

Experiment Number: 88122-04
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/22/2014

Time Report Requested: 01:49:29

First Dose M/F: NA / NA

Lab: BAT

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

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

MALE MOUSE

Organ

Intestine Large, Rectum

Kidney

Liver

Lymph Node, Mandibular

Lymph Node, Mesenteric

Spleen

FEMALE MOUSE

Organ

Intestine Large, Rectum

Kidney

Kidney: Renal Tubule

Liver

Lymph Node, Mandibular

Lymph Node, Mesenteric

Spleen

Thymus

Morphology

Infiltration Cellular Histiocyte

Inflammation

Ulcer

Nephropathy

Inflammation

Vacuolization Cytoplasmic

Infiltration Cellular Histiocyte

Infiltration Cellular Histiocyte

Infiltration Cellular Histiocyte

Morphology

Infiltration Cellular Histiocyte

Inflammation

Casts Protein

Accumulation Hyaline Droplet

Vacuolization Cytoplasmic

Infiltration Cellular Histiocyte

Infiltration Cellular Histiocyte

Infiltration Cellular Histiocyte

Atrophy

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Esophagus						
Inflammation Focal						
LESION RATES						
OVERALL(a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/9 (11%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/9.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	11.1%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/9 (11%)
FIRST INCIDENCE	93(T)	---	---	---	---	93(T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.737
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.737
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.737
COCH-ARM / FISHERS	P=0.616	(e)	(e)	(e)	(e)	P=0.737
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.471
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Gallbladder Inflammation						
LESION RATES						
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)	---	---	---	---	---
STATISTICAL TESTS						
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						

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Gallbladder						
Inflammation Acute						
LESION RATES						
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	---	---	---	---	---	---
STATISTICAL TESTS						
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						

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

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

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Intestine Large, Rectum Inflammation						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	8/10 (80%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	8/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	80%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	8/10 (80%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
STATISTICAL TESTS						
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=0.000**
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						

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Intestine Large, Rectum						
Ulcer						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	20%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
STATISTICAL TESTS						
POLY 3	P=0.008**	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	P=0.008**	(e)	(e)	(e)	(e)	P=0.227
POLY 6	P=0.008**	(e)	(e)	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.010**	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	P=0.008**	(e)	(e)	(e)	(e)	P=0.067
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Kidney						
Casts Protein						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/1.00	0/1.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/1 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
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						

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Kidney						
Nephropathy						
LESION RATES						
OVERALL(a)	0/10 (0%)	1/1 (100%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	1/1.00	1/1.00	0/0.00	0/0.00	2/10.00
POLY-3 PERCENT (g)	0%	100%	100%	0%	0%	20%
TERMINAL (d)	0/10 (0%)	1/1 (100%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
FIRST INCIDENCE	---	93(T)	93(T)	---	---	93(T)
STATISTICAL TESTS						
POLY 3	(e)	P=0.091	P=0.091	(e)	(e)	P=0.227
POLY 1.5	(e)	P=0.091	P=0.091	(e)	(e)	P=0.227
POLY 6	(e)	P=0.091	P=0.091	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.462	P=0.091	P=0.091	(e)	(e)	P=0.237
MAX-ISO-POLY-3	(e)	P=0.000**	P=0.000**	(e)	(e)	P=0.067
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Kidney: Renal Tubule						
Accumulation Hyaline Droplet						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/1.00	0/1.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/1 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
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						

