

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
CAS Number: 9000-38-8

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

F2_R2

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

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HISTORICAL CONTROL STUDIES
From May 2009 report

SAME ROUTE

88105-03 -- Isoeugenol (GAVAGE CORN OIL)
99023-03 -- beta-Myrcene (GAVAGE CORN OIL)
99020-05 -- Pulegone (GAVAGE CORN OIL)

ALL ROUTES

99024-07 -- Androstenedione (GAVAGE METHYLCELLULOSE)
99028-05 -- bis(2-Chloroethoxy)methane (SKIN ETHANOL)
20011-05 -- 1-Bromopropane (INHALATION AIR)
99027-03 -- Chromium picolinate monohydrate (ORAL FEED)
05174-05 -- Cresols (ORAL FEED)
96011-05 -- Cumene (INHALATION AIR)
97003-07 -- 1,2-Dibromo-2,4-dicyanobutane (SKIN ETHANOL)
99017-05 -- Diethylamine (INHALATION AIR)
93020-07 -- Diisopropylcarbodiimide (SKIN ETHANOL)
88123-05 -- Formamide (GAVAGE WATER)
20005-05 -- Ginseng (GAVAGE WATER)
99007-05 -- Goldenseal root powder (ORAL FEED)
95011-07 -- 5-(Hydroxymethyl)-2-furfural (GAVAGE WATER)
88105-03 -- Isoeugenol (GAVAGE CORN OIL)
97006-01 -- Methyl isobutyl ketone (INHALATION AIR)
91005-07 -- Methylene blue trihydrate (GAVAGE METHYLCELLULOSE)
92013-05 -- 4-Methylimidazole (ORAL FEED)
88006-03 -- alpha-Methylstyrene (INHALATION AIR)
20008-03 -- Milk thistle extract (ORAL FEED)
99023-03 -- beta-Myrcene (GAVAGE CORN OIL)
97008-05 -- Propargyl alcohol (INHALATION AIR)
99020-05 -- Pulegone (GAVAGE CORN OIL)
20114-07 -- Sodium dichromate dihydrate (VI) (ORAL WATER)
93025-07 -- Tetralin (INHALATION AIR)

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HISTORICAL CONTROL STUDIES

From May 2009 report

96019-05 -- Water disinfection byproducts (Bromochloroacetic acid) (ORAL WATER)

96017-05 -- Water disinfection byproducts (Dibromoacetic acid) (ORAL WATER)

96015-05 -- 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 Medulla
Clitoral/Preputial Gland
Islets, Pancreatic
Lung
Pancreas
Pituitary Gland
Salivary Glands
Testes
Thyroid Gland

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

MALE RATS

Organ

Adrenal Medulla
Mammary Gland

Pituitary Gland: Pars Distalis or Unspecified Site

Skin

Testes
Thyroid Gland: C-Cell

FEMALE RATS

Organ

Clitoral/Preputial Gland

Mammary Gland

Pituitary Gland: Pars Distalis or Unspecified Site

All Organs

Morphology

Pheochromocytoma: Benign, Complex, Malignant, NOS
Fibroadenoma
Fibroma, Fibroadenoma or Adenoma
Fibroma, Fibroadenoma, Carcinoma, or Adenoma
Adenoma
Carcinoma or Adenoma
Fibroma
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma
Adenoma
Adenoma
Carcinoma or Adenoma

Morphology

Adenoma
Carcinoma or Adenoma
Carcinoma or Adenoma
Fibroadenoma
Fibroma, Fibroadenoma or Adenoma
Fibroma, Fibroadenoma, Carcinoma, or Adenoma
Adenoma
Carcinoma or Adenoma
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated
Osteosarcoma or Osteoma
Benign Tumors
Malignant and Benign Tumors

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Adrenal Medulla				
Pheochromocytoma Benign				
TUMOR RATES				
OVERALL (a)	5/49 (10%)	8/50 (16%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	5/43.41	8/44.61	2/45.55	2/41.46
POLY-3 PERCENT (g)	11.5%	17.9%	4.4%	4.8%
TERMINAL (d)	4/34 (12%)	8/35 (23%)	2/34 (6%)	2/31 (7%)
FIRST INCIDENCE	709	727 (T)	727 (T)	727 (T)
HC TUMORS SAME ROUTE	24/150 (16%)			
HC TUMORS ALL ROUTES	192/1346 (14%)			
STATISTICAL TESTS				
POLY 3	P=0.086N	P=0.292	P=0.196N	P=0.234N
POLY 1.5	P=0.084N	P=0.282	P=0.201N	P=0.231N
POLY 6	P=0.089N	P=0.305	P=0.193N	P=0.238N
COCH-ARM / FISHERS	P=0.074N	P=0.290	P=0.210N	P=0.210N
MAX-ISO-POLY-3	P=0.101N	P=0.201	P=0.110N	P=0.138N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Adrenal Medulla				
Pheochromocytoma Malignant				
TUMOR RATES				
OVERALL (a)	0/49 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.34	2/44.84	0/45.55	0/41.46
POLY-3 PERCENT (g)	0%	4.5%	0%	0%
TERMINAL (d)	0/34 (0%)	1/35 (3%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	666	---	---
HC TUMORS SAME ROUTE	5/150 (3%)			
HC TUMORS ALL ROUTES	27/1346 (2%)			
STATISTICAL TESTS				
POLY 3	P=0.398N	P=0.245	(e)	(e)
POLY 1.5	P=0.400N	P=0.240	(e)	(e)
POLY 6	P=0.395N	P=0.251	(e)	(e)
COCH-ARM / FISHERS	P=0.390N	P=0.253	(e)	(e)
MAX-ISO-POLY-3	P=0.279N	P=0.082	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTEs	(h)	(h)	(e)	(e)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Adrenal Medulla				
Pheochromocytoma: Benign, Complex, Malignant, NOS				
TUMOR RATES				
OVERALL (a)	5/49 (10%)	10/50 (20%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	5/43.41	10/44.84	2/45.55	2/41.46
POLY-3 PERCENT (g)	11.5%	22.3%	4.4%	4.8%
TERMINAL (d)	4/34 (12%)	9/35 (26%)	2/34 (6%)	2/31 (7%)
FIRST INCIDENCE	709	666	727 (T)	727 (T)
HC TUMORS SAME ROUTE	28/150 (19%)			
HC TUMORS ALL ROUTES	222/1346 (17%)			
STATISTICAL TESTS				
POLY 3	P=0.053N	P=0.142	P=0.196N	P=0.234N
POLY 1.5	P=0.052N	P=0.135	P=0.201N	P=0.231N
POLY 6	P=0.054N	P=0.153	P=0.193N	P=0.238N
COCH-ARM / FISHERS	P=0.046N*	P=0.140	P=0.210N	P=0.210N
MAX-ISO-POLY-3	P=0.058N	P=0.090	P=0.110N	P=0.138N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Bone				
Osteosarcoma or Osteoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/49 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.50	1/44.61	0/45.55	0/41.46
POLY-3 PERCENT (g)	2.3%	2.2%	0%	0%
TERMINAL (d)	0/34 (0%)	1/35 (3%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	686	727 (T)	---	---
HC TUMORS SAME ROUTE	3/150 (2%)			
HC TUMORS ALL ROUTES	13/1349 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.330N	P=0.755N	P=0.491N	P=0.510N
POLY 1.5	P=0.329N	P=0.758N	P=0.493N	P=0.508N
POLY 6	P=0.331N	P=0.751N	P=0.490N	P=0.512N
COCH-ARM / FISHERS	P=0.322N	P=0.747N	P=0.495N	P=0.495N
MAX-ISO-POLY-3	P=0.277N	P=0.492N	P=0.157N	P=0.172N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Clitoral/Preputial Gland Adenoma				
TUMOR RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/49 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/43.34	0/44.61	0/44.70	1/41.46
POLY-3 PERCENT (g)	0%	0%	0%	2.4%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	1/31 (3%)
FIRST INCIDENCE	---	---	---	727 (T)
HC TUMORS SAME ROUTE	10/150 (7%)			
HC TUMORS ALL ROUTES	53/1347 (4%)			
STATISTICAL TESTS				
POLY 3	P=0.213	(e)	(e)	P=0.491
POLY 1.5	P=0.215	(e)	(e)	P=0.493
POLY 6	P=0.210	(e)	(e)	P=0.490
COCH-ARM / FISHERS	P=0.223	(e)	(e)	P=0.505
MAX-ISO-POLY-3	P=0.128	(e)	(e)	P=0.160
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Clitoral/Preputial Gland Carcinoma				
TUMOR RATES				
OVERALL (a)	1/49 (2%)	1/50 (2%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.34	1/44.61	0/44.70	0/41.46
POLY-3 PERCENT (g)	2.3%	2.2%	0%	0%
TERMINAL (d)	1/34 (3%)	1/35 (3%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	727 (T)	727 (T)	---	---
HC TUMORS SAME ROUTE	3/150 (2%)			
HC TUMORS ALL ROUTES	19/1347 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.330N	P=0.754N	P=0.494N	P=0.509N
POLY 1.5	P=0.329N	P=0.758N	P=0.496N	P=0.507N
POLY 6	P=0.331N	P=0.749N	P=0.492N	P=0.510N
COCH-ARM / FISHERS	P=0.322N	P=0.747N	P=0.500N	P=0.495N
MAX-ISO-POLY-3	P=0.277N	P=0.491N	P=0.158N	P=0.171N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Clitoral/Preputial Gland Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	1/49 (2%)	1/50 (2%)	0/49 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/43.34	1/44.61	0/44.70	1/41.46
POLY-3 PERCENT (g)	2.3%	2.2%	0%	2.4%
TERMINAL (d)	1/34 (3%)	1/35 (3%)	0/34 (0%)	1/31 (3%)
FIRST INCIDENCE	727 (T)	727 (T)	---	727 (T)
HC TUMORS SAME ROUTE	13/150 (9%)			
HC TUMORS ALL ROUTES	70/1347 (5%)			
STATISTICAL TESTS				
POLY 3	P=0.658	P=0.754N	P=0.494N	P=0.751
POLY 1.5	P=0.661	P=0.758N	P=0.496N	P=0.753
POLY 6	P=0.654	P=0.749N	P=0.492N	P=0.749
COCH-ARM / FISHERS	P=0.675	P=0.747N	P=0.500N	P=0.747N
MAX-ISO-POLY-3	P=0.552N	P=0.491N	P=0.158N	P=0.487
HISTCONT SAME RTE	P=0.722	P=1.000	(e)	P=0.633
HISTCONT ALL RTEs	P=0.701	P=1.000	(e)	P=0.615

