

**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

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

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

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

MALE RATS

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)

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

**MALE RATS**

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
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	69.4%	71.4%	69.4%	66.1%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.652	P=0.880N	P=1.000N	P=0.879
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	613.1 (18.6)	617.1 (38.1)	649.8 (16.9)	611.1 (22.9)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	692.1 (9.4)	682.3 (18.3)	701.3 (7.4)	657.5 (21.7)

(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)

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

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

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

**FEMALE RATS**

FIRST TERMINAL SACRIFICE AT 728 DAYS

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

(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)

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

**FEMALE RATS**

FIRST TERMINAL SACRIFICE AT 728 DAYS

SURVIVAL SUMMARY STATISTICS				
DOSE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	69.7%	69.4%	50.1%	70.9%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.931N	P=1.000N	P=0.077	P=1.000N
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	579.8 (46.3)	612.7 (45.0)	625.6 (14.5)	539.1 (51.3)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	682.8 (16.6)	679.9 (19.9)	662.5 (15.5)	653.5 (23.0)

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

(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)