

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

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/19/2014  
**Time Report Requested:** 16:08:07  
**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

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Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:07

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Male  
0 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	9	9	9	9	9	9	9	9	9	9
	3	3	3	3	3	3	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	1
	1	2	3	4	5	6	7	8	9	0

\*TOTALS

Alimentary System

Esophagus	+	+	+	+	+	+	+	+	+	+	10	
Muscularis, Inflammation, Chronic			1	1			1		3		4	1.5
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	10	
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	10	
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	10	
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	10	
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	10	
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	10	
Liver	+	+	+	+	+	+	+	+	+	+	10	
Inflammation				1		1					2	1.0
Pancreas	+	+	+	+	+	+	+	+	+	+	10	
Atrophy, Acute						1					1	1.0
Salivary Glands	+	+	+	+	+	+	+	+	+	+	10	
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	10	
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	10	

Cardiovascular System

Blood Vessel	+	+	+	+	+	+	+	+	+	+	10	
Heart	+	+	+	+	+	+	+	+	+	+	10	
Myocardium, Degeneration			1	1	1	1	1	1	1		8	1.0

Endocrine System

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

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CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:07

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Male  
0 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	*TOTALS
	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	9	9	9	9	9	9	9	9	9	9	
	3	3	3	3	3	3	3	3	3	3	
	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	1	
	1	2	3	4	5	6	7	8	9	0	
Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	10
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	10
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	10
Parathyroid Gland	+	+	+	M	+	+	+	+	+	+	9
Pituitary Gland	+	+	M	+	+	+	+	+	+	+	9
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	10
<b>General Body System</b>											
NONE											
<b>Genital System</b>											
Epididymis	+	+	+	+	+	+	+	+	+	+	10
Preputial Gland	+	+	+	+	+	+	+	+	+	+	10
Prostate	+	+	+	+	+	+	+	+	+	+	10
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	10
Testes	+	+	+	+	+	+	+	+	+	+	10
<b>Hematopoietic System</b>											
Bone Marrow	+	+	+	+	+	+	+	+	+	+	10
Lymph Node, Mandibular	+	+	+	+	+	+	+	+	+	+	10
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	10
Spleen	+	+	+	+	+	+	+	+	+	+	10
Thymus	+	+	+	+	+	+	+	+	+	+	10
<b>Integumentary System</b>											

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL  
 Test Compound: Elmiron (sodium pentosanpolysulfate)  
 CAS Number: 37319-17-8

Date Report Requested: 10/19/2014  
 Time Report Requested: 16:08:07  
 First Dose M/F: NA / NA  
 Lab: BAT

F 344/N Rat Male  
 0 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	9	9	9	9	9	9	9	9	9	9
	3	3	3	3	3	3	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	1
	1	2	3	4	5	6	7	8	9	0

\*TOTALS

**Integumentary System**

Mammary Gland	+	M	M	+	M	M	+	+	+	+	6
Skin	+	+	+	+	+	+	+	+	+	+	10

**Musculoskeletal System**

Bone	+	+	+	+	+	+	+	+	+	+	10
------	---	---	---	---	---	---	---	---	---	---	----

**Nervous System**

Brain	+	+	+	+	+	+	+	+	+	+	10
-------	---	---	---	---	---	---	---	---	---	---	----

**Respiratory System**

Lung	+	+	+	+	+	+	+	+	+	+	10
Nose	+	+	+	+	+	+	+	+	+	+	10
Trachea	+	+	+	+	+	+	+	+	+	+	10

**Special Senses System**

NONE

**Urinary System**

Kidney	+	+	+	+	+	+	+	+	+	+	10
Infarct				2							1 2.0
Renal Tubule, Cyst				2	2						2 2.0
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	10

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CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:07

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Male  
63 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	5	9	9	9	9	9	9	9	9	9
	7	3	3	3	3	3	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	2
	1	2	3	4	5	6	7	8	9	0
	*TOTALS									

Alimentary System

Esophagus	+										1
Intestine Large, Cecum	+										1
Intestine Large, Colon	+										1
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	10
Intestine Small, Duodenum	+										1
Intestine Small, Ileum	+										1
Intestine Small, Jejunum	+										1
Liver	+								+		2
Hepatodiaphragmatic Nodule	X								X		2
Midzonal, Vacuolization Cytoplasmic	1										1 1.0
Pancreas	+										1
Salivary Glands	+										1
Stomach, Forestomach	+										1
Stomach, Glandular	+										1

