Species/Strain: Rat/F 344/N

Test Type: 14-DAY

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH

AVERAGE SEVERITY GRADES[b]

Date Report Requested: 10/23/2014

Time Report Requested: 01:26:30

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Time Report Requested: 01:26:30

First Dose M/F: NA / NA

Lab: BAT

C Number: C20007

Lock Date: 04/22/2003

Cage Range: ΑII

Date Range: ΑII

Reasons For Removal: ΑII

Removal Date Range: ΑII

Treatment Groups: ΑII

Study Gender: Both

PWG Approval Date NONE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/23/2014 Time Report Requested: 01:26:30

Time Report Requested: 01:26:30

First Dose M/F: NA / NA

Lab: BAT

Route: GAVAGE Species/Strain: Rat/F 344/N

Test Type: 14-DAY

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

F 344/N Rat MALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Disposition Summary						
Animals Initially In Study Early Deaths Survivors	5	5	5	5	5	5
Terminal Sacrifice Animals Examined Microscopically	5 5	5	5	5 1	5 5	5 5
ALIMENTARY SYSTEM						
Liver Hematopoietic Cell Proliferation	(5) 1 [1.0]	(0)	(0)	(0)	(5)	(5)
Hepatocyte, Hypertrophy Hepatocyte, Vacuolization Cytoplasmic	1 [1.0]					5 [1.0]
Hepatodiaphragmatic Nodule Infiltration Cellular, Mononuclear Cl	5 [1.0]				1 [1.0]	1 [1.0] 4 [1.0]
CARDIOVASCULAR SYSTEM None						
ENDOCRINE SYSTEM None						
GENERAL BODY SYSTEM None						
GENITAL SYSTEM None						
HEMATOPOIETIC SYSTEM None						

INTEGUMENTARY SYSTEM

None

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: Rat/F 344/N

Test Type: 14-DAY

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/23/2014 Time Report Requested: 01:26:30

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

First Dose M/F: NA / NA

Lab: BAT

Time Report Requested: 01:26:30

F 344/N Rat MALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
MUSCULOSKELETAL SYSTEM None						
NERVOUS SYSTEM						
Brain	(5)	(0)	(0)	(0)	(0)	(5)
RESPIRATORY SYSTEM						
Lung	(5)	(0)	(0)	(1)	(0)	(5)
Alveolus, Infiltration Cellular, Mononuclear Cl	3 [1.0]			1 [1.0]		5 [1.0]
Hemorrhage				1 [2.0]		
Interstitium, Infiltration Cellular, Mononuclear Cl	5 [1.0]			1 [1.0]		5 [1.0]
Mineralization	1 [1.0]					
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
Kidney	(5)	(0)	(0)	(0)	(0)	(5)
Mineralization	1 [1.0]		. ,	. ,	. ,	,

END OF MALE DATA

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/23/2014 Time Report Requested: 01:26:30

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

First Dose M/F: NA / NA

Time Report Requested: 01:26:30

Lab: BAT

Species/Strain: Rat/F 344/N

Test Type: 14-DAY

Route: GAVAGE

F 344/N Rat FEMALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/K0
Disposition Summary						
Animals Initially In Study	5	5	5	5	5	5
Early Deaths						
Natural Death						1
Survivors						
Terminal Sacrifice	5	5	5	5	5	4
Animals Examined Microscopically	5	5	5	5	5	5
ALIMENTARY SYSTEM						
Liver	(5)	(5)	(5)	(5)	(5)	(5)
Hepatocyte, Hypertrophy	()	` '	5 [1.0]	5 [1.0]	5 [1.0]	5 [1.0]
Hepatodiaphragmatic Nodule			2 [1.0]		1 [1.0]	
Infiltration Cellular, Mononuclear Cl	5 [1.0]	3 [1.0]	5 [1.0]	5 [1.0]	4 [1.0]	2 [1.0]
CARDIOVASCULAR SYSTEM None						
ENDOCRINE SYSTEM None						
GENERAL BODY SYSTEM None						
GENITAL SYSTEM						
Uterus	(0)	(0)	(0)	(1)	(0)	(0)
Endometrium, Hyperplasia, Cystic	,	. ,	,	1 [3.0]	,	. ,
HEMATOPOIETIC SYSTEM						
Lymph Node	(0)	(0)	(0)	(0)	(0)	(1)
Hyperplasia, Lymphoid	(0)	(0)	(0)	(0)	(0)	1 [2.0]
nyperpiasia, Lympholu						1 [2.0]

INTEGUMENTARY SYSTEM

None

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: Rat/F 344/N

Test Type: 14-DAY

Route: GAVAGE

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/23/2014 Time Report Requested: 01:26:30

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

Time Report Requested: 01:26:30 First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat FEMALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
Brain	(5)	(0)	(0)	(0)	(0)	(5)
RESPIRATORY SYSTEM						
Lung	(5)	(0)	(3)	(0)	(0)	(5)
Alveolus, Infiltration Cellular, Mononuclear	3 [1.0]	. ,	2 [1.0]	. ,		2 [1.0]
Hemorrhage			2 [2.0]			
Infiltration Cellular, Mononuclear Cl			1 [1.0]			
Interstitium, Infiltration Cellular, Mononuclear Cl	5 [1.0]		2 [1.0]			5 [1.0]
SPECIAL SENSES SYSTEM						
Eye	(0)	(0)	(0)	(0)	(0)	(1)
Iris, Inflammation						1 [1.0]
Synechia						1 [2.0]
URINARY SYSTEM						
Kidney	(5)	(0)	(0)	(0)	(0)	(5)
Infiltration Cellular, Mononuclear Cl	1 [1.0]		·	·	·	

^{**} END OF REPORT **

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)