

**Experiment Number:** 20007-01  
**Test Type:** 14-DAY  
**Route:** GAVAGE  
**Species/Strain:** Rat/F 344/N

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
**Test Compound:** Kava kava extract  
**CAS Number:** 9000-38-8

**Date Report Requested:** 10/23/2014  
**Time Report Requested:** 01:28:21  
**First Dose M/F:** NA / NA  
**Lab:** BAT

|                             |            |
|-----------------------------|------------|
| <b>C Number:</b>            | C20007     |
| <b>Lock Date:</b>           | 04/22/2003 |
| <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: 20007-01

Test Type: 14-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/23/2014

Time Report Requested: 01:28:21

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Male  
0 G/KG

|             |   |   |   |   |   |         |
|-------------|---|---|---|---|---|---------|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 1 | 1 | 1 | 1 | 1 |         |
|             | 7 | 7 | 7 | 7 | 7 |         |
| ANIMAL ID   | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 1 | 1 | 1 | 1 | 1 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 1 | 2 | 3 | 4 | 5 | *TOTALS |

Alimentary System

|                                       |   |   |   |   |   |   |     |
|---------------------------------------|---|---|---|---|---|---|-----|
| Liver                                 | + | + | + | + | + | 5 |     |
| Hematopoietic Cell Proliferation      |   |   |   |   | 1 | 1 | 1.0 |
| Hepatocyte, Vacuolization Cytoplasmic |   |   | 1 |   |   | 1 | 1.0 |
| Infiltration Cellular, Mononuclear Cl | 1 | 1 | 1 | 1 | 1 | 5 | 1.0 |

Cardiovascular System

NONE

Endocrine System

NONE

General Body System

NONE

Genital System

NONE

Hematopoietic System

NONE

Integumentary System

NONE

Musculoskeletal System

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20007-01

Test Type: 14-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/23/2014

Time Report Requested: 01:28:21

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Male  
0 G/KG

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 |
|-------------|---|---|---|---|---|
|             | 0 | 0 | 0 | 0 | 0 |
|             | 1 | 1 | 1 | 1 | 1 |
|             | 7 | 7 | 7 | 7 | 7 |
| ANIMAL ID   | 0 | 0 | 0 | 0 | 0 |
|             | 0 | 0 | 0 | 0 | 0 |
|             | 1 | 1 | 1 | 1 | 1 |
|             | 0 | 0 | 0 | 0 | 0 |
|             | 1 | 2 | 3 | 4 | 5 |

\*TOTALS

NONE

**Nervous System**

Brain + + + + + 5

**Respiratory System**

Lung + + + + + 5

Alveolus, Infiltration Cellular, Mononuclear Cl 1 1 1 1 1 3 1.0

Interstitialium, Infiltration Cellular, Mononuclear Cl 1 1 1 1 1 5 1.0

Mineralization 1 1 1.0

**Special Senses System**

NONE

**Urinary System**

Kidney + + + + + 5

Mineralization 1 1 1.0

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+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

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**Experiment Number:** 20007-01

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**Route:** GAVAGE

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

**Test Compound:** Kava kava extract

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

**Date Report Requested:** 10/23/2014

**Time Report Requested:** 01:28:21

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

**Lab:** BAT

DAY ON TEST

**F 344/N Rat Male**

**0.125 G/KG**

ANIMAL ID

\*TOTALS

**Alimentary System**

NONE

**Cardiovascular System**

NONE

**Endocrine System**

NONE

**General Body System**

NONE

**Genital System**

NONE

**Hematopoietic System**

NONE

**Integumentary System**

NONE

**Musculoskeletal System**

NONE

**Nervous System**

NONE

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

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Test Type: 14-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/23/2014

Time Report Requested: 01:28:21

First Dose M/F: NA / NA

Lab: BAT

DAY ON TEST

**F 344/N Rat Male**

**0.125 G/KG**

ANIMAL ID

\*TOTALS

**Respiratory System**

NONE

**Special Senses System**

NONE

**Urinary System**

NONE

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
**Test Compound:** Kava kava extract  
**CAS Number:** 9000-38-8