Cardiovascular System

Blood Vessel	+										1
Heart	+										1

Endocrine System

Adrenal Cortex	+										1
Adrenal Medulla	+										1

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

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First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Male  
63 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0
	5	9	9	9	9	9	9	9	9	9	9
	7	3	3	3	3	3	3	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1	2
	1	2	3	4	5	6	7	8	9	9	0
											<b>*TOTALS</b>

Islets, Pancreatic	+											1
Parathyroid Gland	+											1
Pituitary Gland	+											1
Thyroid Gland	+											1
<b>General Body System</b>												
NONE												
<b>Genital System</b>												
Epididymis	+											1
Preputial Gland	+											1
Prostate	+											1
Seminal Vesicle	+											1
Testes	+											1
<b>Hematopoietic System</b>												
Bone Marrow	+											1
Lymph Node, Mandibular	+											1
Lymph Node, Mesenteric	+											1
Spleen	+											1
Thymus	+											1
<b>Integumentary System</b>												
Mammary Gland	+											1
Skin	+											1

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+ ..Tissue examined microscopically

X ..Lesion present

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Species/Strain: Rat/F 344/N

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CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:07

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Male  
63 MG/KG

	DAY ON TEST										
	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	5	9	9	9	9	9	9	9	9	9	
	7	3	3	3	3	3	3	3	3	3	
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	1	1	1	1	1	1	1	1	1	2	
	1	2	3	4	5	6	7	8	9	0	<b>*TOTALS</b>
Skin	+										1
<b>Musculoskeletal System</b>											
Bone	+										1
<b>Nervous System</b>											
Brain	+										1
Peripheral Nerve	+										1
Spinal Cord	+										1
<b>Respiratory System</b>											
Lung	+ + + + + + + + + +										10
Alveolus, Infiltration Cellular, Histiocyte			1				1				2 1.0
Interstitialium, Edema	3										1 3.0
Nose	+										1
Trachea	+										1
<b>Special Senses System</b>											
NONE											
<b>Urinary System</b>											
Kidney	+										1
Urinary Bladder	+										1

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

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1-4 ..Lesion qualified as:

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Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:07

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Male  
125 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	9	9	9	9	9	9	9	9	9	9	
	3	3	3	3	3	3	3	3	3	3	
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	2	2	2	2	2	2	2	2	2	3	
	1	2	3	4	5	6	7	8	9	0	*TOTALS

Alimentary System

Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	10
Infiltration Cellular, Histiocyte	1		1				1				3 1.0
Inflammation, Chronic Active	1						1				2 1.0
Ulcer, Chronic	1										1 1.0
Liver						+		+			2
Hepatodiaphragmatic Nodule						X		X			2

Cardiovascular System

NONE

Endocrine System

NONE

General Body System

NONE

Genital System

NONE

Hematopoietic System

Lymph Node, Mandibular	+	+	+	+	+	+	+	+	+	+	10
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	10

Integumentary System

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

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1-4 ..Lesion qualified as:

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2) Mild 4) Marked



Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:07

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Male  
125 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	9	9	9	9	9	9	9	9	9	9
	3	3	3	3	3	3	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	2	2	2	2	2	2	2	2	2	3
	1	2	3	4	5	6	7	8	9	0
	*TOTALS									

NONE  
Musculoskeletal System

NONE  
Nervous System

NONE  
Respiratory System

Lung	+	+	+	+	+	+	+	+	+	+	10
Alveolus, Infiltration Cellular, Histiocyte			1		1		1	1	1		5 1.0

Special Senses System

NONE  
Urinary System

NONE

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+ ..Tissue examined microscopically

X ..Lesion present

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Species/Strain: Rat/F 344/N

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Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:07

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Male  
250 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	9	9	9	9	9	9	9	9	9	9
	3	3	3	3	3	3	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	3	3	3	3	3	3	3	3	3	4
	1	2	3	4	5	6	7	8	9	0