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 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Liver						
Clear Cell Focus						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/2 (0%)	0/0 (0%)	0/10 (0%)	1/10 (10%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/2.00	0/0.00	0/10.00	1/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%	10%
TERMINAL (d)	0/10 (0%)	0/2 (0%)	0/0 (0%)	0/10 (0%)	1/10 (10%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	93(T)	93(T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	P=0.500	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	P=0.500	P=0.500
POLY 6	(e)	(e)	(e)	(e)	P=0.500	P=0.500
COCH-ARM / FISHERS	P=0.210	(e)	(e)	(e)	P=0.500	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.159	P=0.159
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Liver						
Inflammation						
LESION RATES						
OVERALL(a)	5/10 (50%)	2/2 (100%)	0/0 (0%)	7/10 (70%)	6/10 (60%)	10/10 (100%)
POLY-3 RATE (b)	5/10.00	2/2.00	0/0.00	7/10.00	6/10.00	10/10.00
POLY-3 PERCENT (g)	50%	100%	0%	70%	60%	100%
TERMINAL (d)	5/10 (50%)	2/2 (100%)	0/0 (0%)	7/10 (70%)	6/10 (60%)	10/10 (100%)
FIRST INCIDENCE	93(T)	93(T)	---	93(T)	93(T)	93(T)
STATISTICAL TESTS						
POLY 3	(e)	P=0.303	(e)	P=0.329	P=0.500	P=0.008**
POLY 1.5	(e)	P=0.303	(e)	P=0.329	P=0.500	P=0.008**
POLY 6	(e)	P=0.303	(e)	P=0.329	P=0.500	P=0.008**
COCH-ARM / FISHERS	P=0.030*	P=0.318	(e)	P=0.325	P=0.500	P=0.016*
MAX-ISO-POLY-3	(e)	P=0.159	(e)	P=0.189	P=0.334	P<0.001**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

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 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Liver						
Necrosis						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/2 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/2.00	0/0.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/2 (0%)	0/0 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:29
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Liver						
Vacuolization Cytoplasmic						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/2 (0%)	0/0 (0%)	0/10 (0%)	4/10 (40%)	9/10 (90%)
POLY-3 RATE (b)	0/10.00	0/2.00	0/0.00	0/10.00	4/10.00	9/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	40%	90%
TERMINAL (d)	0/10 (0%)	0/2 (0%)	0/0 (0%)	0/10 (0%)	4/10 (40%)	9/10 (90%)
FIRST INCIDENCE	---	---	---	---	93(T)	93(T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	P=0.033*	P=0.000**
POLY 1.5	(e)	(e)	(e)	(e)	P=0.033*	P=0.000**
POLY 6	(e)	(e)	(e)	(e)	P=0.033*	P=0.000**
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	(e)	P=0.043*	P=0.000**
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.007**	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:29
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Lung						
Inflammation						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	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%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
STATISTICAL TESTS						
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=0.304	(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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:29
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Lung						
Pigmentation Hemosiderin						
LESION RATES						
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	---	---	---	---	---	---
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:29
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Lung: Interstitium Inflammation						
LESION RATES						
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	---	---	---	---	---	---
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:29
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Lymph Node, Mandibular Infiltration Cellular Histiocyte						
LESION RATES						
OVERALL(a)	0/10 (0%)	1/8 (12%)	3/10 (30%)	9/10 (90%)	10/10 (100%)	8/10 (80%)
POLY-3 RATE (b)	0/10.00	1/8.00	3/10.00	9/10.00	10/10.00	8/10.00
POLY-3 PERCENT (g)	0%	12.5%	30%	90%	100%	80%
TERMINAL (d)	0/10 (0%)	1/8 (12%)	3/10 (30%)	9/10 (90%)	10/10 (100%)	8/10 (80%)
FIRST INCIDENCE	---	93(T)	93(T)	93(T)	93(T)	93(T)
STATISTICAL TESTS						
POLY 3	P=0.000**	P=0.455	P=0.095	P=0.000**	P=NA	P=0.000**
POLY 1.5	P=0.000**	P=0.455	P=0.095	P=0.000**	P=NA	P=0.000**
POLY 6	P=0.000**	P=0.455	P=0.095	P=0.000**	P=NA	P=0.000**
COCH-ARM / FISHERS	P=0.000**	P=0.444	P=0.105	P=0.000**	P=0.000**	P=0.000**
MAX-ISO-POLY-3	P=0.000**	P=0.143	P=0.025*	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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:29
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Lymph Node, Mandibular Inflammation						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/8 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/8.00	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%)	0/8 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	93(T)	---	---
STATISTICAL TESTS						
POLY 3	P=0.686N	(e)	(e)	P=0.500	(e)	(e)
POLY 1.5	P=0.686N	(e)	(e)	P=0.500	(e)	(e)
POLY 6	P=0.686N	(e)	(e)	P=0.500	(e)	(e)
COCH-ARM / FISHERS	P=0.688N	(e)	(e)	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.520	(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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Lymph Node, Mesenteric Ectasia						
LESION RATES						
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)	---	---
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Lymph Node, Mesenteric Infiltration Cellular Histiocyte						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/10 (0%)	4/10 (40%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	4/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	40%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	4/10 (40%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	---	93(T)	93(T)	93(T)	93(T)
STATISTICAL TESTS						
POLY 3	P=0.000**	(e)	P=0.033*	P=NA	P=NA	P=NA
POLY 1.5	P=0.000**	(e)	P=0.033*	P=NA	P=NA	P=NA
POLY 6	P=0.000**	(e)	P=0.033*	P=NA	P=NA	P=NA
COCH-ARM / FISHERS	P=0.000**	(e)	P=0.043*	P=0.000**	P=0.000**	P=0.000**
MAX-ISO-POLY-3	P=0.000**	(e)	P=0.007**	(e)	(e)	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Lymph Node, Mesenteric Inflammation						
LESION RATES						
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)
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Parathyroid Gland						
Cyst						
LESION RATES						
OVERALL(a)	0/7 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/5 (0%)
POLY-3 RATE (b)	0/7.00	0/0.00	0/0.00	0/0.00	0/0.00	0/5.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/7 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/5 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Preputial Gland Inflammation						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	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%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
STATISTICAL TESTS						
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=0.304	(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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Spleen						
Hematopoietic Cell Proliferation						
LESION RATES						
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	---	---	---	---	---	---
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Spleen						
Infiltration Cellular Histiocyte						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	9/10 (90%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/10.00	9/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	90%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	9/10 (90%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Spleen: Lymph Follic Atrophy						
LESION RATES						
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	---	---	---	---	---	---
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Stomach, Glandular Inflammation						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	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%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
STATISTICAL TESTS						
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=0.304	(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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 14286 WEEKS**

