Test Type: 90-DAY

Species/Strain: Rat/F 344/N

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 10/16/2014 Time Report Requested: 02:32:54

First Dose M/F: NA / NA

Lab: SRI

C Number: C99007B

Lock Date: 09/23/2002

Cage Range: ΑII

Date Range: ΑII

Reasons For Removal: ΑII

Removal Date Range: ΑII

Treatment Groups: ΑII

Study Gender: Both

PWG Approval Date NONE

Species/Strain: Rat/F 344/N

Test Type: 90-DAY

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 10/16/2014 Time Report Requested: 02:32:54

First Dose M/F: NA / NA

Lab: SRI

Male RAT FIRST TERMINAL SACRIFICE AT 94 DAYS INDIVIDUAL SURVIVAL TIMES (DAYS)

| IND | INIDUAL SURVIVAL TIMES (DAT | <u> </u> | |
|---------------------|---|---|--|
| | | | |
| UNCENSORED DEATHS 0 | CENSORED DEATHS 0 | TERMINAL 10 | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| UNCENSORED DEATHS 0 | CENSORED DEATHS 0 | TERMINAL 10 | |
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| | | | |
| UNCENSORED DEATHS 0 | CENSORED DEATHS 0 | TERMINAL 10 | |
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| | | | |
| UNCENSORED DEATHS 0 | CENSORED DEATHS 0 | TERMINAL 10 | |
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| | UNCENSORED DEATHS 0 UNCENSORED DEATHS 0 UNCENSORED DEATHS 0 | UNCENSORED DEATHS 0 CENSORED DEATHS 0 UNCENSORED DEATHS 0 CENSORED DEATHS 0 UNCENSORED DEATHS 0 CENSORED DEATHS 0 | UNCENSORED DEATHS 0 CENSORED DEATHS 0 TERMINAL 10 UNCENSORED DEATHS 0 CENSORED DEATHS 0 TERMINAL 10 |

⁽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)

Species/Strain: Rat/F 344/N

Test Type: 90-DAY

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 10/16/2014 Time Report Requested: 02:32:54

First Dose M/F: NA / NA

Lab: SRI

Male RAT FIRST TERMINAL SACRIFICE AT 94 DAYS INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = 25000 PPM

TOTAL 10

UNCENSORED DEATHS 0

CENSORED DEATHS 0

TERMINAL 10

UNCENSORED DEATH DAYS

none

CENSORED DEATH DAYS

none

DOSE = 50000 PPM

TOTAL 10

UNCENSORED DEATHS 0

CENSORED DEATHS 0

TERMINAL 10

UNCENSORED DEATH DAYS

none

CENSORED DEATH DAYS

none

⁽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)

Species/Strain: Rat/F 344/N

Test Type: 90-DAY

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 10/16/2014 Time Report Requested: 02:32:54

First Dose M/F: NA / NA

Lab: SRI

Male RAT FIRST TERMINAL SACRIFICE AT 94 DAYS

KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)

| DOSE | | | | | TIME | (DAYS) | | | | |
|-----------|-------|-------|-------|-------|-------|--------|-------|-------|-------|-------|
| | 10 | 20 | 30 | 40 | 50 | 60 | 70 | 80 | 90 | 94(A) |
| 0 PPM | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 3125 PPM | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 6250 PPM | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 12500 PPM | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 25000 PPM | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 50000 PPM | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

⁽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)

Species/Strain: Rat/F 344/N

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Type: 90-DAY

Test Compound: Goldenseal root powder **CAS Number:** GOLDENSEALRT

Date Report Requested: 10/16/2014 Time Report Requested: 02:32:54

First Dose M/F: NA / NA

Lab: SRI

Male RAT FIRST TERMINAL SACRIFICE AT 94 DAYS

| DOSE | 0 PPM | 3125 PPM | 6250 PPM | 12500 PPM | |
|--------------------------------|--------|----------|----------|-----------|--|
| SURVIVAL AT END OF STUDY | 100.0% | 100.0% | 100.0% | 100.0% | |
| (KAPLAN-MEIER) | | | | | |
| SIGNIFICANCE (B) | | | | | |
| (LIFE TABLE) | | | | | |
| MEAN DAY OF NATURAL DEATHS (C) | | | | | |
| (STANDARD ERROR) | (.) | (.) | (.) | (.) | |
| MEAN LIFE SPAN (D) | 94.0 | 94.0 | 94.0 | 94.0 | |
| (STANDARD ERROR) | (0.0) | (0.0) | (0.0) | (0.0) | |

⁽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)

Species/Strain: Rat/F 344/N

Test Type: 90-DAY

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 10/16/2014 Time Report Requested: 02:32:54

First Dose M/F: NA / NA

Lab: SRI

Male RAT FIRST TERMINAL SACRIFICE AT 94 DAYS

| DOSE | 25000 PPM | 50000 PPM |
|--------------------------------|-----------|-----------|
| SURVIVAL AT END OF STUDY | 100.0% | 100.0% |
| (KAPLAN-MEIER) | | |
| SIGNIFICANCE (B) | | |
| (LIFE TABLE) | | |
| MEAN DAY OF NATURAL DEATHS (C) | | |
| (STANDARD ERROR) | (.) | (.) |
| MEAN LIFE SPAN (D) | 94.0 | 94.0 |
| (STANDARD ERROR) | (0.0) | (0.0) |

⁽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)