**Date Report Requested:** 10/23/2014  
**Time Report Requested:** 01:28:21  
**First Dose M/F:** NA / NA  
**Lab:** BAT

DAY ON TEST

**F 344/N Rat Male**  
**0.25 G/KG**

ANIMAL ID

\*TOTALS

**Alimentary System**

NONE

**Cardiovascular System**

NONE

**Endocrine System**

NONE

**General Body System**

NONE

**Genital System**

NONE

**Hematopoietic System**

NONE

**Integumentary System**

NONE

**Musculoskeletal System**

NONE

**Nervous System**

NONE

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

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**Route:** GAVAGE

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

**Test Compound:** Kava kava extract

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

**Date Report Requested:** 10/23/2014

**Time Report Requested:** 01:28:21

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

**Lab:** BAT

DAY ON TEST

**F 344/N Rat Male**

**0.25 G/KG**

ANIMAL ID

\*TOTALS

**Respiratory System**

NONE

**Special Senses System**

NONE

**Urinary System**

NONE

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

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Test Type: 14-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/23/2014

Time Report Requested: 01:28:21

First Dose M/F: NA / NA

Lab: BAT

**F 344/N Rat Male  
0.5 G/KG**

|             |   |   |   |   |   |                |
|-------------|---|---|---|---|---|----------------|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 |                |
|             | 0 | 0 | 0 | 0 | 0 |                |
|             | 1 | 1 | 1 | 1 | 1 |                |
|             | 7 | 7 | 7 | 7 | 7 |                |
| ANIMAL ID   | 0 | 0 | 0 | 0 | 0 |                |
|             | 0 | 0 | 0 | 0 | 0 |                |
|             | 4 | 4 | 4 | 4 | 4 |                |
|             | 0 | 0 | 0 | 0 | 0 |                |
|             | 1 | 2 | 3 | 4 | 5 | <b>*TOTALS</b> |

**Alimentary System**

NONE

**Cardiovascular System**

NONE

**Endocrine System**

NONE

**General Body System**

NONE

**Genital System**

NONE

**Hematopoietic System**

NONE

**Integumentary System**

NONE

**Musculoskeletal System**

NONE

**Nervous System**

NONE

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

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Species/Strain: Rat/F 344/N

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Date Report Requested: 10/23/2014

Time Report Requested: 01:28:21

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Male  
0.5 G/KG

|             |   |   |   |   |   |         |
|-------------|---|---|---|---|---|---------|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 1 | 1 | 1 | 1 | 1 |         |
|             | 7 | 7 | 7 | 7 | 7 |         |
| ANIMAL ID   | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 4 | 4 | 4 | 4 | 4 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 1 | 2 | 3 | 4 | 5 | *TOTALS |

Respiratory System

|                                                        |  |   |   |       |
|--------------------------------------------------------|--|---|---|-------|
| Lung                                                   |  | + | 1 |       |
| Alveolus, Infiltration Cellular, Mononuclear Cl        |  | 1 |   | 1 1.0 |
| Hemorrhage                                             |  | 2 |   | 1 2.0 |
| Interstitialium, Infiltration Cellular, Mononuclear Cl |  | 1 |   | 1 1.0 |

Special Senses System

NONE

Urinary System

NONE

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+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

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Species/Strain: Rat/F 344/N

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Date Report Requested: 10/23/2014

Time Report Requested: 01:28:21

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Male  
1.0 G/KG

|             |   |   |   |   |   |         |
|-------------|---|---|---|---|---|---------|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 1 | 1 | 1 | 1 | 1 |         |
|             | 7 | 7 | 7 | 7 | 7 |         |
| ANIMAL ID   | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 5 | 5 | 5 | 5 | 5 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 1 | 2 | 3 | 4 | 5 | *TOTALS |

