

Experiment Number: 88122-01
Test Type: 14-DAY
Route: GAVAGE
Species/Strain: Rat/F 344/N

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA
Test Compound: Elmiron (sodium pentosanpolysulfate)
CAS Number: 37319-17-8

Date Report Requested: 10/18/2014
Time Report Requested: 14:05:00
First Dose M/F: NA / NA
Lab: MBA

C Number: C88122B
Lock Date: 08/21/1995
Cage Range: All
Date Range: All
Reasons For Removal: All
Removal Date Range: All
Treatment Groups: All
Study Gender: Both
PWG Approval Date: NONE

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First Dose M/F: NA / NA

Lab: MBA

Male RAT
FIRST TERMINAL SACRIFICE AT 17 DAYS
INDIVIDUAL SURVIVAL TIMES (DAYS)

| | | | | |
|------------------------------|--------------|---------------------|-------------------|------------|
| DOSE = 0 | MG/KG | | | |
| TOTAL 5 | | UNCENSORED DEATHS 0 | CENSORED DEATHS 0 | TERMINAL 5 |
| UNCENSORED DEATH DAYS | | | | |
| none | | | | |
| CENSORED DEATH DAYS | | | | |
| none | | | | |

| | | | | |
|------------------------------|--------------|---------------------|-------------------|------------|
| DOSE = 33 | MG/KG | | | |
| TOTAL 5 | | UNCENSORED DEATHS 0 | CENSORED DEATHS 0 | TERMINAL 5 |
| UNCENSORED DEATH DAYS | | | | |
| none | | | | |
| CENSORED DEATH DAYS | | | | |
| none | | | | |

| | | | | |
|------------------------------|--------------|---------------------|-------------------|------------|
| DOSE = 111 | MG/KG | | | |
| TOTAL 5 | | UNCENSORED DEATHS 0 | CENSORED DEATHS 0 | TERMINAL 5 |
| UNCENSORED DEATH DAYS | | | | |
| none | | | | |
| CENSORED DEATH DAYS | | | | |
| none | | | | |

| | | | | |
|------------------------------|--------------|---------------------|-------------------|------------|
| DOSE = 333 | MG/KG | | | |
| TOTAL 5 | | UNCENSORED DEATHS 0 | CENSORED DEATHS 0 | TERMINAL 5 |
| 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)

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Lab: MBA

Male RAT
FIRST TERMINAL SACRIFICE AT 17 DAYS
INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = 1000 MG/KG

TOTAL 5 UNCENSORED DEATHS 0 CENSORED DEATHS 0 TERMINAL 5

UNCENSORED DEATH DAYS

none

CENSORED DEATH DAYS

none

DOSE = 3000 MG/KG

TOTAL 5 UNCENSORED DEATHS 0 CENSORED DEATHS 0 TERMINAL 5

UNCENSORED DEATH DAYS

none

CENSORED DEATH DAYS

none

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First Dose M/F: NA / NA
Lab: MBA

Male RAT
FIRST TERMINAL SACRIFICE AT 17 DAYS

KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)

| DOSE | TIME (DAYS) | | | | | | | | | |
|-------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | 18 | 17(A) |
| 0 MG/KG | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 33 MG/KG | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 111 MG/KG | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 333 MG/KG | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 1000 MG/KG | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 3000 MG/KG | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

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(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

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

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Species/Strain: Rat/F 344/N

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First Dose M/F: NA / NA
Lab: MBA

Male RAT
FIRST TERMINAL SACRIFICE AT 17 DAYS

SURVIVAL SUMMARY STATISTICS

| DOSE | 0 MG/KG | 33 MG/KG | 111 MG/KG | 333 MG/KG |
|---|---------------|---------------|---------------|---------------|
| SURVIVAL AT END OF STUDY (KAPLAN-MEIER) | 100.0% | 100.0% | 100.0% | 100.0% |
| SIGNIFICANCE (B) (LIFE TABLE) | ----- | ----- | ----- | ----- |
| MEAN DAY OF NATURAL DEATHS (C) (STANDARD ERROR) | . (.) | . (.) | . (.) | . (.) |
| MEAN LIFE SPAN (D) (STANDARD ERROR) | 17.0 (0.0) | 17.0 (0.0) | 17.0 (0.0) | 17.0 (0.0) |

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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".

