

**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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 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
<b>Adrenal Medulla</b>				
<b>Pheochromocytoma Benign</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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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 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
<b>Adrenal Medulla</b>				
<b>Pheochromocytoma Malignant</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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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 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
<b>Adrenal Medulla</b>				
<b>Pheochromocytoma: Benign, Complex, Malignant, NOS</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Bone</b>				
<b>Osteosarcoma or Osteoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Clitoral/Preputial Gland Adenoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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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**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
<b>Clitoral/Preputial Gland Carcinoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Clitoral/Preputial Gland Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Ear</b>				
<b>Neural Crest Tumor</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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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**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
<b>Islets, Pancreatic Adenoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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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**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
<b>Lung</b>				
<b>Alveolar/Bronchiolar Adenoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Lung</b>				
<b>Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Mammary Gland Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

TDMS No. 20007 - 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
<b>Mammary Gland Carcinoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 20007 - 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
<b>Mammary Gland Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

TDMS No. 20007 - 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
<b>Mammary Gland Fibroadenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Mammary Gland</b>				
<b>Fibroma, Fibroadenoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Mammary Gland</b>				
<b>Fibroma, Fibroadenoma, Carcinoma, or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Pancreas</b>				
<b>Adenoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Pituitary Gland: Pars Distalis or Unspecified Site Adenoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Pituitary Gland: Pars Distalis or Unspecified Site Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Salivary Glands</b>				
<b>Schwannoma Malignant</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Skin</b>				
<b>Basal Cell Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Skin</b>				
<b>Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Skin</b>				
<b>Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Skin</b>				
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Skin</b>				
<b>Fibroma</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Skin</b>				
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Skin</b>				
<b>Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Testes</b>				
<b>Adenoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Thyroid Gland: C-Cell Adenoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Thyroid Gland: C-Cell Carcinoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Thyroid Gland: C-Cell Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Thyroid Gland: Follicular Cell Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>All Organs</b>				
<b>Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>All Organs</b>				
<b>Mesothelioma: Benign, Malignant, NOS</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>All Organs</b>				
<b>Mesothelioma: Malignant</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>All Organs</b>				
<b>Osteosarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>All Organs</b>				
<b>Osteosarcoma or Osteoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>All Organs</b>				
<b>Benign Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
<b>OVERALL (a)</b>	49/49 (100%)	48/50 (96%)	50/50 (100%)	47/50 (94%)
<b>POLY-3 RATE (b)</b>	49/49.00	48/48.01	50/50.00	47/47.24
<b>POLY-3 PERCENT (g)</b>	100%	100%	100%	99.5%
<b>TERMINAL (d)</b>	34/34 (100%)	35/35 (100%)	34/34 (100%)	31/31 (100%)
<b>FIRST INCIDENCE</b>	504	525	454	447
<b>HC TUMORS SAME ROUTE</b>	145/150 (97%)			
<b>HC TUMORS ALL ROUTES</b>	1301/1349 (96%)			
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.980N	P=1.000N	(e)	P=0.999N
<b>POLY 1.5</b>	P=0.603N	P=1.000N	(e)	P=0.843N
<b>POLY 6</b>	P=1.000N	P=1.000N	(e)	P=1.000N
<b>COCH-ARM / FISHERS</b>	P=0.103N	P=0.253N	(e)	P=0.125N
<b>MAX-ISO-POLY-3</b>	P=0.129N	P=0.161N	(e)	P=0.162N
<b>HISTCONT SAME RTE</b>	(h)	(h)	(e)	(h)
<b>HISTCONT ALL RTEs</b>	(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
<b>All Organs</b>				
<b>Malignant Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>All Organs</b>				
<b>Malignant and Benign Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Adrenal Medulla</b>				
<b>Pheochromocytoma Benign</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Adrenal Medulla</b>				
<b>Pheochromocytoma Malignant</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Adrenal Medulla</b>				
<b>Pheochromocytoma: Benign, Complex, Malignant, NOS</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Bone</b>				
<b>Osteosarcoma or Osteoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Clitoral/Preputial Gland Adenoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Clitoral/Preputial Gland Carcinoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Clitoral/Preputial Gland Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Ear</b>				
<b>Neural Crest Tumor</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Islets, Pancreatic Adenoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Lung</b>				
<b>Alveolar/Bronchiolar Adenoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Lung</b>				
<b>Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Mammary Gland Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Mammary Gland Carcinoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Mammary Gland Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Mammary Gland Fibroadenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Mammary Gland</b>				
<b>Fibroma, Fibroadenoma or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Mammary Gland</b>				
<b>Fibroma, Fibroadenoma, Carcinoma, or Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Pancreas</b>				
<b>Adenoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Pituitary Gland: Pars Distalis or Unspecified Site Adenoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Pituitary Gland: Pars Distalis or Unspecified Site Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Salivary Glands</b>				
<b>Schwannoma Malignant</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	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%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