Alimentary System

|                                       |   |   |   |   |   |   |     |
|---------------------------------------|---|---|---|---|---|---|-----|
| Liver                                 | + | + | + | + | + | 5 |     |
| Infiltration Cellular, Mononuclear CI |   |   |   |   | 1 | 1 | 1.0 |

Cardiovascular System

NONE

Endocrine System

NONE

General Body System

NONE

Genital System

NONE

Hematopoietic System

NONE

Integumentary System

NONE

Musculoskeletal System

NONE

Nervous System

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

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Date Report Requested: 10/23/2014

Time Report Requested: 01:28:21

First Dose M/F: NA / NA

Lab: BAT

**F 344/N Rat Male**  
**1.0 G/KG**

|             |   |   |   |   |   |                |
|-------------|---|---|---|---|---|----------------|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 |                |
|             | 0 | 0 | 0 | 0 | 0 |                |
|             | 1 | 1 | 1 | 1 | 1 |                |
|             | 7 | 7 | 7 | 7 | 7 |                |
| ANIMAL ID   | 0 | 0 | 0 | 0 | 0 |                |
|             | 0 | 0 | 0 | 0 | 0 |                |
|             | 5 | 5 | 5 | 5 | 5 |                |
|             | 0 | 0 | 0 | 0 | 0 |                |
|             | 1 | 2 | 3 | 4 | 5 | <b>*TOTALS</b> |

NONE

**Respiratory System**

NONE

**Special Senses System**

NONE

**Urinary System**

NONE

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

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X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

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Experiment Number: 20007-01

Test Type: 14-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/23/2014

Time Report Requested: 01:28:21

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Male  
2.0 G/KG

|             |   |   |   |   |   |         |
|-------------|---|---|---|---|---|---------|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 1 | 1 | 1 | 1 | 1 |         |
|             | 7 | 7 | 7 | 7 | 7 |         |
| ANIMAL ID   | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 6 | 6 | 6 | 6 | 6 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 1 | 2 | 3 | 4 | 5 | *TOTALS |

Alimentary System

|                                       |   |   |   |   |   |   |     |
|---------------------------------------|---|---|---|---|---|---|-----|
| Liver                                 | + | + | + | + | + | 5 |     |
| Hepatocyte, Hypertrophy               | 1 | 1 | 1 | 1 | 1 | 5 | 1.0 |
| Hepatodiaphragmatic Nodule            |   | 1 |   |   |   | 1 | 1.0 |
| Infiltration Cellular, Mononuclear CI | 1 | 1 | 1 |   | 1 | 4 | 1.0 |

Cardiovascular System

NONE

Endocrine System

NONE

General Body System

NONE

Genital System

NONE

Hematopoietic System

NONE

Integumentary System

NONE

Musculoskeletal System

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

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Time Report Requested: 01:28:21

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Male  
2.0 G/KG

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 |
|-------------|---|---|---|---|---|
|             | 0 | 0 | 0 | 0 | 0 |
|             | 1 | 1 | 1 | 1 | 1 |
|             | 7 | 7 | 7 | 7 | 7 |
| ANIMAL ID   | 0 | 0 | 0 | 0 | 0 |
|             | 0 | 0 | 0 | 0 | 0 |
|             | 6 | 6 | 6 | 6 | 6 |
|             | 0 | 0 | 0 | 0 | 0 |
|             | 1 | 2 | 3 | 4 | 5 |

\*TOTALS

NONE

**Nervous System**

Brain + + + + + 5

**Respiratory System**

Lung + + + + + 5

Alveolus, Infiltration Cellular, Mononuclear Cl 1 1 1 1 1 5 1.0

Interstitialium, Infiltration Cellular, Mononuclear Cl 1 1 1 1 1 5 1.0

Cl

**Special Senses System**

NONE

**Urinary System**

Kidney + + + + + 5

\*\*\*END OF MALE DATA\*\*\*

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

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Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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CAS Number: 9000-38-8

