

**Experiment Number:** 20007-03  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** Rat/F 344/N

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

**Test Compound:** Kava kava extract  
**CAS Number:** 9000-38-8

**Date Report Requested:** 10/17/2014  
**Time Report Requested:** 21:52:20  
**First Dose M/F:** NA / NA  
**Lab:** BAT

<b>C Number:</b>	C20007
<b>Lock Date:</b>	05/24/2004
<b>Cage Range:</b>	All
<b>Date Range:</b>	All
<b>Reasons For Removal:</b>	All
<b>Removal Date Range:</b>	All
<b>Treatment Groups:</b>	All
<b>Study Gender:</b>	Both
<b>PWG Approval Date</b>	NONE

**Experiment Number:** 20007-03

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**Route:** GAVAGE

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

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

**MALE RAT**

**Organ**

Liver

Lung

Spleen

**FEMALE RAT**

**Organ**

Kidney

Liver

Liver: Hepatocyte

Lung: Alveolus

Spleen

Thymus

**Morphology**

Infiltration Cellular Mononuclear CI

Inflammation

Atrophy

**Morphology**

Mineralization

Infiltration Cellular Mononuclear CI

Hypertrophy

Infiltration Cellular Histiocyte

Atrophy

Necrosis

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First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Brain: Cerebrum</b>						
<b>Hemorrhage</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

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Route: GAVAGE

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P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Epididymis Inflammation</b>						
<b>LESION RATES</b>						
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)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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=0.499N	(e)	(e)	P=0.205N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

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First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Eye: Cornea</b>						
<b>Neovascularization</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

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First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Harderian Gland</b>						
<b>Infiltration Cellular Mononuclear CI</b>						
<b>LESION RATES</b>						
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)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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=0.499N	(e)	(e)	P=0.205N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:20

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Heart</b>						
<b>Cardiomyopathy</b>						
<b>LESION RATES</b>						
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
<b>STATISTICAL TESTS</b>						
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=0.490N	(e)	(e)	P=0.472N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:20

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Kidney</b>						
<b>Accumulation Hyaline Droplet</b>						
<b>LESION RATES</b>						
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)
<b>STATISTICAL TESTS</b>						
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=0.499N	(e)	(e)	P=0.346N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 20007-03  
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**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
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 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 12 WEEKS**

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Kidney</b>						
<b>Casts Protein</b>						
<b>LESION RATES</b>						
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)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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=0.499N	(e)	(e)	P=0.205N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:20

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Kidney</b>						
<b>Infiltration Cellular Mononuclear CI</b>						
<b>LESION RATES</b>						
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)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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=0.499N	(e)	(e)	P=0.205N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:20  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 12 WEEKS**

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Kidney</b>						
<b>Mineralization</b>						
<b>LESION RATES</b>						
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)
<b>STATISTICAL TESTS</b>						
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=0.497N	(e)	(e)	P=0.443N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

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Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

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First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Kidney</b>						
<b>Nephropathy</b>						
<b>LESION RATES</b>						
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
<b>STATISTICAL TESTS</b>						
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=1.000	(e)	P=0.364N	(e)	(e)	P=0.686N
MAX-ISO-POLY-3	(e)	(e)	P=0.495N	(e)	(e)	P=0.364
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
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 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
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 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 12 WEEKS**

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Liver</b>						
<b>Congestion</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

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Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:20

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Liver</b>						
<b>Hematopoietic Cell Proliferation</b>						
<b>LESION RATES</b>						
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)	---	---	---	---
<b>STATISTICAL TESTS</b>						
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=0.285N	P=1.000	P=0.185N	P=0.159N	P=0.159N	P=0.205N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:20  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 12 WEEKS**

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Liver</b>						
<b>Hepatodiaphragmatic Nodule</b>						
<b>LESION RATES</b>						
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)	---	---
<b>STATISTICAL TESTS</b>						
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=0.556	(e)	(e)	P=0.159	(e)	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:20  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 12 WEEKS**

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Liver</b>						
<b>Infiltration Cellular Mixed Cell</b>						
<b>LESION RATES</b>						
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)
<b>STATISTICAL TESTS</b>						
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=0.074	(e)	(e)	(e)	(e)	P=0.157
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Liver</b>						
<b>Infiltration Cellular Mononuclear CI</b>						
<b>LESION RATES</b>						
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%	60.5%
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)
<b>STATISTICAL TESTS</b>						
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=0.134N	P=0.138N	P=0.048N*	P=0.020N*	P=0.020N*	P=0.077N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 12 WEEKS**

