

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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

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

### MALE RATS

#### Organ

Bone Marrow  
Eye: Iris  
Eye: Retina  
Intestine Large, Colon  
Kidney  
Kidney: Pelvis, Transitional Epithelium  
Liver

Liver: Bile Duct  
Liver: Centrilobular  
Liver: Hepatocyte  
Lung  
  
Lung: Alveolus  
Lymph Node: Mediastinal  
Nose  
Pancreas: Acinus  
  
Parathyroid Gland  
Pituitary Gland: Pars Distalis  
Prostate  
Prostate: Epithelium  
Spleen  
  
Stomach, Forestomach

#### Morphology

Hyperplasia  
Inflammation  
Degeneration  
Parasite Metazoan  
Mineralization  
Hyperplasia  
Basophilic Focus  
Clear Cell Focus  
Degeneration Cystic  
Hematopoietic Cell Proliferation  
Hepatodiaphragmatic Nodule  
Mixed Cell Focus  
Hyperplasia  
Fatty Change  
Hypertrophy  
Inflammation Granulomatous  
Necrosis  
Infiltration Cellular Histiocyte  
Hyperplasia Lymphoid  
Inflammation  
Hyperplasia  
Metaplasia Hepatocyte  
Hyperplasia  
Hyperplasia  
Inflammation  
Hyperplasia  
Fibrosis  
Thrombosis  
Erosion  
Inflammation  
Mineralization  
Ulcer

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
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

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

Stomach, Forestomach: Epithelium  
Testes: Germinal Epithelium  
Testes: Interstitial Cell

Hyperplasia  
Degeneration  
Hyperplasia

### FEMALE RATS

#### Organ

Adrenal Medulla  
Brain  
Clitoral Gland  
Eye: Retina  
Heart  
Intestine Large, Colon  
Kidney  
Kidney: Cortex  
Kidney: Pelvis  
Kidney: Pelvis, Transitional Epithelium  
Liver

Liver: Centrilobular  
Liver: Hepatocyte  
Lymph Node, Mesenteric  
Nose

Pancreas: Acinus  
Pituitary Gland: Pars Distalis  
Spleen

Stomach, Forestomach

Stomach, Forestomach: Epithelium  
Thymus  
Thyroid Gland: C-Cell  
Thyroid Gland: Follicle  
Uterus: Endometrium

#### Morphology

Hyperplasia  
Necrosis  
Hyperplasia  
Degeneration  
Cardiomyopathy  
Parasite Metazoan  
Nephropathy  
Cyst  
Inflammation  
Hyperplasia  
Basophilic Focus  
Inflammation Chronic  
Mixed Cell Focus  
Fatty Change  
Hypertrophy  
Inflammation  
Foreign Body  
Inflammation  
Metaplasia Hepatocyte  
Hyperplasia  
Fibrosis  
Hematopoietic Cell Proliferation  
Inflammation  
Ulcer  
Hyperplasia  
Atrophy  
Hyperplasia  
Cyst  
Hyperplasia Cystic

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Cortex Degeneration Cystic</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.34	0/44.61	0/45.55	0/41.46
POLY-3 PERCENT (g)	2.3%	0%	0%	0%
TERMINAL (d)	1/34 (3%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	727 (T)	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.500N	P=0.494N	P=0.490N	P=0.509N
POLY 1.5	P=0.497N	P=0.498N	P=0.492N	P=0.507N
POLY 6	P=0.502N	P=0.490N	P=0.488N	P=0.510N
COCH-ARM / FISHERS	P=0.498N	P=0.495N	P=0.495N	P=0.495N
MAX-ISO-POLY-3	P=0.143N	P=0.157N	P=0.157N	P=0.171N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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 Cortex Hypertrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/49 (4%)	5/50 (10%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	2/43.34	5/44.82	3/45.55	3/42.22
POLY-3 PERCENT (g)	4.6%	11.2%	6.6%	7.1%
TERMINAL (d)	2/34 (6%)	4/35 (11%)	3/34 (9%)	2/31 (7%)
FIRST INCIDENCE	727 (T)	673	727 (T)	454
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.582N	P=0.229	P=0.523	P=0.488
POLY 1.5	P=0.578N	P=0.222	P=0.518	P=0.489
POLY 6	P=0.587N	P=0.240	P=0.527	P=0.487
COCH-ARM / FISHERS	P=0.552N	P=0.226	P=0.510	P=0.510
MAX-ISO-POLY-3	P=0.427	P=0.131	P=0.346	P=0.316

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Cortex</b>				
<b>Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/49 (2%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/43.34	1/44.61	1/45.76	1/42.01
POLY-3 PERCENT (g)	2.3%	2.2%	2.2%	2.4%
TERMINAL (d)	1/34 (3%)	1/35 (3%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	727 (T)	727 (T)	673	559
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.658	P=0.754N	P=0.749N	P=0.754
POLY 1.5	P=0.661	P=0.758N	P=0.751N	P=0.754
POLY 6	P=0.654	P=0.749N	P=0.746N	P=0.754
COCH-ARM / FISHERS	P=0.671N	P=0.747N	P=0.747N	P=0.747N
MAX-ISO-POLY-3	P=0.730	P=0.491N	P=0.484N	P=0.490

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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 Cortex: Zona Fasciculata Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	8/49 (16%)	6/50 (12%)	9/50 (18%)	13/50 (26%)
POLY-3 RATE (b)	8/43.83	6/44.91	9/46.09	13/44.19
POLY-3 PERCENT (g)	18.3%	13.4%	19.5%	29.4%
TERMINAL (d)	7/34 (21%)	5/35 (14%)	6/34 (18%)	7/31 (23%)
FIRST INCIDENCE	582	646	664	447
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.052	P=0.367N	P=0.546	P=0.163
POLY 1.5	P=0.052	P=0.380N	P=0.535	P=0.156
POLY 6	P=0.053	P=0.351N	P=0.557	P=0.172
COCH-ARM / FISHERS	P=0.061	P=0.371N	P=0.518	P=0.176
MAX-ISO-POLY-3	P=0.084	P=0.266N	P=0.438	P=0.108

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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 Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	9/49 (18%)	11/50 (22%)	10/50 (20%)	10/50 (20%)
POLY-3 RATE (b)	9/44.84	11/45.44	10/46.81	10/42.62
POLY-3 PERCENT (g)	20.1%	24.2%	21.4%	23.5%
TERMINAL (d)	5/34 (15%)	6/35 (17%)	6/34 (18%)	6/31 (19%)
FIRST INCIDENCE	545	615	590	589
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.476	P=0.413	P=0.542	P=0.450
POLY 1.5	P=0.493	P=0.403	P=0.533	P=0.461
POLY 6	P=0.458	P=0.428	P=0.547	P=0.441
COCH-ARM / FISHERS	P=0.558	P=0.421	P=0.520	P=0.520
MAX-ISO-POLY-3	P=0.564	P=0.319	P=0.439	P=0.354

---



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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Marrow Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	16/49 (33%)	17/50 (34%)	24/50 (48%)	29/50 (58%)
POLY-3 RATE (b)	16/45.46	17/48.23	24/48.54	29/44.64
POLY-3 PERCENT (g)	35.2%	35.3%	49.4%	65%
TERMINAL (d)	9/34 (27%)	7/35 (20%)	13/34 (38%)	19/31 (61%)
FIRST INCIDENCE	511	168	590	451
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.583	P=0.116	P=0.003**
POLY 1.5	P<0.001**	P=0.551	P=0.103	P=0.003**
POLY 6	P<0.001**	P=0.552N	P=0.133	P=0.003**
COCH-ARM / FISHERS	P=0.004**	P=0.528	P=0.088	P=0.010**
MAX-ISO-POLY-3	P=0.002**	P=0.497	P=0.085	P=0.002**

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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 Marrow</b>				
<b>Myelofibrosis</b>				
<b>LESION 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	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Brain Hemorrhage</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/49 (2%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/44.01	1/45.00	0/45.55	2/42.23
POLY-3 PERCENT (g)	2.3%	2.2%	0%	4.7%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	1/31 (3%)
FIRST INCIDENCE	504	615	---	447
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.313	P=0.756N	P=0.493N	P=0.486
POLY 1.5	P=0.317	P=0.759N	P=0.494N	P=0.488
POLY 6	P=0.309	P=0.751N	P=0.493N	P=0.483
COCH-ARM / FISHERS	P=0.329	P=0.747N	P=0.495N	P=0.508
MAX-ISO-POLY-3	P=0.268	P=0.493N	P=0.157N	P=0.273

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Brain Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/49 (4%)	0/50 (0%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	2/43.84	0/44.61	2/46.00	2/41.67
POLY-3 PERCENT (g)	4.6%	0%	4.4%	4.8%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	1/34 (3%)	1/31 (3%)
FIRST INCIDENCE	629	---	598	673
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.411	P=0.233N	P=0.677N	P=0.676
POLY 1.5	P=0.419	P=0.236N	P=0.680N	P=0.680
POLY 6	P=0.401	P=0.230N	P=0.675N	P=0.671
COCH-ARM / FISHERS	P=0.441	P=0.242N	P=0.684N	P=0.684N
MAX-ISO-POLY-3	P=0.433	P=0.075N	P=0.480N	P=0.479

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Coagulating Gland Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/2 (50%)	2/2 (100%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	1/2.00	2/2.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	50%	100%	0%	0%
TERMINAL (d)	0/1 (0%)	2/2 (100%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	545	727 (T)	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	P=0.500	(e)	(e)
POLY 1.5	(e)	P=0.500	(e)	(e)
POLY 6	(e)	P=0.500	(e)	(e)
COCH-ARM / FISHERS	P=1.000	P=0.500	(e)	(e)
MAX-ISO-POLY-3	(e)	P=0.159	(e)	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Epididymis Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/49 (2%)	4/50 (8%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	1/43.34	4/44.61	3/45.79	2/41.46
POLY-3 PERCENT (g)	2.3%	9%	6.6%	4.8%
TERMINAL (d)	1/34 (3%)	4/35 (11%)	2/34 (6%)	2/31 (7%)
FIRST INCIDENCE	727 (T)	727 (T)	664	727 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.581N	P=0.187	P=0.325	P=0.485
POLY 1.5	P=0.575N	P=0.182	P=0.320	P=0.487
POLY 6	P=0.588N	P=0.194	P=0.330	P=0.482
COCH-ARM / FISHERS	P=0.544N	P=0.187	P=0.316	P=0.508
MAX-ISO-POLY-3	P=0.318	P=0.091	P=0.173	P=0.272

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Eye: Cornea Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/43.34	0/44.61	1/45.97	0/41.46
POLY-3 PERCENT (g)	0%	0%	2.2%	0%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	608	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.788N	(e)	P=0.512	(e)
POLY 1.5	P=0.785N	(e)	P=0.509	(e)
POLY 6	P=0.791N	(e)	P=0.515	(e)
COCH-ARM / FISHERS	P=0.778N	(e)	P=0.505	(e)
MAX-ISO-POLY-3	P=0.407	(e)	P=0.172	(e)

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Eye: Iris Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/43.34	0/44.61	0/45.55	2/42.28
POLY-3 PERCENT (g)	0%	0%	0%	4.7%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	---	528
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.039*	(e)	(e)	P=0.231
POLY 1.5	P=0.039*	(e)	(e)	P=0.232
POLY 6	P=0.039*	(e)	(e)	P=0.232
COCH-ARM / FISHERS	P=0.043*	(e)	(e)	P=0.253
MAX-ISO-POLY-3	P=0.035*	(e)	(e)	P=0.077



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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

---

Eye: Lens  
Cataract

---

**LESION RATES**

OVERALL (a)	2/49 (4%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/43.34	1/44.61	2/45.55	0/41.46
POLY-3 PERCENT (g)	4.6%	2.2%	4.4%	0%
TERMINAL (d)	2/34 (6%)	1/35 (3%)	2/34 (6%)	0/31 (0%)
FIRST INCIDENCE	727 (T)	727 (T)	727 (T)	---

---

**STATISTICAL TESTS**

POLY 3	P=0.225N	P=0.490N	P=0.676N	P=0.247N
POLY 1.5	P=0.220N	P=0.496N	P=0.680N	P=0.245N
POLY 6	P=0.231N	P=0.482N	P=0.673N	P=0.249N
COCH-ARM / FISHERS	P=0.206N	P=0.492N	P=0.684N	P=0.242N
MAX-ISO-POLY-3	P=0.180N	P=0.273N	P=0.479N	P=0.086N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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

---

Eye: Retina  
Degeneration

---

**LESION RATES**

OVERALL (a)	6/49 (12%)	6/50 (12%)	10/50 (20%)	16/50 (32%)
POLY-3 RATE (b)	6/43.62	6/44.66	10/45.80	16/41.88
POLY-3 PERCENT (g)	13.8%	13.4%	21.8%	38.2%
TERMINAL (d)	5/34 (15%)	5/35 (14%)	8/34 (24%)	14/31 (45%)
FIRST INCIDENCE	651	714	689	670

---

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.605N	P=0.235	P=0.008**
POLY 1.5	P=0.002**	P=0.615N	P=0.230	P=0.009**
POLY 6	P<0.001**	P=0.592N	P=0.240	P=0.007**
COCH-ARM / FISHERS	P=0.003**	P=0.606N	P=0.220	P=0.016*
MAX-ISO-POLY-3	P=0.002**	P=0.482N	P=0.164	P=0.004**

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Eye: Retina</b>				
<b>Gliososis</b>				
<hr/>				
<b>LESION 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	---	---	---	---
<hr/>				
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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

---

Heart  
Cardiomyopathy

---

**LESION RATES**

OVERALL (a)	48/49 (98%)	49/50 (98%)	48/50 (96%)	46/50 (92%)
POLY-3 RATE (b)	48/48.33	49/49.95	48/49.79	46/48.00
POLY-3 PERCENT (g)	99.3%	98.1%	96.4%	95.8%
TERMINAL (d)	34/34 (100%)	35/35 (100%)	33/34 (97%)	29/31 (94%)
FIRST INCIDENCE	504	30	454	447

---

**STATISTICAL TESTS**

POLY 3	P=0.263N	P=0.657N	P=0.372N	P=0.320N
POLY 1.5	P=0.306N	P=0.709N	P=0.423N	P=0.384N
POLY 6	P=0.217N	P=0.601N	P=0.339N	P=0.263N
COCH-ARM / FISHERS	P=0.078N	P=0.747	P=0.508N	P=0.187N
MAX-ISO-POLY-3	P=0.220N	P=0.281N	P=0.141N	P=0.125N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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

---

Heart: Atrium  
Thrombosis

---

**LESION RATES**

OVERALL (a)	2/49 (4%)	2/50 (4%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	2/43.69	2/45.27	3/46.02	1/41.61
POLY-3 PERCENT (g)	4.6%	4.4%	6.5%	2.4%
TERMINAL (d)	1/34 (3%)	0/35 (0%)	2/34 (6%)	0/31 (0%)
FIRST INCIDENCE	629	571	590	689

---

**STATISTICAL TESTS**

POLY 3	P=0.405N	P=0.681N	P=0.524	P=0.517N
POLY 1.5	P=0.397N	P=0.688N	P=0.518	P=0.513N
POLY 6	P=0.415N	P=0.672N	P=0.528	P=0.521N
COCH-ARM / FISHERS	P=0.368N	P=0.684N	P=0.510	P=0.492N
MAX-ISO-POLY-3	P=0.449N	P=0.485N	P=0.347	P=0.300N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Intestine Large, Colon Parasite Metazoan</b>				
<b>LESION RATES</b>				
OVERALL (a)	7/49 (14%)	2/50 (4%)	5/50 (10%)	2/50 (4%)
POLY-3 RATE (b)	7/43.47	2/44.61	5/46.56	2/41.53
POLY-3 PERCENT (g)	16.1%	4.5%	10.7%	4.8%
TERMINAL (d)	6/34 (18%)	2/35 (6%)	2/34 (6%)	1/31 (3%)
FIRST INCIDENCE	694	727 (T)	608	709
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.172N	P=0.072N	P=0.331N	P=0.089N
POLY 1.5	P=0.165N	P=0.076N	P=0.345N	P=0.087N
POLY 6	P=0.181N	P=0.067N	P=0.316N	P=0.090N
COCH-ARM / FISHERS	P=0.146N	P=0.075N	P=0.365N	P=0.075N
MAX-ISO-POLY-3	P=0.066N	P=0.036N*	P=0.235N	P=0.048N*