DOSE	MALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Thymus						
Atrophy						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/9 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/9.00
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%)	0/9 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Esophagus						
Inflammation Focal						
LESION RATES						
OVERALL(a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	4/10 (40%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/0.74	0/0.00	4/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	40%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	4/10 (40%)
FIRST INCIDENCE	93(T)	---	---	---	---	93(T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	P=0.816N	(e)	P=0.318
POLY 1.5	(e)	(e)	(e)	P=0.802N	(e)	P=0.318
POLY 6	(e)	(e)	(e)	P=0.836N	(e)	P=0.318
COCH-ARM / FISHERS	P=0.209	(e)	(e)	P=0.818N	(e)	P=0.314
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.402N	(e)	P=0.172
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Gallbladder						
Inflammation						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.74	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	---	---	---	---	---	---
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Gallbladder						
Inflammation Acute						
LESION RATES						
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	0/0.74	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%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Intestine Large, Rectum						
Infiltration Cellular Histiocyte						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/9.74	3/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	30%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	3/10 (30%)	10/10 (100%)
FIRST INCIDENCE	---	---	---	---	93(T)	93(T)
STATISTICAL TESTS						
POLY 3	P=0.000**	(e)	(e)	(e)	P=0.095	P=NA
POLY 1.5	P=0.000**	(e)	(e)	(e)	P=0.095	P=NA
POLY 6	P=0.000**	(e)	(e)	(e)	P=0.095	P=NA
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	(e)	P=0.105	P=0.000**
MAX-ISO-POLY-3	P=0.000**	(e)	(e)	(e)	P=0.025*	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Intestine Large, Rectum Inflammation						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	7/10 (70%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/9.74	1/10.00	7/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%	70%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	1/10 (10%)	7/10 (70%)
FIRST INCIDENCE	---	---	---	---	93(T)	93(T)
STATISTICAL TESTS						
POLY 3	P=0.000**	(e)	(e)	(e)	P=0.500	P=0.000**
POLY 1.5	P=0.000**	(e)	(e)	(e)	P=0.500	P=0.000**
POLY 6	P=0.000**	(e)	(e)	(e)	P=0.500	P=0.000**
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	(e)	P=0.500	P=0.002**
MAX-ISO-POLY-3	P=0.000**	(e)	(e)	(e)	P=0.159	P=0.000**
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Intestine Large, Rectum Ulcer						
LESION RATES						
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	0/9.74	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%)	0/9 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
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: 88122-04
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
Time Report Requested: 01:49:30
First Dose M/F: NA / NA
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
LAST REMOVAL AT 12 WEEKS