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Liver</b>						
<b>Inflammation</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Liver</b>						
<b>Vacuolization Cytoplasmic</b>						
<b>LESION RATES</b>						
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)	---	---
<b>STATISTICAL TESTS</b>						
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=0.285N	P=0.159N	P=0.185N	P=1.000	P=0.159N	P=0.205N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Liver: Bile Duct</b>						
<b>Hyperplasia</b>						
<b>LESION RATES</b>						
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)	---	---
<b>STATISTICAL TESTS</b>						
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=0.556	(e)	(e)	P=0.159	(e)	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Liver: Hepatocyte Hypertrophy</b>						
<b>LESION RATES</b>						
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)	---
<b>STATISTICAL TESTS</b>						
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=0.398	(e)	(e)	(e)	P=0.159	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Lung</b>						
<b>Congestion Acute Diffuse</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 12 WEEKS**

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Lung Inflammation</b>						
<b>LESION RATES</b>						
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
<b>STATISTICAL TESTS</b>						
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*
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 12 WEEKS**

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Lung</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Lung</b>						
<b>Inflammation Granulomatous</b>						
<b>LESION RATES</b>						
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%	23.1%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/7 (14%)
FIRST INCIDENCE	---	---	---	---	---	80
<b>STATISTICAL TESTS</b>						
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=0.064
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 12 WEEKS**

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Lung</b>						
<b>Metaplasia Osseous</b>						
<b>LESION RATES</b>						
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)
<b>STATISTICAL TESTS</b>						
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=0.499N	(e)	(e)	P=0.451
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Lung</b>						
<b>Metaplasia Osseous Focal</b>						
<b>LESION RATES</b>						
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)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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=0.499N	(e)	(e)	P=0.205N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 12 WEEKS**

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Lung: Alveolus</b>						
<b>Infiltration Cellular Histiocyte</b>						
<b>LESION RATES</b>						
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)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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=0.499N	(e)	(e)	P=0.109N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Lung: Interstitium</b>						
<b>Infiltration Cellular Mononuclear CI</b>						
<b>LESION RATES</b>						
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)
<b>STATISTICAL TESTS</b>						
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=0.498N	(e)	(e)	P=0.239
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Lung: Interstitium</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
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)
<b>STATISTICAL TESTS</b>						
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=0.499N	(e)	(e)	P=0.451
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 12 WEEKS**

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Mesentery</b>						
<b>Necrosis Fatty</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 12 WEEKS**

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Mesentery</b>						
<b>Necrosis Focal</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Nose</b>						
<b>Inflammation</b>						
<b>LESION RATES</b>						
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)
<b>STATISTICAL TESTS</b>						
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=0.499N	(e)	(e)	P=0.451
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 12 WEEKS**

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Nose</b>						
<b>Inflammation Acute</b>						
<b>LESION RATES</b>						
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)
<b>STATISTICAL TESTS</b>						
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=0.157
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 12 WEEKS**

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Nose: Squam Epithel Hyperplasia</b>						
<b>LESION RATES</b>						
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)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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=0.499N	(e)	(e)	P=0.205N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Pancreas: Acinus</b>						
<b>Atrophy</b>						
<b>LESION RATES</b>						
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)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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=0.499N	(e)	(e)	P=0.205N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 12 WEEKS**

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Pituitary Gland: Pars Distalis</b>						
<b>Hypertrophy</b>						
<b>LESION RATES</b>						
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)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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=0.499N	(e)	(e)	P=0.205N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 12 WEEKS**

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Preputial Gland Inflammation</b>						
<b>LESION RATES</b>						
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)
<b>STATISTICAL TESTS</b>						
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=0.157
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 12 WEEKS**

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Seminal Vesicle</b>						
<b>Atrophy</b>						
<b>LESION RATES</b>						
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
<b>STATISTICAL TESTS</b>						
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=0.158
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Spleen</b>						
<b>Atrophy</b>						
<b>LESION RATES</b>						
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
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	(e)	(e)	(e)	(e)	P=0.095
POLY 1.5	P=0.000**	(e)	(e)	(e)	(e)	P=0.095
POLY 6	P=0.000**	(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*
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Spleen</b>						
<b>Hematopoietic Cell Proliferation</b>						
<b>LESION RATES</b>						
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)	---
<b>STATISTICAL TESTS</b>						
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=0.398	(e)	(e)	(e)	P=0.159	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 12 WEEKS**