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Ear				
Neural Crest Tumor				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/49 (0%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/43.34	2/44.91	1/45.55	0/41.46
POLY-3 PERCENT (g)	0%	4.5%	2.2%	0%
TERMINAL (d)	0/34 (0%)	1/35 (3%)	1/34 (3%)	0/31 (0%)
FIRST INCIDENCE	---	646	727 (T)	---
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	1/1349 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.398N	P=0.245	P=0.510	(e)
POLY 1.5	P=0.397N	P=0.240	P=0.508	(e)
POLY 6	P=0.399N	P=0.251	P=0.512	(e)
COCH-ARM / FISHERS	P=0.380N	P=0.253	P=0.505	(e)
MAX-ISO-POLY-3	P=0.357	P=0.082	P=0.170	(e)
HISTCONT SAME RTE	(h)	(h)	(h)	(e)
HISTCONT ALL RTEs	(h)	(h)	(h)	(e)

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 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Islets, Pancreatic Adenoma				
TUMOR RATES				
OVERALL (a)	4/49 (8%)	2/50 (4%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	4/43.62	2/44.61	2/45.78	3/42.01
POLY-3 PERCENT (g)	9.2%	4.5%	4.4%	7.1%
TERMINAL (d)	3/34 (9%)	2/35 (6%)	0/34 (0%)	2/31 (7%)
FIRST INCIDENCE	651	727 (T)	694	556
HC TUMORS SAME ROUTE	8/150 (5%)			
HC TUMORS ALL ROUTES	86/1345 (6%)			
STATISTICAL TESTS				
POLY 3	P=0.600	P=0.327N	P=0.315N	P=0.521N
POLY 1.5	P=0.607	P=0.334N	P=0.320N	P=0.517N
POLY 6	P=0.592	P=0.319N	P=0.311N	P=0.524N
COCH-ARM / FISHERS	P=0.588N	P=0.329N	P=0.329N	P=0.489N
MAX-ISO-POLY-3	P=0.386N	P=0.194N	P=0.188N	P=0.369N
HISTCONT SAME RTE	P=0.589	P=1.000	P=1.000	P=0.490
HISTCONT ALL RTEs	P=0.754	P=1.000	P=1.000	P=1.000

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lung				
Alveolar/Bronchiolar Adenoma				
TUMOR RATES				
OVERALL (a)	2/49 (4%)	0/50 (0%)	2/50 (4%)	4/50 (8%)
POLY-3 RATE (b)	2/43.34	0/44.61	2/45.97	4/41.46
POLY-3 PERCENT (g)	4.6%	0%	4.4%	9.7%
TERMINAL (d)	2/34 (6%)	0/35 (0%)	1/34 (3%)	4/31 (13%)
FIRST INCIDENCE	727 (T)	---	608	727 (T)
HC TUMORS SAME ROUTE	6/150 (4%)			
HC TUMORS ALL ROUTES	30/1349 (2%)			
STATISTICAL TESTS				
POLY 3	P=0.078	P=0.231N	P=0.673N	P=0.316
POLY 1.5	P=0.082	P=0.235N	P=0.678N	P=0.321
POLY 6	P=0.074	P=0.226N	P=0.668N	P=0.312
COCH-ARM / FISHERS	P=0.092	P=0.242N	P=0.684N	P=0.349
MAX-ISO-POLY-3	P=0.094	P=0.075N	P=0.475N	P=0.190
HISTCONT SAME RTE	P=0.119	(e)	P=1.000	P=0.223
HISTCONT ALL RTEs	P=0.051	(e)	P=0.405	P=0.069

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lung				
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma				
TUMOR RATES				
OVERALL (a)	2/49 (4%)	1/50 (2%)	2/50 (4%)	4/50 (8%)
POLY-3 RATE (b)	2/43.34	1/44.61	2/45.97	4/41.46
POLY-3 PERCENT (g)	4.6%	2.2%	4.4%	9.7%
TERMINAL (d)	2/34 (6%)	1/35 (3%)	1/34 (3%)	4/31 (13%)
FIRST INCIDENCE	727 (T)	727 (T)	608	727 (T)
HC TUMORS SAME ROUTE	8/150 (5%)			
HC TUMORS ALL ROUTES	43/1349 (3%)			
STATISTICAL TESTS				
POLY 3	P=0.130	P=0.490N	P=0.673N	P=0.316
POLY 1.5	P=0.136	P=0.496N	P=0.678N	P=0.321
POLY 6	P=0.125	P=0.482N	P=0.668N	P=0.312
COCH-ARM / FISHERS	P=0.151	P=0.492N	P=0.684N	P=0.349
MAX-ISO-POLY-3	P=0.172	P=0.273N	P=0.475N	P=0.190
HISTCONT SAME RTE	P=0.219	P=1.000	P=1.000	P=0.255
HISTCONT ALL RTEs	P=0.140	P=1.000	P=0.553	P=0.131

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Mammary Gland Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.34	0/44.61	0/45.55	0/41.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	4/1349 (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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Mammary Gland Carcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.34	0/44.61	0/45.55	0/41.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	7/1349 (1%)			
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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Mammary Gland Carcinoma or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.34	0/44.61	0/45.55	0/41.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	11/1349 (1%)			
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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Mammary Gland Fibroadenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/49 (0%)	1/50 (2%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	0/43.34	1/44.68	2/45.55	3/41.46
POLY-3 PERCENT (g)	0%	2.2%	4.4%	7.2%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	2/34 (6%)	3/31 (10%)
FIRST INCIDENCE	---	709	727 (T)	727 (T)
HC TUMORS SAME ROUTE	5/150 (3%)			
HC TUMORS ALL ROUTES	48/1349 (4%)			
STATISTICAL TESTS				
POLY 3	P=0.080	P=0.506	P=0.248	P=0.111
POLY 1.5	P=0.083	P=0.502	P=0.246	P=0.112
POLY 6	P=0.077	P=0.511	P=0.250	P=0.109
COCH-ARM / FISHERS	P=0.094	P=0.505	P=0.253	P=0.125
MAX-ISO-POLY-3	P=0.063	P=0.165	P=0.086	P=0.038*
HISTCONT SAME RTE	P=0.079	P=0.220	P=0.111	P=0.047*
HISTCONT ALL RTEs	P=0.072	P=0.196	P=0.098	P=0.041*

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Mammary Gland				
Fibroma, Fibroadenoma or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/49 (0%)	1/50 (2%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	0/43.34	1/44.68	2/45.55	3/41.46
POLY-3 PERCENT (g)	0%	2.2%	4.4%	7.2%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	2/34 (6%)	3/31 (10%)
FIRST INCIDENCE	---	709	727 (T)	727 (T)
HC TUMORS SAME ROUTE	5/150 (3%)			
HC TUMORS ALL ROUTES	54/1349 (4%)			
STATISTICAL TESTS				
POLY 3	P=0.080	P=0.506	P=0.248	P=0.111
POLY 1.5	P=0.083	P=0.502	P=0.246	P=0.112
POLY 6	P=0.077	P=0.511	P=0.250	P=0.109
COCH-ARM / FISHERS	P=0.094	P=0.505	P=0.253	P=0.125
MAX-ISO-POLY-3	P=0.063	P=0.165	P=0.086	P=0.038*
HISTCONT SAME RTE	P=0.079	P=0.220	P=0.111	P=0.047*
HISTCONT ALL RTEs	P=0.072	P=0.196	P=0.098	P=0.041*

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Mammary Gland				
Fibroma, Fibroadenoma, Carcinoma, or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/49 (0%)	1/50 (2%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	0/43.34	1/44.68	2/45.55	3/41.46
POLY-3 PERCENT (g)	0%	2.2%	4.4%	7.2%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	2/34 (6%)	3/31 (10%)
FIRST INCIDENCE	---	709	727 (T)	727 (T)
HC TUMORS SAME ROUTE	5/150 (3%)			
HC TUMORS ALL ROUTES	60/1349 (4%)			
STATISTICAL TESTS				
POLY 3	P=0.080	P=0.506	P=0.248	P=0.111
POLY 1.5	P=0.083	P=0.502	P=0.246	P=0.112
POLY 6	P=0.077	P=0.511	P=0.250	P=0.109
COCH-ARM / FISHERS	P=0.094	P=0.505	P=0.253	P=0.125
MAX-ISO-POLY-3	P=0.063	P=0.165	P=0.086	P=0.038*
HISTCONT SAME RTE	P=0.079	P=0.220	P=0.111	P=0.047*
HISTCONT ALL RTEs	P=0.072	P=0.196	P=0.098	P=0.041*

