

**Experiment Number:** 20007-03  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** Rat/F 344/N

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

**Date Report Requested:** 10/17/2014  
**Time Report Requested:** 21:44:43  
**First Dose M/F:** NA / NA  
**Lab:** BAT

<b>C Number:</b>	C20007
<b>Lock Date:</b>	05/24/2004
<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

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Lab: BAT

Male RAT  
FIRST TERMINAL SACRIFICE AT 93 DAYS  
INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = 0 G/KG	UNCENSORED DEATHS	CENSORED DEATHS	TERMINAL
TOTAL 10	0	0	10
UNCENSORED DEATH DAYS	none		
CENSORED DEATH DAYS	none		
DOSE = 0.125 G/KG	UNCENSORED DEATHS	CENSORED DEATHS	TERMINAL
TOTAL 10	0	0	10
UNCENSORED DEATH DAYS	none		
CENSORED DEATH DAYS	none		
DOSE = 0.25 G/KG	UNCENSORED DEATHS	CENSORED DEATHS	TERMINAL
TOTAL 10	1	0	9
UNCENSORED DEATH DAYS	22		
CENSORED DEATH DAYS	none		
DOSE = 0.5 G/KG	UNCENSORED DEATHS	CENSORED DEATHS	TERMINAL
TOTAL 10	0	0	10
UNCENSORED DEATH DAYS	none		
CENSORED DEATH DAYS	none		

(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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**Lab:** BAT

**Male RAT**  
**FIRST TERMINAL SACRIFICE AT 93 DAYS**  
**INDIVIDUAL SURVIVAL TIMES (DAYS)**

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**DOSE = 1.0 G/KG**

TOTAL 10                      UNCENSORED DEATHS 0                      CENSORED DEATHS 0                      TERMINAL 10

**UNCENSORED DEATH DAYS**

none

**CENSORED DEATH DAYS**

none

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**DOSE = 2.0 G/KG**

TOTAL 10                      UNCENSORED DEATHS 3                      CENSORED DEATHS 0                      TERMINAL 7

**UNCENSORED DEATH DAYS**

5                      80                      80

**CENSORED DEATH DAYS**

none

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Lab: BAT

Male RAT  
FIRST TERMINAL SACRIFICE AT 93 DAYS

KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)

DOSE	TIME (DAYS)									
	10	20	30	40	50	60	70	80	90	93(A)
0 G/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
0.125 G/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
0.25 G/KG	100.0	100.0	90.0	90.0	90.0	90.0	90.0	90.0	90.0	90.0
0.5 G/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
1.0 G/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
2.0 G/KG	90.0	90.0	90.0	90.0	90.0	90.0	90.0	70.0	70.0	70.0

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(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

(D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

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

Male RAT  
 FIRST TERMINAL SACRIFICE AT 93 DAYS

SURVIVAL SUMMARY STATISTICS

DOSE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	100.0%	100.0%	90.0%	100.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.017	-----	P=1.000	-----
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	. (.)	. (.)	22.0 (.)	. (.)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	93.0 (0.0)	93.0 (0.0)	85.9 (7.1)	93.0 (0.0)

(A) FIRST TERMINAL SACRIFICE

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(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

(D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

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

Male RAT  
FIRST TERMINAL SACRIFICE AT 93 DAYS

SURVIVAL SUMMARY STATISTICS

DOSE	1.0 G/KG	2.0 G/KG
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	100.0%	70.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	-----	P=0.215
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	. (.)	55.0 (25.0)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	93.0 (0.0)	81.6 (8.7)

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(D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

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Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

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First Dose M/F: NA / NA

Lab: BAT

Female RAT  
FIRST TERMINAL SACRIFICE AT 93 DAYS  
INDIVIDUAL SURVIVAL TIMES (DAYS)

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<b>DOSE = 0 G/KG</b>			
TOTAL 10	UNCENSORED DEATHS 1	CENSORED DEATHS 0	TERMINAL 9
<b>UNCENSORED DEATH DAYS</b>			
18			
<b>CENSORED DEATH DAYS</b>			
none			

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<b>DOSE = 0.125 G/KG</b>			
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10
<b>UNCENSORED DEATH DAYS</b>			
none			
<b>CENSORED DEATH DAYS</b>			
none			

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<b>DOSE = 0.25 G/KG</b>			
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10
<b>UNCENSORED DEATH DAYS</b>			
none			
<b>CENSORED DEATH DAYS</b>			
none			

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<b>DOSE = 0.5 G/KG</b>			
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10
<b>UNCENSORED DEATH DAYS</b>			
none			
<b>CENSORED DEATH DAYS</b>			
none			

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(A) FIRST TERMINAL SACRIFICE

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(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

(D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

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**Lab:** BAT

**Female RAT**  
**FIRST TERMINAL SACRIFICE AT 93 DAYS**  
**INDIVIDUAL SURVIVAL TIMES (DAYS)**

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<b>DOSE = 1.0 G/KG</b>			
TOTAL 10	UNCENSORED DEATHS 1	CENSORED DEATHS 0	TERMINAL 9
<b>UNCENSORED DEATH DAYS</b>			
32			
<b>CENSORED DEATH DAYS</b>			
none			

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<b>DOSE = 2.0 G/KG</b>			
TOTAL 10	UNCENSORED DEATHS 4	CENSORED DEATHS 0	TERMINAL 6
<b>UNCENSORED DEATH DAYS</b>			
2	4	4	44
<b>CENSORED DEATH DAYS</b>			
none			

- (A) FIRST TERMINAL SACRIFICE
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- (C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE
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Female RAT  
FIRST TERMINAL SACRIFICE AT 93 DAYS

KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)

DOSE	TIME (DAYS)									
	10	20	30	40	50	60	70	80	90	93(A)
0 G/KG	100.0	90.0	90.0	90.0	90.0	90.0	90.0	90.0	90.0	90.0
0.125 G/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
0.25 G/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
0.5 G/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
1.0 G/KG	100.0	100.0	100.0	90.0	90.0	90.0	90.0	90.0	90.0	90.0
2.0 G/KG	70.0	70.0	70.0	70.0	60.0	60.0	60.0	60.0	60.0	60.0

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**Female RAT**  
**FIRST TERMINAL SACRIFICE AT 93 DAYS**

**SURVIVAL SUMMARY STATISTICS**

DOSE	0 G/KG	0.125 G/KG	0.25 G/KG	0.5 G/KG
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	90.0%	100.0%	100.0%	100.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.002	P=1.000N	P=1.000N	P=1.000N
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	18.0 (.)	. (.)	. (.)	. (.)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	85.5 (7.5)	93.0 (0.0)	93.0 (0.0)	93.0 (0.0)

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Female RAT  
FIRST TERMINAL SACRIFICE AT 93 DAYS

SURVIVAL SUMMARY STATISTICS

DOSE	1.0 G/KG	2.0 G/KG
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	90.0%	60.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=1.000N	P=0.274
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	32.0 (.)	13.5 (10.2)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	86.9 (6.1)	61.2 (13.5)

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**Lab:** BAT

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

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