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Stomach, Forestomach Inflammation</b>						
<b>LESION RATES</b>						
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
<b>STATISTICAL TESTS</b>						
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=0.158
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 12 WEEKS

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Stomach, Forestomach</b>						
<b>Mineralization</b>						
<b>LESION RATES</b>						
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
<b>STATISTICAL TESTS</b>						
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=0.158
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 12 WEEKS**

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Stomach, Forestomach Ulcer</b>						
<b>LESION RATES</b>						
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
<b>STATISTICAL TESTS</b>						
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=0.158
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 12 WEEKS**

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Thymus</b>						
<b>Necrosis</b>						
<b>LESION RATES</b>						
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
<b>STATISTICAL TESTS</b>						
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=0.074	(e)	(e)	(e)	(e)	P=0.158
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 12 WEEKS**

DOSE	MALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Thyroid Gland</b>						
<b>Cyst</b>						
<b>LESION RATES</b>						
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)
<b>STATISTICAL TESTS</b>						
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=0.499N	(e)	(e)	P=0.346N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 7 WEEKS

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Brain: Cerebrum</b>						
<b>Hemorrhage</b>						
<b>LESION RATES</b>						
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
<b>STATISTICAL TESTS</b>						
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=0.156
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Eye: Cornea</b>						
<b>Neovascularization</b>						
<b>LESION RATES</b>						
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%	32.7%
TERMINAL (d)	0/9 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/6 (33%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
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=0.058
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 7 WEEKS

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Harderian Gland</b>						
<b>Infiltration Cellular Mononuclear CI</b>						
<b>LESION RATES</b>						
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
<b>STATISTICAL TESTS</b>						
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=0.156
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Heart</b>						
<b>Cardiomyopathy</b>						
<b>LESION RATES</b>						
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
<b>STATISTICAL TESTS</b>						
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=0.487N	P=0.177N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Kidney</b>						
<b>Accumulation Hyaline Droplet</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 7 WEEKS

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Kidney</b>						
<b>Casts Protein</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 7 WEEKS

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Kidney</b>						
<b>Infiltration Cellular Mononuclear CI</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Kidney</b>						
<b>Mineralization</b>						
<b>LESION RATES</b>						
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)
<b>STATISTICAL TESTS</b>						
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=0.400	P=0.074N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Kidney</b>						
<b>Nephropathy</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Liver</b>						
<b>Congestion</b>						
<b>LESION RATES</b>						
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	---
<b>STATISTICAL TESTS</b>						
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=0.468	(e)	(e)	(e)	P=0.185	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Liver</b>						
<b>Hematopoietic Cell Proliferation</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Liver</b>						
<b>Hepatodiaphragmatic Nodule</b>						
<b>LESION RATES</b>						
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)	---	---
<b>STATISTICAL TESTS</b>						
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=0.207N	P=0.253N	P=0.065N	P=0.253N	P=0.065N	P=0.156N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 7 WEEKS

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Liver</b>						
<b>Infiltration Cellular Mixed Cell</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Liver</b>						
<b>Infiltration Cellular Mononuclear CI</b>						
<b>LESION RATES</b>						
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%	32.7%
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)
<b>STATISTICAL TESTS</b>						
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=0.070N	P=0.316N	P=0.011N*	P=0.177N	P=0.316N	P=0.020N*
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Liver</b>						
<b>Inflammation</b>						
<b>LESION RATES</b>						
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)	---
<b>STATISTICAL TESTS</b>						
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=0.373N	P=0.158N	P=0.158N	P=0.158N	P=0.499N	P=0.249N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Liver</b>						
<b>Vacuolization Cytoplasmic</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Liver: Bile Duct</b>						
<b>Hyperplasia</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 7 WEEKS