Date Report Requested: 10/23/2014

Time Report Requested: 01:28:21

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
0 G/KG

|             |   |   |   |   |   |         |
|-------------|---|---|---|---|---|---------|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 1 | 1 | 1 | 1 | 1 |         |
|             | 7 | 7 | 7 | 7 | 7 |         |
| ANIMAL ID   | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 1 | 1 | 1 | 1 | 1 |         |
|             | 5 | 5 | 5 | 5 | 5 |         |
|             | 1 | 2 | 3 | 4 | 5 | *TOTALS |

Alimentary System

|                                       |   |   |   |   |   |   |     |
|---------------------------------------|---|---|---|---|---|---|-----|
| Liver                                 | + | + | + | + | + | 5 |     |
| Infiltration Cellular, Mononuclear CI | 1 | 1 | 1 | 1 | 1 | 5 | 1.0 |

Cardiovascular System

NONE

Endocrine System

NONE

General Body System

NONE

Genital System

NONE

Hematopoietic System

NONE

Integumentary System

NONE

Musculoskeletal System

NONE

Nervous System

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Time Report Requested: 01:28:21

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
0 G/KG

|                                                        | DAY ON TEST |   |   |   |   |                |   |     |
|--------------------------------------------------------|-------------|---|---|---|---|----------------|---|-----|
|                                                        | 0           | 0 | 0 | 0 | 0 |                |   |     |
|                                                        | 0           | 0 | 0 | 0 | 0 |                |   |     |
|                                                        | 1           | 1 | 1 | 1 | 1 |                |   |     |
|                                                        | 7           | 7 | 7 | 7 | 7 |                |   |     |
| ANIMAL ID                                              | 0           | 0 | 0 | 0 | 0 |                |   |     |
|                                                        | 0           | 0 | 0 | 0 | 0 |                |   |     |
|                                                        | 1           | 1 | 1 | 1 | 1 |                |   |     |
|                                                        | 5           | 5 | 5 | 5 | 5 |                |   |     |
|                                                        | 1           | 2 | 3 | 4 | 5 |                |   |     |
|                                                        |             |   |   |   |   | <b>*TOTALS</b> |   |     |
| Brain                                                  | +           | + | + | + | + | 5              |   |     |
| <b>Respiratory System</b>                              |             |   |   |   |   |                |   |     |
| Lung                                                   | +           | + | + | + | + | 5              |   |     |
| Alveolus, Infiltration Cellular, Mononuclear Cl        | 1           | 1 | 1 |   |   |                | 3 | 1.0 |
| Interstitialium, Infiltration Cellular, Mononuclear Cl | 1           | 1 | 1 | 1 | 1 |                | 5 | 1.0 |
| <b>Special Senses System</b>                           |             |   |   |   |   |                |   |     |
| NONE                                                   |             |   |   |   |   |                |   |     |
| <b>Urinary System</b>                                  |             |   |   |   |   |                |   |     |
| Kidney                                                 | +           | + | + | + | + | 5              |   |     |
| Infiltration Cellular, Mononuclear Cl                  |             |   |   | 1 |   |                | 1 | 1.0 |

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First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
0.125 G/KG

|             |   |   |   |   |   |         |
|-------------|---|---|---|---|---|---------|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 1 | 1 | 1 | 1 | 1 |         |
|             | 7 | 7 | 7 | 7 | 7 |         |
| ANIMAL ID   | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 2 | 2 | 2 | 2 | 2 |         |
|             | 5 | 5 | 5 | 5 | 5 |         |
|             | 1 | 2 | 3 | 4 | 5 | *TOTALS |

Alimentary System

|                                       |   |   |   |   |   |   |     |
|---------------------------------------|---|---|---|---|---|---|-----|
| Liver                                 | + | + | + | + | + | 5 |     |
| Infiltration Cellular, Mononuclear CI | 1 | 1 |   |   | 1 | 3 | 1.0 |

Cardiovascular System

NONE

Endocrine System

NONE

General Body System

NONE

Genital System

NONE

Hematopoietic System

NONE

Integumentary System

NONE

Musculoskeletal System

NONE

Nervous System

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

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Species/Strain: Rat/F 344/N

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Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/23/2014

