

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)

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

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

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

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)
0 G/KG	100.0	100.0	100.0	100.0	98.0	96.0	94.0	88.0	76.0	68.0
0.25 G/KG	100.0	100.0	100.0	98.0	96.0	90.0	90.0	82.0	76.0	66.0
0.5 G/KG	100.0	100.0	100.0	100.0	100.0	98.0	94.0	90.0	82.0	68.0
1.0 G/KG	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

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

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

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

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

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

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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SURVIVAL SUMMARY STATISTICS

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

*** END OF REPORT ***

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