

Experiment Number: 20007 - 03

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**

Date Report Requested: 09/13/2016

Test Type: 90-DAY

Kava kava extract

Time Report Requested: 11:41:17

Route: GAVAGE

CAS Number: 9000-38-8

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

Species/Strain: RATS/F 344/N

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

Test Type: 90-DAY

Kava kava extract

Time Report Requested: 11:41:17

Route: GAVAGE

CAS Number: 9000-38-8

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

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS 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	10	10	10	10	10	10
Early Deaths						
Moribund Sacrifice			1			
Natural Death						3
Survivors						
Terminal Sacrifice	10	10	9	10	10	7
Animals Examined Microscopically	10	10	10	10	10	10

ALIMENTARY SYSTEM

Esophagus	(10)	(0)	(1)	(0)	(0)	(10)
Intestine Large, Cecum	(10)	(0)	(1)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(1)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(0)	(1)	(0)	(0)	(10)
Intestine Small, Duodenum	(10)	(0)	(1)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(1)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(1)	(0)	(0)	(10)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Hematopoietic Cell Proliferation	1 [1.0]	1 [1.0]				
Hepatodiaphragmatic Nodule				1		
Infiltration Cellular, Mixed Cell						1 [1.0]
Infiltration Cellular, Mononuclear Cell	9 [1.0]	7 [1.0]	5 [1.0]	5 [1.0]	5 [1.0]	5 [1.0]
Vacuolization Cytoplasmic	1 [1.0]			1 [1.0]		
Bile Duct, Hyperplasia				1 [1.0]		
Hepatocyte, Hypertrophy					1 [1.0]	
Pancreas	(10)	(0)	(1)	(0)	(0)	(10)
Acinus, Atrophy	1 [1.0]					
Salivary Glands	(10)	(0)	(1)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(1)	(0)	(0)	(10)
Inflammation						1 [1.0]
Mineralization						1 [2.0]
Ulcer						1 [2.0]
Stomach, Glandular	(10)	(0)	(1)	(0)	(0)	(10)

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)

Test Type: 90-DAY

Kava kava extract

Time Report Requested: 11:41:17

Route: GAVAGE

CAS Number: 9000-38-8

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

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS MALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(1)	(0)	(0)	(10)
Heart	(10)	(0)	(1)	(0)	(0)	(10)
Cardiomyopathy	9 [1.3]					8 [1.0]
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(1)	(0)	(0)	(10)
Adrenal Medulla	(10)	(0)	(1)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(1)	(0)	(0)	(10)
Parathyroid Gland	(10)	(0)	(1)	(0)	(0)	(9)
Pituitary Gland	(10)	(0)	(1)	(0)	(0)	(10)
Pars Distalis, Hypertrophy	1 [1.0]					
Thyroid Gland	(10)	(0)	(1)	(0)	(0)	(10)
Cyst	2					1
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Epididymis	(10)	(0)	(1)	(0)	(0)	(10)
Inflammation	1 [1.0]					
Preputial Gland	(10)	(0)	(1)	(0)	(0)	(10)
Inflammation						1 [1.0]
Prostate	(10)	(0)	(1)	(0)	(0)	(10)
Seminal Vesicle	(10)	(0)	(1)	(0)	(0)	(10)
Atrophy						1 [3.0]
Testes	(10)	(0)	(1)	(0)	(0)	(10)

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)

Test Type: 90-DAY

Kava kava extract

Time Report Requested: 11:41:17

Route: GAVAGE

CAS Number: 9000-38-8

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

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS MALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Lymph Node, Mesenteric	(10)	(0)	(1)	(0)	(0)	(10)
Spleen	(10)	(10)	(10)	(10)	(10)	(10)
Atrophy						3 [1.7]
Hematopoietic Cell Proliferation					1 [2.0]	
Thymus	(10)	(10)	(10)	(10)	(10)	(10)
Necrosis						1 [2.0]
INTEGUMENTARY SYSTEM						
Mammary Gland	(7)	(0)	(1)	(0)	(0)	(9)
Skin	(10)	(0)	(1)	(0)	(0)	(10)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(1)	(0)	(0)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(1)	(0)	(0)	(10)
RESPIRATORY SYSTEM						
Lung	(10)	(0)	(1)	(0)	(0)	(10)
Inflammation						3 [1.0]
Inflammation, Granulomatous						2 [1.0]
Metaplasia, Osseous, Focal	1 [1.0]					
Metaplasia, Osseous	1 [1.0]					1 [1.0]
Alveolus, Infiltration Cellular, Histiocyte	2 [1.0]					
Interstitialium, Infiltration Cellular, Mononuclear Cell	3 [1.0]					4 [1.0]
Interstitialium, Inflammation, Chronic	1 [1.0]					1 [1.0]

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)

Test Type: 90-DAY

Kava kava extract

Time Report Requested: 11:41:17

Route: GAVAGE

CAS Number: 9000-38-8

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

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS MALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Nose	(10)	(0)	(1)	(0)	(0)	(10)
Inflammation						1 [1.0]
Inflammation, Suppurative	1 [1.0]					
Inflammation, Acute						1 [1.0]
Squamous Epithelium, Hyperplasia, Squamous	1 [1.0]					
Trachea	(10)	(0)	(1)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
Eye	(10)	(0)	(1)	(0)	(0)	(10)
Harderian Gland	(10)	(0)	(1)	(0)	(0)	(10)
Infiltration Cellular, Mononuclear Cell	1 [1.0]					
URINARY SYSTEM						
Kidney	(10)	(0)	(1)	(0)	(0)	(10)
Accumulation, Hyaline Droplet	2 [2.0]					1 [2.0]
Casts Protein	1 [1.0]					
Infiltration Cellular, Mononuclear Cell	1 [1.0]					
Mineralization	4 [1.0]					3 [1.0]
Nephropathy	7 [1.0]					7 [1.0]
Urinary Bladder	(10)	(0)	(1)	(0)	(0)	(10)