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Pancreas				
Adenoma				
TUMOR RATES				
OVERALL (a)	1/49 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/43.83	0/44.61	1/45.55	0/41.46
POLY-3 PERCENT (g)	2.3%	0%	2.2%	0%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	1/34 (3%)	0/31 (0%)
FIRST INCIDENCE	582	---	727 (T)	---
HC TUMORS SAME ROUTE	10/150 (7%)			
HC TUMORS ALL ROUTES	24/1343 (2%)			
STATISTICAL TESTS				
POLY 3	P=0.476N	P=0.496N	P=0.752N	P=0.511N
POLY 1.5	P=0.472N	P=0.499N	P=0.753N	P=0.508N
POLY 6	P=0.482N	P=0.493N	P=0.752N	P=0.514N
COCH-ARM / FISHERS	P=0.461N	P=0.495N	P=0.747N	P=0.495N
MAX-ISO-POLY-3	P=0.280N	P=0.157N	P=0.488N	P=0.173N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Pituitary Gland: Pars Distalis or Unspecified Site Adenoma				
TUMOR RATES				
OVERALL (a)	21/49 (43%)	20/50 (40%)	15/50 (30%)	8/50 (16%)
POLY-3 RATE (b)	21/46.81	20/45.28	15/46.57	8/42.97
POLY-3 PERCENT (g)	44.9%	44.2%	32.2%	18.6%
TERMINAL (d)	14/34 (41%)	18/35 (51%)	9/34 (27%)	4/31 (13%)
FIRST INCIDENCE	504	525	590	447
HC TUMORS SAME ROUTE	36/150 (24%)			
HC TUMORS ALL ROUTES	620/1344 (46%)			
STATISTICAL TESTS				
POLY 3	P=0.003N**	P=0.557N	P=0.146N	P=0.006N**
POLY 1.5	P=0.002N**	P=0.542N	P=0.140N	P=0.005N**
POLY 6	P=0.003N**	P=0.575N	P=0.154N	P=0.007N**
COCH-ARM / FISHERS	P<0.001N**	P=0.466N	P=0.131N	P=0.003N**
MAX-ISO-POLY-3	P=0.005N**	P=0.472N	P=0.104N	P=0.004N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Pituitary Gland: Pars Distalis or Unspecified Site Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	21/49 (43%)	20/50 (40%)	15/50 (30%)	8/50 (16%)
POLY-3 RATE (b)	21/46.81	20/45.28	15/46.57	8/42.97
POLY-3 PERCENT (g)	44.9%	44.2%	32.2%	18.6%
TERMINAL (d)	14/34 (41%)	18/35 (51%)	9/34 (27%)	4/31 (13%)
FIRST INCIDENCE	504	525	590	447
HC TUMORS SAME ROUTE	36/150 (24%)			
HC TUMORS ALL ROUTES	626/1344 (47%)			
STATISTICAL TESTS				
POLY 3	P=0.003N**	P=0.557N	P=0.146N	P=0.006N**
POLY 1.5	P=0.002N**	P=0.542N	P=0.140N	P=0.005N**
POLY 6	P=0.003N**	P=0.575N	P=0.154N	P=0.007N**
COCH-ARM / FISHERS	P<0.001N**	P=0.466N	P=0.131N	P=0.003N**
MAX-ISO-POLY-3	P=0.005N**	P=0.472N	P=0.104N	P=0.004N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Salivary Glands				
Schwannoma Malignant				
TUMOR RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/43.34	0/44.61	2/46.10	0/41.46
POLY-3 PERCENT (g)	0%	0%	4.3%	0%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	616	---
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	0/1345 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.696N	(e)	P=0.251	(e)
POLY 1.5	P=0.691N	(e)	P=0.247	(e)
POLY 6	P=0.701N	(e)	P=0.255	(e)
COCH-ARM / FISHERS	P=0.673N	(e)	P=0.253	(e)
MAX-ISO-POLY-3	P=0.276	(e)	P=0.088	(e)
HISTCONT SAME RTE	(h)	(e)	(h)	(e)
HISTCONT ALL RTEs	(h)	(e)	(h)	(e)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Skin				
Basal Cell Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	2/49 (4%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/43.34	0/44.61	2/45.79	1/41.93
POLY-3 PERCENT (g)	4.6%	0%	4.4%	2.4%
TERMINAL (d)	2/34 (6%)	0/35 (0%)	1/34 (3%)	0/31 (0%)
FIRST INCIDENCE	727 (T)	---	664	589
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	13/1349 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.609N	P=0.231N	P=0.674N	P=0.512N
POLY 1.5	P=0.603N	P=0.235N	P=0.679N	P=0.510N
POLY 6	P=0.615N	P=0.226N	P=0.670N	P=0.512N
COCH-ARM / FISHERS	P=0.588N	P=0.242N	P=0.684N	P=0.492N
MAX-ISO-POLY-3	P=0.427N	P=0.075N	P=0.477N	P=0.294N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Skin				
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma				
TUMOR RATES	#	#	#	#
OVERALL (a)	2/49 (4%)	0/50 (0%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	2/43.34	0/44.61	3/45.79	1/41.93
POLY-3 PERCENT (g)	4.6%	0%	6.6%	2.4%
TERMINAL (d)	2/34 (6%)	0/35 (0%)	2/34 (6%)	0/31 (0%)
FIRST INCIDENCE	727 (T)	---	664	589
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	18/1349 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.585N	P=0.231N	P=0.525	P=0.512N
POLY 1.5	P=0.579N	P=0.235N	P=0.519	P=0.510N
POLY 6	P=0.593N	P=0.226N	P=0.531	P=0.512N
COCH-ARM / FISHERS	P=0.559N	P=0.242N	P=0.510	P=0.492N
MAX-ISO-POLY-3	P=0.462	P=0.075N	P=0.349	P=0.294N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Skin				
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma				
TUMOR RATES	#	#	#	#
OVERALL (a)	2/49 (4%)	0/50 (0%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	2/43.34	0/44.61	3/45.79	1/41.93
POLY-3 PERCENT (g)	4.6%	0%	6.6%	2.4%
TERMINAL (d)	2/34 (6%)	0/35 (0%)	2/34 (6%)	0/31 (0%)
FIRST INCIDENCE	727 (T)	---	664	589
HC TUMORS SAME ROUTE	2/150 (1%)			
HC TUMORS ALL ROUTES	29/1349 (2%)			
STATISTICAL TESTS				
POLY 3	P=0.585N	P=0.231N	P=0.525	P=0.512N
POLY 1.5	P=0.579N	P=0.235N	P=0.519	P=0.510N
POLY 6	P=0.593N	P=0.226N	P=0.531	P=0.512N
COCH-ARM / FISHERS	P=0.559N	P=0.242N	P=0.510	P=0.492N
MAX-ISO-POLY-3	P=0.462	P=0.075N	P=0.349	P=0.294N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Skin				
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma				
TUMOR RATES	#	#	#	#
OVERALL (a)	2/49 (4%)	0/50 (0%)	5/50 (10%)	1/50 (2%)
POLY-3 RATE (b)	2/43.34	0/44.61	5/45.79	1/41.93
POLY-3 PERCENT (g)	4.6%	0%	10.9%	2.4%
TERMINAL (d)	2/34 (6%)	0/35 (0%)	4/34 (12%)	0/31 (0%)
FIRST INCIDENCE	727 (T)	---	664	589
HC TUMORS SAME ROUTE	14/150 (9%)			
HC TUMORS ALL ROUTES	114/1349 (9%)			
STATISTICAL TESTS				
POLY 3	P=0.549N	P=0.231N	P=0.239	P=0.512N
POLY 1.5	P=0.541N	P=0.235N	P=0.233	P=0.510N
POLY 6	P=0.558N	P=0.226N	P=0.244	P=0.512N
COCH-ARM / FISHERS	P=0.513N	P=0.242N	P=0.226	P=0.492N
MAX-ISO-POLY-3	P=0.263	P=0.075N	P=0.140	P=0.294N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Skin				
Fibroma				
TUMOR RATES	#	#	#	#
OVERALL (a)	7/49 (14%)	5/50 (10%)	7/50 (14%)	2/50 (4%)
POLY-3 RATE (b)	7/43.41	5/44.72	7/46.45	2/42.40
POLY-3 PERCENT (g)	16.1%	11.2%	15.1%	4.7%
TERMINAL (d)	6/34 (18%)	4/35 (11%)	4/34 (12%)	0/31 (0%)
FIRST INCIDENCE	709	700	608	454
HC TUMORS SAME ROUTE	11/150 (7%)			
HC TUMORS ALL ROUTES	118/1349 (9%)			
STATISTICAL TESTS				
POLY 3	P=0.089N	P=0.358N	P=0.561N	P=0.083N
POLY 1.5	P=0.087N	P=0.371N	P=0.576N	P=0.084N
POLY 6	P=0.092N	P=0.341N	P=0.544N	P=0.082N
COCH-ARM / FISHERS	P=0.075N	P=0.365N	P=0.597N	P=0.075N
MAX-ISO-POLY-3	P=0.090N	P=0.253N	P=0.445N	P=0.043N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Skin				
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	7/49 (14%)	6/50 (12%)	7/50 (14%)	2/50 (4%)
POLY-3 RATE (b)	7/43.41	6/45.23	7/46.45	2/42.40
POLY-3 PERCENT (g)	16.1%	13.3%	15.1%	4.7%
TERMINAL (d)	6/34 (18%)	4/35 (11%)	4/34 (12%)	0/31 (0%)
FIRST INCIDENCE	709	571	608	454
HC TUMORS SAME ROUTE	14/150 (9%)			
HC TUMORS ALL ROUTES	147/1349 (11%)			
STATISTICAL TESTS				
POLY 3	P=0.073N	P=0.468N	P=0.561N	P=0.083N
POLY 1.5	P=0.071N	P=0.486N	P=0.576N	P=0.084N
POLY 6	P=0.076N	P=0.446N	P=0.544N	P=0.082N
COCH-ARM / FISHERS	P=0.060N	P=0.484N	P=0.597N	P=0.075N
MAX-ISO-POLY-3	P=0.096N	P=0.354N	P=0.445N	P=0.043N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Skin				
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/49 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/43.34	0/44.61	2/45.55	0/41.46
POLY-3 PERCENT (g)	0%	0%	4.4%	0%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	2/34 (6%)	0/31 (0%)
FIRST INCIDENCE	---	---	727 (T)	---
HC TUMORS SAME ROUTE	12/150 (8%)			
HC TUMORS ALL ROUTES	89/1349 (7%)			
STATISTICAL TESTS				
POLY 3	P=0.696N	(e)	P=0.248	(e)
POLY 1.5	P=0.691N	(e)	P=0.246	(e)
POLY 6	P=0.702N	(e)	P=0.250	(e)
COCH-ARM / FISHERS	P=0.673N	(e)	P=0.253	(e)
MAX-ISO-POLY-3	P=0.273	(e)	P=0.086	(e)
HISTCONT SAME RTE	(h)	(e)	(h)	(e)
HISTCONT ALL RTEs	(h)	(e)	(h)	(e)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Testes				
Adenoma				
TUMOR RATES				
OVERALL (a)	37/49 (76%)	44/50 (88%)	49/50 (98%)	46/50 (92%)
POLY-3 RATE (b)	37/46.15	44/47.39	49/49.87	46/46.47
POLY-3 PERCENT (g)	80.2%	92.9%	98.3%	99%
TERMINAL (d)	28/34 (82%)	32/35 (91%)	34/34 (100%)	31/31 (100%)
FIRST INCIDENCE	545	571	454	454
HC TUMORS SAME ROUTE	139/150 (93%)			
HC TUMORS ALL ROUTES	1123/1349 (83%)			
STATISTICAL TESTS				
POLY 3	P=0.003**	P=0.056	P=0.002**	P<0.001**
POLY 1.5	P=0.004**	P=0.043*	P<0.001**	P=0.002**
POLY 6	P=0.004**	P=0.087	P=0.005**	P=0.002**
COCH-ARM / FISHERS	P=0.053	P=0.088	P<0.001**	P=0.024*
MAX-ISO-POLY-3	P<0.001**	P=0.029*	P<0.001**	P<0.001**
HISTCONT SAME RTE	P<0.001**	P=0.034*	P<0.001**	P<0.001**
HISTCONT ALL RTEs	P<0.001**	P=0.029*	P<0.001**	P<0.001**

