

Experiment Number: 20007 - 04
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 09/13/2016
Time Report Requested: 11:24:53
First Dose M/F: 09/18/03 / 09/17/03
Lab: BAT

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

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

MALE MICE

Organ

Liver

Liver: Centrilobular

Thymus

FEMALE MICE

Organ

Liver

Liver: Centrilobular

Thymus

Morphology

Necrosis

Hypertrophy

Necrosis

Morphology

Inflammation Chronic

Hypertrophy

Necrosis

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Adrenal Cortex Hypertrophy						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/6.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	16.7%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/6 (17%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.637
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.638
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.636
COCH-ARM / FISHERS	P=0.645	(e)	(e)	(e)	(e)	P=0.763N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.384

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Adrenal Cortex						
Hypertrophy Focal						
<hr/>						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/6.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	16.7%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/6 (17%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
<hr/>						
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.402
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.403
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.402
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.152

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Adrenal Cortex: Subcapsular Hyperplasia						
LESION RATES						
OVERALL (a)	5/10 (50%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	6/10 (60%)
POLY-3 RATE (b)	5/10.00	0/0.00	0/0.00	0/0.00	0/0.00	6/7.00
POLY-3 PERCENT (g)	50%	0%	0%	0%	0%	85.7%
TERMINAL (d)	5/10 (50%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	5/6 (83%)
FIRST INCIDENCE	93 (T)	---	---	---	---	3
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.164
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.167
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.164
COCH-ARM / FISHERS	P=0.411	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.100

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
<hr/>						
Esophagus Hemorrhage						
<hr/>						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/6.00
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%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<hr/>						
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Esophagus						
Inflammation Acute						
<hr/>						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/6.00
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%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<hr/>						
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Kidney Mineralization						
LESION RATES						
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/6.00
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%)	0/6 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.360N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.358N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.360N
COCH-ARM / FISHERS	P=0.132N	(e)	(e)	(e)	(e)	P=0.237N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.186N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Kidney						
Nephropathy						
LESION RATES						
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/6.00
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%)	0/6 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.360N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.358N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.360N
COCH-ARM / FISHERS	P=0.132N	(e)	(e)	(e)	(e)	P=0.237N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.186N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver						
Inflammation Chronic						
LESION RATES						
OVERALL (a)	6/10 (60%)	7/10 (70%)	4/10 (40%)	7/10 (70%)	7/10 (70%)	4/10 (40%)
POLY-3 RATE (b)	6/10.00	7/10.00	4/10.00	7/10.00	7/10.00	4/6.00
POLY-3 PERCENT (g)	60%	70%	40%	70%	70%	66.7%
TERMINAL (d)	6/10 (60%)	7/10 (70%)	4/10 (40%)	7/10 (70%)	7/10 (70%)	4/6 (67%)
FIRST INCIDENCE	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)
STATISTICAL TESTS						
POLY 3	P=0.343	P=0.500	P=0.333N	P=0.500	P=0.500	P=0.594
POLY 1.5	P=0.347	P=0.500	P=0.333N	P=0.500	P=0.500	P=0.599
POLY 6	P=0.343	P=0.500	P=0.333N	P=0.500	P=0.500	P=0.594
COCH-ARM / FISHERS	P=0.255N	P=0.500	P=0.328N	P=0.500	P=0.500	P=0.328N
MAX-ISO-POLY-3	P=0.341	P=0.325	P=0.193N	P=0.325	P=0.325	P=0.420

