

**Experiment Number:** 20007 - 04  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** MICE/B6C3F1

**P11: STATISTICAL ANALYSIS OF SURVIVAL DATA**

Kava kava extract  
**CAS Number:** 9000-38-8

**Date Report Requested:** 09/13/2016  
**Time Report Requested:** 11:24:53  
**First Dose M/F:** 09/18/03 / 09/17/03  
**Lab:** BAT

**NTP Study Number:** C20007  
**Lock Date:** 05/24/2004  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 3.0.2.3\_002  
**PWG Approval Date:** NONE

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Lab: BAT

**MALE MICE**

FIRST TERMINAL SACRIFICE AT 93 DAYS

INDIVIDUAL SURVIVAL TIMES (DAYS)

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**DOSE = 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 = 0.125 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 = 0.25 G/KG**

TOTAL 10                      UNCENSORED DEATHS 0                      CENSORED DEATHS 0                      TERMINAL 10

UNCENSORED DEATH DAYS

None

CENSORED DEATH DAYS

None

---

**DOSE = 0.5 G/KG**

TOTAL 10                      UNCENSORED DEATHS 0                      CENSORED DEATHS 0                      TERMINAL 10

UNCENSORED DEATH DAYS

None

CENSORED DEATH DAYS

None

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**MALE MICE**

FIRST TERMINAL SACRIFICE AT 93 DAYS

INDIVIDUAL SURVIVAL TIMES (DAYS)

---

**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 4

CENSORED DEATHS 0

TERMINAL 6

UNCENSORED DEATH DAYS

2 3 3 6

CENSORED DEATH DAYS

None

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Lab: BAT

MALE MICE

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	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	100.0	100.0	100.0	100.0	100.0	100.0	100.0
2.0 G/KG	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0	60.0

(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)

Experiment Number: 20007 - 04

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Lab: BAT

MALE MICE

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%	100.0%	100.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P<0.001	-----	-----	-----
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	(.)	(.)	(.)	(.)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	93.0 (0.0)	93.0 (0.0)	93.0 (0.0)	93.0 (0.0)

  

DOSE	1.0 G/KG	2.0 G/KG
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	100.0%	60.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	-----	P=0.095
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	(.)	3.5 (0.9)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	93.0 (0.0)	57.2 (14.6)

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

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

Experiment Number: 20007 - 04

Test Type: 90-DAY

Route: GAVAGE

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First Dose M/F: 09/18/03 / 09/17/03

Lab: BAT

**FEMALE MICE**

FIRST TERMINAL SACRIFICE AT 93 DAYS

INDIVIDUAL SURVIVAL TIMES (DAYS)

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**DOSE = 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 = 0.125 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 = 0.25 G/KG**

TOTAL 10                      UNCENSORED DEATHS 0                      CENSORED DEATHS 0                      TERMINAL 10

UNCENSORED DEATH DAYS

None

CENSORED DEATH DAYS

None

---

**DOSE = 0.5 G/KG**

TOTAL 10                      UNCENSORED DEATHS 0                      CENSORED DEATHS 0                      TERMINAL 10

UNCENSORED DEATH DAYS

None

CENSORED DEATH DAYS

None

Experiment Number: 20007 - 04

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Route: GAVAGE

Species/Strain: MICE/B6C3F1

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Lab: BAT

**FEMALE MICE**

FIRST TERMINAL SACRIFICE AT 93 DAYS

INDIVIDUAL SURVIVAL TIMES (DAYS)

---

**DOSE = 1.0 G/KG**

TOTAL 10

UNCENSORED DEATHS 0

CENSORED DEATHS 0

TERMINAL 10

UNCENSORED DEATH DAYS

None

CENSORED DEATH DAYS

None

---

**DOSE = 2.0 G/KG**

TOTAL 10

UNCENSORED DEATHS 3

CENSORED DEATHS 1

TERMINAL 6

UNCENSORED DEATH DAYS

2      2      2

CENSORED DEATH DAYS

37

Experiment Number: 20007 - 04

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Lab: BAT

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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)
<b>0 G/KG</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
<b>0.125 G/KG</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
<b>0.25 G/KG</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
<b>0.5 G/KG</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
<b>1.0 G/KG</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
<b>2.0 G/KG</b>	70.0	70.0	70.0	70.0	70.0	70.0	70.0	70.0	70.0	70.0

(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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FEMALE MICE

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%	100.0%	100.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.002	----	----	----
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	(.)	(.)	(.)	(.)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	93.0 (0.0)	93.0 (0.0)	93.0 (0.0)	93.0 (0.0)

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=0.222
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	(.)	2.0 (0.0)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	93.0 (0.0)	60.1 (13.8)

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

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

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