

TDMS No. 20007 - 05
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/F 344/N

E05: CLINICAL OBSERVATIONS SUMMARY

Kava kava extract
CAS Number: 9000-38-8

Date Report Requested: 02/20/2009
Time Report Requested: 08:00:44
First Dose M/F: 08/18/04 / 08/19/04
Lab: BAT

C Number: C20007
Lock Date: 03/27/2007
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.1.0

| OBSERVATION | 0.0 G/KG | | 0.1 G/KG | | 0.3 G/KG | | 1.0 G/KG | |
|------------------------------|-----------|-------------------|----------|-------------------|----------|-------------------|----------|-------------------|
| | CURRENT* | TOTAL+ | CURRENT | TOTAL | CURRENT | TOTAL | CURRENT | TOTAL |
| | SEX: MALE | WEEK: 105 | | | | | | |
| Abnormal Breathing | 0 / 0 | 0/49 | 0 / 0 | 0/50 | 0 / 0 | 1 / 50 DAY 701 | 0 / 0 | 0/50 |
| Ataxia | 0 / 0 | 0/49 | 0 / 0 | 0/50 | 0 / 0 | 1 / 50 DAY 701 | 0 / 0 | 0/50 |
| Eye Abnormality | 0 / 0 | 1 / 49 DAY 225 | 0 / 0 | 0/50 | 0 / 0 | 0/50 | 0 / 0 | 0/50 |
| Impaired Gait | 0 / 0 | 0/49 | 0 / 0 | 0/50 | 0 / 0 | 1 / 50 DAY 701 | 0 / 0 | 0/50 |
| Lethargic | 0 / 0 | 0/49 | 0 / 0 | 0/50 | 0 / 0 | 2 / 50 DAY 673 | 0 / 0 | 3 / 50 DAY 533 |
| Mass Torso/Ventral | 0 / 0 | 2 / 49 DAY 645 | 0 / 0 | 5 / 50 DAY 617 | 0 / 0 | 6 / 50 DAY 533 | 0 / 0 | 3 / 50 DAY 449 |
| Mass Head | 0 / 0 | 0/49 | 0 / 0 | 2 / 50 DAY 477 | 0 / 0 | 2 / 50 DAY 505 | 0 / 0 | 0/50 |
| Mass Torso/Dorsal | 0 / 0 | 3 / 49 DAY 617 | 0 / 0 | 1 / 50 DAY 589 | 0 / 0 | 2 / 50 DAY 617 | 0 / 0 | 1 / 50 DAY 673 |

* ANIMALS WITH OBSERVATION IN CURRENT PERIOD / TOTAL ANIMALS OBSERVED IN CURRENT PERIOD (WITHIN 30 DAYS OF RUN DATE)

+ ROW 1 = CUMULATIVE NO. OF ANIMALS WITH OBSERVATION / TOTAL ANIMALS STARTED ON STUDY

ROW 2 = DAY OF ONSET

| SEX: MALE | | WEEK: 105 | | | | | | | |
|---------------------------------------|----------|-------------------|----------|--------------------|----------|-------------------|----------|--------------------|--|
| OBSERVATION | 0.0 G/KG | | 0.1 G/KG | | 0.3 G/KG | | 1.0 G/KG | | |
| | CURRENT* | TOTAL+ | CURRENT | TOTAL | CURRENT | TOTAL | CURRENT | TOTAL | |
| Mass Torso/Lateral | 0 / 0 | 6 / 49 DAY 533 | 0 / 0 | 2 / 50 DAY 561 | 0 / 0 | 2 / 50 DAY 617 | 0 / 0 | 1 / 50 DAY 337 | |
| Nasal/Eye Discharge | 0 / 0 | 9 / 49 DAY 505 | 0 / 0 | 15 / 50 DAY 449 | 0 / 0 | 6 / 50 DAY 393 | 0 / 0 | 19 / 50 DAY 337 | |
| Ruffled Fur | 0 / 0 | 1 / 49 DAY 617 | 0 / 0 | 0 / 50 | 0 / 0 | 4 / 50 DAY 617 | 0 / 0 | 7 / 50 DAY 589 | |
| Thin | 0 / 0 | 0 / 49 | 0 / 0 | 2 / 50 DAY 673 | 0 / 0 | 3 / 50 DAY 673 | 0 / 0 | 3 / 50 DAY 533 | |
| Ulcer/Abscess Head | 0 / 0 | 1 / 49 DAY 505 | 0 / 0 | 0 / 50 | 0 / 0 | 2 / 50 DAY 365 | 0 / 0 | 0 / 50 | |
| Ulcer/Abscess Torso/Ventral | 0 / 0 | 0 / 49 | 0 / 0 | 1 / 50 DAY 505 | 0 / 0 | 0 / 50 | 0 / 0 | 0 / 50 | |
| Ulcer/Abscess Torso/Dorsal | 0 / 0 | 1 / 49 DAY 701 | 0 / 0 | 0 / 50 | 0 / 0 | 2 / 50 DAY 533 | 0 / 0 | 1 / 50 DAY 561 | |
| Ulcer/Abscess Torso/Lateral | 0 / 0 | 1 / 49 DAY 589 | 0 / 0 | 0 / 50 | 0 / 0 | 0 / 50 | 0 / 0 | 0 / 50 | |

