

TDMS No. 20008 - 03
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: RATS/F 344/N

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Milk thistle extract
CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
Time Report Requested: 11:00:55
First Dose M/F: 03/04/03 / 03/04/03
Lab: SRI

F1_R2

C Number: C20008
Lock Date: 06/29/2006
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.0.0

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MALE RATS
FIRST TERMINAL SACRIFICE AT 729 DAYS
INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = 0 PPM

TOTAL 50 UNCENSORED DEATHS 14 CENSORED DEATHS 0 TERMINAL 36
UNCENSORED DEATH DAYS:
477 591 599 600 601 613 619 660 672 687 699 702 710 711
CENSORED DEATH DAYS:
None

DOSE = 12500 PPM

TOTAL 50 UNCENSORED DEATHS 14 CENSORED DEATHS 0 TERMINAL 36
UNCENSORED DEATH DAYS:
501 587 591 623 638 643 647 647 647 667 672 702 711 721
CENSORED DEATH DAYS:
None

DOSE = 25000 PPM

TOTAL 50 UNCENSORED DEATHS 15 CENSORED DEATHS 0 TERMINAL 35
UNCENSORED DEATH DAYS:
86 310 428 549 591 604 637 638 646 647 667 687 702 721
721
CENSORED DEATH DAYS:
None

DOSE = 50000 PPM

TOTAL 50 UNCENSORED DEATHS 12 CENSORED DEATHS 0 TERMINAL 38
UNCENSORED DEATH DAYS:
546 591 638 638 645 676 682 702 710 711 711 714
CENSORED DEATH DAYS:
None

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MALE RATS

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 PPM	100.0	100.0	100.0	100.0	100.0	98.0	98.0	90.0	84.0	72.0
12500 PPM	100.0	100.0	100.0	100.0	100.0	100.0	98.0	94.0	82.0	72.0
25000 PPM	98.0	98.0	98.0	96.0	96.0	94.0	94.0	88.0	80.0	70.0
50000 PPM	100.0	100.0	100.0	100.0	100.0	100.0	100.0	96.0	90.0	76.0

- (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 RATS
FIRST TERMINAL SACRIFICE AT 729 DAYS

SURVIVAL SUMMARY STATISTICS				
DOSE	0 PPM	12500 PPM	25000 PPM	50000 PPM
SURVIVAL AT END OF STUDY (KAPLAN-MEIER)	72.0%	72.0%	70.0%	76.0%
SIGNIFICANCE (B) (LIFE TABLE)	P=0.656N	P=1.000N	P=0.936	P=0.715N
MEAN DAY OF NATURAL DEATHS (C) (STANDARD ERROR)	638.6 (17.5)	642.6 (15.2)	575.6 (45.3)	663.7 (15.5)
MEAN LIFE SPAN (D) (STANDARD ERROR)	703.7 (7.5)	704.8 (6.9)	683.0 (16.6)	713.3 (5.4)

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

DOSE = 0 PPM

TOTAL 50 UNCENSORED DEATHS 12 CENSORED DEATHS 0 TERMINAL 38
UNCENSORED DEATH DAYS:
200 302 434 575 618 623 637 660 687 687 710 725
CENSORED DEATH DAYS:
None

DOSE = 12500 PPM

TOTAL 50 UNCENSORED DEATHS 14 CENSORED DEATHS 0 TERMINAL 36
UNCENSORED DEATH DAYS:
459 477 592 599 609 618 619 619 637 660 660 672 722 725
CENSORED DEATH DAYS:
None

DOSE = 25000 PPM

TOTAL 50 UNCENSORED DEATHS 16 CENSORED DEATHS 0 TERMINAL 34
UNCENSORED DEATH DAYS:
80 451 477 484 507 567 647 660 667 676 687 703 703 703
711 725
CENSORED DEATH DAYS:
None

DOSE = 50000 PPM

TOTAL 50 UNCENSORED DEATHS 13 CENSORED DEATHS 0 TERMINAL 37
UNCENSORED DEATH DAYS:
546 613 619 619 638 647 664 667 674 693 703 721 722
CENSORED DEATH DAYS:
None

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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 PPM	100.0	100.0	98.0	96.0	96.0	94.0	94.0	92.0	84.0	76.0
12500 PPM	100.0	100.0	100.0	100.0	100.0	96.0	96.0	92.0	78.0	72.0
25000 PPM	98.0	98.0	98.0	98.0	98.0	92.0	90.0	88.0	84.0	68.0
50000 PPM	100.0	100.0	100.0	100.0	100.0	100.0	100.0	98.0	86.0	74.0

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SURVIVAL SUMMARY STATISTICS

DOSE	0 PPM	12500 PPM	25000 PPM	50000 PPM
SURVIVAL AT END OF STUDY (KAPLAN-MEIER)	76.0%	72.0%	68.0%	74.0%
SIGNIFICANCE (B) (LIFE TABLE)	P=1.000	P=0.798	P=0.521	P=1.000
MEAN DAY OF NATURAL DEATHS (C) (STANDARD ERROR)	571.5 (48.9)	619.1 (20.3)	590.5 (41.5)	655.8 (13.8)
MEAN LIFE SPAN (D) (STANDARD ERROR)	691.2 (14.9)	698.2 (9.0)	684.7 (15.9)	710.0 (5.8)

*** END OF REPORT ***

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