

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)

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

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

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

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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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)
0.0 G/KG	100.0	100.0	100.0	100.0	100.0	100.0	91.8	87.8	79.6	69.4
0.1 G/KG	100.0	98.0	98.0	98.0	98.0	98.0	95.9	91.8	87.8	71.4
0.3 G/KG	100.0	100.0	100.0	100.0	100.0	98.0	98.0	96.0	83.7	69.4
1.0 G/KG	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
SURVIVAL AT END OF STUDY (KAPLAN-MEIER)	69.4%	71.4%	69.4%	66.1%
SIGNIFICANCE (B) (LIFE TABLE)	P=0.652	P=0.880N	P=1.000N	P=0.879
MEAN DAY OF NATURAL DEATHS (C) (STANDARD ERROR)	613.1 (18.6)	617.1 (38.1)	649.8 (16.9)	611.1 (22.9)
MEAN LIFE SPAN (D) (STANDARD ERROR)	692.1 (9.4)	682.3 (18.3)	701.3 (7.4)	657.5 (21.7)

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FEMALE RATS

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

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			

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			

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			

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
SURVIVAL AT END OF STUDY (KAPLAN-MEIER)	69.7%	69.4%	50.1%	70.9%
SIGNIFICANCE (B) (LIFE TABLE)	P=0.931N	P=1.000N	P=0.077	P=1.000N
MEAN DAY OF NATURAL DEATHS (C) (STANDARD ERROR)	579.8 (46.3)	612.7 (45.0)	625.6 (14.5)	539.1 (51.3)
MEAN LIFE SPAN (D) (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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