

**Experiment Number:** 88122-03  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

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

**Date Report Requested:** 10/19/2014

**Time Report Requested:** 16:08:11

**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

**Experiment Number:** 88122-03

**Test Type:** 90-DAY

**Route:** GAVAGE

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

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

**Date Report Requested:** 10/19/2014

**Time Report Requested:** 16:08:11

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

**Lab:** BAT

**SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF ELMIRON (SODIUM**

**MALE RAT**

**Organ**

Esophagus

Intestine Large, Rectum

Kidney: Renal Tubule

Liver

Liver: Midzonal

Lung: Alveolus

Lung: Interstitium

Lymph Node, Mandibular

Lymph Node, Mesenteric

Pancreas

Stomach, Forestomach

Thymus

Trachea

**FEMALE RAT**

**Organ**

Intestine Large, Cecum

Intestine Large, Rectum

Kidney: Renal Tubule

Liver: Midzonal

Lung: Alveolus

Lung: Interstitium

Lymph Node, Mandibular

Lymph Node, Mesenteric

**Morphology**

Ulcer

Infiltration Cellular Histiocyte

Inflammation Chronic

Ulcer Chronic

Vacuolization Cytoplasmic

Hepatodiaphragmatic Nodule

Inflammation Granulomatous

Vacuolization Cytoplasmic

Infiltration Cellular Histiocyte

Edema

Inflammation Chronic

Infiltration Cellular Histiocyte

Infiltration Cellular Histiocyte

Hemorrhage

Hemorrhage

Atrophy

Hemorrhage

**Morphology**

Infiltration Cellular Histiocyte

Inflammation Chronic

Infiltration Cellular Histiocyte

Ulcer Chronic

Vacuolization Cytoplasmic

Vacuolization Cytoplasmic

Infiltration Cellular Histiocyte

Inflammation Chronic

Infiltration Cellular Histiocyte

Infiltration Cellular Histiocyte

**Experiment Number:** 88122-03

**Test Type:** 90-DAY

**Route:** GAVAGE

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

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

**Date Report Requested:** 10/19/2014

**Time Report Requested:** 16:08:11

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

**Lab:** BAT

**SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF ELMIRON (SODIUM**

Ovary

Cyst

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:11  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Epididymis</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.23	0/0.00	0/0.00	0/0.04	1/9.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	11.1%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	---	4
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.480
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.483
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.479
COCH-ARM / FISHERS	P=0.285	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.158
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:11  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Esophagus</b>						
<b>Ulcer</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/2 (50%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.23	0/0.00	0/0.00	1/1.04	0/8.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	96.2%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	93(T)	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	P=0.065	(e)
POLY 1.5	(e)	(e)	(e)	(e)	P=0.074	(e)
POLY 6	(e)	(e)	(e)	(e)	P=0.063	(e)
COCH-ARM / FISHERS	P=0.691	(e)	(e)	(e)	P=0.167	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.007**	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:11

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Esophagus: Muscularis</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL(a)	4/10 (40%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/2 (50%)	7/10 (70%)
POLY-3 RATE (b)	4/10.00	0/0.23	0/0.00	0/0.00	1/1.04	7/10.00
POLY-3 PERCENT (g)	40%	0%	0%	0%	96.2%	70%
TERMINAL (d)	4/10 (40%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	5/8 (62%)
FIRST INCIDENCE	93(T)	---	---	---	93(T)	4
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	P=0.791N	(e)	(e)	P=0.483	P=0.186
POLY 1.5	(e)	P=0.738N	(e)	(e)	P=0.522	P=0.186
POLY 6	(e)	P=0.824N	(e)	(e)	P=0.473	P=0.186
COCH-ARM / FISHERS	P=0.097	P=0.636N	(e)	(e)	P=0.682	P=0.185
MAX-ISO-POLY-3	(e)	P=0.450N	(e)	(e)	P=0.282	P=0.090
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:11

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 9 WEEKS

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Heart: Myocardium</b>						
<b>Degeneration</b>						
<b>LESION RATES</b>						
OVERALL(a)	8/10 (80%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	7/10 (70%)
POLY-3 RATE (b)	8/10.00	0/0.23	0/0.00	0/0.00	0/0.04	7/10.00
POLY-3 PERCENT (g)	80%	0%	0%	0%	0%	70%
TERMINAL (d)	8/10 (80%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	5/8 (62%)
FIRST INCIDENCE	93(T)	---	---	---	---	4
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	P=0.781N	(e)	(e)	P=0.867N	P=0.500N
POLY 1.5	(e)	P=0.629N	(e)	(e)	P=0.795N	P=0.500N
POLY 6	(e)	P=0.862N	(e)	(e)	P=0.882N	P=0.500N
COCH-ARM / FISHERS	P=0.518N	P=0.273N	(e)	(e)	P=0.273N	P=0.500N
MAX-ISO-POLY-3	(e)	P=0.379N	(e)	(e)	P=0.478N	P=0.311N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:11  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Intestine Large, Cecum</b>						
<b>Infiltration Cellular Histiocyte</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.23	0/0.00	0/0.00	0/0.04	0/8.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:11  
 First Dose M/F: NA / NA  
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 9 WEEKS

