.417	P=0.108	P=0.200	P=0.311
POLY 1.5	P=0.409	P=0.106	P=0.192	P=0.308
POLY 6	P=0.425	P=0.109	P=0.209	P=0.315
COCH-ARM / FISHERS	P=0.404	P=0.102	P=0.181	P=0.309
MAX-ISO-POLY-3	P=0.197	P=0.050*	P=0.104	P=0.161
HISTCONT SAME RTE	P=0.243	P=0.061	P=0.131	P=0.208
HISTCONT ALL RTEs	P=0.227	P=0.055	P=0.119	P=0.190

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>All Organs</b>				
<b>Histiocytic Sarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	3/50 (6%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	3/45.95	0/46.04	0/47.88	2/45.35
POLY-3 PERCENT (g)	6.5%	0%	0%	4.4%
TERMINAL (d)	0/38 (0%)	0/34 (0%)	0/45 (0%)	1/37 (3%)
FIRST INCIDENCE	544	---	---	725
HC TUMORS SAME ROUTE	4/198 (2%)			
HC TUMORS ALL ROUTES	39/1498 (3%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.527N	P=0.118N	P=0.112N	P=0.506N
POLY 1.5	P=0.529N	P=0.118N	P=0.114N	P=0.505N
POLY 6	P=0.523N	P=0.120N	P=0.109N	P=0.510N
COCH-ARM / FISHERS	P=0.531N	P=0.121N	P=0.121N	P=0.500N
MAX-ISO-POLY-3	P=0.107N	P=0.038N*	P=0.038N*	P=0.330N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>All Organs</b>				
<b>Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	6/50 (12%)	7/50 (14%)	1/50 (2%)	6/50 (12%)
POLY-3 RATE (b)	6/44.80	7/46.31	1/47.88	6/45.53
POLY-3 PERCENT (g)	13.4%	15.1%	2.1%	13.2%
TERMINAL (d)	6/38 (16%)	5/34 (15%)	1/45 (2%)	5/37 (14%)
FIRST INCIDENCE	729 (T)	669	729 (T)	678
HC TUMORS SAME ROUTE	26/198 (13%)			
HC TUMORS ALL ROUTES	307/1498 (21%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.424N	P=0.526	P=0.046N*	P=0.609N
POLY 1.5	P=0.430N	P=0.516	P=0.050N*	P=0.616N
POLY 6	P=0.417N	P=0.534	P=0.042N*	P=0.603N
COCH-ARM / FISHERS	P=0.437N	P=0.500	P=0.056N	P=0.620N
MAX-ISO-POLY-3	P=0.247N	P=0.407	P=0.022N*	P=0.487N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>All Organs</b>				
<b>Osteosarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.80	2/46.36	0/47.88	1/45.91
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	---	548
HC TUMORS SAME ROUTE	1/198 (1%)			
HC TUMORS ALL ROUTES	8/1498 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.552	P=0.245	(e)	P=0.505
POLY 1.5	P=0.546	P=0.242	(e)	P=0.502
POLY 6	P=0.557	P=0.247	(e)	P=0.507
COCH-ARM / FISHERS	P=0.539	P=0.247	(e)	P=0.500
MAX-ISO-POLY-3	P=0.341	P=0.083	(e)	P=0.165
HISTCONT SAME RTE	P=0.421	P=0.085	(e)	P=0.206
HISTCONT ALL RTEs	P=0.291	P=0.019*	(e)	P=0.191

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS  
 Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>All Organs</b>				
<b>Osteosarcoma or Osteoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.80	2/46.36	0/47.88	1/45.91
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	---	548
HC TUMORS SAME ROUTE	1/198 (1%)			
HC TUMORS ALL ROUTES	9/1498 (1%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.552	P=0.245	(e)	P=0.505
POLY 1.5	P=0.546	P=0.242	(e)	P=0.502
POLY 6	P=0.557	P=0.247	(e)	P=0.507
COCH-ARM / FISHERS	P=0.539	P=0.247	(e)	P=0.500
MAX-ISO-POLY-3	P=0.341	P=0.083	(e)	P=0.165
HISTCONT SAME RTE	P=0.421	P=0.085	(e)	P=0.206
HISTCONT ALL RTEs	P=0.339	P=0.023*	(e)	P=0.196