(C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

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

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Route: GAVAGE
Species/Strain: Rat/F 344/N

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Time Report Requested: 14:05:00
First Dose M/F: NA / NA
Lab: MBA

Male RAT
FIRST TERMINAL SACRIFICE AT 17 DAYS

SURVIVAL SUMMARY STATISTICS

| DOSE | 1000 MG/KG | 3000 MG/KG |
|---|---------------|---------------|
| SURVIVAL AT END OF STUDY (KAPLAN-MEIER) | 100.0% | 100.0% |
| SIGNIFICANCE (B) (LIFE TABLE) | ----- | ----- |
| MEAN DAY OF NATURAL DEATHS (C) (STANDARD ERROR) | . (.) | . (.) |
| MEAN LIFE SPAN (D) (STANDARD ERROR) | 17.0 (0.0) | 17.0 (0.0) |

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Experiment Number: 88122-01
Test Type: 14-DAY
Route: GAVAGE
Species/Strain: Rat/F 344/N

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA
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CAS Number: 37319-17-8

Date Report Requested: 10/18/2014
Time Report Requested: 14:05:00
First Dose M/F: NA / NA
Lab: MBA

Female RAT
FIRST TERMINAL SACRIFICE AT 17 DAYS
INDIVIDUAL SURVIVAL TIMES (DAYS)

| | | | | |
|------------------------------|--------------|---------------------|-------------------|------------|
| DOSE = 0 | MG/KG | | | |
| TOTAL 5 | | UNCENSORED DEATHS 0 | CENSORED DEATHS 0 | TERMINAL 5 |
| UNCENSORED DEATH DAYS | | | | |
| none | | | | |
| CENSORED DEATH DAYS | | | | |
| none | | | | |

| | | | | |
|------------------------------|--------------|---------------------|-------------------|------------|
| DOSE = 33 | MG/KG | | | |
| TOTAL 5 | | UNCENSORED DEATHS 0 | CENSORED DEATHS 0 | TERMINAL 5 |
| UNCENSORED DEATH DAYS | | | | |
| none | | | | |
| CENSORED DEATH DAYS | | | | |
| none | | | | |

| | | | | |
|------------------------------|--------------|---------------------|-------------------|------------|
| DOSE = 111 | MG/KG | | | |
| TOTAL 5 | | UNCENSORED DEATHS 0 | CENSORED DEATHS 0 | TERMINAL 5 |
| UNCENSORED DEATH DAYS | | | | |
| none | | | | |
| CENSORED DEATH DAYS | | | | |
| none | | | | |

| | | | | |
|------------------------------|--------------|---------------------|-------------------|------------|
| DOSE = 333 | MG/KG | | | |
| TOTAL 5 | | UNCENSORED DEATHS 0 | CENSORED DEATHS 0 | TERMINAL 5 |
| UNCENSORED DEATH DAYS | | | | |
| none | | | | |
| CENSORED DEATH DAYS | | | | |
| none | | | | |

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Lab: MBA

Female RAT
FIRST TERMINAL SACRIFICE AT 17 DAYS
INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = 1000 MG/KG

TOTAL 5 UNCENSORED DEATHS 0 CENSORED DEATHS 0 TERMINAL 5

UNCENSORED DEATH DAYS

none

CENSORED DEATH DAYS

none

DOSE = 3000 MG/KG

TOTAL 5 UNCENSORED DEATHS 0 CENSORED DEATHS 0 TERMINAL 5

UNCENSORED DEATH DAYS

none

CENSORED DEATH DAYS

none

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Female RAT
FIRST TERMINAL SACRIFICE AT 17 DAYS

KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)

| DOSE | TIME (DAYS) | | | | | | | | | |
|-------------------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | 18 | 17(A) |
| 0 MG/KG | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 33 MG/KG | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 111 MG/KG | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
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| 1000 MG/KG | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |
| 3000 MG/KG | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

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Female RAT
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| DOSE | 0 MG/KG | 33 MG/KG | 111 MG/KG | 333 MG/KG |
|---|---------------|---------------|---------------|---------------|
| SURVIVAL AT END OF STUDY (KAPLAN-MEIER) | 100.0% | 100.0% | 100.0% | 100.0% |
| SIGNIFICANCE (B) (LIFE TABLE) | ----- | ----- | ----- | ----- |
| MEAN DAY OF NATURAL DEATHS (C) (STANDARD ERROR) | . (.) | . (.) | . (.) | . (.) |
| MEAN LIFE SPAN (D) (STANDARD ERROR) | 17.0 (0.0) | 17.0 (0.0) | 17.0 (0.0) | 17.0 (0.0) |

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|---|---------------|---------------|
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Lab: MBA

**** END OF REPORT ****

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