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Thyroid Gland: C-Cell Adenoma				
TUMOR RATES				
OVERALL (a)	8/49 (16%)	9/50 (18%)	8/50 (16%)	2/50 (4%)
POLY-3 RATE (b)	8/44.20	9/44.87	8/45.69	2/41.46
POLY-3 PERCENT (g)	18.1%	20.1%	17.5%	4.8%
TERMINAL (d)	6/34 (18%)	7/35 (20%)	7/34 (21%)	2/31 (7%)
FIRST INCIDENCE	545	673	694	727 (T)
HC TUMORS SAME ROUTE	29/150 (19%)			
HC TUMORS ALL ROUTES	167/1342 (12%)			
STATISTICAL TESTS				
POLY 3	P=0.030N*	P=0.514	P=0.580N	P=0.055N
POLY 1.5	P=0.028N*	P=0.503	P=0.583N	P=0.053N
POLY 6	P=0.034N*	P=0.528	P=0.581N	P=0.059N
COCH-ARM / FISHERS	P=0.021N*	P=0.518	P=0.590N	P=0.043N*
MAX-ISO-POLY-3	P=0.049N*	P=0.405	P=0.470N	P=0.031N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Thyroid Gland: C-Cell Carcinoma				
TUMOR RATES				
OVERALL (a)	0/49 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/43.34	0/44.61	2/45.63	0/41.46
POLY-3 PERCENT (g)	0%	0%	4.4%	0%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	1/34 (3%)	0/31 (0%)
FIRST INCIDENCE	---	---	709	---
HC TUMORS SAME ROUTE	6/150 (4%)			
HC TUMORS ALL ROUTES	41/1342 (3%)			
STATISTICAL TESTS				
POLY 3	P=0.696N	(e)	P=0.249	(e)
POLY 1.5	P=0.691N	(e)	P=0.246	(e)
POLY 6	P=0.702N	(e)	P=0.251	(e)
COCH-ARM / FISHERS	P=0.673N	(e)	P=0.253	(e)
MAX-ISO-POLY-3	P=0.274	(e)	P=0.086	(e)
HISTCONT SAME RTE	(h)	(e)	(h)	(e)
HISTCONT ALL RTEs	(h)	(e)	(h)	(e)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Thyroid Gland: C-Cell Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	8/49 (16%)	9/50 (18%)	9/50 (18%)	2/50 (4%)
POLY-3 RATE (b)	8/44.20	9/44.87	9/45.76	2/41.46
POLY-3 PERCENT (g)	18.1%	20.1%	19.7%	4.8%
TERMINAL (d)	6/34 (18%)	7/35 (20%)	7/34 (21%)	2/31 (7%)
FIRST INCIDENCE	545	673	694	727 (T)
HC TUMORS SAME ROUTE	35/150 (23%)			
HC TUMORS ALL ROUTES	206/1342 (15%)			
STATISTICAL TESTS				
POLY 3	P=0.031N*	P=0.514	P=0.531	P=0.055N
POLY 1.5	P=0.028N*	P=0.503	P=0.527	P=0.053N
POLY 6	P=0.035N*	P=0.528	P=0.532	P=0.059N
COCH-ARM / FISHERS	P=0.021N*	P=0.518	P=0.518	P=0.043N*
MAX-ISO-POLY-3	P=0.050N*	P=0.405	P=0.424	P=0.031N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Thyroid Gland: Follicular Cell Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	1/49 (2%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/43.34	0/44.61	2/46.10	0/41.46
POLY-3 PERCENT (g)	2.3%	0%	4.3%	0%
TERMINAL (d)	1/34 (3%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	727 (T)	---	598	---
HC TUMORS SAME ROUTE	5/150 (3%)			
HC TUMORS ALL ROUTES	25/1342 (2%)			
STATISTICAL TESTS				
POLY 3	P=0.462N	P=0.494N	P=0.522	P=0.509N
POLY 1.5	P=0.455N	P=0.498N	P=0.516	P=0.507N
POLY 6	P=0.469N	P=0.490N	P=0.527	P=0.510N
COCH-ARM / FISHERS	P=0.438N	P=0.495N	P=0.508	P=0.495N
MAX-ISO-POLY-3	P=0.351N	P=0.157N	P=0.303	P=0.171N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
All Organs				
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated				
TUMOR RATES	#	#	#	#
OVERALL (a)	7/49 (14%)	8/50 (16%)	7/50 (14%)	11/50 (22%)
POLY-3 RATE (b)	7/44.18	8/45.34	7/46.12	11/41.97
POLY-3 PERCENT (g)	15.8%	17.7%	15.2%	26.2%
TERMINAL (d)	4/34 (12%)	5/35 (14%)	5/34 (15%)	8/31 (26%)
FIRST INCIDENCE	610	615	590	665
HC TUMORS SAME ROUTE	23/150 (15%)			
HC TUMORS ALL ROUTES	529/1349 (39%)			
STATISTICAL TESTS				
POLY 3	P=0.125	P=0.522	P=0.580N	P=0.179
POLY 1.5	P=0.136	P=0.508	P=0.586N	P=0.188
POLY 6	P=0.114	P=0.539	P=0.579N	P=0.169
COCH-ARM / FISHERS	P=0.172	P=0.517	P=0.597N	P=0.232
MAX-ISO-POLY-3	P=0.191	P=0.409	P=0.465N	P=0.125
HISTCONT SAME RTE	P=0.234	P=0.544	P=1.000	P=0.165
HISTCONT ALL RTEs	P=0.222	P=0.520	P=1.000	P=0.146

