

Experiment Number: 20007 - 03
Test Type: 90-DAY
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: 09/13/2016
Time Report Requested: 11:41:17
First Dose M/F: 09/15/03 / 09/16/03
Lab: BAT

NTP Study Number: C20007
Lock Date: 05/24/2004
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 3.0.2.3_002
PWG Approval Date: NONE

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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF KAVA KAVA EXTRACT

MALE RATS

Organ

Liver

Lung

Spleen

Thymus

FEMALE RATS

Organ

Kidney

Liver

Liver: Hepatocyte

Lung: Alveolus

Spleen

Thymus

Morphology

Infiltration Cellular Mixed Cell

Infiltration Cellular Mononuclear Cell

Inflammation

Atrophy

Necrosis

Morphology

Mineralization

Infiltration Cellular Mononuclear Cell

Hypertrophy

Infiltration Cellular Histiocyte

Atrophy

Necrosis

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<hr/>						
Brain: Cerebrum						
Hemorrhage						
<hr/>						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.01	0/0.00	0/0.00	0/8.27
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<hr/>						
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

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TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Epididymis Inflammation						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.01	0/0.00	0/0.00	0/8.27
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/7 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	P=0.943N	(e)	(e)	P=0.537N
POLY 1.5	(e)	(e)	P=0.941N	(e)	(e)	P=0.530N
POLY 6	(e)	(e)	P=0.943N	(e)	(e)	P=0.548N
COCH-ARM / FISHERS	P=0.315N	(e)	P=0.909N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	P=0.497N	(e)	(e)	P=0.204N

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TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Eye: Cornea						
Neovascularization						
<hr/>						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.01	0/0.00	0/0.00	0/8.27
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<hr/>						
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Harderian Gland						
Infiltration Cellular Mononuclear Cell						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.01	0/0.00	0/0.00	0/8.27
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/7 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	P=0.943N	(e)	(e)	P=0.537N
POLY 1.5	(e)	(e)	P=0.941N	(e)	(e)	P=0.530N
POLY 6	(e)	(e)	P=0.943N	(e)	(e)	P=0.548N
COCH-ARM / FISHERS	P=0.315N	(e)	P=0.909N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	P=0.497N	(e)	(e)	P=0.204N

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Heart						
Cardiomyopathy						
LESION RATES						
OVERALL (a)	9/10 (90%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	8/10 (80%)
POLY-3 RATE (b)	9/10.00	0/0.00	0/0.01	0/0.00	0/0.00	8/9.00
POLY-3 PERCENT (g)	90%	0%	0%	0%	0%	88.9%
TERMINAL (d)	9/10 (90%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	6/7 (86%)
FIRST INCIDENCE	93 (T)	---	---	---	---	80
STATISTICAL TESTS						
POLY 3	(e)	(e)	P=0.939N	(e)	(e)	P=0.737N
POLY 1.5	(e)	(e)	P=0.898N	(e)	(e)	P=0.734N
POLY 6	(e)	(e)	P=0.943N	(e)	(e)	P=0.737N
COCH-ARM / FISHERS	P=0.524N	(e)	P=0.182N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	P=0.488N	(e)	(e)	P=0.469N

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Kidney						
Accumulation, Hyaline Droplet						
LESION RATES						
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.01	0/0.00	0/0.00	1/8.27
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	12.1%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/7 (14%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	P=0.881N	(e)	(e)	P=0.568N
POLY 1.5	(e)	(e)	P=0.874N	(e)	(e)	P=0.554N
POLY 6	(e)	(e)	P=0.882N	(e)	(e)	P=0.588N
COCH-ARM / FISHERS	P=0.402N	(e)	P=0.818N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	P=0.497N	(e)	(e)	P=0.344N

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TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Kidney						
Casts Protein						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.01	0/0.00	0/0.00	0/8.27
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/7 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	P=0.943N	(e)	(e)	P=0.537N
POLY 1.5	(e)	(e)	P=0.941N	(e)	(e)	P=0.530N
POLY 6	(e)	(e)	P=0.943N	(e)	(e)	P=0.548N
COCH-ARM / FISHERS	P=0.315N	(e)	P=0.909N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	P=0.497N	(e)	(e)	P=0.204N

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Kidney						
Infiltration Cellular Mononuclear Cell						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.01	0/0.00	0/0.00	0/8.27
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/7 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	P=0.943N	(e)	(e)	P=0.537N
POLY 1.5	(e)	(e)	P=0.941N	(e)	(e)	P=0.530N
POLY 6	(e)	(e)	P=0.943N	(e)	(e)	P=0.548N
COCH-ARM / FISHERS	P=0.315N	(e)	P=0.909N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	P=0.497N	(e)	(e)	P=0.204N

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Kidney Mineralization						
LESION RATES						
OVERALL (a)	4/10 (40%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	4/10.00	0/0.00	0/0.01	0/0.00	0/0.00	3/8.27
POLY-3 PERCENT (g)	40%	0%	0%	0%	0%	36.3%
TERMINAL (d)	4/10 (40%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/7 (43%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	P=0.831N	(e)	(e)	P=0.619N
POLY 1.5	(e)	(e)	P=0.813N	(e)	(e)	P=0.594N
POLY 6	(e)	(e)	P=0.834N	(e)	(e)	P=0.654N
COCH-ARM / FISHERS	P=0.453N	(e)	P=0.636N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	P=0.496N	(e)	(e)	P=0.441N