\*TOTALS

Alimentary System

Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	10	
Infiltration Cellular, Histiocyte			1	1	1	1	1		2	1	7	1.1
Inflammation, Chronic Active			1	1	1	1	1		1	1	7	1.0
Ulcer, Chronic			1			1				1	3	1.0
Liver	+	+	+	+	+	+	+	+	+	+	10	
Inflammation	1										1	1.0

Cardiovascular System

NONE

Endocrine System

NONE

General Body System

NONE

Genital System

NONE

Hematopoietic System

Lymph Node, Mandibular	+	+	+	+	+	+	+	+	+	+	10	
Infiltration Cellular, Histiocyte	1				1	1					3	1.0
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	10	

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

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Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:07

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Male  
250 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0
	9	9	9	9	9	9	9	9	9	9	9
	3	3	3	3	3	3	3	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0
	3	3	3	3	3	3	3	3	3	4	
	1	2	3	4	5	6	7	8	9	0	
	<b>*TOTALS</b>										
Infiltration Cellular, Histiocyte	1	1	1	1	1				1		6 1.0
Spleen	+	+	+	+	+	+	+	+	+	+	10

Integumentary System

NONE

Musculoskeletal System

NONE

Nervous System

NONE

Respiratory System

Lung + + + + + + + + + 10

Alveolus, Infiltration Cellular, Histiocyte 1 1 2 1 1 1 6 1.2

Special Senses System

NONE

Urinary System

NONE

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X ..Lesion present

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CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:08

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Male  
500 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	9	9	9	9	9	3	9	9	9	9
	3	3	3	3	3	2	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	4	4	4	4	4	4	4	4	4	5
	1	2	3	4	5	6	7	8	9	0

\*TOTALS

Hemorrhage						2					1	2.0
Stomach, Glandular						+					1	
<b>Cardiovascular System</b>												
Blood Vessel						+					1	
Heart						+					1	
<b>Endocrine System</b>												
Adrenal Cortex						+					1	
Adrenal Medulla						+					1	
Islets, Pancreatic						+					1	
Parathyroid Gland						+					1	
Pituitary Gland						M					0	
Thyroid Gland						+					1	
<b>General Body System</b>												
NONE												
<b>Genital System</b>												
Epididymis						+					1	
Preputial Gland						+					1	
Prostate						+					1	
Seminal Vesicle						+					1	
Testes						+					1	

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:08

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Male  
500 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	9	9	9	9	9	3	9	9	9	9
	3	3	3	3	3	2	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	4	4	4	4	4	4	4	4	4	5
	1	2	3	4	5	6	7	8	9	0
	*TOTALS									

Hematopoietic System

Bone Marrow											+	1										
Lymph Node, Mandibular											+	+	+	+	+	+	+	+	+	+	10	
Infiltration Cellular, Histiocyte											1	1	1	1	2	1	1	1	1	1	8	1.1
Lymph Node, Mesenteric											+	+	+	+	+	+	+	+	+	+	10	
Infiltration Cellular, Histiocyte											1	1	2	2	1	2	1	1	1	1	8	1.4
Spleen											+	+	+	+	+	+	+	+	+	+	10	
Lymph Follic, Depletion Cellular											3	3	3	3	3	3	3	3	3	3	1	3.0
Thymus											+	+	+	+	+	+	+	+	+	+	1	
Atrophy											2	2	2	2	2	2	2	2	2	2	1	2.0

Integumentary System

Mammary Gland											+	1	
Skin											+	1	

Musculoskeletal System

Bone											+	1	
------	--	--	--	--	--	--	--	--	--	--	---	---	--

Nervous System

Brain											+	1	
-------	--	--	--	--	--	--	--	--	--	--	---	---	--

Respiratory System

Lung											+	+	+	+	+	+	+	+	+	+	10		
Alveolus, Infiltration Cellular, Histiocyte											1	2	1	1	1	1	1	1	1	1	1	10	1.1

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:08

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Male  
500 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	9	9	9	9	9	3	9	9	9	9
	3	3	3	3	3	2	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	4	4	4	4	4	4	4	4	4	5
	1	2	3	4	5	6	7	8	9	0

\*TOTALS

Inflammation, Acute						3					1	3.0
Interstitial, Inflammation, Chronic									1		1	1.0
Nose						+					1	
Trachea						+					1	
Hemorrhage						1					1	1.0