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/49 (4%)	2/50 (4%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	2/43.99	2/44.66	2/46.18	3/41.46
POLY-3 PERCENT (g)	4.6%	4.5%	4.3%	7.2%
TERMINAL (d)	1/34 (3%)	1/35 (3%)	0/34 (0%)	3/31 (10%)
FIRST INCIDENCE	511	714	616	727 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.364	P=0.689N	P=0.676N	P=0.473
POLY 1.5	P=0.374	P=0.693N	P=0.680N	P=0.480
POLY 6	P=0.354	P=0.683N	P=0.672N	P=0.466
COCH-ARM / FISHERS	P=0.402	P=0.684N	P=0.684N	P=0.510
MAX-ISO-POLY-3	P=0.466	P=0.493N	P=0.479N	P=0.306

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Kidney</b>				
Accumulation, Hyaline Droplet				
<b>LESION RATES</b>				
OVERALL (a)	1/49 (2%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/43.69	0/44.61	1/45.55	2/41.53
POLY-3 PERCENT (g)	2.3%	0%	2.2%	4.8%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	1/34 (3%)	1/31 (3%)
FIRST INCIDENCE	629	---	727 (T)	709
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.222	P=0.496N	P=0.751N	P=0.482
POLY 1.5	P=0.228	P=0.499N	P=0.753N	P=0.486
POLY 6	P=0.216	P=0.493N	P=0.751N	P=0.478
COCH-ARM / FISHERS	P=0.241	P=0.495N	P=0.747N	P=0.508
MAX-ISO-POLY-3	P=0.225	P=0.157N	P=0.487N	P=0.271



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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Kidney Infarct</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/49 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/43.34	0/44.61	1/45.55	0/41.46
POLY-3 PERCENT (g)	2.3%	0%	2.2%	0%
TERMINAL (d)	1/34 (3%)	0/35 (0%)	1/34 (3%)	0/31 (0%)
FIRST INCIDENCE	727 (T)	---	727 (T)	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.476N	P=0.494N	P=0.750N	P=0.509N
POLY 1.5	P=0.472N	P=0.498N	P=0.752N	P=0.507N
POLY 6	P=0.482N	P=0.490N	P=0.748N	P=0.510N
COCH-ARM / FISHERS	P=0.461N	P=0.495N	P=0.747N	P=0.495N
MAX-ISO-POLY-3	P=0.276N	P=0.157N	P=0.485N	P=0.171N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Kidney Mineralization</b>				
<b>LESION RATES</b>				
OVERALL (a)	38/49 (78%)	43/50 (86%)	41/50 (82%)	34/50 (68%)
POLY-3 RATE (b)	38/48.07	43/47.78	41/49.32	34/45.59
POLY-3 PERCENT (g)	79.1%	90%	83.1%	74.6%
TERMINAL (d)	26/34 (77%)	31/35 (89%)	27/34 (79%)	24/31 (77%)
FIRST INCIDENCE	504	525	454	451
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.127N	P=0.111	P=0.398	P=0.392N
POLY 1.5	P=0.100N	P=0.107	P=0.392	P=0.351N
POLY 6	P=0.174N	P=0.121	P=0.404	P=0.448N
COCH-ARM / FISHERS	P=0.042N*	P=0.204	P=0.382	P=0.200N
MAX-ISO-POLY-3	P=0.176N	P=0.067	P=0.303	P=0.305N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Kidney</b>				
<b>Nephropathy</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	46/49 (94%)	47/50 (94%)	48/50 (96%)	48/50 (96%)
<b>POLY-3 RATE (b)</b>	46/48.33	47/48.01	48/50.00	48/48.00
<b>POLY-3 PERCENT (g)</b>	95.2%	97.9%	96%	100%
<b>TERMINAL (d)</b>	32/34 (94%)	34/35 (97%)	32/34 (94%)	31/31 (100%)
<b>FIRST INCIDENCE</b>	504	525	454	447
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.175	P=0.430	P=0.616	P=0.177
<b>POLY 1.5</b>	P=0.151	P=0.404	P=0.569	P=0.151
<b>POLY 6</b>	P=0.197	P=0.475	P=0.659	P=0.215
<b>COCH-ARM / FISHERS</b>	P=0.412	P=0.651	P=0.490	P=0.490
<b>MAX-ISO-POLY-3</b>	P=0.116	P=0.229	P=0.419	P=0.053

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Kidney: Cortex Cyst</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/49 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/43.34	0/44.61	0/45.55	1/41.46
POLY-3 PERCENT (g)	2.3%	0%	0%	2.4%
TERMINAL (d)	1/34 (3%)	0/35 (0%)	0/34 (0%)	1/31 (3%)
FIRST INCIDENCE	727 (T)	---	---	727 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.524	P=0.494N	P=0.490N	P=0.751
POLY 1.5	P=0.528	P=0.498N	P=0.492N	P=0.753
POLY 6	P=0.518	P=0.490N	P=0.488N	P=0.749
COCH-ARM / FISHERS	P=0.539	P=0.495N	P=0.495N	P=0.747N
MAX-ISO-POLY-3	P=0.398	P=0.157N	P=0.157N	P=0.487

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Kidney: Pelvis Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/49 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/43.92	0/44.61	0/45.55	1/41.68
POLY-3 PERCENT (g)	2.3%	0%	0%	2.4%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	545	---	---	670
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.525	P=0.497N	P=0.493N	P=0.749
POLY 1.5	P=0.529	P=0.499N	P=0.494N	P=0.751
POLY 6	P=0.520	P=0.494N	P=0.492N	P=0.747
COCH-ARM / FISHERS	P=0.539	P=0.495N	P=0.495N	P=0.747N
MAX-ISO-POLY-3	P=0.398	P=0.157N	P=0.157N	P=0.485

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Kidney: Pelvis, Transitional Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	1/50 (2%)	1/50 (2%)	15/50 (30%)
POLY-3 RATE (b)	0/43.34	1/44.61	1/45.55	15/42.91
POLY-3 PERCENT (g)	0%	2.2%	2.2%	35%
TERMINAL (d)	0/34 (0%)	1/35 (3%)	1/34 (3%)	9/31 (29%)
FIRST INCIDENCE	---	727 (T)	727 (T)	589
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.506	P=0.510	P<0.001**
POLY 1.5	P<0.001**	P=0.502	P=0.508	P<0.001**
POLY 6	P<0.001**	P=0.510	P=0.512	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.505	P=0.505	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.164	P=0.170	P<0.001**

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Kidney: Renal Tubule Necrosis</b>				
<b>LESION 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	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
<b>Angiectasis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	1/50 (2%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/43.34	1/44.61	2/45.55	1/41.46
POLY-3 PERCENT (g)	0%	2.2%	4.4%	2.4%
TERMINAL (d)	0/34 (0%)	1/35 (3%)	2/34 (6%)	1/31 (3%)
FIRST INCIDENCE	---	727 (T)	727 (T)	727 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.497	P=0.506	P=0.248	P=0.491
POLY 1.5	P=0.503	P=0.502	P=0.246	P=0.493
POLY 6	P=0.490	P=0.510	P=0.250	P=0.490
COCH-ARM / FISHERS	P=0.529	P=0.505	P=0.253	P=0.505
MAX-ISO-POLY-3	P=0.252	P=0.164	P=0.086	P=0.160



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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
<b>Basophilic Focus</b>				
<b>LESION RATES</b>				
OVERALL (a)	21/49 (43%)	30/50 (60%)	18/50 (36%)	13/50 (26%)
POLY-3 RATE (b)	21/43.92	30/45.47	18/46.05	13/41.74
POLY-3 PERCENT (g)	47.8%	66%	39.1%	31.2%
TERMINAL (d)	20/34 (59%)	25/35 (71%)	15/34 (44%)	11/31 (36%)
FIRST INCIDENCE	545	646	664	673
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.007N**	P=0.057	P=0.264N	P=0.083N
POLY 1.5	P=0.006N**	P=0.050*	P=0.284N	P=0.081N
POLY 6	P=0.007N**	P=0.074	P=0.242N	P=0.082N
COCH-ARM / FISHERS	P=0.004N**	P=0.066	P=0.311N	P=0.060N
MAX-ISO-POLY-3	P=0.011N*	P=0.037*	P=0.203N	P=0.058N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
<b>Clear Cell Focus</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	18/49 (37%)	25/50 (50%)	25/50 (50%)	11/50 (22%)
<b>POLY-3 RATE (b)</b>	18/43.34	25/44.91	25/45.69	11/42.01
<b>POLY-3 PERCENT (g)</b>	41.5%	55.7%	54.7%	26.2%
<b>TERMINAL (d)</b>	18/34 (53%)	24/35 (69%)	24/34 (71%)	10/31 (32%)
<b>FIRST INCIDENCE</b>	727 (T)	646	694	556
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.011N*	P=0.126	P=0.144	P=0.098N
<b>POLY 1.5</b>	P=0.011N*	P=0.113	P=0.138	P=0.101N
<b>POLY 6</b>	P=0.011N*	P=0.147	P=0.147	P=0.093N
<b>COCH-ARM / FISHERS</b>	P=0.008N**	P=0.129	P=0.129	P=0.082N
<b>MAX-ISO-POLY-3</b>	P=0.017N*	P=0.089	P=0.105	P=0.067N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
<b>Degeneration Cystic</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	4/50 (8%)	3/50 (6%)	5/50 (10%)
POLY-3 RATE (b)	0/43.34	4/44.61	3/46.43	5/42.42
POLY-3 PERCENT (g)	0%	9%	6.5%	11.8%
TERMINAL (d)	0/34 (0%)	4/35 (11%)	0/34 (0%)	1/31 (3%)
FIRST INCIDENCE	---	727 (T)	608	556
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.080	P=0.064	P=0.131	P=0.028*
POLY 1.5	P=0.081	P=0.062	P=0.128	P=0.028*
POLY 6	P=0.081	P=0.066	P=0.135	P=0.029*
COCH-ARM / FISHERS	P=0.094	P=0.061	P=0.125	P=0.030*
MAX-ISO-POLY-3	P=0.027*	P=0.022*	P=0.048*	P=0.010**

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
<b>Eosinophilic Focus</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	15/49 (31%)	18/50 (36%)	14/50 (28%)	13/50 (26%)
<b>POLY-3 RATE (b)</b>	15/43.50	18/44.84	14/46.52	13/42.54
<b>POLY-3 PERCENT (g)</b>	34.5%	40.1%	30.1%	30.6%
<b>TERMINAL (d)</b>	14/34 (41%)	17/35 (49%)	10/34 (29%)	10/31 (32%)
<b>FIRST INCIDENCE</b>	686	666	616	556
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.299N	P=0.370	P=0.413N	P=0.437N
<b>POLY 1.5</b>	P=0.294N	P=0.347	P=0.439N	P=0.440N
<b>POLY 6</b>	P=0.301N	P=0.400	P=0.384N	P=0.428N
<b>COCH-ARM / FISHERS</b>	P=0.244N	P=0.361	P=0.474N	P=0.387N
<b>MAX-ISO-POLY-3</b>	P=0.404N	P=0.292	P=0.332N	P=0.349N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
<b>Fatty Change Diffuse</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	11/49 (22%)	8/50 (16%)	12/50 (24%)	8/50 (16%)
<b>POLY-3 RATE (b)</b>	11/46.20	8/45.70	12/46.52	8/42.85
<b>POLY-3 PERCENT (g)</b>	23.8%	17.5%	25.8%	18.7%
<b>TERMINAL (d)</b>	5/34 (15%)	4/35 (11%)	8/34 (24%)	3/31 (10%)
<b>FIRST INCIDENCE</b>	504	525	598	559
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.417N	P=0.313N	P=0.508	P=0.370N
<b>POLY 1.5</b>	P=0.395N	P=0.315N	P=0.514	P=0.353N
<b>POLY 6</b>	P=0.437N	P=0.308N	P=0.499	P=0.385N
<b>COCH-ARM / FISHERS</b>	P=0.329N	P=0.288N	P=0.522	P=0.288N
<b>MAX-ISO-POLY-3</b>	P=0.462N	P=0.231N	P=0.411	P=0.286N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
<b>Hematopoietic Cell Proliferation</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/49 (6%)	3/50 (6%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	3/44.15	3/45.25	1/45.55	0/41.46
POLY-3 PERCENT (g)	6.8%	6.6%	2.2%	0%
TERMINAL (d)	1/34 (3%)	0/35 (0%)	1/34 (3%)	0/31 (0%)
FIRST INCIDENCE	511	571	727 (T)	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.078N	P=0.651N	P=0.294N	P=0.130N
POLY 1.5	P=0.075N	P=0.658N	P=0.295N	P=0.127N
POLY 6	P=0.081N	P=0.641N	P=0.294N	P=0.133N
COCH-ARM / FISHERS	P=0.068N	P=0.651N	P=0.301N	P=0.117N
MAX-ISO-POLY-3	P=0.100N	P=0.487N	P=0.148N	P=0.048N*

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
<b>Hepatodiaphragmatic Nodule</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	2/49 (4%)	7/50 (14%)	4/50 (8%)	1/50 (2%)
<b>POLY-3 RATE (b)</b>	2/43.75	7/44.66	4/45.81	1/41.81
<b>POLY-3 PERCENT (g)</b>	4.6%	15.7%	8.7%	2.4%
<b>TERMINAL (d)</b>	1/34 (3%)	6/35 (17%)	2/34 (6%)	0/31 (0%)
<b>FIRST INCIDENCE</b>	610	714	689	629
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.138N	P=0.083	P=0.358	P=0.516N
<b>POLY 1.5</b>	P=0.135N	P=0.080	P=0.354	P=0.513N
<b>POLY 6</b>	P=0.141N	P=0.086	P=0.362	P=0.519N
<b>COCH-ARM / FISHERS</b>	P=0.117N	P=0.085	P=0.349	P=0.492N
<b>MAX-ISO-POLY-3</b>	P=0.160N	P=0.041*	P=0.221	P=0.298N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
<b>Inflammation Chronic</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	36/49 (73%)	39/50 (78%)	32/50 (64%)	34/50 (68%)
<b>POLY-3 RATE (b)</b>	36/44.82	39/46.00	32/46.96	34/45.25
<b>POLY-3 PERCENT (g)</b>	80.3%	84.8%	68.1%	75.1%
<b>TERMINAL (d)</b>	32/34 (94%)	33/35 (94%)	27/34 (79%)	26/31 (84%)
<b>FIRST INCIDENCE</b>	504	571	598	447
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.249N	P=0.378	P=0.122N	P=0.359N
<b>POLY 1.5</b>	P=0.278N	P=0.323	P=0.159N	P=0.409N
<b>POLY 6</b>	P=0.220N	P=0.486	P=0.082N	P=0.293N
<b>COCH-ARM / FISHERS</b>	P=0.243N	P=0.385	P=0.212N	P=0.353N
<b>MAX-ISO-POLY-3</b>	P=0.151N	P=0.272	P=0.081N	P=0.263N



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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
<b>Mixed Cell Focus</b>				
<b>LESION RATES</b>				
OVERALL (a)	4/49 (8%)	5/50 (10%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	4/44.05	5/44.89	4/46.41	0/41.46
POLY-3 PERCENT (g)	9.1%	11.1%	8.6%	0%
TERMINAL (d)	2/34 (6%)	3/35 (9%)	2/34 (6%)	0/31 (0%)
FIRST INCIDENCE	545	666	598	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.041N*	P=0.512	P=0.614N	P=0.068N
POLY 1.5	P=0.039N*	P=0.503	P=0.621N	P=0.066N
POLY 6	P=0.044N*	P=0.523	P=0.608N	P=0.070N
COCH-ARM / FISHERS	P=0.032N*	P=0.513	P=0.631N	P=0.056N
MAX-ISO-POLY-3	P=0.067N	P=0.374	P=0.469N	P=0.026N*

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
<b>Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/49 (2%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/43.54	2/44.61	0/45.55	1/41.46
POLY-3 PERCENT (g)	2.3%	4.5%	0%	2.4%
TERMINAL (d)	0/34 (0%)	2/35 (6%)	0/34 (0%)	1/31 (3%)
FIRST INCIDENCE	675	727 (T)	---	727 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.588N	P=0.508	P=0.491N	P=0.750
POLY 1.5	P=0.586N	P=0.503	P=0.493N	P=0.752
POLY 6	P=0.590N	P=0.515	P=0.490N	P=0.747
COCH-ARM / FISHERS	P=0.573N	P=0.508	P=0.495N	P=0.747N
MAX-ISO-POLY-3	P=0.409N	P=0.289	P=0.157N	P=0.486

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
Pigmentation Hemosiderin				
<b>LESION RATES</b>				
OVERALL (a)	1/49 (2%)	0/50 (0%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	1/43.69	0/44.61	2/45.66	2/41.78
POLY-3 PERCENT (g)	2.3%	0%	4.4%	4.8%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	1/34 (3%)	1/31 (3%)
FIRST INCIDENCE	629	---	701	640
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.260	P=0.496N	P=0.515	P=0.484
POLY 1.5	P=0.266	P=0.499N	P=0.512	P=0.487
POLY 6	P=0.254	P=0.493N	P=0.517	P=0.482
COCH-ARM / FISHERS	P=0.285	P=0.495N	P=0.508	P=0.508
MAX-ISO-POLY-3	P=0.268	P=0.157N	P=0.296	P=0.272

