

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

**P11: STATISTICAL ANALYSIS OF SURVIVAL DATA**  
Kava kava extract  
**CAS Number:** 9000-38-8

**Date Report Requested:** 09/21/2010  
**Time Report Requested:** 09:10:56  
**First Dose M/F:** 08/18/04 / 08/19/04  
**Lab:** BAT

F2\_R2

**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:** 2.2.0

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**MALE RATS**

FIRST TERMINAL SACRIFICE AT 727 DAYS  
INDIVIDUAL SURVIVAL TIMES (DAYS)

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**DOSE = 0.0 G/KG**

TOTAL 49                                      UNCENSORED DEATHS 15                                      CENSORED DEATHS 0                                      TERMINAL 34  
UNCENSORED DEATH DAYS  
504    504    511    545    582    594    610    613    629    651    675    686    689    694  
709  
CENSORED DEATH DAYS  
None

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**DOSE = 0.1 G/KG**

TOTAL 50                                      UNCENSORED DEATHS 14                                      CENSORED DEATHS 1                                      TERMINAL 35  
UNCENSORED DEATH DAYS  
168    525    571    571    615    646    666    673    679    689    700    709    714    714  
CENSORED DEATH DAYS  
30

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**DOSE = 0.3 G/KG**

TOTAL 50                                      UNCENSORED DEATHS 15                                      CENSORED DEATHS 1                                      TERMINAL 34  
UNCENSORED DEATH DAYS  
454    590    608    616    630    664    664    664    673    689    689    694    701    702  
709  
CENSORED DEATH DAYS  
598

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**DOSE = 1.0 G/KG**

TOTAL 50                                      UNCENSORED DEATHS 16                                      CENSORED DEATHS 3                                      TERMINAL 31  
UNCENSORED DEATH DAYS  
447    451    454    556    559    589    629    640    665    670    673    673    679    689  
694    709  
CENSORED DEATH DAYS  
3    30    528

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**MALE RATS**

FIRST TERMINAL SACRIFICE AT 727 DAYS

KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)										
DOSE	TIME (DAYS)									
	90	180	270	365	425	485	545	605	665	727(A)
<b>0.0 G/KG</b>	100.0	100.0	100.0	100.0	100.0	100.0	91.8	87.8	79.6	69.4
<b>0.1 G/KG</b>	100.0	98.0	98.0	98.0	98.0	98.0	95.9	91.8	87.8	71.4
<b>0.3 G/KG</b>	100.0	100.0	100.0	100.0	100.0	98.0	98.0	96.0	83.7	69.4
<b>1.0 G/KG</b>	100.0	100.0	100.0	100.0	100.0	93.8	93.8	87.4	81.0	66.1

(A) FIRST TERMINAL SACRIFICE  
 (B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".  
 (C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE  
 (D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

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FIRST TERMINAL SACRIFICE AT 727 DAYS

SURVIVAL SUMMARY STATISTICS				
DOSE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	69.4%	71.4%	69.4%	66.1%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.652	P=0.880N	P=1.000N	P=0.879
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	613.1 (18.6)	617.1 (38.1)	649.8 (16.9)	611.1 (22.9)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	692.1 (9.4)	682.3 (18.3)	701.3 (7.4)	657.5 (21.7)

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Lab: BAT

FEMALE RATS

FIRST TERMINAL SACRIFICE AT 728 DAYS  
INDIVIDUAL SURVIVAL TIMES (DAYS)

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**DOSE = 0.0 G/KG**

TOTAL 50	UNCENSORED DEATHS 15					CENSORED DEATHS 1					TERMINAL 34				
UNCENSORED DEATH DAYS															
9	450	506	510	519	615	621	637	664	669	693	693	701	705		
705															
CENSORED DEATH DAYS															
692															

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**DOSE = 0.1 G/KG**

TOTAL 50	UNCENSORED DEATHS 15					CENSORED DEATHS 1					TERMINAL 34				
UNCENSORED DEATH DAYS															
5	558	605	615	631	632	632	639	670	678	688	701	705	705		
727															
CENSORED DEATH DAYS															
51															

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**DOSE = 0.3 G/KG**

TOTAL 50	UNCENSORED DEATHS 24					CENSORED DEATHS 2					TERMINAL 24				
UNCENSORED DEATH DAYS															
439	518	519	532	532	579	615	618	628	629	632	639	647	652		
653	658	664	672	681	688	702	705	705	708						
CENSORED DEATH DAYS															
98	539														

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**DOSE = 1.0 G/KG**

TOTAL 50	UNCENSORED DEATHS 14					CENSORED DEATHS 2					TERMINAL 34				
UNCENSORED DEATH DAYS															
140	194	380	399	489	559	616	629	664	687	688	688	694	721		
CENSORED DEATH DAYS															
111	265														

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KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)										
DOSE	TIME (DAYS)									
	90	180	270	365	425	485	545	605	665	728(A)
0.0 G/KG	98.0	98.0	98.0	98.0	98.0	96.0	90.0	90.0	82.0	69.7
0.1 G/KG	98.0	98.0	98.0	98.0	98.0	98.0	98.0	93.9	83.7	69.4
0.3 G/KG	100.0	100.0	100.0	100.0	100.0	98.0	89.8	87.7	64.7	50.1
1.0 G/KG	100.0	98.0	95.9	95.9	91.7	91.7	89.7	87.6	81.3	70.9

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SURVIVAL SUMMARY STATISTICS				
DOSE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	69.7%	69.4%	50.1%	70.9%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.931N	P=1.000N	P=0.077	P=1.000N
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	579.8 (46.3)	612.7 (45.0)	625.6 (14.5)	539.1 (51.3)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	682.8 (16.6)	679.9 (19.9)	662.5 (15.5)	653.5 (23.0)

\*\*\* END OF REPORT \*\*\*

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