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
All Organs				
Mesothelioma: Benign, Malignant, NOS				
TUMOR RATES	#	#	#	#
OVERALL (a)	3/49 (6%)	4/50 (8%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	3/43.54	4/45.44	1/45.55	3/41.46
POLY-3 PERCENT (g)	6.9%	8.8%	2.2%	7.2%
TERMINAL (d)	2/34 (6%)	1/35 (3%)	1/34 (3%)	3/31 (10%)
FIRST INCIDENCE	675	571	727 (T)	727 (T)
HC TUMORS SAME ROUTE	7/150 (5%)			
HC TUMORS ALL ROUTES	33/1349 (2%)			
STATISTICAL TESTS				
POLY 3	P=0.591N	P=0.523	P=0.289N	P=0.640
POLY 1.5	P=0.583N	P=0.510	P=0.292N	P=0.645
POLY 6	P=0.599N	P=0.540	P=0.287N	P=0.635
COCH-ARM / FISHERS	P=0.557N	P=0.511	P=0.301N	P=0.651N
MAX-ISO-POLY-3	P=0.445N	P=0.371	P=0.147N	P=0.475
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
All Organs				
Mesothelioma: Malignant				
TUMOR RATES	#	#	#	#
OVERALL (a)	3/49 (6%)	4/50 (8%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	3/43.54	4/45.44	1/45.55	3/41.46
POLY-3 PERCENT (g)	6.9%	8.8%	2.2%	7.2%
TERMINAL (d)	2/34 (6%)	1/35 (3%)	1/34 (3%)	3/31 (10%)
FIRST INCIDENCE	675	571	727 (T)	727 (T)
HC TUMORS SAME ROUTE	7/150 (5%)			
HC TUMORS ALL ROUTES	32/1349 (2%)			
STATISTICAL TESTS				
POLY 3	P=0.591N	P=0.523	P=0.289N	P=0.640
POLY 1.5	P=0.583N	P=0.510	P=0.292N	P=0.645
POLY 6	P=0.599N	P=0.540	P=0.287N	P=0.635
COCH-ARM / FISHERS	P=0.557N	P=0.511	P=0.301N	P=0.651N
MAX-ISO-POLY-3	P=0.445N	P=0.371	P=0.147N	P=0.475
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
All Organs				
Osteosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/49 (2%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/43.50	2/44.68	1/45.65	0/41.46
POLY-3 PERCENT (g)	2.3%	4.5%	2.2%	0%
TERMINAL (d)	0/34 (0%)	1/35 (3%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	686	709	702	---
HC TUMORS SAME ROUTE	3/150 (2%)			
HC TUMORS ALL ROUTES	13/1349 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.253N	P=0.509	P=0.750N	P=0.510N
POLY 1.5	P=0.250N	P=0.504	P=0.752N	P=0.508N
POLY 6	P=0.256N	P=0.516	P=0.748N	P=0.512N
COCH-ARM / FISHERS	P=0.236N	P=0.508	P=0.747N	P=0.495N
MAX-ISO-POLY-3	P=0.257N	P=0.290	P=0.486N	P=0.172N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
All Organs				
Osteosarcoma or Osteoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/49 (2%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/43.50	2/44.68	1/45.65	0/41.46
POLY-3 PERCENT (g)	2.3%	4.5%	2.2%	0%
TERMINAL (d)	0/34 (0%)	1/35 (3%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	686	709	702	---
HC TUMORS SAME ROUTE	3/150 (2%)			
HC TUMORS ALL ROUTES	14/1349 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.253N	P=0.509	P=0.750N	P=0.510N
POLY 1.5	P=0.250N	P=0.504	P=0.752N	P=0.508N
POLY 6	P=0.256N	P=0.516	P=0.748N	P=0.512N
COCH-ARM / FISHERS	P=0.236N	P=0.508	P=0.747N	P=0.495N
MAX-ISO-POLY-3	P=0.257N	P=0.290	P=0.486N	P=0.172N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
All Organs				
Benign Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	49/49 (100%)	48/50 (96%)	50/50 (100%)	47/50 (94%)
POLY-3 RATE (b)	49/49.00	48/48.01	50/50.00	47/47.24
POLY-3 PERCENT (g)	100%	100%	100%	99.5%
TERMINAL (d)	34/34 (100%)	35/35 (100%)	34/34 (100%)	31/31 (100%)
FIRST INCIDENCE	504	525	454	447
HC TUMORS SAME ROUTE	145/150 (97%)			
HC TUMORS ALL ROUTES	1301/1349 (96%)			
STATISTICAL TESTS				
POLY 3	P=0.980N	P=1.000N	(e)	P=0.999N
POLY 1.5	P=0.603N	P=1.000N	(e)	P=0.843N
POLY 6	P=1.000N	P=1.000N	(e)	P=1.000N
COCH-ARM / FISHERS	P=0.103N	P=0.253N	(e)	P=0.125N
MAX-ISO-POLY-3	P=0.129N	P=0.161N	(e)	P=0.162N
HISTCONT SAME RTE	(h)	(h)	(e)	(h)
HISTCONT ALL RTEs	(h)	(h)	(e)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
All Organs				
Malignant Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	17/49 (35%)	23/50 (46%)	20/50 (40%)	17/50 (34%)
POLY-3 RATE (b)	17/45.94	23/48.70	20/47.90	17/43.68
POLY-3 PERCENT (g)	37%	47.2%	41.8%	38.9%
TERMINAL (d)	8/34 (24%)	10/35 (29%)	11/34 (32%)	10/31 (32%)
FIRST INCIDENCE	545	168	590	451
HC TUMORS SAME ROUTE	62/150 (41%)			
HC TUMORS ALL ROUTES	767/1349 (57%)			
STATISTICAL TESTS				
POLY 3	P=0.442N	P=0.212	P=0.398	P=0.512
POLY 1.5	P=0.405N	P=0.187	P=0.387	P=0.530
POLY 6	P=0.489N	P=0.242	P=0.401	P=0.487
COCH-ARM / FISHERS	P=0.296N	P=0.173	P=0.368	P=0.555N
MAX-ISO-POLY-3	P=0.477	P=0.163	P=0.321	P=0.426
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
All Organs				
Malignant and Benign Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	49/49 (100%)	49/50 (98%)	50/50 (100%)	48/50 (96%)
POLY-3 RATE (b)	49/49.00	49/49.00	50/50.00	48/48.00
POLY-3 PERCENT (g)	100%	100%	100%	100%
TERMINAL (d)	34/34 (100%)	35/35 (100%)	34/34 (100%)	31/31 (100%)
FIRST INCIDENCE	504	168	454	447
HC TUMORS SAME ROUTE	147/150 (98%)			
HC TUMORS ALL ROUTES	1339/1349 (99%)			
STATISTICAL TESTS				
POLY 3	P=1.000N	P=1.000N	(e)	P=1.000N
POLY 1.5	P=1.000N	P=1.000N	(e)	P=1.000N
POLY 6	P=0.150N	P=0.505N	(e)	P=0.253N
COCH-ARM / FISHERS	P=0.150N	P=0.505N	(e)	P=0.253N
MAX-ISO-POLY-3	P=0.263N	P=0.163N	(e)	P=0.162N
HISTCONT SAME RTE	(h)	(h)	(e)	(h)
HISTCONT ALL RTEs	(h)	(h)	(e)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Adrenal Medulla				
Pheochromocytoma Benign				
TUMOR RATES				
OVERALL (a)	3/50 (6%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	3/44.11	1/44.40	1/40.83	1/41.52
POLY-3 PERCENT (g)	6.8%	2.3%	2.5%	2.4%
TERMINAL (d)	2/34 (6%)	1/34 (3%)	0/24 (0%)	1/34 (3%)
FIRST INCIDENCE	701	728 (T)	519	728 (T)
HC TUMORS SAME ROUTE	6/150 (4%)			
HC TUMORS ALL ROUTES	34/1288 (3%)			
STATISTICAL TESTS				
POLY 3	P=0.371N	P=0.303N	P=0.333N	P=0.327N
POLY 1.5	P=0.369N	P=0.306N	P=0.319N	P=0.325N
POLY 6	P=0.368N	P=0.302N	P=0.356N	P=0.324N
COCH-ARM / FISHERS	P=0.355N	P=0.309N	P=0.309N	P=0.309N
MAX-ISO-POLY-3	P=0.228N	P=0.153N	P=0.182N	P=0.177N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Adrenal Medulla				
Pheochromocytoma Malignant				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	1/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	0%	2.3%	0%	0%