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Intestine Large, Cecum</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.23	0/0.00	0/0.00	0/0.04	0/8.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:11  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Intestine Large, Rectum</b>						
<b>Infiltration Cellular Histiocyte</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	3/10 (30%)	7/10 (70%)	9/10 (90%)	8/9 (89%)
POLY-3 RATE (b)	0/10.00	0/9.23	3/10.00	7/10.00	9/10.00	8/8.00
POLY-3 PERCENT (g)	0%	0%	30%	70%	90%	100%
TERMINAL (d)	0/10 (0%)	0/9 (0%)	3/10 (30%)	7/10 (70%)	8/9 (89%)	8/8 (100%)
FIRST INCIDENCE	---	---	93(T)	93(T)	32	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	(e)	P=0.095	P=0.000**	P=0.000**	P=0.000**
POLY 1.5	P=0.000**	(e)	P=0.095	P=0.000**	P=0.000**	P=0.000**
POLY 6	P=0.000**	(e)	P=0.095	P=0.000**	P=0.000**	P=0.000**
COCH-ARM / FISHERS	P=0.000**	(e)	P=0.105	P=0.002**	P=0.000**	P=0.000**
MAX-ISO-POLY-3	P=0.000**	(e)	P=0.025*	P=0.000**	P=0.000**	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:11  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Intestine Large, Rectum</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	2/10 (20%)	7/10 (70%)	8/10 (80%)	8/9 (89%)
POLY-3 RATE (b)	0/10.00	0/9.23	2/10.00	7/10.00	8/9.04	8/8.00
POLY-3 PERCENT (g)	0%	0%	20%	70%	88.5%	100%
TERMINAL (d)	0/10 (0%)	0/9 (0%)	2/10 (20%)	7/10 (70%)	8/9 (89%)	8/8 (100%)
FIRST INCIDENCE	---	---	93(T)	93(T)	93(T)	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	(e)	P=0.227	P=0.000**	P=0.000**	P=0.000**
POLY 1.5	P=0.000**	(e)	P=0.227	P=0.000**	P=0.000**	P=0.000**
POLY 6	P=0.000**	(e)	P=0.227	P=0.000**	P=0.000**	P=0.000**
COCH-ARM / FISHERS	P=0.000**	(e)	P=0.237	P=0.002**	P=0.000**	P=0.000**
MAX-ISO-POLY-3	P=0.000**	(e)	P=0.067	P=0.000**	P=0.000**	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:11  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Intestine Large, Rectum</b>						
<b>Ulcer Chronic</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	1/10 (10%)	3/10 (30%)	7/10 (70%)	7/9 (78%)
POLY-3 RATE (b)	0/10.00	0/9.23	1/10.00	3/10.00	7/9.04	7/8.00
POLY-3 PERCENT (g)	0%	0%	10%	30%	77.4%	87.5%
TERMINAL (d)	0/10 (0%)	0/9 (0%)	1/10 (10%)	3/10 (30%)	7/9 (78%)	7/8 (88%)
FIRST INCIDENCE	---	---	93(T)	93(T)	93(T)	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	(e)	P=0.500	P=0.095	P=0.000**	P=0.000**
POLY 1.5	P=0.000**	(e)	P=0.500	P=0.095	P=0.000**	P=0.000**
POLY 6	P=0.000**	(e)	P=0.500	P=0.095	P=0.000**	P=0.000**
COCH-ARM / FISHERS	P=0.000**	(e)	P=0.500	P=0.105	P=0.002**	P<0.001**
MAX-ISO-POLY-3	P=0.000**	(e)	P=0.159	P=0.025*	P=0.000**	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:11  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Kidney</b>						
<b>Hemorrhage</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	1/9 (11%)
POLY-3 RATE (b)	0/10.00	0/0.23	0/0.00	0/0.00	0/9.04	1/9.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	11.1%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/9 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	---	31
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.479
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.479
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.479
COCH-ARM / FISHERS	P=0.240	(e)	(e)	(e)	(e)	P=0.474
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.152
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:11

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Kidney</b>						
<b>Infarct</b>						
<b>LESION RATES</b>						
OVERALL(a)	1/10 (10%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/9 (0%)
POLY-3 RATE (b)	1/10.00	0/0.23	0/0.00	0/0.00	0/9.04	0/8.04
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/9 (0%)	0/8 (0%)
FIRST INCIDENCE	93(T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	P=0.938N	(e)	(e)	P=0.520N	P=0.543N
POLY 1.5	(e)	P=0.932N	(e)	(e)	P=0.517N	P=0.539N
POLY 6	(e)	P=0.942N	(e)	(e)	P=0.521N	P=0.544N
COCH-ARM / FISHERS	P=0.291N	P=0.909N	(e)	(e)	P=0.500N	P=0.526N
MAX-ISO-POLY-3	(e)	P=0.480N	(e)	(e)	P=0.184N	P=0.206N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:11  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Kidney</b>						
<b>Inflammation</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)	1/9 (11%)
POLY-3 RATE (b)	0/10.00	0/0.23	0/0.00	0/0.00	1/9.04	1/8.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	11.1%	12.4%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/9 (11%)	1/8 (12%)
FIRST INCIDENCE	---	---	---	---	93(T)	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	P=0.480	P=0.456
POLY 1.5	(e)	(e)	(e)	(e)	P=0.483	P=0.460
POLY 6	(e)	(e)	(e)	(e)	P=0.479	P=0.455
COCH-ARM / FISHERS	P=0.286	(e)	(e)	(e)	P=0.500	P=0.474
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.158	P=0.151
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:11

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Kidney: Renal Tubule Cyst</b>						
<b>LESION RATES</b>						
OVERALL(a)	2/10 (20%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/9 (0%)
POLY-3 RATE (b)	2/10.00	0/0.23	0/0.00	0/0.00	0/9.04	0/8.04
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	0%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/9 (0%)	0/8 (0%)
FIRST INCIDENCE	93(T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	P=0.865N	(e)	(e)	P=0.251N	P=0.280N
POLY 1.5	(e)	P=0.842N	(e)	(e)	P=0.246N	P=0.275N
POLY 6	(e)	P=0.878N	(e)	(e)	P=0.252N	P=0.281N
COCH-ARM / FISHERS	P=0.107N	P=0.818N	(e)	(e)	P=0.237N	P=0.263N
MAX-ISO-POLY-3	(e)	P=0.469N	(e)	(e)	P=0.089N	P=0.110N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:11