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver						
Necrosis						
LESION RATES						
OVERALL (a)	0/10 (0%)	1/10 (10%)	0/10 (0%)	1/10 (10%)	1/10 (10%)	4/10 (40%)
POLY-3 RATE (b)	0/10.00	1/10.00	0/10.00	1/10.00	1/10.00	4/7.00
POLY-3 PERCENT (g)	0%	10%	0%	10%	10%	57.1%
TERMINAL (d)	0/10 (0%)	1/10 (10%)	0/10 (0%)	1/10 (10%)	1/10 (10%)	3/6 (50%)
FIRST INCIDENCE	---	93 (T)	---	93 (T)	93 (T)	2
STATISTICAL TESTS						
POLY 3	P<0.001**	P=0.500	(e)	P=0.500	P=0.500	P=0.007**
POLY 1.5	P<0.001**	P=0.500	(e)	P=0.500	P=0.500	P=0.007**
POLY 6	P<0.001**	P=0.500	(e)	P=0.500	P=0.500	P=0.007**
COCH-ARM / FISHERS	P=0.003**	P=0.500	(e)	P=0.500	P=0.500	P=0.043*
MAX-ISO-POLY-3	P<0.001**	P=0.158	(e)	P=0.158	P=0.158	P=0.003**

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver: Centrilobular Hypertrophy						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	9/10 (90%)	10/10 (100%)	7/10 (70%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	9/10.00	10/10.00	7/7.00
POLY-3 PERCENT (g)	0%	0%	0%	90%	100%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	9/10 (90%)	10/10 (100%)	6/6 (100%)
FIRST INCIDENCE	---	---	---	93 (T)	93 (T)	6
STATISTICAL TESTS						
POLY 3	P<0.001**	(e)	(e)	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	(e)	(e)	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P<0.001**	P<0.001**	P=0.002**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P<0.001**	(e)	P<0.001**

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Lung Congestion						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	2/8.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	25%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	3
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.176
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.176
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.176
COCH-ARM / FISHERS	P=0.132	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.062

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Lung						
Inflammation Chronic						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/6.00
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%)	0/6 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.595N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.594N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.595N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.275N

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Kava kava extract
 CAS Number: 9000-38-8

Date Report Requested: 09/13/2016
 Time Report Requested: 11:24:53
 First Dose M/F: 09/18/03 / 09/17/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Pancreas: Acinus						
Vacuolization Cytoplasmic						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/6.00
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%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

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

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Pancreas: Artery Inflammation						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/6.00
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%)	0/6 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.595N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.594N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.595N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.275N

Experiment Number: 20007 - 04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Kava kava extract
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 First Dose M/F: 09/18/03 / 09/17/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Parathyroid Gland Cyst						
LESION RATES						
OVERALL (a)	1/7 (14%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/7 (0%)
POLY-3 RATE (b)	1/7.00	0/0.00	0/0.00	0/0.00	0/0.00	0/4.00
POLY-3 PERCENT (g)	14.3%	0%	0%	0%	0%	0%
TERMINAL (d)	1/7 (14%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/4 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.603N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.602N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.603N
COCH-ARM / FISHERS	P=0.302N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.285N

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

CAS Number: 9000-38-8

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First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Skin Inflammation						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/6.00
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%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

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First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Stomach, Forestomach Inflammation Chronic						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/7.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	14.3%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	6
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.430
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.430
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.430
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.154

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:24:53

First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Stomach, Forestomach Mineralization						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/7.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	14.3%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	6
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.430
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.430
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.430
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.154

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

CAS Number: 9000-38-8

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First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Stomach, Glandular Cyst						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/6.00
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%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Stomach, Glandular Inflammation						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/6.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	16.7%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/6 (17%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.637
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.638
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.636
COCH-ARM / FISHERS	P=0.645	(e)	(e)	(e)	(e)	P=0.763N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.384

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

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First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Stomach, Glandular Inflammation Chronic						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/6.00
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%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Stomach, Glandular Mineralization						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/6.00
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%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

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First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Testes						
Hypoplasia						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/7.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	14.3%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	3
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.430
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.431
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.430
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.154

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Thymus Necrosis						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	3/9.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	33.3%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	2
STATISTICAL TESTS						
POLY 3	P<0.001**	(e)	(e)	(e)	(e)	P=0.076
POLY 1.5	P<0.001**	(e)	(e)	(e)	(e)	P=0.076
POLY 6	P<0.001**	(e)	(e)	(e)	(e)	P=0.076
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=0.023*