TERMINAL (d)	0/34 (0%)	1/34 (3%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	728 (T)	---	---
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	8/1288 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.601N	P=0.502	(e)	(e)
POLY 1.5	P=0.603N	P=0.500	(e)	(e)
POLY 6	P=0.597N	P=0.503	(e)	(e)
COCH-ARM / FISHERS	P=0.601N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.409N	P=0.161	(e)	(e)
HISTCONT SAME RTE	(h)	(h)	(e)	(e)
HISTCONT ALL RTEs	(h)	(h)	(e)	(e)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Adrenal Medulla				
Pheochromocytoma: Benign, Complex, Malignant, NOS				
TUMOR RATES				
OVERALL (a)	3/50 (6%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	3/44.11	2/44.40	1/40.83	1/41.52
POLY-3 PERCENT (g)	6.8%	4.5%	2.5%	2.4%
TERMINAL (d)	2/34 (6%)	2/34 (6%)	0/24 (0%)	1/34 (3%)
FIRST INCIDENCE	701	728 (T)	519	728 (T)
HC TUMORS SAME ROUTE	6/150 (4%)			
HC TUMORS ALL ROUTES	46/1288 (4%)			
STATISTICAL TESTS				
POLY 3	P=0.293N	P=0.497N	P=0.333N	P=0.327N
POLY 1.5	P=0.292N	P=0.501N	P=0.319N	P=0.325N
POLY 6	P=0.289N	P=0.496N	P=0.356N	P=0.324N
COCH-ARM / FISHERS	P=0.277N	P=0.500N	P=0.309N	P=0.309N
MAX-ISO-POLY-3	P=0.262N	P=0.321N	P=0.182N	P=0.177N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Bone				
Osteosarcoma or Osteoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	2/40.29	0/41.52
POLY-3 PERCENT (g)	0%	0%	5%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/24 (4%)	0/34 (0%)
FIRST INCIDENCE	---	---	702	---
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	5/1300 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.698N	(e)	P=0.218	(e)
POLY 1.5	P=0.694N	(e)	P=0.227	(e)
POLY 6	P=0.696N	(e)	P=0.205	(e)
COCH-ARM / FISHERS	P=0.675N	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.248	(e)	P=0.075	(e)
HISTCONT SAME RTE	(h)	(e)	(h)	(e)
HISTCONT ALL RTEs	(h)	(e)	(h)	(e)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Clitoral/Preputial Gland Adenoma				
TUMOR RATES				
OVERALL (a)	2/50 (4%)	7/49 (14%)	3/50 (6%)	1/49 (2%)
POLY-3 RATE (b)	2/44.00	7/43.90	3/40.34	1/41.53
POLY-3 PERCENT (g)	4.6%	15.9%	7.4%	2.4%
TERMINAL (d)	2/34 (6%)	6/34 (18%)	2/24 (8%)	0/34 (0%)
FIRST INCIDENCE	728 (T)	701	688	688
HC TUMORS SAME ROUTE	13/148 (9%)			
HC TUMORS ALL ROUTES	123/1297 (10%)			
STATISTICAL TESTS				
POLY 3	P=0.130N	P=0.077	P=0.460	P=0.520N
POLY 1.5	P=0.132N	P=0.075	P=0.479	P=0.521N
POLY 6	P=0.122N	P=0.079	P=0.432	P=0.514N
COCH-ARM / FISHERS	P=0.123N	P=0.075	P=0.500	P=0.508N
MAX-ISO-POLY-3	P=0.144N	P=0.038*	P=0.297	P=0.302N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Clitoral/Preputial Gland Carcinoma				
TUMOR RATES				
OVERALL (a)	2/50 (4%)	1/49 (2%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	2/44.50	1/43.80	0/40.19	0/41.37
POLY-3 PERCENT (g)	4.5%	2.3%	0%	0%
TERMINAL (d)	0/34 (0%)	1/34 (3%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	615	728 (T)	---	---
HC TUMORS SAME ROUTE	2/148 (1%)			
HC TUMORS ALL ROUTES	35/1297 (3%)			
STATISTICAL TESTS				
POLY 3	P=0.190N	P=0.506N	P=0.260N	P=0.254N
POLY 1.5	P=0.190N	P=0.508N	P=0.249N	P=0.253N
POLY 6	P=0.187N	P=0.505N	P=0.279N	P=0.252N
COCH-ARM / FISHERS	P=0.187N	P=0.508N	P=0.247N	P=0.253N
MAX-ISO-POLY-3	P=0.100N	P=0.286N	P=0.098N	P=0.091N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Clitoral/Preputial Gland Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	4/50 (8%)	8/49 (16%)	3/50 (6%)	1/49 (2%)
POLY-3 RATE (b)	4/44.50	8/43.90	3/40.34	1/41.53
POLY-3 PERCENT (g)	9%	18.2%	7.4%	2.4%
TERMINAL (d)	2/34 (6%)	7/34 (21%)	2/24 (8%)	0/34 (0%)
FIRST INCIDENCE	615	701	688	688
HC TUMORS SAME ROUTE	15/148 (10%)			
HC TUMORS ALL ROUTES	158/1297 (12%)			
STATISTICAL TESTS				
POLY 3	P=0.050N*	P=0.169	P=0.553N	P=0.200N
POLY 1.5	P=0.050N*	P=0.166	P=0.528N	P=0.199N
POLY 6	P=0.047N*	P=0.169	P=0.592N	P=0.197N
COCH-ARM / FISHERS	P=0.046N*	P=0.168	P=0.500N	P=0.187N
MAX-ISO-POLY-3	P=0.065N	P=0.102	P=0.401N	P=0.103N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Ear				
Neural Crest Tumor				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/44.00	0/44.40	0/40.19	1/41.52
POLY-3 PERCENT (g)	2.3%	0%	0%	2.4%
TERMINAL (d)	1/34 (3%)	0/34 (0%)	0/24 (0%)	1/34 (3%)
FIRST INCIDENCE	728 (T)	---	---	728 (T)
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	0/1300 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.524	P=0.498N	P=0.518N	P=0.748
POLY 1.5	P=0.526	P=0.500N	P=0.509N	P=0.749
POLY 6	P=0.525	P=0.497N	P=0.531N	P=0.750
COCH-ARM / FISHERS	P=0.536	P=0.500N	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.403	P=0.158N	P=0.180N	P=0.483
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Islets, Pancreatic Adenoma				
TUMOR RATES				
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.00	1/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	2.3%	2.3%	0%	0%
TERMINAL (d)	1/34 (3%)	1/34 (3%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	---	---
HC TUMORS SAME ROUTE	2/150 (1%)			
HC TUMORS ALL ROUTES	22/1290 (2%)			
STATISTICAL TESTS				
POLY 3	P=0.328N	P=0.759N	P=0.518N	P=0.512N
POLY 1.5	P=0.329N	P=0.761	P=0.509N	P=0.511N
POLY 6	P=0.325N	P=0.758N	P=0.531N	P=0.510N
COCH-ARM / FISHERS	P=0.325N	P=0.753N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.280N	P=0.497N	P=0.180N	P=0.173N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lung				
Alveolar/Bronchiolar Adenoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/44.00	0/44.40	1/40.19	1/41.52
POLY-3 PERCENT (g)	0%	0%	2.5%	2.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/24 (4%)	1/34 (3%)
FIRST INCIDENCE	---	---	728 (T)	728 (T)
HC TUMORS SAME ROUTE	7/150 (5%)			
HC TUMORS ALL ROUTES	24/1300 (2%)			
STATISTICAL TESTS				
POLY 3	P=0.304	(e)	P=0.482	P=0.488
POLY 1.5	P=0.308	(e)	P=0.491	P=0.489
POLY 6	P=0.306	(e)	P=0.469	P=0.490
COCH-ARM / FISHERS	P=0.325	(e)	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.251	(e)	P=0.158	P=0.158
HISTCONT SAME RTE	P=0.318	(e)	P=0.211	P=0.211
HISTCONT ALL RTEs	P=0.291	(e)	P=0.188	P=0.188