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver: Bile Duct Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	32/49 (65%)	39/50 (78%)	40/50 (80%)	34/50 (68%)
POLY-3 RATE (b)	32/46.31	39/46.13	40/48.37	34/45.34
POLY-3 PERCENT (g)	69.1%	84.6%	82.7%	75%
TERMINAL (d)	24/34 (71%)	30/35 (86%)	29/34 (85%)	22/31 (71%)
FIRST INCIDENCE	504	615	590	447
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.514N	P=0.056	P=0.087	P=0.343
POLY 1.5	P=0.508N	P=0.059	P=0.081	P=0.346
POLY 6	P=0.510N	P=0.057	P=0.094	P=0.351
COCH-ARM / FISHERS	P=0.379N	P=0.119	P=0.078	P=0.472
MAX-ISO-POLY-3	P=0.135	P=0.033*	P=0.056	P=0.263

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver: Centrilobular Fatty Change</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/49 (2%)	7/50 (14%)	4/50 (8%)	21/50 (42%)
POLY-3 RATE (b)	1/43.50	7/44.61	4/45.95	21/42.62
POLY-3 PERCENT (g)	2.3%	15.7%	8.7%	49.3%
TERMINAL (d)	0/34 (0%)	7/35 (20%)	3/34 (9%)	19/31 (61%)
FIRST INCIDENCE	686	727 (T)	616	528
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.032*	P=0.195	P<0.001**
POLY 1.5	P<0.001**	P=0.031*	P=0.192	P<0.001**
POLY 6	P<0.001**	P=0.034*	P=0.199	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.032*	P=0.187	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.013*	P=0.098	P<0.001**

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver: Centrilobular Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/43.34	2/45.12	0/45.55	1/41.68
POLY-3 PERCENT (g)	0%	4.4%	0%	2.4%
TERMINAL (d)	0/34 (0%)	1/35 (3%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	571	---	670
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.604	P=0.246	(e)	P=0.492
POLY 1.5	P=0.604	P=0.241	(e)	P=0.493
POLY 6	P=0.604	P=0.253	(e)	P=0.492
COCH-ARM / FISHERS	P=0.620	P=0.253	(e)	P=0.505
MAX-ISO-POLY-3	P=0.335	P=0.083	(e)	P=0.160

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver: Hepatocyte Hypertrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	2/50 (4%)	2/50 (4%)	22/50 (44%)
POLY-3 RATE (b)	0/43.34	2/44.61	2/45.55	22/44.64
POLY-3 PERCENT (g)	0%	4.5%	4.4%	49.3%
TERMINAL (d)	0/34 (0%)	2/35 (6%)	2/34 (6%)	15/31 (48%)
FIRST INCIDENCE	---	727 (T)	727 (T)	30
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.243	P=0.248	P<0.001**
POLY 1.5	P<0.001**	P=0.240	P=0.246	P<0.001**
POLY 6	P<0.001**	P=0.248	P=0.250	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.253	P=0.253	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.081	P=0.086	P<0.001**

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver: Oval Cell Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/43.34	2/45.06	1/45.55	1/41.46
POLY-3 PERCENT (g)	0%	4.4%	2.2%	2.4%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	1/34 (3%)	1/31 (3%)
FIRST INCIDENCE	---	615	727 (T)	727 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.604	P=0.246	P=0.510	P=0.491
POLY 1.5	P=0.608	P=0.241	P=0.508	P=0.493
POLY 6	P=0.600	P=0.252	P=0.512	P=0.490
COCH-ARM / FISHERS	P=0.630	P=0.253	P=0.505	P=0.505
MAX-ISO-POLY-3	P=0.302	P=0.083	P=0.170	P=0.160



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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Inflammation Chronic</b>				
<b>LESION RATES</b>				
OVERALL (a)	6/49 (12%)	3/50 (6%)	9/50 (18%)	9/50 (18%)
POLY-3 RATE (b)	6/44.59	3/44.71	9/46.00	9/42.01
POLY-3 PERCENT (g)	13.5%	6.7%	19.6%	21.4%
TERMINAL (d)	3/34 (9%)	1/35 (3%)	6/34 (18%)	6/31 (19%)
FIRST INCIDENCE	582	714	664	670
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.090	P=0.240N	P=0.309	P=0.244
POLY 1.5	P=0.099	P=0.244N	P=0.308	P=0.255
POLY 6	P=0.083	P=0.237N	P=0.307	P=0.233
COCH-ARM / FISHERS	P=0.127	P=0.233N	P=0.303	P=0.303
MAX-ISO-POLY-3	P=0.127	P=0.146N	P=0.220	P=0.173

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Inflammation Granulomatous</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	0/43.34	0/44.61	0/45.55	3/41.69
POLY-3 PERCENT (g)	0%	0%	0%	7.2%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	2/31 (7%)
FIRST INCIDENCE	---	---	---	665
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.007**	(e)	(e)	P=0.111
POLY 1.5	P=0.007**	(e)	(e)	P=0.113
POLY 6	P=0.007**	(e)	(e)	P=0.111
COCH-ARM / FISHERS	P=0.009**	(e)	(e)	P=0.125
MAX-ISO-POLY-3	P=0.010**	(e)	(e)	P=0.038*

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/49 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/43.84	0/44.61	0/45.55	0/41.46
POLY-3 PERCENT (g)	4.6%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	629	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.262N	P=0.233N	P=0.229N	P=0.250N
POLY 1.5	P=0.259N	P=0.236N	P=0.230N	P=0.247N
POLY 6	P=0.264N	P=0.230N	P=0.229N	P=0.254N
COCH-ARM / FISHERS	P=0.260N	P=0.242N	P=0.242N	P=0.242N
MAX-ISO-POLY-3	P=0.045N*	P=0.075N	P=0.075N	P=0.089N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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: Alveolar Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	19/49 (39%)	13/50 (26%)	20/50 (40%)	15/50 (30%)
POLY-3 RATE (b)	19/44.71	13/44.79	20/46.58	15/42.35
POLY-3 PERCENT (g)	42.5%	29%	42.9%	35.4%
TERMINAL (d)	16/34 (47%)	12/35 (34%)	15/34 (44%)	13/31 (42%)
FIRST INCIDENCE	504	679	608	454
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.470N	P=0.131N	P=0.567	P=0.322N
POLY 1.5	P=0.443N	P=0.139N	P=0.552	P=0.308N
POLY 6	P=0.504N	P=0.119N	P=0.586N	P=0.339N
COCH-ARM / FISHERS	P=0.362N	P=0.126N	P=0.532	P=0.240N
MAX-ISO-POLY-3	P=0.411N	P=0.090N	P=0.482	P=0.254N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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: Alveolar Epithelium Hypertrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/49 (4%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/43.75	0/44.61	2/45.90	1/41.46
POLY-3 PERCENT (g)	4.6%	0%	4.4%	2.4%
TERMINAL (d)	1/34 (3%)	0/35 (0%)	0/34 (0%)	1/31 (3%)
FIRST INCIDENCE	610	---	664	727 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.613N	P=0.233N	P=0.677N	P=0.519N
POLY 1.5	P=0.605N	P=0.236N	P=0.680N	P=0.514N
POLY 6	P=0.622N	P=0.229N	P=0.674N	P=0.524N
COCH-ARM / FISHERS	P=0.588N	P=0.242N	P=0.684N	P=0.492N
MAX-ISO-POLY-3	P=0.438N	P=0.075N	P=0.480N	P=0.302N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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: Alveolar Epithelium Metaplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/49 (2%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/43.34	1/44.61	2/46.07	0/41.46
POLY-3 PERCENT (g)	2.3%	2.2%	4.3%	0%
TERMINAL (d)	1/34 (3%)	1/35 (3%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	727 (T)	727 (T)	608	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.346N	P=0.754N	P=0.521	P=0.509N
POLY 1.5	P=0.341N	P=0.758N	P=0.516	P=0.507N
POLY 6	P=0.352N	P=0.749N	P=0.527	P=0.510N
COCH-ARM / FISHERS	P=0.322N	P=0.747N	P=0.508	P=0.495N
MAX-ISO-POLY-3	P=0.308N	P=0.491N	P=0.303	P=0.171N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 104 WEEKS

---

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG

---

Lung: Alveolus  
Infiltration Cellular Histiocyte

---

LESION RATES				
OVERALL (a)	8/49 (16%)	3/50 (6%)	11/50 (22%)	9/50 (18%)
POLY-3 RATE (b)	8/43.47	3/44.79	11/45.66	9/41.83
POLY-3 PERCENT (g)	18.4%	6.7%	24.1%	21.5%
TERMINAL (d)	7/34 (21%)	2/35 (6%)	10/34 (29%)	7/31 (23%)
FIRST INCIDENCE	694	679	701	670

---

STATISTICAL TESTS				
POLY 3	P=0.192	P=0.088N	P=0.346	P=0.465
POLY 1.5	P=0.206	P=0.094N	P=0.337	P=0.470
POLY 6	P=0.179	P=0.081N	P=0.351	P=0.462
COCH-ARM / FISHERS	P=0.250	P=0.094N	P=0.323	P=0.518
MAX-ISO-POLY-3	P=0.178	P=0.048N*	P=0.260	P=0.362

---

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Lymph Node, Mesenteric Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/49 (4%)	2/50 (4%)	0/50 (0%)	5/50 (10%)
POLY-3 RATE (b)	2/43.50	2/44.82	0/45.55	5/42.09
POLY-3 PERCENT (g)	4.6%	4.5%	0%	11.9%
TERMINAL (d)	1/34 (3%)	1/35 (3%)	0/34 (0%)	2/31 (7%)
FIRST INCIDENCE	686	673	---	629
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.061	P=0.683N	P=0.227N	P=0.202
POLY 1.5	P=0.063	P=0.690N	P=0.229N	P=0.204
POLY 6	P=0.060	P=0.675N	P=0.226N	P=0.202
COCH-ARM / FISHERS	P=0.071	P=0.684N	P=0.242N	P=0.226
MAX-ISO-POLY-3	P=0.055	P=0.487N	P=0.075N	P=0.114



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Lymph Node, Mesenteric Inflammation</b>				
<b>LESION 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	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Lymph Node: Mediastinal Hyperplasia Lymphoid</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/4 (75%)	0/3 (0%)	0/2 (0%)	1/5 (20%)
POLY-3 RATE (b)	3/4.00	0/2.55	0/1.59	1/4.82
POLY-3 PERCENT (g)	75%	0%	0%	20.8%
TERMINAL (d)	3/4 (75%)	0/1 (0%)	0/1 (0%)	1/4 (25%)
FIRST INCIDENCE	727 (T)	---	---	727 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.245N	P=0.097N	P=0.246N	P=0.162N
POLY 1.5	P=0.269N	P=0.078N	P=0.203N	P=0.157N
POLY 6	P=0.215N	P=0.135N	P=0.316N	P=0.173N
COCH-ARM / FISHERS	P=0.326N	P=0.114N	P=0.200N	P=0.167N
MAX-ISO-POLY-3	P=0.017N*	P=0.023N*	P=0.089N	P=0.050N*

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/48 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/43.01	0/44.61	0/45.55	0/41.46
POLY-3 PERCENT (g)	2.3%	0%	0%	0%
TERMINAL (d)	1/34 (3%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	727 (T)	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.495N	P=0.493N	P=0.489N	P=0.507N
POLY 1.5	P=0.494N	P=0.495N	P=0.490N	P=0.505N
POLY 6	P=0.497N	P=0.489N	P=0.488N	P=0.510N
COCH-ARM / FISHERS	P=0.496N	P=0.490N	P=0.490N	P=0.490N
MAX-ISO-POLY-3	P=0.141N	P=0.156N	P=0.156N	P=0.170N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Mesentery: Fat Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	4/6 (67%)	7/8 (88%)	6/7 (86%)	5/6 (83%)
POLY-3 RATE (b)	4/5.52	7/7.49	6/6.54	5/6.00
POLY-3 PERCENT (g)	72.5%	93.5%	91.8%	83.3%
TERMINAL (d)	2/2 (100%)	4/4 (100%)	4/4 (100%)	4/5 (80%)
FIRST INCIDENCE	504	615	598	559
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.713N	P=0.383	P=0.447	P=0.603
POLY 1.5	P=0.640	P=0.382	P=0.440	P=0.552
POLY 6	P=0.627N	P=0.427	P=0.494	P=0.699
COCH-ARM / FISHERS	P=0.554	P=0.385	P=0.437	P=0.500
MAX-ISO-POLY-3	P=0.305	P=0.136	P=0.174	P=0.337

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Nose</b>				
<b>Foreign Body</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/49 (2%)	4/50 (8%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/44.01	4/44.61	1/45.55	2/41.67
POLY-3 PERCENT (g)	2.3%	9%	2.2%	4.8%
TERMINAL (d)	0/34 (0%)	4/35 (11%)	1/34 (3%)	1/31 (3%)
FIRST INCIDENCE	504	727 (T)	727 (T)	673
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.617N	P=0.182	P=0.753N	P=0.481
POLY 1.5	P=0.612N	P=0.179	P=0.754N	P=0.485
POLY 6	P=0.620N	P=0.187	P=0.753N	P=0.478
COCH-ARM / FISHERS	P=0.586N	P=0.187	P=0.747N	P=0.508
MAX-ISO-POLY-3	P=0.419	P=0.086	P=0.489N	P=0.271

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Nose Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	18/49 (37%)	14/50 (28%)	10/50 (20%)	18/50 (36%)
POLY-3 RATE (b)	18/45.50	14/45.68	10/46.16	18/44.90
POLY-3 PERCENT (g)	39.6%	30.7%	21.7%	40.1%
TERMINAL (d)	13/34 (38%)	10/35 (29%)	7/34 (21%)	10/31 (32%)
FIRST INCIDENCE	504	571	630	447
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.317	P=0.250N	P=0.048N*	P=0.565
POLY 1.5	P=0.318	P=0.260N	P=0.049N*	P=0.559
POLY 6	P=0.317	P=0.238N	P=0.050N*	P=0.573
COCH-ARM / FISHERS	P=0.354	P=0.238N	P=0.052N	P=0.553N
MAX-ISO-POLY-3	P=0.274	P=0.186N	P=0.029N*	P=0.478

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Nose: Olfactory Epithelium Metaplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/49 (4%)	1/50 (2%)	3/50 (6%)	5/50 (10%)
POLY-3 RATE (b)	2/43.34	1/44.61	3/45.55	5/43.20
POLY-3 PERCENT (g)	4.6%	2.2%	6.6%	11.6%
TERMINAL (d)	2/34 (6%)	1/35 (3%)	3/34 (9%)	1/31 (3%)
FIRST INCIDENCE	727 (T)	727 (T)	727 (T)	528
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.072	P=0.490N	P=0.523	P=0.214
POLY 1.5	P=0.072	P=0.496N	P=0.518	P=0.211
POLY 6	P=0.072	P=0.482N	P=0.527	P=0.220
COCH-ARM / FISHERS	P=0.079	P=0.492N	P=0.510	P=0.226
MAX-ISO-POLY-3	P=0.097	P=0.273N	P=0.346	P=0.119

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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

---

Nose: Respiratory Epithelium  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	1/49 (2%)	3/50 (6%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	1/43.34	3/44.87	1/45.55	4/41.93
POLY-3 PERCENT (g)	2.3%	6.7%	2.2%	9.5%
TERMINAL (d)	1/34 (3%)	1/35 (3%)	1/34 (3%)	3/31 (10%)
FIRST INCIDENCE	727 (T)	679	727 (T)	589

---

**STATISTICAL TESTS**

POLY 3	P=0.154	P=0.318	P=0.750N	P=0.168
POLY 1.5	P=0.156	P=0.310	P=0.752N	P=0.170
POLY 6	P=0.151	P=0.328	P=0.748N	P=0.167
COCH-ARM / FISHERS	P=0.172	P=0.316	P=0.747N	P=0.187
MAX-ISO-POLY-3	P=0.115	P=0.166	P=0.485N	P=0.081