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 9 WEEKS

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Kidney: Renal Tubule</b>						
<b>Necrosis</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)	0/9 (0%)
POLY-3 RATE (b)	0/10.00	0/0.23	0/0.00	0/0.00	1/10.00	0/8.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/9 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	32	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	P=0.500	(e)
POLY 1.5	(e)	(e)	(e)	(e)	P=0.500	(e)
POLY 6	(e)	(e)	(e)	(e)	P=0.500	(e)
COCH-ARM / FISHERS	P=0.709	(e)	(e)	(e)	P=0.500	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.159	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:11  
 First Dose M/F: NA / NA  
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 9 WEEKS

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Kidney: Renal Tubule</b>						
<b>Vacuolization Cytoplasmic</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	8/9 (89%)
POLY-3 RATE (b)	0/10.00	0/0.23	0/0.00	0/0.00	0/9.04	8/8.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	99.5%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/9 (0%)	8/8 (100%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.000**
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.000**
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.000**
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	(e)	(e)	P=0.000**
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:11  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Liver</b>						
<b>Hepatodiaphragmatic Nodule</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	2/2 (100%)	2/2 (100%)	0/10 (0%)	1/10 (10%)	4/10 (40%)
POLY-3 RATE (b)	0/10.00	2/2.00	2/2.00	0/10.00	1/9.04	4/9.04
POLY-3 PERCENT (g)	0%	100%	100%	0%	11.1%	44.2%
TERMINAL (d)	0/10 (0%)	1/1 (100%)	2/2 (100%)	0/10 (0%)	1/9 (11%)	3/8 (38%)
FIRST INCIDENCE	---	57	93(T)	---	93(T)	4
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.060	P=NA	P=NA	(e)	P=0.480	P=0.022*
POLY 1.5	P=0.064	P=NA	P=NA	(e)	P=0.483	P=0.024*
POLY 6	P=0.060	P=NA	P=NA	(e)	P=0.479	P=0.022*
COCH-ARM / FISHERS	P=0.161	P=0.015*	P=0.015*	(e)	P=0.500	P=0.043*
MAX-ISO-POLY-3	P=0.002**	P=0.000**	P=0.000**	(e)	P=0.158	P=0.006**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:11

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Liver</b>						
<b>Inflammation</b>						
<b>LESION RATES</b>						
OVERALL(a)	2/10 (20%)	0/2 (0%)	0/2 (0%)	1/10 (10%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/1.23	0/2.00	1/10.00	1/9.04	0/8.04
POLY-3 PERCENT (g)	20%	0%	0%	10%	11.1%	0%
TERMINAL (d)	2/10 (20%)	0/1 (0%)	0/2 (0%)	1/10 (10%)	1/9 (11%)	0/8 (0%)
FIRST INCIDENCE	93(T)	---	---	93(T)	93(T)	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.214N	P=0.704N	P=0.627N	P=0.500N	P=0.536N	P=0.281N
POLY 1.5	P=0.215N	P=0.679N	P=0.627N	P=0.500N	P=0.530N	P=0.276N
POLY 6	P=0.212N	P=0.721N	P=0.627N	P=0.500N	P=0.538N	P=0.282N
COCH-ARM / FISHERS	P=0.185N	P=0.682N	P=0.682N	P=0.500N	P=0.500N	P=0.237N
MAX-ISO-POLY-3	P=0.211N	P=0.380N	P=0.308N	P=0.274N	P=0.313N	P=0.116N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:11  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Liver</b>						
<b>Inflammation Granulomatous</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/2 (0%)	0/2 (0%)	0/10 (0%)	4/10 (40%)	6/10 (60%)
POLY-3 RATE (b)	0/10.00	0/1.23	0/2.00	0/10.00	4/9.04	6/8.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	44.2%	74.6%
TERMINAL (d)	0/10 (0%)	0/1 (0%)	0/2 (0%)	0/10 (0%)	4/9 (44%)	6/8 (75%)
FIRST INCIDENCE	---	---	---	---	93(T)	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	(e)	(e)	(e)	P=0.022*	P=0.000**
POLY 1.5	P=0.000**	(e)	(e)	(e)	P=0.024*	P=0.000**
POLY 6	P=0.000**	(e)	(e)	(e)	P=0.022*	P=0.000**
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	(e)	P=0.043*	P=0.005**
MAX-ISO-POLY-3	P=0.000**	(e)	(e)	(e)	P=0.006**	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:11  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Liver: Midzonal</b>						
<b>Vacuolization Cytoplasmic</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	1/2 (50%)	0/2 (0%)	0/10 (0%)	4/10 (40%)	8/10 (80%)
POLY-3 RATE (b)	0/10.00	1/2.00	0/2.00	0/10.00	4/9.04	8/8.04
POLY-3 PERCENT (g)	0%	50%	0%	0%	44.2%	99.5%
TERMINAL (d)	0/10 (0%)	0/1 (0%)	0/2 (0%)	0/10 (0%)	4/9 (44%)	8/8 (100%)
FIRST INCIDENCE	---	57	---	---	93(T)	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	P=0.124	(e)	(e)	P=0.022*	P=0.000**
POLY 1.5	P=0.000**	P=0.124	(e)	(e)	P=0.024*	P=0.000**
POLY 6	P=0.000**	P=0.124	(e)	(e)	P=0.022*	P=0.000**
COCH-ARM / FISHERS	P=0.000**	P=0.167	(e)	(e)	P=0.043*	P=0.000**
MAX-ISO-POLY-3	P=0.000**	P=0.013*	(e)	(e)	P=0.006**	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:11