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WEEK: 105

*** END OF MALE DATA ***

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|------------------------------|--------------------|--------------------|----------|--------------------|----------|--------------------|----------|-------------------|
| | CURRENT* | TOTAL+ | CURRENT | TOTAL | CURRENT | TOTAL | CURRENT | TOTAL |
| | SEX: FEMALE | WEEK: 105 | | | | | | |
| Abnormal Breathing | 0 / 0 | 1 / 50 DAY 449 | 0 / 0 | 0 / 50 | 0 / 0 | 1 / 50 DAY 701 | 0 / 0 | 0 / 50 |
| Ataxia | 0 / 0 | 0 / 50 | 0 / 0 | 0 / 50 | 0 / 0 | 0 / 50 | 0 / 0 | 8 / 50 DAY 29 |
| Eye Abnormality | 0 / 0 | 4 / 50 DAY 169 | 0 / 0 | 2 / 50 DAY 197 | 0 / 0 | 2 / 50 DAY 337 | 0 / 0 | 4 / 50 DAY 197 |
| Head Tilt | 0 / 0 | 3 / 50 DAY 589 | 0 / 0 | 0 / 50 | 0 / 0 | 1 / 50 DAY 617 | 0 / 0 | 0 / 50 |
| Lethargic | 0 / 0 | 0 / 50 | 0 / 0 | 0 / 50 | 0 / 0 | 0 / 50 | 0 / 0 | 10 / 50 DAY 29 |
| Mass Torso/Ventral | 0 / 0 | 22 / 50 DAY 365 | 0 / 0 | 21 / 50 DAY 505 | 0 / 0 | 10 / 50 DAY 477 | 0 / 0 | 4 / 50 DAY 589 |
| Mass Head | 0 / 0 | 1 / 50 DAY 673 | 0 / 0 | 0 / 50 | 0 / 0 | 0 / 50 | 0 / 0 | 2 / 50 DAY 505 |
| Mass Torso/Dorsal | 0 / 0 | 0 / 50 | 0 / 0 | 0 / 50 | 0 / 0 | 1 / 50 DAY 505 | 0 / 0 | 0 / 50 |

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|---------------------------------------|-------------|-------------------|----------|-------------------|----------|--------------------|----------|-------------------|
| | CURRENT* | TOTAL+ | CURRENT | TOTAL | CURRENT | TOTAL | CURRENT | TOTAL |
| | SEX: FEMALE | WEEK: 105 | | | | | | |
| Mass Torso/Lateral | 0 / 0 | 1 / 50 DAY 421 | 0 / 0 | 3 / 50 DAY 617 | 0 / 0 | 4 / 50 DAY 673 | 0 / 0 | 2 / 50 DAY 617 |
| Nasal/Eye Discharge | 0 / 0 | 8 / 50 DAY 57 | 0 / 0 | 3 / 50 DAY 169 | 0 / 0 | 10 / 50 DAY 169 | 0 / 0 | 5 / 50 DAY 225 |
| Ruffled Fur | 0 / 0 | 2 / 50 DAY 449 | 0 / 0 | 1 / 50 DAY 701 | 0 / 0 | 4 / 50 DAY 617 | 0 / 0 | 1 / 50 DAY 617 |
| Thin | 0 / 0 | 7 / 50 DAY 449 | 0 / 0 | 1 / 50 DAY 701 | 0 / 0 | 1 / 50 DAY 701 | 0 / 0 | 2 / 50 DAY 617 |
| Ulcer/Abscess Torso/Ventral | 0 / 0 | 2 / 50 DAY 533 | 0 / 0 | 1 / 50 DAY 701 | 0 / 0 | 0 / 50 | 0 / 0 | 1 / 50 DAY 533 |
| Ulcer/Abscess Appendage | 0 / 0 | 0 / 50 | 0 / 0 | 0 / 50 | 0 / 0 | 0 / 50 | 0 / 0 | 1 / 50 DAY 505 |
| Ulcer/Abscess Torso/Dorsal | 0 / 0 | 0 / 50 | 0 / 0 | 0 / 50 | 0 / 0 | 1 / 50 DAY 533 | 0 / 0 | 1 / 50 DAY 505 |

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