

TDMS No. 20008 - 04
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: MICE/B6C3F1

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Milk thistle extract
CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
Time Report Requested: 13:13:48
First Dose M/F: 03/25/03 / 03/25/03
Lab: SRI

F1_M3

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

DOSE = 0 PPM

TOTAL 50 UNCENSORED DEATHS 5 CENSORED DEATHS 0 TERMINAL 45
UNCENSORED DEATH DAYS:
389 427 588 699 712
CENSORED DEATH DAYS:
None

DOSE = 12500 PPM

TOTAL 50 UNCENSORED DEATHS 4 CENSORED DEATHS 0 TERMINAL 46
UNCENSORED DEATH DAYS:
437 633 642 716
CENSORED DEATH DAYS:
None

DOSE = 25000 PPM

TOTAL 50 UNCENSORED DEATHS 7 CENSORED DEATHS 0 TERMINAL 43
UNCENSORED DEATH DAYS:
460 638 657 659 663 693 712
CENSORED DEATH DAYS:
None

DOSE = 50000 PPM

TOTAL 50 UNCENSORED DEATHS 1 CENSORED DEATHS 0 TERMINAL 49
UNCENSORED DEATH DAYS:
693
CENSORED DEATH DAYS:
None

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MALE MICE

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	98.0	96.0	96.0	94.0	94.0	90.0
12500 PPM	100.0	100.0	100.0	100.0	100.0	98.0	98.0	98.0	94.0	92.0
25000 PPM	100.0	100.0	100.0	100.0	100.0	98.0	98.0	98.0	90.0	86.0
50000 PPM	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	98.0

(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 729 DAYS

SURVIVAL SUMMARY STATISTICS

DOSE	0 PPM	12500 PPM	25000 PPM	50000 PPM
SURVIVAL AT END OF STUDY (KAPLAN-MEIER)	90.0%	92.0%	86.0%	98.0%
SIGNIFICANCE (B) (LIFE TABLE)	P=0.241N	P=0.972N	P=0.764	P=0.204N
MEAN DAY OF NATURAL DEATHS (C) (STANDARD ERROR)	563.0 (67.1)	607.0 (59.6)	640.3 (31.5)	693.0 (.)
MEAN LIFE SPAN (D) (STANDARD ERROR)	712.4 (9.3)	719.2 (6.3)	716.6 (6.0)	728.3 (0.7)

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

DOSE = 0 PPM

TOTAL 50 UNCENSORED DEATHS 10 CENSORED DEATHS 0 TERMINAL 40
UNCENSORED DEATH DAYS:
549 560 582 618 629 644 685 705 717 728
CENSORED DEATH DAYS:
None

DOSE = 12500 PPM

TOTAL 50 UNCENSORED DEATHS 7 CENSORED DEATHS 0 TERMINAL 43
UNCENSORED DEATH DAYS:
371 406 450 649 664 675 725
CENSORED DEATH DAYS:
None

DOSE = 25000 PPM

TOTAL 50 UNCENSORED DEATHS 8 CENSORED DEATHS 0 TERMINAL 42
UNCENSORED DEATH DAYS:
602 637 659 661 665 674 688 697
CENSORED DEATH DAYS:
None

DOSE = 50000 PPM

TOTAL 50 UNCENSORED DEATHS 4 CENSORED DEATHS 1 TERMINAL 45
UNCENSORED DEATH DAYS:
632 659 688 721
CENSORED DEATH DAYS:
196

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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	100.0	100.0	94.0	88.0	80.0
12500 PPM	100.0	100.0	100.0	100.0	96.0	94.0	94.0	94.0	90.0	86.0
25000 PPM	100.0	100.0	100.0	100.0	100.0	100.0	100.0	98.0	90.0	84.0
50000 PPM	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	95.9	91.8

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SURVIVAL SUMMARY STATISTICS

DOSE	0 PPM	12500 PPM	25000 PPM	50000 PPM
SURVIVAL AT END OF STUDY (KAPLAN-MEIER)	80.0%	86.0%	84.0%	91.8%
SIGNIFICANCE (B) (LIFE TABLE)	P=0.145N	P=0.610N	P=0.757N	P=0.146N
MEAN DAY OF NATURAL DEATHS (C) (STANDARD ERROR)	641.7 (20.7)	562.9 (55.8)	660.4 (10.6)	675.0 (19.1)
MEAN LIFE SPAN (D) (STANDARD ERROR)	711.5 (6.4)	705.7 (11.0)	718.0 (3.9)	714.0 (10.9)

*** END OF REPORT ***

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