---



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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 Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	16/49 (33%)	13/50 (26%)	18/50 (36%)	18/50 (36%)
POLY-3 RATE (b)	16/44.94	13/45.20	18/46.76	18/43.12
POLY-3 PERCENT (g)	35.6%	28.8%	38.5%	41.8%
TERMINAL (d)	11/34 (32%)	11/35 (31%)	13/34 (38%)	11/31 (36%)
FIRST INCIDENCE	582	571	608	559
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.202	P=0.319N	P=0.472	P=0.354
POLY 1.5	P=0.217	P=0.328N	P=0.463	P=0.365
POLY 6	P=0.193	P=0.312N	P=0.476	P=0.347
COCH-ARM / FISHERS	P=0.283	P=0.306N	P=0.445	P=0.445
MAX-ISO-POLY-3	P=0.295	P=0.244N	P=0.387	P=0.281

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/43.34	0/44.61	2/45.65	1/41.46
POLY-3 PERCENT (g)	0%	0%	4.4%	2.4%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	1/34 (3%)	1/31 (3%)
FIRST INCIDENCE	---	---	702	727 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.356	(e)	P=0.249	P=0.491
POLY 1.5	P=0.363	(e)	P=0.246	P=0.493
POLY 6	P=0.348	(e)	P=0.251	P=0.490
COCH-ARM / FISHERS	P=0.386	(e)	P=0.253	P=0.505
MAX-ISO-POLY-3	P=0.196	(e)	P=0.086	P=0.160

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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: Acinus Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	6/49 (12%)	9/50 (18%)	9/50 (18%)	2/50 (4%)
POLY-3 RATE (b)	6/43.50	9/44.61	9/46.14	2/41.81
POLY-3 PERCENT (g)	13.8%	20.2%	19.5%	4.8%
TERMINAL (d)	5/34 (15%)	9/35 (26%)	7/34 (21%)	1/31 (3%)
FIRST INCIDENCE	686	727 (T)	630	629
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.056N	P=0.304	P=0.330	P=0.145N
POLY 1.5	P=0.053N	P=0.294	P=0.319	P=0.144N
POLY 6	P=0.058N	P=0.317	P=0.341	P=0.146N
COCH-ARM / FISHERS	P=0.043N*	P=0.303	P=0.303	P=0.128N
MAX-ISO-POLY-3	P=0.079N	P=0.215	P=0.241	P=0.081N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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: Acinus Metaplasia Hepatocyte</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	6/50 (12%)
POLY-3 RATE (b)	0/43.34	0/44.61	0/45.55	6/41.65
POLY-3 PERCENT (g)	0%	0%	0%	14.4%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	5/31 (16%)
FIRST INCIDENCE	---	---	---	679
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	(e)	(e)	P=0.013*
POLY 1.5	P<0.001**	(e)	(e)	P=0.013*
POLY 6	P<0.001**	(e)	(e)	P=0.013*
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.014*
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P=0.005**

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Parathyroid Gland Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/49 (2%)	0/50 (0%)	1/48 (2%)	10/50 (20%)
POLY-3 RATE (b)	1/44.01	0/44.61	1/43.87	10/42.56
POLY-3 PERCENT (g)	2.3%	0%	2.3%	23.5%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/33 (0%)	6/31 (19%)
FIRST INCIDENCE	504	---	701	559
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.497N	P=0.760	P=0.003**
POLY 1.5	P<0.001**	P=0.500N	P=0.758	P=0.003**
POLY 6	P<0.001**	P=0.494N	P=0.760N	P=0.003**
COCH-ARM / FISHERS	P<0.001**	P=0.495N	P=0.747	P=0.004**
MAX-ISO-POLY-3	P<0.001**	P=0.157N	P=0.498	P<0.001**

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Angiectasis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/43.34	0/44.61	1/45.55	0/41.46
POLY-3 PERCENT (g)	0%	0%	2.2%	0%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	1/34 (3%)	0/31 (0%)
FIRST INCIDENCE	---	---	727 (T)	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.788N	(e)	P=0.510	(e)
POLY 1.5	P=0.785N	(e)	P=0.508	(e)
POLY 6	P=0.791N	(e)	P=0.512	(e)
COCH-ARM / FISHERS	P=0.778N	(e)	P=0.505	(e)
MAX-ISO-POLY-3	P=0.405	(e)	P=0.170	(e)

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	17/49 (35%)	20/50 (40%)	21/50 (42%)	11/50 (22%)
POLY-3 RATE (b)	17/44.07	20/46.75	21/46.59	11/43.66
POLY-3 PERCENT (g)	38.6%	42.8%	45.1%	25.2%
TERMINAL (d)	13/34 (38%)	11/35 (31%)	17/34 (50%)	6/31 (19%)
FIRST INCIDENCE	629	571	608	454
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.052N	P=0.423	P=0.338	P=0.130N
POLY 1.5	P=0.051N	P=0.377	P=0.321	P=0.136N
POLY 6	P=0.057N	P=0.489	P=0.353	P=0.124N
COCH-ARM / FISHERS	P=0.039N*	P=0.368	P=0.295	P=0.119N
MAX-ISO-POLY-3	P=0.083N	P=0.344	P=0.269	P=0.089N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Preputial Gland Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	0/50 (0%)	1/49 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/43.34	0/44.61	1/44.70	2/42.01
POLY-3 PERCENT (g)	0%	0%	2.2%	4.8%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	1/34 (3%)	1/31 (3%)
FIRST INCIDENCE	---	---	727 (T)	559
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.084	(e)	P=0.506	P=0.230
POLY 1.5	P=0.085	(e)	P=0.504	P=0.231
POLY 6	P=0.082	(e)	P=0.508	P=0.230
COCH-ARM / FISHERS	P=0.092	(e)	P=0.500	P=0.253
MAX-ISO-POLY-3	P=0.081	(e)	P=0.166	P=0.077



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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Prostate Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	28/49 (57%)	24/50 (48%)	21/50 (42%)	16/50 (32%)
POLY-3 RATE (b)	28/47.77	24/45.93	21/46.35	16/44.64
POLY-3 PERCENT (g)	58.6%	52.3%	45.3%	35.8%
TERMINAL (d)	18/34 (53%)	20/35 (57%)	15/34 (44%)	7/31 (23%)
FIRST INCIDENCE	504	525	664	447
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.019N*	P=0.340N	P=0.135N	P=0.021N*
POLY 1.5	P=0.017N*	P=0.320N	P=0.117N	P=0.018N*
POLY 6	P=0.019N*	P=0.365N	P=0.164N	P=0.023N*
COCH-ARM / FISHERS	P=0.011N*	P=0.239N	P=0.096N	P=0.010N**
MAX-ISO-POLY-3	P=0.025N*	P=0.272N	P=0.099N	P=0.015N*

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Prostate: Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	9/49 (18%)	8/50 (16%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	9/43.47	8/45.27	2/45.70	3/41.46
POLY-3 PERCENT (g)	20.7%	17.7%	4.4%	7.2%
TERMINAL (d)	8/34 (24%)	6/35 (17%)	1/34 (3%)	3/31 (10%)
FIRST INCIDENCE	694	571	689	727 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.051N	P=0.463N	P=0.019N*	P=0.069N
POLY 1.5	P=0.048N*	P=0.484N	P=0.021N*	P=0.067N
POLY 6	P=0.054N	P=0.437N	P=0.018N*	P=0.070N
COCH-ARM / FISHERS	P=0.042N*	P=0.482N	P=0.023N*	P=0.056N
MAX-ISO-POLY-3	P=0.035N*	P=0.360N	P=0.009N**	P=0.040N*

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Seminal Vesicle Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/43.34	0/44.61	1/45.79	2/41.75
POLY-3 PERCENT (g)	0%	0%	2.2%	4.8%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	664	670
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.082	(e)	P=0.511	P=0.229
POLY 1.5	P=0.084	(e)	P=0.508	P=0.230
POLY 6	P=0.081	(e)	P=0.514	P=0.228
COCH-ARM / FISHERS	P=0.091	(e)	P=0.505	P=0.253
MAX-ISO-POLY-3	P=0.081	(e)	P=0.171	P=0.077

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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 Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/43.34	2/44.61	0/45.55	1/41.46
POLY-3 PERCENT (g)	0%	4.5%	0%	2.4%
TERMINAL (d)	0/34 (0%)	2/35 (6%)	0/34 (0%)	1/31 (3%)
FIRST INCIDENCE	---	727 (T)	---	727 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.601	P=0.243	(e)	P=0.491
POLY 1.5	P=0.603	P=0.240	(e)	P=0.493
POLY 6	P=0.600	P=0.248	(e)	P=0.490
COCH-ARM / FISHERS	P=0.620	P=0.253	(e)	P=0.505
MAX-ISO-POLY-3	P=0.335	P=0.081	(e)	P=0.160

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Spleen Fibrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/43.34	0/44.61	0/45.55	2/41.82
POLY-3 PERCENT (g)	0%	0%	0%	4.8%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	---	673
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.038*	(e)	(e)	P=0.229
POLY 1.5	P=0.039*	(e)	(e)	P=0.230
POLY 6	P=0.038*	(e)	(e)	P=0.229
COCH-ARM / FISHERS	P=0.043*	(e)	(e)	P=0.253
MAX-ISO-POLY-3	P=0.035*	(e)	(e)	P=0.077

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Spleen</b>				
<b>Hematopoietic Cell Proliferation</b>				
<b>LESION RATES</b>				
OVERALL (a)	10/49 (20%)	10/50 (20%)	7/50 (14%)	5/50 (10%)
POLY-3 RATE (b)	10/45.09	10/47.69	7/46.67	5/43.82
POLY-3 PERCENT (g)	22.2%	21%	15%	11.4%
TERMINAL (d)	5/34 (15%)	2/35 (6%)	2/34 (6%)	1/31 (3%)
FIRST INCIDENCE	504	168	616	447
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.107N	P=0.544N	P=0.269N	P=0.141N
POLY 1.5	P=0.102N	P=0.566N	P=0.275N	P=0.140N
POLY 6	P=0.116N	P=0.516N	P=0.263N	P=0.144N
COCH-ARM / FISHERS	P=0.083N	P=0.579N	P=0.282N	P=0.122N
MAX-ISO-POLY-3	P=0.158N	P=0.444N	P=0.191N	P=0.091N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Spleen</b>				
Pigmentation Hemosiderin				
<b>LESION RATES</b>				
OVERALL (a)	31/49 (63%)	32/50 (64%)	35/50 (70%)	32/50 (64%)
POLY-3 RATE (b)	31/46.89	32/45.08	35/48.36	32/46.15
POLY-3 PERCENT (g)	66.1%	71%	72.4%	69.3%
TERMINAL (d)	24/34 (71%)	29/35 (83%)	25/34 (74%)	21/31 (68%)
FIRST INCIDENCE	504	666	454	447
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.510	P=0.387	P=0.326	P=0.455
POLY 1.5	P=0.486	P=0.418	P=0.319	P=0.446
POLY 6	P=0.555	P=0.359	P=0.340	P=0.483
COCH-ARM / FISHERS	P=0.549N	P=0.553	P=0.310	P=0.553
MAX-ISO-POLY-3	P=0.488	P=0.306	P=0.252	P=0.368

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Spleen Thrombosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/43.34	0/44.61	0/45.55	2/41.46
POLY-3 PERCENT (g)	0%	0%	0%	4.8%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	2/31 (7%)
FIRST INCIDENCE	---	---	---	727 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.038*	(e)	(e)	P=0.227
POLY 1.5	P=0.039*	(e)	(e)	P=0.229
POLY 6	P=0.037*	(e)	(e)	P=0.225
COCH-ARM / FISHERS	P=0.043*	(e)	(e)	P=0.253
MAX-ISO-POLY-3	P=0.035*	(e)	(e)	P=0.077



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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Spleen: Lymphoid Follicle Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/49 (4%)	2/50 (4%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/44.41	2/45.18	2/46.01	1/42.08
POLY-3 PERCENT (g)	4.5%	4.4%	4.4%	2.4%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	504	571	630	528
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.410N	P=0.688N	P=0.681N	P=0.519N
POLY 1.5	P=0.403N	P=0.692N	P=0.683N	P=0.514N
POLY 6	P=0.417N	P=0.682N	P=0.680N	P=0.524N
COCH-ARM / FISHERS	P=0.379N	P=0.684N	P=0.684N	P=0.492N
MAX-ISO-POLY-3	P=0.502N	P=0.492N	P=0.485N	P=0.302N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Stomach, Forestomach Erosion</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	0/50 (0%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	0/43.34	0/44.61	1/45.95	4/42.21
POLY-3 PERCENT (g)	0%	0%	2.2%	9.5%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	2/31 (7%)
FIRST INCIDENCE	---	---	616	559
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.004**	(e)	P=0.512	P=0.057
POLY 1.5	P=0.004**	(e)	P=0.509	P=0.057
POLY 6	P=0.004**	(e)	P=0.515	P=0.057
COCH-ARM / FISHERS	P=0.006**	(e)	P=0.505	P=0.061
MAX-ISO-POLY-3	P=0.007**	(e)	P=0.172	P=0.020*

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Stomach, Forestomach Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	8/49 (16%)	4/50 (8%)	9/50 (18%)	22/50 (44%)
POLY-3 RATE (b)	8/46.37	4/45.68	9/47.00	22/44.31
POLY-3 PERCENT (g)	17.3%	8.8%	19.2%	49.7%
TERMINAL (d)	1/34 (3%)	1/35 (3%)	3/34 (9%)	11/31 (36%)
FIRST INCIDENCE	504	525	590	559
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.184N	P=0.512	P<0.001**
POLY 1.5	P<0.001**	P=0.184N	P=0.514	P<0.001**
POLY 6	P<0.001**	P=0.183N	P=0.510	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.168N	P=0.518	P=0.002**
MAX-ISO-POLY-3	P<0.001**	P=0.116N	P=0.405	P<0.001**

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Stomach, Forestomach Mineralization</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	2/50 (4%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	0/43.34	2/44.91	1/45.69	3/41.74
POLY-3 PERCENT (g)	0%	4.5%	2.2%	7.2%
TERMINAL (d)	0/34 (0%)	1/35 (3%)	0/34 (0%)	1/31 (3%)
FIRST INCIDENCE	---	646	694	689
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.120	P=0.245	P=0.511	P=0.112
POLY 1.5	P=0.123	P=0.240	P=0.508	P=0.113
POLY 6	P=0.119	P=0.251	P=0.513	P=0.111
COCH-ARM / FISHERS	P=0.135	P=0.253	P=0.505	P=0.125
MAX-ISO-POLY-3	P=0.063	P=0.082	P=0.170	P=0.038*

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Stomach, Forestomach Ulcer</b>				
<b>LESION RATES</b>				
OVERALL (a)	4/49 (8%)	0/50 (0%)	6/50 (12%)	13/50 (26%)
POLY-3 RATE (b)	4/44.89	0/44.61	6/46.61	13/43.34
POLY-3 PERCENT (g)	8.9%	0%	12.9%	30%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	1/34 (3%)	5/31 (16%)
FIRST INCIDENCE	504	---	590	589
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.061N	P=0.393	P=0.011*
POLY 1.5	P<0.001**	P=0.061N	P=0.389	P=0.011*
POLY 6	P<0.001**	P=0.060N	P=0.397	P=0.011*
COCH-ARM / FISHERS	P<0.001**	P=0.056N	P=0.383	P=0.017*
MAX-ISO-POLY-3	P<0.001**	P=0.020N*	P=0.276	P=0.006**

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Stomach, Forestomach: Epithelium Dysplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/49 (2%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/43.50	0/44.61	2/46.02	1/41.46
POLY-3 PERCENT (g)	2.3%	0%	4.4%	2.4%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	1/34 (3%)	1/31 (3%)
FIRST INCIDENCE	686	---	590	727 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.549	P=0.495N	P=0.520	P=0.750
POLY 1.5	P=0.558	P=0.498N	P=0.515	P=0.752
POLY 6	P=0.539	P=0.491N	P=0.524	P=0.748
COCH-ARM / FISHERS	P=0.580	P=0.495N	P=0.508	P=0.747N
MAX-ISO-POLY-3	P=0.404	P=0.157N	P=0.301	P=0.486

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Stomach, Forestomach: Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	6/49 (12%)	4/50 (8%)	11/50 (22%)	27/50 (54%)
POLY-3 RATE (b)	6/45.55	4/45.68	11/47.24	27/45.78
POLY-3 PERCENT (g)	13.2%	8.8%	23.3%	59%
TERMINAL (d)	1/34 (3%)	1/35 (3%)	4/34 (12%)	14/31 (45%)
FIRST INCIDENCE	504	525	590	447
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.368N	P=0.160	P<0.001**
POLY 1.5	P<0.001**	P=0.372N	P=0.157	P<0.001**
POLY 6	P<0.001**	P=0.362N	P=0.165	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.357N	P=0.154	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.252N	P=0.106	P<0.001**