Special Senses System

NONE

Urinary System

Kidney												10
Inflammation									1			1 1.0
Renal Tubule, Necrosis						3						1 3.0
Urinary Bladder						+						1

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:08

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Male  
1000 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	9	3	9	0	9	9	9	9	9	9
	3	1	3	4	3	3	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	5	5	5	5	5	5	5	5	5	6
	1	2	3	4	5	6	7	8	9	0
	*TOTALS									

Alimentary System

Esophagus	+	+	+	+	+	+	+	+	+	+	10	
Muscularis, Inflammation, Chronic	1	1	1	1				1	1	1	7	1.0
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	10	
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	10	
Intestine Large, Rectum	+	A	+	+	+	+	+	+	+	+	9	
Infiltration Cellular, Histiocyte	2		2		2	2	2	2	2	2	8	2.0
Inflammation, Chronic Active	2		1		2	2	2	2	2	1	8	1.8
Ulcer, Chronic	2		1		2	2	1	1	1		7	1.4
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	10	
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	10	
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	10	
Liver	+	+	+	+	+	+	+	+	+	+	10	
Hepatodiaphragmatic Nodule				X	X	X			X		4	
Inflammation, Granulomatous	1		1		2			1	1	1	6	1.2
Midzonal, Vacuolization Cytoplasmic	2		2		2	1	2	2	1	1	8	1.6
Pancreas	+	+	+	+	+	+	+	+	+	+	10	
Acinus, Atrophy							1		1		2	1.0
Salivary Glands	+	+	+	+	+	+	+	+	+	+	10	
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	10	
Stomach, Glandular	+	A	+	+	+	+	+	+	+	+	9	

Cardiovascular System

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked



Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:08

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Male  
1000 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	9	3	9	0	9	9	9	9	9	9
	3	1	3	4	3	3	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	5	5	5	5	5	5	5	5	5	6
	1	2	3	4	5	6	7	8	9	0
	<b>*TOTALS</b>									

Blood Vessel	+	+	+	+	+	+	+	+	+	+	10		
Heart	+	+	+	+	+	+	+	+	+	+	10		
Myocardium, Degeneration			1		1	1	1	1	1		7	1.0	
<b>Endocrine System</b>													
Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	10		
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	10		
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	10		
Parathyroid Gland	M	M	+	+	+	+	+	+	+	+	8		
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	10		
Pars Distalis, Hyperplasia, Focal					1						1	1.0	
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	10		
<b>General Body System</b>													
NONE													
<b>Genital System</b>													
Epididymis	+	+	+	+	+	+	+	+	+	+	10		
Inflammation, Chronic				2							1	2.0	
Preputial Gland	+	+	+	+	+	+	+	+	+	+	10		
Prostate	+	+	+	+	+	+	+	+	+	+	10		
Inflammation, Chronic				2							1	2.0	
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	10		
Inflammation, Chronic				3							1	3.0	

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:08

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Male  
1000 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	9	3	9	0	9	9	9	9	9	9
	3	1	3	4	3	3	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	5	5	5	5	5	5	5	5	5	6
	1	2	3	4	5	6	7	8	9	0
	<b>*TOTALS</b>									

Testes	+	+	+	+	+	+	+	+	+	+	10	
<b>Hematopoietic System</b>												
Bone Marrow	+	+	+	+	+	+	+	+	+	+	10	
Lymph Node, Mandibular	+	+	+	+	+	+	+	+	+	+	10	
Infiltration Cellular, Histiocyte		1	1	2	1		2	1		1	7	1.3
Lymph Node, Mesenteric	+	A	+	+	+	+	+	+	+	+	9	
Infiltration Cellular, Histiocyte	2		2		2	1	1	2	2	2	8	1.8
Spleen	+	+	+	+	+	+	+	+	+	+	10	
Lymph Follic, Depletion Cellular				3							1	3.0
Thymus	+	+	+	+	+	+	+	+	+	+	10	
<b>Integumentary System</b>												
Mammary Gland	+	+	+	+	M	M	+	+	+	M	7	
Skin	+	+	+	+	+	+	+	+	+	+	10	
<b>Musculoskeletal System</b>												
Bone	+	+	+	+	+	+	+	+	+	+	10	
<b>Nervous System</b>												
Brain	+	+	+	+	+	+	+	+	+	+	10	
<b>Respiratory System</b>												
Lung	+	+	+	+	+	+	+	+	+	+	10	
Alveolus, Infiltration Cellular, Histiocyte	1	1	1		2		1	2	1	1	8	1.3