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 9 WEEKS

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lung</b>						
<b>Congestion</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/9.23	0/10.00	0/10.00	0/9.04	1/9.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	11.1%
TERMINAL (d)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	---	31
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.100	(e)	(e)	(e)	(e)	P=0.479
POLY 1.5	P=0.099	(e)	(e)	(e)	(e)	P=0.479
POLY 6	P=0.100	(e)	(e)	(e)	(e)	P=0.479
COCH-ARM / FISHERS	P=0.105	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.074	(e)	(e)	(e)	(e)	P=0.158
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:11  
 First Dose M/F: NA / NA  
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 9 WEEKS

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lung</b>						
<b>Hematopoietic Cell Proliferation</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/9.23	0/10.00	0/10.00	0/9.04	0/8.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:11

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lung</b>						
<b>Hemorrhage</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/9.23	0/10.00	0/10.00	0/9.04	1/9.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	11.1%
TERMINAL (d)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	---	4
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.100	(e)	(e)	(e)	(e)	P=0.480
POLY 1.5	P=0.101	(e)	(e)	(e)	(e)	P=0.483
POLY 6	P=0.100	(e)	(e)	(e)	(e)	P=0.479
COCH-ARM / FISHERS	P=0.105	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.074	(e)	(e)	(e)	(e)	P=0.158
<b>HISTCONT SAME RTE</b>						
<b>HISTCONT ALL RTES</b>						
<b>CURR VS HC SAME RTE</b>						
<b>CURR VS HC ALL RTES</b>						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lung</b>						
<b>Infiltration Cellular Histiocyte</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/9.23	0/10.00	0/10.00	0/9.04	0/8.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lung</b>						
<b>Inflammation Acute</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/9.23	0/10.00	0/10.00	1/10.00	0/8.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%	0%
TERMINAL (d)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	32	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.455	(e)	(e)	(e)	P=0.500	(e)
POLY 1.5	P=0.465	(e)	(e)	(e)	P=0.500	(e)
POLY 6	P=0.454	(e)	(e)	(e)	P=0.500	(e)
COCH-ARM / FISHERS	P=0.585	(e)	(e)	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.405	(e)	(e)	(e)	P=0.159	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lung: Alveolus</b>						
<b>Foreign Body</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/9.23	0/10.00	0/10.00	0/9.04	0/8.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 9 WEEKS

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lung: Alveolus</b>						
<b>Infiltration Cellular Histiocyte</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	2/10 (20%)	5/10 (50%)	6/10 (60%)	10/10 (100%)	8/10 (80%)
POLY-3 RATE (b)	0/10.00	2/9.23	5/10.00	6/10.00	10/10.00	8/9.00
POLY-3 PERCENT (g)	0%	21.7%	50%	60%	100%	88.9%
TERMINAL (d)	0/10 (0%)	2/9 (22%)	5/10 (50%)	6/10 (60%)	9/9 (100%)	7/8 (88%)
FIRST INCIDENCE	---	93(T)	93(T)	93(T)	32	31
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	P=0.207	P=0.008**	P<0.001**	P=NA	P=0.000**
POLY 1.5	P=0.000**	P=0.213	P=0.008**	P<0.001**	P=NA	P=0.000**
POLY 6	P=0.000**	P=0.203	P=0.008**	P<0.001**	P=NA	P=0.000**
COCH-ARM / FISHERS	P=0.000**	P=0.237	P=0.016*	P=0.005**	P=0.000**	P=0.000**
MAX-ISO-POLY-3	P=0.000**	P=0.065	P<0.001**	P=0.000**	(e)	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lung: Bronchiole</b>						
<b>Foreign Body</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/9.23	0/10.00	0/10.00	0/9.04	0/8.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lung: Interstitium</b>						
<b>Edema</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	1/10.00	0/10.00	0/10.00	0/9.04	2/10.00
POLY-3 PERCENT (g)	0%	10%	0%	0%	0%	20%
TERMINAL (d)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/8 (0%)
FIRST INCIDENCE	---	57	---	---	---	4
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.067	P=0.500	(e)	(e)	(e)	P=0.227
POLY 1.5	P=0.068	P=0.500	(e)	(e)	(e)	P=0.227
POLY 6	P=0.067	P=0.500	(e)	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.073	P=0.500	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	P=0.034*	P=0.159	(e)	(e)	(e)	P=0.067
<b>HISTCONT SAME RTE</b>						
<b>HISTCONT ALL RTES</b>						
<b>CURR VS HC SAME RTE</b>						
<b>CURR VS HC ALL RTES</b>						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 9 WEEKS

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lung: Interstitium</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	3/10 (30%)
POLY-3 RATE (b)	0/10.00	0/9.23	0/10.00	0/10.00	1/9.04	3/8.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	11.1%	37.3%
TERMINAL (d)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)	1/9 (11%)	3/8 (38%)
FIRST INCIDENCE	---	---	---	---	93(T)	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	(e)	(e)	(e)	P=0.480	P=0.058
POLY 1.5	P=0.000**	(e)	(e)	(e)	P=0.483	P=0.061
POLY 6	P=0.000**	(e)	(e)	(e)	P=0.479	P=0.057
COCH-ARM / FISHERS	P=0.002**	(e)	(e)	(e)	P=0.500	P=0.105
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	P=0.158	P=0.021*
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 9 WEEKS