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Kidney						
Casts Protein						
LESION RATES						
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%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	84	---	---
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Kidney						
Nephropathy						
LESION RATES						
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	0/0.74	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%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Kidney: Renal Tubule						
Accumulation Hyaline Droplet						
LESION RATES						
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%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	84	---	---
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Liver						
Clear Cell Focus						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/5 (0%)	0/5 (0%)	0/8 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/5.00	0/5.00	0/7.74	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/5 (0%)	0/5 (0%)	0/7 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Liver						
Inflammation						
LESION RATES						
OVERALL(a)	8/10 (80%)	5/5 (100%)	5/5 (100%)	7/8 (88%)	7/10 (70%)	9/10 (90%)
POLY-3 RATE (b)	8/10.00	5/5.00	5/5.00	7/7.74	7/10.00	9/10.00
POLY-3 PERCENT (g)	80%	100%	100%	90.4%	70%	90%
TERMINAL (d)	8/10 (80%)	5/5 (100%)	5/5 (100%)	7/7 (100%)	7/10 (70%)	9/10 (90%)
FIRST INCIDENCE	93(T)	93(T)	93(T)	93(T)	93(T)	93(T)
STATISTICAL TESTS						
POLY 3	P=0.540N	P=0.397	P=0.397	P=0.522	P=0.500N	P=0.500
POLY 1.5	P=0.545N	P=0.397	P=0.397	P=0.550	P=0.500N	P=0.500
POLY 6	P=0.533N	P=0.397	P=0.397	P=0.473	P=0.500N	P=0.500
COCH-ARM / FISHERS	P=0.552N	P=0.429	P=0.429	P=0.588	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.473N	P=0.184	P=0.184	P=0.289	P=0.311N	P=0.274
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Liver						
Necrosis						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/5 (0%)	0/5 (0%)	1/8 (12%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/5.00	0/5.00	1/8.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	12.5%	0%	10%
TERMINAL (d)	0/10 (0%)	0/5 (0%)	0/5 (0%)	0/7 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	84	---	93(T)
STATISTICAL TESTS						
POLY 3	P=0.314	(e)	(e)	P=0.455	(e)	P=0.500
POLY 1.5	P=0.314	(e)	(e)	P=0.455	(e)	P=0.500
POLY 6	P=0.314	(e)	(e)	P=0.455	(e)	P=0.500
COCH-ARM / FISHERS	P=0.309	(e)	(e)	P=0.444	(e)	P=0.500
MAX-ISO-POLY-3	P=0.254	(e)	(e)	P=0.143	(e)	P=0.159
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Liver						
Vacuolization Cytoplasmic						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/5 (0%)	0/5 (0%)	0/8 (0%)	0/10 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/5.00	0/5.00	0/7.74	0/10.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	20%
TERMINAL (d)	0/10 (0%)	0/5 (0%)	0/5 (0%)	0/7 (0%)	0/10 (0%)	2/10 (20%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
STATISTICAL TESTS						
POLY 3	P=0.021*	(e)	(e)	(e)	(e)	P=0.227
POLY 1.5	P=0.021*	(e)	(e)	(e)	(e)	P=0.227
POLY 6	P=0.021*	(e)	(e)	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.024*	(e)	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	P=0.019*	(e)	(e)	(e)	(e)	P=0.067
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-04
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
Time Report Requested: 01:49:30
First Dose M/F: NA / NA
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
LAST REMOVAL AT 12 WEEKS

