

**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)

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**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

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**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

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**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

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**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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**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)
<b>0 PPM</b>	100.0	100.0	100.0	100.0	96.0	94.0	92.0	78.0	72.0	66.0
<b>3000 PPM</b>	100.0	100.0	100.0	98.0	98.0	96.0	88.0	82.0	70.0	58.0
<b>9000 PPM</b>	100.0	100.0	100.0	98.0	98.0	96.0	94.0	88.0	76.0	60.0
<b>25000 PPM</b>	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**

<b>DOSE</b>	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	66.0%	58.0%	60.0%	50.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.186	P=0.574	P=0.794	P=0.195
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	582.1 (22.9)	600.1 (21.1)	623.5 (23.0)	597.5 (23.1)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	679.0 (12.5)	674.9 (12.6)	686.8 (11.7)	663.3 (14.8)

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Lab: SRI

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

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**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

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**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

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**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

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**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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**FEMALE RATS**  
FIRST TERMINAL SACRIFICE AT 729 DAYS

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**KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)**

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DOSE	TIME (DAYS)									
	90	180	270	365	425	485	545	605	665	729(A)
<b>0 PPM</b>	100.0	100.0	100.0	100.0	98.0	98.0	96.0	92.0	84.0	60.0
<b>3000 PPM</b>	98.0	98.0	98.0	98.0	98.0	98.0	98.0	92.0	76.0	72.0
<b>9000 PPM</b>	98.0	98.0	98.0	98.0	98.0	96.0	96.0	90.0	86.0	84.0
<b>25000 PPM</b>	100.0	98.0	98.0	98.0	98.0	98.0	98.0	92.0	90.0	72.0

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FIRST TERMINAL SACRIFICE AT 729 DAYS

**SURVIVAL SUMMARY STATISTICS**

DOSE	0 PPM	3000 PPM	9000 PPM	25000 PPM
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	60.0%	72.0%	84.0%	72.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.425N	P=0.367N	P=0.025N	P=0.283N
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	651.7 (17.9)	599.1 (43.1)	520.6 (76.1)	625.8 (41.7)
<b>MEAN LIFE SPAN (D)</b> (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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(D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)