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Liver: Hepatocyte Hypertrophy</b>						
<b>LESION RATES</b>						
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
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	(e)	(e)	P=0.115	P=0.115	P=0.000**
POLY 1.5	P=0.000**	(e)	(e)	P=0.113	P=0.113	P=0.000**
POLY 6	P=0.000**	(e)	(e)	P=0.115	P=0.115	P=0.000**
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	P=0.105	P=0.105	P=0.000**
MAX-ISO-POLY-3	P=0.000**	(e)	(e)	P=0.039*	P=0.039*	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Lung</b>						
<b>Congestion Acute Diffuse</b>						
<b>LESION RATES</b>						
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
<b>STATISTICAL TESTS</b>						
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=0.156
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Lung Inflammation</b>						
<b>LESION RATES</b>						
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)
<b>STATISTICAL TESTS</b>						
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=0.154
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Lung</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
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)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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=0.496N	P=0.249N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 7 WEEKS

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Lung</b>						
<b>Inflammation Granulomatous</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Lung</b>						
<b>Metaplasia Osseous</b>						
<b>LESION RATES</b>						
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)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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=0.496N	P=0.249N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 7 WEEKS

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Lung</b>						
<b>Metaplasia Osseous Focal</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 7 WEEKS

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Lung: Alveolus</b>						
<b>Infiltration Cellular Histiocyte</b>						
<b>LESION RATES</b>						
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
<b>STATISTICAL TESTS</b>						
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=0.496N	P=0.034*
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Lung: Interstitium</b>						
<b>Infiltration Cellular Mononuclear CI</b>						
<b>LESION RATES</b>						
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
<b>STATISTICAL TESTS</b>						
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=0.159	P=0.378
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Lung: Interstitium</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 7 WEEKS

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Mesentery</b>						
<b>Necrosis Fatty</b>						
<b>LESION RATES</b>						
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)	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Mesentery</b>						
<b>Necrosis Focal</b>						
<b>LESION RATES</b>						
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)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 7 WEEKS

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Nose</b>						
<b>Inflammation</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Nose</b>						
<b>Inflammation Acute</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 7 WEEKS

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Nose: Squam Epithel</b>						
<b>Hyperplasia</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 7 WEEKS

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Pancreas: Acinus</b>						
<b>Atrophy</b>						
<b>LESION RATES</b>						
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
<b>STATISTICAL TESTS</b>						
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=0.156
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Pituitary Gland: Pars Distalis</b>						
<b>Hypertrophy</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Spleen</b>						
<b>Atrophy</b>						
<b>LESION RATES</b>						
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%	32.9%
TERMINAL (d)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/6 (0%)
FIRST INCIDENCE	18	---	---	---	---	2
<b>STATISTICAL TESTS</b>						
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=0.006**	P=0.159N	P=0.159N	P=0.159N	P=0.184N	P=0.124
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Spleen</b>						
<b>Hematopoietic Cell Proliferation</b>						
<b>LESION RATES</b>						
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	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
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)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 7 WEEKS

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Stomach, Forestomach Inflammation</b>						
<b>LESION RATES</b>						
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)
<b>STATISTICAL TESTS</b>						
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=0.154
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Stomach, Forestomach</b>						
<b>Mineralization</b>						
<b>LESION RATES</b>						
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
<b>STATISTICAL TESTS</b>						
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=0.156
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/17/2014

Time Report Requested: 21:52:21

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 7 WEEKS

DOSE	FEMALE					
	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						
<b>LESION RATES</b>						
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
<b>STATISTICAL TESTS</b>						
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=0.156
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Thymus</b>						
<b>Necrosis</b>						
<b>LESION RATES</b>						
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%	32.9%
TERMINAL (d)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/6 (0%)
FIRST INCIDENCE	18	---	---	---	---	2
<b>STATISTICAL TESTS</b>						
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=0.006**	P=0.159N	P=0.159N	P=0.159N	P=0.184N	P=0.124
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 20007-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Kava kava extract  
 CAS Number: 9000-38-8

Date Report Requested: 10/17/2014  
 Time Report Requested: 21:52:21  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 7 WEEKS**

DOSE	FEMALE					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<b>Thyroid Gland</b>						
<b>Cyst</b>						
<b>LESION RATES</b>						
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)
<b>STATISTICAL TESTS</b>						
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=0.495N	P=0.445N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

**Experiment Number:** 20007-03

**Test Type:** 90-DAY

**Route:** GAVAGE

**Species/Strain:** Rat/F 344/N

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

**Test Compound:** Kava kava extract

**CAS Number:** 9000-38-8

**Date Report Requested:** 10/17/2014

**Time Report Requested:** 21:52:21

**First Dose M/F:** NA / NA

**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.
  - (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 \*\***