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Lung				
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/44.00	0/44.40	1/40.19	2/41.52
POLY-3 PERCENT (g)	0%	0%	2.5%	4.8%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/24 (4%)	2/34 (6%)
FIRST INCIDENCE	---	---	728 (T)	728 (T)
HC TUMORS SAME ROUTE	7/150 (5%)			
HC TUMORS ALL ROUTES	30/1300 (2%)			
STATISTICAL TESTS				
POLY 3	P=0.081	(e)	P=0.482	P=0.224
POLY 1.5	P=0.082	(e)	P=0.491	P=0.225
POLY 6	P=0.081	(e)	P=0.469	P=0.226
COCH-ARM / FISHERS	P=0.090	(e)	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.080	(e)	P=0.158	P=0.076
HISTCONT SAME RTE	P=0.100	(e)	P=0.211	P=0.098
HISTCONT ALL RTEs	P=0.091	(e)	P=0.188	P=0.086

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Mammary Gland Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.00	1/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	4.6%	2.3%	0%	0%
TERMINAL (d)	2/34 (6%)	1/34 (3%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	---	---
HC TUMORS SAME ROUTE	2/150 (1%)			
HC TUMORS ALL ROUTES	18/1300 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.189N	P=0.497N	P=0.258N	P=0.250N
POLY 1.5	P=0.189N	P=0.500N	P=0.248N	P=0.249N
POLY 6	P=0.187N	P=0.495N	P=0.274N	P=0.248N
COCH-ARM / FISHERS	P=0.186N	P=0.500N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.096N	P=0.279N	P=0.095N	P=0.089N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Mammary Gland Carcinoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	3/50 (6%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/44.14	3/44.40	1/40.19	0/41.52
POLY-3 PERCENT (g)	2.3%	6.8%	2.5%	0%
TERMINAL (d)	0/34 (0%)	3/34 (9%)	1/24 (4%)	0/34 (0%)
FIRST INCIDENCE	693	728 (T)	728 (T)	---
HC TUMORS SAME ROUTE	4/150 (3%)			
HC TUMORS ALL ROUTES	73/1300 (6%)			
STATISTICAL TESTS				
POLY 3	P=0.188N	P=0.307	P=0.740	P=0.512N
POLY 1.5	P=0.188N	P=0.305	P=0.750	P=0.511N
POLY 6	P=0.185N	P=0.308	P=0.723	P=0.511N
COCH-ARM / FISHERS	P=0.177N	P=0.309	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.185N	P=0.156	P=0.473	P=0.174N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Mammary Gland Carcinoma or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	3/50 (6%)	3/50 (6%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	3/44.14	3/44.40	1/40.19	0/41.52
POLY-3 PERCENT (g)	6.8%	6.8%	2.5%	0%
TERMINAL (d)	2/34 (6%)	3/34 (9%)	1/24 (4%)	0/34 (0%)
FIRST INCIDENCE	693	728 (T)	728 (T)	---
HC TUMORS SAME ROUTE	6/150 (4%)			
HC TUMORS ALL ROUTES	91/1300 (7%)			
STATISTICAL TESTS				
POLY 3	P=0.075N	P=0.660N	P=0.339N	P=0.130N
POLY 1.5	P=0.075N	P=0.661	P=0.323N	P=0.129N
POLY 6	P=0.073N	P=0.659N	P=0.366N	P=0.128N
COCH-ARM / FISHERS	P=0.070N	P=0.661N	P=0.309N	P=0.121N
MAX-ISO-POLY-3	P=0.099N	P=0.496N	P=0.188N	P=0.047N*
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Mammary Gland Fibroadenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	24/50 (48%)	24/50 (48%)	15/50 (30%)	4/50 (8%)
POLY-3 RATE (b)	24/45.32	24/45.65	15/41.99	4/41.67
POLY-3 PERCENT (g)	53%	52.6%	35.7%	9.6%
TERMINAL (d)	20/34 (59%)	19/34 (56%)	8/24 (33%)	3/34 (9%)
FIRST INCIDENCE	450	615	615	688
HC TUMORS SAME ROUTE	64/150 (43%)			
HC TUMORS ALL ROUTES	677/1300 (52%)			
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.570N	P=0.075N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.577	P=0.061N	P<0.001N**
POLY 6	P<0.001N**	P=0.551N	P=0.099N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.579N	P=0.050N*	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.485N	P=0.054N	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Mammary Gland				
Fibroma, Fibroadenoma or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	25/50 (50%)	24/50 (48%)	15/50 (30%)	4/50 (8%)
POLY-3 RATE (b)	25/45.32	24/45.65	15/41.99	4/41.67
POLY-3 PERCENT (g)	55.2%	52.6%	35.7%	9.6%
TERMINAL (d)	21/34 (62%)	19/34 (56%)	8/24 (33%)	3/34 (9%)
FIRST INCIDENCE	450	615	615	688
HC TUMORS SAME ROUTE	65/150 (43%)			
HC TUMORS ALL ROUTES	686/1300 (53%)			
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.485N	P=0.048N*	P<0.001N**
POLY 1.5	P<0.001N**	P=0.506N	P=0.039N*	P<0.001N**
POLY 6	P<0.001N**	P=0.463N	P=0.065N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.500N	P=0.033N*	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.399N	P=0.035N*	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Mammary Gland				
Fibroma, Fibroadenoma, Carcinoma, or Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	26/50 (52%)	25/50 (50%)	16/50 (32%)	4/50 (8%)
POLY-3 RATE (b)	26/45.46	25/45.65	16/41.99	4/41.67
POLY-3 PERCENT (g)	57.2%	54.8%	38.1%	9.6%
TERMINAL (d)	21/34 (62%)	20/34 (59%)	9/24 (38%)	3/34 (9%)
FIRST INCIDENCE	450	615	615	688
HC TUMORS SAME ROUTE	67/150 (45%)			
HC TUMORS ALL ROUTES	722/1300 (56%)			
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.491N	P=0.052N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.509N	P=0.041N*	P<0.001N**
POLY 6	P<0.001N**	P=0.475N	P=0.073N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.500N	P=0.034N*	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.405N	P=0.037N*	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Pancreas				
Adenoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	2/40.19	0/41.52
POLY-3 PERCENT (g)	0%	0%	5%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	2/24 (8%)	0/34 (0%)
FIRST INCIDENCE	---	---	728 (T)	---
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	1/1291 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.698N	(e)	P=0.217	(e)
POLY 1.5	P=0.694N	(e)	P=0.227	(e)
POLY 6	P=0.696N	(e)	P=0.204	(e)
COCH-ARM / FISHERS	P=0.675N	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.247	(e)	P=0.075	(e)
HISTCONT SAME RTE	(h)	(e)	(h)	(e)
HISTCONT ALL RTEs	(h)	(e)	(h)	(e)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Pituitary Gland: Pars Distalis or Unspecified Site Adenoma				
TUMOR RATES				
OVERALL (a)	29/50 (58%)	20/50 (40%)	24/50 (48%)	8/50 (16%)
POLY-3 RATE (b)	29/46.03	20/45.74	24/44.06	8/41.91
POLY-3 PERCENT (g)	63%	43.7%	54.5%	19.1%
TERMINAL (d)	20/34 (59%)	15/34 (44%)	12/24 (50%)	6/34 (18%)
FIRST INCIDENCE	615	558	518	664
HC TUMORS SAME ROUTE	77/150 (51%)			
HC TUMORS ALL ROUTES	715/1294 (55%)			
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.046N*	P=0.267N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.050N*	P=0.233N	P<0.001N**
POLY 6	P<0.001N**	P=0.049N*	P=0.333N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.055N	P=0.212N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.029N*	P=0.206N	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Pituitary Gland: Pars Distalis or Unspecified Site Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	30/50 (60%)	20/50 (40%)	24/50 (48%)	8/50 (16%)
POLY-3 RATE (b)	30/46.03	20/45.74	24/44.06	8/41.91
POLY-3 PERCENT (g)	65.2%	43.7%	54.5%	19.1%
TERMINAL (d)	21/34 (62%)	15/34 (44%)	12/24 (50%)	6/34 (18%)
FIRST INCIDENCE	615	558	518	664
HC TUMORS SAME ROUTE	77/150 (51%)			
HC TUMORS ALL ROUTES	728/1294 (56%)			
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.028N*	P=0.200N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.031N*	P=0.172N	P<0.001N**
POLY 6	P<0.001N**	P=0.029N*	P=0.256N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.036N*	P=0.158N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.017N*	P=0.148N	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Salivary Glands				
Schwannoma Malignant				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	0/149 (0%)			
HC TUMORS ALL ROUTES	0/1299 (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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Skin				
Basal Cell Adenoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	1/150 (1%)			
HC TUMORS ALL ROUTES	3/1300 (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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Skin				
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	1/150 (1%)			
HC TUMORS ALL ROUTES	8/1300 (1%)			
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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Skin				
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	1/150 (1%)			
HC TUMORS ALL ROUTES	9/1300 (1%)			
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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Skin				
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	2/150 (1%)			
HC TUMORS ALL ROUTES	24/1300 (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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Skin				
Fibroma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/44.09	0/44.40	1/40.19	0/41.52
POLY-3 PERCENT (g)	2.3%	0%	2.5%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/24 (4%)	0/34 (0%)
FIRST INCIDENCE	705	---	728 (T)	---
HC TUMORS SAME ROUTE	5/150 (3%)			
HC TUMORS ALL ROUTES	24/1300 (2%)			
STATISTICAL TESTS				
POLY 3	P=0.476N	P=0.499N	P=0.740	P=0.512N
POLY 1.5	P=0.474N	P=0.500N	P=0.750	P=0.511N
POLY 6	P=0.475N	P=0.498N	P=0.724	P=0.510N
COCH-ARM / FISHERS	P=0.464N	P=0.500N	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.281N	P=0.158N	P=0.474	P=0.173N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Skin				
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/44.09	0/44.40	1/40.19	0/41.52
POLY-3 PERCENT (g)	2.3%	0%	2.5%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/24 (4%)	0/34 (0%)
FIRST INCIDENCE	705	---	728 (T)	---
HC TUMORS SAME ROUTE	6/150 (4%)			
HC TUMORS ALL ROUTES	31/1300 (2%)			
STATISTICAL TESTS				
POLY 3	P=0.476N	P=0.499N	P=0.740	P=0.512N
POLY 1.5	P=0.474N	P=0.500N	P=0.750	P=0.511N
POLY 6	P=0.475N	P=0.498N	P=0.724	P=0.510N
COCH-ARM / FISHERS	P=0.464N	P=0.500N	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.281N	P=0.158N	P=0.474	P=0.173N
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Skin				
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	1/150 (1%)			
HC TUMORS ALL ROUTES	16/1300 (1%)			
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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Thyroid Gland: C-Cell Adenoma				
TUMOR RATES				
OVERALL (a)	5/50 (10%)	6/50 (12%)	5/50 (10%)	5/50 (10%)
POLY-3 RATE (b)	5/44.00	6/44.40	5/40.73	5/41.52
POLY-3 PERCENT (g)	11.4%	13.5%	12.3%	12%
TERMINAL (d)	5/34 (15%)	6/34 (18%)	3/24 (13%)	5/34 (15%)
FIRST INCIDENCE	728 (T)	728 (T)	647	728 (T)
HC TUMORS SAME ROUTE	20/150 (13%)			
HC TUMORS ALL ROUTES	136/1288 (11%)			
STATISTICAL TESTS				
POLY 3	P=0.567N	P=0.506	P=0.581	P=0.594
POLY 1.5	P=0.562N	P=0.500	P=0.605	P=0.596
POLY 6	P=0.559N	P=0.510	P=0.546	P=0.601
COCH-ARM / FISHERS	P=0.524N	P=0.500	P=0.630N	P=0.630N
MAX-ISO-POLY-3	P=0.665	P=0.379	P=0.449	P=0.461
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Thyroid Gland: C-Cell Carcinoma				
TUMOR RATES				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	3/150 (2%)			
HC TUMORS ALL ROUTES	17/1288 (1%)			
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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Thyroid Gland: C-Cell Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	5/50 (10%)	6/50 (12%)	5/50 (10%)	5/50 (10%)
POLY-3 RATE (b)	5/44.00	6/44.40	5/40.73	5/41.52
POLY-3 PERCENT (g)	11.4%	13.5%	12.3%	12%
TERMINAL (d)	5/34 (15%)	6/34 (18%)	3/24 (13%)	5/34 (15%)
FIRST INCIDENCE	728 (T)	728 (T)	647	728 (T)
HC TUMORS SAME ROUTE	22/150 (15%)			
HC TUMORS ALL ROUTES	152/1288 (12%)			
STATISTICAL TESTS				
POLY 3	P=0.567N	P=0.506	P=0.581	P=0.594
POLY 1.5	P=0.562N	P=0.500	P=0.605	P=0.596
POLY 6	P=0.559N	P=0.510	P=0.546	P=0.601
COCH-ARM / FISHERS	P=0.524N	P=0.500	P=0.630N	P=0.630N
MAX-ISO-POLY-3	P=0.665	P=0.379	P=0.449	P=0.461
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Thyroid Gland: Follicular Cell Carcinoma or Adenoma				
TUMOR RATES				
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/44.00	0/44.40	1/40.83	1/41.52
POLY-3 PERCENT (g)	2.3%	0%	2.5%	2.4%
TERMINAL (d)	1/34 (3%)	0/34 (0%)	0/24 (0%)	1/34 (3%)
FIRST INCIDENCE	728 (T)	---	519	728 (T)
HC TUMORS SAME ROUTE	1/150 (1%)			
HC TUMORS ALL ROUTES	11/1288 (1%)			
STATISTICAL TESTS				
POLY 3	P=0.537	P=0.498N	P=0.744	P=0.748
POLY 1.5	P=0.541	P=0.500N	P=0.752	P=0.749
POLY 6	P=0.539	P=0.497N	P=0.731	P=0.750
COCH-ARM / FISHERS	P=0.559	P=0.500N	P=0.753N	P=0.753N
MAX-ISO-POLY-3	P=0.524	P=0.158N	P=0.478	P=0.483
HISTCONT SAME RTE	P=0.324	(e)	P=0.255	P=0.256
HISTCONT ALL RTEs	P=0.498	(e)	P=0.340	P=0.343