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lymph Node, Mandibular Infiltration Cellular Histiocyte</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/10 (0%)	3/10 (30%)	8/10 (80%)	7/10 (70%)
POLY-3 RATE (b)	0/10.00	0/0.23	0/10.00	3/10.00	8/10.00	7/10.00
POLY-3 PERCENT (g)	0%	0%	0%	30%	80%	70%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/10 (0%)	3/10 (30%)	7/9 (78%)	5/8 (62%)
FIRST INCIDENCE	---	---	---	93(T)	32	4
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	(e)	(e)	P=0.095	P=0.000**	P=0.000**
POLY 1.5	P=0.000**	(e)	(e)	P=0.095	P=0.000**	P=0.000**
POLY 6	P=0.000**	(e)	(e)	P=0.095	P=0.000**	P=0.000**
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	P=0.105	P=0.000**	P=0.002**
MAX-ISO-POLY-3	P=0.000**	(e)	(e)	P=0.025*	P=0.000**	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lymph Node, Mesenteric Infiltration Cellular Histiocyte</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/10 (0%)	6/10 (60%)	8/10 (80%)	8/9 (89%)
POLY-3 RATE (b)	0/10.00	0/0.23	0/10.00	6/10.00	8/9.04	8/8.00
POLY-3 PERCENT (g)	0%	0%	0%	60%	88.5%	100%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/10 (0%)	6/10 (60%)	8/9 (89%)	8/8 (100%)
FIRST INCIDENCE	---	---	---	93(T)	93(T)	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	(e)	(e)	P<0.001**	P=0.000**	P=0.000**
POLY 1.5	P=0.000**	(e)	(e)	P<0.001**	P=0.000**	P=0.000**
POLY 6	P=0.000**	(e)	(e)	P<0.001**	P=0.000**	P=0.000**
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	P=0.005**	P=0.000**	P=0.000**
MAX-ISO-POLY-3	P=0.000**	(e)	(e)	P=0.000**	P=0.000**	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 9 WEEKS

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Pancreas</b>						
<b>Atrophy Acute</b>						
<b>LESION RATES</b>						
OVERALL(a)	1/10 (10%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.23	0/0.00	0/0.00	0/0.04	0/8.04
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/8 (0%)
FIRST INCIDENCE	93(T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	P=0.938N	(e)	(e)	P=0.942N	P=0.543N
POLY 1.5	(e)	P=0.932N	(e)	(e)	P=0.939N	P=0.539N
POLY 6	(e)	P=0.942N	(e)	(e)	P=0.943N	P=0.544N
COCH-ARM / FISHERS	P=0.314N	P=0.909N	(e)	(e)	P=0.909N	P=0.500N
MAX-ISO-POLY-3	(e)	P=0.480N	(e)	(e)	P=0.497N	P=0.212N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 9 WEEKS