TDMS No. 20007 - 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
<b>Skin</b>				
<b>Basal Cell Adenoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	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%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

TDMS No. 20007 - 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
<b>Skin</b>				
<b>Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	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%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

TDMS No. 20007 - 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
<b>Skin</b>				
<b>Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	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%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

TDMS No. 20007 - 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
<b>Skin</b>				
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 20007 - 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
<b>Skin</b>				
<b>Fibroma</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Skin</b>				
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Skin</b>				
<b>Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	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%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTES	(e)	(e)	(e)	(e)

TDMS No. 20007 - 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
<b>Thyroid Gland: C-Cell Adenoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Thyroid Gland: C-Cell Carcinoma</b>				
<b>TUMOR RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	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%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

TDMS No. 20007 - 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
<b>Thyroid Gland: C-Cell Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Thyroid Gland: Follicular Cell Carcinoma or Adenoma</b>				
<b>TUMOR RATES</b>				
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Uterus</b>				
<b>Polyp Stromal</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>Uterus</b>				
<b>Sarcoma Stromal or Polyp Stromal</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>All Organs</b>				
<b>Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>All Organs</b>				
<b>Mesothelioma: Benign, Malignant, NOS</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	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%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

TDMS No. 20007 - 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
<b>All Organs</b>				
<b>Mesothelioma: Malignant</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	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%)			
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)
HISTCONT SAME RTE	(e)	(e)	(e)	(e)
HISTCONT ALL RTEs	(e)	(e)	(e)	(e)

TDMS No. 20007 - 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
<b>All Organs</b>				
<b>Osteosarcoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	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%)			
<b>STATISTICAL TESTS</b>				
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
<b>All Organs</b>				
<b>Osteosarcoma or Osteoma</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>All Organs</b>				
<b>Benign Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
<b>OVERALL (a)</b>	43/50 (86%)	41/50 (82%)	42/50 (84%)	22/50 (44%)
<b>POLY-3 RATE (b)</b>	43/46.90	41/47.35	42/46.79	22/42.07
<b>POLY-3 PERCENT (g)</b>	91.7%	86.6%	89.8%	52.3%
<b>TERMINAL (d)</b>	32/34 (94%)	30/34 (88%)	23/24 (96%)	19/34 (56%)
<b>FIRST INCIDENCE</b>	450	558	518	664
<b>HC TUMORS SAME ROUTE</b>	123/150 (82%)			
<b>HC TUMORS ALL ROUTES</b>	1133/1300 (87%)			
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P<0.001N**	P=0.313N	P=0.515N	P<0.001N**
<b>POLY 1.5</b>	P<0.001N**	P=0.376N	P=0.498N	P<0.001N**
<b>POLY 6</b>	P<0.001N**	P=0.261N	P=0.558N	P<0.001N**
<b>COCH-ARM / FISHERS</b>	P<0.001N**	P=0.393N	P=0.500N	P<0.001N**
<b>MAX-ISO-POLY-3</b>	P<0.001N**	P=0.204N	P=0.360N	P<0.001N**
<b>HISTCONT SAME RTE</b>	(h)	(h)	(h)	(h)
<b>HISTCONT ALL RTEs</b>	(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
<b>All Organs</b>				
<b>Malignant Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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
<b>All Organs</b>				
<b>Malignant and Benign Tumors</b>				
<b>TUMOR RATES</b>	#	#	#	#
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%)			
<b>STATISTICAL TESTS</b>				
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 \*\*\*