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Thyroid Gland Cyst						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/6.00
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%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

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First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Adrenal Cortex Hypertrophy						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/6.06
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%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:24:53

First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Adrenal Cortex						
Hypertrophy Focal						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/6.06
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%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:24:53

First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Adrenal Cortex: Subcapsular Hyperplasia						
LESION RATES						
OVERALL (a)	10/10 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	8/10 (80%)
POLY-3 RATE (b)	10/10.00	0/0.00	0/0.00	0/0.00	0/0.00	8/9.00
POLY-3 PERCENT (g)	100%	0%	0%	0%	0%	88.9%
TERMINAL (d)	10/10 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	5/6 (83%)
FIRST INCIDENCE	93 (T)	---	---	---	---	2
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.479N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.478N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.479N
COCH-ARM / FISHERS	P=0.132N	(e)	(e)	(e)	(e)	P=0.237N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.157N

Experiment Number: 20007 - 04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/13/2016
 Time Report Requested: 11:24:53
 First Dose M/F: 09/18/03 / 09/17/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Esophagus Hemorrhage						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/7.06
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	14.2%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	2
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.432
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.437
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.430
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.154

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:24:53

First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Esophagus						
Inflammation Acute						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/7.06
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	14.2%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	2
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.432
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.437
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.430
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.154

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:24:53

First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Kidney Mineralization						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/6.06
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%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:24:53

First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Kidney						
Nephropathy						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/6.06
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	16.5%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/6 (17%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.404
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.409
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.402
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.152

Experiment Number: 20007 - 04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/13/2016
 Time Report Requested: 11:24:53
 First Dose M/F: 09/18/03 / 09/17/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver						
Inflammation Chronic						
LESION RATES						
OVERALL (a)	9/10 (90%)	10/10 (100%)	10/10 (100%)	9/10 (90%)	8/10 (80%)	4/10 (40%)
POLY-3 RATE (b)	9/10.00	10/10.00	10/10.00	9/10.00	8/10.00	4/6.06
POLY-3 PERCENT (g)	90%	100%	100%	90%	80%	66%
TERMINAL (d)	9/10 (90%)	10/10 (100%)	10/10 (100%)	9/10 (90%)	8/10 (80%)	4/6 (67%)
FIRST INCIDENCE	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)
STATISTICAL TESTS						
POLY 3	P=0.030N*	P=0.500	P=0.500	P=0.760	P=0.500N	P=0.310N
POLY 1.5	P=0.022N*	P=0.500	P=0.500	P=0.760	P=0.500N	P=0.268N
POLY 6	P=0.033N*	P=0.500	P=0.500	P=0.760	P=0.500N	P=0.323N
COCH-ARM / FISHERS	P<0.001N**	P=0.500	P=0.500	P=0.763N	P=0.500N	P=0.029N*
MAX-ISO-POLY-3	P=0.030N*	P=0.158	P=0.158	P=1.000	P=0.274N	P=0.180N

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:24:53

First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver						
Necrosis						
LESION RATES						
OVERALL (a)	0/10 (0%)	1/10 (10%)	1/10 (10%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	1/10.00	1/10.00	1/10.00	0/10.00	0/6.06
POLY-3 PERCENT (g)	0%	10%	10%	10%	0%	0%
TERMINAL (d)	0/10 (0%)	1/10 (10%)	1/10 (10%)	1/10 (10%)	0/10 (0%)	0/6 (0%)
FIRST INCIDENCE	---	93 (T)	93 (T)	93 (T)	---	---
STATISTICAL TESTS						
POLY 3	P=0.351N	P=0.500	P=0.500	P=0.500	(e)	(e)
POLY 1.5	P=0.345N	P=0.500	P=0.500	P=0.500	(e)	(e)
POLY 6	P=0.353N	P=0.500	P=0.500	P=0.500	(e)	(e)
COCH-ARM / FISHERS	P=0.314N	P=0.500	P=0.500	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.323N	P=0.158	P=0.158	P=0.158	(e)	(e)

