

**TDMS No.** 99007 - 06  
**Test Type:** CHRONIC  
**Route:** DOSED FEED  
**Species/Strain:** MICE/B6C3F1

**P11: STATISTICAL ANALYSIS OF SURVIVAL DATA**

Goldenseal root powder

**CAS Number:** GOLDENSEALRT

**Date Report Requested:** 06/25/2008

**Time Report Requested:** 13:40:20

**First Dose M/F:** 05/12/03 / 05/12/03

**Lab:** SRI

**C Number:** C99007B  
**Lock Date:** 08/29/2006  
**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

TDMS No. 99007 - 06  
Test Type: CHRONIC  
Route: DOSED FEED  
Species/Strain: MICE/B6C3F1

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA  
Goldenseal root powder  
CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
Time Report Requested: 13:40:20  
First Dose M/F: 05/12/03 / 05/12/03  
Lab: SRI

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

---

**DOSE = 0 PPM**

TOTAL 50                      UNCENSORED DEATHS 7                      CENSORED DEATHS 0                      TERMINAL 43  
UNCENSORED DEATH DAYS:  
496   550   632   664   677   681   705  
CENSORED DEATH DAYS:  
None

---

**DOSE = 3000 PPM**

TOTAL 50                      UNCENSORED DEATHS 12                      CENSORED DEATHS 0                      TERMINAL 38  
UNCENSORED DEATH DAYS:  
555   557   563   624   625   636   673   677   680   703   709   713  
CENSORED DEATH DAYS:  
None

---

**DOSE = 9000 PPM**

TOTAL 50                      UNCENSORED DEATHS 5                      CENSORED DEATHS 0                      TERMINAL 45  
UNCENSORED DEATH DAYS:  
551   551   563   624   666  
CENSORED DEATH DAYS:  
None

---

**DOSE = 25000 PPM**

TOTAL 50                      UNCENSORED DEATHS 5                      CENSORED DEATHS 0                      TERMINAL 45  
UNCENSORED DEATH DAYS:  
596   631   697   710   722  
CENSORED DEATH DAYS:  
None

**TDMS No.** 99007 - 06  
**Test Type:** CHRONIC  
**Route:** DOSED FEED  
**Species/Strain:** MICE/B6C3F1

**P11: STATISTICAL ANALYSIS OF SURVIVAL DATA**  
 Goldenseal root powder  
**CAS Number:** GOLDENSEALRT

**Date Report Requested:** 06/25/2008  
**Time Report Requested:** 13:40:20  
**First Dose M/F:** 05/12/03 / 05/12/03  
**Lab:** SRI

**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)
<b>0 PPM</b>	100.0	100.0	100.0	100.0	100.0	100.0	98.0	96.0	92.0	86.0
<b>3000 PPM</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	94.0	88.0	76.0
<b>9000 PPM</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	94.0	92.0	90.0
<b>25000 PPM</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	98.0	96.0	90.0

- (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)

TDMS No. 99007 - 06  
Test Type: CHRONIC  
Route: DOSED FEED  
Species/Strain: MICE/B6C3F1

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA  
Goldenseal root powder  
CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
Time Report Requested: 13:40:20  
First Dose M/F: 05/12/03 / 05/12/03  
Lab: SRI

**MALE MICE**  
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)	86.0%	76.0%	90.0%	90.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.245N	P=0.310	P=0.771N	P=0.716N
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	629.3 (29.3)	642.9 (17.1)	591.0 (23.1)	671.2 (24.5)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	715.0 (6.3)	708.3 (6.6)	715.2 (6.3)	723.2 (3.3)

- (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. 99007 - 06  
Test Type: CHRONIC  
Route: DOSED FEED  
Species/Strain: MICE/B6C3F1

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA  
Goldenseal root powder  
CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
Time Report Requested: 13:40:20  
First Dose M/F: 05/12/03 / 05/12/03  
Lab: SRI

**FEMALE 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:  
516    535    604    621    709  
CENSORED DEATH DAYS:  
None

---

**DOSE = 3000 PPM**

TOTAL 50                      UNCENSORED DEATHS 6                      CENSORED DEATHS 0                      TERMINAL 44  
UNCENSORED DEATH DAYS:  
428    482    522    696    696    719  
CENSORED DEATH DAYS:  
None

---

**DOSE = 9000 PPM**

TOTAL 50                      UNCENSORED DEATHS 14                      CENSORED DEATHS 0                      TERMINAL 36  
UNCENSORED DEATH DAYS:  
5       359    516    633    652    654    657    672    677    679    693    703    708    719  
CENSORED DEATH DAYS:  
None

---

**DOSE = 25000 PPM**

TOTAL 50                      UNCENSORED DEATHS 7                      CENSORED DEATHS 0                      TERMINAL 43  
UNCENSORED DEATH DAYS:  
307    521    544    563    684    692    695  
CENSORED DEATH DAYS:  
None

**TDMS No.** 99007 - 06  
**Test Type:** CHRONIC  
**Route:** DOSED FEED  
**Species/Strain:** MICE/B6C3F1

**P11: STATISTICAL ANALYSIS OF SURVIVAL DATA**  
 Goldenseal root powder  
**CAS Number:** GOLDENSEALRT

**Date Report Requested:** 06/25/2008  
**Time Report Requested:** 13:40:20  
**First Dose M/F:** 05/12/03 / 05/12/03  
**Lab:** SRI

**FEMALE 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)
<b>0 PPM</b>	100.0	100.0	100.0	100.0	100.0	100.0	96.0	94.0	92.0	90.0
<b>3000 PPM</b>	100.0	100.0	100.0	100.0	100.0	96.0	94.0	94.0	94.0	88.0
<b>9000 PPM</b>	98.0	98.0	98.0	96.0	96.0	96.0	94.0	94.0	86.0	72.0
<b>25000 PPM</b>	100.0	100.0	100.0	98.0	98.0	98.0	94.0	92.0	92.0	86.0

- (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)

TDMS No. 99007 - 06  
Test Type: CHRONIC  
Route: DOSED FEED  
Species/Strain: MICE/B6C3F1

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA  
Goldenseal root powder  
CAS Number: GOLDENSEALRT

Date Report Requested: 06/25/2008  
Time Report Requested: 13:40:20  
First Dose M/F: 05/12/03 / 05/12/03  
Lab: SRI

**FEMALE MICE**  
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)	90.0%	88.0%	72.0%	86.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	P=0.744	P=0.985	P=0.046	P=0.744
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	597.0 (34.3)	590.5 (52.2)	594.8 (51.9)	572.3 (52.5)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	715.8 (6.5)	712.4 (8.6)	691.4 (16.6)	707.1 (10.4)

\*\*\* 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)