Time Report Requested: 01:28:21

First Dose M/F: NA / NA

Lab: BAT

**F 344/N Rat Female  
0.125 G/KG**

|             |   |   |   |   |   |                |
|-------------|---|---|---|---|---|----------------|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 |                |
|             | 0 | 0 | 0 | 0 | 0 |                |
|             | 1 | 1 | 1 | 1 | 1 |                |
|             | 7 | 7 | 7 | 7 | 7 |                |
| ANIMAL ID   | 0 | 0 | 0 | 0 | 0 |                |
|             | 0 | 0 | 0 | 0 | 0 |                |
|             | 2 | 2 | 2 | 2 | 2 |                |
|             | 5 | 5 | 5 | 5 | 5 |                |
|             | 1 | 2 | 3 | 4 | 5 | <b>*TOTALS</b> |

NONE  
**Respiratory System**

NONE  
**Special Senses System**

NONE  
**Urinary System**

NONE

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20007-01

Test Type: 14-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/23/2014

Time Report Requested: 01:28:21

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
0.25 G/KG

|             |   |   |   |   |   |         |
|-------------|---|---|---|---|---|---------|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 1 | 1 | 1 | 1 | 1 |         |
|             | 7 | 7 | 7 | 7 | 7 |         |
| ANIMAL ID   | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 3 | 3 | 3 | 3 | 3 |         |
|             | 5 | 5 | 5 | 5 | 5 |         |
|             | 1 | 2 | 3 | 4 | 5 | *TOTALS |

Alimentary System

|                                       |   |   |   |   |   |   |     |
|---------------------------------------|---|---|---|---|---|---|-----|
| Liver                                 | + | + | + | + | + | 5 |     |
| Hepatocyte, Hypertrophy               | 1 | 1 | 1 | 1 | 1 | 5 | 1.0 |
| Hepatodiaphragmatic Nodule            |   | 1 |   |   | 1 | 2 | 1.0 |
| Infiltration Cellular, Mononuclear CI | 1 | 1 | 1 | 1 | 1 | 5 | 1.0 |

Cardiovascular System

NONE

Endocrine System

NONE

General Body System

NONE

Genital System

NONE

Hematopoietic System

NONE

Integumentary System

NONE

Musculoskeletal System

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20007-01

Test Type: 14-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/23/2014

Time Report Requested: 01:28:21

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
0.25 G/KG

|             |   |   |   |   |   |         |
|-------------|---|---|---|---|---|---------|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 1 | 1 | 1 | 1 | 1 |         |
|             | 7 | 7 | 7 | 7 | 7 |         |
| ANIMAL ID   | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 3 | 3 | 3 | 3 | 3 |         |
|             | 5 | 5 | 5 | 5 | 5 |         |
|             | 1 | 2 | 3 | 4 | 5 | *TOTALS |

NONE  
Nervous System

NONE  
Respiratory System

|                                                        |   |   |  |   |   |     |
|--------------------------------------------------------|---|---|--|---|---|-----|
| Lung                                                   | + | + |  | + | 3 |     |
| Alveolus, Infiltration Cellular, Mononuclear Cl        | 1 | 1 |  |   | 2 | 1.0 |
| Hemorrhage                                             | 2 | 2 |  |   | 2 | 2.0 |
| Infiltration Cellular, Mononuclear Cl                  |   |   |  | 1 | 1 | 1.0 |
| Interstitialium, Infiltration Cellular, Mononuclear Cl | 1 | 1 |  |   | 2 | 1.0 |

Special Senses System

NONE  
Urinary System

NONE

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20007-01

Test Type: 14-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/23/2014

Time Report Requested: 01:28:21

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
0.5 G/KG

|             |   |   |   |   |   |         |
|-------------|---|---|---|---|---|---------|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 1 | 1 | 1 | 1 | 1 |         |
|             | 7 | 7 | 7 | 7 | 7 |         |
| ANIMAL ID   | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 4 | 4 | 4 | 4 | 4 |         |
|             | 5 | 5 | 5 | 5 | 5 |         |
|             | 1 | 2 | 3 | 4 | 5 | *TOTALS |