Species/Strain: Rat/F 344/N

Test Type: 90-DAY

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 10/16/2014 Time Report Requested: 02:32:54

First Dose M/F: NA / NA

Lab: SRI

Female RAT FIRST TERMINAL SACRIFICE AT 94 DAYS INDIVIDUAL SURVIVAL TIMES (DAYS)

| | 1112 | THEORE CONTINAL TIMES (BATT | | |
|-----------------------|---------------------|-----------------------------|-------------|--|
| DOSE = 0 PPM | | | | |
| TOTAL 10 | UNCENSORED DEATHS 0 | CENSORED DEATHS 0 | TERMINAL 10 | |
| UNCENSORED DEATH DAYS | | | | |
| none | | | | |
| CENSORED DEATH DAYS | | | | |
| none | | | | |
| DOSE = 3125 PPM | | | | |
| TOTAL 10 | UNCENSORED DEATHS 0 | CENSORED DEATHS 0 | TERMINAL 10 | |
| UNCENSORED DEATH DAYS | | | | |
| none | | | | |
| CENSORED DEATH DAYS | | | | |
| none | | | | |
| DOSE = 6250 PPM | | | | |
| TOTAL 10 | UNCENSORED DEATHS 0 | CENSORED DEATHS 0 | TERMINAL 10 | |
| UNCENSORED DEATH DAYS | | | | |
| none | | | | |
| CENSORED DEATH DAYS | | | | |
| none | | | | |
| DOSE = 12500 PPM | | | | |
| TOTAL 10 | UNCENSORED DEATHS 0 | CENSORED DEATHS 0 | TERMINAL 10 | |
| UNCENSORED DEATH DAYS | | | | |
| none | | | | |
| CENSORED DEATH DAYS | | | | |
| none | | | | |

⁽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)

Species/Strain: Rat/F 344/N

Test Type: 90-DAY

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 10/16/2014 Time Report Requested: 02:32:54

First Dose M/F: NA / NA

Lab: SRI

Female RAT FIRST TERMINAL SACRIFICE AT 94 DAYS INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = 25000 PPM

TOTAL 10

UNCENSORED DEATHS 0

CENSORED DEATHS 0

TERMINAL 10

UNCENSORED DEATH DAYS

none

CENSORED DEATH DAYS

none

DOSE = 50000 PPM

TOTAL 10

UNCENSORED DEATHS 0

CENSORED DEATHS 0

TERMINAL 10

UNCENSORED DEATH DAYS

none

CENSORED DEATH DAYS

none

⁽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".

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Species/Strain: Rat/F 344/N

Test Type: 90-DAY

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 10/16/2014 Time Report Requested: 02:32:54

First Dose M/F: NA / NA

Lab: SRI

Female RAT FIRST TERMINAL SACRIFICE AT 94 DAYS

KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)

| DOSE | | | | | TIME | (DAYS) | | | | |
|-----------|-------|-------|-------|-------|-------|--------|-------|-------|-------|-------|
| | 10 | 20 | 30 | 40 | 50 | 60 | 70 | 80 | 90 | 94(A) |
| 0 PPM | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 3125 PPM | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 6250 PPM | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 12500 PPM | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 25000 PPM | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 50000 PPM | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

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⁽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".

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P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Type: 90-DAY

Test Compound: Goldenseal root powder **CAS Number:** GOLDENSEALRT

Species/Strain: Rat/F 344/N

Time Report Requested: 02:32:54

Date Report Requested: 10/16/2014

First Dose M/F: NA / NA

Lab: SRI

Female RAT FIRST TERMINAL SACRIFICE AT 94 DAYS

| DOSE | 0 PPM | 3125 PPM | 6250 PPM | 12500 PPM | |
|--------------------------------|--------|----------|----------|-----------|--|
| SURVIVAL AT END OF STUDY | 100.0% | 100.0% | 100.0% | 100.0% | |
| (KAPLAN-MEIER) | | | | | |
| SIGNIFICANCE (B) | | | | | |
| (LIFE TABLE) | | | | | |
| MEAN DAY OF NATURAL DEATHS (C) | • | | | | |
| (STANDARD ERROR) | (.) | (.) | (.) | (.) | |
| MEAN LIFE SPAN (D) | 94.0 | 94.0 | 94.0 | 94.0 | |
| (STANDARD ERROR) | (0.0) | (0.0) | (0.0) | (0.0) | |

⁽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".

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⁽D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Species/Strain: Rat/F 344/N

Test Type: 90-DAY

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 10/16/2014 Time Report Requested: 02:32:54

First Dose M/F: NA / NA

Lab: SRI

Female RAT FIRST TERMINAL SACRIFICE AT 94 DAYS

| DOSE | 25000 PPM | 50000 PPM |
|--------------------------------|-----------|-----------|
| SURVIVAL AT END OF STUDY | 100.0% | 100.0% |
| (KAPLAN-MEIER) | | |
| SIGNIFICANCE (B) | | |
| (LIFE TABLE) | | |
| MEAN DAY OF NATURAL DEATHS (C) | • | |
| (STANDARD ERROR) | (.) | (.) |
| MEAN LIFE SPAN (D) | 94.0 | 94.0 |
| (STANDARD ERROR) | (0.0) | (0.0) |

⁽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".

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⁽D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Test Type: 90-DAY

Species/Strain: Rat/F 344/N

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 10/16/2014 Time Report Requested: 02:32:54

First Dose M/F: NA / NA

Lab: SRI

** 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)