

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
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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

FEMALE MICE

Organ

Intestine Small: Site Unspecified

Liver

Ovary
Skeletal Muscle
Stomach, Forestomach

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

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
Adrenal Medulla				
Pheochromocytoma Benign				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/43.49	0/42.37	2/44.99	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%)			
STATISTICAL TESTS				
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
Bone Marrow				
Hemangiosarcoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
Bone				
Osteosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.49	0/42.37	0/44.59	0/44.23
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/33 (0%)	0/34 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	0/200 (0%)			
HC TUMORS ALL ROUTES	3/1449 (0%)			
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)
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
Harderian Gland Adenoma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Harderian Gland Carcinoma or Adenoma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Intestine Small: Site Unspecified Adenoma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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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**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
Intestine Small: Site Unspecified Carcinoma or Adenoma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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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DOSE	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Kidney: Renal Tubule Adenoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
Liver				
Hemangiosarcoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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)

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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
Liver				
Hepatoblastoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
Liver				
Hepatocellular Adenoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
Liver				
Hepatocellular Carcinoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
Liver				
Hepatocellular Carcinoma or Hepatoblastoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
Liver				
Hepatocellular Carcinoma or Hepatocellular Adenoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
Liver				
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
 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
Liver				
Hepatocholangiocarcinoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
Lung				
Alveolar/Bronchiolar Adenoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
Lung				
Alveolar/Bronchiolar Carcinoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
Lung				
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
 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
Pituitary Gland: Pars Distalis or Unspecified Site Adenoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
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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
Skeletal Muscle				
Rhabdomyosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.49	0/42.37	0/44.59	0/44.23
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/33 (0%)	0/34 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	1/200 (1%)			
HC TUMORS ALL ROUTES	2/1449 (0%)			
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)
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
Spleen				
Hemangiosarcoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
Stomach, Forestomach Squamous Cell Carcinoma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
Stomach, Forestomach Squamous Cell Carcinoma or Papilloma Squamous				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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

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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
Stomach, Forestomach Squamous Cell Papilloma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
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 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
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 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
Thyroid Gland: Follicular Cell Adenoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
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 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
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 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
All Organs				
Hemangioma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
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 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	Males			
	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
All Organs				
Hemangiosarcoma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
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 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
All Organs				
Hemangiosarcoma or Hemangioma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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)

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 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
All Organs				
Histiocytic Sarcoma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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

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

TDMS No. 20007 - 06
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P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

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 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
All Organs				
Malignant Tumors				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
All Organs				
Malignant and Benign Tumors				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
Adrenal Medulla				
Pheochromocytoma Benign				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.80	1/46.04	0/47.88	1/45.33
POLY-3 PERCENT (g)	0%	2.2%	0%	2.2%
TERMINAL (d)	0/38 (0%)	1/34 (3%)	0/45 (0%)	1/37 (3%)
FIRST INCIDENCE	---	729 (T)	---	729 (T)
HC TUMORS SAME ROUTE	1/196 (1%)			
HC TUMORS ALL ROUTES	15/1488 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.410	P=0.505	(e)	P=0.502
POLY 1.5	P=0.408	P=0.504	(e)	P=0.501
POLY 6	P=0.413	P=0.507	(e)	P=0.504
COCH-ARM / FISHERS	P=0.405	P=0.500	(e)	P=0.500
MAX-ISO-POLY-3	P=0.260	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
Bone Marrow				
Hemangiosarcoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
Bone				
Osteosarcoma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
Harderian Gland Adenoma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
Harderian Gland Carcinoma or Adenoma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
Intestine Small: Site Unspecified Adenoma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
Intestine Small: Site Unspecified Carcinoma or Adenoma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
Kidney: Renal Tubule Adenoma				
TUMOR 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	---	---	---	---
HC TUMORS SAME ROUTE	1/195 (1%)			
HC TUMORS ALL ROUTES	1/1488 (0%)			
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)
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
Liver				
Hemangiosarcoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
Liver				
Hepatoblastoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.80	0/46.04	1/47.88	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%)			
STATISTICAL TESTS				
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
Liver				
Hepatocellular Adenoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
Liver				
Hepatocellular Carcinoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
Liver				
Hepatocellular Carcinoma or Hepatoblastoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
Liver				
Hepatocellular Carcinoma or Hepatocellular Adenoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
Liver				
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
Liver				
Hepatocholangiocarcinoma				
TUMOR 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	---	---	---	---
HC TUMORS SAME ROUTE	0/197 (0%)			
HC TUMORS ALL ROUTES	2/1494 (0%)			
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)
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
Lung				
Alveolar/Bronchiolar Adenoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
Lung				
Alveolar/Bronchiolar Carcinoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
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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
Lung				
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
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 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
Ovary				
Cystadenoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
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 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
Ovary Hemangioma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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

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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
Pituitary Gland: Pars Distalis or Unspecified Site Adenoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
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 Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS
 Kava kava extract
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 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
Skeletal Muscle				
Rhabdomyosarcoma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
Spleen				
Hemangiosarcoma				
TUMOR RATES				
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%)			
STATISTICAL TESTS				
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
Stomach, Forestomach Squamous Cell Carcinoma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
Stomach, Forestomach Squamous Cell Carcinoma or Papilloma Squamous				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
Stomach, Forestomach Squamous Cell Papilloma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
Thyroid Gland: Follicular Cell Adenoma				
TUMOR 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	---	---	---	---
HC TUMORS SAME ROUTE	2/196 (1%)			
HC TUMORS ALL ROUTES	25/1483 (2%)			
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)
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
Uterus				
Polyp Stromal				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
All Organs				
Hemangioma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
All Organs				
Hemangiosarcoma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
All Organs				
Hemangiosarcoma or Hemangioma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
All Organs				
Histiocytic Sarcoma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
All Organs				
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
All Organs				
Osteosarcoma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
All Organs				
Osteosarcoma or Osteoma				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
 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
All Organs				
Benign Tumors				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
All Organs				
Malignant Tumors				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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

Kava kava extract
 CAS Number: 9000-38-8

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 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
All Organs				
Malignant and Benign Tumors				
TUMOR RATES	#	#	#	#
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%)			
STATISTICAL TESTS				
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
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
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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 ***