**Test Type:** 90-DAY **Route:** GAVAGE

Species/Strain: Mouse/B6C3F1

# P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

**Test Compound:** Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/22/2014 Time Report Requested: 01:46:27

First Dose M/F: NA / NA

Lab: BAT

**C Number:** C88122

**Lock Date:** 11/13/1996

Cage Range: All

Date Range: All

Reasons For Removal:

Removal Date Range: All

Treatment Groups: All

Study Gender: Both

PWG Approval Date NONE

Test Type: 90-DAY

Species/Strain: Mouse/B6C3F1

Route: GAVAGE

#### P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Elmiron (sodium pentosanpolysulfate)

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

Date Report Requested: 10/22/2014 Time Report Requested: 01:46:27

First Dose M/F: NA / NA

Lab: BAT

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

	IIID	TAIDOVE SOLVILATE LINES (DVI)	3)	
DOSE = 0 MG/KG			_	
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 63 MG/KG				
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 125 MG/KG				
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 250 MG/KG				
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>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".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Test Type: 90-DAY

Species/Strain: Mouse/B6C3F1

Route: GAVAGE

#### P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

**Test Compound:** Elmiron (sodium pentosanpolysulfate)

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

Date Report Requested: 10/22/2014 Time Report Requested: 01:46:27

First Dose M/F: NA / NA

Lab: BAT

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

DOSE = 500 MG/KG

TOTAL 10

**UNCENSORED DEATHS 0** 

CENSORED DEATHS 0

**TERMINAL 10** 

**UNCENSORED DEATH DAYS** 

none

**CENSORED DEATH DAYS** 

DOSE = 1000 MG/KG

TOTAL 10

UNCENSORED DEATHS 0

**CENSORED DEATHS 0** 

**TERMINAL 10** 

**UNCENSORED DEATH DAYS** 

none

**CENSORED DEATH DAYS** 

none

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>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".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Test Type: 90-DAY

Route: GAVAGE Species/Strain: Mouse/B6C3F1 P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Elmiron (sodium pentosanpolysulfate)

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

Date Report Requested: 10/22/2014 Time Report Requested: 01:46:27

First Dose M/F: NA / NA

Lab: BAT

# Male MOUSE 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)
0 MG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
63 MG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
125 MG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
250 MG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
500 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

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>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".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Mouse/B6C3F1

#### P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

**Test Compound:** Elmiron (sodium pentosanpolysulfate)

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

Date Report Requested: 10/22/2014 Time Report Requested: 01:46:27

First Dose M/F: NA / NA

Lab: BAT

# Male MOUSE FIRST TERMINAL SACRIFICE AT 93 DAYS

DOSE	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	
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)	93.0	93.0	93.0	93.0	
(STANDARD ERROR)	(0.0)	(0.0)	(0.0)	(0.0)	

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>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".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Mouse/B6C3F1

#### P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

**Test Compound:** Elmiron (sodium pentosanpolysulfate)

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

Date Report Requested: 10/22/2014 Time Report Requested: 01:46:27

First Dose M/F: NA / NA

Lab: BAT

# Male MOUSE FIRST TERMINAL SACRIFICE AT 93 DAYS

DOSE	500 MG/KG	1000 MG/KG
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)	93.0	93.0
(STANDARD ERROR)	(0.0)	(0.0)

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>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".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Test Type: 90-DAY

Species/Strain: Mouse/B6C3F1

Route: GAVAGE

#### P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Elmiron (sodium pentosanpolysulfate)

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

Date Report Requested: 10/22/2014 Time Report Requested: 01:46:27

First Dose M/F: NA / NA

Lab: BAT

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

		TIDOAL CORTITAL TIMES (BAT		
DOSE = 0 MG/KG				
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 63 MG/KG				
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 125 MG/KG				
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 250 MG/KG				
TOTAL 10	UNCENSORED DEATHS 1	CENSORED DEATHS 0	TERMINAL 9	
UNCENSORED DEATH DAYS				
84				
CENSORED DEATH DAYS				
none				

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>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".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Species/Strain: Mouse/B6C3F1

Test Type: 90-DAY

Route: GAVAGE

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

**Test Compound:** Elmiron (sodium pentosanpolysulfate)

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

Date Report Requested: 10/22/2014
Time Report Requested: 01:46:27

First Dose M/F: NA / NA

Lab: BAT

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

DOSE = 500 MG/KG

TOTAL 10

**UNCENSORED DEATHS 0** 

**CENSORED DEATHS 0** 

**TERMINAL 10** 

UNCENSORED DEATH DAYS

none

**CENSORED DEATH DAYS** 

none

DOSE = 1000 MG/KG

TOTAL 10

UNCENSORED DEATHS 0

**CENSORED DEATHS 0** 

**TERMINAL 10** 

**UNCENSORED DEATH DAYS** 

none

**CENSORED DEATH DAYS** 

none

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>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".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Mouse/B6C3F1

#### P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Elmiron (sodium pentosanpolysulfate)

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

Date Report Requested: 10/22/2014 Time Report Requested: 01:46:27

First Dose M/F: NA / NA

Lab: BAT

# Female MOUSE 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)
0 MG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
63 MG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
125 MG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
250 MG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	90.0	90.0
500 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

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>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".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Mouse/B6C3F1

#### P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Elmiron (sodium pentosanpolysulfate)

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

Date Report Requested: 10/22/2014 Time Report Requested: 01:46:27

First Dose M/F: NA / NA

Lab: BAT

# Female MOUSE FIRST TERMINAL SACRIFICE AT 93 DAYS

DOSE	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	
SURVIVAL AT END OF STUDY	100.0%	100.0%	100.0%	90.0%	
(KAPLAN-MEIER)					
SIGNIFICANCE (B)	P=1.000N			P=1.000	
(LIFE TABLE)					
MEAN DAY OF NATURAL DEATHS (C)				84.0	
(STANDARD ERROR)	(.)	(.)	(.)	(.)	
MEAN LIFE SPAN (D)	93.0	93.0	93.0	92.1	
(STANDARD ERROR)	(0.0)	(0.0)	(0.0)	(0.9)	

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>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".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Mouse/B6C3F1

# P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Elmiron (sodium pentosanpolysulfate)

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

Date Report Requested: 10/22/2014 Time Report Requested: 01:46:27

First Dose M/F: NA / NA

Lab: BAT

# Female MOUSE FIRST TERMINAL SACRIFICE AT 93 DAYS

DOSE	500 MG/KG	1000 MG/KG
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)	93.0	93.0
(STANDARD ERROR)	(0.0)	(0.0)

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>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".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

**Test Type:** 90-DAY **Route:** GAVAGE

Species/Strain: Mouse/B6C3F1

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

**Test Compound:** Elmiron (sodium pentosanpolysulfate)

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

Date Report Requested: 10/22/2014 Time Report Requested: 01:46:27

First Dose M/F: NA / NA

Lab: BAT

\*\* END OF REPORT \*\*

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>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".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)