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Kidney						
Nephropathy						
LESION RATES						
OVERALL (a)	7/10 (70%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	7/10 (70%)
POLY-3 RATE (b)	7/10.00	0/0.00	0/0.01	0/0.00	0/0.00	7/9.00
POLY-3 PERCENT (g)	70%	0%	0%	0%	0%	77.8%
TERMINAL (d)	7/10 (70%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	5/7 (71%)
FIRST INCIDENCE	93 (T)	---	---	---	---	80
STATISTICAL TESTS						
POLY 3	(e)	(e)	P=0.845N	(e)	(e)	P=0.552
POLY 1.5	(e)	(e)	P=0.810N	(e)	(e)	P=0.554
POLY 6	(e)	(e)	P=0.850N	(e)	(e)	P=0.552
COCH-ARM / FISHERS	P=0.500	(e)	P=0.364N	(e)	(e)	P=0.686N
MAX-ISO-POLY-3	(e)	(e)	P=0.493N	(e)	(e)	P=0.362

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TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<hr/>						
Liver Congestion						
<hr/>						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.01	0/10.00	0/10.00	0/8.27
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<hr/>						
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

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TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver						
Hematopoietic Cell Proliferation						
LESION RATES						
OVERALL (a)	1/10 (10%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	1/10.00	0/9.01	0/10.00	0/10.00	0/8.27
POLY-3 PERCENT (g)	10%	10%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	1/10 (10%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/7 (0%)
FIRST INCIDENCE	93 (T)	93 (T)	---	---	---	---
STATISTICAL TESTS						
POLY 3	P=0.220N	P=0.760	P=0.521N	P=0.500N	P=0.500N	P=0.537N
POLY 1.5	P=0.225N	P=0.760	P=0.518N	P=0.500N	P=0.500N	P=0.530N
POLY 6	P=0.213N	P=0.760	P=0.521N	P=0.500N	P=0.500N	P=0.548N
COCH-ARM / FISHERS	P=0.242N	P=0.763N	P=0.500N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.155N	P=1.000	P=0.184N	P=0.158N	P=0.158N	P=0.204N

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver						
Hepatodiaphragmatic Nodule						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.01	1/10.00	0/10.00	0/8.27
POLY-3 PERCENT (g)	0%	0%	0%	10%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	1/10 (10%)	0/10 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	93 (T)	---	---
STATISTICAL TESTS						
POLY 3	P=0.688N	(e)	(e)	P=0.500	(e)	(e)
POLY 1.5	P=0.690N	(e)	(e)	P=0.500	(e)	(e)
POLY 6	P=0.684N	(e)	(e)	P=0.500	(e)	(e)
COCH-ARM / FISHERS	P=0.699N	(e)	(e)	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.305	(e)	(e)	P=0.158	(e)	(e)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver						
Infiltration Cellular Mixed Cell						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.01	0/10.00	0/10.00	1/8.27
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	12.1%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	1/7 (14%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	P=0.093	(e)	(e)	(e)	(e)	P=0.462
POLY 1.5	P=0.096	(e)	(e)	(e)	(e)	P=0.470
POLY 6	P=0.090	(e)	(e)	(e)	(e)	P=0.451
COCH-ARM / FISHERS	P=0.105	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.041*	(e)	(e)	(e)	(e)	P=0.156

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver						
Infiltration Cellular Mononuclear Cell						
LESION RATES						
OVERALL (a)	9/10 (90%)	7/10 (70%)	5/10 (50%)	5/10 (50%)	5/10 (50%)	5/10 (50%)
POLY-3 RATE (b)	9/10.00	7/10.00	5/9.01	5/10.00	5/10.00	5/8.27
POLY-3 PERCENT (g)	90%	70%	55.5%	50%	50%	60.4%
TERMINAL (d)	9/10 (90%)	7/10 (70%)	5/9 (56%)	5/10 (50%)	5/10 (50%)	5/7 (71%)
FIRST INCIDENCE	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)
STATISTICAL TESTS						
POLY 3	P=0.183N	P=0.292N	P=0.112N	P=0.061N	P=0.061N	P=0.165N
POLY 1.5	P=0.166N	P=0.292N	P=0.104N	P=0.061N	P=0.061N	P=0.137N
POLY 6	P=0.212N	P=0.292N	P=0.114N	P=0.061N	P=0.061N	P=0.220N
COCH-ARM / FISHERS	P=0.115N	P=0.291N	P=0.070N	P=0.070N	P=0.070N	P=0.070N
MAX-ISO-POLY-3	P=0.073N	P=0.136N	P=0.048N*	P=0.020N*	P=0.020N*	P=0.076N