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Pancreas</b>						
<b>Hemorrhage</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.23	0/0.00	0/0.00	1/1.00	0/8.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	100%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	32	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	P=0.091	(e)
POLY 1.5	(e)	(e)	(e)	(e)	P=0.091	(e)
POLY 6	(e)	(e)	(e)	(e)	P=0.091	(e)
COCH-ARM / FISHERS	P=0.686	(e)	(e)	(e)	P=0.091	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.000**	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Pancreas: Acinus</b>						
<b>Atrophy</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/0.23	0/0.00	0/0.00	0/0.04	2/8.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	24.9%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/8 (25%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.177
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.181
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.176
COCH-ARM / FISHERS	P=0.114	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.063
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Pituitary Gland: Pars Distalis</b>						
<b>Hyperplasia Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/9 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/9.00	0/0.23	0/0.00	0/0.00	0/0.00	1/8.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	12.4%
TERMINAL (d)	0/9 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/8 (12%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.477
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.481
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.477
COCH-ARM / FISHERS	P=0.305	(e)	(e)	(e)	(e)	P=0.526
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.164
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Prostate</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.23	0/0.00	0/0.00	0/0.04	1/9.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	11.1%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	---	4
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.480
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.483
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.479
COCH-ARM / FISHERS	P=0.285	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.158
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Seminal Vesicle</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.23	0/0.00	0/0.00	0/0.04	1/9.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	11.1%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	---	4
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.480
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.483
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.479
COCH-ARM / FISHERS	P=0.285	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.158
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Spleen: Capsule</b>						
<b>Inflammation Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.23	0/0.00	0/10.00	0/9.04	0/8.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/9 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Spleen: Lymph Follic Depletion Cellular</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/10 (0%)	1/10 (10%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.23	0/0.00	0/10.00	1/10.00	1/9.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%	11.1%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/9 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	32	4
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	P=0.500	P=0.480
POLY 1.5	(e)	(e)	(e)	(e)	P=0.500	P=0.483
POLY 6	(e)	(e)	(e)	(e)	P=0.500	P=0.479
COCH-ARM / FISHERS	P=0.220	(e)	(e)	(e)	P=0.500	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.159	P=0.158
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Stomach, Forestomach</b>						
<b>Hemorrhage</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.23	0/0.00	0/0.00	1/1.00	0/8.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	100%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	32	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	P=0.091	(e)
POLY 1.5	(e)	(e)	(e)	(e)	P=0.091	(e)
POLY 6	(e)	(e)	(e)	(e)	P=0.091	(e)
COCH-ARM / FISHERS	P=0.686	(e)	(e)	(e)	P=0.091	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.000**	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Thymus</b>						
<b>Atrophy</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.23	0/0.00	0/0.00	1/1.00	0/8.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	100%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	32	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	P=0.091	(e)
POLY 1.5	(e)	(e)	(e)	(e)	P=0.091	(e)
POLY 6	(e)	(e)	(e)	(e)	P=0.091	(e)
COCH-ARM / FISHERS	P=0.686	(e)	(e)	(e)	P=0.091	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.000**	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 9 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Trachea						
Hemorrhage						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.23	0/0.00	0/0.00	1/1.00	0/8.04
POLY-3 PERCENT (g)	0%	0%	0%	0%	100%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/8 (0%)
FIRST INCIDENCE	---	---	---	---	32	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	P=0.091	(e)
POLY 1.5	(e)	(e)	(e)	(e)	P=0.091	(e)
POLY 6	(e)	(e)	(e)	(e)	P=0.091	(e)
COCH-ARM / FISHERS	P=0.686	(e)	(e)	(e)	P=0.091	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.000**	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Esophagus</b>						
<b>Ulcer</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Esophagus: Muscularis</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL(a)	4/10 (40%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	7/10 (70%)
POLY-3 RATE (b)	4/10.00	0/0.00	0/0.00	0/0.00	0/0.00	7/10.00
POLY-3 PERCENT (g)	40%	0%	0%	0%	0%	70%
TERMINAL (d)	4/10 (40%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	7/10 (70%)
FIRST INCIDENCE	93(T)	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.186
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.186
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.186
COCH-ARM / FISHERS	P=0.131	(e)	(e)	(e)	(e)	P=0.185
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.090
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Heart: Myocardium</b>						
<b>Degeneration</b>						
<b>LESION RATES</b>						
OVERALL(a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	5/10 (50%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/0.00	0/0.00	5/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	50%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	5/10 (50%)
FIRST INCIDENCE	93(T)	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.174
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.174
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.174
COCH-ARM / FISHERS	P=0.121	(e)	(e)	(e)	(e)	P=0.175
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.080
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Intestine Large, Cecum</b>						
<b>Infiltration Cellular Histiocyte</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	1/1.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	100%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	93(T)	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	P=0.091	(e)	(e)
POLY 1.5	(e)	(e)	(e)	P=0.091	(e)	(e)
POLY 6	(e)	(e)	(e)	P=0.091	(e)	(e)
COCH-ARM / FISHERS	P=0.510N	(e)	(e)	P=0.091	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.000**	(e)	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Intestine Large, Cecum</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/1.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.292	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.159
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Intestine Large, Rectum</b>						
<b>Infiltration Cellular Histiocyte</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	2/10 (20%)	1/10 (10%)	2/10 (20%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	2/10.00	1/10.00	2/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	20%	10%	20%	100%	100%
TERMINAL (d)	0/10 (0%)	2/10 (20%)	1/10 (10%)	2/10 (20%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	93(T)	93(T)	93(T)	93(T)	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	P=0.227	P=0.500	P=0.227	P=NA	P=NA
POLY 1.5	P=0.000**	P=0.227	P=0.500	P=0.227	P=NA	P=NA
POLY 6	P=0.000**	P=0.227	P=0.500	P=0.227	P=NA	P=NA
COCH-ARM / FISHERS	P=0.000**	P=0.237	P=0.500	P=0.237	P=0.000**	P=0.000**
MAX-ISO-POLY-3	P=0.000**	P=0.067	P=0.159	P=0.067	(e)	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Intestine Large, Rectum</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	9/10 (90%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	9/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	90%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	9/10 (90%)	10/10 (100%)
FIRST INCIDENCE	---	---	---	---	93(T)	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	(e)	(e)	(e)	P=0.000**	P=NA
POLY 1.5	P=0.000**	(e)	(e)	(e)	P=0.000**	P=NA
POLY 6	P=0.000**	(e)	(e)	(e)	P=0.000**	P=NA
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	(e)	P=0.000**	P=0.000**
MAX-ISO-POLY-3	P=0.000**	(e)	(e)	(e)	P=0.000**	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Intestine Large, Rectum</b>						
<b>Ulcer Chronic</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	6/10 (60%)	8/10 (80%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	6/10.00	8/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	60%	80%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	6/10 (60%)	8/10 (80%)
FIRST INCIDENCE	---	---	---	---	93(T)	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	(e)	(e)	(e)	P<0.001**	P=0.000**
POLY 1.5	P=0.000**	(e)	(e)	(e)	P<0.001**	P=0.000**
POLY 6	P=0.000**	(e)	(e)	(e)	P<0.001**	P=0.000**
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	(e)	P=0.005**	P=0.000**
MAX-ISO-POLY-3	P=0.000**	(e)	(e)	(e)	P=0.000**	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Kidney</b>						
<b>Hemorrhage</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Kidney</b>						
<b>Infarct</b>						
<b>LESION RATES</b>						
<b>OVERALL(a)</b>	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)
<b>POLY-3 RATE (b)</b>	0/10.00	0/0.00	0/0.00	0/0.00	0/10.00	0/10.00
<b>POLY-3 PERCENT (g)</b>	0%	0%	0%	0%	0%	0%
<b>TERMINAL (d)</b>	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)