*** END OF MALE ***

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)

Test Type: 90-DAY

Kava kava extract

Time Report Requested: 11:41:17

Route: GAVAGE

CAS Number: 9000-38-8

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

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE	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	10	10	10	10	10	10
Early Deaths						
Moribund Sacrifice	1					
Natural Death					1	4
Survivors						
Terminal Sacrifice	9	10	10	10	9	6
Animals Examined Microscopically	10	10	10	10	10	10

ALIMENTARY SYSTEM

Esophagus	(10)	(0)	(0)	(0)	(1)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(1)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(1)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(1)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(1)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(1)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(1)	(10)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Congestion					1 [2.0]	
Hepatodiaphragmatic Nodule	2	1		1		
Infiltration Cellular, Mononuclear Cell	8 [1.0]	8 [1.0]	4 [1.0]	7 [1.0]	8 [1.0]	2 [1.0]
Inflammation	1 [1.0]				1 [1.0]	
Hepatocyte, Hypertrophy				3 [1.0]	3 [1.3]	10 [1.7]
Mesentery	(1)	(0)	(0)	(1)	(0)	(0)
Necrosis, Fatty				1 [2.0]		
Necrosis, Focal	1 [2.0]					
Pancreas	(10)	(0)	(0)	(0)	(1)	(10)
Acinus, Atrophy						1 [1.0]
Salivary Glands	(10)	(0)	(0)	(0)	(1)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(1)	(10)
Inflammation						1 [1.0]
Mineralization						1 [1.0]
Ulcer						1 [2.0]
Stomach, Glandular	(10)	(0)	(0)	(0)	(1)	(10)

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)

Test Type: 90-DAY

Kava kava extract

Time Report Requested: 11:41:17

Route: GAVAGE

CAS Number: 9000-38-8

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

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
-------------------------	--------	------------	-----------	----------	----------	----------

CARDIOVASCULAR SYSTEM

Blood Vessel	(10)	(0)	(0)	(0)	(1)	(10)
Heart	(10)	(0)	(0)	(0)	(1)	(10)
Cardiomyopathy	5 [1.0]					2 [1.0]

ENDOCRINE SYSTEM

Adrenal Cortex	(10)	(0)	(0)	(0)	(1)	(10)
Adrenal Medulla	(10)	(0)	(0)	(0)	(1)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(1)	(10)
Parathyroid Gland	(10)	(0)	(0)	(0)	(1)	(10)
Pituitary Gland	(10)	(0)	(0)	(0)	(1)	(10)
Thyroid Gland	(10)	(0)	(0)	(0)	(1)	(9)
Cyst	2					1

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(10)	(0)	(0)	(0)	(1)	(10)
Ovary	(10)	(0)	(0)	(0)	(1)	(10)
Uterus	(10)	(0)	(0)	(0)	(1)	(10)

HEMATOPOIETIC SYSTEM

Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(1)	(10)
Spleen	(10)	(10)	(10)	(10)	(10)	(10)
Atrophy	1 [2.0]					3 [2.0]

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)

Test Type: 90-DAY

Kava kava extract

Time Report Requested: 11:41:17

Route: GAVAGE

CAS Number: 9000-38-8

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

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Thymus	(10)	(10)	(10)	(10)	(10)	(10)
Necrosis	1 [2.0]					3 [2.0]
INTEGUMENTARY SYSTEM						
Mammary Gland	(10)	(0)	(0)	(0)	(1)	(10)
Skin	(10)	(0)	(0)	(0)	(1)	(10)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(1)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(1)	(10)
Cerebrum, Hemorrhage						1 [2.0]
RESPIRATORY SYSTEM						
Lung	(10)	(0)	(0)	(0)	(1)	(10)
Congestion, Diffuse, Acute						1 [2.0]
Inflammation						1 [1.0]
Inflammation, Chronic	1 [1.0]					
Metaplasia, Osseous	1 [1.0]					
Alveolus, Infiltration Cellular, Histiocyte	1 [1.0]					4 [1.0]
Interstitialium, Infiltration Cellular, Mononuclear Cell	3 [1.0]				1 [1.0]	3 [1.0]
Nose	(10)	(0)	(0)	(0)	(1)	(10)
Trachea	(10)	(0)	(0)	(0)	(1)	(10)
SPECIAL SENSES SYSTEM						
Eye	(10)	(0)	(0)	(0)	(1)	(10)

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)

Experiment Number: 20007 - 03

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**

Date Report Requested: 09/13/2016

Test Type: 90-DAY

Kava kava extract

Time Report Requested: 11:41:17

Route: GAVAGE

CAS Number: 9000-38-8

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

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG	2.0 G/KG
Cornea, Neovascularization						2 [2.0]
Harderian Gland	(10)	(0)	(0)	(0)	(1)	(10)
Infiltration Cellular, Mononuclear Cell						1 [2.0]
<hr/>						
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(0)	(1)	(10)
Mineralization	8 [1.0]				1 [1.0]	3 [1.0]
Urinary Bladder	(10)	(0)	(0)	(0)	(1)	(10)

*** 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)