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Stomach, Glandular Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/49 (4%)	3/50 (6%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	2/43.97	3/45.06	3/46.36	3/41.81
POLY-3 PERCENT (g)	4.6%	6.7%	6.5%	7.2%
TERMINAL (d)	0/34 (0%)	1/35 (3%)	0/34 (0%)	1/31 (3%)
FIRST INCIDENCE	629	615	590	670
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.462	P=0.511	P=0.524	P=0.477
POLY 1.5	P=0.472	P=0.504	P=0.518	P=0.482
POLY 6	P=0.451	P=0.519	P=0.529	P=0.472
COCH-ARM / FISHERS	P=0.506	P=0.510	P=0.510	P=0.510
MAX-ISO-POLY-3	P=0.504	P=0.334	P=0.348	P=0.308



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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Stomach, Glandular: Epithelium Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/49 (4%)	1/50 (2%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	2/43.69	1/45.12	2/46.00	3/41.59
POLY-3 PERCENT (g)	4.6%	2.2%	4.4%	7.2%
TERMINAL (d)	1/34 (3%)	0/35 (0%)	0/34 (0%)	2/31 (7%)
FIRST INCIDENCE	629	571	664	694
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.278	P=0.489N	P=0.675N	P=0.478
POLY 1.5	P=0.287	P=0.495N	P=0.680N	P=0.482
POLY 6	P=0.269	P=0.481N	P=0.672N	P=0.472
COCH-ARM / FISHERS	P=0.310	P=0.492N	P=0.684N	P=0.510
MAX-ISO-POLY-3	P=0.340	P=0.273N	P=0.478N	P=0.309

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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: Germinal Epithelium Degeneration</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/49 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/44.29	0/44.61	0/45.55	0/41.46
POLY-3 PERCENT (g)	6.8%	0%	0%	0%
TERMINAL (d)	1/34 (3%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	504	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.146N	P=0.117N	P=0.114N	P=0.131N
POLY 1.5	P=0.144N	P=0.119N	P=0.114N	P=0.128N
POLY 6	P=0.148N	P=0.115N	P=0.114N	P=0.134N
COCH-ARM / FISHERS	P=0.147N	P=0.117N	P=0.117N	P=0.117N
MAX-ISO-POLY-3	P=0.015N*	P=0.038N*	P=0.037N*	P=0.049N*

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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: Interstitial Cell Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	17/49 (35%)	15/50 (30%)	10/50 (20%)	4/50 (8%)
POLY-3 RATE (b)	17/46.01	15/46.20	10/47.03	4/44.06
POLY-3 PERCENT (g)	37%	32.5%	21.3%	9.1%
TERMINAL (d)	11/34 (32%)	9/35 (26%)	4/34 (12%)	0/31 (0%)
FIRST INCIDENCE	504	525	608	447
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001N**	P=0.408N	P=0.073N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.419N	P=0.075N	P<0.001N**
POLY 6	P<0.001N**	P=0.390N	P=0.071N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.388N	P=0.078N	P<0.001N**
MAX-ISO-POLY-3	P=0.002N**	P=0.326N	P=0.046N*	P<0.001N**

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Thymus Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	47/48 (98%)	49/50 (98%)	49/50 (98%)	46/50 (92%)
POLY-3 RATE (b)	47/48.00	49/49.00	49/49.79	46/47.79
POLY-3 PERCENT (g)	97.9%	100%	98.4%	96.3%
TERMINAL (d)	33/34 (97%)	35/35 (100%)	34/34 (100%)	30/31 (97%)
FIRST INCIDENCE	504	168	454	447
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.269N	P=0.496	P=0.724	P=0.549N
POLY 1.5	P=0.251N	P=0.499	P=0.738	P=0.523N
POLY 6	P=0.304N	P=0.496	P=0.694	P=0.592N
COCH-ARM / FISHERS	P=0.060N	P=0.742	P=0.742	P=0.194N
MAX-ISO-POLY-3	P=0.251N	P=0.156	P=0.424	P=0.312N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG

---

Thyroid Gland: C-Cell  
Hyperplasia

---

**LESION RATES**

OVERALL (a)	8/49 (16%)	12/50 (24%)	12/50 (24%)	7/50 (14%)
POLY-3 RATE (b)	8/43.47	12/44.66	12/46.12	7/42.12
POLY-3 PERCENT (g)	18.4%	26.9%	26%	16.6%
TERMINAL (d)	7/34 (21%)	11/35 (31%)	10/34 (29%)	4/31 (13%)
FIRST INCIDENCE	694	714	608	665

---

**STATISTICAL TESTS**

POLY 3	P=0.289N	P=0.243	P=0.270	P=0.527N
POLY 1.5	P=0.282N	P=0.232	P=0.259	P=0.525N
POLY 6	P=0.291N	P=0.258	P=0.281	P=0.524N
COCH-ARM / FISHERS	P=0.237N	P=0.242	P=0.242	P=0.483N
MAX-ISO-POLY-3	P=0.354N	P=0.173	P=0.199	P=0.414N

---

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS IN RATS(F 344/N)  
TERMINAL SACRIFICE AT 104 WEEKS**

---

DOSE	Males			
	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG

---

Thyroid Gland: Follicle  
Cyst

---

**LESION RATES**

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.34	0/44.61	0/45.55	0/41.46
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	---	---	---	---

---

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/49 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/43.34	2/44.61	0/45.55	1/41.46
POLY-3 PERCENT (g)	0%	4.5%	0%	2.4%
TERMINAL (d)	0/34 (0%)	2/35 (6%)	0/34 (0%)	1/31 (3%)
FIRST INCIDENCE	---	727 (T)	---	727 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.601	P=0.243	(e)	P=0.491
POLY 1.5	P=0.603	P=0.240	(e)	P=0.493
POLY 6	P=0.600	P=0.248	(e)	P=0.490
COCH-ARM / FISHERS	P=0.620	P=0.253	(e)	P=0.505
MAX-ISO-POLY-3	P=0.335	P=0.081	(e)	P=0.160

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Tooth Malformation</b>				
<b>LESION RATES</b>				
OVERALL (a)	10/10 (100%)	6/6 (100%)	9/9 (100%)	11/11 (100%)
POLY-3 RATE (b)	10/10.00	6/6.00	9/9.00	11/11.00
POLY-3 PERCENT (g)	100%	100%	100%	100%
TERMINAL (d)	10/10 (100%)	4/4 (100%)	5/5 (100%)	7/7 (100%)
FIRST INCIDENCE	727 (T)	525	590	589
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---



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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Urinary Bladder Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/49 (4%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/43.92	0/44.61	1/45.79	2/42.32
POLY-3 PERCENT (g)	4.6%	0%	2.2%	4.7%
TERMINAL (d)	1/34 (3%)	0/35 (0%)	0/34 (0%)	0/31 (0%)
FIRST INCIDENCE	545	---	664	559
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.394	P=0.234N	P=0.485N	P=0.681
POLY 1.5	P=0.398	P=0.236N	P=0.488N	P=0.682
POLY 6	P=0.389	P=0.230N	P=0.483N	P=0.681
COCH-ARM / FISHERS	P=0.412	P=0.242N	P=0.492N	P=0.684N
MAX-ISO-POLY-3	P=0.405	P=0.075N	P=0.271N	P=0.485

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Cortex Degeneration Cystic</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/50 (6%)	6/50 (12%)	7/50 (14%)	6/50 (12%)
POLY-3 RATE (b)	3/44.11	6/44.49	7/40.88	6/41.90
POLY-3 PERCENT (g)	6.8%	13.5%	17.1%	14.3%
TERMINAL (d)	2/34 (6%)	5/34 (15%)	3/24 (13%)	4/34 (12%)
FIRST INCIDENCE	701	705	647	629
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.308	P=0.246	P=0.126	P=0.216
POLY 1.5	P=0.312	P=0.242	P=0.141	P=0.218
POLY 6	P=0.319	P=0.247	P=0.108	P=0.222
COCH-ARM / FISHERS	P=0.353	P=0.243	P=0.159	P=0.243
MAX-ISO-POLY-3	P=0.185	P=0.150	P=0.076	P=0.133

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Cortex Hypertrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	3/50 (6%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	2/44.00	3/44.99	1/40.19	3/41.67
POLY-3 PERCENT (g)	4.6%	6.7%	2.5%	7.2%
TERMINAL (d)	2/34 (6%)	1/34 (3%)	1/24 (4%)	2/34 (6%)
FIRST INCIDENCE	728 (T)	615	728 (T)	688
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.440	P=0.510	P=0.532N	P=0.475
POLY 1.5	P=0.442	P=0.503	P=0.516N	P=0.477
POLY 6	P=0.446	P=0.517	P=0.555N	P=0.481
COCH-ARM / FISHERS	P=0.465	P=0.500	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.476	P=0.334	P=0.315N	P=0.306

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Cortex</b>				
<b>Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/44.14	0/44.40	1/40.51	2/42.73
POLY-3 PERCENT (g)	4.5%	0%	2.5%	4.7%
TERMINAL (d)	1/34 (3%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	692	---	639	380
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.397	P=0.236N	P=0.530N	P=0.682
POLY 1.5	P=0.397	P=0.238N	P=0.516N	P=0.681
POLY 6	P=0.403	P=0.235N	P=0.552N	P=0.689
COCH-ARM / FISHERS	P=0.408	P=0.247N	P=0.500N	P=0.691N
MAX-ISO-POLY-3	P=0.411	P=0.076N	P=0.313N	P=0.486

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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 Cortex: Zona Fasciculata Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	6/50 (12%)	6/50 (12%)	4/50 (8%)	9/50 (18%)
POLY-3 RATE (b)	6/44.00	6/44.51	4/40.51	9/41.55
POLY-3 PERCENT (g)	13.6%	13.5%	9.9%	21.7%
TERMINAL (d)	6/34 (18%)	5/34 (15%)	3/24 (13%)	8/34 (24%)
FIRST INCIDENCE	728 (T)	701	639	721
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.145	P=0.613N	P=0.422N	P=0.245
POLY 1.5	P=0.149	P=0.620N	P=0.397N	P=0.249
POLY 6	P=0.149	P=0.609N	P=0.461N	P=0.251
COCH-ARM / FISHERS	P=0.176	P=0.620N	P=0.370N	P=0.288
MAX-ISO-POLY-3	P=0.193	P=0.491N	P=0.304N	P=0.172

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/50 (6%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	3/45.23	0/44.40	1/40.19	1/41.67
POLY-3 PERCENT (g)	6.6%	0%	2.5%	2.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/24 (4%)	0/34 (0%)
FIRST INCIDENCE	450	---	728 (T)	688
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.466N	P=0.122N	P=0.349N	P=0.335N
POLY 1.5	P=0.465N	P=0.122N	P=0.328N	P=0.330N
POLY 6	P=0.462N	P=0.123N	P=0.379N	P=0.335N
COCH-ARM / FISHERS	P=0.454N	P=0.121N	P=0.309N	P=0.309N
MAX-ISO-POLY-3	P=0.143N	P=0.040N*	P=0.198N	P=0.185N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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 Marrow Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	26/50 (52%)	27/50 (54%)	19/50 (38%)	23/50 (46%)
POLY-3 RATE (b)	26/47.27	27/47.01	19/43.27	23/44.15
POLY-3 PERCENT (g)	55%	57.4%	43.9%	52.1%
TERMINAL (d)	16/34 (47%)	17/34 (50%)	8/24 (33%)	14/34 (41%)
FIRST INCIDENCE	450	605	518	380
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.404N	P=0.488	P=0.196N	P=0.473N
POLY 1.5	P=0.386N	P=0.475	P=0.154N	P=0.455N
POLY 6	P=0.391N	P=0.505	P=0.259N	P=0.460N
COCH-ARM / FISHERS	P=0.293N	P=0.500	P=0.114N	P=0.345N
MAX-ISO-POLY-3	P=0.361N	P=0.404	P=0.152N	P=0.392N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Marrow</b>				
<b>Myelofibrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/44.76	1/44.51	1/40.28	1/42.06
POLY-3 PERCENT (g)	4.5%	2.3%	2.5%	2.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	506	701	705	559
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.514N	P=0.502N	P=0.537N	P=0.522N
POLY 1.5	P=0.513N	P=0.503N	P=0.520N	P=0.520N
POLY 6	P=0.509N	P=0.502N	P=0.561N	P=0.519N
COCH-ARM / FISHERS	P=0.500N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.461N	P=0.282N	P=0.320N	P=0.304N



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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Brain Hemorrhage</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	2/45.02	2/41.04	0/41.52
POLY-3 PERCENT (g)	0%	4.4%	4.9%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	605	579	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.396N	P=0.242	P=0.222	(e)
POLY 1.5	P=0.394N	P=0.239	P=0.229	(e)
POLY 6	P=0.392N	P=0.245	P=0.211	(e)
COCH-ARM / FISHERS	P=0.373N	P=0.247	P=0.247	(e)
MAX-ISO-POLY-3	P=0.286	P=0.081	P=0.075	(e)

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Brain Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	3/50 (6%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	3/45.05	2/40.54	0/41.52
POLY-3 PERCENT (g)	0%	6.7%	4.9%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/24 (4%)	0/34 (0%)
FIRST INCIDENCE	---	605	629	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.300N	P=0.123	P=0.219	(e)
POLY 1.5	P=0.299N	P=0.120	P=0.228	(e)
POLY 6	P=0.295N	P=0.125	P=0.207	(e)
COCH-ARM / FISHERS	P=0.281N	P=0.121	P=0.247	(e)
MAX-ISO-POLY-3	P=0.237	P=0.041*	P=0.075	(e)

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Gland Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	3/49 (6%)	5/50 (10%)	1/49 (2%)
POLY-3 RATE (b)	0/44.00	3/43.80	5/40.37	1/41.37
POLY-3 PERCENT (g)	0%	6.9%	12.4%	2.4%
TERMINAL (d)	0/34 (0%)	3/34 (9%)	4/24 (17%)	1/34 (3%)
FIRST INCIDENCE	---	728 (T)	681	728 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.537N	P=0.118	P=0.024*	P=0.488
POLY 1.5	P=0.535N	P=0.116	P=0.027*	P=0.488
POLY 6	P=0.530N	P=0.119	P=0.019*	P=0.490
COCH-ARM / FISHERS	P=0.506N	P=0.117	P=0.028*	P=0.495
MAX-ISO-POLY-3	P=0.109	P=0.038*	P=0.009**	P=0.157

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Gland Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	2/49 (4%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	1/44.00	2/44.14	0/40.19	0/41.37
POLY-3 PERCENT (g)	2.3%	4.5%	0%	0%
TERMINAL (d)	1/34 (3%)	1/34 (3%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	728 (T)	632	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.232N	P=0.501	P=0.518N	P=0.512N
POLY 1.5	P=0.234N	P=0.496	P=0.509N	P=0.512N
POLY 6	P=0.228N	P=0.507	P=0.531N	P=0.510N
COCH-ARM / FISHERS	P=0.230N	P=0.492	P=0.500N	P=0.505N
MAX-ISO-POLY-3	P=0.198N	P=0.283	P=0.180N	P=0.173N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Coagulating Gland Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/0.00	0/0.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Eye: Cornea Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	1/44.00	0/44.40	2/40.89	2/41.52
POLY-3 PERCENT (g)	2.3%	0%	4.9%	4.8%
TERMINAL (d)	1/34 (3%)	0/34 (0%)	0/24 (0%)	2/34 (6%)
FIRST INCIDENCE	728 (T)	---	532	728 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.257	P=0.498N	P=0.474	P=0.480
POLY 1.5	P=0.261	P=0.500N	P=0.487	P=0.481
POLY 6	P=0.259	P=0.497N	P=0.455	P=0.483
COCH-ARM / FISHERS	P=0.281	P=0.500N	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.262	P=0.158N	P=0.266	P=0.269

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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

---

Eye: Iris  
Inflammation

---

**LESION RATES**

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	---	---

---

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Eye: Lens</b>				
<b>Cataract</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	3/50 (6%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	2/44.24	3/44.62	1/40.47	3/41.52
POLY-3 PERCENT (g)	4.5%	6.7%	2.5%	7.2%
TERMINAL (d)	1/34 (3%)	2/34 (6%)	0/24 (0%)	3/34 (9%)
FIRST INCIDENCE	664	670	652	728 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.438	P=0.504	P=0.531N	P=0.471
POLY 1.5	P=0.441	P=0.500	P=0.516N	P=0.474
POLY 6	P=0.441	P=0.506	P=0.553N	P=0.474
COCH-ARM / FISHERS	P=0.465	P=0.500	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.472	P=0.328	P=0.314N	P=0.303