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

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 PRIMARY TUMORS 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>All Organs</b>				
<b>Benign Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	26/50 (52%)	26/50 (52%)	27/50 (54%)	19/50 (38%)
POLY-3 RATE (b)	26/46.44	26/46.63	27/49.05	19/46.14
POLY-3 PERCENT (g)	56%	55.8%	55.1%	41.2%
TERMINAL (d)	22/38 (58%)	20/34 (59%)	25/45 (56%)	17/37 (46%)
FIRST INCIDENCE	421	669	534	548
HC TUMORS SAME ROUTE	92/198 (47%)			
HC TUMORS ALL ROUTES	752/1498 (50%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.075N	P=0.575N	P=0.545N	P=0.108N
POLY 1.5	P=0.081N	P=0.577N	P=0.572	P=0.113N
POLY 6	P=0.071N	P=0.574N	P=0.495N	P=0.104N
COCH-ARM / FISHERS	P=0.083N	P=0.579N	P=0.500	P=0.114N
MAX-ISO-POLY-3	P=0.119N	P=0.490N	P=0.463N	P=0.074N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

Kava kava extract  
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>All Organs</b>				
<b>Malignant Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	19/50 (38%)	24/50 (48%)	17/50 (34%)	18/50 (36%)
POLY-3 RATE (b)	19/46.88	24/47.75	17/48.55	18/46.99
POLY-3 PERCENT (g)	40.5%	50.3%	35%	38.3%
TERMINAL (d)	13/38 (34%)	14/34 (41%)	15/45 (33%)	11/37 (30%)
FIRST INCIDENCE	544	521	534	548
HC TUMORS SAME ROUTE	68/198 (34%)			
HC TUMORS ALL ROUTES	716/1498 (48%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.288N	P=0.228	P=0.366N	P=0.496N
POLY 1.5	P=0.295N	P=0.222	P=0.382N	P=0.502N
POLY 6	P=0.285N	P=0.230	P=0.355N	P=0.494N
COCH-ARM / FISHERS	P=0.295N	P=0.210	P=0.418N	P=0.500N
MAX-ISO-POLY-3	P=0.313N	P=0.173	P=0.293N	P=0.411N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS 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>All Organs</b>				
<b>Malignant and Benign Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	39/50 (78%)	38/50 (76%)	35/50 (70%)	30/50 (60%)
POLY-3 RATE (b)	39/48.53	38/47.90	35/49.11	30/47.57
POLY-3 PERCENT (g)	80.4%	79.3%	71.3%	63.1%
TERMINAL (d)	29/38 (76%)	26/34 (77%)	32/45 (71%)	22/37 (60%)
FIRST INCIDENCE	421	521	534	548
HC TUMORS SAME ROUTE	133/198 (67%)			
HC TUMORS ALL ROUTES	1122/1498 (75%)			
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.019N*	P=0.551N	P=0.206N	P=0.045N*
POLY 1.5	P=0.020N*	P=0.528N	P=0.215N	P=0.044N*
POLY 6	P=0.020N*	P=0.586N	P=0.209N	P=0.049N*
COCH-ARM / FISHERS	P=0.020N*	P=0.500N	P=0.247N	P=0.041N*
MAX-ISO-POLY-3	P=0.029N*	P=0.447N	P=0.146N	P=0.028N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)



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

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**LEGEND**

- (a) Number of tumor-bearing animals/number of animals examined at site.
  - (b) Number of tumor-bearing animals/Poly-3 number
  - (d) Observed incidence at terminal kill.
  - (e) Value of Statistic cannot be computed.
  - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
  - (g) Poly-3 adjusted lifetime tumor incidence.
  - (h) Value of Historical Controls statistic is only calculated when Poly-3 trend is positive and when there is more than one tumor in the treatment groups.
  - (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 \*\*\*