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:08

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Male  
1000 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	9	3	9	0	9	9	9	9	9	9
	3	1	3	4	3	3	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	5	5	5	5	5	5	5	5	5	6
	1	2	3	4	5	6	7	8	9	0

\*TOTALS

Congestion	2										1	2.0
Hemorrhage			3								1	3.0
Interstitialium, Edema	2		2								2	2.0
Interstitialium, Inflammation, Chronic			1		1					1	3	1.0
Nose	+	+	+	+	+	+	+	+	+	+	10	
Trachea	+	+	+	+	+	+	+	+	+	+	10	

Special Senses System

NONE

Urinary System

Kidney	+	+	+	A	+	+	+	+	+	+	9	
Hemorrhage		2									1	2.0
Inflammation			1								1	1.0
Renal Tubule, Vacuolization Cytoplasmic	1		1		1	1	1	1	1	1	8	1.0
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	10	

\*\*\*END OF MALE DATA\*\*\*

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:08

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
0 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	9	9	9	9	9	9	9	9	9	9
	3	3	3	3	3	3	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	6	6	6	6	6	6	6	6	6	7
	1	2	3	4	5	6	7	8	9	0
	*TOTALS									

Alimentary System

Esophagus	+	+	+	+	+	+	+	+	+	+	10		
Muscularis, Inflammation, Chronic			1	1		1			2		4	1.3	
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	10		
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	10		
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	10		
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	10		
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	10		
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	10		
Liver	+	+	+	+	+	+	+	+	+	+	10		
Hepatodiaphragmatic Nodule										X	1		
Inflammation, Granulomatous	1	1	1	1	2	2		1	1	1	9	1.2	
Pancreas	+	+	+	+	+	+	+	+	+	+	10		
Acinus, Atrophy				1			1				2	1.0	
Salivary Glands	+	+	+	+	+	+	+	+	+	+	10		
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	10		
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	10		

Cardiovascular System

Blood Vessel	+	+	+	+	+	+	+	+	+	+	10		
Heart	+	+	+	+	+	+	+	+	+	+	10		
Myocardium, Degeneration	1							1			2	1.0	

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:08

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
0 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0
	9	9	9	9	9	9	9	9	9	9	9
	3	3	3	3	3	3	3	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0
	6	6	6	6	6	6	6	6	6	7	7
	1	2	3	4	5	6	7	8	9	0	0
	*TOTALS										

Endocrine System

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	10
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	10
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	10
Parathyroid Gland	+	+	+	+	+	+	+	+	+	+	10
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	10
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	10

General Body System

NONE

Genital System

Clitoral Gland	+	+	+	+	+	+	+	M	+	+	9
Ovary	+	+	+	+	+	+	+	+	+	+	10
Cyst							3				1 3.0
Uterus	+	+	+	+	+	+	+	+	+	+	10
Endometrium, Hyperplasia, Cystic							1				1 1.0

Hematopoietic System

Bone Marrow	+	+	+	+	+	+	+	+	+	+	10
Lymph Node, Mandibular	+	+	+	+	+	+	+	+	+	+	10
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	10
Spleen	+	+	+	+	+	+	+	+	+	+	10
Thymus	+	+	+	+	+	+	+	+	+	+	10

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:08

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
0 MG/KG

	DAY ON TEST										
	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	*TOTALS
	3	3	3	3	3	3	3	3	3	3	
Thymus	+	+	+	+	+	+	+	+	+	+	10
<b>Integumentary System</b>											
Mammary Gland	+	M	+	+	+	+	+	+	+	+	9
Skin	+	+	+	+	+	+	+	+	+	+	10
<b>Musculoskeletal System</b>											
Bone	+	+	+	+	+	+	+	+	+	+	10
<b>Nervous System</b>											
Brain	+	+	+	+	+	+	+	+	+	+	10
<b>Respiratory System</b>											
Lung	+	+	+	+	+	+	+	+	+	+	10
Nose	+	+	+	+	+	+	+	+	+	+	10
Trachea	+	+	+	+	+	+	+	+	+	+	10
<b>Special Senses System</b>											
NONE											
<b>Urinary System</b>											
Kidney	+	+	+	+	+	+	+	+	+	+	10
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	10

