

**Experiment Number:** 88122-03  
**Test Type:** 90-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:** 10/19/2014  
**Time Report Requested:** 16:05:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

<b>C Number:</b>	C88122
<b>Lock Date:</b>	11/13/1996
<b>Cage Range:</b>	All
<b>Date Range:</b>	All
<b>Reasons For Removal:</b>	All
<b>Removal Date Range:</b>	All
<b>Treatment Groups:</b>	All
<b>Study Gender:</b>	Both
<b>PWG Approval Date</b>	NONE

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First Dose M/F: NA / NA

Lab: BAT

Male RAT  
FIRST TERMINAL SACRIFICE AT 93 DAYS  
INDIVIDUAL SURVIVAL TIMES (DAYS)

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<b>DOSE = 0 MG/KG</b>			
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10
<b>UNCENSORED DEATH DAYS</b>			
none			
<b>CENSORED DEATH DAYS</b>			
none			

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<b>DOSE = 63 MG/KG</b>			
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 1	TERMINAL 9
<b>UNCENSORED DEATH DAYS</b>			
none			
<b>CENSORED DEATH DAYS</b>			
57			

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<b>DOSE = 125 MG/KG</b>			
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10
<b>UNCENSORED DEATH DAYS</b>			
none			
<b>CENSORED DEATH DAYS</b>			
none			

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<b>DOSE = 250 MG/KG</b>			
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10
<b>UNCENSORED DEATH DAYS</b>			
none			
<b>CENSORED DEATH DAYS</b>			
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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**First Dose M/F:** NA / NA  
**Lab:** BAT

**Male RAT**  
**FIRST TERMINAL SACRIFICE AT 93 DAYS**  
**INDIVIDUAL SURVIVAL TIMES (DAYS)**

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**DOSE = 500 MG/KG**

TOTAL 10                      UNCENSORED DEATHS 0                      CENSORED DEATHS 1                      TERMINAL 9

**UNCENSORED DEATH DAYS**

none

**CENSORED DEATH DAYS**

32

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**DOSE = 1000 MG/KG**

TOTAL 10                      UNCENSORED DEATHS 0                      CENSORED DEATHS 2                      TERMINAL 8

**UNCENSORED DEATH DAYS**

none

**CENSORED DEATH DAYS**

4                      31

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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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**CAS Number:** 37319-17-8

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**First Dose M/F:** NA / NA  
**Lab:** BAT

**Male RAT**  
**FIRST TERMINAL SACRIFICE AT 93 DAYS**

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

DOSE	TIME (DAYS)									
	10	20	30	40	50	60	70	80	90	93(A)
<b>0 MG/KG</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
<b>63 MG/KG</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
<b>125 MG/KG</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
<b>250 MG/KG</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
<b>500 MG/KG</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
<b>1000 MG/KG</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

(A) FIRST TERMINAL SACRIFICE

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

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**First Dose M/F:** NA / NA  
**Lab:** BAT

Male RAT  
FIRST TERMINAL SACRIFICE AT 93 DAYS

SURVIVAL SUMMARY STATISTICS

DOSE	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	100.0%	100.0%	100.0%	100.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	-----	-----	-----	-----
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	. (.)	. (.)	. (.)	. (.)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	93.0 (0.0)	89.4 (3.6)	93.0 (0.0)	93.0 (0.0)

(A) FIRST TERMINAL SACRIFICE

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

**P11: STATISTICAL ANALYSIS OF SURVIVAL DATA**  
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**Time Report Requested:** 16:05:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

Male RAT  
FIRST TERMINAL SACRIFICE AT 93 DAYS

SURVIVAL SUMMARY STATISTICS

DOSE	500 MG/KG	1000 MG/KG
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	100.0%	100.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	-----	-----
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	. (.)	. (.)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	86.9 (6.1)	77.9 (10.3)

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**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** Rat/F 344/N

**P11: STATISTICAL ANALYSIS OF SURVIVAL DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
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**First Dose M/F:** NA / NA  
**Lab:** BAT

**Female RAT**  
**FIRST TERMINAL SACRIFICE AT 93 DAYS**  
**INDIVIDUAL SURVIVAL TIMES (DAYS)**

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<b>DOSE = 0 MG/KG</b>			
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10
<b>UNCENSORED DEATH DAYS</b>			
none			
<b>CENSORED DEATH DAYS</b>			
none			
<hr/>			
<b>DOSE = 63 MG/KG</b>			
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10
<b>UNCENSORED DEATH DAYS</b>			
none			
<b>CENSORED DEATH DAYS</b>			
none			
<hr/>			
<b>DOSE = 125 MG/KG</b>			
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10
<b>UNCENSORED DEATH DAYS</b>			
none			
<b>CENSORED DEATH DAYS</b>			
none			
<hr/>			
<b>DOSE = 250 MG/KG</b>			
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10
<b>UNCENSORED DEATH DAYS</b>			
none			
<b>CENSORED DEATH DAYS</b>			
none			

(A) FIRST TERMINAL SACRIFICE

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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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**Lab:** BAT

**Female RAT**  
**FIRST TERMINAL SACRIFICE AT 93 DAYS**  
**INDIVIDUAL SURVIVAL TIMES (DAYS)**

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**DOSE = 500 MG/KG**

TOTAL 10                      UNCENSORED DEATHS 0                      CENSORED DEATHS 0                      TERMINAL 10

**UNCENSORED DEATH DAYS**

none

**CENSORED DEATH DAYS**

none

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**DOSE = 1000 MG/KG**

TOTAL 10                      UNCENSORED DEATHS 0                      CENSORED DEATHS 0                      TERMINAL 10

**UNCENSORED DEATH DAYS**

none

**CENSORED DEATH DAYS**

none

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

DOSE	TIME (DAYS)									
	10	20	30	40	50	60	70	80	90	93(A)
<b>0 MG/KG</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
<b>63 MG/KG</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
<b>125 MG/KG</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
<b>250 MG/KG</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
<b>500 MG/KG</b>	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
<b>1000 MG/KG</b>	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  
 FIRST TERMINAL SACRIFICE AT 93 DAYS

SURVIVAL SUMMARY STATISTICS

DOSE	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	100.0%	100.0%	100.0%	100.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	-----	-----	-----	-----
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	. (.)	. (.)	. (.)	. (.)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	93.0 (0.0)	93.0 (0.0)	93.0 (0.0)	93.0 (0.0)

(A) FIRST TERMINAL SACRIFICE

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DOSE	500 MG/KG	1000 MG/KG
<b>SURVIVAL AT END OF STUDY</b> (KAPLAN-MEIER)	100.0%	100.0%
<b>SIGNIFICANCE (B)</b> (LIFE TABLE)	-----	-----
<b>MEAN DAY OF NATURAL DEATHS (C)</b> (STANDARD ERROR)	. (.)	. (.)
<b>MEAN LIFE SPAN (D)</b> (STANDARD ERROR)	93.0 (0.0)	93.0 (0.0)

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**\*\* END OF REPORT \*\***

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