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver Inflammation						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.01	0/10.00	0/10.00	0/8.27
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver						
Vacuolization Cytoplasmic						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00	0/9.01	1/10.00	0/10.00	0/8.27
POLY-3 PERCENT (g)	10%	0%	0%	10%	0%	0%
TERMINAL (d)	1/10 (10%)	0/10 (0%)	0/9 (0%)	1/10 (10%)	0/10 (0%)	0/7 (0%)
FIRST INCIDENCE	93 (T)	---	---	93 (T)	---	---
STATISTICAL TESTS						
POLY 3	P=0.369N	P=0.500N	P=0.521N	P=0.760	P=0.500N	P=0.537N
POLY 1.5	P=0.372N	P=0.500N	P=0.518N	P=0.760	P=0.500N	P=0.530N
POLY 6	P=0.366N	P=0.500N	P=0.521N	P=0.760	P=0.500N	P=0.548N
COCH-ARM / FISHERS	P=0.380N	P=0.500N	P=0.500N	P=0.763N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.155N	P=0.158N	P=0.184N	P=1.000	P=0.158N	P=0.204N

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver: Bile Duct Hyperplasia						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.01	1/10.00	0/10.00	0/8.27
POLY-3 PERCENT (g)	0%	0%	0%	10%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	1/10 (10%)	0/10 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	93 (T)	---	---
STATISTICAL TESTS						
POLY 3	P=0.688N	(e)	(e)	P=0.500	(e)	(e)
POLY 1.5	P=0.690N	(e)	(e)	P=0.500	(e)	(e)
POLY 6	P=0.684N	(e)	(e)	P=0.500	(e)	(e)
COCH-ARM / FISHERS	P=0.699N	(e)	(e)	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.305	(e)	(e)	P=0.158	(e)	(e)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver: Hepatocyte Hypertrophy						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.01	0/10.00	1/10.00	0/8.27
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/10 (0%)	1/10 (10%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	---	93 (T)	---
STATISTICAL TESTS						
POLY 3	P=0.473	(e)	(e)	(e)	P=0.500	(e)
POLY 1.5	P=0.498	(e)	(e)	(e)	P=0.500	(e)
POLY 6	P=0.435	(e)	(e)	(e)	P=0.500	(e)
COCH-ARM / FISHERS	P=0.585	(e)	(e)	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.216	(e)	(e)	(e)	P=0.158	(e)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Lung						
Congestion Acute Diffuse						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.01	0/0.00	0/0.00	0/8.27
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Lung Inflammation						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.01	0/0.00	0/0.00	3/8.64
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	34.7%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/7 (29%)
FIRST INCIDENCE	---	---	---	---	---	80
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.068
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.072
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.064
COCH-ARM / FISHERS	P=0.050*	(e)	(e)	(e)	(e)	P=0.105
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.022*

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Lung						
Inflammation Chronic						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.01	0/0.00	0/0.00	0/8.27
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Lung						
Inflammation Granulomatous						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.01	0/0.00	0/0.00	2/8.64
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	23.2%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/7 (14%)
FIRST INCIDENCE	---	---	---	---	---	80
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.192
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.197
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.186
COCH-ARM / FISHERS	P=0.119	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.063

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Lung						
Metaplasia Focal Osseous						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.01	0/0.00	0/0.00	0/8.27
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/7 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	P=0.943N	(e)	(e)	P=0.537N
POLY 1.5	(e)	(e)	P=0.941N	(e)	(e)	P=0.530N
POLY 6	(e)	(e)	P=0.943N	(e)	(e)	P=0.548N
COCH-ARM / FISHERS	P=0.315N	(e)	P=0.909N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	P=0.497N	(e)	(e)	P=0.204N

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Lung						
Metaplasia Osseous						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.01	0/0.00	0/0.00	1/8.27
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	12.1%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/7 (14%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	P=0.943N	(e)	(e)	P=0.717
POLY 1.5	(e)	(e)	P=0.941N	(e)	(e)	P=0.727
POLY 6	(e)	(e)	P=0.943N	(e)	(e)	P=0.703
COCH-ARM / FISHERS	P=0.626	(e)	P=0.909N	(e)	(e)	P=0.763N
MAX-ISO-POLY-3	(e)	(e)	P=0.497N	(e)	(e)	P=0.449

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Lung: Alveolus Infiltration Cellular Histiocyte						
LESION RATES						
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.01	0/0.00	0/0.00	0/8.27
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	0%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/7 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	P=0.881N	(e)	(e)	P=0.273N
POLY 1.5	(e)	(e)	P=0.874N	(e)	(e)	P=0.263N
POLY 6	(e)	(e)	P=0.882N	(e)	(e)	P=0.288N
COCH-ARM / FISHERS	P=0.141N	(e)	P=0.818N	(e)	(e)	P=0.237N
MAX-ISO-POLY-3	(e)	(e)	P=0.497N	(e)	(e)	P=0.107N