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Lung						
Inflammation						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.74	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	---	---	---	---	---	---
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Lung						
Pigmentation Hemosiderin						
LESION RATES						
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	0/0.74	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%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Lung: Interstitium Inflammation						
LESION RATES						
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	0/0.74	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%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Lymph Node, Mandibular Infiltration Cellular Histiocyte						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/10 (0%)	2/10 (20%)	7/9 (78%)	9/10 (90%)	9/9 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	2/10.00	7/9.00	9/10.00	9/9.00
POLY-3 PERCENT (g)	0%	0%	20%	77.8%	90%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	2/10 (20%)	6/8 (75%)	9/10 (90%)	9/9 (100%)
FIRST INCIDENCE	---	---	93(T)	84	93(T)	93(T)
STATISTICAL TESTS						
POLY 3	P=0.000**	(e)	P=0.227	P=0.000**	P=0.000**	P=NA
POLY 1.5	P=0.000**	(e)	P=0.227	P=0.000**	P=0.000**	P=NA
POLY 6	P=0.000**	(e)	P=0.227	P=0.000**	P=0.000**	P=NA
COCH-ARM / FISHERS	P=0.000**	(e)	P=0.237	P<0.001**	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: 88122-04
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
Time Report Requested: 01:49:30
First Dose M/F: NA / NA
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Lymph Node, Mandibular Inflammation						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/9 (0%)	0/10 (0%)	0/9 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/8.74	0/10.00	0/9.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/8 (0%)	0/10 (0%)	0/9 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Lymph Node, Mesenteric Ectasia						
LESION RATES						
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	0/9.74	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%)	0/9 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Lymph Node, Mesenteric Infiltration Cellular Histiocyte						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/10 (0%)	1/10 (10%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	1/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	10%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	1/10 (10%)	9/9 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	---	93(T)	84	93(T)	93(T)
STATISTICAL TESTS						
POLY 3	P=0.000**	(e)	P=0.500	P=NA	P=NA	P=NA
POLY 1.5	P=0.000**	(e)	P=0.500	P=NA	P=NA	P=NA
POLY 6	P=0.000**	(e)	P=0.500	P=NA	P=NA	P=NA
COCH-ARM / FISHERS	P=0.000**	(e)	P=0.500	P=0.000**	P=0.000**	P=0.000**
MAX-ISO-POLY-3	P=0.000**	(e)	P=0.159	(e)	(e)	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/22/2014

Time Report Requested: 01:49:30

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Lymph Node, Mesenteric Inflammation						
LESION RATES						
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	0/9.74	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%)	0/9 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Parathyroid Gland						
Cyst						
LESION RATES						
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	0/0.74	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%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93(T)
STATISTICAL TESTS						
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Spleen						
Hematopoietic Cell Proliferation						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	2/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	20%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/9 (11%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	84	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	P=0.227	(e)	(e)
POLY 1.5	(e)	(e)	(e)	P=0.227	(e)	(e)
POLY 6	(e)	(e)	(e)	P=0.227	(e)	(e)
COCH-ARM / FISHERS	P=0.403N	(e)	(e)	P=0.237	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.067	(e)	(e)
HISTCONT SAME RTE						
HISTCONT ALL RTES						
CURR VS HC SAME RTE						
CURR VS HC ALL RTES						

Experiment Number: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Spleen						
Infiltration Cellular Histiocyte						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)	4/10 (40%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/9.74	4/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	40%	100%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/9 (0%)	4/10 (40%)	10/10 (100%)
FIRST INCIDENCE	---	---	---	---	93(T)	93(T)
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	P=0.033*	P=NA
POLY 1.5	(e)	(e)	(e)	(e)	P=0.033*	P=NA
POLY 6	(e)	(e)	(e)	(e)	P=0.033*	P=NA
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	(e)	P=0.043*	P=0.000**
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: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
 Time Report Requested: 01:49:30
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
 LAST REMOVAL AT 12 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Spleen: Lymph Follic Atrophy						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	1/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/9 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	84	---	---
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	P=0.500	(e)	(e)
POLY 1.5	(e)	(e)	(e)	P=0.500	(e)	(e)
POLY 6	(e)	(e)	(e)	P=0.500	(e)	(e)
COCH-ARM / FISHERS	P=0.568N	(e)	(e)	P=0.500	(e)	(e)
MAX-ISO-POLY-3	(e)	(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: 88122-04
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
Time Report Requested: 01:49:30
First Dose M/F: NA / NA
Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
LAST REMOVAL AT 12 WEEKS**

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Stomach, Glandular Inflammation						
LESION RATES						
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.74	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	---	---	---	---	---	---
STATISTICAL TESTS						
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: 88122-04
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Mouse/B6C3F1

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

Date Report Requested: 10/22/2014
Time Report Requested: 01:49:30
First Dose M/F: NA / NA
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(B6C3F1)
LAST REMOVAL AT 12 WEEKS

DOSE	FEMALE					
	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Thymus						
Atrophy						
LESION RATES						
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%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	84	---	---
STATISTICAL TESTS						
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: 88122-04
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Mouse/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/22/2014

Time Report Requested: 01:49:30

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 ****