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:08

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
63 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	9	9	9	9	9	9	9	9	9	9	
	3	3	3	3	3	3	3	3	3	3	
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	7	7	7	7	7	7	7	7	7	8	
	1	2	3	4	5	6	7	8	9	0	*TOTALS

Alimentary System

Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	10	
Infiltration Cellular, Histiocyte						1	1				2	1.0
Liver	+	+	+	+	+	+	+	+	+	+	10	
Inflammation, Granulomatous	1	1	1	1	1	1	1	1	1	1	10	1.0

Cardiovascular System

NONE

Endocrine System

NONE

General Body System

NONE

Genital System

NONE

Hematopoietic System

Lymph Node, Mandibular											+		1		
Infiltration Cellular, Histiocyte											1			1	1.0
Lymph Node, Mesenteric											+	+		2	
Infiltration Cellular, Histiocyte											1	1		2	1.0

Integumentary System

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:08

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
63 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	9	9	9	9	9	9	9	9	9	9	
	3	3	3	3	3	3	3	3	3	3	
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	7	7	7	7	7	7	7	7	7	8	
	1	2	3	4	5	6	7	8	9	0	*TOTALS

NONE  
Musculoskeletal System

NONE  
Nervous System

NONE  
Respiratory System

Lung	+	+	+	+	+	+	+	+	+	+	10
Alveolus, Infiltration Cellular, Histiocyte	1		1		1		1	1	1	1	7 1.0
Bronchiole, Foreign Body				X							1
Interstitialium, Inflammation, Chronic							1				1 1.0

Special Senses System

NONE  
Urinary System

NONE

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked



Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:08

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
125 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	9	9	9	9	9	9	9	9	9	9	
	3	3	3	3	3	3	3	3	3	3	
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	8	8	8	8	8	8	8	8	8	9	
	1	2	3	4	5	6	7	8	9	0	*TOTALS

Alimentary System

Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	10	
Infiltration Cellular, Histiocyte							1				1	1.0
Liver	+	+	+	+	+	+	+	+	+	+	10	
Inflammation, Granulomatous	1	1	1	1	1	1	1	1	1	1	10	1.0

Cardiovascular System

NONE

Endocrine System

NONE

General Body System

NONE

Genital System

NONE

Hematopoietic System

Lymph Node, Mandibular				+						+	2	
Infiltration Cellular, Histiocyte				1						1	2	1.0
Lymph Node, Mesenteric				+		+		+	+	+	5	
Infiltration Cellular, Histiocyte				1		1		1	2	1	5	1.2

Integumentary System

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:09

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
125 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	9	9	9	9	9	9	9	9	9	9	
	3	3	3	3	3	3	3	3	3	3	
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	
	8	8	8	8	8	8	8	8	8	9	
	1	2	3	4	5	6	7	8	9	0	*TOTALS

NONE  
Musculoskeletal System

NONE  
Nervous System

NONE  
Respiratory System

Lung	+	+	+	+	+	+	+	+	+	+	10
Alveolus, Infiltration Cellular, Histiocyte	1	1	1					1	1		5 1.0

Special Senses System

NONE  
Urinary System

NONE

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:09

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
250 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	9	9	9	9	9	9	9	9	9	9
	3	3	3	3	3	3	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	1
	9	9	9	9	9	9	9	9	9	0
	1	2	3	4	5	6	7	8	9	0
	*TOTALS									

Alimentary System

Intestine Large, Cecum											+	1		
Infiltration Cellular, Histiocyte											1		1	1.0
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+		10		
Infiltration Cellular, Histiocyte			1				1					2	1.0	
Liver	+	+	+	+	+	+	+	+	+	+		10		
Hepatodiaphragmatic Nodule			X									1		
Inflammation, Granulomatous	1	1	1	1	1	1	1	1	1	1		10	1.0	

Cardiovascular System

NONE

Endocrine System

NONE

General Body System

NONE

Genital System

Ovary											+	1		
Cyst											3		1	3.0

Hematopoietic System

Lymph Node, Mandibular	+	+	+	+	+	+	+	+	+	+		10		
------------------------	---	---	---	---	---	---	---	---	---	---	--	----	--	--