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Uterus				
Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	7/50 (14%)	9/50 (18%)	8/50 (16%)	8/50 (16%)
POLY-3 RATE (b)	7/44.76	9/45.07	8/41.23	8/41.83
POLY-3 PERCENT (g)	15.6%	20%	19.4%	19.1%
TERMINAL (d)	6/34 (18%)	7/34 (21%)	5/24 (21%)	6/34 (18%)
FIRST INCIDENCE	450	632	532	688
HC TUMORS SAME ROUTE	21/150 (14%)			
HC TUMORS ALL ROUTES	234/1300 (18%)			
STATISTICAL TESTS				
POLY 3	P=0.480	P=0.397	P=0.431	P=0.443
POLY 1.5	P=0.489	P=0.390	P=0.463	P=0.449
POLY 6	P=0.491	P=0.406	P=0.385	P=0.453
COCH-ARM / FISHERS	P=0.549	P=0.393	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.521	P=0.297	P=0.329	P=0.339
HISTCONT SAME RTE	P=0.420	P=0.248	P=0.305	P=0.322
HISTCONT ALL RTEs	P=0.611	P=0.372	P=0.415	P=0.427

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Uterus				
Sarcoma Stromal or Polyp Stromal				
TUMOR RATES	#	#	#	#
OVERALL (a)	7/50 (14%)	9/50 (18%)	9/50 (18%)	8/50 (16%)
POLY-3 RATE (b)	7/44.76	9/45.07	9/41.53	8/41.83
POLY-3 PERCENT (g)	15.6%	20%	21.7%	19.1%
TERMINAL (d)	6/34 (18%)	7/34 (21%)	5/24 (21%)	6/34 (18%)
FIRST INCIDENCE	450	632	532	688
HC TUMORS SAME ROUTE	21/150 (14%)			
HC TUMORS ALL ROUTES	243/1300 (19%)			
STATISTICAL TESTS				
POLY 3	P=0.485	P=0.397	P=0.329	P=0.443
POLY 1.5	P=0.496	P=0.390	P=0.358	P=0.449
POLY 6	P=0.496	P=0.406	P=0.290	P=0.453
COCH-ARM / FISHERS	P=0.558	P=0.393	P=0.393	P=0.500
MAX-ISO-POLY-3	P=0.471	P=0.297	P=0.244	P=0.339
HISTCONT SAME RTE	P=0.368	P=0.248	P=0.196	P=0.322
HISTCONT ALL RTEs	P=0.552	P=0.372	P=0.301	P=0.427

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
All Organs				
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated				
TUMOR RATES	#	#	#	#
OVERALL (a)	5/50 (10%)	11/50 (22%)	6/50 (12%)	9/50 (18%)
POLY-3 RATE (b)	5/45.53	11/45.85	6/41.79	9/43.47
POLY-3 PERCENT (g)	11%	24%	14.4%	20.7%
TERMINAL (d)	1/34 (3%)	5/34 (15%)	0/24 (0%)	4/34 (12%)
FIRST INCIDENCE	506	605	518	380
HC TUMORS SAME ROUTE	17/150 (11%)			
HC TUMORS ALL ROUTES	283/1300 (22%)			
STATISTICAL TESTS				
POLY 3	P=0.322	P=0.085	P=0.440	P=0.166
POLY 1.5	P=0.323	P=0.083	P=0.467	P=0.168
POLY 6	P=0.335	P=0.088	P=0.402	P=0.173
COCH-ARM / FISHERS	P=0.363	P=0.086	P=0.500	P=0.194
MAX-ISO-POLY-3	P=0.191	P=0.050*	P=0.325	P=0.108
HISTCONT SAME RTE	P=0.242	P=0.063	P=0.437	P=0.143
HISTCONT ALL RTEs	P=0.221	P=0.054	P=0.409	P=0.126

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
All Organs				
Mesothelioma: Benign, Malignant, NOS				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	2/150 (1%)			
HC TUMORS ALL ROUTES	5/1300 (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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
All Organs				
Mesothelioma: Malignant				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	---	---
HC TUMORS SAME ROUTE	2/150 (1%)			
HC TUMORS ALL ROUTES	4/1300 (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 - 05
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/F 344/N

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
All Organs				
Osteosarcoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	2/40.80	0/41.52
POLY-3 PERCENT (g)	0%	0%	4.9%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/24 (4%)	0/34 (0%)
FIRST INCIDENCE	---	---	532	---
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	5/1300 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.697N	(e)	P=0.220	(e)
POLY 1.5	P=0.694N	(e)	P=0.229	(e)
POLY 6	P=0.696N	(e)	P=0.208	(e)
COCH-ARM / FISHERS	P=0.675N	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.250	(e)	P=0.075	(e)
HISTCONT SAME RTE	(h)	(e)	(h)	(e)
HISTCONT ALL RTEs	(h)	(e)	(h)	(e)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
All Organs				
Osteosarcoma or Osteoma				
TUMOR RATES	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	3/40.90	0/41.52
POLY-3 PERCENT (g)	0%	0%	7.3%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/24 (4%)	0/34 (0%)
FIRST INCIDENCE	---	---	532	---
HC TUMORS SAME ROUTE	0/150 (0%)			
HC TUMORS ALL ROUTES	5/1300 (0%)			
STATISTICAL TESTS				
POLY 3	P=0.648N	(e)	P=0.106	(e)
POLY 1.5	P=0.644N	(e)	P=0.112	(e)
POLY 6	P=0.646N	(e)	P=0.097	(e)
COCH-ARM / FISHERS	P=0.617N	(e)	P=0.121	(e)
MAX-ISO-POLY-3	P=0.167	(e)	P=0.037*	(e)
HISTCONT SAME RTE	(h)	(e)	(h)	(e)
HISTCONT ALL RTEs	(h)	(e)	(h)	(e)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
All Organs				
Benign Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	43/50 (86%)	41/50 (82%)	42/50 (84%)	22/50 (44%)
POLY-3 RATE (b)	43/46.90	41/47.35	42/46.79	22/42.07
POLY-3 PERCENT (g)	91.7%	86.6%	89.8%	52.3%
TERMINAL (d)	32/34 (94%)	30/34 (88%)	23/24 (96%)	19/34 (56%)
FIRST INCIDENCE	450	558	518	664
HC TUMORS SAME ROUTE	123/150 (82%)			
HC TUMORS ALL ROUTES	1133/1300 (87%)			
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.313N	P=0.515N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.376N	P=0.498N	P<0.001N**
POLY 6	P<0.001N**	P=0.261N	P=0.558N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.393N	P=0.500N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.204N	P=0.360N	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
All Organs				
Malignant Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	11/50 (22%)	16/50 (32%)	12/50 (24%)	12/50 (24%)
POLY-3 RATE (b)	11/47.46	16/45.85	12/43.48	12/43.64
POLY-3 PERCENT (g)	23.2%	34.9%	27.6%	27.5%
TERMINAL (d)	3/34 (9%)	10/34 (29%)	3/24 (13%)	5/34 (15%)
FIRST INCIDENCE	450	605	439	380
HC TUMORS SAME ROUTE	37/150 (25%)			
HC TUMORS ALL ROUTES	480/1300 (37%)			
STATISTICAL TESTS				
POLY 3	P=0.544N	P=0.153	P=0.404	P=0.409
POLY 1.5	P=0.528N	P=0.159	P=0.447	P=0.425
POLY 6	P=0.538N	P=0.147	P=0.348	P=0.409
COCH-ARM / FISHERS	P=0.450N	P=0.184	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.390	P=0.109	P=0.321	P=0.325
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
 CAS Number: 9000-38-8

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

**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 104 WEEKS**

DOSE	Females			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
All Organs				
Malignant and Benign Tumors				
TUMOR RATES	#	#	#	#
OVERALL (a)	46/50 (92%)	45/50 (90%)	44/50 (88%)	30/50 (60%)
POLY-3 RATE (b)	46/48.86	45/48.00	44/47.67	30/43.64
POLY-3 PERCENT (g)	94.2%	93.8%	92.3%	68.8%
TERMINAL (d)	32/34 (94%)	31/34 (91%)	23/24 (96%)	23/34 (68%)
FIRST INCIDENCE	450	558	439	380
HC TUMORS SAME ROUTE	135/150 (90%)			
HC TUMORS ALL ROUTES	1225/1300 (94%)			
STATISTICAL TESTS				
POLY 3	P<0.001N**	P=0.634N	P=0.519N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.641N	P=0.435N	P<0.001N**
POLY 6	P<0.001N**	P=0.618N	P=0.640N	P=0.002N**
COCH-ARM / FISHERS	P<0.001N**	P=0.500N	P=0.370N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.466N	P=0.351N	P<0.001N**
HISTCONT SAME RTE	(h)	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)	(h)

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

P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Kava kava extract
CAS Number: 9000-38-8

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

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 ***