

**TDMS No.** 20007 - 06  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** MICE/B6C3F1

**P11: STATISTICAL ANALYSIS OF SURVIVAL DATA**

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

**Date Report Requested:** 04/13/2009  
**Time Report Requested:** 10:57:30  
**First Dose M/F:** 08/24/04 / 08/23/04  
**Lab:** BAT

F\_M3

**C Number:** C20007  
**Lock Date:** 05/10/2007  
**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

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**MALE MICE**  
FIRST TERMINAL SACRIFICE AT 730 DAYS  
INDIVIDUAL SURVIVAL TIMES (DAYS)

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**DOSE = 0 G/KG**

TOTAL 50                      UNCENSORED DEATHS 16                      CENSORED DEATHS 0                      TERMINAL 34  
UNCENSORED DEATH DAYS:  
369 455 513 570 579 587 617 626 644 647 648 652 668 668  
683 703  
CENSORED DEATH DAYS:  
None

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**DOSE = 0.25 G/KG**

TOTAL 50                      UNCENSORED DEATHS 17                      CENSORED DEATHS 0                      TERMINAL 33  
UNCENSORED DEATH DAYS:  
319 423 431 437 484 546 553 553 596 623 664 664 687 693  
695 707 720  
CENSORED DEATH DAYS:  
None

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**DOSE = 0.5 G/KG**

TOTAL 50                      UNCENSORED DEATHS 16                      CENSORED DEATHS 0                      TERMINAL 34  
UNCENSORED DEATH DAYS:  
455 494 534 580 605 616 623 653 660 668 670 679 683 683  
711 729  
CENSORED DEATH DAYS:  
None

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**DOSE = 1.0 G/KG**

TOTAL 50                      UNCENSORED DEATHS 14                      CENSORED DEATHS 0                      TERMINAL 36  
UNCENSORED DEATH DAYS:  
392 465 547 574 582 582 595 596 596 668 673 692 707 718

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**MALE MICE**

FIRST TERMINAL SACRIFICE AT **730** DAYS  
INDIVIDUAL SURVIVAL TIMES (DAYS)

CENSORED DEATH DAYS:  
None

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**MALE MICE**  
FIRST TERMINAL SACRIFICE AT 730 DAYS

**KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)**

DOSE	TIME (DAYS)									
	90	180	270	365	425	485	545	605	665	730(A)
<b>0 G/KG</b>	100.0	100.0	100.0	100.0	98.0	96.0	94.0	88.0	76.0	68.0
<b>0.25 G/KG</b>	100.0	100.0	100.0	98.0	96.0	90.0	90.0	82.0	76.0	66.0
<b>0.5 G/KG</b>	100.0	100.0	100.0	100.0	100.0	98.0	94.0	90.0	82.0	68.0
<b>1.0 G/KG</b>	100.0	100.0	100.0	100.0	98.0	96.0	96.0	82.0	82.0	72.0

- (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)

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**MALE MICE**  
FIRST TERMINAL SACRIFICE AT 730 DAYS

**SURVIVAL SUMMARY STATISTICS**

<b>DOSE</b>	<b>0 G/KG</b>	<b>0.25 G/KG</b>	<b>0.5 G/KG</b>	<b>1.0 G/KG</b>
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	68.0%	66.0%	68.0%	72.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.629N	P=0.956	P=1.000N	P=0.798N
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	601.8 (22.4)	576.2 (29.5)	627.7 (19.4)	599.1 (24.5)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	689.0 (11.0)	677.7 (14.3)	697.3 (9.1)	693.3 (10.7)

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Lab: BAT

**FEMALE MICE**  
FIRST TERMINAL SACRIFICE AT 729 DAYS  
INDIVIDUAL SURVIVAL TIMES (DAYS)

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**DOSE = 0 G/KG**

TOTAL 50                      UNCENSORED DEATHS 11                      CENSORED DEATHS 1                      TERMINAL 38  
UNCENSORED DEATH DAYS:  
421 523 544 560 581 610 639 684 688 700 701  
CENSORED DEATH DAYS:  
394

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**DOSE = 0.25 G/KG**

TOTAL 50                      UNCENSORED DEATHS 16                      CENSORED DEATHS 0                      TERMINAL 34  
UNCENSORED DEATH DAYS:  
372 521 565 575 666 669 669 681 697 701 708 711 715 718  
723 724  
CENSORED DEATH DAYS:  
None

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**DOSE = 0.5 G/KG**

TOTAL 50                      UNCENSORED DEATHS 5                      CENSORED DEATHS 0                      TERMINAL 45  
UNCENSORED DEATH DAYS:  
534 554 556 638 712  
CENSORED DEATH DAYS:  
None

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**DOSE = 1.0 G/KG**

TOTAL 50                      UNCENSORED DEATHS 12                      CENSORED DEATHS 1                      TERMINAL 37  
UNCENSORED DEATH DAYS:  
523 548 548 576 604 654 669 678 684 719 723 725  
CENSORED DEATH DAYS:  
148

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FIRST TERMINAL SACRIFICE AT 729 DAYS

**KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)**

DOSE	TIME (DAYS)									
	90	180	270	365	425	485	545	605	665	729(A)
0 G/KG	100.0	100.0	100.0	100.0	98.0	98.0	93.9	89.8	85.7	77.6
0.25 G/KG	100.0	100.0	100.0	100.0	98.0	98.0	96.0	92.0	92.0	68.0
0.5 G/KG	100.0	100.0	100.0	100.0	100.0	100.0	98.0	94.0	92.0	90.0
1.0 G/KG	100.0	100.0	100.0	100.0	100.0	100.0	98.0	89.8	87.8	75.5

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FIRST TERMINAL SACRIFICE AT 729 DAYS

**SURVIVAL SUMMARY STATISTICS**

DOSE	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	77.6%	68.0%	90.0%	75.5%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.796N	P=0.481	P=0.159N	P=1.000
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	604.6 (26.9)	650.9 (24.2)	598.8 (33.5)	637.6 (21.4)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	694.9 (11.1)	704.0 (9.2)	716.0 (6.3)	695.4 (13.4)

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

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