Experiment Number: 20007 - 04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/13/2016
 Time Report Requested: 11:24:53
 First Dose M/F: 09/18/03 / 09/17/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Liver: Centrilobular Hypertrophy						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	5/10 (50%)	4/10 (40%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	2/10.00	5/10.00	4/6.06
POLY-3 PERCENT (g)	0%	0%	0%	20%	50%	66%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	5/10 (50%)	4/6 (67%)
FIRST INCIDENCE	---	---	---	93 (T)	93 (T)	93 (T)
STATISTICAL TESTS						
POLY 3	P<0.001**	(e)	(e)	P=0.227	P=0.008**	P=0.003**
POLY 1.5	P<0.001**	(e)	(e)	P=0.227	P=0.008**	P=0.003**
POLY 6	P<0.001**	(e)	(e)	P=0.227	P=0.008**	P=0.003**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.237	P=0.016*	P=0.043*
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P=0.066	P<0.001**	P=0.002**

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:24:53

First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Lung Congestion						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/7.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	14.3%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	37
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.430
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.430
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.430
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.154

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:24:53

First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Lung						
Inflammation Chronic						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/6.06
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%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/13/2016
 Time Report Requested: 11:24:53
 First Dose M/F: 09/18/03 / 09/17/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Pancreas: Acinus Vacuolization Cytoplasmic						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	2/6.06
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	33%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/6 (33%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.327
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.337
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.324
COCH-ARM / FISHERS	P=0.377	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.190

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:24:53

First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Pancreas: Artery Inflammation						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/6.06
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%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:24:53

First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Parathyroid Gland Cyst						
LESION RATES						
OVERALL (a)	0/7 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/7.00	0/0.00	0/0.00	0/0.00	0/0.00	0/6.06
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/7 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

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First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Skin Inflammation						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/6.06
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	16.5%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/6 (17%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.404
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.409
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.402
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.152

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:24:53

First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Stomach, Forestomach Inflammation Chronic						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/6.06
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%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:24:53

First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Stomach, Forestomach Mineralization						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/7.06
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	14.2%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	2
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.432
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.437
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.430
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.154

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:24:53

First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Stomach, Glandular Cyst						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/7.06
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	14.2%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	2
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.678
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.685
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.676
COCH-ARM / FISHERS	P=0.645	(e)	(e)	(e)	(e)	P=0.763N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.414

Experiment Number: 20007 - 04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/13/2016
 Time Report Requested: 11:24:53
 First Dose M/F: 09/18/03 / 09/17/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Stomach, Glandular Inflammation						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/6.06
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%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:24:53

First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Stomach, Glandular Inflammation Chronic						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/6.06
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	16.5%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/6 (17%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.404
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.409
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.402
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.152

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:24:53

First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Stomach, Glandular Mineralization						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/7.06
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	14.2%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	2
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.432
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.437
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.430
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.154

Experiment Number: 20007 - 04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/13/2016
 Time Report Requested: 11:24:53
 First Dose M/F: 09/18/03 / 09/17/03
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Thymus Necrosis						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	2/8.06
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	24.8%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	2
STATISTICAL TESTS						
POLY 3	P=0.007**	(e)	(e)	(e)	(e)	P=0.177
POLY 1.5	P=0.007**	(e)	(e)	(e)	(e)	P=0.182
POLY 6	P=0.007**	(e)	(e)	(e)	(e)	P=0.176
COCH-ARM / FISHERS	P=0.010**	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	P=0.004**	(e)	(e)	(e)	(e)	P=0.062

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 09/13/2016

Time Report Requested: 11:24:53

First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Females					
	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Thyroid Gland Cyst						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/7.06
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	14.2%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---	2
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.432
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.437
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.430
COCH-ARM / FISHERS	P=0.304	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.154

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Kava kava extract

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First Dose M/F: 09/18/03 / 09/17/03

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 ***