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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Eye: Retina Degeneration</b>				
<b>LESION RATES</b>				
OVERALL (a)	5/50 (10%)	5/50 (10%)	5/50 (10%)	12/50 (24%)
POLY-3 RATE (b)	5/44.24	5/45.05	5/40.65	12/41.81
POLY-3 PERCENT (g)	11.3%	11.1%	12.3%	28.7%
TERMINAL (d)	4/34 (12%)	3/34 (9%)	2/24 (8%)	10/34 (29%)
FIRST INCIDENCE	664	605	652	688
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.008**	P=0.619N	P=0.577	P=0.037*
POLY 1.5	P=0.008**	P=0.627N	P=0.602	P=0.039*
POLY 6	P=0.008**	P=0.613N	P=0.538	P=0.039*
COCH-ARM / FISHERS	P=0.013*	P=0.630N	P=0.630N	P=0.054
MAX-ISO-POLY-3	P=0.013*	P=0.487N	P=0.444	P=0.023*

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Eye: Retina</b>				
<b>Gliososis</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	1/50 (2%)	0/50 (0%)	3/50 (6%)	1/50 (2%)
<b>POLY-3 RATE (b)</b>	1/44.00	0/44.40	3/40.27	1/41.52
<b>POLY-3 PERCENT (g)</b>	2.3%	0%	7.5%	2.4%
<b>TERMINAL (d)</b>	1/34 (3%)	0/34 (0%)	2/24 (8%)	1/34 (3%)
<b>FIRST INCIDENCE</b>	728 (T)	---	708	728 (T)
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.557	P=0.498N	P=0.274	P=0.748
<b>POLY 1.5</b>	P=0.563	P=0.500N	P=0.289	P=0.749
<b>POLY 6</b>	P=0.560	P=0.497N	P=0.252	P=0.750
<b>COCH-ARM / FISHERS</b>	P=0.592	P=0.500N	P=0.309	P=0.753N
<b>MAX-ISO-POLY-3</b>	P=0.257	P=0.158N	P=0.143	P=0.483

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Heart</b>				
<b>Cardiomyopathy</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	42/50 (84%)	45/50 (90%)	45/50 (90%)	47/50 (94%)
<b>POLY-3 RATE (b)</b>	42/46.05	45/47.22	45/47.17	47/47.15
<b>POLY-3 PERCENT (g)</b>	91.2%	95.3%	95.4%	99.7%
<b>TERMINAL (d)</b>	33/34 (97%)	34/34 (100%)	24/24 (100%)	34/34 (100%)
<b>FIRST INCIDENCE</b>	615	558	518	194
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.043*	P=0.336	P=0.322	P=0.040*
<b>POLY 1.5</b>	P=0.044*	P=0.257	P=0.296	P=0.033*
<b>POLY 6</b>	P=0.069	P=0.429	P=0.363	P=0.084
<b>COCH-ARM / FISHERS</b>	P=0.119	P=0.277	P=0.277	P=0.100
<b>MAX-ISO-POLY-3</b>	P=0.019*	P=0.189	P=0.175	P=0.010**

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Heart: Atrium Thrombosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.00	1/44.51	0/40.19	1/41.67
POLY-3 PERCENT (g)	0%	2.3%	0%	2.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	701	---	688
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.451	P=0.502	(e)	P=0.489
POLY 1.5	P=0.451	P=0.500	(e)	P=0.490
POLY 6	P=0.455	P=0.504	(e)	P=0.492
COCH-ARM / FISHERS	P=0.464	P=0.500	(e)	P=0.500
MAX-ISO-POLY-3	P=0.257	P=0.161	(e)	P=0.158

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Intestine Large, Colon</b>				
<b>Parasite Metazoan</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/50 (6%)	1/50 (2%)	8/50 (16%)	6/50 (12%)
POLY-3 RATE (b)	3/44.40	1/44.40	8/42.87	6/42.24
POLY-3 PERCENT (g)	6.8%	2.3%	18.7%	14.2%
TERMINAL (d)	2/34 (6%)	1/34 (3%)	3/24 (13%)	4/34 (12%)
FIRST INCIDENCE	615	728 (T)	98	489
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.095	P=0.305N	P=0.086	P=0.217
POLY 1.5	P=0.098	P=0.307N	P=0.095	P=0.219
POLY 6	P=0.099	P=0.305N	P=0.073	P=0.221
COCH-ARM / FISHERS	P=0.121	P=0.309N	P=0.100	P=0.243
MAX-ISO-POLY-3	P=0.058	P=0.154N	P=0.048*	P=0.134

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	0/50 (0%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	1/44.14	0/44.40	3/40.49	1/41.52
POLY-3 PERCENT (g)	2.3%	0%	7.4%	2.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/24 (4%)	1/34 (3%)
FIRST INCIDENCE	692	---	672	728 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.557	P=0.499N	P=0.275	P=0.747
POLY 1.5	P=0.563	P=0.500N	P=0.289	P=0.748
POLY 6	P=0.559	P=0.498N	P=0.254	P=0.749
COCH-ARM / FISHERS	P=0.592	P=0.500N	P=0.309	P=0.753N
MAX-ISO-POLY-3	P=0.258	P=0.158N	P=0.143	P=0.482

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Kidney</b>				
Accumulation, Hyaline Droplet				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/44.00	2/45.09	1/40.19	1/41.52
POLY-3 PERCENT (g)	0%	4.4%	2.5%	2.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/24 (4%)	1/34 (3%)
FIRST INCIDENCE	---	631	728 (T)	728 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.604	P=0.243	P=0.482	P=0.488
POLY 1.5	P=0.606	P=0.239	P=0.491	P=0.489
POLY 6	P=0.608	P=0.246	P=0.469	P=0.490
COCH-ARM / FISHERS	P=0.627	P=0.247	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.285	P=0.081	P=0.158	P=0.158

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Kidney Infarct</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	3/50 (6%)	4/50 (8%)	3/50 (6%)
POLY-3 RATE (b)	2/44.00	3/44.40	4/41.07	3/41.52
POLY-3 PERCENT (g)	4.6%	6.8%	9.7%	7.2%
TERMINAL (d)	2/34 (6%)	3/34 (9%)	2/24 (8%)	3/34 (9%)
FIRST INCIDENCE	728 (T)	728 (T)	518	728 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.475	P=0.504	P=0.305	P=0.474
POLY 1.5	P=0.480	P=0.500	P=0.321	P=0.476
POLY 6	P=0.481	P=0.506	P=0.282	P=0.478
COCH-ARM / FISHERS	P=0.515	P=0.500	P=0.339	P=0.500
MAX-ISO-POLY-3	P=0.398	P=0.328	P=0.184	P=0.305



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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Kidney Mineralization</b>				
<b>LESION RATES</b>				
OVERALL (a)	43/50 (86%)	43/50 (86%)	45/50 (90%)	46/50 (92%)
POLY-3 RATE (b)	43/48.86	43/47.41	45/49.37	46/48.47
POLY-3 PERCENT (g)	88%	90.7%	91.2%	94.9%
TERMINAL (d)	29/34 (85%)	31/34 (91%)	21/24 (88%)	32/34 (94%)
FIRST INCIDENCE	450	558	98	111
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.171	P=0.461	P=0.427	P=0.192
POLY 1.5	P=0.197	P=0.487	P=0.454	P=0.223
POLY 6	P=0.159	P=0.425	P=0.388	P=0.174
COCH-ARM / FISHERS	P=0.197	P=0.613N	P=0.380	P=0.262
MAX-ISO-POLY-3	P=0.177	P=0.334	P=0.303	P=0.108

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Kidney</b>				
<b>Nephropathy</b>				
<b>LESION RATES</b>				
OVERALL (a)	34/50 (68%)	35/50 (70%)	37/50 (74%)	43/50 (86%)
POLY-3 RATE (b)	34/45.98	35/46.59	37/46.71	43/44.94
POLY-3 PERCENT (g)	74%	75.1%	79.2%	95.7%
TERMINAL (d)	26/34 (77%)	27/34 (79%)	19/24 (79%)	34/34 (100%)
FIRST INCIDENCE	510	605	518	194
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.002**	P=0.545	P=0.357	P=0.002**
POLY 1.5	P=0.003**	P=0.506	P=0.347	P=0.003**
POLY 6	P=0.002**	P=0.579	P=0.370	P=0.002**
COCH-ARM / FISHERS	P=0.017*	P=0.500	P=0.330	P=0.028*
MAX-ISO-POLY-3	P=0.003**	P=0.446	P=0.269	P<0.001**

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Kidney: Cortex Cyst</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.38	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	4.5%	0%	0%	0%
TERMINAL (d)	1/34 (3%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	621	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.261N	P=0.237N	P=0.260N	P=0.252N
POLY 1.5	P=0.261N	P=0.238N	P=0.249N	P=0.250N
POLY 6	P=0.258N	P=0.237N	P=0.277N	P=0.251N
COCH-ARM / FISHERS	P=0.262N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.047N*	P=0.076N	P=0.097N	P=0.090N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Kidney: Pelvis Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	1/50 (2%)	5/50 (10%)	4/50 (8%)
POLY-3 RATE (b)	1/44.00	1/44.40	5/40.43	4/41.52
POLY-3 PERCENT (g)	2.3%	2.3%	12.4%	9.6%
TERMINAL (d)	1/34 (3%)	1/34 (3%)	4/24 (17%)	4/34 (12%)
FIRST INCIDENCE	728 (T)	728 (T)	664	728 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.108	P=0.759N	P=0.082	P=0.161
POLY 1.5	P=0.112	P=0.761	P=0.091	P=0.163
POLY 6	P=0.110	P=0.758N	P=0.070	P=0.163
COCH-ARM / FISHERS	P=0.133	P=0.753N	P=0.102	P=0.181
MAX-ISO-POLY-3	P=0.087	P=0.497N	P=0.040*	P=0.079

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 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 NON-NEOPLASTIC LESIONS 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>Kidney: Pelvis, Transitional Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	4/50 (8%)	6/50 (12%)
POLY-3 RATE (b)	0/44.00	0/44.40	4/40.43	6/41.55
POLY-3 PERCENT (g)	0%	0%	9.9%	14.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	3/24 (13%)	5/34 (15%)
FIRST INCIDENCE	---	---	664	721
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.002**	(e)	P=0.050*	P=0.012*
POLY 1.5	P=0.002**	(e)	P=0.055	P=0.013*
POLY 6	P=0.002**	(e)	P=0.043*	P=0.013*
COCH-ARM / FISHERS	P=0.003**	(e)	P=0.059	P=0.013*
MAX-ISO-POLY-3	P=0.002**	(e)	P=0.019*	P=0.004**

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Kidney: Renal Tubule Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/44.00	0/44.40	1/40.97	2/43.35
POLY-3 PERCENT (g)	0%	0%	2.4%	4.6%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	439	140
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.087	(e)	P=0.486	P=0.234
POLY 1.5	P=0.087	(e)	P=0.493	P=0.233
POLY 6	P=0.088	(e)	P=0.474	P=0.237
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

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
<b>Angiectasis</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	1/44.00	2/44.40	0/40.19	3/41.52
POLY-3 PERCENT (g)	2.3%	4.5%	0%	7.2%
TERMINAL (d)	1/34 (3%)	2/34 (6%)	0/24 (0%)	3/34 (9%)
FIRST INCIDENCE	728 (T)	728 (T)	---	728 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.200	P=0.503	P=0.518N	P=0.284
POLY 1.5	P=0.201	P=0.500	P=0.509N	P=0.286
POLY 6	P=0.203	P=0.505	P=0.531N	P=0.288
COCH-ARM / FISHERS	P=0.213	P=0.500	P=0.500N	P=0.309
MAX-ISO-POLY-3	P=0.184	P=0.284	P=0.180N	P=0.146

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
<b>Basophilic Focus</b>				
<b>LESION RATES</b>				
OVERALL (a)	44/50 (88%)	42/50 (84%)	41/50 (82%)	11/50 (22%)
POLY-3 RATE (b)	44/46.81	42/46.66	41/46.58	11/42.21
POLY-3 PERCENT (g)	94%	90%	88%	26.1%
TERMINAL (d)	34/34 (100%)	33/34 (97%)	22/24 (92%)	7/34 (21%)
FIRST INCIDENCE	450	558	519	664
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001N**	P=0.357N	P=0.233N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.402N	P=0.244N	P<0.001N**
POLY 6	P<0.001N**	P=0.332N	P=0.229N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.387N	P=0.288N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.214N	P=0.129N	P<0.001N**



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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
<b>Clear Cell Focus</b>				
<b>LESION RATES</b>				
OVERALL (a)	12/50 (24%)	14/50 (28%)	11/50 (22%)	8/50 (16%)
POLY-3 RATE (b)	12/44.11	14/44.72	11/40.19	8/41.52
POLY-3 PERCENT (g)	27.2%	31.3%	27.4%	19.3%
TERMINAL (d)	11/34 (32%)	13/34 (38%)	11/24 (46%)	8/34 (24%)
FIRST INCIDENCE	701	639	728 (T)	728 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.155N	P=0.424	P=0.590	P=0.270N
POLY 1.5	P=0.152N	P=0.412	P=0.554N	P=0.267N
POLY 6	P=0.145N	P=0.433	P=0.514	P=0.262N
COCH-ARM / FISHERS	P=0.121N	P=0.410	P=0.500N	P=0.227N
MAX-ISO-POLY-3	P=0.248N	P=0.336	P=0.493	P=0.200N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
<b>Degeneration Cystic</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	1/41.67
POLY-3 PERCENT (g)	0%	0%	0%	2.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	---	688
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.212	(e)	(e)	P=0.489
POLY 1.5	P=0.213	(e)	(e)	P=0.490
POLY 6	P=0.213	(e)	(e)	P=0.492
COCH-ARM / FISHERS	P=0.221	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.126	(e)	(e)	P=0.158

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
<b>Eosinophilic Focus</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	23/50 (46%)	31/50 (62%)	24/50 (48%)	23/50 (46%)
<b>POLY-3 RATE (b)</b>	23/44.00	31/45.66	24/42.29	23/41.52
<b>POLY-3 PERCENT (g)</b>	52.3%	67.9%	56.8%	55.4%
<b>TERMINAL (d)</b>	23/34 (68%)	27/34 (79%)	17/24 (71%)	23/34 (68%)
<b>FIRST INCIDENCE</b>	728 (T)	615	532	728 (T)
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.402N	P=0.089	P=0.418	P=0.470
<b>POLY 1.5</b>	P=0.379N	P=0.077	P=0.459	P=0.480
<b>POLY 6</b>	P=0.391N	P=0.106	P=0.358	P=0.491
<b>COCH-ARM / FISHERS</b>	P=0.269N	P=0.080	P=0.500	P=0.579N
<b>MAX-ISO-POLY-3</b>	P=0.369	P=0.061	P=0.335	P=0.385

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
<b>Fatty Change Diffuse</b>				
<b>LESION RATES</b>				
OVERALL (a)	9/50 (18%)	10/50 (20%)	10/50 (20%)	11/50 (22%)
POLY-3 RATE (b)	9/45.64	10/45.96	10/42.10	11/41.67
POLY-3 PERCENT (g)	19.7%	21.8%	23.8%	26.4%
TERMINAL (d)	4/34 (12%)	4/34 (12%)	4/24 (17%)	10/34 (29%)
FIRST INCIDENCE	450	605	532	688
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.285	P=0.507	P=0.421	P=0.314
POLY 1.5	P=0.307	P=0.497	P=0.457	P=0.331
POLY 6	P=0.274	P=0.515	P=0.372	P=0.306
COCH-ARM / FISHERS	P=0.384	P=0.500	P=0.500	P=0.402
MAX-ISO-POLY-3	P=0.389	P=0.403	P=0.330	P=0.240

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
<b>Hematopoietic Cell Proliferation</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	3/50 (6%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.40	3/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	2.3%	6.8%	0%	0%
TERMINAL (d)	0/34 (0%)	3/34 (9%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	615	728 (T)	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.171N	P=0.305	P=0.520N	P=0.513N
POLY 1.5	P=0.172N	P=0.304	P=0.510N	P=0.512N
POLY 6	P=0.169N	P=0.304	P=0.534N	P=0.513N
COCH-ARM / FISHERS	P=0.166N	P=0.309	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.144N	P=0.154	P=0.183N	P=0.175N

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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

---

Liver  
Hepatodiaphragmatic Nodule

---

**LESION RATES**

OVERALL (a)	5/50 (10%)	6/50 (12%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	5/44.14	6/44.72	1/40.47	2/41.52
POLY-3 PERCENT (g)	11.3%	13.4%	2.5%	4.8%
TERMINAL (d)	4/34 (12%)	5/34 (15%)	0/24 (0%)	2/34 (6%)
FIRST INCIDENCE	693	639	653	728 (T)

---

**STATISTICAL TESTS**

POLY 3	P=0.132N	P=0.509	P=0.122N	P=0.241N
POLY 1.5	P=0.132N	P=0.502	P=0.112N	P=0.239N
POLY 6	P=0.128N	P=0.514	P=0.139N	P=0.237N
COCH-ARM / FISHERS	P=0.121N	P=0.500	P=0.102N	P=0.218N
MAX-ISO-POLY-3	P=0.122N	P=0.383	P=0.063N	P=0.143N

---

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
<b>Inflammation Chronic</b>				
<b>LESION RATES</b>				
OVERALL (a)	43/50 (86%)	40/50 (80%)	38/50 (76%)	35/50 (70%)
POLY-3 RATE (b)	43/47.47	40/47.55	38/46.20	35/45.07
POLY-3 PERCENT (g)	90.6%	84.1%	82.3%	77.7%
TERMINAL (d)	32/34 (94%)	31/34 (91%)	22/24 (92%)	28/34 (82%)
FIRST INCIDENCE	450	51	98	194
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.080N	P=0.250N	P=0.168N	P=0.067N
POLY 1.5	P=0.077N	P=0.259N	P=0.131N	P=0.061N
POLY 6	P=0.067N	P=0.263N	P=0.255N	P=0.067N
COCH-ARM / FISHERS	P=0.046N*	P=0.298N	P=0.154N	P=0.045N*
MAX-ISO-POLY-3	P=0.065N	P=0.158N	P=0.101N	P=0.039N*

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
<b>Mixed Cell Focus</b>				
<b>LESION RATES</b>				
OVERALL (a)	15/50 (30%)	10/50 (20%)	9/50 (18%)	3/50 (6%)
POLY-3 RATE (b)	15/44.70	10/44.72	9/41.66	3/41.52
POLY-3 PERCENT (g)	33.6%	22.4%	21.6%	7.2%
TERMINAL (d)	12/34 (35%)	9/34 (27%)	4/24 (17%)	3/34 (9%)
FIRST INCIDENCE	621	639	532	728 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.004N**	P=0.171N	P=0.156N	P=0.002N**
POLY 1.5	P=0.004N**	P=0.177N	P=0.137N	P=0.002N**
POLY 6	P=0.003N**	P=0.170N	P=0.191N	P=0.002N**
COCH-ARM / FISHERS	P=0.003N**	P=0.178N	P=0.121N	P=0.002N**
MAX-ISO-POLY-3	P=0.003N**	P=0.117N	P=0.113N	P<0.001N**



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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
<b>Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.14	1/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	4.5%	2.3%	0%	0%
TERMINAL (d)	1/34 (3%)	1/34 (3%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	692	728 (T)	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.189N	P=0.498N	P=0.258N	P=0.251N
POLY 1.5	P=0.189N	P=0.501N	P=0.248N	P=0.250N
POLY 6	P=0.187N	P=0.497N	P=0.275N	P=0.249N
COCH-ARM / FISHERS	P=0.186N	P=0.500N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.097N	P=0.279N	P=0.096N	P=0.089N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver</b>				
Pigmentation Hemosiderin				
<b>LESION 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	1/40.58	1/41.76
POLY-3 PERCENT (g)	2.3%	0%	2.5%	2.4%
TERMINAL (d)	1/34 (3%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	728 (T)	---	618	664
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.539	P=0.498N	P=0.743	P=0.749
POLY 1.5	P=0.542	P=0.500N	P=0.751	P=0.749
POLY 6	P=0.543	P=0.497N	P=0.729	P=0.753
COCH-ARM / FISHERS	P=0.559	P=0.500N	P=0.753N	P=0.753N
MAX-ISO-POLY-3	P=0.523	P=0.158N	P=0.477	P=0.485

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver: Bile Duct Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	12/50 (24%)	15/50 (30%)	10/50 (20%)	10/50 (20%)
POLY-3 RATE (b)	12/45.91	15/45.75	10/41.15	10/43.19
POLY-3 PERCENT (g)	26.1%	32.8%	24.3%	23.2%
TERMINAL (d)	7/34 (21%)	8/34 (24%)	5/24 (21%)	6/34 (18%)
FIRST INCIDENCE	506	605	632	380
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.298N	P=0.320	P=0.520N	P=0.468N
POLY 1.5	P=0.292N	P=0.315	P=0.467N	P=0.460N
POLY 6	P=0.290N	P=0.324	P=0.592N	P=0.464N
COCH-ARM / FISHERS	P=0.247N	P=0.326	P=0.405N	P=0.405N
MAX-ISO-POLY-3	P=0.413N	P=0.244	P=0.424N	P=0.375N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver: Centrilobular Fatty Change</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	2/41.52
POLY-3 PERCENT (g)	0%	0%	0%	4.8%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	2/34 (6%)
FIRST INCIDENCE	---	---	---	728 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.038*	(e)	(e)	P=0.224
POLY 1.5	P=0.038*	(e)	(e)	P=0.225
POLY 6	P=0.038*	(e)	(e)	P=0.226
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.034*	(e)	(e)	P=0.076

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Liver: Centrilobular Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.00	1/44.40	0/40.19	1/41.65
POLY-3 PERCENT (g)	0%	2.3%	0%	2.4%
TERMINAL (d)	0/34 (0%)	1/34 (3%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	728 (T)	---	694
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.451	P=0.502	(e)	P=0.489
POLY 1.5	P=0.451	P=0.500	(e)	P=0.490
POLY 6	P=0.455	P=0.503	(e)	P=0.492
COCH-ARM / FISHERS	P=0.464	P=0.500	(e)	P=0.500
MAX-ISO-POLY-3	P=0.257	P=0.161	(e)	P=0.158

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver: Hepatocyte Hypertrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	5/50 (10%)	2/50 (4%)	3/50 (6%)	33/50 (66%)
POLY-3 RATE (b)	5/44.24	2/44.40	3/40.27	33/41.81
POLY-3 PERCENT (g)	11.3%	4.5%	7.5%	78.9%
TERMINAL (d)	3/34 (9%)	2/34 (6%)	2/24 (8%)	31/34 (91%)
FIRST INCIDENCE	693	728 (T)	708	688
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.214N	P=0.409N	P<0.001**
POLY 1.5	P<0.001**	P=0.217N	P=0.384N	P<0.001**
POLY 6	P<0.001**	P=0.214N	P=0.449N	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.218N	P=0.357N	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.118N	P=0.283N	P<0.001**

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Liver: Oval Cell Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	2/44.83	2/40.37	0/41.52
POLY-3 PERCENT (g)	0%	4.5%	5%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	605	705	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.396N	P=0.241	P=0.218	(e)
POLY 1.5	P=0.394N	P=0.238	P=0.227	(e)
POLY 6	P=0.391N	P=0.244	P=0.205	(e)
COCH-ARM / FISHERS	P=0.373N	P=0.247	P=0.247	(e)
MAX-ISO-POLY-3	P=0.283	P=0.080	P=0.075	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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 Inflammation Chronic</b>				
<b>LESION RATES</b>				
OVERALL (a)	4/50 (8%)	5/50 (10%)	2/50 (4%)	7/50 (14%)
POLY-3 RATE (b)	4/44.14	5/44.83	2/40.34	7/41.76
POLY-3 PERCENT (g)	9.1%	11.2%	5%	16.8%
TERMINAL (d)	3/34 (9%)	3/34 (9%)	1/24 (4%)	6/34 (18%)
FIRST INCIDENCE	693	605	688	664
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.155	P=0.510	P=0.379N	P=0.229
POLY 1.5	P=0.158	P=0.502	P=0.359N	P=0.231
POLY 6	P=0.160	P=0.515	P=0.411N	P=0.234
COCH-ARM / FISHERS	P=0.179	P=0.500	P=0.339N	P=0.262
MAX-ISO-POLY-3	P=0.181	P=0.372	P=0.243N	P=0.149



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Inflammation Granulomatous</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	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	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	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	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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: Alveolar Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	11/50 (22%)	14/50 (28%)	6/50 (12%)	7/50 (14%)
POLY-3 RATE (b)	11/44.09	14/45.47	6/40.19	7/41.67
POLY-3 PERCENT (g)	25%	30.8%	14.9%	16.8%
TERMINAL (d)	10/34 (29%)	9/34 (27%)	6/24 (25%)	6/34 (18%)
FIRST INCIDENCE	705	632	728 (T)	688
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.124N	P=0.352	P=0.190N	P=0.254N
POLY 1.5	P=0.122N	P=0.332	P=0.166N	P=0.253N
POLY 6	P=0.117N	P=0.375	P=0.234N	P=0.244N
COCH-ARM / FISHERS	P=0.102N	P=0.322	P=0.143N	P=0.218N
MAX-ISO-POLY-3	P=0.153N	P=0.272	P=0.135N	P=0.184N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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: Alveolar Epithelium Hypertrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.00	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)	---	---
<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

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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: Alveolar Epithelium Metaplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	3/50 (6%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.14	3/44.62	0/40.19	0/41.52
POLY-3 PERCENT (g)	4.5%	6.7%	0%	0%
TERMINAL (d)	1/34 (3%)	2/34 (6%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	693	670	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.104N	P=0.505	P=0.258N	P=0.251N
POLY 1.5	P=0.105N	P=0.500	P=0.248N	P=0.250N
POLY 6	P=0.102N	P=0.508	P=0.275N	P=0.249N
COCH-ARM / FISHERS	P=0.101N	P=0.500	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.106N	P=0.329	P=0.096N	P=0.089N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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: Alveolus Infiltration Cellular Histiocyte</b>				
<b>LESION RATES</b>				
OVERALL (a)	12/50 (24%)	17/50 (34%)	12/50 (24%)	16/50 (32%)
POLY-3 RATE (b)	12/44.32	17/45.55	12/41.38	16/42.24
POLY-3 PERCENT (g)	27.1%	37.3%	29%	37.9%
TERMINAL (d)	10/34 (29%)	13/34 (38%)	7/24 (29%)	14/34 (41%)
FIRST INCIDENCE	669	558	628	489
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.269	P=0.207	P=0.517	P=0.198
POLY 1.5	P=0.278	P=0.194	P=0.553	P=0.202
POLY 6	P=0.276	P=0.218	P=0.463	P=0.204
COCH-ARM / FISHERS	P=0.344	P=0.189	P=0.592N	P=0.252
MAX-ISO-POLY-3	P=0.238	P=0.151	P=0.422	P=0.145

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Lymph Node, Mesenteric Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/44.14	1/44.40	1/40.40	0/41.52
POLY-3 PERCENT (g)	2.3%	2.3%	2.5%	0%
TERMINAL (d)	0/34 (0%)	1/34 (3%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	693	728 (T)	672	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.342N	P=0.759N	P=0.741	P=0.512N
POLY 1.5	P=0.340N	P=0.760	P=0.750	P=0.511N
POLY 6	P=0.339N	P=0.759N	P=0.726	P=0.511N
COCH-ARM / FISHERS	P=0.327N	P=0.753N	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.349N	P=0.498N	P=0.475	P=0.174N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Lymph Node, Mesenteric Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.00	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	4.6%	0%	0%	0%
TERMINAL (d)	2/34 (6%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	728 (T)	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.262N	P=0.235N	P=0.258N	P=0.250N
POLY 1.5	P=0.262N	P=0.237N	P=0.248N	P=0.249N
POLY 6	P=0.260N	P=0.234N	P=0.274N	P=0.248N
COCH-ARM / FISHERS	P=0.262N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.045N*	P=0.076N	P=0.095N	P=0.089N



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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Lymph Node: Mediastinal Hyperplasia Lymphoid</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/1 (0%)	0/3 (0%)	0/3 (0%)	0/2 (0%)
POLY-3 RATE (b)	0/0.34	0/2.01	0/1.91	0/2.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/2 (0%)
FIRST INCIDENCE	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Hyperplasia</b>				
<b>LESION 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	2/40.51	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	---	---	639	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.698N	(e)	P=0.219	(e)
POLY 1.5	P=0.694N	(e)	P=0.228	(e)
POLY 6	P=0.696N	(e)	P=0.207	(e)
COCH-ARM / FISHERS	P=0.675N	(e)	P=0.247	(e)
MAX-ISO-POLY-3	P=0.249	(e)	P=0.075	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Mesentery: Fat Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	10/10 (100%)	9/9 (100%)	7/7 (100%)	9/9 (100%)
POLY-3 RATE (b)	10/10.00	9/9.00	7/7.00	9/9.00
POLY-3 PERCENT (g)	100%	100%	100%	100%
TERMINAL (d)	5/5 (100%)	7/7 (100%)	4/4 (100%)	6/6 (100%)
FIRST INCIDENCE	506	558	532	616
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Nose</b>				
<b>Foreign Body</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/44.00	0/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	4.6%	0%	0%	0%
TERMINAL (d)	2/34 (6%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	728 (T)	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.262N	P=0.235N	P=0.258N	P=0.250N
POLY 1.5	P=0.262N	P=0.237N	P=0.248N	P=0.249N
POLY 6	P=0.260N	P=0.234N	P=0.274N	P=0.248N
COCH-ARM / FISHERS	P=0.262N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.045N*	P=0.076N	P=0.095N	P=0.089N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Nose Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	8/50 (16%)	2/50 (4%)	9/50 (18%)	8/50 (16%)
POLY-3 RATE (b)	8/44.58	2/44.75	9/41.70	8/42.21
POLY-3 PERCENT (g)	18%	4.5%	21.6%	19%
TERMINAL (d)	5/34 (15%)	1/34 (3%)	5/24 (21%)	7/34 (21%)
FIRST INCIDENCE	621	632	539	489
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.232	P=0.044N*	P=0.439	P=0.562
POLY 1.5	P=0.239	P=0.045N*	P=0.469	P=0.565
POLY 6	P=0.235	P=0.043N*	P=0.394	P=0.567
COCH-ARM / FISHERS	P=0.280	P=0.046N*	P=0.500	P=0.607N
MAX-ISO-POLY-3	P=0.204	P=0.021N*	P=0.340	P=0.452

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Nose: Olfactory Epithelium Metaplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/44.00	0/44.40	1/40.19	0/41.52
POLY-3 PERCENT (g)	2.3%	0%	2.5%	0%
TERMINAL (d)	1/34 (3%)	0/34 (0%)	1/24 (4%)	0/34 (0%)
FIRST INCIDENCE	728 (T)	---	728 (T)	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.476N	P=0.498N	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=0.497N	P=0.725	P=0.510N
COCH-ARM / FISHERS	P=0.464N	P=0.500N	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.280N	P=0.158N	P=0.474	P=0.173N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Nose: Respiratory Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	0/44.40	1/40.37	0/41.52
POLY-3 PERCENT (g)	0%	0%	2.5%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	---	681	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.789N	(e)	P=0.483	(e)
POLY 1.5	P=0.787N	(e)	P=0.491	(e)
POLY 6	P=0.788N	(e)	P=0.471	(e)
COCH-ARM / FISHERS	P=0.779N	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.384	(e)	P=0.158	(e)

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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
Ovary Cyst				
<b>LESION RATES</b>				
OVERALL (a)	8/50 (16%)	9/50 (18%)	6/50 (12%)	5/50 (10%)
POLY-3 RATE (b)	8/44.33	9/44.56	6/40.92	5/41.92
POLY-3 PERCENT (g)	18.1%	20.2%	14.7%	11.9%
TERMINAL (d)	6/34 (18%)	8/34 (24%)	4/24 (17%)	3/34 (9%)
FIRST INCIDENCE	664	688	618	664
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.210N	P=0.505	P=0.449N	P=0.312N
POLY 1.5	P=0.209N	P=0.498	P=0.419N	P=0.310N
POLY 6	P=0.198N	P=0.506	P=0.496N	P=0.303N
COCH-ARM / FISHERS	P=0.181N	P=0.500	P=0.387N	P=0.277N
MAX-ISO-POLY-3	P=0.308N	P=0.397	P=0.342N	P=0.221N



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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	13/50 (26%)	10/50 (20%)	16/50 (32%)	17/50 (34%)
POLY-3 RATE (b)	13/45.52	10/45.76	16/42.46	17/42.92
POLY-3 PERCENT (g)	28.6%	21.9%	37.7%	39.6%
TERMINAL (d)	10/34 (29%)	6/34 (18%)	10/24 (42%)	14/34 (41%)
FIRST INCIDENCE	450	631	519	489
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.077	P=0.310N	P=0.246	P=0.190
POLY 1.5	P=0.084	P=0.321N	P=0.282	P=0.196
POLY 6	P=0.079	P=0.295N	P=0.199	P=0.199
COCH-ARM / FISHERS	P=0.125	P=0.318N	P=0.330	P=0.257
MAX-ISO-POLY-3	P=0.123	P=0.231N	P=0.188	P=0.142

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	1/41.52
POLY-3 PERCENT (g)	0%	0%	0%	2.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	1/34 (3%)
FIRST INCIDENCE	---	---	---	728 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.211	(e)	(e)	P=0.488
POLY 1.5	P=0.213	(e)	(e)	P=0.489
POLY 6	P=0.212	(e)	(e)	P=0.490
COCH-ARM / FISHERS	P=0.221	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.126	(e)	(e)	P=0.158

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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: Acinus Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	3/50 (6%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.00	3/44.40	0/40.19	0/41.52
POLY-3 PERCENT (g)	2.3%	6.8%	0%	0%
TERMINAL (d)	1/34 (3%)	3/34 (9%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	728 (T)	728 (T)	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.170N	P=0.308	P=0.518N	P=0.512N
POLY 1.5	P=0.171N	P=0.305	P=0.509N	P=0.511N
POLY 6	P=0.166N	P=0.310	P=0.531N	P=0.510N
COCH-ARM / FISHERS	P=0.166N	P=0.309	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.143N	P=0.157	P=0.180N	P=0.173N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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: Acinus Metaplasia Hepatocyte</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	4/50 (8%)
POLY-3 RATE (b)	0/44.00	1/44.40	0/40.19	4/41.83
POLY-3 PERCENT (g)	0%	2.3%	0%	9.6%
TERMINAL (d)	0/34 (0%)	1/34 (3%)	0/24 (0%)	2/34 (6%)
FIRST INCIDENCE	---	728 (T)	---	687
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.008**	P=0.502	(e)	P=0.054
POLY 1.5	P=0.008**	P=0.500	(e)	P=0.054
POLY 6	P=0.009**	P=0.503	(e)	P=0.056
COCH-ARM / FISHERS	P=0.010**	P=0.500	(e)	P=0.059
MAX-ISO-POLY-3	P=0.008**	P=0.161	(e)	P=0.019*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Parathyroid Gland Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/44 (0%)	0/47 (0%)	0/44 (0%)	0/47 (0%)
POLY-3 RATE (b)	0/38.47	0/41.49	0/36.06	0/39.92
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/31 (0%)	0/32 (0%)	0/24 (0%)	0/33 (0%)
FIRST INCIDENCE	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Angiectasis</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	1/50 (2%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/44.00	1/44.40	1/40.19	2/41.52
POLY-3 PERCENT (g)	2.3%	2.3%	2.5%	4.8%
TERMINAL (d)	1/34 (3%)	0/34 (0%)	1/24 (4%)	2/34 (6%)
FIRST INCIDENCE	728 (T)	727	728 (T)	728 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.343	P=0.759N	P=0.740	P=0.480
POLY 1.5	P=0.346	P=0.761	P=0.750	P=0.481
POLY 6	P=0.347	P=0.758N	P=0.725	P=0.483
COCH-ARM / FISHERS	P=0.364	P=0.753N	P=0.753N	P=0.500
MAX-ISO-POLY-3	P=0.404	P=0.497N	P=0.474	P=0.269

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	11/50 (22%)	20/50 (40%)	16/50 (32%)	23/50 (46%)
POLY-3 RATE (b)	11/45.96	20/45.49	16/42.99	23/43.72
POLY-3 PERCENT (g)	23.9%	44%	37.2%	52.6%
TERMINAL (d)	8/34 (24%)	15/34 (44%)	10/24 (42%)	17/34 (50%)
FIRST INCIDENCE	506	632	439	399
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.014*	P=0.033*	P=0.126	P=0.004**
POLY 1.5	P=0.016*	P=0.033*	P=0.151	P=0.004**
POLY 6	P=0.015*	P=0.033*	P=0.095	P=0.004**
COCH-ARM / FISHERS	P=0.030*	P=0.041*	P=0.184	P=0.010**
MAX-ISO-POLY-3	P=0.005**	P=0.020*	P=0.091	P=0.002**

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	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	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)



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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Spleen Fibrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	3/50 (6%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/44.00	3/45.18	0/40.19	2/41.79
POLY-3 PERCENT (g)	0%	6.6%	0%	4.8%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	605	---	664
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.394	P=0.123	(e)	P=0.226
POLY 1.5	P=0.392	P=0.120	(e)	P=0.226
POLY 6	P=0.402	P=0.126	(e)	P=0.229
COCH-ARM / FISHERS	P=0.408	P=0.121	(e)	P=0.247
MAX-ISO-POLY-3	P=0.160	P=0.042*	(e)	P=0.076

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Spleen</b>				
<b>Hematopoietic Cell Proliferation</b>				
<b>LESION RATES</b>				
OVERALL (a)	19/50 (38%)	18/50 (36%)	17/50 (34%)	7/50 (14%)
POLY-3 RATE (b)	19/45.60	18/45.65	17/43.26	7/42.04
POLY-3 PERCENT (g)	41.7%	39.4%	39.3%	16.7%
TERMINAL (d)	14/34 (41%)	13/34 (38%)	8/24 (33%)	5/34 (15%)
FIRST INCIDENCE	450	615	532	616
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.004N**	P=0.498N	P=0.496N	P=0.008N**
POLY 1.5	P=0.004N**	P=0.510N	P=0.459N	P=0.008N**
POLY 6	P=0.004N**	P=0.489N	P=0.548N	P=0.008N**
COCH-ARM / FISHERS	P=0.003N**	P=0.500N	P=0.418N	P=0.006N**
MAX-ISO-POLY-3	P=0.007N**	P=0.412N	P=0.410N	P=0.005N**

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Spleen Pigmentation Hemosiderin</b>				
<b>LESION RATES</b>				
OVERALL (a)	37/50 (74%)	37/50 (74%)	41/50 (82%)	42/50 (84%)
POLY-3 RATE (b)	37/45.64	37/46.20	41/48.57	42/48.99
POLY-3 PERCENT (g)	81.1%	80.1%	84.4%	85.7%
TERMINAL (d)	29/34 (85%)	30/34 (88%)	19/24 (79%)	28/34 (82%)
FIRST INCIDENCE	621	558	98	111
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.283	P=0.560N	P=0.435	P=0.365
POLY 1.5	P=0.226	P=0.593N	P=0.376	P=0.288
POLY 6	P=0.383	P=0.551N	P=0.493	P=0.470
COCH-ARM / FISHERS	P=0.117	P=0.590N	P=0.235	P=0.163
MAX-ISO-POLY-3	P=0.407	P=0.449N	P=0.331	P=0.271

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Spleen Thrombosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	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	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Spleen: Lymphoid Follicle Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	1/50 (2%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	1/44.00	1/44.56	4/41.62	2/43.35
POLY-3 PERCENT (g)	2.3%	2.2%	9.6%	4.6%
TERMINAL (d)	1/34 (3%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	728 (T)	688	439	140
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.431	P=0.758N	P=0.161	P=0.495
POLY 1.5	P=0.432	P=0.760N	P=0.170	P=0.493
POLY 6	P=0.438	P=0.756N	P=0.149	P=0.500
COCH-ARM / FISHERS	P=0.445	P=0.753N	P=0.181	P=0.500
MAX-ISO-POLY-3	P=0.233	P=0.496N	P=0.079	P=0.277

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Stomach, Forestomach Erosion</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	1/44.75	2/40.63	0/41.52
POLY-3 PERCENT (g)	0%	2.2%	4.9%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	631	652	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.524N	P=0.503	P=0.220	(e)
POLY 1.5	P=0.521N	P=0.501	P=0.228	(e)
POLY 6	P=0.521N	P=0.505	P=0.208	(e)
COCH-ARM / FISHERS	P=0.500N	P=0.500	P=0.247	(e)
MAX-ISO-POLY-3	P=0.329	P=0.163	P=0.075	(e)

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Stomach, Forestomach Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	5/50 (10%)	7/50 (14%)	7/50 (14%)	13/50 (26%)
POLY-3 RATE (b)	5/46.44	7/45.23	7/41.82	13/44.73
POLY-3 PERCENT (g)	10.8%	15.5%	16.7%	29.1%
TERMINAL (d)	1/34 (3%)	3/34 (9%)	1/24 (4%)	9/34 (27%)
FIRST INCIDENCE	450	631	579	111
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.014*	P=0.361	P=0.307	P=0.025*
POLY 1.5	P=0.015*	P=0.363	P=0.338	P=0.027*
POLY 6	P=0.013*	P=0.358	P=0.271	P=0.023*
COCH-ARM / FISHERS	P=0.018*	P=0.380	P=0.380	P=0.033*
MAX-ISO-POLY-3	P=0.018*	P=0.256	P=0.220	P=0.014*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Stomach, Forestomach Mineralization</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	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	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---



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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Stomach, Forestomach Ulcer</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	1/50 (2%)	3/50 (6%)	7/50 (14%)
POLY-3 RATE (b)	1/44.76	1/44.40	3/40.90	7/42.75
POLY-3 PERCENT (g)	2.2%	2.3%	7.3%	16.4%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	1/24 (4%)	5/34 (15%)
FIRST INCIDENCE	450	727	579	140
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.003**	P=0.759	P=0.273	P=0.025*
POLY 1.5	P=0.003**	P=0.758	P=0.288	P=0.026*
POLY 6	P=0.003**	P=0.759	P=0.254	P=0.026*
COCH-ARM / FISHERS	P=0.004**	P=0.753N	P=0.309	P=0.030*
MAX-ISO-POLY-3	P=0.005**	P=0.497	P=0.143	P=0.011*

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Stomach, Forestomach: Epithelium Dysplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	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	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Stomach, Forestomach: Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	5/50 (10%)	6/50 (12%)	8/50 (16%)	19/50 (38%)
POLY-3 RATE (b)	5/46.57	6/45.30	8/41.82	19/43.90
POLY-3 PERCENT (g)	10.7%	13.3%	19.1%	43.3%
TERMINAL (d)	0/34 (0%)	2/34 (6%)	2/24 (8%)	15/34 (44%)
FIRST INCIDENCE	450	631	579	111
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001**	P=0.481	P=0.209	P<0.001**
POLY 1.5	P<0.001**	P=0.483	P=0.237	P<0.001**
POLY 6	P<0.001**	P=0.477	P=0.176	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500	P=0.277	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.357	P=0.145	P<0.001**

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Stomach, Glandular Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	2/44.75	0/40.19	0/41.52
POLY-3 PERCENT (g)	0%	4.5%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	---	631	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.395N	P=0.241	(e)	(e)
POLY 1.5	P=0.397N	P=0.238	(e)	(e)
POLY 6	P=0.389N	P=0.243	(e)	(e)
COCH-ARM / FISHERS	P=0.392N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.280N	P=0.080	(e)	(e)

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Stomach, Glandular: Epithelium Necrosis</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.64	1/44.75	0/40.19	0/41.52
POLY-3 PERCENT (g)	2.2%	2.2%	0%	0%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	0/34 (0%)
FIRST INCIDENCE	519	631	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.329N	P=0.760N	P=0.521N	P=0.514N
POLY 1.5	P=0.329N	P=0.760	P=0.511N	P=0.512N
POLY 6	P=0.327N	P=0.759N	P=0.535N	P=0.514N
COCH-ARM / FISHERS	P=0.325N	P=0.753N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.286N	P=0.499N	P=0.184N	P=0.176N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Thymus Atrophy</b>				
<b>LESION RATES</b>				
OVERALL (a)	48/50 (96%)	43/50 (86%)	47/49 (96%)	45/48 (94%)
POLY-3 RATE (b)	48/48.34	43/46.91	47/47.65	45/45.92
POLY-3 PERCENT (g)	99.3%	91.7%	98.6%	98%
TERMINAL (d)	34/34 (100%)	33/34 (97%)	23/23 (100%)	33/33 (100%)
FIRST INCIDENCE	450	558	439	140
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.435	P=0.068N	P=0.825N	P=0.663N
POLY 1.5	P=0.432	P=0.074N	P=0.765N	P=0.616N
POLY 6	P=0.515	P=0.077N	P=0.945N	P=0.674N
COCH-ARM / FISHERS	P=0.454	P=0.080N	P=0.684N	P=0.480N
MAX-ISO-POLY-3	P=0.253N	P=0.022N*	P=0.336N	P=0.262N

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	15/50 (30%)	15/50 (30%)	6/50 (12%)	4/50 (8%)
POLY-3 RATE (b)	15/44.52	15/45.00	6/40.89	4/41.52
POLY-3 PERCENT (g)	33.7%	33.3%	14.7%	9.6%
TERMINAL (d)	12/34 (35%)	11/34 (32%)	4/24 (17%)	4/34 (12%)
FIRST INCIDENCE	664	632	629	728 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.002N**	P=0.575N	P=0.034N*	P=0.006N**
POLY 1.5	P=0.002N**	P=0.586N	P=0.028N*	P=0.006N**
POLY 6	P=0.002N**	P=0.569N	P=0.047N*	P=0.006N**
COCH-ARM / FISHERS	P=0.002N**	P=0.586N	P=0.024N*	P=0.005N**
MAX-ISO-POLY-3	P=0.004N**	P=0.485N	P=0.023N*	P=0.003N**

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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: Follicle Cyst</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/44.00	0/44.40	0/40.19	2/41.65
POLY-3 PERCENT (g)	0%	0%	0%	4.8%
TERMINAL (d)	0/34 (0%)	0/34 (0%)	0/24 (0%)	1/34 (3%)
FIRST INCIDENCE	---	---	---	694
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.038*	(e)	(e)	P=0.225
POLY 1.5	P=0.038*	(e)	(e)	P=0.226
POLY 6	P=0.039*	(e)	(e)	P=0.228
COCH-ARM / FISHERS	P=0.042*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.034*	(e)	(e)	P=0.076



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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/50 (2%)	1/50 (2%)	4/50 (8%)	4/50 (8%)
POLY-3 RATE (b)	1/44.00	1/44.59	4/40.40	4/41.67
POLY-3 PERCENT (g)	2.3%	2.2%	9.9%	9.6%
TERMINAL (d)	1/34 (3%)	0/34 (0%)	3/24 (13%)	3/34 (9%)
FIRST INCIDENCE	728 (T)	678	672	688
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.095	P=0.758N	P=0.153	P=0.162
POLY 1.5	P=0.098	P=0.760N	P=0.165	P=0.163
POLY 6	P=0.097	P=0.756N	P=0.136	P=0.166
COCH-ARM / FISHERS	P=0.114	P=0.753N	P=0.181	P=0.181
MAX-ISO-POLY-3	P=0.120	P=0.495N	P=0.077	P=0.079

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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>Tooth Malformation</b>				
<b>LESION RATES</b>				
OVERALL (a)	5/5 (100%)	3/3 (100%)	4/4 (100%)	2/2 (100%)
POLY-3 RATE (b)	5/5.00	3/3.00	4/4.00	2/2.00
POLY-3 PERCENT (g)	100%	100%	100%	100%
TERMINAL (d)	5/5 (100%)	2/2 (100%)	1/1 (100%)	2/2 (100%)
FIRST INCIDENCE	728 (T)	678	629	728 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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 NON-NEOPLASTIC LESIONS 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>Urinary Bladder Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.00	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	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

---

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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 Hemorrhage</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.00	2/44.40	0/40.19	1/41.52
POLY-3 PERCENT (g)	0%	4.5%	0%	2.4%
TERMINAL (d)	0/34 (0%)	2/34 (6%)	0/24 (0%)	1/34 (3%)
FIRST INCIDENCE	---	728 (T)	---	728 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.603	P=0.239	(e)	P=0.488
POLY 1.5	P=0.603	P=0.237	(e)	P=0.489
POLY 6	P=0.607	P=0.240	(e)	P=0.490
COCH-ARM / FISHERS	P=0.617	P=0.247	(e)	P=0.500
MAX-ISO-POLY-3	P=0.334	P=0.078	(e)	P=0.158

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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 NON-NEOPLASTIC LESIONS 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: Endometrium Hyperplasia Cystic</b>				
<b>LESION RATES</b>				
OVERALL (a)	5/50 (10%)	5/50 (10%)	6/50 (12%)	10/50 (20%)
POLY-3 RATE (b)	5/44.14	5/44.40	6/41.37	10/41.68
POLY-3 PERCENT (g)	11.3%	11.3%	14.5%	24%
TERMINAL (d)	4/34 (12%)	5/34 (15%)	3/24 (13%)	9/34 (27%)
FIRST INCIDENCE	692	728 (T)	439	687
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.045*	P=0.627N	P=0.454	P=0.102
POLY 1.5	P=0.048*	P=0.629	P=0.478	P=0.105
POLY 6	P=0.047*	P=0.626N	P=0.417	P=0.105
COCH-ARM / FISHERS	P=0.062	P=0.630N	P=0.500	P=0.131
MAX-ISO-POLY-3	P=0.073	P=0.495N	P=0.335	P=0.065

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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.
  - (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 \*\*\*