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:09

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
250 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	9	9	9	9	9	9	9	9	9	9
	3	3	3	3	3	3	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	1
	9	9	9	9	9	9	9	9	9	0
	1	2	3	4	5	6	7	8	9	0

\*TOTALS

Infiltration Cellular, Histiocyte						1		1	1		3	1.0
Lymph Node, Mesenteric	+	+				+	+	+	+	+	7	
Infiltration Cellular, Histiocyte	1	1				1	1	1	1	1	7	1.0

Integumentary System

NONE

Musculoskeletal System

NONE

Nervous System

NONE

Respiratory System

Lung	+	+	+	+	+	+	+	+	+	+	10		
Alveolus, Infiltration Cellular, Histiocyte					1	1	1		1	1	1	6	1.0
Infiltration Cellular, Histiocyte	1										1	1.0	
Interstitialium, Inflammation, Chronic				1							1	1.0	

Special Senses System

NONE

Urinary System

NONE

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:09

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
500 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	9	9	9	9	9	9	9	9	9	9
	3	3	3	3	3	3	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1
	0	0	0	0	0	0	0	0	0	1
	1	2	3	4	5	6	7	8	9	0

\*TOTALS

Alimentary System

Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	10	
Infiltration Cellular, Histiocyte	2	2	1	2	1	1	1	1	2	2	10	1.5
Inflammation, Chronic Active	1	1		1	1	1	1	1	1	1	9	1.0
Ulcer, Chronic		1		1	1	1	1		1		6	1.0
Liver	+	+	+	+	+	+	+	+	+	+	10	
Inflammation, Granulomatous	1	1	2	1	1	1		1	1	2	9	1.2

Cardiovascular System

NONE

Endocrine System

NONE

General Body System

NONE

Genital System

NONE

Hematopoietic System

Lymph Node, Mandibular	+	+	+	+	+	+	+	+	+	+	10	
Infiltration Cellular, Histiocyte	1		1						1		3	1.0
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	10	

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:09

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
500 MG/KG

	DAY ON TEST											
	0	0	0	0	0	0	0	0	0	0		
	0	0	0	0	0	0	0	0	0	0		
	9	9	9	9	9	9	9	9	9	9		
	3	3	3	3	3	3	3	3	3	3		
ANIMAL ID	0	0	0	0	0	0	0	0	0	0		
	0	0	0	0	0	0	0	0	0	0		
	1	1	1	1	1	1	1	1	1	1		
	0	0	0	0	0	0	0	0	0	1		
	1	2	3	4	5	6	7	8	9	0	<b>*TOTALS</b>	
Infiltration Cellular, Histiocyte		1		1	1	1	1	1	1		7	1.0
Spleen	+	+	+	+	+	+	+	+	+	+	10	
<b>Integumentary System</b>												
NONE												
<b>Musculoskeletal System</b>												
NONE												
<b>Nervous System</b>												
NONE												
<b>Respiratory System</b>												
Lung	+	+	+	+	+	+	+	+	+	+	10	
Alveolus, Foreign Body	X										1	
Alveolus, Infiltration Cellular, Histiocyte	1	1		1			1	1	1	1	7	1.0
Interstitialium, Inflammation, Chronic	1				1	1					3	1.0
<b>Special Senses System</b>												
NONE												
<b>Urinary System</b>												
Kidney	+	+	+	+	+	+	+	+	+	+	10	

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:09

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
1000 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	9	9	9	9	9	9	9	9	9	9
	3	3	3	3	3	3	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1
	1	1	1	1	1	1	1	1	1	2
	1	2	3	4	5	6	7	8	9	0
	*TOTALS									

Alimentary System

Esophagus	+	+	+	+	+	+	+	+	+	+	10		
Muscularis, Inflammation, Chronic			1	1	1	1			1	1	1	7	1.0
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	10		
Inflammation, Chronic Active							2				1	2.0	
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	10		
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	10		
Infiltration Cellular, Histiocyte	2	2	2	2	2	2	2	2	2	2	10	2.0	
Inflammation, Chronic Active	2	1	1	1	1	1	2	2	2	1	10	1.4	
Ulcer, Chronic	1	1	1	1		1		1	1	1	8	1.0	
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	10		
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	10		
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	10		
Liver	+	+	+	+	+	+	+	+	+	+	10		
Hepatodiaphragmatic Nodule										X	1		
Inflammation, Granulomatous	2	1	1	1	1	1	1	1	2	2	10	1.3	
Midzonal, Vacuolization Cytoplasmic	1	1	1	1			1		1	1	7	1.0	
Pancreas	+	+	+	+	+	+	+	+	+	+	10		
Salivary Glands	+	+	+	+	+	+	+	+	+	+	10		
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	10		
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	10		

