

TDMS No. 99007 - 05
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: RATS/F 344

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Goldenseal root powder
CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
Time Report Requested: 08:34:31
First Dose M/F: 04/21/03 / 04/21/03
Lab: SRI

F1_R2

C Number: C99007B
Lock Date: 08/07/2006
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 17 CENSORED DEATHS 0 TERMINAL 33
UNCENSORED DEATH DAYS:
407 422 456 501 561 563 571 575 583 593 600 611 656 663
706 711 716
CENSORED DEATH DAYS:
None

DOSE = 3000 PPM

TOTAL 50 UNCENSORED DEATHS 21 CENSORED DEATHS 0 TERMINAL 29
UNCENSORED DEATH DAYS:
355 437 506 509 517 530 563 565 576 632 642 645 649 656
663 666 678 684 696 711 723
CENSORED DEATH DAYS:
None

DOSE = 9000 PPM

TOTAL 50 UNCENSORED DEATHS 20 CENSORED DEATHS 0 TERMINAL 30
UNCENSORED DEATH DAYS:
316 431 534 556 563 594 618 635 644 649 659 663 688 690
696 696 701 703 709 724
CENSORED DEATH DAYS:
None

DOSE = 25000 PPM

TOTAL 50 UNCENSORED DEATHS 25 CENSORED DEATHS 0 TERMINAL 25
UNCENSORED DEATH DAYS:
208 450 451 478 509 523 547 572 590 590 612 612 627 630
635 653 656 674 684 688 696 703 711 716 723

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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	100.0	100.0	96.0	94.0	92.0	78.0	72.0	66.0
3000 PPM	100.0	100.0	100.0	98.0	98.0	96.0	88.0	82.0	70.0	58.0
9000 PPM	100.0	100.0	100.0	98.0	98.0	96.0	94.0	88.0	76.0	60.0
25000 PPM	100.0	100.0	98.0	98.0	98.0	92.0	88.0	80.0	66.0	50.0

(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	3000 PPM	9000 PPM	25000 PPM
SURVIVAL AT END OF STUDY (KAPLAN-MEIER)	66.0%	58.0%	60.0%	50.0%
SIGNIFICANCE (B) (LIFE TABLE)	P=0.186	P=0.574	P=0.794	P=0.195
MEAN DAY OF NATURAL DEATHS (C) (STANDARD ERROR)	582.1 (22.9)	600.1 (21.1)	623.5 (23.0)	597.5 (23.1)
MEAN LIFE SPAN (D) (STANDARD ERROR)	679.0 (12.5)	674.9 (12.6)	686.8 (11.7)	663.3 (14.8)

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

DOSE = 0 PPM

TOTAL 50 UNCENSORED DEATHS 20 CENSORED DEATHS 0 TERMINAL 30
UNCENSORED DEATH DAYS:
404 537 575 575 611 627 627 663 666 682 689 690 696 703
709 711 711 716 719 723
CENSORED DEATH DAYS:
None

DOSE = 3000 PPM

TOTAL 50 UNCENSORED DEATHS 14 CENSORED DEATHS 0 TERMINAL 36
UNCENSORED DEATH DAYS:
59 568 585 589 627 635 639 642 647 647 653 661 709 726
CENSORED DEATH DAYS:
None

DOSE = 9000 PPM

TOTAL 50 UNCENSORED DEATHS 8 CENSORED DEATHS 0 TERMINAL 42
UNCENSORED DEATH DAYS:
13 474 563 565 569 652 663 666
CENSORED DEATH DAYS:
None

DOSE = 25000 PPM

TOTAL 50 UNCENSORED DEATHS 14 CENSORED DEATHS 0 TERMINAL 36
UNCENSORED DEATH DAYS:
122 563 568 575 641 666 678 684 687 701 716 716 718 726
CENSORED DEATH DAYS:
None

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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	98.0	98.0	96.0	92.0	84.0	60.0
3000 PPM	98.0	98.0	98.0	98.0	98.0	98.0	98.0	92.0	76.0	72.0
9000 PPM	98.0	98.0	98.0	98.0	98.0	96.0	96.0	90.0	86.0	84.0
25000 PPM	100.0	98.0	98.0	98.0	98.0	98.0	98.0	92.0	90.0	72.0

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SURVIVAL SUMMARY STATISTICS

DOSE	0 PPM	3000 PPM	9000 PPM	25000 PPM
SURVIVAL AT END OF STUDY (KAPLAN-MEIER)	60.0%	72.0%	84.0%	72.0%
SIGNIFICANCE (B) (LIFE TABLE)	P=0.425N	P=0.367N	P=0.025N	P=0.283N
MEAN DAY OF NATURAL DEATHS (C) (STANDARD ERROR)	651.7 (17.9)	599.1 (43.1)	520.6 (76.1)	625.8 (41.7)
MEAN LIFE SPAN (D) (STANDARD ERROR)	698.1 (8.9)	692.6 (14.4)	695.7 (15.9)	700.1 (13.1)

*** END OF REPORT ***

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