Alimentary System

|                                       |   |   |   |   |   |   |     |
|---------------------------------------|---|---|---|---|---|---|-----|
| Liver                                 | + | + | + | + | + | 5 |     |
| Hepatocyte, Hypertrophy               | 1 | 1 | 1 | 1 | 1 | 5 | 1.0 |
| Infiltration Cellular, Mononuclear CI | 1 | 1 | 1 | 1 | 1 | 5 | 1.0 |

Cardiovascular System

NONE

Endocrine System

NONE

General Body System

NONE

Genital System

|                                  |  |  |   |   |  |   |     |
|----------------------------------|--|--|---|---|--|---|-----|
| Uterus                           |  |  |   | + |  | 1 |     |
| Endometrium, Hyperplasia, Cystic |  |  | 3 |   |  | 1 | 3.0 |

Hematopoietic System

NONE

Integumentary System

NONE

Musculoskeletal System

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20007-01

Test Type: 14-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/23/2014

Time Report Requested: 01:28:22

First Dose M/F: NA / NA

Lab: BAT

**F 344/N Rat Female  
0.5 G/KG**

|             |   |   |   |   |   |                |
|-------------|---|---|---|---|---|----------------|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 |                |
|             | 0 | 0 | 0 | 0 | 0 |                |
|             | 1 | 1 | 1 | 1 | 1 |                |
|             | 7 | 7 | 7 | 7 | 7 |                |
| ANIMAL ID   | 0 | 0 | 0 | 0 | 0 |                |
|             | 0 | 0 | 0 | 0 | 0 |                |
|             | 4 | 4 | 4 | 4 | 4 |                |
|             | 5 | 5 | 5 | 5 | 5 |                |
|             | 1 | 2 | 3 | 4 | 5 | <b>*TOTALS</b> |

NONE  
**Nervous System**

NONE  
**Respiratory System**

NONE  
**Special Senses System**

NONE  
**Urinary System**

NONE

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20007-01

Test Type: 14-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/23/2014

Time Report Requested: 01:28:22

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
1.0 G/KG

|             |   |   |   |   |   |         |
|-------------|---|---|---|---|---|---------|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 1 | 1 | 1 | 1 | 1 |         |
|             | 7 | 7 | 7 | 7 | 7 |         |
| ANIMAL ID   | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 5 | 5 | 5 | 5 | 5 |         |
|             | 5 | 5 | 5 | 5 | 5 |         |
|             | 1 | 2 | 3 | 4 | 5 | *TOTALS |

Alimentary System

|                                       |   |   |   |   |   |   |     |
|---------------------------------------|---|---|---|---|---|---|-----|
| Liver                                 | + | + | + | + | + | 5 |     |
| Hepatocyte, Hypertrophy               | 1 | 1 | 1 | 1 | 1 | 5 | 1.0 |
| Hepatodiaphragmatic Nodule            |   | 1 |   |   |   | 1 | 1.0 |
| Infiltration Cellular, Mononuclear CI | 1 | 1 |   | 1 | 1 | 4 | 1.0 |

Cardiovascular System

NONE

Endocrine System

NONE

General Body System

NONE

Genital System

NONE

Hematopoietic System

NONE

Integumentary System

NONE

Musculoskeletal System

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20007-01

Test Type: 14-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/23/2014

Time Report Requested: 01:28:22

First Dose M/F: NA / NA

Lab: BAT

**F 344/N Rat Female  
1.0 G/KG**

|             |   |   |   |   |   |                |
|-------------|---|---|---|---|---|----------------|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 |                |
|             | 0 | 0 | 0 | 0 | 0 |                |
|             | 1 | 1 | 1 | 1 | 1 |                |
|             | 7 | 7 | 7 | 7 | 7 |                |
| ANIMAL ID   | 0 | 0 | 0 | 0 | 0 |                |
|             | 0 | 0 | 0 | 0 | 0 |                |
|             | 5 | 5 | 5 | 5 | 5 |                |
|             | 5 | 5 | 5 | 5 | 5 |                |
|             | 1 | 2 | 3 | 4 | 5 | <b>*TOTALS</b> |