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Lung: Interstitium Infiltration Cellular Mononuclear Cell						
LESION RATES						
OVERALL (a)	3/10 (30%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	4/10 (40%)
POLY-3 RATE (b)	3/10.00	0/0.00	0/0.01	0/0.00	0/0.00	4/8.27
POLY-3 PERCENT (g)	30%	0%	0%	0%	0%	48.4%
TERMINAL (d)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	4/7 (57%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	P=0.848N	(e)	(e)	P=0.379
POLY 1.5	(e)	(e)	P=0.835N	(e)	(e)	P=0.405
POLY 6	(e)	(e)	P=0.850N	(e)	(e)	P=0.343
COCH-ARM / FISHERS	P=0.363	(e)	P=0.727N	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	P=0.496N	(e)	(e)	P=0.238

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Lung: Interstitium Inflammation Chronic						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.01	0/0.00	0/0.00	1/8.27
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	12.1%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/7 (14%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	P=0.943N	(e)	(e)	P=0.717
POLY 1.5	(e)	(e)	P=0.941N	(e)	(e)	P=0.727
POLY 6	(e)	(e)	P=0.943N	(e)	(e)	P=0.703
COCH-ARM / FISHERS	P=0.626	(e)	P=0.909N	(e)	(e)	P=0.763N
MAX-ISO-POLY-3	(e)	(e)	P=0.497N	(e)	(e)	P=0.449

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Mesentery						
Necrosis Fatty						
LESION RATES						
OVERALL (a)	0/0 (0%)	0/0 (0%)	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	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Mesentery						
Necrosis Focal						
LESION RATES						
OVERALL (a)	0/0 (0%)	0/0 (0%)	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	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Nose Inflammation						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.01	0/0.00	0/0.00	1/8.27
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	12.1%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/7 (14%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	P=0.943N	(e)	(e)	P=0.717
POLY 1.5	(e)	(e)	P=0.941N	(e)	(e)	P=0.727
POLY 6	(e)	(e)	P=0.943N	(e)	(e)	P=0.703
COCH-ARM / FISHERS	P=0.626	(e)	P=0.909N	(e)	(e)	P=0.763N
MAX-ISO-POLY-3	(e)	(e)	P=0.497N	(e)	(e)	P=0.449

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Nose						
Inflammation Acute						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.01	0/0.00	0/0.00	1/8.27
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	12.1%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/7 (14%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.462
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.470
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.451
COCH-ARM / FISHERS	P=0.289	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.156

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Nose: Squamous Epithelium Hyperplasia						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.01	0/0.00	0/0.00	0/8.27
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/7 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	P=0.943N	(e)	(e)	P=0.537N
POLY 1.5	(e)	(e)	P=0.941N	(e)	(e)	P=0.530N
POLY 6	(e)	(e)	P=0.943N	(e)	(e)	P=0.548N
COCH-ARM / FISHERS	P=0.315N	(e)	P=0.909N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	P=0.497N	(e)	(e)	P=0.204N

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Pancreas: Acinus Atrophy						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.01	0/0.00	0/0.00	0/8.27
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/7 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	P=0.943N	(e)	(e)	P=0.537N
POLY 1.5	(e)	(e)	P=0.941N	(e)	(e)	P=0.530N
POLY 6	(e)	(e)	P=0.943N	(e)	(e)	P=0.548N
COCH-ARM / FISHERS	P=0.315N	(e)	P=0.909N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	P=0.497N	(e)	(e)	P=0.204N

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Pituitary Gland: Pars Distalis Hypertrophy						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.01	0/0.00	0/0.00	0/8.27
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/7 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	P=0.943N	(e)	(e)	P=0.537N
POLY 1.5	(e)	(e)	P=0.941N	(e)	(e)	P=0.530N
POLY 6	(e)	(e)	P=0.943N	(e)	(e)	P=0.548N
COCH-ARM / FISHERS	P=0.315N	(e)	P=0.909N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	P=0.497N	(e)	(e)	P=0.204N

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Preputial Gland Inflammation						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.01	0/0.00	0/0.00	1/8.27
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	12.1%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/7 (14%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.462
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.470
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.451
COCH-ARM / FISHERS	P=0.289	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.156

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Seminal Vesicle Atrophy						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.01	0/0.00	0/0.00	1/9.27
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10.8%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	---	---	5
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.485
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.492
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.475
COCH-ARM / FISHERS	P=0.289	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.157

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Spleen Atrophy						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.01	0/10.00	0/10.00	3/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	30%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	---	---	5
STATISTICAL TESTS						
POLY 3	P<0.001**	(e)	(e)	(e)	(e)	P=0.095
POLY 1.5	P<0.001**	(e)	(e)	(e)	(e)	P=0.095
POLY 6	P<0.001**	(e)	(e)	(e)	(e)	P=0.095
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	(e)	P=0.105
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	P=0.025*

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Spleen						
Hematopoietic Cell Proliferation						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.01	0/10.00	1/10.00	0/8.27
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/10 (0%)	1/10 (10%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	---	93 (T)	---
STATISTICAL TESTS						
POLY 3	P=0.473	(e)	(e)	(e)	P=0.500	(e)
POLY 1.5	P=0.498	(e)	(e)	(e)	P=0.500	(e)
POLY 6	P=0.435	(e)	(e)	(e)	P=0.500	(e)
COCH-ARM / FISHERS	P=0.585	(e)	(e)	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.216	(e)	(e)	(e)	P=0.158	(e)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Stomach, Forestomach Inflammation						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.01	0/0.00	0/0.00	1/8.64
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	11.6%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	---	---	80
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.471
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.475
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.465
COCH-ARM / FISHERS	P=0.289	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.157

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Stomach, Forestomach Mineralization						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.01	0/0.00	0/0.00	1/8.64
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	11.6%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	---	---	80
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.471
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.475
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.465
COCH-ARM / FISHERS	P=0.289	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.157

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Stomach, Forestomach Ulcer						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.01	0/0.00	0/0.00	1/9.27
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10.8%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	---	---	5
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.485
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.492
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.475
COCH-ARM / FISHERS	P=0.289	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.157

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Thymus Necrosis						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/9.01	0/10.00	0/10.00	1/9.27
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10.8%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/7 (0%)
FIRST INCIDENCE	---	---	---	---	---	5
STATISTICAL TESTS						
POLY 3	P=0.102	(e)	(e)	(e)	(e)	P=0.485
POLY 1.5	P=0.105	(e)	(e)	(e)	(e)	P=0.492
POLY 6	P=0.098	(e)	(e)	(e)	(e)	P=0.475
COCH-ARM / FISHERS	P=0.105	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.041*	(e)	(e)	(e)	(e)	P=0.157

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Thyroid Gland Cyst						
LESION RATES						
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.01	0/0.00	0/0.00	1/8.27
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	12.1%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/7 (14%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	P=0.881N	(e)	(e)	P=0.568N
POLY 1.5	(e)	(e)	P=0.874N	(e)	(e)	P=0.554N
POLY 6	(e)	(e)	P=0.882N	(e)	(e)	P=0.588N
COCH-ARM / FISHERS	P=0.402N	(e)	P=0.818N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	P=0.497N	(e)	(e)	P=0.344N

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Brain: Cerebrum						
Hemorrhage						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/9.01	0/0.00	0/0.00	0/0.00	0/0.04	1/7.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	14.1%
TERMINAL (d)	0/9 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	2
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.453
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.457
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.450
COCH-ARM / FISHERS	P=0.300	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.155

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Eye: Cornea						
Neovascularization						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/9.01	0/0.00	0/0.00	0/0.00	0/0.04	2/6.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	32.8%
TERMINAL (d)	0/9 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/6 (33%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.142
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.147
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.140
COCH-ARM / FISHERS	P=0.127	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.057

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Harderian Gland Infiltration Cellular Mononuclear Cell						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/9.01	0/0.00	0/0.00	0/0.00	0/0.04	1/7.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	14.1%
TERMINAL (d)	0/9 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	4
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.453
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.457
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.450
COCH-ARM / FISHERS	P=0.300	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.155

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Heart						
Cardiomyopathy						
LESION RATES						
OVERALL (a)	5/10 (50%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	2/10 (20%)
POLY-3 RATE (b)	5/9.01	0/0.00	0/0.00	0/0.00	0/0.04	2/7.00
POLY-3 PERCENT (g)	55.5%	0%	0%	0%	0%	28.6%
TERMINAL (d)	5/9 (56%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/6 (17%)
FIRST INCIDENCE	93 (T)	---	---	---	---	44
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	P=0.833N	P=0.292N
POLY 1.5	(e)	(e)	(e)	(e)	P=0.789N	P=0.295N
POLY 6	(e)	(e)	(e)	(e)	P=0.842N	P=0.291N
COCH-ARM / FISHERS	P=0.118N	(e)	(e)	(e)	P=0.545N	P=0.175N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.485N	P=0.177N

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Kidney						
Accumulation, Hyaline Droplet						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/9.01	0/0.00	0/0.00	0/0.00	0/0.04	0/6.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/9 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

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First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Kidney						
Casts Protein						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/9.01	0/0.00	0/0.00	0/0.00	0/0.04	0/6.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/9 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Kidney						
Infiltration Cellular Mononuclear Cell						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/9.01	0/0.00	0/0.00	0/0.00	0/0.04	0/6.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/9 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 03
 Test Type: 90-DAY
 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: 09/13/2016
 Time Report Requested: 11:41:17
 First Dose M/F: 09/15/03 / 09/16/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Kidney Mineralization						
LESION RATES						
OVERALL (a)	8/10 (80%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	3/10 (30%)
POLY-3 RATE (b)	8/9.01	0/0.00	0/0.00	0/0.00	1/1.00	3/6.11
POLY-3 PERCENT (g)	88.8%	0%	0%	0%	100%	49.1%
TERMINAL (d)	8/9 (89%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/6 (50%)
FIRST INCIDENCE	93 (T)	---	---	---	32	93 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	P=0.909	P=0.134N
POLY 1.5	(e)	(e)	(e)	(e)	P=0.904	P=0.115N
POLY 6	(e)	(e)	(e)	(e)	P=0.909	P=0.145N
COCH-ARM / FISHERS	P=0.021N*	(e)	(e)	(e)	P=0.818	P=0.035N*
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.398	P=0.073N

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Kidney						
Nephropathy						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/9.01	0/0.00	0/0.00	0/0.00	0/0.04	0/6.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/9 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver						
Congestion						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	0/9.01	0/10.00	0/10.00	0/10.00	1/10.00	0/6.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%	0%
TERMINAL (d)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	32	---
STATISTICAL TESTS						
POLY 3	P=0.312	(e)	(e)	(e)	P=0.521	(e)
POLY 1.5	P=0.321	(e)	(e)	(e)	P=0.519	(e)
POLY 6	P=0.308	(e)	(e)	(e)	P=0.521	(e)
COCH-ARM / FISHERS	P=0.585	(e)	(e)	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.255	(e)	(e)	(e)	P=0.184	(e)

Experiment Number: 20007 - 03
 Test Type: 90-DAY
 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: 09/13/2016
 Time Report Requested: 11:41:17
 First Dose M/F: 09/15/03 / 09/16/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver						
Hematopoietic Cell Proliferation						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/9.01	0/10.00	0/10.00	0/10.00	0/9.04	0/6.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 03
 Test Type: 90-DAY
 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: 09/13/2016
 Time Report Requested: 11:41:17
 First Dose M/F: 09/15/03 / 09/16/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver						
Hepatodiaphragmatic Nodule						
LESION RATES						
OVERALL (a)	2/10 (20%)	1/10 (10%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	2/9.01	1/10.00	0/10.00	1/10.00	0/9.04	0/6.11
POLY-3 PERCENT (g)	22.2%	10%	0%	10%	0%	0%
TERMINAL (d)	2/9 (22%)	1/10 (10%)	0/10 (0%)	1/10 (10%)	0/9 (0%)	0/6 (0%)
FIRST INCIDENCE	93 (T)	93 (T)	---	93 (T)	---	---
STATISTICAL TESTS						
POLY 3	P=0.148N	P=0.462N	P=0.202N	P=0.462N	P=0.224N	P=0.325N
POLY 1.5	P=0.146N	P=0.465N	P=0.204N	P=0.465N	P=0.222N	P=0.317N
POLY 6	P=0.148N	P=0.462N	P=0.202N	P=0.462N	P=0.225N	P=0.329N
COCH-ARM / FISHERS	P=0.136N	P=0.500N	P=0.237N	P=0.500N	P=0.237N	P=0.237N
MAX-ISO-POLY-3	P=0.112N	P=0.253N	P=0.064N	P=0.253N	P=0.065N	P=0.154N

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver						
Infiltration Cellular Mixed Cell						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/9.01	0/10.00	0/10.00	0/10.00	0/9.04	0/6.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 03
 Test Type: 90-DAY
 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: 09/13/2016
 Time Report Requested: 11:41:17
 First Dose M/F: 09/15/03 / 09/16/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver						
Infiltration Cellular Mononuclear Cell						
LESION RATES						
OVERALL (a)	8/10 (80%)	8/10 (80%)	4/10 (40%)	7/10 (70%)	8/10 (80%)	2/10 (20%)
POLY-3 RATE (b)	8/9.01	8/10.00	4/10.00	7/10.00	8/10.00	2/6.11
POLY-3 PERCENT (g)	88.8%	80%	40%	70%	80%	32.8%
TERMINAL (d)	8/9 (89%)	8/10 (80%)	4/10 (40%)	7/10 (70%)	7/9 (78%)	2/6 (33%)
FIRST INCIDENCE	93 (T)	93 (T)	93 (T)	93 (T)	32	93 (T)
STATISTICAL TESTS						
POLY 3	P=0.154N	P=0.539N	P=0.030N*	P=0.334N	P=0.539N	P=0.035N*
POLY 1.5	P=0.131N	P=0.556N	P=0.033N*	P=0.347N	P=0.556N	P=0.028N*
POLY 6	P=0.164N	P=0.538N	P=0.030N*	P=0.333N	P=0.538N	P=0.039N*
COCH-ARM / FISHERS	P=0.011N*	P=0.709N	P=0.085N	P=0.500N	P=0.709N	P=0.012N*
MAX-ISO-POLY-3	P=0.039N*	P=0.315N	P=0.011N*	P=0.177N	P=0.315N	P=0.020N*

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver Inflammation						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	1/9.01	0/10.00	0/10.00	0/10.00	1/9.04	0/6.11
POLY-3 PERCENT (g)	11.1%	0%	0%	0%	11.1%	0%
TERMINAL (d)	1/9 (11%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/9 (11%)	0/6 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	93 (T)	---
STATISTICAL TESTS						
POLY 3	P=0.617	P=0.479N	P=0.479N	P=0.479N	P=0.761N	P=0.575N
POLY 1.5	P=0.630	P=0.481N	P=0.481N	P=0.481N	P=0.759N	P=0.569N
POLY 6	P=0.611	P=0.479N	P=0.479N	P=0.479N	P=0.762N	P=0.577N
COCH-ARM / FISHERS	P=0.586N	P=0.500N	P=0.500N	P=0.500N	P=0.763N	P=0.500N
MAX-ISO-POLY-3	P=0.202N	P=0.157N	P=0.157N	P=0.157N	P=0.498N	P=0.248N