Cardiovascular System

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:09

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
1000 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	9	9	9	9	9	9	9	9	9	9
	3	3	3	3	3	3	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1
	1	1	1	1	1	1	1	1	1	2
	1	2	3	4	5	6	7	8	9	0
	<b>*TOTALS</b>									

Blood Vessel	+	+	+	+	+	+	+	+	+	+	10
Heart	+	+	+	+	+	+	+	+	+	+	10
Myocardium, Degeneration			1	1	1	1		1			5 1.0
<b>Endocrine System</b>											
Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	10
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	10
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	10
Parathyroid Gland	+	M	+	+	+	+	+	+	+	+	9
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	10
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	10
<b>General Body System</b>											
NONE											
<b>Genital System</b>											
Clitoral Gland	+	+	+	+	+	+	+	+	+	+	10
Ovary	+	+	+	+	+	+	+	+	+	+	10
Cyst					3						1 3.0
Uterus	+	+	+	+	+	+	+	+	+	+	10
<b>Hematopoietic System</b>											
Bone Marrow	+	+	+	+	+	+	+	+	+	+	10
Lymph Node, Mandibular	+	+	+	+	+	+	+	+	+	+	10
Infiltration Cellular, Histiocyte	1	1	1	1	2	1	1	2	1	1	10 1.2

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked



Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:09

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female 1000 MG/KG	DAY ON TEST											
	0	0	0	0	0	0	0	0	0	0		
ANIMAL ID	0	0	0	0	0	0	0	0	0	0	*TOTALS	
	1	1	1	1	1	1	1	1	1	1		
Infiltration Cellular, Histiocyte	1	1	1	1	2	1	1	2	1	1	10	1.2
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	10	
Infiltration Cellular, Histiocyte	1	1	1	1	1	1	1	1	1	2	10	1.1
Spleen	+	+	+	+	+	+	+	+	+	+	10	
Capsule, Inflammation, Focal				1							1	1.0
Thymus	+	+	+	+	+	+	+	+	+	+	10	
<b>Integumentary System</b>												
Mammary Gland	+	+	+	+	+	+	+	+	+	+	10	
Skin	+	+	+	+	+	+	+	+	+	+	10	
<b>Musculoskeletal System</b>												
Bone	+	+	+	+	+	+	+	+	+	+	10	
<b>Nervous System</b>												
Brain	+	+	+	+	+	+	+	+	+	+	10	
<b>Respiratory System</b>												
Lung	+	+	+	+	+	+	+	+	+	+	10	
Alveolus, Infiltration Cellular, Histiocyte	1	2	2	1	1	1	1	2		1	9	1.3
Hematopoietic Cell Proliferation		1									1	1.0
Interstitial, Inflammation, Chronic		1	1		1	1		1		1	6	1.0
Nose	+	+	+	+	+	+	+	+	+	+	10	
Trachea	+	+	+	+	+	+	+	+	+	+	10	

\* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ ..Tissue examined microscopically

X ..Lesion present

I ..Insufficient tissue

M ..Missing tissue

A ..Autolysis precludes evaluation

BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

Experiment Number: 88122-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/19/2014

Time Report Requested: 16:08:09

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat Female  
1000 MG/KG

DAY ON TEST	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	9	9	9	9	9	9	9	9	9	9
	3	3	3	3	3	3	3	3	3	3
ANIMAL ID	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1
	1	1	1	1	1	1	1	1	1	2
	1	2	3	4	5	6	7	8	9	0

\*TOTALS

Special Senses System

NONE

Urinary System

Kidney	+	+	+	+	+	+	+	+	+	+	10
Renal Tubule, Vacuolization Cytoplasmic	1	1	1	1	1	1	1	1	1	1	10 1.0
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	10

\*\* END OF REPORT \*\*

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