<b>FIRST INCIDENCE</b>	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	(n)	(n)	(n)	(n)	(n)	(n)
<b>POLY 1.5</b>	(n)	(n)	(n)	(n)	(n)	(n)
<b>POLY 6</b>	(n)	(n)	(n)	(n)	(n)	(n)
<b>COCH-ARM / FISHERS</b>	(n)	(n)	(n)	(n)	(n)	(n)
<b>MAX-ISO-POLY-3</b>	(n)	(n)	(n)	(n)	(n)	(n)
<b>HISTCONT SAME RTE</b>						
<b>HISTCONT ALL RTES</b>						
<b>CURR VS HC SAME RTE</b>						
<b>CURR VS HC ALL RTES</b>						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Kidney</b>						
<b>Inflammation</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Kidney: Renal Tubule Cyst</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Kidney: Renal Tubule</b>						
<b>Necrosis</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Kidney: Renal Tubule</b>						
<b>Vacuolization Cytoplasmic</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	100%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	10/10 (100%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=NA
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=NA
POLY 6	(e)	(e)	(e)	(e)	(e)	P=NA
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	(e)	(e)	P=0.000**
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Liver</b>						
<b>Hepatodiaphragmatic Nodule</b>						
<b>LESION RATES</b>						
OVERALL(a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00	1/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	10%	0%	0%	10%	0%	10%
TERMINAL (d)	1/10 (10%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	93(T)	---	---	93(T)	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.479	P=0.500N	P=0.500N	P=0.760	P=0.500N	P=0.760
POLY 1.5	P=0.479	P=0.500N	P=0.500N	P=0.760	P=0.500N	P=0.760
POLY 6	P=0.479	P=0.500N	P=0.500N	P=0.760	P=0.500N	P=0.760
COCH-ARM / FISHERS	P=0.479	P=0.500N	P=0.500N	P=0.763N	P=0.500N	P=0.763N
MAX-ISO-POLY-3	P=0.462	P=0.159N	P=0.159N	P=1.000	P=0.159N	P=1.000
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Liver</b>						
<b>Inflammation</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Liver</b>						
<b>Inflammation Granulomatous</b>						
<b>LESION RATES</b>						
OVERALL(a)	9/10 (90%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	9/10 (90%)	10/10 (100%)
POLY-3 RATE (b)	9/10.00	10/10.00	10/10.00	10/10.00	9/10.00	10/10.00
POLY-3 PERCENT (g)	90%	100%	100%	100%	90%	100%
TERMINAL (d)	9/10 (90%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	9/10 (90%)	10/10 (100%)
FIRST INCIDENCE	93(T)	93(T)	93(T)	93(T)	93(T)	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.585	P=0.500	P=0.500	P=0.500	P=0.760	P=0.500
POLY 1.5	P=0.585	P=0.500	P=0.500	P=0.500	P=0.760	P=0.500
POLY 6	P=0.585	P=0.500	P=0.500	P=0.500	P=0.760	P=0.500
COCH-ARM / FISHERS	P=0.586	P=0.500	P=0.500	P=0.500	P=0.763N	P=0.500
MAX-ISO-POLY-3	P=0.202	P=0.159	P=0.159	P=0.159	P=1.000	P=0.159
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Liver: Midzonal</b>						
<b>Vacuolization Cytoplasmic</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	7/10 (70%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	7/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	70%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	7/10 (70%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	(e)	(e)	(e)	(e)	P=0.000**
POLY 1.5	P=0.000**	(e)	(e)	(e)	(e)	P=0.000**
POLY 6	P=0.000**	(e)	(e)	(e)	(e)	P=0.000**
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	(e)	(e)	P=0.002**
MAX-ISO-POLY-3	P=0.000**	(e)	(e)	(e)	(e)	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lung</b>						
<b>Congestion</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lung</b>						
<b>Hematopoietic Cell Proliferation</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.107	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	P=0.107	(e)	(e)	(e)	(e)	P=0.500
POLY 6	P=0.107	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.105	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.075	(e)	(e)	(e)	(e)	P=0.159
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lung</b>						
<b>Hemorrhage</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lung</b>						
<b>Infiltration Cellular Histiocyte</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	1/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	93(T)	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.697N	(e)	(e)	P=0.500	(e)	(e)
POLY 1.5	P=0.697N	(e)	(e)	P=0.500	(e)	(e)
POLY 6	P=0.697N	(e)	(e)	P=0.500	(e)	(e)
COCH-ARM / FISHERS	P=0.699N	(e)	(e)	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.514	(e)	(e)	P=0.159	(e)	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lung</b>						
<b>Inflammation Acute</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lung: Alveolus</b>						
<b>Foreign Body</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	1/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	93(T)	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.584	(e)	(e)	(e)	P=0.500	(e)
POLY 1.5	P=0.584	(e)	(e)	(e)	P=0.500	(e)
POLY 6	P=0.584	(e)	(e)	(e)	P=0.500	(e)
COCH-ARM / FISHERS	P=0.585	(e)	(e)	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.356	(e)	(e)	(e)	P=0.159	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lung: Alveolus</b>						
<b>Infiltration Cellular Histiocyte</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	7/10 (70%)	5/10 (50%)	6/10 (60%)	7/10 (70%)	9/10 (90%)
POLY-3 RATE (b)	0/10.00	7/10.00	5/10.00	6/10.00	7/10.00	9/10.00
POLY-3 PERCENT (g)	0%	70%	50%	60%	70%	90%
TERMINAL (d)	0/10 (0%)	7/10 (70%)	5/10 (50%)	6/10 (60%)	7/10 (70%)	9/10 (90%)
FIRST INCIDENCE	---	93(T)	93(T)	93(T)	93(T)	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	P=0.000**	P=0.008**	P<0.001**	P=0.000**	P=0.000**
POLY 1.5	P=0.000**	P=0.000**	P=0.008**	P<0.001**	P=0.000**	P=0.000**
POLY 6	P=0.000**	P=0.000**	P=0.008**	P<0.001**	P=0.000**	P=0.000**
COCH-ARM / FISHERS	P=0.002**	P=0.002**	P=0.016*	P=0.005**	P=0.002**	P=0.000**
MAX-ISO-POLY-3	P=0.000**	P=0.000**	P<0.001**	P=0.000**	P=0.000**	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lung: Bronchiole</b>						
<b>Foreign Body</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	1/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	10%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	93(T)	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.488N	P=0.500	(e)	(e)	(e)	(e)
POLY 1.5	P=0.488N	P=0.500	(e)	(e)	(e)	(e)
POLY 6	P=0.488N	P=0.500	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.488N	P=0.500	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.356N	P=0.159	(e)	(e)	(e)	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lung: Interstitium</b>						
<b>Edema</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lung: Interstitium</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	1/10 (10%)	0/10 (0%)	1/10 (10%)	3/10 (30%)	6/10 (60%)
POLY-3 RATE (b)	0/10.00	1/10.00	0/10.00	1/10.00	3/10.00	6/10.00
POLY-3 PERCENT (g)	0%	10%	0%	10%	30%	60%
TERMINAL (d)	0/10 (0%)	1/10 (10%)	0/10 (0%)	1/10 (10%)	3/10 (30%)	6/10 (60%)
FIRST INCIDENCE	---	93(T)	---	93(T)	93(T)	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	P=0.500	(e)	P=0.500	P=0.095	P<0.001**
POLY 1.5	P=0.000**	P=0.500	(e)	P=0.500	P=0.095	P<0.001**
POLY 6	P=0.000**	P=0.500	(e)	P=0.500	P=0.095	P<0.001**
COCH-ARM / FISHERS	P=0.000**	P=0.500	(e)	P=0.500	P=0.105	P=0.005**
MAX-ISO-POLY-3	P=0.000**	P=0.159	(e)	P=0.159	P=0.025*	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lymph Node, Mandibular Infiltration Cellular Histiocyte</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	1/1 (100%)	2/2 (100%)	3/10 (30%)	3/10 (30%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	1/1.00	2/2.00	3/10.00	3/10.00	10/10.00
POLY-3 PERCENT (g)	0%	100%	100%	30%	30%	100%
TERMINAL (d)	0/10 (0%)	1/1 (100%)	2/2 (100%)	3/10 (30%)	3/10 (30%)	10/10 (100%)
FIRST INCIDENCE	---	93(T)	93(T)	93(T)	93(T)	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	P=0.091	P=NA	P=0.095	P=0.095	P=NA
POLY 1.5	P=0.000**	P=0.091	P=NA	P=0.095	P=0.095	P=NA
POLY 6	P=0.000**	P=0.091	P=NA	P=0.095	P=0.095	P=NA
COCH-ARM / FISHERS	P=0.000**	P=0.091	P=0.015*	P=0.105	P=0.105	P=0.000**
MAX-ISO-POLY-3	P=0.000**	P=0.000**	P=0.000**	P=0.025*	P=0.025*	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Lymph Node, Mesenteric Infiltration Cellular Histiocyte</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	2/2 (100%)	5/5 (100%)	7/7 (100%)	7/10 (70%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	2/2.00	5/5.00	7/7.00	7/10.00	10/10.00
POLY-3 PERCENT (g)	0%	100%	100%	100%	70%	100%
TERMINAL (d)	0/10 (0%)	2/2 (100%)	5/5 (100%)	7/7 (100%)	7/10 (70%)	10/10 (100%)
FIRST INCIDENCE	---	93(T)	93(T)	93(T)	93(T)	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.000**	P=NA	P=NA	P=NA	P=0.000**	P=NA
POLY 1.5	P=0.000**	P=NA	P=NA	P=NA	P=0.000**	P=NA
POLY 6	P=0.000**	P=NA	P=NA	P=NA	P=0.000**	P=NA
COCH-ARM / FISHERS	P<0.001**	P=0.015*	P=0.000**	P=0.000**	P=0.002**	P=0.000**
MAX-ISO-POLY-3	P=0.000**	P=0.000**	P=0.000**	(e)	P=0.000**	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Ovary						
Cyst						
<b>LESION RATES</b>						
OVERALL(a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	1/1.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	10%	0%	0%	100%	0%	10%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	93(T)	---	---	93(T)	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	P=0.146	(e)	P=0.760
POLY 1.5	(e)	(e)	(e)	P=0.146	(e)	P=0.760
POLY 6	(e)	(e)	(e)	P=0.146	(e)	P=0.760
COCH-ARM / FISHERS	P=0.518N	(e)	(e)	P=0.182	(e)	P=0.763N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.022*	(e)	P=1.000
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Pancreas</b>						
<b>Atrophy Acute</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Pancreas</b>						
<b>Hemorrhage</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Pancreas: Acinus</b>						
<b>Atrophy</b>						
<b>LESION RATES</b>						
OVERALL(a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	0%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93(T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.227N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.227N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.227N
COCH-ARM / FISHERS	P=0.132N	(e)	(e)	(e)	(e)	P=0.237N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.067N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Pituitary Gland: Pars Distalis</b>						
<b>Hyperplasia Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						



Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Spleen: Capsule</b>						
<b>Inflammation Focal</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.267	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.159
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Spleen: Lymph Follic Depletion Cellular</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Stomach, Forestomach</b>						
<b>Hemorrhage</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Thymus</b>						
<b>Atrophy</b>						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03  
 Test Type: 90-DAY  
 Route: GAVAGE  
 Species/Strain: Rat/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:12  
 First Dose M/F: NA / NA  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
 LAST REMOVAL AT 14286 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Trachea						
Hemorrhage						
<b>LESION RATES</b>						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(n)	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:12

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)  
LAST REMOVAL AT 14286 WEEKS

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>Uterus: Endometrium</b>						
<b>Hyperplasia Cystic</b>						
<b>LESION RATES</b>						
OVERALL(a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	93(T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.159N
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

**Experiment Number:** 88122-03

**Test Type:** 90-DAY

**Route:** GAVAGE

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

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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

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

**Date Report Requested:** 10/19/2014

**Time Report Requested:** 16:08:12

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

**Lab:** BAT

**LEGEND**

- (a) Number of tumor-bearing animals/number of animals examined at site.
  - (b) Number of tumor-bearing animals/Poly-3 number
  - (d) Observed incidence at terminal kill.
  - (e) Value of statistic cannot be computed.
  - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
  - (g) Poly-3 adjusted lifetime tumor incidence.
  - (n) No statistics are calculated if all dose groups have fewer than two tumors.
  - (I) Interim sacrifice
  - (T) Terminal sacrifice
  - # Tumor rates based on numbers of animals necropsied.
  - \* To the right of any statistical result, indicates significance at ( $P \leq 0.05$ ).
  - \*\* To the right of any statistical result, indicates significance at ( $P \leq 0.01$ ).
  - N Indicates a negative trend for all tests
- The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

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