

**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						
<b>Abnormal Breathing</b>	0 / 0	0/49	0 / 0	0/50	0 / 0	1 / 50 DAY 701	0 / 0	0/50
<b>Ataxia</b>	0 / 0	0/49	0 / 0	0/50	0 / 0	1 / 50 DAY 701	0 / 0	0/50
<b>Eye Abnormality</b>	0 / 0	1 / 49 DAY 225	0 / 0	0/50	0 / 0	0/50	0 / 0	0/50
<b>Impaired Gait</b>	0 / 0	0/49	0 / 0	0/50	0 / 0	1 / 50 DAY 701	0 / 0	0/50
<b>Lethargic</b>	0 / 0	0/49	0 / 0	0/50	0 / 0	2 / 50 DAY 673	0 / 0	3 / 50 DAY 533
<b>Mass</b> 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
<b>Mass</b> Head	0 / 0	0/49	0 / 0	2 / 50 DAY 477	0 / 0	2 / 50 DAY 505	0 / 0	0/50
<b>Mass</b> 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	
<b>Mass</b> 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	
<b>Nasal/Eye Discharge</b>	0 / 0	9 / 49 DAY 505	0 / 0	15 / 50 DAY 449	0 / 0	6 / 50 DAY 393	0 / 0	19 / 50 DAY 337	
<b>Ruffled Fur</b>	0 / 0	1 / 49 DAY 617	0 / 0	0 / 50	0 / 0	4 / 50 DAY 617	0 / 0	7 / 50 DAY 589	
<b>Thin</b>	0 / 0	0 / 49	0 / 0	2 / 50 DAY 673	0 / 0	3 / 50 DAY 673	0 / 0	3 / 50 DAY 533	
<b>Ulcer/Abscess</b> Head	0 / 0	1 / 49 DAY 505	0 / 0	0 / 50	0 / 0	2 / 50 DAY 365	0 / 0	0 / 50	
<b>Ulcer/Abscess</b> Torso/Ventral	0 / 0	0 / 49	0 / 0	1 / 50 DAY 505	0 / 0	0 / 50	0 / 0	0 / 50	
<b>Ulcer/Abscess</b> Torso/Dorsal	0 / 0	1 / 49 DAY 701	0 / 0	0 / 50	0 / 0	2 / 50 DAY 533	0 / 0	1 / 50 DAY 561	
<b>Ulcer/Abscess</b> Torso/Lateral	0 / 0	1 / 49 DAY 589	0 / 0	0 / 50	0 / 0	0 / 50	0 / 0	0 / 50	

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**SEX:** MALE

**WEEK:** 105

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

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
	<b>SEX:</b> FEMALE	<b>WEEK:</b> 105						
<b>Abnormal Breathing</b>	0 / 0	1 / 50 DAY 449	0 / 0	0 / 50	0 / 0	1 / 50 DAY 701	0 / 0	0 / 50
<b>Ataxia</b>	0 / 0	0 / 50	0 / 0	0 / 50	0 / 0	0 / 50	0 / 0	8 / 50 DAY 29
<b>Eye Abnormality</b>	0 / 0	4 / 50 DAY 169	0 / 0	2 / 50 DAY 197	0 / 0	2 / 50 DAY 337	0 / 0	4 / 50 DAY 197
<b>Head Tilt</b>	0 / 0	3 / 50 DAY 589	0 / 0	0 / 50	0 / 0	1 / 50 DAY 617	0 / 0	0 / 50
<b>Lethargic</b>	0 / 0	0 / 50	0 / 0	0 / 50	0 / 0	0 / 50	0 / 0	10 / 50 DAY 29
<b>Mass</b> 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
<b>Mass</b> Head	0 / 0	1 / 50 DAY 673	0 / 0	0 / 50	0 / 0	0 / 50	0 / 0	2 / 50 DAY 505
<b>Mass</b> Torso/Dorsal	0 / 0	0 / 50	0 / 0	0 / 50	0 / 0	1 / 50 DAY 505	0 / 0	0 / 50

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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: FEMALE	WEEK: 105						
<b>Mass</b> 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
<b>Nasal/Eye Discharge</b>	0 / 0	8 / 50 DAY 57	0 / 0	3 / 50 DAY 169	0 / 0	10 / 50 DAY 169	0 / 0	5 / 50 DAY 225
<b>Ruffled Fur</b>	0 / 0	2 / 50 DAY 449	0 / 0	1 / 50 DAY 701	0 / 0	4 / 50 DAY 617	0 / 0	1 / 50 DAY 617
<b>Thin</b>	0 / 0	7 / 50 DAY 449	0 / 0	1 / 50 DAY 701	0 / 0	1 / 50 DAY 701	0 / 0	2 / 50 DAY 617
<b>Ulcer/Abscess</b> Torso/Ventral	0 / 0	2 / 50 DAY 533	0 / 0	1 / 50 DAY 701	0 / 0	0 / 50	0 / 0	1 / 50 DAY 533
<b>Ulcer/Abscess</b> Appendage	0 / 0	0 / 50	0 / 0	0 / 50	0 / 0	0 / 50	0 / 0	1 / 50 DAY 505
<b>Ulcer/Abscess</b> 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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\*\*\* END OF REPORT \*\*\*