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver						
Vacuolization Cytoplasmic						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/9.01	0/10.00	0/10.00	0/10.00	0/9.04	0/6.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver: Bile Duct Hyperplasia						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/9.01	0/10.00	0/10.00	0/10.00	0/9.04	0/6.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver: Hepatocyte Hypertrophy						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)	3/10 (30%)	10/10 (100%)
POLY-3 RATE (b)	0/9.01	0/10.00	0/10.00	3/10.00	3/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	0%	30%	30%	100%
TERMINAL (d)	0/9 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)	2/9 (22%)	6/6 (100%)
FIRST INCIDENCE	---	---	---	93 (T)	32	2
STATISTICAL TESTS						
POLY 3	P<0.001**	(e)	(e)	P=0.115	P=0.115	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	P=0.113	P=0.113	P<0.001**
POLY 6	P<0.001**	(e)	(e)	P=0.115	P=0.115	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.105	P=0.105	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P=0.039*	P=0.039*	P<0.001**

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Lung						
Congestion Acute Diffuse						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/9.01	0/0.00	0/0.00	0/0.00	0/0.04	1/7.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	14.1%
TERMINAL (d)	0/9 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	4
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.453
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.457
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.450
COCH-ARM / FISHERS	P=0.300	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.155

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Lung Inflammation						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/9.01	0/0.00	0/0.00	0/0.00	0/0.04	1/6.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	16.4%
TERMINAL (d)	0/9 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/6 (17%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.424
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.429
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.421
COCH-ARM / FISHERS	P=0.300	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.153

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Lung						
Inflammation Chronic						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/9.01	0/0.00	0/0.00	0/0.00	0/0.04	0/6.11
POLY-3 PERCENT (g)	11.1%	0%	0%	0%	0%	0%
TERMINAL (d)	1/9 (11%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	P=0.943N	P=0.575N
POLY 1.5	(e)	(e)	(e)	(e)	P=0.940N	P=0.569N
POLY 6	(e)	(e)	(e)	(e)	P=0.944N	P=0.577N
COCH-ARM / FISHERS	P=0.300N	(e)	(e)	(e)	P=0.909N	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.494N	P=0.248N

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Lung						
Inflammation Granulomatous						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/9.01	0/0.00	0/0.00	0/0.00	0/0.04	0/6.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/9 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Lung						
Metaplasia Focal Osseous						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/9.01	0/0.00	0/0.00	0/0.00	0/0.04	0/6.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/9 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Lung						
Metaplasia Osseous						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/9.01	0/0.00	0/0.00	0/0.00	0/0.04	0/6.11
POLY-3 PERCENT (g)	11.1%	0%	0%	0%	0%	0%
TERMINAL (d)	1/9 (11%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	P=0.943N	P=0.575N
POLY 1.5	(e)	(e)	(e)	(e)	P=0.940N	P=0.569N
POLY 6	(e)	(e)	(e)	(e)	P=0.944N	P=0.577N
COCH-ARM / FISHERS	P=0.300N	(e)	(e)	(e)	P=0.909N	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.494N	P=0.248N

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Lung: Alveolus Infiltration Cellular Histiocyte						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	4/10 (40%)
POLY-3 RATE (b)	1/9.01	0/0.00	0/0.00	0/0.00	0/0.04	4/7.00
POLY-3 PERCENT (g)	11.1%	0%	0%	0%	0%	57.1%
TERMINAL (d)	1/9 (11%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/6 (50%)
FIRST INCIDENCE	93 (T)	---	---	---	---	44
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	P=0.943N	P=0.069
POLY 1.5	(e)	(e)	(e)	(e)	P=0.940N	P=0.068
POLY 6	(e)	(e)	(e)	(e)	P=0.944N	P=0.069
COCH-ARM / FISHERS	P=0.095	(e)	(e)	(e)	P=0.909N	P=0.152
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.494N	P=0.033*

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Lung: Interstitium Infiltration Cellular Mononuclear Cell						
LESION RATES						
OVERALL (a)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	3/10 (30%)
POLY-3 RATE (b)	3/9.01	0/0.00	0/0.00	0/0.00	1/1.00	3/7.11
POLY-3 PERCENT (g)	33.3%	0%	0%	0%	100%	42.2%
TERMINAL (d)	3/9 (33%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/6 (33%)
FIRST INCIDENCE	93 (T)	---	---	---	32	2
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	P=0.412	P=0.557
POLY 1.5	(e)	(e)	(e)	(e)	P=0.409	P=0.570
POLY 6	(e)	(e)	(e)	(e)	P=0.412	P=0.549
COCH-ARM / FISHERS	P=0.594	(e)	(e)	(e)	P=0.364	P=0.686N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.158	P=0.375

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Lung: Interstitium Inflammation Chronic						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/9.01	0/0.00	0/0.00	0/0.00	0/0.04	0/6.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/9 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Mesentery						
Necrosis Fatty						
LESION RATES						
OVERALL (a)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/1.00	0/0.00	0/0.00	1/1.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%	100%	0%	0%
TERMINAL (d)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	93 (T)	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.921	(e)	(e)	P=0.500	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

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First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Mesentery						
Necrosis Focal						
LESION RATES						
OVERALL (a)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	1/1.00	0/0.00	0/0.00	0/1.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	100%	0%	0%	0%	0%	0%
TERMINAL (d)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.921N	(e)	(e)	P=0.500N	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Nose Inflammation						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/9.01	0/0.00	0/0.00	0/0.00	0/0.04	0/6.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/9 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Nose						
Inflammation Acute						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/9.01	0/0.00	0/0.00	0/0.00	0/0.04	0/6.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/9 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Nose: Squamous Epithelium Hyperplasia						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/9.01	0/0.00	0/0.00	0/0.00	0/0.04	0/6.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/9 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Pancreas: Acinus Atrophy						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/9.01	0/0.00	0/0.00	0/0.00	0/0.04	1/7.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	14.3%
TERMINAL (d)	0/9 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	44
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.450
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.449
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.450
COCH-ARM / FISHERS	P=0.300	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.155

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Pituitary Gland: Pars Distalis Hypertrophy						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/9.01	0/0.00	0/0.00	0/0.00	0/0.04	0/6.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/9 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

CAS Number: 9000-38-8

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Spleen Atrophy						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00	0/10.00	0/9.04	3/9.11
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	33%
TERMINAL (d)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/6 (0%)
FIRST INCIDENCE	18	---	---	---	---	2
STATISTICAL TESTS						
POLY 3	P=0.008**	P=0.500N	P=0.500N	P=0.500N	P=0.520N	P=0.255
POLY 1.5	P=0.009**	P=0.500N	P=0.500N	P=0.500N	P=0.517N	P=0.264
POLY 6	P=0.008**	P=0.500N	P=0.500N	P=0.500N	P=0.521N	P=0.251
COCH-ARM / FISHERS	P=0.014*	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.291
MAX-ISO-POLY-3	P=0.003**	P=0.158N	P=0.158N	P=0.158N	P=0.183N	P=0.122

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Spleen						
Hematopoietic Cell Proliferation						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/9.01	0/10.00	0/10.00	0/10.00	0/9.04	0/6.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Stomach, Forestomach Inflammation						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/9.01	0/0.00	0/0.00	0/0.00	0/0.04	1/6.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	16.4%
TERMINAL (d)	0/9 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/6 (17%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.424
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.429
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.421
COCH-ARM / FISHERS	P=0.300	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.153

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Stomach, Forestomach Mineralization						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/9.01	0/0.00	0/0.00	0/0.00	0/0.04	1/7.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	14.1%
TERMINAL (d)	0/9 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	4
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.453
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.457
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.450
COCH-ARM / FISHERS	P=0.300	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.155

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Stomach, Forestomach Ulcer						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/9.01	0/0.00	0/0.00	0/0.00	0/0.04	1/7.11
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	14.1%
TERMINAL (d)	0/9 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	4
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.453
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.457
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.450
COCH-ARM / FISHERS	P=0.300	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.155

Experiment Number: 20007 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

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First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Thymus Necrosis						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00	0/10.00	0/9.04	3/9.11
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	33%
TERMINAL (d)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/6 (0%)
FIRST INCIDENCE	18	---	---	---	---	2
STATISTICAL TESTS						
POLY 3	P=0.008**	P=0.500N	P=0.500N	P=0.500N	P=0.520N	P=0.255
POLY 1.5	P=0.009**	P=0.500N	P=0.500N	P=0.500N	P=0.517N	P=0.264
POLY 6	P=0.008**	P=0.500N	P=0.500N	P=0.500N	P=0.521N	P=0.251
COCH-ARM / FISHERS	P=0.014*	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.291
MAX-ISO-POLY-3	P=0.003**	P=0.158N	P=0.158N	P=0.158N	P=0.183N	P=0.122

Experiment Number: 20007 - 03

Test Type: 90-DAY

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: 09/13/2016

Time Report Requested: 11:41:17

First Dose M/F: 09/15/03 / 09/16/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Thyroid Gland Cyst						
LESION RATES						
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	1/9 (11%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/0.00	0/0.04	1/6.11
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	16.4%
TERMINAL (d)	1/9 (11%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/6 (17%)
FIRST INCIDENCE	18	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	P=0.879N	P=0.667N
POLY 1.5	(e)	(e)	(e)	(e)	P=0.867N	P=0.656N
POLY 6	(e)	(e)	(e)	(e)	P=0.882N	P=0.672N
COCH-ARM / FISHERS	P=0.411N	(e)	(e)	(e)	P=0.818N	P=0.542N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.493N	P=0.443N

Experiment Number: 20007 - 03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

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LEGEND

- (a) Number of tumor-bearing animals/number of animals examined at site.
 - (b) Number of tumor-bearing animals/Poly-3 number
 - (d) Observed incidence at terminal kill.
 - (e) Value of statistic cannot be computed.
 - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
 - (g) Poly-3 adjusted lifetime tumor incidence.
 - (n) No statistics are calculated if all dose groups have fewer than two tumors.
 - (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 ***