NONE  
**Nervous System**

NONE  
**Respiratory System**

NONE  
**Special Senses System**

NONE  
**Urinary System**

NONE

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 20007-01

Test Type: 14-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/23/2014

Time Report Requested: 01:28:22

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
2.0 G/KG

|             |   |   |   |   |   |         |
|-------------|---|---|---|---|---|---------|
| DAY ON TEST | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 1 | 1 | 0 | 1 | 1 |         |
|             | 7 | 7 | 3 | 7 | 7 |         |
| ANIMAL ID   | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 6 | 6 | 6 | 6 | 6 |         |
|             | 5 | 5 | 5 | 5 | 5 |         |
|             | 1 | 2 | 3 | 4 | 5 | *TOTALS |

Alimentary System

|                                       |   |   |   |   |   |   |       |
|---------------------------------------|---|---|---|---|---|---|-------|
| Liver                                 | + | + | + | + | + | 5 |       |
| Hepatocyte, Hypertrophy               | 1 | 1 | 1 | 1 | 1 |   | 5 1.0 |
| Infiltration Cellular, Mononuclear CI | 1 |   |   | 1 |   |   | 2 1.0 |

Cardiovascular System

NONE

Endocrine System

NONE

General Body System

NONE

Genital System

NONE

Hematopoietic System

|                       |  |  |   |  |  |   |       |
|-----------------------|--|--|---|--|--|---|-------|
| Lymph Node            |  |  | + |  |  | 1 |       |
| Hyperplasia, Lymphoid |  |  | 2 |  |  |   | 1 2.0 |

Integumentary System

NONE

Musculoskeletal System

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked



Experiment Number: 20007-01

Test Type: 14-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Kava kava extract

CAS Number: 9000-38-8

Date Report Requested: 10/23/2014

Time Report Requested: 01:28:22

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
2.0 G/KG

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 |         |
|-------------|---|---|---|---|---|---------|
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 1 | 1 | 0 | 1 | 1 |         |
|             | 7 | 7 | 3 | 7 | 7 |         |
| ANIMAL ID   | 0 | 0 | 0 | 0 | 0 |         |
|             | 0 | 0 | 0 | 0 | 0 |         |
|             | 6 | 6 | 6 | 6 | 6 |         |
|             | 5 | 5 | 5 | 5 | 5 |         |
|             | 1 | 2 | 3 | 4 | 5 | *TOTALS |

|                                                     |   |   |   |   |   |       |
|-----------------------------------------------------|---|---|---|---|---|-------|
| NONE                                                |   |   |   |   |   |       |
| <b>Nervous System</b>                               |   |   |   |   |   |       |
| Brain                                               | + | + | + | + | + | 5     |
| <b>Respiratory System</b>                           |   |   |   |   |   |       |
| Lung                                                | + | + | + | + | + | 5     |
| Alveolus, Infiltration Cellular, Mononuclear Cl     |   |   |   | 1 | 1 | 2 1.0 |
| Interstitial, Infiltration Cellular, Mononuclear Cl | 1 | 1 | 1 | 1 | 1 | 5 1.0 |
| <b>Special Senses System</b>                        |   |   |   |   |   |       |
| Eye                                                 |   |   | + |   |   | 1     |
| Iris, Inflammation                                  |   |   | 1 |   |   | 1 1.0 |
| Synechia                                            |   |   | 2 |   |   | 1 2.0 |
| <b>Urinary System</b>                               |   |   |   |   |   |       |
| Kidney                                              | + | + | + | + | + | 5     |

\*\* END OF REPORT \*\*

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked