

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

<b>C Number:</b>	C88122
<b>Lock Date:</b>	04/14/2000
<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>	04/26/2001

Experiment Number: 88122-07

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: Mouse/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/16/2014

Time Report Requested: 12:23:15

First Dose M/F: NA / NA

Lab: BAT

<b>ANIMAL ID:</b> 1	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901721

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Trachea
* Urinary Bladder			

MISSING

* Lymph Node, Mandibular	* Mammary Gland
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INSUFFICIENT TISSUE

* Thyroid Gland
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OBSERVATIONS

* Adrenal Cortex	Hypertrophy	Moderate
* Kidney	Nephropathy	Minimal
* Liver	Clear Cell Focus	
	Hepatocellular Adenoma	Multiple
Note: TGL 3, "nodule, 3x3x2mm, red" noted at necropsy, was not apparent microscopically.		
	[ Clear Cell Focus TGLS = 2-4 ]	
	[ Hepatocellular Adenoma TGLS = 4,5-11+12 ]	
* Lung	Alveolar/Bronchiolar Carcinoma	
	[ Alveolar/Bronchiolar Carcinoma TGLS = 1-3 ]	
Tooth	Malformation	Moderate

PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

<b>ANIMAL ID:</b> 2	<b>TRT#:</b> 1 <b>DOSE:</b> 0 MG/KG	<b>SEX:</b> Male <b>DISP:</b> Terminal Sacrifice	<b>DAY ON TEST:</b> 731 <b>HISTO:</b> 9901722
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**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Hyperplasia	Mild
* Kidney	Nephropathy	Mild
* Liver	Basophilic Focus	
	Eosinophilic Focus	
	Fatty Change	Minimal
	Inflammation	Chronic, Minimal
<p>Note: TGL 1, "focus, 3x2mm, white" noted at necropsy, was not apparent microscopically.            [ Basophilic Focus TGLS = 4-12 ]            [ Eosinophilic Focus TGLS = 5-13 ]</p>		
* Lung	Inflammation	Chronic Active, Moderate
	[ Inflammation TGLS = 3-3 ]	
Mesentery	Fat	Necrosis
	[ Necrosis TGLS = 2-10 ]	Mild
Tooth	Malformation	Minimal

PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 3	<b>TRT#:</b> 1 <b>DOSE:</b> 0 MG/KG	<b>SEX:</b> Male <b>DISP:</b> Natural Death	<b>DAY ON TEST:</b> 420 <b>HISTO:</b> 9901723
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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

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**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Pituitary Gland
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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Stomach, Forestomach	* Stomach, Glandular		

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**OBSERVATIONS**

* Liver	Basophilic Focus
	Hepatocellular Adenoma

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[ Hepatocellular Adenoma TGLS = 1-4 ]

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**PRIMARY CAUSE OF DEATH** - Liver Hepatocellular Adenoma

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07

**Test Type:** CHRONIC

**Route:** GAVAGE

**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

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

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

**Date Report Requested:** 10/16/2014

**Time Report Requested:** 12:23:15

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

**Lab:** BAT

**ANIMAL ID:** 4

**TRT#:** 1

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901724

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Islets, Pancreatic	* Liver
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Hyperplasia	Mild
	Hypertrophy	Mild
* Intestine Small, Jejunum [ Carcinoma TGLS = 1-10 ]	Carcinoma	
* Kidney	Nephropathy	Mild
Tooth	Malformation	Minimal

PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 5	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901725

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

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**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
* Kidney	Nephropathy	Minimal
* Liver	Eosinophilic Focus	
	Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric	Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 1-6 ]		

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**PRIMARY CAUSE OF DEATH** -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 6	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901726

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Liver	* Lung	* Lymph Node, Mandibular	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

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**MISSING**

\* Mammary Gland

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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
* Kidney	Infarct	Mild
	Nephropathy	Minimal
* Lymph Node, Mesenteric	Angiectasis	Mild
[ Angiectasis TGLS = 1-6 ]		

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**PRIMARY CAUSE OF DEATH** -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

<b>ANIMAL ID:</b> 7	<b>TRT#:</b> 1 <b>DOSE:</b> 0 MG/KG	<b>SEX:</b> Male <b>DISP:</b> Terminal Sacrifice	<b>DAY ON TEST:</b> 731 <b>HISTO:</b> 9901727
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**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Parathyroid Gland	* Thymus
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Mild
* Liver	Eosinophilic Focus	
	Hepatocellular Adenoma	Multiple
	Hepatocellular Carcinoma	
[ Hepatocellular Adenoma TGLS = 1,3-11+12 ]		
[ Hepatocellular Carcinoma TGLS = 1-11 ]		
Mesentery	Fat	Necrosis
[ Necrosis TGLS = 2-10 ]		Mild
Tooth	Malformation	Mild

PRIMARY CAUSE OF DEATH -

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 8	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901728

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Liver	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

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**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
* Kidney	Nephropathy	Minimal
* Lung	Alveolar/Bronchiolar Carcinoma	
[ Alveolar/Bronchiolar Carcinoma TGLS = 2-3 ]		
* Testes	Hemangiosarcoma	
[ Hemangiosarcoma TGLS = 1-7 ]		
Tooth	Inflammation	Chronic Active, Moderate
	Malformation	Mild

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PRIMARY CAUSE OF DEATH -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 9	<b>TRT#:</b> 1 <b>DOSE:</b> 0 MG/KG	<b>SEX:</b> Male <b>DISP:</b> Terminal Sacrifice	<b>DAY ON TEST:</b> 731 <b>HISTO:</b> 9901729
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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

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**MISSING**

\* Mammary Gland

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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Moderate
Harderian Gland		Adenoma	
[ Adenoma TGLS = 1-10 ]			
* Kidney		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
* Lung		Alveolar/Bronchiolar Adenoma	
[ Alveolar/Bronchiolar Carcinoma TGLS = 3-13,4-12 ]		Alveolar/Bronchiolar Carcinoma	Multiple
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-11 ]			
Tooth		Malformation	Mild

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**PRIMARY CAUSE OF DEATH** -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 10	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901730

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

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**MISSING**

\* Mammary Gland

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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Marked
Harderian Gland	Adenoma	
* Heart	Cardiomyopathy	Minimal
* Kidney	Metaplasia	Osseous, Mild
	Nephropathy	Minimal
* Liver	Basophilic Focus	
	Clear Cell Focus	
	Eosinophilic Focus	
	Fatty Change	Mild
[ Basophilic Focus TGLS = 1-4 ]		
[ Clear Cell Focus TGLS = 3-11 ]		
[ Eosinophilic Focus TGLS = 2-10 ]		
Tooth	Malformation	Minimal

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**PRIMARY CAUSE OF DEATH** -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 11	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901731

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

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**MISSING**

\* Mammary Gland

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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Mild
* Liver	Clear Cell Focus	
	Hepatocellular Adenoma	
	Inflammation	Chronic, Minimal
[ Hepatocellular Adenoma TGLS = 2-10 ]		
* Preputial Gland	Hemangiosarcoma	
[ Hemangiosarcoma TGLS = 1-7 ]		
Tooth	Malformation	Mild

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PRIMARY CAUSE OF DEATH -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 12

**TRT#:** 1

**SEX:** Male

**DAY ON TEST:** 606

**DOSE:** 0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9901732

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

Harderian Gland	Adenoma	
* Kidney	Nephropathy	Mild
* Liver	Eosinophilic Focus	
* Lung	Alveolar/Bronchiolar Carcinoma	
[ Alveolar/Bronchiolar Carcinoma TGLS = 2-3 ]		
* Preputial GI		
Note: TGL 1, "enlarged 1.5x, green" noted at necropsy, was not apparent microscopically.		
* Spleen	Hematopoietic Cell Proliferation	Mild
* Stomach, Forestomach	Hyperplasia	Squamous, Moderate

**PRIMARY CAUSE OF DEATH**

- Lung Alveolar/Bronchiolar Carcinoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 13	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901733

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

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**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Mild
* Intestine Small, Jejunum [ Carcinoma TGLS = 3-13 ]	Carcinoma	
* Kidney	Nephropathy	Minimal
* Liver	Hepatocellular Adenoma Inflammation	Multiple Chronic, Minimal
Note: TGL 4, "mass, 3mm dia, mottled" noted at trim, was not apparent microscopically. [ Hepatocellular Adenoma TGLS = 1,2-12+10 ]		
Tooth	Malformation	Mild

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**PRIMARY CAUSE OF DEATH** -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 14	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901734

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

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**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Kidney	Nephropathy	Minimal
* Liver	Hepatocellular Carcinoma Inflammation	Chronic, Minimal
[ Hepatocellular Carcinoma TGLS = 3-4+11 ]		
* Lung	Hepatocellular Carcinoma	Metastatic (Liver)
[ Hepatocellular Carcinoma TGLS = 1,2-3+10 ]		
* Spleen	Hematopoietic Cell Proliferation	Mild

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 15	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 590
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Moribund Sacrifice	<b>HISTO:</b> 9901735

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Islets, Pancreatic	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

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**MISSING**

* Gallbladder	* Mammary Gland
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**OBSERVATIONS**

* Bone Marrow	Hemangiosarcoma	
* Intestine Small, Jejunum [ Carcinoma TGLS = 4-6 ]	Carcinoma	
* Kidney	Nephropathy	Moderate
* Liver [ Hepatocellular Carcinoma TGLS = 2,3-10+11 ]	Hepatocellular Carcinoma	Multiple
* Lung	Hepatocellular Carcinoma	Metastatic (Liver)
* Preputial Gland [ Ectasia TGLS = 1-7 ]	Ectasia	Moderate
* Spleen	Hematopoietic Cell Proliferation	Moderate

---

**PRIMARY CAUSE OF DEATH** - Liver Hepatocellular Carcinoma

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\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 16	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901736

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

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**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Parathyroid Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Mild
* Gallbladder	Degeneration	Hyaline, Moderate
* Kidney	Nephropathy	Minimal
* Liver	Clear Cell Focus	
	Hepatocellular Adenoma	
[ Clear Cell Focus TGLS = 3,4-4+11 ]		
[ Hepatocellular Adenoma TGLS = 2-11 ]		
* Lung	Alveolar/Bronchiolar Adenoma	
* Preputial GI		
Note: TGL 1, "discoloration, green" noted at necropsy, was not apparent microscopically.		
Tooth	Malformation	Minimal

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**PRIMARY CAUSE OF DEATH** -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

<b>ANIMAL ID:</b> 17	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 690
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 9901737

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Intestine Large, Rectum
* Islets, Pancreatic	* Kidney	* Lymph Node, Mandibular	* Nose
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Skin	* Testes	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Gallbladder	* Mammary Gland	* Thymus
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**AUTO PRECLUDES DIAG.**

* Intestine Large, Cecum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Spleen
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Mild
* Heart	Sarcoma	Metastatic (Liver)
* Intestine Large, Colon	Sarcoma	Metastatic (Liver)
* Intestine Small, Jejunum	Sarcoma	Metastatic (Liver)
[ Sarcoma TGLS = 6-12 ]		
* Liver	Histiocytic Sarcoma	
[ Histiocytic Sarcoma TGLS = 1,3,4-10+14+11 ]		
* Lung	Histiocytic Sarcoma	
[ Histiocytic Sarcoma TGLS = 2-3 ]		
* Lymph Node, Mesenteric	Histiocytic Sarcoma	
* Pancreas	Histiocytic Sarcoma	
[ Histiocytic Sarcoma TGLS = 5-13 ]		
* Seminal Vesicle	Sarcoma	Metastatic (Liver)
Skel Muscle		
Note: TGL 4, "mass, 11x9x5mm, pale" noted at necropsy, actually involved liver.		
* Stomach, Forestomach	Hyperplasia	Squamous, Minimal
* Stomach, Glandular	Sarcoma	Metastatic (Liver)

**PRIMARY CAUSE OF DEATH** - Liver Histiocytic Sarcoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 18	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901738

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

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**MISSING**

* Gallbladder	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Adenoma	
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Fatty Change	Minimal
[ Clear Cell Focus TGLS = 2,3-10+11 ]			
* Lung	Alveolar Epith	Hyperplasia	Moderate
* Testes		Atrophy	Moderate
[ Atrophy TGLS = 1-7 ]			

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**PRIMARY CAUSE OF DEATH** -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 19                      **TRT#:** 1                      **SEX:** Male                      **DAY ON TEST:** 730  
**DOSE:** 0 MG/KG                      **DISP:** Terminal Sacrifice                      **HISTO:** 9901739

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Brain	* Epididymis
* Esophagus	Harderian Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Islets, Pancreatic	* Lymph Node, Mandibular	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Gallbladder	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Mild
* Bone Marrow	Hemangiosarcoma	
* Intestine Small, Jejunum	Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 9-18 ]		
* Kidney	Nephropathy	Mild
* Liver	Clear Cell Focus	
	Eosinophilic Focus	
	Hepatocellular Adenoma	Multiple
	Hepatocellular Carcinoma	
[ Eosinophilic Focus TGLS = 4-12 ]		
[ Hepatocellular Adenoma TGLS = 3,6,7-13+14+15 ]		
[ Hepatocellular Carcinoma TGLS = 5-16 ]		
* Lung	Alveolar/Bronchiolar Adenoma	
[ Alveolar/Bronchiolar Adenoma TGLS = 2-3+10 ]		
* Lymph Node, Mesenteric	Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 8-17 ]		
* Spleen	Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 1-11 ]		
Tooth	Inflammation	Chronic Active, Moderate

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 19

**TRT#:** 1

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901739

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 20

**TRT#:** 1

**SEX:** Male

**DAY ON TEST:** 477

**DOSE:** 0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9901740

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Urinary Bladder	

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Esophagus		Hyperplasia	Squamous, Moderate
		Inflammation	Chronic Active, Mild
* Gallbladder		Inflammation	Chronic Active, Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Moderate
* Liver		Fatty Change	Minimal
		Mineralization	Mild
		Necrosis	Moderate
[ Necrosis TGLS = 2,3,4-4 ]			
* Lymph Node, Mesenteric		Angiectasis	Moderate
Mesentery		Mineralization	Mild
	Fat	Necrosis	Moderate
[ Necrosis TGLS = 5-10 ]			
* Spleen			
Note: TGL 1, "small, 0.7x" noted at necropsy, was within normal limits microscopically.			
* Stomach, Forestomach		Hyperplasia	Squamous, Mild
[ Hyperplasia TGLS = 6-8 ]			
* Trachea		Mineralization	Minimal

**PRIMARY CAUSE OF DEATH** - Mesentery Fat Necrosis

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 20

**TRT#:** 1

**SEX:** Male

**DAY ON TEST:** 477

**DOSE:** 0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9901740

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

---

<b>ANIMAL ID:</b> 21	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901741

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

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**MISSING**

\* Mammary Gland

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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Mild
Harderian Gland		Adenoma	
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Fatty Change	Minimal
		Hepatoblastoma	
[ Hepatoblastoma TGLS = 2-11 ]			
* Lung	Alveolar Epith	Hyperplasia	Minimal
Lymph Node	Renal	Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 1-10 ]			
* Lymph Node, Mesenteric		Lymphoma Malignant	
* Spleen		Lymphoma Malignant	

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 22	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 646
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Moribund Sacrifice	<b>HISTO:</b> 9901742

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

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**MISSING**

\* Mammary Gland

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**OBSERVATIONS**

* Kidney	Nephropathy	Minimal
* Liver	Basophilic Focus	
	Hemangiosarcoma	
Note: TGL 2, "nodule, 2x2x1mm, pale" noted at necropsy, was not apparent microscopically. [ Hemangiosarcoma TGLS = 1-10 ]		
Tooth	Malformation	

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PRIMARY CAUSE OF DEATH	- Tooth Malformation
CONTRIBUTORY CAUSE OF DEATH	- Liver Hemangiosarcoma

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 23	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901743

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone Marrow	* Brain	* Epididymis
* Esophagus	* Gallbladder	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

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**MISSING**

\* Mammary Gland

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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
* Bone	Chondroma	
[ Chondroma TGLS = 1-11 ]		
* Kidney	Nephropathy	Minimal
* Liver	Clear Cell Focus	
[ Eosinophilic Focus TGLS = 2-10 ]	Eosinophilic Focus	
Tooth	Malformation	Mild

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PRIMARY CAUSE OF DEATH -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 24	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901744

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

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**MISSING**

* Mammary Gland	* Parathyroid Gland
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**INSUFFICIENT TISSUE**

\* Intestine Large, Rectum

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**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Mild
		Hypertrophy	Mild
* Kidney		Nephropathy	Mild
* Liver		Fatty Change	Minimal
Note: TGL 3, "nodule, 1x1mm, white" noted at trim, was not apparent microscopically.			
Mesentery	Fat	Necrosis	Moderate
[ Necrosis TGLS = 1,2-10+11 ]			
Tooth		Malformation	Minimal

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**PRIMARY CAUSE OF DEATH** -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 25

**TRT#:** 1

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901745

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
Harderian Gland	Adenoma	
* Kidney	Nephropathy	Minimal
* Liver	Basophilic Focus	
	Clear Cell Focus	
	Inflammation	Chronic, Minimal
Note: TGL 3, "mass, 6x6x3mm, mottled" noted at necropsy, was not apparent microscopically. [ Basophilic Focus TGLS = 1,2-10+11 ]		
* Nose	Inflammation	Suppurative, Mild
* Stomach, Forestomach	Hyperplasia	Squamous, Mild
Tooth	Malformation	Moderate

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 26

**TRT#:** 1

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901746

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Mammary Gland	* Preputial Gland
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**OBSERVATIONS**

* Kidney [ Nephropathy TGLS = 1-5 ]	Nephropathy	Marked
* Liver  [ Hepatocellular Adenoma TGLS = 2-4 ] [ Hepatocellular Carcinoma TGLS = 3,4-11+10 ]	Basophilic Focus Clear Cell Focus Eosinophilic Focus Hepatocellular Adenoma Hepatocellular Carcinoma Necrosis	Multiple Minimal
* Lung	Hepatocellular Carcinoma	Metastatic (Liver)
* Spleen	Hematopoietic Cell Proliferation	Mild
Tooth	Inflammation	Chronic Active, Moderate

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 27

**TRT#:** 1

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901747

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Gallbladder	* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Mild
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
[ Clear Cell Focus TGLS = 1-4 ]			
* Lung		Alveolar/Bronchiolar Adenoma	
* Lymph Node, Mesenteric		Angiectasis	Minimal
[ Angiectasis TGLS = 2-10 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-11 ]			
Tooth		Malformation	Mild

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:15  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 28

**TRT#:** 1

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901748

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Nose	* Pancreas	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Lymph Node, Mesenteric	* Mammary Gland	* Parathyroid Gland
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Moderate
* Heart		Cardiomyopathy	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Hepatocellular Adenoma	
[ Clear Cell Focus TGLS = 1-4+10 ]			
[ Hepatocellular Adenoma TGLS = 2-11 ]			
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Mild
[ Infiltration Cellular TGLS = 3-3 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 4-12 ]			
* Spleen		Hematopoietic Cell Proliferation	Mild
Tooth		Malformation	Mild

PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 29

**TRT#:** 1

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901749

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Hyperplasia	Minimal
* Kidney	Nephropathy	Mild
* Liver	Clear Cell Focus	
	Hemangiosarcoma	
	Hepatocellular Carcinoma	

[ Clear Cell Focus TGLS = 2-11 ]

[ Hepatocellular Carcinoma TGLS = 1-10 ]

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 30

**TRT#:** 1

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901750

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Mammary Gland

**INSUFFICIENT TISSUE**

\* Skin

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Adenoma	
		Hypertrophy	Mild
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Fatty Change	Minimal
		Hepatocellular Adenoma	Multiple
		[ Clear Cell Focus TGLS = 1,3,5-14+13+11 ]	
		[ Hepatocellular Adenoma TGLS = 2,4-12+10 ]	
Tooth		Malformation	Minimal

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 31	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901751

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

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**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Kidney [ Nephropathy TGLS = 1-5 ]	Nephropathy	Moderate
* Liver [ Hepatocellular Adenoma TGLS = 2-10 ]	Hepatocellular Adenoma	
* Lung [ Alveolar/Bronchiolar Carcinoma TGLS = 3-3 ]	Alveolar/Bronchiolar Carcinoma	
* Stomach, Forestomach [ Inflammation TGLS = 4-11 ]	Inflammation	Acute, Moderate
Tooth	Malformation	Minimal

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PRIMARY CAUSE OF DEATH -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 32

**TRT#:** 1

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901752

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Mild
* Kidney		Nephropathy	Mild
* Liver		Basophilic Focus	
		Clear Cell Focus	
[ Basophilic Focus TGLS = 1-11 ]			
[ Clear Cell Focus TGLS = 2-4 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-10 ]			
Tooth		Inflammation	Chronic Active, Moderate
		Malformation	Minimal

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 33	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901753

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

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**MISSING**

\* Mammary Gland

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**OBSERVATIONS**

* Kidney	Nephropathy	Minimal
* Liver	Basophilic Focus	
	Clear Cell Focus	
	Fatty Change	Minimal
	Hepatocellular Adenoma	
[ Basophilic Focus TGLS = 1-10 ]		
[ Hepatocellular Adenoma TGLS = 2-4 ]		
Tooth	Malformation	Mild

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PRIMARY CAUSE OF DEATH -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 34

**TRT#:** 1

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901754

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Pituitary Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
* Heart	Cardiomyopathy	Minimal
* Kidney	Nephropathy	Minimal
* Liver	Clear Cell Focus	
	Inflammation	Chronic, Minimal
* Lung		
Note: TGL 2, "focus, 1mm dia, red" noted at trim, was artifact.		
* Preputial Gland	Inflammation	Chronic Active, Minimal
[ Inflammation TGLS = 1-7 ]		
Tooth	Malformation	Minimal

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 35

**TRT#:** 1

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901755

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Gallbladder	* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
Harderian Gland		Adenoma	
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Fatty Change	Minimal
		Hepatocellular Adenoma	Multiple
Note: TGL 2, "nodule, 1x1x1mm" noted at necropsy, was not apparent microscopically.			
		[ Clear Cell Focus TGLS = 4,5-12+14 ]	
		[ Hepatocellular Adenoma TGLS = 1,3-4+11 ]	
* Lung		Alveolar/Bronchiolar Adenoma	
		[ Alveolar/Bronchiolar Adenoma TGLS = 6-10 ]	
Mesentery	Fat	Necrosis	Mild
		[ Necrosis TGLS = 7-15 ]	
Tooth		Malformation	Moderate

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 36	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 664
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 9901756

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Islets, Pancreatic	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

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**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**AUTO PRECLUDES DIAG.**

* Intestine Small, Ileum	* Intestine Small, Jejunum
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**OBSERVATIONS**

* Gallbladder	Degeneration	Hyaline, Mild
* Kidney	Nephropathy	Mild
* Liver	Clear Cell Focus	
	Hepatocellular Adenoma	
[ Clear Cell Focus TGLS = 2-4 ]		
[ Hepatocellular Adenoma TGLS = 1-10 ]		
* Lung	Alveolar/Bronchiolar Adenoma	Multiple
[ Alveolar/Bronchiolar Adenoma TGLS = 3-3 ]		

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**PRIMARY CAUSE OF DEATH** - Liver Hepatocellular Adenoma

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

<b>ANIMAL ID:</b> 37	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901757

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Islets, Pancreatic	* Kidney
* Lung	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Thymus
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**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Mild
* Intestine Small, Jejunum		Carcinoma	
[ Carcinoma TGLS = 3,5-12+10 ]			
* Liver		Hepatocellular Adenoma	
Note: TGL 4, "deformity, 10x2mm" noted at necropsy, was not apparent microscopically.			
[ Hepatocellular Adenoma TGLS = 2-14 ]			
* Lung			
Note: TGL 7, "focus, 3mm dia, red" noted at trim, was not apparent microscopically.			
* Lym Node Mesen			
Note: TGL 5,"enlarged, .9 x .7cm, pale" noted at trim, was actually jejunal carcinoma.			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 6-11 ]			
* Preputial Gland		Ectasia	Marked
[ Ectasia TGLS = 1-7 ]			
* Spleen		Hematopoietic Cell Proliferation	Mild

PRIMARY CAUSE OF DEATH -

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 38

**TRT#:** 1

**SEX:** Male

**DAY ON TEST:** 599

**DOSE:** 0 MG/KG

**DISP:** Natural Death

**HISTO:** 9901758

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Islets, Pancreatic	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Mammary Gland	* Thymus
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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
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**OBSERVATIONS**

* Kidney	Nephropathy	Moderate
* Liver	Hepatocellular Adenoma	
	Hepatocellular Carcinoma	Multiple
[ Hepatocellular Carcinoma TGLS = 2,3-10+4 ]		
* Lung	Alveolar/Bronchiolar Adenoma	
	Hepatocellular Carcinoma	Metastatic (Liver)
[ Hepatocellular Carcinoma TGLS = 4,5,6-3 ]		
* Nose	Inflammation	Suppurative, Moderate
* Spleen	Hematopoietic Cell Proliferation	Mild
[ Hematopoietic Cell Proliferation TGLS = 1-4 ]		
* Stomach, Forestomach	Hyperplasia	Squamous, Moderate

**PRIMARY CAUSE OF DEATH** - Liver Hepatocellular Carcinoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 39	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901759

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

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**MISSING**

\* Mammary Gland

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**OBSERVATIONS**

* Liver	Basophilic Focus	
	Clear Cell Focus	
	Inflammation	Chronic, Minimal
[ Basophilic Focus TGLS = 1-10 ]		
Tooth	Malformation	Minimal

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 40	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901760

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

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**MISSING**

\* Mammary Gland

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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Mild
* Kidney	Nephropathy	Minimal
* Liver	Basophilic Focus	
[ Basophilic Focus TGLS = 1-4 ]		
Tooth	Malformation	Mild

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**PRIMARY CAUSE OF DEATH** -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 41

**TRT#:** 1

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901761

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Pituitary Gland	* Thymus
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
Harderian Gland		Hyperplasia	Mild
* Kidney		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
[ Eosinophilic Focus TGLS = 3,4-11+12 ]			
* Lung		Alveolar/Bronchiolar Adenoma	
	Alveolar Epith	Hyperplasia	Moderate
[ Alveolar/Bronchiolar Adenoma TGLS = 1-3 ]			
[ Hyperplasia TGLS = 2-10 ]			
Tooth		Malformation	Minimal

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 42

**TRT#:** 1

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901762

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Thymus
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**OBSERVATIONS**

* Kidney	Nephropathy	Moderate
* Liver	Clear Cell Focus	
	Eosinophilic Focus	
	Hepatocellular Adenoma	Multiple
	Hepatocellular Carcinoma	Multiple
	Inflammation	Chronic, Minimal
[ Eosinophilic Focus TGLS = 7-11 ]		
[ Hepatocellular Adenoma TGLS = 3,4-13+10 ]		
[ Hepatocellular Carcinoma TGLS = 2,5,6-12+15+14 ]		
* Preputial Gland	Ectasia	Moderate
[ Ectasia TGLS = 1-7 ]		
* Spleen	Hematopoietic Cell Proliferation	Mild
Tooth	Inflammation	Chronic Active, Mild

PRIMARY CAUSE OF DEATH -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 43	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901763

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

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**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Kidney	Nephropathy	Minimal
* Liver	Inflammation	Chronic, Minimal
Tooth	Malformation	Minimal

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**PRIMARY CAUSE OF DEATH** -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 44	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 702
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Moribund Sacrifice	<b>HISTO:</b> 9901764

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Liver	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Pancreas	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Trachea
* Urinary Bladder			

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**MISSING**

* Mammary Gland	* Parathyroid Gland	* Thymus	* Thyroid Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
* Kidney	Nephropathy	Mild
* Nose	Inflammation	Suppurative, Moderate
	Polyp, Inflammatory	Moderate
Tooth	Malformation	Marked

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**PRIMARY CAUSE OF DEATH** - Tooth Malformation

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 45

**TRT#:** 1

**SEX:** Male

**DAY ON TEST:** 632

**DOSE:** 0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9901765

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Gallbladder	* Mammary Gland	* Thymus
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**OBSERVATIONS**

* Heart		Mineralization	Minimal
* Kidney		Nephropathy	Minimal
* Liver	Bile Duct	Cyst	Minimal
		Tension Lipidosis	
		Vacuolization Cytoplasmic	Focal, Mild
Note: TGL 2, "nodule, 3mm dia, pale" noted at trim, was not apparent microscopically. [ Vacuolization Cytoplasmic TGLS = 1-10 ]			
* Nose		Inflammation	Suppurative, Mild
* Stomach, Forestomach		Hyperplasia	Squamous, Minimal
Tooth		Malformation	Moderate

**PRIMARY CAUSE OF DEATH** - Tooth Malformation

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 46

**TRT#:** 1

**SEX:** Male

**DAY ON TEST:** 620

**DOSE:** 0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9901766

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Gallbladder	* Mammary Gland
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**OBSERVATIONS**

* Kidney	Nephropathy	Marked
* Liver	Basophilic Focus	
	Hepatocellular Adenoma	Multiple
	Hepatocellular Carcinoma	
[ Hepatocellular Adenoma TGLS = 2,3-4+10 ]		
[ Hepatocellular Carcinoma TGLS = 1-4 ]		
* Lung	Hepatocellular Carcinoma	Metastatic (Liver)
* Spleen	Hematopoietic Cell Proliferation	Mild

**PRIMARY CAUSE OF DEATH** - Liver Hepatocellular Carcinoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 47	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901767

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

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**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Thymus
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**OBSERVATIONS**

* Kidney	Nephropathy	Minimal
* Liver	Hepatocellular Carcinoma Inflammation	Chronic, Mild
[ Hepatocellular Carcinoma TGLS = 1-10 ]		
* Lung	Hepatocellular Carcinoma	Metastatic (Liver)
* Nose	Inflammation	Suppurative, Minimal
* Spleen	Hematopoietic Cell Proliferation	Minimal

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PRIMARY CAUSE OF DEATH -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 48	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901768

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	Coagulating Gland	* Epididymis	* Esophagus
* Gallbladder	Harderian Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Liver	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

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**MISSING**

* Lymph Node, Mandibular	* Parathyroid Gland
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**OBSERVATIONS**

* Kidney	Nephropathy	Minimal
Tooth	Malformation	Minimal

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PRIMARY CAUSE OF DEATH -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 49

**TRT#:** 1

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901769

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
* Kidney	Nephropathy	Minimal
* Liver	Tension Lipidosis	
* Lung	Alveolar/Bronchiolar Adenoma	
Tooth	Inflammation	Chronic Active, Minimal

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 50	<b>TRT#:</b> 1	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901770

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**ORGAN AND ACCOUNTABLE SITE STATUS**

---

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea
* Urinary Bladder			

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**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Thymus
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**OBSERVATIONS**

* Gallbladder	Degeneration	Hyaline, Marked
* Kidney	Nephropathy	Moderate
* Liver	Hepatocellular Adenoma	Multiple
	Hepatocellular Carcinoma	
[ Hepatocellular Adenoma TGLS = 1-10 ]		
[ Hepatocellular Carcinoma TGLS = 2-11 ]		
* Lung	Alveolar/Bronchiolar Adenoma	
	Hepatocellular Carcinoma	Metastatic (Liver)

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**PRIMARY CAUSE OF DEATH** -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 51	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901771

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**ORGAN AND ACCOUNTABLE SITE STATUS**

---

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

---

**MISSING**

\* Mammary Gland

---

**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
* Gallbladder	Cyst	Minimal
* Kidney	Nephropathy	Minimal
* Liver	Clear Cell Focus	
	Eosinophilic Focus	
[ Eosinophilic Focus TGLS = 1-12 ]		
* Lung	Alveolar/Bronchiolar Adenoma	
	Alveolar/Bronchiolar Carcinoma	
[ Alveolar/Bronchiolar Adenoma TGLS = 3-11 ]		
[ Alveolar/Bronchiolar Carcinoma TGLS = 2-10 ]		
Tooth	Malformation	Minimal

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**PRIMARY CAUSE OF DEATH** -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

---

<b>ANIMAL ID:</b> 52	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901772

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thyroid Gland
* Trachea	* Urinary Bladder		

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**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Thymus
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Mild
* Kidney	Nephropathy	Minimal
* Liver	Clear Cell Focus	
	Fatty Change	Minimal
Tooth	Malformation	Mild

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**PRIMARY CAUSE OF DEATH** -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 53	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901773

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**ORGAN AND ACCOUNTABLE SITE STATUS**

---

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Nose	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

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**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Parathyroid Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
* Kidney	Infarct	Mild
	Nephropathy	Minimal
* Liver	Hepatocellular Adenoma	
[ Hepatocellular Adenoma TGLS = 2-10 ]		
* Lymph Node, Mesenteric	Lymphoma Malignant	
* Pancreas	Lymphoma Malignant	
* Spleen	Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 1-11 ]		
Tooth	Malformation	Minimal

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PRIMARY CAUSE OF DEATH -

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\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 54	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901774

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

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**MISSING**

\* Mammary Gland

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**OBSERVATIONS**

* Liver		Basophilic Focus	
		Clear Cell Focus	
		Fatty Change	Minimal
[ Basophilic Focus TGLS = 1-11 ]			
[ Clear Cell Focus TGLS = 1-11 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-10 ]			
Tooth		Malformation	Minimal

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 55

**TRT#:** 3

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901775

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Bone Marrow		Angiectasis	Mild
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Fatty Change	Minimal
[ Basophilic Focus TGLS = 4-12 ]			
[ Clear Cell Focus TGLS = 2-4+11 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-10 ]			
* Preputial GI			
Note: TGL 1, "enlarged, 2x, green" noted at necropsy, was within normal limits microscopically.			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 56	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901776

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

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**MISSING**

* Mammary Gland	* Parathyroid Gland
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
Eye	Cornea	Inflammation	Chronic, Moderate
[ Inflammation TGLS = 1-10 ]			
Harderian Gland		Adenoma	
[ Adenoma TGLS = 2-10 ]			
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
Tooth		Malformation	Minimal

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PRIMARY CAUSE OF DEATH

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-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 57

**TRT#:** 3

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901777

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Thymus
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**OBSERVATIONS**

Harderian Gland [ Adenoma TGLS = 1-10 ]		Adenoma	
* Kidney		Nephropathy	Minimal
* Liver [ Hepatocellular Carcinoma TGLS = 2,3,4,5,6-11+4+12+13+14+15 ]		Hepatocellular Carcinoma	Multiple
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
* Nose	Olfactory Epi	Metaplasia	Mild
* Preputial Gland		Inflammation	Chronic Active, Mild
* Spleen		Hematopoietic Cell Proliferation	Minimal

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 58

**TRT#:** 3

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901778

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Bone	* Bone Marrow	* Brain	* Epididymis
* Esophagus	* Gallbladder	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Lymph Node, Mesenteric	* Mammary Gland	* Thymus
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
* Adrenal Medulla		Hyperplasia	Moderate
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Hepatocellular Adenoma	
[ Clear Cell Focus TGLS = 2-11 ]			
[ Hepatocellular Adenoma TGLS = 1-10 ]			
Mesentery	Fat	Necrosis	Moderate
[ Necrosis TGLS = 3-12 ]			
Tooth		Malformation	Mild

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 59	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901779

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Liver	* Lung	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

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**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
* Kidney	Nephropathy	Mild
Tooth	Malformation	Minimal

---

**PRIMARY CAUSE OF DEATH** -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 60	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901780

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**ORGAN AND ACCOUNTABLE SITE STATUS**

---

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

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**MISSING**

\* Mammary Gland

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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Mild
* Liver	Clear Cell Focus	
	Eosinophilic Focus	
	Fatty Change	Minimal
	Hepatocellular Adenoma	
[ Eosinophilic Focus TGLS = 2-4 ]		
[ Hepatocellular Adenoma TGLS = 1-10 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Minimal
Tooth	Malformation	Mild

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PRIMARY CAUSE OF DEATH -

---

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 61	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901781

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

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**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
Harderian Gland		Hyperplasia	Moderate
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Hepatocellular Adenoma	
[ Hepatocellular Adenoma TGLS = 1-10 ]			
* Lung		Alveolar/Bronchiolar Adenoma	
	Alveolar Epith	Hyperplasia	Minimal
Tooth		Malformation	Minimal

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**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 62

**TRT#:** 3

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901782

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
Harderian Gland		Adenoma	
[ Adenoma TGLS = 1-10 ]			
* Kidney		Infarct	Mild
		Nephropathy	Mild
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Inflammation	Chronic, Minimal
* Lung		Alveolar/Bronchiolar Adenoma	
[ Alveolar/Bronchiolar Adenoma TGLS = 3-3 ]			
* Nose	Olfactory Epi	Metaplasia	Minimal
* Preputial Gland		Inflammation	Chronic Active, Mild
[ Inflammation TGLS = 2-7 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

<b>ANIMAL ID:</b> 63	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 728
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 9901783

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Heart	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Trachea	* Urinary Bladder	

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Parathyroid Gland	* Thyroid Gland

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
Harderian Gland		Adenoma	
* Intestine Small, Jejunum		Mineralization	Moderate
		Necrosis	Moderate
[ Necrosis TGLS = 6-10 ]			
* Kidney		Inflammation	Suppurative, Moderate
* Liver	Centrilobular	Degeneration	Moderate
		Necrosis	Marked
[ Degeneration TGLS = 3,4,5-4+11+12 ]			
[ Necrosis TGLS = 3,4,5-4+11+12 ]			
* Skin	Subcut Tiss	Edema	Moderate
[ Edema TGLS = 1-13 ]			
* Spleen		Hematopoietic Cell Proliferation	Moderate
Tooth		Malformation	Minimal

**PRIMARY CAUSE OF DEATH** - Liver Centrilobular Degeneration

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 64	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901784

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Nose	* Pancreas	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

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**MISSING**

* Gallbladder	* Mammary Gland	* Parathyroid Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
* Kidney	Nephropathy	Minimal
* Liver	Clear Cell Focus	
	Eosinophilic Focus	
	Hepatocellular Adenoma	
[ Eosinophilic Focus TGLS = 3-12 ]		
[ Hepatocellular Adenoma TGLS = 1-11+4 ]		
* Lung	Alveolar/Bronchiolar Carcinoma	
[ Alveolar/Bronchiolar Carcinoma TGLS = 2-10 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Minimal
Tooth	Inflammation	Chronic Active, Mild
	Malformation	Mild

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PRIMARY CAUSE OF DEATH -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 65	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901785

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thyroid Gland
* Trachea	* Urinary Bladder		

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**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**INSUFFICIENT TISSUE**

\* Thymus

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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
* Kidney	Nephropathy	Mild
* Liver	Clear Cell Focus	
	Eosinophilic Focus	
	Hepatocellular Adenoma	Multiple
	Inflammation	Chronic, Minimal

[ Eosinophilic Focus TGLS = 2-4+11 ]

[ Hepatocellular Adenoma TGLS = 1-4+10+11 ]

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**PRIMARY CAUSE OF DEATH** -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 66	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901786

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

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**MISSING**

\* Mammary Gland

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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
Harderian Gland		Atrophy	Mild
* Kidney		Nephropathy	Minimal
* Liver		Hepatocellular Adenoma	
		Hepatocellular Carcinoma	
		Inflammation	Chronic, Minimal
[ Hepatocellular Adenoma TGLS = 2-11 ]			
[ Hepatocellular Carcinoma TGLS = 1-10 ]			
* Pancreas	Artery	Inflammation	Marked
[ Inflammation TGLS = 3-12 ]			
* Testes	Interstit Cell	Adenoma	

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**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 67

**TRT#:** 3

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901787

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

Harderian Gland	Adenoma	
* Kidney	Nephropathy	Moderate
* Liver	Hepatocellular Carcinoma	
	Inflammation	Chronic, Minimal
[ Hepatocellular Carcinoma TGLS = 1-10 ]		
* Spleen	Hematopoietic Cell Proliferation	Minimal
Tooth	Inflammation	Chronic Active, Mild

PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 68	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901788

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

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**MISSING**

\* Mammary Gland

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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Mild
* Kidney	Nephropathy	Mild
* Liver	Basophilic Focus	
	Clear Cell Focus	
	Eosinophilic Focus	
	Fatty Change	Minimal
	Inflammation	Chronic, Minimal
[ Clear Cell Focus TGLS = 1,2-4+10+11 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Minimal
Tooth	Malformation	Mild

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**PRIMARY CAUSE OF DEATH** -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 69	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901789

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

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**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Kidney		Infarct	Moderate
		Inflammation	Suppurative, Moderate
[ Inflammation TGLS = 4-11 ]			
* Liver		Clear Cell Focus	
		Hepatocellular Adenoma	Multiple
		Hepatocellular Carcinoma	
[ Hepatocellular Adenoma TGLS = 2,3-13+14 ]			
[ Hepatocellular Carcinoma TGLS = 2-12 ]			
* Lung	Alveolar Epith	Hyperplasia	Moderate
[ Hyperplasia TGLS = 5-10 ]			
* Preputial GI			
Note: TGL 1, "discolored, green" noted at necropsy, was not apparent microscopically.			

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**PRIMARY CAUSE OF DEATH** -

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\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 70

**TRT#:** 3

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901790

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Thymus
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**OBSERVATIONS**

* Kidney	Nephropathy	Mild
* Liver	Clear Cell Focus	
	Hepatocellular Carcinoma	
[ Hepatocellular Carcinoma TGLS = 1-10 ]		
Tooth	Malformation	Mild

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 71	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 508
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Moribund Sacrifice	<b>HISTO:</b> 9901791

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Liver	* Lung	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

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**MISSING**

\* Lymph Node, Mandibular

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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Mild
* Kidney	Nephropathy	Mild
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Minimal

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**PRIMARY CAUSE OF DEATH** - UNCERTAIN

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 72

**TRT#:** 3

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901792

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
* Gallbladder	Degeneration	Hyaline, Marked
* Kidney	Nephropathy	Minimal
* Liver	Clear Cell Focus	

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 73	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 346
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 9901793

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	Harderian Gland
* Heart	* Islets, Pancreatic	* Kidney	* Lung
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Testes
* Thymus	* Thyroid Gland	* Trachea	

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**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Stomach, Glandular
* Urinary Bladder			

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**OBSERVATIONS**

* Liver	Hepatoblastoma	
[ Hepatoblastoma TGLS = 1-10 ]		
* Spleen	Hematopoietic Cell Proliferation	Mild

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**PRIMARY CAUSE OF DEATH** - Liver Hepatoblastoma

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 74	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901794

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

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**MISSING**

\* Mammary Gland

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**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Inflammation	Chronic, Minimal
[ Basophilic Focus TGLS = 1-10 ]			
* Lung	Alveolar Epith	Hyperplasia	Mild
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
Tooth		Malformation	Minimal

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 75	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901795

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**ORGAN AND ACCOUNTABLE SITE STATUS**

---

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

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**MISSING**

* Lymph Node, Mesenteric	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Mild
* Kidney		Nephropathy	Mild
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
[ Clear Cell Focus TGLS = 1-4+10 ]			
[ Eosinophilic Focus TGLS = 1-4+10 ]			
* Lung	Alveolar Epith	Hyperplasia	Mild

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**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 76	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901796

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Pancreas	* Parathyroid Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

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**MISSING**

* Lymph Node, Mesenteric	* Mammary Gland
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**INSUFFICIENT TISSUE**

\* Pituitary Gland

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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
* Kidney		Nephropathy	Mild
* Liver		Hepatocellular Carcinoma	
		Inflammation	Chronic, Minimal
		Necrosis	Mild
[ Hepatocellular Carcinoma TGLS = 2-10 ]			
* Lung		Hepatocellular Carcinoma	Metastatic (Liver)
[ Hepatocellular Carcinoma TGLS = 3-3 ]			
* Nose	Olfactory Epi	Atrophy	Mild
* Preputial Gland		Ectasia	Mild
[ Ectasia TGLS = 1-7 ]			

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**PRIMARY CAUSE OF DEATH** -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 77

**TRT#:** 3

**SEX:** Male

**DAY ON TEST:** 11

**DOSE:** 56 MG/KG

**DISP:** Dosing Accident

**HISTO:** 9901797

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Liver	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Esophagus		Inflammation	Acute, Mild
[ Inflammation TGLS = 1-2 ]			
* Lung	Mediastinum	Inflammation	Acute, Mild

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 78

**TRT#:** 3

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901798

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hyperplasia	Mild
* Intestine Small, Jejunum [ Polyp Adenomatous TGLS = 3-12 ]	Polyp Adenomatous	
* Kidney	Nephropathy	Minimal
* Liver  [ Hepatocellular Adenoma TGLS = 2-11 ] [ Hepatocellular Carcinoma TGLS = 1-10 ]	Hepatocellular Adenoma Hepatocellular Carcinoma Inflammation	Chronic, Minimal

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 79                      **TRT#:** 3                      **SEX:** Male                      **DAY ON TEST:** 731  
**DOSE:** 56 MG/KG                      **DISP:** Terminal Sacrifice                      **HISTO:** 9901799

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Mild
Harderian Gland	Adenoma	
	Inflammation	Acute, Minimal
* Kidney	Nephropathy	Minimal
* Liver	Hepatocellular Adenoma	
[ Hepatocellular Adenoma TGLS = 1-10 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Minimal
Mesentery		
Note: TGL 1, "fat, nodule, 10x10x7mm, mottled" noted at necropsy, was actually a necrotic hepatocellular adenoma with secondary inflammation.		
* Nose	Olfactory Epi	Atrophy
Tooth		Malformation
		Mild
		Moderate

PRIMARY CAUSE OF DEATH -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 80	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 455
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 9901800

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

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**MISSING**

\* Mammary Gland

---

**OBSERVATIONS**

* Kidney	Nephropathy	Minimal
* Liver	Eosinophilic Focus	
	Fatty Change	Minimal
	Hepatocellular Adenoma	
	Inflammation	Chronic, Minimal
	Tension Lipidosis	

---

[ Hepatocellular Adenoma TGLS = 1-10 ]

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**PRIMARY CAUSE OF DEATH** - Liver Hepatocellular Adenoma

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 81	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901801

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

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**MISSING**

* Mammary Gland	* Parathyroid Gland
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**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Mild
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Hepatocellular Adenoma	
		Inflammation	Chronic, Minimal
[ Basophilic Focus TGLS = 5-12 ]			
[ Hepatocellular Adenoma TGLS = 4-4+11 ]			
* Lym Node Mand			
Note: TGL 3, "enlarged, 2x, red" noted at necropsy, was within normal limits microscopically.			
* Preputial GI			
Note: TGL 2, "discoloration, green" noted at necropsy, was within normal limits microscopically.			
* Skin	Subcut Tiss	Melanoma Malignant	
[ Melanoma Malignant TGLS = 1-10 ]			
Tooth		Inflammation	Chronic Active, Mild

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**PRIMARY CAUSE OF DEATH** -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 82	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901802

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

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**MISSING**

\* Gallbladder

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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
* Kidney	Nephropathy	Minimal
* Liver	Clear Cell Focus	
	Eosinophilic Focus	
	Inflammation	Chronic, Minimal
Tooth	Inflammation	Chronic Active, Mild

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PRIMARY CAUSE OF DEATH -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 83

**TRT#:** 3

**SEX:** Male

**DAY ON TEST:** 688

**DOSE:** 56 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9901803

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	Mesentery	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Prostate
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Mammary Gland                      \* Thymus

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
Harderian Gland		Adenoma	
* Kidney	Papilla	Necrosis	Marked
* Liver		Basophilic Focus	
		Hepatocellular Carcinoma	
		Tension Lipidosis	

Note: TGL 4, "cyst, 2x2x2mm, black" noted at necropsy, was not apparent microscopically.  
 [ Hepatocellular Carcinoma TGLS = 3-10 ]

Mesentery

Note: TGL 2, "nodule, red" noted at necropsy, was actually part of seminal vesicle.

* Preputial Gland		Ectasia	Mild
* Seminal Vesicle		Congestion	Marked

[ Ectasia TGLS = 1-7 ]

[ Congestion TGLS = 2-12 ]

**PRIMARY CAUSE OF DEATH**                      - Liver    Hepatocellular Carcinoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 84	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901804

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

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**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**INSUFFICIENT TISSUE**

\* Gallbladder

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**OBSERVATIONS**

* Kidney	Nephropathy	Minimal
* Liver	Clear Cell Focus	
	Hepatocellular Adenoma	
	Hepatocellular Carcinoma	
[ Hepatocellular Adenoma TGLS = 1-10 ]		
[ Hepatocellular Carcinoma TGLS = 2-4+11 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Minimal
* Stomach, Forestomach	Ulcer	Mild
Tooth	Inflammation	Chronic Active, Mild

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**PRIMARY CAUSE OF DEATH** -

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\* PROTOCOL REQUIRED TISSUE

Experiment Number: 88122-07

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/16/2014

Time Report Requested: 12:23:16

First Dose M/F: NA / NA

Lab: BAT

ANIMAL ID: 85

TRT#: 3

SEX: Male

DAY ON TEST: 730

DOSE: 56 MG/KG

DISP: Terminal Sacrifice

HISTO: 9901805

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Liver	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Mammary Gland	* Thymus
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**OBSERVATIONS**

* Adrenal Cortex	Hyperplasia	Mild
* Kidney	Nephropathy	Minimal
* Lym Node Mand		
Note: TGL 1, "enlarged, 2x, dark" noted at necropsy, was within normal limits microscopically.		
Tooth	Malformation	Mild

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 86	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 508
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Moribund Sacrifice	<b>HISTO:</b> 9901806

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Liver	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

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**MISSING**

Harderian Gland	* Mammary Gland
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**OBSERVATIONS**

* Kidney	Nephropathy	Minimal
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PRIMARY CAUSE OF DEATH	- UNCERTAIN
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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 87

**TRT#:** 3

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901807

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Kidney	Nephropathy	Minimal
* Liver	Fatty Change	Minimal
Tooth	Malformation	Mild

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 88

**TRT#:** 3

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901808

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Pancreas	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Mammary Gland	* Parathyroid Gland
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**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Minimal
Harderian Gland		Adenoma	
[ Adenoma TGLS = 4-10 ]			
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Inflammation	Chronic, Minimal
Note: TGL 2, "focus, 2x1mm, tan" noted at necropsy, was not apparent microscopically.			
[ Basophilic Focus TGLS = 1-11 ]			
[ Eosinophilic Focus TGLS = 3-13 ]			
* Nose	Olfactory Epi	Atrophy	Moderate
Tooth		Malformation	Minimal

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 89

**TRT#:** 3

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901809

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Testes	* Thymus
* Trachea	* Urinary Bladder		

**MISSING**

* Gallbladder	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Hepatocellular Carcinoma	
Note: TGL 3, "nodule, 2x2x1mm, pale" noted at necropsy, was not apparent microscopically.			
[ Clear Cell Focus TGLS = 4-12 ]			
[ Hepatocellular Carcinoma TGLS = 1-13 ]			
* Lung		Alveolar/Bronchiolar Carcinoma	
[ Alveolar/Bronchiolar Carcinoma TGLS = 2-10 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Stomach, Glandular		Hyperplasia	Marked
* Thyroid Gland	C Cell	Carcinoma	
Tooth		Malformation	Mild

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 90

**TRT#:** 3

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901810

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
* Kidney	Metaplasia	Osseous, Minimal
	Nephropathy	Minimal
* Liver	Clear Cell Focus	
	Fatty Change	Minimal
[ Clear Cell Focus TGLS = 3,4,5-11+12+10 ]		
* Lym Node Mand		
Note: TGL 1, "enlarged, 2x" noted at necropsy, was not apparent microscopically.		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Minimal
* Preputial Gland	Ectasia	Moderate
[ Ectasia TGLS = 2-7 ]		

PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 91	<b>TRT#:</b> 3	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901811

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

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**MISSING**

* Gallbladder	* Mammary Gland
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**INSUFFICIENT TISSUE**

* Pituitary Gland
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Inflammation	Chronic, Minimal
* Lung	Alveolar Epith	Hyperplasia	Mild

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**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 92

**TRT#:** 3

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901812

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Brain	* Epididymis	* Esophagus
* Gallbladder	Harderian Gland	* Heart	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Testes	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Mammary Gland	* Thymus
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Marked
		Mast Cell Tumor Malignant	Metastatic (Bone Marrow)
* Bone		Mast Cell Tumor Malignant	Metastatic (Bone Marrow)
* Bone Marrow		Mast Cell Tumor Malignant	
* Intestine Large, Cecum		Mast Cell Tumor Malignant	Metastatic (Bone Marrow)
* Kidney		Nephropathy	Minimal
* Liver		Mast Cell Tumor Malignant	Metastatic (Bone Marrow)
* Lung	Mediastinum	Mast Cell Tumor Malignant	Metastatic (Bone Marrow)
Lymph Node	Mediastinal	Mast Cell Tumor Malignant	Metastatic (Bone Marrow)
* Lymph Node, Mandibular		Mast Cell Tumor Malignant	Metastatic (Bone Marrow)
[ Mast Cell Tumor Malignant TGLS = 1-7 ]			
* Nose		Mast Cell Tumor Malignant	Metastatic (Bone Marrow)
Peritoneum		Mast Cell Tumor Malignant	Metastatic (Bone Marrow)
Skeletal Muscle		Mast Cell Tumor Malignant	Metastatic (Bone Marrow)
* Spleen		Mast Cell Tumor Malignant	Metastatic (Bone Marrow)
* Stomach, Forestomach		Mast Cell Tumor Malignant	Metastatic (Bone Marrow)
* Stomach, Glandular		Mast Cell Tumor Malignant	Metastatic (Bone Marrow)

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 93      **TRT#:** 3      **SEX:** Male      **DAY ON TEST:** 731  
**DOSE:** 56 MG/KG      **DISP:** Terminal Sacrifice      **HISTO:** 9901813

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Bone	* Bone Marrow	* Brain	* Epididymis
* Esophagus	Harderian Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Islets, Pancreatic	* Lymph Node, Mandibular	* Nose	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Mammary Gland

**INSUFFICIENT TISSUE**

\* Gallbladder      \* Prostate

**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Mild
* Adrenal Medulla		Hyperplasia	Moderate
* Intestine Small, Jejunum		Carcinoma	
[ Carcinoma TGLS = 3-10 ]			
* Kidney		Nephropathy	Minimal
* Liver		Hepatocellular Adenoma	
		Hepatocellular Carcinoma	
		Inflammation	Chronic, Mild
[ Hepatocellular Adenoma TGLS = 2-11 ]			
[ Hepatocellular Carcinoma TGLS = 1-12 ]			
* Lung		Hepatocellular Carcinoma	Metastatic (Liver)
	Alveolar Epith	Hyperplasia	Mild
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
* Pancreas		Atrophy	Moderate
* Spleen		Hematopoietic Cell Proliferation	Minimal
Tooth		Inflammation	Chronic Active, Moderate

**PRIMARY CAUSE OF DEATH**      -

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 94

**TRT#:** 3

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901814

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Mild
* Kidney	Nephropathy	Minimal
* Liver	Clear Cell Focus	
	Fatty Change	Minimal
[ Clear Cell Focus TGLS = 1-4 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Minimal

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 95

**TRT#:** 3

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901815

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Parathyroid Gland
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**INSUFFICIENT TISSUE**

\* Gallbladder

**OBSERVATIONS**

Blood Vessel	Angiectasis	Moderate
	Thrombosis	Mild
Note: Blood vessel lesions were in adipose tissue at hilus of kidney.		
[ Angiectasis TGLS = 3-5 ]		
[ Thrombosis TGLS = 3-5 ]		
Harderian Gland	Adenoma	
* Kidney	Nephropathy	Minimal
Note: TGL 3, "mass, 1x5mm, dark" noted at trim, actually involved adipose tissue and blood vessels at hilus of kidney.		
* Liver	Clear Cell Focus	
	Fatty Change	Minimal
[ Clear Cell Focus TGLS = 1,2-4+10+11 ]		
Tooth	Malformation	Mild
* Urinary Bladder	Transit Epithe	Moderate
	Hyperplasia	

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 96	<b>TRT#:</b> 3 <b>DOSE:</b> 56 MG/KG	<b>SEX:</b> Male <b>DISP:</b> Natural Death	<b>DAY ON TEST:</b> 707 <b>HISTO:</b> 9901816
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**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Bone	* Bone Marrow	* Brain	* Epididymis
* Esophagus	Harderian Gland	* Heart	* Islets, Pancreatic
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Salivary Glands	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

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**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mesenteric

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**OBSERVATIONS**

* Adrenal Cortex	Hyperplasia	Mild
* Adrenal Medulla	Hyperplasia	Mild
* Kidney	Inflammation	Suppurative, Mild
* Liver	Hepatocellular Carcinoma	
[ Hepatocellular Carcinoma TGLS = 1-4+12 ]		
* Lung	Hepatocellular Carcinoma	Metastatic (Liver)
[ Hepatocellular Carcinoma TGLS = 2,3-10+11 ]		
* Prostate	Inflammation	Suppurative, Marked
* Seminal Vesicle	Inflammation	Suppurative, Moderate

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**PRIMARY CAUSE OF DEATH** - Liver Hepatocellular Carcinoma

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 97

**TRT#:** 3

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901817

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Gallbladder	* Lymph Node, Mandibular	* Mammary Gland
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**INSUFFICIENT TISSUE**

\* Thymus

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Fatty Change	Minimal
		Hepatocellular Adenoma	Multiple
		[ Clear Cell Focus TGLS = 2-11 ]	
		[ Hepatocellular Adenoma TGLS = 1,3-13+12 ]	
* Lung		Hemorrhage	Mild
	Alveolar Epith	Hyperplasia	Mild
		[ Hemorrhage TGLS = 4-10 ]	
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
Tooth		Malformation	Minimal

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 98

**TRT#:** 3

**SEX:** Male

**DAY ON TEST:** 311

**DOSE:** 56 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9901818

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Nose	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Skin
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Thymus
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**OBSERVATIONS**

* Adrenal Medulla	Squamous Cell Carcinoma	Metastatic (Stomach, Forestomach)
* Heart		
Note: TGL 6, "left ventricle, thick, 3x, pale" noted at trim, was not apparent microscopically.		
* Kidney	Squamous Cell Carcinoma	Metastatic (Stomach, Forestomach)
* Liver	Basophilic Focus	
	Fatty Change	Mild
	Hematopoietic Cell Proliferation	Minimal
	Squamous Cell Carcinoma	Metastatic (Stomach, Forestomach)
[ Basophilic Focus TGLS = 3-11 ]		
[ Squamous Cell Carcinoma TGLS = 2,4-10+4 ]		
* Lymph Node, Mesenteric	Squamous Cell Carcinoma	Metastatic (Stomach, Forestomach)
* Pancreas	Squamous Cell Carcinoma	Metastatic (Stomach, Forestomach)
* Seminal Vesicle	Squamous Cell Carcinoma	Metastatic (Stomach, Forestomach)
Skeletal Muscle	Squamous Cell Carcinoma	Metastatic (Stomach, Forestomach)
[ Squamous Cell Carcinoma TGLS = 5-12 ]		
* Spleen	Hematopoietic Cell Proliferation	Mild
	Squamous Cell Carcinoma	Metastatic (Stomach, Forestomach)
[ Squamous Cell Carcinoma TGLS = 7-4 ]		
* Stomach, Forestomach	Squamous Cell Carcinoma	
[ Squamous Cell Carcinoma TGLS = 1-8+13 ]		

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 98

**TRT#:** 3

**SEX:** Male

**DAY ON TEST:** 311

**DOSE:** 56 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9901818

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* Stomach, Glandular

Squamous Cell Carcinoma

Metastatic (Stomach, Forestomach)

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PRIMARY CAUSE OF DEATH

- Stomach, Forestomach Squamous Cell Carcinoma

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 99

**TRT#:** 3

**SEX:** Male

**DAY ON TEST:** 508

**DOSE:** 56 MG/KG

**DISP:** Natural Death

**HISTO:** 9901819

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Mammary Gland

**AUTO PRECLUDES DIAG.**

\* Gallbladder                      \* Intestine Small, Jejunum

**OBSERVATIONS**

* Kidney	Nephropathy	Mild
* Liver	Hepatocellular Carcinoma	
[ Hepatocellular Carcinoma TGLS = 1-10 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Mild
* Spleen	Hematopoietic Cell Proliferation	Minimal
	Infiltration Cellular	Histiocyte, Minimal

**PRIMARY CAUSE OF DEATH**

- Liver Hepatocellular Carcinoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 100

**TRT#:** 3

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901820

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Pancreas	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Parathyroid Gland	* Thymus
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Mild
* Kidney		Nephropathy	Mild
* Liver		Inflammation	Chronic, Minimal
* Nose	Olfactory Epi	Metaplasia	Mild
Tooth		Malformation	Minimal

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 101

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901821

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
* Kidney	Cyst	Mild
	Nephropathy	Mild
[ Cyst TGLS = 5-5 ]		
* Liver	Hemangiosarcoma	
	Inflammation	Chronic, Minimal
Note: TGL 3, "foci, 1x1mm, diffuse, tan" noted at necropsy, was not apparent microscopically.		
[ Hemangiosarcoma TGLS = 2,4-10+11 ]		
* Lung	Alveolar/Bronchiolar Adenoma	
[ Alveolar/Bronchiolar Adenoma TGLS = 6-3 ]		
* Preputial Gland	Ectasia	Mild
[ Ectasia TGLS = 1-7 ]		
Tooth	Malformation	Minimal

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 102

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901822

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
Harderian Gland	Bilateral	Adenoma	
[ Adenoma TGLS = 1-11 ]			
* Kidney		Cyst	Moderate
[ Cyst TGLS = 2-5 ]		Nephropathy	Minimal
* Liver		Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-10 ]			
Tooth		Malformation	Mild

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 103

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901823

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Liver
* Lymph Node, Mandibular	* Nose	* Pancreas	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Mammary Gland	* Parathyroid Gland
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**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Mild
		Hypertrophy	Minimal
Harderian Gland		Hyperplasia	Mild
* Kidney		Nephropathy	Minimal
* Lung		Alveolar/Bronchiolar Carcinoma	
[ Alveolar/Bronchiolar Carcinoma TGLS = 1-3 ]			
* Lymph Node, Mesenteric		Hemorrhage	Mild
		Infiltration Cellular	Histiocyte, Minimal
[ Hemorrhage TGLS = 2-6 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-10 ]			
Tooth		Malformation	Minimal

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 104

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 548

**DOSE:** 168 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9901824

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
* Kidney	Nephropathy	Mild
* Liver	Fatty Change	Minimal
	Hepatocellular Carcinoma	
	Necrosis	Minimal
[ Hepatocellular Carcinoma TGLS = 1-4 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Moderate
* Spleen	Hematopoietic Cell Proliferation	Mild

**PRIMARY CAUSE OF DEATH**

- Liver Hepatocellular Carcinoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 105

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901825

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Liver	* Lung	* Lymph Node, Mandibular	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Mammary Gland

**INSUFFICIENT TISSUE**

\* Thymus

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Mild
* Kidney		Nephropathy	Mild
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 1-10 ]			
Tooth		Malformation	Minimal

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 106

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901826

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Moderate
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Inflammation	Chronic, Minimal
* Lung		Alveolar/Bronchiolar Adenoma	
[ Alveolar/Bronchiolar Adenoma TGLS = 1-10 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-11 ]			
* Stomach, Forestomach		Hyperplasia	Squamous, Minimal
Tooth		Malformation	Mild

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 107

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901827

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Mild
Harderian Gland		Adenoma	
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Hepatocellular Adenoma	Multiple
	[ Hepatocellular Adenoma TGLS = 1,2-11+12 ]		
* Lung		Alveolar/Bronchiolar Adenoma	
	[ Alveolar/Bronchiolar Adenoma TGLS = 3-10 ]		
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
Tooth		Inflammation	Chronic Active, Mild
		Malformation	Minimal

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 108

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 653

**DOSE:** 168 MG/KG

**DISP:** Natural Death

**HISTO:** 9901828

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Colon	* Intestine Small, Duodenum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Pancreas	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Mammary Gland	* Parathyroid Gland
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**AUTO PRECLUDES DIAG.**

* Intestine Large, Cecum	* Intestine Small, Ileum	* Intestine Small, Jejunum
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**INSUFFICIENT TISSUE**

\* Intestine Large, Rectum

**OBSERVATIONS**

* Bone Marrow		Hemangiosarcoma	
* Kidney		Nephropathy	Mild
* Liver		Hepatocellular Carcinoma	
[ Hepatocellular Carcinoma TGLS = 1-4 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
* Nose	Sinus	Inflammation	Chronic Active, Moderate
* Spleen		Hematopoietic Cell Proliferation	Minimal

**PRIMARY CAUSE OF DEATH**

- Liver Hepatocellular Carcinoma

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 109

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901829

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Mild
* Kidney	Nephropathy	Minimal
* Liver	Clear Cell Focus	
	Fatty Change	Minimal
	Inflammation	Chronic, Minimal
Note: TGL 1, "focus, 1x1mm, tan" noted at necropsy, was not apparent microscopically. [ Clear Cell Focus TGLS = 2-11 ]		
* Lung	Alveolar/Bronchiolar Adenoma	
[ Alveolar/Bronchiolar Adenoma TGLS = 3-10 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Moderate
* Nose	Inflammation	Suppurative, Mild
Tooth	Malformation	Mild

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 110	<b>TRT#:</b> 5	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 581
	<b>DOSE:</b> 168 MG/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 9901830

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Lymph Node, Mandibular	* Nose	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea	* Urinary Bladder	

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**MISSING**

Harderian Gland	* Mammary Gland	* Thymus	
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**AUTO PRECLUDES DIAG.**

* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Pancreas		

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**OBSERVATIONS**

* Kidney	Nephropathy	Moderate
* Liver	Hepatocellular Carcinoma	Multiple
[ Hepatocellular Carcinoma TGLS = 2,3-4+10 ]		
* Lung	Alveolar/Bronchiolar Adenoma	
[ Alveolar/Bronchiolar Adenoma TGLS = 1-3 ]	Hepatocellular Carcinoma	Metastatic (Liver)
* Spleen	Hematopoietic Cell Proliferation	Mild

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**PRIMARY CAUSE OF DEATH** - Liver Hepatocellular Carcinoma

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 111

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901831

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Brain	* Epididymis
* Esophagus	* Gallbladder	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Pancreas	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Lymph Node, Mesenteric	* Mammary Gland	* Parathyroid Gland
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
* Bone Marrow		Sarcoma	
* Kidney		Nephropathy	Minimal
* Liver		Tension Lipidosis	
* Nose	Olfactory Epi	Metaplasia	Minimal
Tooth		Malformation	Minimal

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 112

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901832

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Mild
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Hepatocellular Adenoma	
[ Basophilic Focus TGLS = 1-4 ]			
[ Hepatocellular Adenoma TGLS = 2-11 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-10 ]			
Tooth		Inflammation	Chronic Active, Mild

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 113

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901833

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymsus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

Harderian Gland		Adenoma	
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Fatty Change	Minimal
[ Clear Cell Focus TGLS = 1-4+11 ]			
* Lung		Alveolar/Bronchiolar Adenoma	
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-10 ]			
* Seminal Vesicle		Dilatation	Moderate
		Inflammation	Chronic Active, Minimal
[ Dilatation TGLS = 4-13 ]			
[ Inflammation TGLS = 3-12 ]			
Tooth		Malformation	Minimal

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 114

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901834

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Mild
* Kidney		Nephropathy	Mild
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Hepatocellular Adenoma	
		Inflammation	Chronic, Minimal
[ Clear Cell Focus TGLS = 1-4+13 ]			
[ Hepatocellular Adenoma TGLS = 2-12 ]			
* Lung		Alveolar/Bronchiolar Carcinoma	
[ Alveolar/Bronchiolar Carcinoma TGLS = 3-11 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 4-10 ]			
* Nose		Inflammation	Suppurative, Minimal
Tooth		Malformation	Minimal

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 115

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901835

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Mild
Eye	Cornea	Inflammation	Chronic, Mild
[ Inflammation TGLS = 1-10 ]			
Harderian Gland		Adenoma	
[ Adenoma TGLS = 2-10 ]			
* Kidney	Renal Tubule	Cyst	Mild
		Hyperplasia	Minimal
		Nephropathy	Mild
[ Cyst TGLS = 6-12 ]			
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
[ Basophilic Focus TGLS = 4-4 ]			
[ Clear Cell Focus TGLS = 3-14 ]			
[ Eosinophilic Focus TGLS = 7-13 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 5-11 ]			

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 115

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901835

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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Tooth

Malformation

Minimal

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 116

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901836

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex		Adenoma	
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Fatty Change	Minimal
[ Clear Cell Focus TGLS = 1-11 ]			
* Lung		Alveolar/Bronchiolar Adenoma	
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-10 ]			
* Nose	Glands	Degeneration	Hyaline, Marked
Tooth		Malformation	Mild

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 117      **TRT#:** 5      **SEX:** Male      **DAY ON TEST:** 731  
**DOSE:** 168 MG/KG      **DISP:** Terminal Sacrifice      **HISTO:** 9901837

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Nose
* Pancreas	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Parathyroid Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
* Intestine Small, Duodenum [ Carcinoma TGLS = 3-12 ]	Carcinoma	
* Kidney	Nephropathy	Minimal
* Liver	Hepatocellular Adenoma	
	Hepatocellular Carcinoma	
	[ Hepatocellular Adenoma TGLS = 2-10 ]	
	[ Hepatocellular Carcinoma TGLS = 1-4+11 ]	
* Lung	Hepatocellular Carcinoma	Metastatic (Liver)
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Moderate
* Spleen	Hematopoietic Cell Proliferation	Mild

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 118

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901838

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Nose	* Pancreas	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Parathyroid Gland	* Thymus
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**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Mild
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
		Hepatocellular Adenoma	
		Hepatocellular Carcinoma	
[ Clear Cell Focus TGLS = 3-14 ]			
[ Eosinophilic Focus TGLS = 1-4 ]			
[ Hepatocellular Adenoma TGLS = 4-11 ]			
[ Hepatocellular Carcinoma TGLS = 2-13 ]			
Lymph Node	Renal	Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 5-5 ]			
* Lymph Node, Mesenteric		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 7-10 ]			
Mesentery	Fat	Necrosis	Mild
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 6-12 ]			

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 118

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901838

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 119

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 592

**DOSE:** 168 MG/KG

**DISP:** Natural Death

**HISTO:** 9901839

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	Harderian Gland
* Heart	* Islets, Pancreatic	* Kidney	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Testes	* Thymus	* Thyroid Gland

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mesenteric
* Stomach, Glandular	* Trachea	* Urinary Bladder	

**OBSERVATIONS**

* Liver	Hepatocellular Adenoma	Multiple
	Hepatocellular Carcinoma	Multiple
	[ Hepatocellular Adenoma TGLS = 2,4,5,7-12+10+4+13 ]	
	[ Hepatocellular Carcinoma TGLS = 3,6-11+13 ]	
* Lung	Hepatocellular Carcinoma	Metastatic (Liver)
	[ Hepatocellular Carcinoma TGLS = 8,9,10-3 ]	
* Spleen	Hematopoietic Cell Proliferation	Mild
	Infiltration Cellular	Histiocyte, Minimal
	[ Hematopoietic Cell Proliferation TGLS = 1-4 ]	

**PRIMARY CAUSE OF DEATH** - Liver Hepatocellular Carcinoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 120	<b>TRT#:</b> 5	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 168 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901840

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	

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**MISSING**

* Mammary Gland	* Thymus
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
* Heart	Artery	Inflammation	Chronic Active, Mild
* Kidney		Nephropathy	Minimal
* Liver		Inflammation	Chronic, Minimal
		Tension Lipidosis	
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
* Nose	Olfactory Epi	Hyperplasia	Mild
		Inflammation	Suppurative, Mild
Tooth		Malformation	Moderate
* Urinary Bladder	Artery	Inflammation	Chronic Active, Mild

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**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 121

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901841

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Gallbladder	* Mammary Gland
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**OBSERVATIONS**

* Kidney	Nephropathy	Moderate
* Liver	Hepatocellular Adenoma	
	Hepatocellular Carcinoma	
	Inflammation	Chronic, Minimal
[ Hepatocellular Adenoma TGLS = 2-4 ]		
[ Hepatocellular Carcinoma TGLS = 1-10 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Minimal
* Nose	Inflammation	Suppurative, Mild
* Spleen	Hematopoietic Cell Proliferation	Minimal

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 122

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901842

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Pancreas	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Mammary Gland	* Parathyroid Gland	* Thymus
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**OBSERVATIONS**

* Intestine Small, Jejunum [ Lymphoma Malignant TGLS = 2-10 ]	Lymphoma Malignant	
* Kidney	Nephropathy	Mild
* Liver	Eosinophilic Focus	
	Hematopoietic Cell Proliferation	Minimal
	Hepatocellular Carcinoma	
	Necrosis	Minimal
[ Hepatocellular Carcinoma TGLS = 1-11 ]		
* Lung	Hepatocellular Carcinoma	Metastatic (Liver)
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Moderate
* Nose	Inflammation	Suppurative, Minimal
* Spleen	Hematopoietic Cell Proliferation	Marked

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 123

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 611

**DOSE:** 168 MG/KG

**DISP:** Natural Death

**HISTO:** 9901843

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mandibular	* Nose	* Pancreas
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Mammary Gland	* Parathyroid Gland
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**OBSERVATIONS**

* Kidney	Nephropathy	Mild
* Liver	Clear Cell Focus	
	Hepatocellular Carcinoma	Multiple
	Inflammation	Chronic, Minimal
[ Hepatocellular Carcinoma TGLS = 1,2-4 ]		
* Lung	Hepatocellular Carcinoma	Metastatic (Liver)
[ Hepatocellular Carcinoma TGLS = 3-3 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Moderate
* Spleen	Hematopoietic Cell Proliferation	Mild

**PRIMARY CAUSE OF DEATH**

- Liver Hepatocellular Carcinoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 124

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901844

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hyperplasia	Moderate
	Hypertrophy	Minimal
* Gallbladder	Cyst	Minimal
* Kidney	Infarct	Mild
	Nephropathy	Minimal
* Liver	Clear Cell Focus	
	Inflammation	Chronic, Minimal
* Lung	Alveolar/Bronchiolar Carcinoma	
[ Alveolar/Bronchiolar Carcinoma TGLS = 1-10 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Mild
* Seminal Vesicle	Dilatation	Moderate
[ Dilatation TGLS = 2-11 ]		
* Stom Forestom		
Note: TGL 3, "nodule, 3mm dia, pale, firm" noted at trim, was not apparent microscopically.		
Tooth	Malformation	Moderate

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 125

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901845

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Gallbladder	* Mammary Gland	* Thymus
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**OBSERVATIONS**

Harderian Gland	Atrophy	Mild
* Kidney	Nephropathy	Mild
* Liver	Hepatocellular Carcinoma	
	Inflammation	Chronic, Minimal
[ Hepatocellular Carcinoma TGLS = 2-4+10 ]		
* Lung	Hepatocellular Carcinoma	Metastatic (Liver)
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Mild
* Nose	Inflammation	Suppurative, Mild
* Preputial Gland	Ectasia	Mild
[ Ectasia TGLS = 1-7 ]		
* Spleen	Hematopoietic Cell Proliferation	Minimal

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 126

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 465

**DOSE:** 168 MG/KG

**DISP:** Natural Death

**HISTO:** 9901846

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	Harderian Gland
* Intestine Large, Colon	* Islets, Pancreatic	* Lung	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum		

**OBSERVATIONS**

* Brain Note: There were bacterial emboli in the brain.			
* Heart Note: There were masses of bacteria in the areas of inflammation.	Inflammation		Suppurative, Moderate
* Kidney Note: There were bacterial emboli in areas of inflammation.	Inflammation		Suppurative, Moderate
* Liver	Fatty Change Inflammation		Minimal Chronic, Minimal
* Lymph Node, Mesenteric	Infiltration Cellular		Histiocyte, Mild
* Spleen	Hematopoietic Cell Proliferation		Mild

[ Hematopoietic Cell Proliferation TGLS = 1-4 ]

**PRIMARY CAUSE OF DEATH**

- Heart Inflammation

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 127

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901847

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Liver	* Lung	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Parathyroid Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Mild
* Kidney	Nephropathy	Mild
Note: TGL 1, "cyst, 0.5x0.5mm, clear" noted at necropsy, was not apparent microscopically.		
Tooth	Malformation	Mild

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 128

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901848

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Nose	* Pancreas
* Pituitary Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Parathyroid Gland
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**OBSERVATIONS**

* Kidney		Nephropathy	Minimal
* Liver		Fatty Change	Minimal
		Hemangiosarcoma	
[ Hemangiosarcoma TGLS = 2-4+11 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-10 ]			
* Preputial Gland		Ectasia	Mild
[ Ectasia TGLS = 1-7 ]			
* Stomach, Forestomach		Squamous Cell Papilloma	
Tooth		Malformation	Minimal

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 129

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901849

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Heart	Cardiomyopathy	Minimal
* Kidney	Nephropathy	Moderate
[ Nephropathy TGLS = 2-5 ]		
* Liver	Eosinophilic Focus	
	Hepatocellular Carcinoma	
	Inflammation	Chronic, Mild
[ Hepatocellular Carcinoma TGLS = 3-10 ]		
* Lung	Hepatocellular Carcinoma	Metastatic (Liver)
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Mild
* Preputial Gland	Inflammation	Chronic Active, Mild
[ Inflammation TGLS = 1-7 ]		

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 130

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901850

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Liver
* Nose	* Pancreas	* Parathyroid Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Pituitary Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
Harderian Gland	Adenoma	
[ Adenoma TGLS = 1-10 ]		
* Kidney	Nephropathy	Minimal
* Lung	Alveolar/Bronchiolar Adenoma	
	Inflammation	Chronic Active, Minimal
* Lym Node Mand		
Note: TGL 3, "enlarged, 5x3mm" noted at trim, was actually salivary gland.		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Mild
* Spleen		
Note: TGL 2, "focus, 3x3mm, dark" noted at necropsy, was not apparent microscopically.		

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 131

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901851

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Nose	* Pancreas
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Gallbladder	* Mammary Gland	* Parathyroid Gland
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**OBSERVATIONS**

* Kidney		Nephropathy	Minimal
* Liver		Hepatocellular Adenoma	Multiple
		Inflammation	Chronic, Minimal
	[ Hepatocellular Adenoma TGLS = 3,4-4+12+13 ]		
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
	[ Necrosis TGLS = 2-11 ]		
* Skin		Keratoacanthoma	
	[ Keratoacanthoma TGLS = 1-10 ]		
Tooth		Malformation	Minimal

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 132

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901852

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea		

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
* Kidney		Hydronephrosis	Moderate
		Nephropathy	Mild
	[ Hydronephrosis TGLS = 2-5 ]		
* Liver		Inflammation	Chronic, Minimal
* Preputial Gland		Ectasia	Moderate
	[ Ectasia TGLS = 1-7 ]		
* Urinary Bladder	Transit Epithe	Papilloma	
	[ Papilloma TGLS = 4-8+11 ]		

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 133      **TRT#:** 5      **SEX:** Male      **DAY ON TEST:** 641  
**DOSE:** 168 MG/KG      **DISP:** Moribund Sacrifice      **HISTO:** 9901853

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Gallbladder	* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Kidney	Nephropathy	Mild
* Liver	Hepatocellular Carcinoma	
[ Hepatocellular Carcinoma TGLS = 2-4+10 ]		
* Lung	Hepatocellular Carcinoma	Metastatic (Liver)
* Preputial GI		
Note: TGL 1, "small, 0.3x" noted at necropsy, was not apparent microscopically.		
* Spleen	Hematopoietic Cell Proliferation	Mild

**PRIMARY CAUSE OF DEATH**      - Liver    Hepatocellular Carcinoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 134

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901854

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular
* Nose	* Pancreas	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Mammary Gland	* Parathyroid Gland	* Thymus
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**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Mild
Harderian Gland		Inflammation	Acute, Minimal
* Heart	Artery	Inflammation	Chronic Active, Moderate
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
* Lung			
Note: TGL 1, "focus, 1x1mm, tan" noted at necropsy, was not apparent microscopically.			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Tooth		Inflammation	Chronic Active, Mild
		Malformation	Minimal

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 135

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901855

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Moderate
* Intestine Large, Rectum		Inflammation	Chronic Active, Minimal
* Kidney	Renal Tubule	Hyperplasia	Mild
		Nephropathy	Mild
* Liver		Clear Cell Focus	
		Inflammation	Chronic, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-11 ]			
Tooth		Inflammation	Chronic Active, Moderate

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

<b>ANIMAL ID:</b> 136	<b>TRT#:</b> 5	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 731
	<b>DOSE:</b> 168 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901856

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Nose	* Pancreas	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Gallbladder	* Lymph Node, Mandibular	* Mammary Gland
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**INSUFFICIENT TISSUE**

\* Parathyroid Gland

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Mild
* Kidney		Nephropathy	Mild
* Liver		Clear Cell Focus	
		Fatty Change	Minimal
		Hepatocellular Adenoma	Multiple
		Inflammation	Chronic, Minimal
[ Clear Cell Focus TGLS = 3-13 ]			
[ Hepatocellular Adenoma TGLS = 1,2-11+12 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Moderate
[ Necrosis TGLS = 4-10 ]			
Tooth		Malformation	Mild

PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 137      **TRT#:** 5      **SEX:** Male      **DAY ON TEST:** 680  
**DOSE:** 168 MG/KG      **DISP:** Natural Death      **HISTO:** 9901857

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Heart
* Islets, Pancreatic	* Lung	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Preputial Gland	* Thymus
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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Lymph Node, Mesenteric	* Testes	

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
* Intestine Large, Cecum [ Carcinoma TGLS = 2-6+11 ]		Carcinoma	
* Intestine Large, Rectum		Inflammation	Acute, Marked
* Kidney		Nephropathy	Minimal
* Liver	Centrilobular	Degeneration	Mild
Mesentery [ Necrosis TGLS = 3-10 ]	Fat	Necrosis	Mild
* Nose		Inflammation	Suppurative, Minimal
* Preputial GI			
Note: TGL 1, "enlarged, 3x, green" noted at necropsy, was not apparent microscopically.			
Tooth		Malformation	Minimal

**PRIMARY CAUSE OF DEATH**      - Intestine Large, Cecum    Carcinoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 138

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901858

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Nose	* Pancreas	* Parathyroid Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
* Kidney		Infarct	Mild
		Nephropathy	Mild
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Hepatocellular Adenoma	
	[ Clear Cell Focus TGLS = 3-12 ]		
	[ Eosinophilic Focus TGLS = 2-11 ]		
	[ Hepatocellular Adenoma TGLS = 1-13 ]		
* Lung		Alveolar/Bronchiolar Carcinoma	
	[ Alveolar/Bronchiolar Carcinoma TGLS = 4-3 ]		
* Lymph Node, Mesenteric		Angiectasis	Mild
		Infiltration Cellular	Histiocyte, Mild
	[ Angiectasis TGLS = 5-6 ]		
Mesentery	Fat	Necrosis	Mild
	[ Necrosis TGLS = 6-10 ]		
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
Tooth		Malformation	Minimal

PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 138

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901858

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 139

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 597

**DOSE:** 168 MG/KG

**DISP:** Natural Death

**HISTO:** 9901859

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Testes	* Thymsus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Mammary Gland

**AUTO PRECLUDES DIAG.**

* Bone Marrow	* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Lymph Node, Mesenteric	* Spleen	* Stomach, Glandular	

**OBSERVATIONS**

* Heart	Artery	Inflammation	Chronic Active, Mild
Note: There were masses of bacteria in the area of inflammation.			
* Kidney		Infarct	Mild
		Inflammation	Suppurative, Mild
Note: There were septic emboli in the kidneys.			
* Liver	Centrilobular	Degeneration	Minimal
		Hepatocellular Adenoma	
		Inflammation	Chronic, Minimal
Note: TGL 2, "discoloration, diffuse, pale" noted at necropsy, was not apparent microscopically. [ Hepatocellular Adenoma TGLS = 3-4 ]			
* Lym Node Mesen			
Note: The nature of TGL 4, "enlarged, 4x" noted at necropsy, was obscured by post mortem autolysis.			
* Spleen			
Note: The nature of TGL 1, "enlarged, 20x8x5mm" noted at necropsy, was obscured by post mortem autolysis.			

**PRIMARY CAUSE OF DEATH**

- Heart Artery Inflammation

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 140

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901860

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mandibular	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Kidney		Infarct	Mild
		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Hemangiosarcoma	
		Hepatocellular Adenoma	
		Inflammation	Chronic, Minimal
	[ Basophilic Focus TGLS = 2-10 ]		
	[ Hemangiosarcoma TGLS = 1-11 ]		
	[ Hepatocellular Adenoma TGLS = 3-12 ]		
* Lung	Alveolar Epith	Hyperplasia	Mild
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Tooth		Malformation	Minimal

PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 141

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 653

**DOSE:** 168 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9901861

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Testes	* Thymus	* Thyroid Gland
* Trachea			

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Bone Marrow	Hemangiosarcoma	
* Intestine Large, Colon	Necrosis	Minimal
* Islets, Pancreatic	Adenoma	
* Kidney	Inflammation	Suppurative, Mild
	Nephropathy	Minimal
* Liver	Hepatocellular Carcinoma	
[ Hepatocellular Carcinoma TGLS = 4-10 ]		
* Lung	Thrombosis	Mild
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Mild
* Nose	Inflammation	Suppurative, Minimal
* Preputial Gland	Ectasia	Moderate
[ Ectasia TGLS = 1,2-7 ]		
* Prostate	Inflammation	Chronic Active, Moderate
* Stomach, Forestomach	Hyperplasia	Squamous, Minimal
[ Hyperplasia TGLS = 5-8 ]		
* Stomach, Glandular	Necrosis	Mild
Tooth	Malformation	Mild
* Urinary Bladder	Hemangiosarcoma	
[ Hemangiosarcoma TGLS = 3-8 ]		

**PRIMARY CAUSE OF DEATH** - Urinary Bladder Hemangiosarcoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 141

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 653

**DOSE:** 168 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9901861

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 142

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901862

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Mild
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
[ Eosinophilic Focus TGLS = 1-4 ]			
* Lung	Alveolar Epith Alveolus	Hyperplasia	Mild
		Infiltration Cellular	Histiocyte, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Moderate
* Nose		Inflammation	Suppurative, Minimal
* Seminal Vesicle		Dilatation	Mild
[ Dilatation TGLS = 2-10 ]			
Tooth		Malformation	Minimal

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 143      **TRT#:** 5      **SEX:** Male      **DAY ON TEST:** 731  
**DOSE:** 168 MG/KG      **DISP:** Terminal Sacrifice      **HISTO:** 9901863

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lung	* Lymph Node, Mandibular
* Parathyroid Gland	* Pituitary Gland	* Prostate	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Mild
* Gallbladder	Epithelium	Hyperplasia	Minimal
* Islets, Pancreatic		Adenoma	
* Kidney		Nephropathy	Mild
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
[ Clear Cell Focus TGLS = 3-4 ]			
[ Eosinophilic Focus TGLS = 3-4 ]			
* Lymph Node, Mesenteric		Hematopoietic Cell Proliferation	Moderate
		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 4-10 ]			
* Nose	Olfactory Epi	Atrophy	Mild
* Pancreas		Atrophy	Marked
		Cyst	Marked
[ Cyst TGLS = 1-11 ]			
* Preputial Gland		Inflammation	Chronic Active, Moderate
[ Inflammation TGLS = 2-7 ]			
* Seminal Vesicle		Dilatation	Moderate

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 143

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901863

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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[ Dilatation TGLS = 5-12 ]

Tooth

Malformation

Moderate

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 144

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901864

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
* Heart	Mineralization	Minimal
* Kidney	Nephropathy	Mild
* Liver	Clear Cell Focus	
	Hemangiosarcoma	
	Hepatocellular Adenoma	
	Inflammation	Chronic, Minimal
[ Hemangiosarcoma TGLS = 1-4 ]		
[ Hepatocellular Adenoma TGLS = 2-10 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Moderate
* Seminal Vesicle	Dilatation	Moderate
[ Dilatation TGLS = 3-11 ]		
* Spleen	Hematopoietic Cell Proliferation	Mild

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 145

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901865

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Nose	* Pancreas	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Intestine Small, Ileum	* Mammary Gland	* Parathyroid Gland	* Thymus
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Inflammation	Chronic, Minimal
[ Eosinophilic Focus TGLS = 3-11 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-10 ]			
* Preputial GI			
Note: TGL 1, "discolored, green" noted at necropsy, was not apparent microscopically.			
Tooth		Malformation	Minimal

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 146

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901866

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Medulla		Pheochromocytoma Benign Vacuolization Cytoplasmic	Mild
* Kidney		Nephropathy	Marked
* Liver	Centrilobular	Degeneration Hepatocellular Carcinoma	Moderate Multiple
	[ Hepatocellular Carcinoma TGLS = 2,3-4+11 ]		
* Lung		Hepatocellular Carcinoma	Metastatic (Liver)
* Lymph Node, Mesenteric		Angiectasis	Mild
* Spleen		Hemangiosarcoma Hematopoietic Cell Proliferation	Mild
	[ Hemangiosarcoma TGLS = 1-10 ]		
Tooth		Inflammation	Chronic Active, Moderate

PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 147

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901867

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Mild
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Fatty Change	Minimal
		Inflammation	Chronic, Minimal
* Lung	Alveolar Epith	Hyperplasia	Moderate
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 1-10 ]			
Tooth		Malformation	Minimal

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 148

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901868

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Mammary Gland	* Thymus
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**INSUFFICIENT TISSUE**

\* Gallbladder

**OBSERVATIONS**

Eye	Cornea	Inflammation	Chronic, Minimal
Harderian Gland		Carcinoma	
[ Carcinoma TGLS = 1-10 ]			
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Hepatocellular Adenoma	
		Inflammation	Chronic, Minimal
[ Hepatocellular Adenoma TGLS = 2-11 ]			
* Lung		Hemorrhage	Minimal
[ Hemorrhage TGLS = 3-3 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
* Nose		Inflammation	Suppurative, Minimal

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 149

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 620

**DOSE:** 168 MG/KG

**DISP:** Natural Death

**HISTO:** 9901869

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Small, Duodenum
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**OBSERVATIONS**

* Kidney	Nephropathy	Mild
* Liver	Hepatocellular Adenoma	Multiple
[ Hepatocellular Adenoma TGLS = 2-4 ]		
* Lung	Alveolar/Bronchiolar Carcinoma	
Alveolar Epith	Hyperplasia	Mild
[ Alveolar/Bronchiolar Carcinoma TGLS = 4-3 ]		
* Lymph Node, Mesenteric	Sarcoma	Metastatic (Mesentery)
[ Sarcoma TGLS = 5-6 ]		
Mesentery	Sarcoma	
[ Sarcoma TGLS = 3-10 ]		
* Nose	Inflammation	Suppurative, Minimal
* Spleen	Hematopoietic Cell Proliferation	Mild
[ Hematopoietic Cell Proliferation TGLS = 1-4 ]		
* Stom Gland		
Note: TGL 7, "lesion, 1mm diam, dark" noted at trim, was not apparent microscopically.		
* Stomach, Forestomach	Squamous Cell Papilloma	
[ Squamous Cell Papilloma TGLS = 6-8 ]		

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 149

**TRT#:** 5

**SEX:** Male

**DAY ON TEST:** 620

**DOSE:** 168 MG/KG

**DISP:** Natural Death

**HISTO:** 9901869

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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PRIMARY CAUSE OF DEATH

- Mesentery Sarcoma

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 150      **TRT#:** 5      **SEX:** Male      **DAY ON TEST:** 725  
**DOSE:** 168 MG/KG      **DISP:** Moribund Sacrifice      **HISTO:** 9901870

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Thymus
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**OBSERVATIONS**

Harderian Gland	Inflammation	Acute, Moderate
* Heart	Hepatocellular Carcinoma	Metastatic (Liver)
* Kidney	Nephropathy	Mild
* Liver	Hepatocellular Carcinoma	
	Infarct	Mild
	Inflammation	Chronic, Minimal
[ Hepatocellular Carcinoma TGLS = 2-11 ]		
[ Infarct TGLS = 1-10 ]		
* Lung	Hepatocellular Carcinoma	Metastatic (Liver)
[ Hepatocellular Carcinoma TGLS = 3-3 ]		
* Lymph Node, Mesenteric	Angiectasis	Moderate
[ Angiectasis TGLS = 4-6 ]		
* Spleen	Hematopoietic Cell Proliferation	Mild
* Testes	Germinal Epith Degeneration	Mild

**PRIMARY CAUSE OF DEATH** - Liver Hepatocellular Carcinoma

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

<b>ANIMAL ID:</b> 151	<b>TRT#:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 676
	<b>DOSE:</b> 504 MG/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 9901871

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Heart
* Islets, Pancreatic	* Lymph Node, Mandibular	* Nose	* Pancreas
* Parathyroid Gland	* Prostate	* Seminal Vesicle	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Mammary Gland	* Pituitary Gland	* Thymus
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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mesenteric

**INSUFFICIENT TISSUE**

\* Salivary Glands

**OBSERVATIONS**

Harderian Gland [ Adenoma TGLS = 1-11 ]	Adenoma	
* Kidney	Nephropathy	Minimal
* Liver	Eosinophilic Focus	
	Hepatocellular Adenoma	Multiple
Note: TGL 8, "foci, 1x1mm, two, tan" noted at necropsy, was not apparent microscopically.		
Note: TGL 9, "nodule, 4x3x1mm, tan" noted at necropsy, was not apparent microscopically.		
[ Eosinophilic Focus TGLS = 6,7-16+14 ]		
[ Hepatocellular Adenoma TGLS = 5,11-17+10 ]		
* Lung [ Alveolar/Bronchiolar Carcinoma TGLS = 10-3 ]	Alveolar/Bronchiolar Carcinoma	
Mesentery Note: TGL 11, "mesentery, fat, nodule, 20x11x10mm" noted at necropsy, was actually liver.		
* Preputial Gland [ Ectasia TGLS = 3-7 ]	Ectasia	Mild

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 151	<b>TRT#:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 676
	<b>DOSE:</b> 504 MG/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 9901871

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Prostate			
Note: TGL 4, "discolored, green" noted at necropsy, was not apparent microscopically.			
* Skin	[ Inflammation TGLS = 2-12 ]	Inflammation	Chronic Active, Moderate
* Spleen		Hematopoietic Cell Proliferation	Mild

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PRIMARY CAUSE OF DEATH	- Lung Alveolar/Bronchiolar Carcinoma
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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 152

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901872

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Mild
* Heart		Cardiomyopathy	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Fatty Change	Minimal
		Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 1-10 ]			
* Preputial Gland		Infiltration Cellular	Histiocyte, Moderate
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Infiltration Cellular	Histiocyte, Minimal

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 153

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901873

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Gallbladder	* Mammary Gland
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**OBSERVATIONS**

* Heart		Cardiomyopathy	Minimal
* Kidney		Nephropathy	Mild
* Liver		Clear Cell Focus	
		Fatty Change	Minimal
		Hemangiosarcoma	
		Hepatocellular Adenoma	Multiple
		Inflammation	Chronic, Minimal
[ Clear Cell Focus TGLS = 4-10 ]			
[ Hemangiosarcoma TGLS = 1-4 ]			
[ Hepatocellular Adenoma TGLS = 2,3,5-4+11+12 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Moderate
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 6-13 ]			
* Spleen		Infiltration Cellular	Histiocyte, Minimal
* Stomach, Forestomach		Hyperplasia	Squamous, Mild
		Inflammation	Acute, Mild
[ Hyperplasia TGLS = 7-14 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 154

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 621

**DOSE:** 504 MG/KG

**DISP:** Natural Death

**HISTO:** 9901874

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Colon	* Intestine Large, Rectum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Testes	* Thymus	* Trachea	* Urinary Bladder

**MISSING**

\* Mammary Gland

**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Lymph Node, Mesenteric	* Stomach, Glandular	

**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Moderate
* Kidney		Nephropathy	Minimal
* Liver	Centrilobular	Degeneration	Mild
		Hemangiosarcoma	
		Hepatocellular Adenoma	
	[ Hemangiosarcoma TGLS = 1-4 ]		
	[ Hepatocellular Adenoma TGLS = 3-4 ]		
* Thyroid Gland	Follicular Cel	Adenoma	
	[ Adenoma TGLS = 2-2 ]		
Tooth		Malformation	Mild

**PRIMARY CAUSE OF DEATH**

- Liver Hemangiosarcoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 155

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 657

**DOSE:** 504 MG/KG

**DISP:** Natural Death

**HISTO:** 9901875

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Rectum	* Islets, Pancreatic	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Testes	* Thymus	* Thyroid Gland	* Trachea

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Kidney	* Lymph Node, Mesenteric
* Spleen	* Stomach, Glandular	* Urinary Bladder	

**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Mild
* Liver	Hepatocellular Carcinoma	
	Necrosis	Mild
[ Hepatocellular Carcinoma TGLS = 1-10 ]		
* Lung	Alveolar/Bronchiolar Adenoma	
	Hepatocellular Carcinoma	Metastatic (Liver)
[ Alveolar/Bronchiolar Adenoma TGLS = 2-3 ]		
* Stom Gland		
Note: TGL 3, "lesion, 2-3mm dia, multiple, dark" noted at trim, was obscured microscopically by post mortem autolysis.		

**PRIMARY CAUSE OF DEATH**

- Liver Hepatocellular Carcinoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 156      **TRT#:** 7      **SEX:** Male      **DAY ON TEST:** 731  
**DOSE:** 504 MG/KG      **DISP:** Terminal Sacrifice      **HISTO:** 9901876

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Pancreas	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Mammary Gland	* Parathyroid Gland
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**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Mild
* Intestine Small, Duodenum		Polyp Adenomatous	
[ Polyp Adenomatous TGLS = 2-12 ]			
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Hepatocellular Adenoma	
		Inflammation	Chronic, Minimal
[ Hepatocellular Adenoma TGLS = 1-11 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-10 ]			
* Nose	Olfactory Epi	Metaplasia	Minimal
* Spleen		Infiltration Cellular	Histiocyte, Minimal

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 157

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 17

**DOSE:** 504 MG/KG

**DISP:** Dosing Accident

**HISTO:** 9901877

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

\* Adrenal Cortex  
\* Brain  
\* Heart  
\* Kidney  
\* Pituitary Gland  
\* Seminal Vesicle  
\* Testes

\* Adrenal Medulla  
\* Epididymis  
\* Intestine Large, Rectum  
\* Liver  
\* Preputial Gland  
\* Skin  
\* Thymus

\* Bone  
\* Esophagus  
\* Intestine Small, Jejunum  
\* Lymph Node, Mandibular  
\* Prostate  
\* Stomach, Forestomach  
\* Trachea

\* Bone Marrow  
\* Harderian Gland  
\* Islets, Pancreatic  
\* Pancreas  
\* Salivary Glands  
\* Stomach, Glandular  
\* Urinary Bladder

**MISSING**

\* Mammary Gland

\* Parathyroid Gland

\* Thyroid Gland

**AUTO PRECLUDES DIAG.**

\* Gallbladder  
\* Intestine Small, Ileum

\* Intestine Large, Cecum  
\* Lymph Node, Mesenteric

\* Intestine Large, Colon  
\* Nose

\* Intestine Small, Duodenum

**OBSERVATIONS**

\* Lung  
[ Hemorrhage TGLS = 1,2-3 ]  
\* Spleen

Hemorrhage

Mild

Infiltration Cellular

Histiocyte, Minimal

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 158

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 646

**DOSE:** 504 MG/KG

**DISP:** Natural Death

**HISTO:** 9901878

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Brain	* Epididymis
* Esophagus	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Pancreas
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Parathyroid Gland	* Thymus
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**AUTO PRECLUDES DIAG.**

\* Gallbladder

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
* Bone Marrow		Histiocytic Sarcoma	
* Heart		Mineralization	Mild
* Intestine Large, Rectum		Infiltration Cellular	Histiocyte, Minimal
		Myxomatous Change	Minimal
* Kidney		Hydronephrosis	Mild
		Nephropathy	Mild
	[ Hydronephrosis TGLS = 2-5 ]		
	[ Nephropathy TGLS = 1-5 ]		
* Liver		Hemangiosarcoma	
		Inflammation	Chronic, Mild
		Necrosis	Mild
	[ Hemangiosarcoma TGLS = 3-4 ]		
* Lung		Alveolar/Bronchiolar Adenoma	
	Alveolar Epith	Hyperplasia	Mild
	[ Alveolar/Bronchiolar Adenoma TGLS = 5-3 ]		
	[ Hyperplasia TGLS = 6-3 ]		
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
* Spleen		Hematopoietic Cell Proliferation	Mild

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 158

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 646

**DOSE:** 504 MG/KG

**DISP:** Natural Death

**HISTO:** 9901878

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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PRIMARY CAUSE OF DEATH

- Liver Hemangiosarcoma

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 159

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 658

**DOSE:** 504 MG/KG

**DISP:** Natural Death

**HISTO:** 9901879

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Heart
* Islets, Pancreatic	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Thymus
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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mesenteric

**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Mild
* Kidney		Nephropathy	Mild
* Liver	Centrilobular	Degeneration	Mild
		Hepatocellular Carcinoma	
		Necrosis	Mild
	[ Hepatocellular Carcinoma TGLS = 2-11 ]		
* Lung		Alveolar/Bronchiolar Adenoma	
		Mineralization	Minimal
	[ Alveolar/Bronchiolar Adenoma TGLS = 3-10 ]		
* Spleen		Hematopoietic Cell Proliferation	Mild
	[ Hematopoietic Cell Proliferation TGLS = 1-4 ]		
* Stomach, Glandular		Mineralization	Mild
* Testes	Germinal Epith	Degeneration	Mild
Tooth		Malformation	Minimal

**PRIMARY CAUSE OF DEATH**

- Liver Hepatocellular Carcinoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 160

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 617

**DOSE:** 504 MG/KG

**DISP:** Natural Death

**HISTO:** 9901880

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Bone	* Bone Marrow	* Brain	* Epididymis
* Esophagus	* Islets, Pancreatic	* Lymph Node, Mandibular	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Adrenal Cortex	* Adrenal Medulla	* Mammary Gland	* Seminal Vesicle
* Thymus			

**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum		

**OBSERVATIONS**

Harderian Gland		Adenoma	
* Heart		Mineralization	Minimal
* Intestine Large, Rectum		Inflammation	Chronic Active, Minimal
		Metaplasia	Squamous, Moderate
* Kidney		Nephropathy	Mild
* Liver		Hepatocellular Carcinoma	Multiple
[ Hepatocellular Carcinoma TGLS = 1,2-4 ]			
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Moderate
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild

**PRIMARY CAUSE OF DEATH**

- Liver Hepatocellular Carcinoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 161

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901881

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Nose	* Pancreas
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Mammary Gland	* Parathyroid Gland
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**OBSERVATIONS**

Harderian Gland [ Adenoma TGLS = 1-10 ]	Adenoma	
* Kidney [ Cyst TGLS = 2-5 ]	Cyst Nephropathy	Mild Mild
* Liver [ Clear Cell Focus TGLS = 3-12 ]	Clear Cell Focus Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric Tooth	Infiltration Cellular Malformation	Histiocyte, Moderate Minimal

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 162

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 483

**DOSE:** 504 MG/KG

**DISP:** Natural Death

**HISTO:** 9901882

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Colon	* Intestine Large, Rectum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Mammary Gland

**AUTO PRECLUDES DIAG.**

* Intestine Large, Cecum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Stomach, Glandular			

**OBSERVATIONS**

* Liver	Hepatocellular Adenoma Hepatocellular Carcinoma		
[ Hepatocellular Adenoma TGLS = 2-11 ]			
[ Hepatocellular Carcinoma TGLS = 1-10 ]			
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Moderate	
* Stomach, Forestomach	Hyperplasia	Squamous, Minimal	

**PRIMARY CAUSE OF DEATH**

- Liver Hepatocellular Carcinoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 163

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 626

**DOSE:** 504 MG/KG

**DISP:** Natural Death

**HISTO:** 9901883

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Gallbladder	* Mammary Gland
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**AUTO PRECLUDES DIAG.**

* Intestine Large, Rectum	* Intestine Small, Ileum	* Intestine Small, Jejunum
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**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Moderate
* Liver	Centrilobular	Degeneration Hemangiosarcoma	Mild
Note: TGLs 4-11-No corresponding lesion [ Hemangiosarcoma TGLS = 2,3-4+10 ]			
* Spleen		Hematopoietic Cell Proliferation Infiltration Cellular	Moderate Mast Cell, Moderate
[ Hematopoietic Cell Proliferation TGLS = 1-4 ] [ Infiltration Cellular TGLS = 5-4+10 ]			

**PRIMARY CAUSE OF DEATH**

- Liver Hemangiosarcoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 164

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901884

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Hyperplasia	Mild
	Hypertrophy	Minimal
* Intestine Large, Rectum	Infiltration Cellular	Histiocyte, Minimal
* Kidney	Nephropathy	Minimal
* Liver	Basophilic Focus	
	Eosinophilic Focus	
	Fatty Change	Minimal
	Hepatocellular Adenoma	Multiple
	Inflammation	Chronic, Minimal
[ Hepatocellular Adenoma TGLS = 1,2,3-10+11+12 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Mild
* Spleen	Infiltration Cellular	Histiocyte, Minimal
Tooth	Malformation	Minimal

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 165

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 576

**DOSE:** 504 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9901885

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Intestine Large, Rectum	Myxomatous Change	Minimal
* Kidney	Nephropathy	Minimal
* Liver	Fatty Change	Minimal
	Hepatocellular Adenoma	Multiple
	Inflammation	Chronic, Minimal
[ Hepatocellular Adenoma TGLS = 1,2,3-4+10 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Mild
* Spleen	Infiltration Cellular	Histiocyte, Minimal

**PRIMARY CAUSE OF DEATH**

- Liver Hepatocellular Adenoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 166

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901886

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Nose	* Pancreas
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Mammary Gland

**INSUFFICIENT TISSUE**

\* Parathyroid Gland

**OBSERVATIONS**

* Adrenal Cortex	Hyperplasia	Mild
	Hypertrophy	Mild
* Kidney	Nephropathy	Minimal
* Liver	Fatty Change	Minimal
	Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Minimal
* Spleen	Infiltration Cellular	Histiocyte, Minimal
Tooth	Malformation	Minimal

**PRIMARY CAUSE OF DEATH**

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Animal Note: TGL 1 = No Correlating Lesion

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 167

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 590

**DOSE:** 504 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9901887

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

Harderian Gland	* Lymph Node, Mandibular	* Mammary Gland	* Thymus
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**OBSERVATIONS**

* Intestine Large, Rectum	Myxomatous Change	Minimal
* Kidney	Nephropathy	Mild
* Liver	Hepatocellular Carcinoma	
[ Hepatocellular Carcinoma TGLS = 1-10 ]		
* Lung	Hepatocellular Carcinoma	Metastatic (Liver)
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Minimal
* Spleen	Hematopoietic Cell Proliferation	Mild
	Infiltration Cellular	Histiocyte, Minimal

**PRIMARY CAUSE OF DEATH**

- Liver Hepatocellular Carcinoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 168      **TRT#:** 7      **SEX:** Male      **DAY ON TEST:** 731  
**DOSE:** 504 MG/KG      **DISP:** Terminal Sacrifice      **HISTO:** 9901888

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Epididymis	* Esophagus
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Gallbladder		Degeneration	Hyaline, Moderate
* Intestine Large, Rectum		Inflammation	Chronic Active, Mild
		Metaplasia	Squamous, Minimal
		Myxomatous Change	Minimal
		Necrosis	Minimal
* Kidney		Nephropathy	Mild
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Inflammation	Chronic, Minimal
Note: TGL 2, "focus, 1x1mm, tan" noted at necropsy, was not apparent microscopically. [ Clear Cell Focus TGLS = 1-12 ]			
* Lung			
Note: TGL 4, "focus, 2mm dia, dark" noted at trim, was artifact.			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-10 ]			
* Nose		Inflammation	Suppurative, Minimal
* Spleen		Infiltration Cellular	Histiocyte, Minimal
* Stomach, Forestomach		Ulcer	Moderate

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 168

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901888

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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[ Ulcer TGLS = 5-13 ]

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 169

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901889

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Mild
* Intestine Large, Rectum	Infiltration Cellular	Histiocyte, Minimal
	Inflammation	Chronic Active, Moderate
	Metaplasia	Squamous, Minimal
	Necrosis	Mild
* Kidney	Nephropathy	Mild
* Liver	Basophilic Focus	
	Clear Cell Focus	
	Eosinophilic Focus	
	Hepatocellular Carcinoma	
	Inflammation	Chronic, Minimal
[ Basophilic Focus TGLS = 4-4 ]		
[ Clear Cell Focus TGLS = 2-11 ]		
[ Hepatocellular Carcinoma TGLS = 1-10, 3-12 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Moderate

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 170

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901890

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hyperplasia	Mild
* Kidney	Nephropathy	Minimal
* Liver	Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Minimal
* Spleen	Infiltration Cellular	Histiocyte, Minimal
Tooth	Inflammation	Chronic Active, Mild
	Malformation	Minimal

PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 171      **TRT#:** 7      **SEX:** Male      **DAY ON TEST:** 539  
**DOSE:** 504 MG/KG      **DISP:** Natural Death      **HISTO:** 9901891

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Islets, Pancreatic
* Lung	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Thymus
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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	

**OBSERVATIONS**

Harderian Gland		Adenoma	
* Heart		Hemangiosarcoma	
* Kidney		Inflammation	Suppurative, Mild
* Liver	Centrilobular	Degeneration	Mild
		Hemangiosarcoma	
		Inflammation	Chronic, Minimal
		Necrosis	Moderate
[ Hemangiosarcoma TGLS = 1,3-10+11+12 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
* Prostate		Inflammation	Chronic Active, Marked
* Spleen		Hemangiosarcoma	
[ Hemangiosarcoma TGLS = 2-4 ]			

**PRIMARY CAUSE OF DEATH**      - Liver Hemangiosarcoma

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 172

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901892

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	Spinal Cord	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Trachea
* Urinary Bladder			

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Moderate
* Int Sm Jejunum			
Note: TGL 1, "enlarged, 3x, pale" noted at necropsy, was within normal limits microscopically.			
* Kidney		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
		Fatty Change	Minimal
		Inflammation	Chronic, Mild
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-10 ]			
* Spleen		Infiltration Cellular	Histiocyte, Minimal
* Thyroid Gland	Follicular Cel	Hyperplasia	Minimal
Tooth		Malformation	Minimal

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 173

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901893

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular
* Nose	* Pancreas	* Pituitary Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Mammary Gland	* Thymus
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**INSUFFICIENT TISSUE**

* Gallbladder	* Parathyroid Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Mild
* Intestine Large, Rectum	Myxomatous Change	Minimal
* Kidney	Nephropathy	Moderate
* Liver	Clear Cell Focus	
	Fatty Change	Minimal
	Hepatocellular Adenoma	Multiple
	Inflammation	Chronic, Minimal
[ Hepatocellular Adenoma TGLS = 3,4-10+11 ]		
* Lym Node Mand		
Note: TGL 1, "enlarged, 2x" noted at necropsy, was within normal limits microscopically.		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Minimal
* Preputial Gland	Inflammation	Chronic Active, Mild
[ Inflammation TGLS = 2-7 ]		
* Spleen	Hematopoietic Cell Proliferation	Moderate
[ Hematopoietic Cell Proliferation TGLS = 5-4 ]		

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 174

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901894

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Mammary Gland	* Thymus
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**OBSERVATIONS**

Harderian Gland	Adenoma	
* Intestine Large, Rectum	Myxomatous Change	Mild
* Kidney	Nephropathy	Mild
* Liver	Eosinophilic Focus	
	Fatty Change	Minimal
	Hepatocellular Adenoma	
[ Eosinophilic Focus TGLS = 3-11 ]		
[ Hepatocellular Adenoma TGLS = 1-4+10 ]		
* Lung	Alveolar/Bronchiolar Carcinoma	
[ Alveolar/Bronchiolar Carcinoma TGLS = 2-3 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Mild
* Spleen	Hematopoietic Cell Proliferation	Minimal

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 175

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901895

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Bone Marrow	Hemangiosarcoma	
* Intestine Large, Rectum	Inflammation	Chronic Active, Minimal
* Kidney	Infiltration Cellular	Mast Cell, Minimal
	Nephropathy	Mild
* Liver	Fatty Change	Minimal
	Hemangiosarcoma	
	Inflammation	Chronic, Minimal
Note: TGL 4, "foci, 1x1mm, diffuse, tan" noted at necropsy, was not apparent microscopically. [ Hemangiosarcoma TGLS = 1,2,3,5,6-10+12+4+11+13 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Moderate
* Spleen	Hemangiosarcoma	
	Infiltration Cellular	Histiocyte, Minimal
[ Hemangiosarcoma TGLS = 7-4 ]		
Tooth	Malformation	Mild

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 176	<b>TRT#:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 492
	<b>DOSE:</b> 504 MG/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 9901896

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Islets, Pancreatic	* Lymph Node, Mandibular	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

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**MISSING**

\* Mammary Gland

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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Lymph Node, Mesenteric			

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**OBSERVATIONS**

* Kidney	Nephropathy	Minimal
* Liver	Hepatocellular Carcinoma	
[ Hepatocellular Carcinoma TGLS = 1-10 ]		
* Lung	Hepatocellular Carcinoma	Metastatic (Liver)

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**PRIMARY CAUSE OF DEATH** - Liver Hepatocellular Carcinoma

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 177

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901897

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Gallbladder	* Mammary Gland	* Thymus
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Mild
* Intestine Small, Jejunum [ Lymphoma Malignant TGLS = 1-10 ]	Lymphoma Malignant	
* Kidney	Nephropathy	Minimal
* Liver	Fatty Change	Mild
	Inflammation	Chronic, Mild
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Moderate
Tooth	Malformation	Minimal

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 178

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 668

**DOSE:** 504 MG/KG

**DISP:** Natural Death

**HISTO:** 9901898

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Islets, Pancreatic	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Gallbladder	* Lymph Node, Mandibular	* Mammary Gland
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**AUTO PRECLUDES DIAG.**

\* Intestine Small, Jejunum

**OBSERVATIONS**

* Intestine Large, Rectum	Inflammation	Chronic Active, Moderate
	Metaplasia	Squamous, Mild
	Necrosis	Mild
* Kidney	Nephropathy	Minimal
* Liver	Hepatocellular Carcinoma	Multiple
	Inflammation	Chronic, Minimal
[ Hepatocellular Carcinoma TGLS = 3,7-10+4 ]		
* Lung	Alveolar/Bronchiolar Carcinoma	
	Hepatocellular Carcinoma	Metastatic (Liver)
[ Alveolar/Bronchiolar Carcinoma TGLS = 4-3 ]		
[ Hepatocellular Carcinoma TGLS = 5-11 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Mild
Pleura	Alveolar/Bronchiolar Carcinoma	Metastatic (Lung)
* Preputial GI		
Note: TGL 1, "enlarged, 2x, green" noted at necropsy, was within normal limits microscopically.		
* Seminal Vesicle	Inflammation	Chronic Active, Mild
Skeletal Muscle	Alveolar/Bronchiolar Carcinoma	Metastatic (Lung)

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 178	<b>TRT#:</b> 7	<b>SEX:</b> Male	<b>DAY ON TEST:</b> 668
	<b>DOSE:</b> 504 MG/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 9901898

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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[ Alveolar/Bronchiolar Carcinoma TGLS = 6-12 ]

* Spleen	Hematopoietic Cell Proliferation	Mild
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PRIMARY CAUSE OF DEATH	- Lung Alveolar/Bronchiolar Carcinoma
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\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 179

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 721

**DOSE:** 504 MG/KG

**DISP:** Natural Death

**HISTO:** 9901899

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Brain	* Epididymis
* Esophagus	* Gallbladder	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Nose	* Pancreas	* Parathyroid Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Testes	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Lymph Node, Mesenteric	* Mammary Gland	* Thymus
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**INSUFFICIENT TISSUE**

\* Pituitary Gland

**OBSERVATIONS**

* Adrenal Cortex	Hyperplasia	Mild
* Bone Marrow	Angiectasis	Moderate
* Kidney	Nephropathy	Minimal
* Liver	Eosinophilic Focus	
	Histiocytic Sarcoma	
[ Histiocytic Sarcoma TGLS = 2-4 ]		
* Spleen	Hematopoietic Cell Proliferation	Moderate
[ Hematopoietic Cell Proliferation TGLS = 1-4 ]		
* Stomach, Glandular	Inflammation	Chronic Active, Mild
Tooth	Malformation	Minimal

**PRIMARY CAUSE OF DEATH** - Liver Histiocytic Sarcoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 180

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901900

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Marked
Harderian Gland	Hyperplasia	Moderate
* Kidney	Nephropathy	Minimal
* Liver	Clear Cell Focus	
	Eosinophilic Focus	
	Hepatocellular Adenoma	
	Inflammation	Chronic, Moderate
[ Clear Cell Focus TGLS = 2-11 ]		
[ Hepatocellular Adenoma TGLS = 1-10 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Mild
* Spleen	Infiltration Cellular	Histiocyte, Minimal
Tooth	Malformation	Minimal

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 181

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901901

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Nose	* Pancreas	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Gallbladder	* Mammary Gland	* Parathyroid Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hyperplasia	Mild
* Intestine Large, Rectum	Myxomatous Change	Minimal
* Intestine Small, Jejunum [ Hyperplasia TGLS = 4-13 ]	Hyperplasia	Lymphoid, Marked
* Liver	Basophilic Focus	
	Clear Cell Focus	
	Hemangiosarcoma	
	Hepatocellular Carcinoma	
	Inflammation	Chronic, Minimal
[ Hemangiosarcoma TGLS = 2-11 ]		
[ Hepatocellular Carcinoma TGLS = 1-10 ]		
* Lymph Node, Mesenteric	Hemangiosarcoma	
	Infiltration Cellular	Histiocyte, Mild
[ Hemangiosarcoma TGLS = 3-12 ]		

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 182

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 498

**DOSE:** 504 MG/KG

**DISP:** Natural Death

**HISTO:** 9901902

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Nose	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Testes
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Thymus
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**OBSERVATIONS**

* Intestine Large, Rectum	Infiltration Cellular Myxomatous Change	Histiocyte, Minimal Mild
* Kidney	Nephropathy	Minimal
* Liver	Hepatocellular Carcinoma Inflammation	Chronic, Minimal
[ Hepatocellular Carcinoma TGLS = 1-4 ]		
* Pancreas	Atrophy	Mild
* Spleen	Amyloid Deposition	Moderate
* Stomach, Glandular	Necrosis	Mild
[ Necrosis TGLS = 2-8 ]		

**PRIMARY CAUSE OF DEATH**

- Liver Hepatocellular Carcinoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 183

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901903

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Nose	* Pancreas
* Parathyroid Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Kidney	Nephropathy	Minimal
* Liver	Fatty Change	Minimal
	Hepatocellular Carcinoma	
	Inflammation	Chronic, Minimal
Note: TGL 1, "nodule, 1x1x1mm" noted at necropsy, was not apparent microscopically. [ Hepatocellular Carcinoma TGLS = 2-11 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Mild
* Pituitary Gland	Pars Distalis	Mild
* Spleen	Infiltration Cellular	Histiocyte, Minimal

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 184

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901904

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Intestine Small, Ileum		Inflammation	Acute, Mild
* Kidney		Nephropathy	Mild
* Liver		Eosinophilic Focus	
		Hepatocellular Adenoma	Multiple
		Inflammation	Chronic, Minimal
[ Eosinophilic Focus TGLS = 4-12 ]			
[ Hepatocellular Adenoma TGLS = 1,2,3-10+11+13 ]			
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Infiltration Cellular	Histiocyte, Minimal

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 185

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901905

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Bone	* Bone Marrow	* Brain	* Epididymis
* Esophagus	* Gallbladder	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Testes	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex	Hyperplasia	Mild
* Adrenal Medulla	Hyperplasia	Minimal
* Kidney	Nephropathy	Minimal
* Liver	Clear Cell Focus	
	Inflammation	Chronic, Minimal
[ Clear Cell Focus TGLS = 2-10 ]		
* Lym Node Mand		
Note: TGL 1, "enlarged, 2x" noted at necropsy, was within normal limits microscopically.		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Mild
	Lymphoma Malignant	
* Spleen	Infiltration Cellular	Histiocyte, Minimal
Tooth	Malformation	Minimal

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 186      **TRT#:** 7      **SEX:** Male      **DAY ON TEST:** 731  
**DOSE:** 504 MG/KG      **DISP:** Terminal Sacrifice      **HISTO:** 9901906

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Lymph Node, Mandibular      \* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Fatty Change	Minimal
		Hepatocellular Adenoma	Multiple
		Inflammation	Chronic, Minimal
	[ Hepatocellular Adenoma TGLS = 2,3,4-10+4 ]		
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
	[ Necrosis TGLS = 5-11 ]		
* Preputial Gland		Inflammation	Chronic Active, Mild
	[ Inflammation TGLS = 1-7 ]		
* Spleen		Infiltration Cellular	Histiocyte, Minimal
Tooth		Inflammation	Chronic Active, Minimal
		Malformation	Minimal

PRIMARY CAUSE OF DEATH      -

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 187      **TRT#:** 7      **SEX:** Male      **DAY ON TEST:** 731  
**DOSE:** 504 MG/KG      **DISP:** Terminal Sacrifice      **HISTO:** 9901907

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Intestine Large, Rectum	Inflammation Metaplasia Myxomatous Change	Chronic Active, Mild Squamous, Minimal Mild
* Kidney [ Nephropathy TGLS = 2-5 ]	Nephropathy	Marked
* Liver [ Hepatocellular Adenoma TGLS = 4-10 ] [ Hepatocellular Carcinoma TGLS = 3-4 ]	Hepatocellular Adenoma Hepatocellular Carcinoma Inflammation	Chronic, Minimal
* Lung	Hepatocellular Carcinoma	Metastatic (Liver)
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Mild
* Preputial Gland [ Inflammation TGLS = 1-7 ]	Inflammation	Chronic Active, Mild
* Spleen	Hematopoietic Cell Proliferation	Mild
Tooth	Inflammation	Chronic Active, Mild

PRIMARY CAUSE OF DEATH -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:16  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 188      **TRT#:** 7      **SEX:** Male      **DAY ON TEST:** 631  
**DOSE:** 504 MG/KG      **DISP:** Natural Death      **HISTO:** 9901908

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Islets, Pancreatic	* Kidney
* Lymph Node, Mandibular	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Mammary Gland

**AUTO PRECLUDES DIAG.**

* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mesenteric	

**OBSERVATIONS**

\* Int Sm Ileum

Note: TGL 3, "lymphoid tissue, enlarged, 3x, white" noted at necropsy, was a normal Peyer's patch.

* Liver		Hepatocellular Adenoma	Multiple
		Necrosis	Minimal
	[ Hepatocellular Adenoma TGLS = 2-4 ]		
* Lung		Alveolar/Bronchiolar Adenoma	
Mesentery	Fat	Necrosis	Mild
	[ Necrosis TGLS = 4-10 ]		
* Preputial Gland		Ectasia	Moderate
	[ Ectasia TGLS = 1-7 ]		
* Spleen		Hematopoietic Cell Proliferation	Minimal

**PRIMARY CAUSE OF DEATH**      - Liver    Hepatocellular Adenoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 189      **TRT#:** 7      **SEX:** Male      **DAY ON TEST:** 731  
**DOSE:** 504 MG/KG      **DISP:** Terminal Sacrifice      **HISTO:** 9901909

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
		Hepatocellular Adenoma	
		Inflammation	Chronic, Mild
[ Basophilic Focus TGLS = 3-10 ]			
[ Hepatocellular Adenoma TGLS = 1,2-4 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 4-11 ]			
Tooth		Malformation	Minimal

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 190

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 11

**DOSE:** 504 MG/KG

**DISP:** Dosing Accident

**HISTO:** 9901910

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Liver	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Preputial Gland	* Prostate	* Salivary Glands
* Seminal Vesicle	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder	Zymbal's Gland	

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Lung	Mediastinum	Hemorrhage	Moderate
	Mediastinum	Inflammation	Acute, Moderate

[ Hemorrhage TGLS = 2-2 ]

\* Thymus

Note: TGL 2, "enlarged, 6x3mm, dark" noted at trim, was actually hemorrhage around thymus in mediastinum.

\* Trachea

Note: TGL 1, "laceration, 2mm" noted at necropsy, could not be seen microscopically; however, there were extensive hemorrhage & inflammation in adjacent mediastinum.

PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 191

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 695

**DOSE:** 504 MG/KG

**DISP:** Natural Death

**HISTO:** 9901911

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Epididymis
* Esophagus	Harderian Gland	* Heart	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Pancreas	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Testes	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Mammary Gland	* Parathyroid Gland	* Thymus
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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mesenteric
* Nose	* Stomach, Glandular		

**OBSERVATIONS**

* Bone Marrow	Histiocytic Sarcoma	
* Brain	Hemorrhage	Mild
* Kidney	Histiocytic Sarcoma	
* Liver	Eosinophilic Focus	
	Histiocytic Sarcoma	
[ Histiocytic Sarcoma TGLS = 2-11 ]		
* Lym Node Mesen		
Note: TGL 3, "enlarged, 2x, red" noted at necropsy, was obscured by post mortem autolysis.		
* Spleen	Histiocytic Sarcoma	
[ Histiocytic Sarcoma TGLS = 1-10 ]		
* Stomach, Forestomach	Hyperplasia	Squamous, Mild

**PRIMARY CAUSE OF DEATH** - Liver Histiocytic Sarcoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 192

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901912

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Prostate	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Mild
* Int Lg Cecum			
Note: TGL 4, "focus, 2mm dia, red" noted at trim, was blood in normal vessel.			
* Kidney		Lymphoma Malignant	
		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
		Inflammation	Chronic, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
Lymph Node	Mediastinal	Infiltration Cellular	Histiocyte, Minimal
	Mediastinal	Lymphoma Malignant	
* Lymph Node, Mesenteric		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 3-10 ]			
* Preputial Gland		Ectasia	Moderate
[ Ectasia TGLS = 1-7 ]			
* Seminal Vesicle		Inflammation	Chronic Active, Mild
* Spleen		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 2-4 ]			
Tooth		Malformation	Minimal

PRIMARY CAUSE OF DEATH -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 192

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901912

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 193

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 731

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901913

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular
* Nose	* Pancreas	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Mammary Gland	* Parathyroid Gland	* Thymus
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**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Mild
* Intestine Large, Cecum		Inflammation	Chronic Active, Mild
* Intestine Large, Rectum		Myxomatous Change	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Inflammation	Chronic, Minimal
Note: TGL 2, "nodule, 2x1x1mm, tan" noted at necropsy, was not apparent microscopically. [ Basophilic Focus TGLS = 1-4 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Moderate
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-11 ]			
Tooth		Malformation	Minimal

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 194      **TRT#:** 7      **SEX:** Male      **DAY ON TEST:** 730  
**DOSE:** 504 MG/KG      **DISP:** Terminal Sacrifice      **HISTO:** 9901914

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Nose	* Pancreas	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Mammary Gland	* Parathyroid Gland
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**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Moderate
Harderian Gland		Carcinoma	
[ Carcinoma TGLS = 1-14 ]			
* Kidney		Nephropathy	Moderate
* Liver		Hemangiosarcoma	
		Hepatocellular Adenoma	Multiple
		Inflammation	Chronic, Minimal
[ Hemangiosarcoma TGLS = 4,5-12+13 ]			
[ Hepatocellular Adenoma TGLS = 2,3,4,5-10+11+12+13 ]			
* Lung		Alveolar/Bronchiolar Carcinoma	
[ Alveolar/Bronchiolar Carcinoma TGLS = 6-3 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
* Pituitary Gland	Pars Intermed	Adenoma	
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Infiltration Cellular	Histiocyte, Minimal
Tooth		Inflammation	Chronic Active, Mild

PRIMARY CAUSE OF DEATH -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 195

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901915

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Thymus
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
* Intestine Large, Rectum		Myxomatous Change	Minimal
* Kidney		Nephropathy	Mild
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Hepatocellular Adenoma	
		Inflammation	Chronic, Moderate
[ Basophilic Focus TGLS = 2-11 ]			
[ Hepatocellular Adenoma TGLS = 1-10 ]			
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-12 ]			
* Spleen		Hematopoietic Cell Proliferation	Minimal
Tooth		Inflammation	Chronic Active, Moderate
		Malformation	Minimal

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 196      **TRT#:** 7      **SEX:** Male      **DAY ON TEST:** 731  
**DOSE:** 504 MG/KG      **DISP:** Terminal Sacrifice      **HISTO:** 9901916

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Preputial Gland	* Prostate
* Salivary Glands	* Seminal Vesicle	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Testes	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland
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**OBSERVATIONS**

* Kidney	Nephropathy	Minimal
* Liver	Clear Cell Focus	
	Hemangiosarcoma	
	Hepatocellular Adenoma	
	Inflammation	Chronic, Moderate
[ Clear Cell Focus TGLS = 3,4-11+4 ]		
[ Hemangiosarcoma TGLS = 2-4 ]		
[ Hepatocellular Adenoma TGLS = 1-10 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Mild
* Spleen	Infiltration Cellular	Histiocyte, Minimal
Tooth	Malformation	Minimal

PRIMARY CAUSE OF DEATH -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 197

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901917

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Epididymis	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Pancreas	* Parathyroid Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Lymph Node, Mandibular	* Mammary Gland	* Thymus
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**OBSERVATIONS**

* Kidney		Nephropathy	Mild
* Liver		Hepatocellular Adenoma	
[ Hepatocellular Adenoma TGLS = 2-4 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
* Nose		Inflammation	Suppurative, Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Skin	Subcut Tiss	Fibrous Histiocytoma	
[ Fibrous Histiocytoma TGLS = 1-10 ]			
* Spleen		Infiltration Cellular	Histiocyte, Minimal
Tooth		Inflammation	Chronic Active, Mild

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 198

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901918

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Mammary Gland	* Thymus
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**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Moderate
Harderian Gland	Adenoma	
* Kidney	Nephropathy	Minimal
* Liver	Basophilic Focus	
	Inflammation	Chronic, Minimal
* Lung	Alveolar/Bronchiolar Adenoma	
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Moderate
* Spleen	Infiltration Cellular	Histiocyte, Minimal
Tooth	Malformation	Minimal

PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 199

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901919

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Epididymis	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Islets, Pancreatic	* Lymph Node, Mandibular	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Preputial Gland
* Prostate	* Salivary Glands	* Seminal Vesicle	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Testes	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Mammary Gland

**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Moderate
* Intestine Large, Rectum		Infiltration Cellular	Histiocyte, Minimal
		Inflammation	Chronic Active, Mild
		Myxomatous Change	Mild
		Necrosis	Mild
* Intestine Small, Jejunum		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 3-6 ]			
* Kidney		Nephropathy	Mild
* Liver		Clear Cell Focus	
		Fatty Change	Minimal
		Hepatocellular Adenoma	Multiple
		Inflammation	Chronic, Minimal
[ Hepatocellular Adenoma TGLS = 1,2-10+11 ]			
* Lung	Alveolar Epith	Hyperplasia	Mild
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
		Lymphoma Malignant	
* Spleen		Infiltration Cellular	Histiocyte, Minimal
Tooth		Malformation	Minimal

PRIMARY CAUSE OF DEATH -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 199

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901919

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 200

**TRT#:** 7

**SEX:** Male

**DAY ON TEST:** 584

**DOSE:** 504 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9901920

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Epididymis	* Esophagus	Eye	* Gallbladder
* Heart	* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Preputial Gland	* Prostate	* Salivary Glands	* Seminal Vesicle
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Testes
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Mammary Gland                      \* Thymus

**OBSERVATIONS**

* Brain	Carcinoma	Metastatic (Harderian Gland)
Eye		
Note: TGL 2, "discolored, opaque" noted at necropsy, was not apparent microscopically.		
Harderian Gland	Carcinoma	
[ Carcinoma TGLS = 1-10 ]		
* Intestine Large, Cecum	Inflammation	Chronic Active, Mild
	Necrosis	Mild
* Intestine Large, Rectum	Infiltration Cellular	Histiocyte, Minimal
	Inflammation	Chronic Active, Mild
	Myxomatous Change	Mild
	Necrosis	Moderate
* Kidney	Nephropathy	Mild
* Liver	Hepatocellular Carcinoma	
[ Hepatocellular Carcinoma TGLS = 3-4 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Moderate
* Spleen	Infiltration Cellular	Histiocyte, Minimal

**PRIMARY CAUSE OF DEATH**                      - Harderian Gland    Carcinoma

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 201

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901921

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

**MISSING**

\* Thymus

**OBSERVATIONS**

* Liver	Inflammation	Chronic, Minimal
* Skin	Basal Cell Adenoma	

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 202

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 685

**DOSE:** 0 MG/KG

**DISP:** Natural Death

**HISTO:** 9901922

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	Blood Vessel	* Bone
* Bone Marrow	* Brain	* Clitoral Gland	* Esophagus
Harderian Gland	* Heart	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Pituitary Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Uterus			

**MISSING**

* Lymph Node, Mandibular	* Parathyroid Gland
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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Lymph Node, Mesenteric	* Thyroid Gland
* Trachea	* Urinary Bladder		

**OBSERVATIONS**

* Liver	Hepatocellular Carcinoma	
[ Hepatocellular Carcinoma TGLS = 2-10 ]		
* Spleen	Hematopoietic Cell Proliferation	Moderate
[ Hematopoietic Cell Proliferation TGLS = 1-4 ]		

**PRIMARY CAUSE OF DEATH**

- Liver Hepatocellular Carcinoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 203

**TRT#:** 2  
**DOSE:** 0 MG/KG

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:** 730  
**HISTO:** 9901923

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Parathyroid Gland

**OBSERVATIONS**

* Liver		Basophilic Focus	
		Hepatocellular Adenoma	
		Inflammation	Chronic, Minimal
		Lymphoma Malignant	
[ Hepatocellular Adenoma TGLS = 2-10 ]			
Lymph Node	Pancreatic	Lymphoma Malignant	
* Lymph Node, Mandibular		Lymphoma Malignant	
* Lymph Node, Mesenteric		Lymphoma Malignant	
* Spleen		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 1-4 ]			
* Uterus		Hyperplasia	Cystic, Moderate

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 204

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901924

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

**MISSING**

\* Lymph Node, Mandibular

**OBSERVATIONS**

* Intestine Large, Rectum	Inflammation	Acute, Minimal
* Kidney	Nephropathy	Minimal
* Liver	Eosinophilic Focus	
	Hepatocellular Adenoma	

[ Hepatocellular Adenoma TGLS = 1-10 ]

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 205

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901925

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone Marrow	* Brain
* Esophagus	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Pancreas	* Parathyroid Gland	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Clitoral Gland

**INSUFFICIENT TISSUE**

\* Gallbladder

**OBSERVATIONS**

* Bone		Fibrous Osteodystrophy	Minimal
* Intestine Small, Jejunum [ Hyperplasia TGLS = 6-10 ]		Hyperplasia	Lymphoid, Moderate
* Kidney		Nephropathy	Minimal
* Liver [ Hepatocellular Adenoma TGLS = 4-4 ]		Hepatocellular Adenoma	
* Lym Node Mesen Note: TGL 5, "cyst, 4x" noted at necropsy, actually involved mesentery.			
Mesentery [ Necrosis TGLS = 5-12 ]	Fat	Necrosis	Moderate
* Ovary [ Cyst TGLS = 1-7 ]		Cyst	Marked
* Pituitary Gland [ Adenoma TGLS = 3-8 ]	Pars Distalis	Adenoma	
* Uterus [ Hydrometra TGLS = 2-11 ]		Hydrometra	Marked

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 206      **TRT#:** 2      **SEX:** Female      **DAY ON TEST:** 456  
**DOSE:** 0 MG/KG      **DISP:** Moribund Sacrifice      **HISTO:** 9901926

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Esophagus	* Gallbladder	Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Thymus	* Thyroid Gland
* Trachea	* Uterus		

**MISSING**

\* Clitoral Gland

**OBSERVATIONS**

* Brain	Artery	Inflammation	Chronic Active, Moderate
* Heart		Inflammation	Chronic Active, Moderate
* Int Sm Jejunum			
Note: TGL 2, "nodule, 1x3mm" seen at trim, was a Peyer's patch.			
* Kidney	Artery	Inflammation	Chronic Active, Mild
		Nephropathy	Minimal
* Liver		Inflammation	Chronic, Minimal
Mesentery	Artery	Inflammation	Chronic Active, Moderate
* Ovary		Angiectasis	Moderate
		Cyst	Moderate
[ Cyst TGLS = 1-7 ]			
* Pancreas	Artery	Inflammation	Moderate
Skeletal Muscle	Artery	Inflammation	Chronic Active, Mild
* Skin	Artery	Inflammation	Chronic Active, Mild
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Stomach, Forestomach	Artery	Inflammation	Chronic Active, Moderate
* Stomach, Glandular	Artery	Inflammation	Chronic Active, Mild
* Urinary Bladder	Artery	Inflammation	Chronic Active, Moderate

**PRIMARY CAUSE OF DEATH** - Brain Artery Inflammation

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 207

**TRT#:** 2  
**DOSE:** 0 MG/KG

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:** 729  
**HISTO:** 9901927

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**OBSERVATIONS**

Harderian Gland		Hyperplasia	Minimal
* Liver		Angiectasis	Moderate
		Inflammation	Chronic, Minimal
[ Angiectasis TGLS = 3-4 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 4-10 ]			
* Ovary		Cyst	Mild
[ Cyst TGLS = 2-7 ]			
* Pituitary Gland	Pars Distalis	Hyperplasia	Moderate
* Uterus		Hydrometra	Moderate
[ Hydrometra TGLS = 1-8 ]			

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 208	<b>TRT#:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901928

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

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**MISSING**

* Lymph Node, Mandibular	* Parathyroid Gland
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**OBSERVATIONS**

* Kidney		Nephropathy	Minimal
* Liver		Inflammation	Chronic, Minimal
Lymph Node			
Note: TGL 3, "pancreatic, nodule, 2mm dia, yellow" noted at trim, actually involved adipose tissue next to pancreas.			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2,3-10+4 ]			
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Uterus		Hydrometra	Marked
[ Hydrometra TGLS = 1-8 ]			

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**PRIMARY CAUSE OF DEATH** -

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\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 209

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901929

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone Marrow	* Brain	* Clitoral Gland
* Esophagus	* Gallbladder	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney
* Liver	* Lung	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

**MISSING**

\* Lymph Node, Mandibular

**OBSERVATIONS**

* Adrenal Cortex	Hyperplasia	Minimal
* Bone	Fibrous Osteodystrophy	Minimal

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 210

**TRT#:** 2  
**DOSE:** 0 MG/KG

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:** 729  
**HISTO:** 9901930

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lymph Node, Mandibular	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**OBSERVATIONS**

* Liver		Inflammation	Chronic, Minimal
Note: TGL 1, "focus, 1x1mm, tan" noted at necropsy, was not apparent microscopically.			
Note: TGL 2, "focus, 2x1mm diam, pale" noted at trim, was not apparent microscopically.			
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Plasma Cell, Moderate
* Uterus		Hydrometra	Minimal

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 211

**TRT#:** 2  
**DOSE:** 0 MG/KG

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:** 730  
**HISTO:** 9901931

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

**OBSERVATIONS**

Harderian Gland		Adenoma	
* Kidney		Nephropathy	Minimal
* Liver		Inflammation	Chronic, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 1-10 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 212

**TRT#:** 2  
**DOSE:** 0 MG/KG

**SEX:** Female  
**DISP:** Natural Death

**DAY ON TEST:** 536  
**HISTO:** 9901932

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Bone	* Bone Marrow	* Brain	* Esophagus
Harderian Gland	* Heart	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Pituitary Gland	* Salivary Glands	* Skin	* Thymus
* Trachea	* Uterus		

**MISSING**

* Clitoral Gland	* Parathyroid Gland
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**AUTO PRECLUDES DIAG.**

* Adrenal Cortex	* Adrenal Medulla	* Gallbladder	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney	* Pancreas
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Urinary Bladder			

**OBSERVATIONS**

* Liver		Hepatocellular Adenoma	
Mesentery	Fat	Necrosis	Moderate
[ Necrosis TGLS = 1-10 ]			

**PRIMARY CAUSE OF DEATH**

- UNCERTAIN

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 213

**TRT#:** 2  
**DOSE:** 0 MG/KG

**SEX:** Female  
**DISP:** Natural Death

**DAY ON TEST:** 667  
**HISTO:** 9901933

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	Harderian Gland
* Heart	* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea

**MISSING**

\* Ovary

**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mesenteric
* Spleen	* Urinary Bladder		

**OBSERVATIONS**

* Kidney	Nephropathy	Minimal
* Liver	Eosinophilic Focus	
* Uterus	Hydrometra	Mild

[ Hydrometra TGLS = 1-8 ]

**PRIMARY CAUSE OF DEATH**

- UNCERTAIN

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 214

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901934

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Mammary Gland	* Nose	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea

**MISSING**

\* Parathyroid Gland

**OBSERVATIONS**

* Bone Marrow		Lymphoma Malignant	
* Kidney		Lymphoma Malignant	
* Liver		Eosinophilic Focus	
		Hepatocellular Adenoma	
		Inflammation	Chronic, Minimal
[ Hepatocellular Adenoma TGLS = 1-10 ]			
Lymph Node	Bronchial	Lymphoma Malignant	
	Inguinal	Lymphoma Malignant	
	Mediastinal	Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 4-11 ]			
[ Lymphoma Malignant TGLS = 3-2 ]			
* Lymph Node, Mandibular		Lymphoma Malignant	
* Lymph Node, Mesenteric		Lymphoma Malignant	
* Ovary		Lymphoma Malignant	
* Pancreas		Lymphoma Malignant	
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Salivary Glands		Lymphoma Malignant	
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Lymphoma Malignant	
* Thymus		Lymphoma Malignant	
* Urinary Bladder		Lymphoma Malignant	

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 214

**TRT#:** 2  
**DOSE:** 0 MG/KG

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:** 730  
**HISTO:** 9901934

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**ORGAN AND ACCOUNTABLE SITE STATUS**

---

\* Uterus  
[ Hydrometra TGLS = 2-8 ]

Hydrometra

Moderate

---

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 215

**TRT#:** 2  
**DOSE:** 0 MG/KG

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:** 730  
**HISTO:** 9901935

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**OBSERVATIONS**

* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Inflammation	Chronic, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-10 ]			
* Ovary		Cyst	Mild
[ Cyst TGLS = 2-7 ]			
* Pituitary Gland	Pars Distalis	Hyperplasia	Moderate
* Uterus		Angiectasis	Moderate
		Hydrometra	Moderate
[ Angiectasis TGLS = 1-8 ]			
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 216

**TRT#:** 2  
**DOSE:** 0 MG/KG

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:** 729  
**HISTO:** 9901936

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone Marrow	* Brain
* Esophagus	* Gallbladder	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Pancreas	* Parathyroid Gland	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder
* Uterus			

**MISSING**

\* Clitoral Gland

**OBSERVATIONS**

* Bone		Osteosarcoma	
[ Osteosarcoma TGLS = 2-10 ]			
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Inflammation	Chronic, Minimal
[ Basophilic Focus TGLS = 1-4 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-11 ]			
* Ovary		Cyst	Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
	Pars Intermed	Hypertrophy	Mild
* Skin			

Note: TGL 2, "nodule, 4mm dia" noted at trim, actually involved bone.

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 217

**TRT#:** 2  
**DOSE:** 0 MG/KG

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:** 730  
**HISTO:** 9901937

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder			

**INSUFFICIENT TISSUE**

\* Intestine Small, Duodenum

**OBSERVATIONS**

Harderian Gland	Bilateral	Adenoma	
[ Adenoma TGLS = 1-11 ]			
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Hemangiosarcoma	
		Hepatocellular Adenoma	
		Inflammation	Chronic, Minimal
[ Hepatocellular Adenoma TGLS = 3-10 ]			
* Lymph Node, Mesenteric		Hyperplasia	Lymphoid, Marked
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 5-12 ]			
* Ovary		Cyst	Mild
* Spleen		Hyperplasia	Lymphoid, Moderate
[ Hyperplasia TGLS = 4-4 ]			
* Thymus		Hyperplasia	Lymphoid, Moderate
* Uterus		Polyp Stromal	
[ Polyp Stromal TGLS = 2-8 ]			

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 218

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901938

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

\* Thymus

**OBSERVATIONS**

* Bone	Fibrous Osteodystrophy	Mild
Harderian Gland	Hyperplasia	Mild
* Kidney	Nephropathy	Mild
* Liver	Inflammation	Chronic, Minimal
* Lymph Node, Mandibular	Hyperplasia	Lymphoid, Marked
* Lymph Node, Mesenteric	Hyperplasia	Lymphoid, Moderate
* Uterus	Hydrometra	Moderate
	Hyperplasia	Cystic, Mild

[ Hydrometra TGLS = 1-8 ]

[ Hyperplasia TGLS = 2-10 ]

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 219

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901939

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Clitoral Gland

**OBSERVATIONS**

* Liver		Inflammation	Chronic, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-10 ]			
* Uterus		Hydrometra	Mild
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 220

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901940

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Brain	* Clitoral Gland
* Esophagus	* Gallbladder	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Pituitary Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Lymph Node, Mandibular	* Parathyroid Gland
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**OBSERVATIONS**

* Bone		Fibrous Osteodystrophy	Minimal
* Bone Marrow		Lymphoma Malignant	
* Kidney		Nephropathy	Minimal
* Liver		Inflammation	Chronic, Minimal
Lymph Node	Mediastinal	Lymphoma Malignant	
* Lymph Node, Mesenteric		Lymphoma Malignant	
* Spleen		Lymphoma Malignant	
* Uterus		Hydrometra	Mild

[ Hydrometra TGLS = 1-8 ]

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 221

**TRT#:** 2  
**DOSE:** 0 MG/KG

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:** 730  
**HISTO:** 9901941

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**OBSERVATIONS**

* Intestine Small, Jejunum [ Lymphoma Malignant TGLS = 2-10 ]		Lymphoma Malignant	
* Liver		Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric Mesentery [ Necrosis TGLS = 3-11 ]	Fat	Lymphoma Malignant Necrosis	Mild
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Uterus [ Hyperplasia TGLS = 1-8 ]		Hyperplasia	Cystic, Mild

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 222

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901942

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Esophagus	* Gallbladder	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Clitoral Gland

**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Minimal
		Hypertrophy	Minimal
* Intestine Small, Ileum		Lymphoma Malignant	
* Intestine Small, Jejunum		Inflammation	Acute, Marked
		Lymphoma Malignant	
* Liver		Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric		Hyperplasia	Lymphoid, Marked
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-10 ]			
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Uterus		Hyperplasia	Cystic, Minimal
[ Hyperplasia TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 223

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901943

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea

**OBSERVATIONS**

Harderian Gland		Adenoma	
* Liver		Inflammation	Chronic, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-10 ]			
* Salivary Glands		Lymphoma Malignant	
* Spleen		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 2-4 ]			
* Urinary Bladder		Lymphoma Malignant	
* Uterus		Hydrometra	Moderate
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 224

**TRT#:** 2  
**DOSE:** 0 MG/KG

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:** 730  
**HISTO:** 9901944

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Salivary Glands	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**OBSERVATIONS**

* Liver		Inflammation	Chronic, Minimal
Note: TGL2, "focus, 2mm dia, pale" noted at trim, was not apparent microscopically.			
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Uterus		Hydrometra	Moderate
		Polyp Stromal	

[ Hydrometra TGLS = 1-8 ]

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 225

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901945

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Lymph Node, Mandibular	* Thymus
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**OBSERVATIONS**

* Liver	Eosinophilic Focus	
	Inflammation	Chronic, Minimal
* Uterus	Hydrometra	Moderate
[ Hydrometra TGLS = 1-8 ]		

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 226

**TRT#:** 2  
**DOSE:** 0 MG/KG

**SEX:** Female  
**DISP:** Moribund Sacrifice

**DAY ON TEST:** 661  
**HISTO:** 9901946

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Pituitary Gland
* Salivary Glands	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Clitoral Gland	* Parathyroid Gland
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**OBSERVATIONS**

* Kidney		Mineralization	Mild
* Liver		Cyst	Mild
		Inflammation	Chronic, Minimal
[ Cyst TGLS = 2-4 ]			
Lymph Node	Mediastinal	Sarcoma	Metastatic (Skin)
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 4-11 ]			
* Skin	Subcut Tiss	Sarcoma	
[ Sarcoma TGLS = 3-10 ]			
* Spleen		Hematopoietic Cell Proliferation	Mild
* Stomach, Forestomach		Hyperplasia	Squamous, Minimal
		Ulcer	Mild
* Uterus		Hyperplasia	Cystic, Mild
[ Hyperplasia TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH** - Skin Subcut Tiss Sarcoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 227

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901947

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Pituitary Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Lymph Node, Mandibular	* Parathyroid Gland
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**OBSERVATIONS**

* Adrenal Cortex	Hyperplasia	Minimal
* Liver	Hepatocellular Carcinoma	
	Inflammation	Chronic, Minimal
[ Hepatocellular Carcinoma TGLS = 2-4 ]		
* Uterus	Hydrometra	Marked
[ Hydrometra TGLS = 1-8 ]		

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 228

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901948

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**OBSERVATIONS**

* Liver	Inflammation	Chronic, Minimal
* Uterus	Hydrometra	Moderate

[ Hydrometra TGLS = 1-8 ]

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 229

**TRT#:** 2  
**DOSE:** 0 MG/KG

**SEX:** Female  
**DISP:** Natural Death

**DAY ON TEST:** 647  
**HISTO:** 9901949

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Thymus	* Thyroid Gland	* Trachea	

**AUTO PRECLUDES DIAG.**

* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Pancreas
* Stomach, Glandular	* Urinary Bladder		

**OBSERVATIONS**

* Kidney [ Hydronephrosis TGLS = 3-5 ]		Hydronephrosis	Marked
* Liver [ Infarct TGLS = 6-12 ]		Infarct Inflammation Mineralization	Marked Chronic, Minimal Moderate
* Lym Node Mand Note: TGL 5, "enlarged, 2x" noted at necropsy, was within normal limits microscopically. Lymph Node Note: TGL 4, "pancreatic, enlarged, 3x" noted at necropsy, was actually metastatic sarcoma in mesentery.			
Mesentery [ Necrosis TGLS = 7-13 ] [ Sarcoma TGLS = 4-4 ]	Fat	Necrosis Sarcoma	Mild Metastatic (Uterus)
Skeletal Muscle [ Sarcoma TGLS = 1-10 ]		Sarcoma	Metastatic (Uterus)
* Spleen		Hematopoietic Cell Proliferation	Mild
* Stomach, Forestomach		Ulcer	Moderate
* Uterus		Sarcoma	

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 229

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 647

**DOSE:** 0 MG/KG

**DISP:** Natural Death

**HISTO:** 9901949

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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[ Sarcoma TGLS = 2-11 ]

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PRIMARY CAUSE OF DEATH

- Uterus Sarcoma

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 230

**TRT#:** 2  
**DOSE:** 0 MG/KG

**SEX:** Female  
**DISP:** Moribund Sacrifice

**DAY ON TEST:** 703  
**HISTO:** 9901950

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Lymph Node, Mandibular	* Ovary	* Thymus
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**INSUFFICIENT TISSUE**

* Intestine Large, Cecum	* Parathyroid Gland
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**OBSERVATIONS**

* Adrenal Cortex		Hematopoietic Cell Proliferation	Moderate
* Kidney		Mineralization	Minimal
		Nephropathy	Moderate
* Liver		Eosinophilic Focus	
		Hematopoietic Cell Proliferation	Mild
		Inflammation	Chronic, Minimal
Mesentery		Inflammation	Suppurative, Moderate
	Fat	Necrosis	Marked
[ Necrosis TGLS = 2-10 ]			
* Pancreas		Atrophy	Moderate
		Inflammation	Acute, Moderate
* Spleen		Hematopoietic Cell Proliferation	Marked
[ Hematopoietic Cell Proliferation TGLS = 1-4 ]			
* Uterus		Hydrometra	Minimal

**PRIMARY CAUSE OF DEATH**

- Mesentery Fat Necrosis

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 231

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901951

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Lymph Node, Mandibular

**OBSERVATIONS**

* Liver		Inflammation	Chronic, Minimal
* Lung		Alveolar/Bronchiolar Adenoma	
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-10 ]			
* Salivary Glands		Basophilic Focus	
* Uterus		Hydrometra	Moderate
[ Hydrometra TGLS = 1-8 ]			

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 232

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901952

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**OBSERVATIONS**

* Liver		Inflammation	Chronic, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Uterus		Hydrometra	Mild

[ Hydrometra TGLS = 1-8 ]

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 233

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901953

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**OBSERVATIONS**

* Intestine Small, Jejunum [ Carcinoma TGLS = 6-11 ]		Carcinoma	
* Kidney		Nephropathy	Minimal
* Liver  [ Hepatocellular Carcinoma TGLS = 3-4+10 ]		Hepatocellular Carcinoma Inflammation	Chronic, Minimal
* Lung Mesentery [ Necrosis TGLS = 5-12 ]	Fat	Hepatocellular Carcinoma Necrosis	Metastatic (Liver) Mild
* Nose		Inflammation	Suppurative, Minimal
* Ovary  [ Cystadenoma TGLS = 2-7 ]		Cystadenoma	
* Pituitary Gland * Spleen [ Hematopoietic Cell Proliferation TGLS = 4-4 ]	Pars Distalis	Hyperplasia Hematopoietic Cell Proliferation	Moderate Moderate
* Uterus  [ Hyperplasia TGLS = 1-8 ] [ Polyp Stromal TGLS = 7-8 ]		Hyperplasia Polyp Stromal	Cystic, Mild

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 234

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901954

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Lymph Node, Mandibular

**OBSERVATIONS**

Harderian Gland		Adenoma	
* Liver		Inflammation	Chronic, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-10 ]			
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Uterus		Hydrometra	Marked
		Inflammation	Suppurative, Mild
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 235

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 717

**DOSE:** 0 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9901955

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Gallbladder

**OBSERVATIONS**

* Kidney		Mineralization	Minimal
* Liver		Eosinophilic Focus	
		Fatty Change	Minimal
		Hematopoietic Cell Proliferation	Minimal
		Inflammation	Chronic, Minimal
		Sarcoma	Metastatic (Skin)
* Lung	Alveolar Epith	Hyperplasia	Moderate
Lymph Node	Pancreatic	Sarcoma	Metastatic (Skin)
[ Sarcoma TGLS = 2-10 ]			
Mesentery	Fat	Necrosis	Moderate
[ Necrosis TGLS = 3-11 ]		Sarcoma	Metastatic (Skin)
* Ovary		Cyst	Mild
* Skin	Subcut Tiss	Sarcoma	
[ Sarcoma TGLS = 4-12 ]			
* Uterus		Hydrometra	Mild
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

- Skin Subcut Tiss Sarcoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 236

**TRT#:** 2  
**DOSE:** 0 MG/KG

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:** 730  
**HISTO:** 9901956

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

\* Lymph Node, Mandibular

**OBSERVATIONS**

* Gallbladder		Degeneration	Hyaline, Minimal
* Int Sm Jejunum			
Note: TGL 5, "nodule, 2mm dia" noted at trim, was normal Peyer's patch (lymphoid nodule).			
* Liver		Eosinophilic Focus	
		Hepatocellular Adenoma	Multiple
		Inflammation	Chronic, Minimal
[ Eosinophilic Focus TGLS = 4-4 ]			
[ Hepatocellular Adenoma TGLS = 2,3-10+11 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 6-12 ]			
* Uterus		Hyperplasia	Cystic, Mild
		Inflammation	Suppurative, Minimal
[ Hyperplasia TGLS = 1-8 ]			

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 237

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 411

**DOSE:** 0 MG/KG

**DISP:** Natural Death

**HISTO:** 9901957

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder
* Uterus			

**OBSERVATIONS**

* Liver		Fatty Change	Minimal
Mesentery	Fat	Necrosis	Moderate
[ Necrosis TGLS = 1-10 ]			

**PRIMARY CAUSE OF DEATH**

- UNCERTAIN

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 238	<b>TRT#:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 183
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Accidentally Killed	<b>HISTO:</b> 9901958

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Colon	* Intestine Large, Rectum	* Liver	* Lung
* Mammary Gland	* Nose	* Pituitary Gland	* Salivary Glands
* Skin	* Thymus		

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**MISSING**

* Clitoral Gland	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Parathyroid Gland
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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney	* Pancreas
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

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**OBSERVATIONS**

* Ovary		Cyst	Minimal
[ Cyst TGLS = 1-7 ]			

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**PRIMARY CAUSE OF DEATH** - UNCERTAIN

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\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 239

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901959

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Thymus

**INSUFFICIENT TISSUE**

\* Clitoral Gland

**OBSERVATIONS**

* Kidney	Nephropathy	Minimal
* Liver	Inflammation	Chronic, Minimal
* Lung	Alveolar/Bronchiolar Carcinoma	
[ Alveolar/Bronchiolar Carcinoma TGLS = 1-3+10 ]		
* Stomach, Forestomach	Hyperplasia	Squamous, Minimal
* Uterus	Hydrometra	Moderate
[ Hydrometra TGLS = 2-8 ]		

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 240	<b>TRT#:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 583
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 9901960

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Heart
* Intestine Large, Colon	* Intestine Large, Rectum	* Islets, Pancreatic	* Kidney
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder
* Uterus			

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**MISSING**

\* Lymph Node, Mandibular

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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum			

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**OBSERVATIONS**

Harderian Gland	Hyperplasia	Minimal
* Liver	Fatty Change	Minimal
	Inflammation	Chronic, Minimal
* Ovary	Cyst	Mild
[ Cyst TGLS = 1-7 ]		

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**PRIMARY CAUSE OF DEATH** - UNCERTAIN

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 241

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901961

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Lymph Node, Mandibular

**OBSERVATIONS**

* Liver		Inflammation	Chronic, Minimal
Mesentery	Fat	Necrosis	Moderate
[ Necrosis TGLS = 1-10 ]			
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Uterus		Hydrometra	Mild
[ Hydrometra TGLS = 2-8 ]			

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 242

**TRT#:** 2  
**DOSE:** 0 MG/KG

**SEX:** Female  
**DISP:** Natural Death

**DAY ON TEST:** 723  
**HISTO:** 9901962

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Bone	* Bone Marrow	* Brain	* Clitoral Gland
* Esophagus	* Heart	* Ovary	* Pituitary Gland
* Salivary Glands	* Skin		

**MISSING**

\* Parathyroid Gland

**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Mammary Gland	* Pancreas	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder
* Uterus			

**OBSERVATIONS**

* Adrenal Cortex		Lymphoma Malignant	
* Adrenal Medulla		Lymphoma Malignant	
Harderian Gland		Atrophy	Minimal
* Kidney		Lymphoma Malignant	
* Liver		Lymphoma Malignant	
* Lung		Lymphoma Malignant	
Lymph Node	Lumbar	Lymphoma Malignant	
	Mediastinal	Lymphoma Malignant	
	Renal	Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 4-12 ]			
[ Lymphoma Malignant TGLS = 6-2 ]			
[ Lymphoma Malignant TGLS = 5-13 ]			
* Lymph Node, Mandibular		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 3-11 ]			
* Lymph Node, Mesenteric		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 2-10 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 7-14 ]			

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 242

**TRT#:** 2  
**DOSE:** 0 MG/KG

**SEX:** Female  
**DISP:** Natural Death

**DAY ON TEST:** 723  
**HISTO:** 9901962

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Nose	Inflammation	Suppurative, Mild
* Spleen	Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 1-4 ]		

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**PRIMARY CAUSE OF DEATH** - Lymph Node, Mesenteric Lymphoma Malignant

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 243

**TRT#:** 2  
**DOSE:** 0 MG/KG

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:** 729  
**HISTO:** 9901963

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Esophagus	* Gallbladder	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Clitoral Gland	* Lymph Node, Mandibular
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**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Inflammation	Chronic, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-10 ]			
* Uterus		Hydrometra	Mild
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 244	<b>TRT#:</b> 2	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 0 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901964

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

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**MISSING**

\* Gallbladder

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**OBSERVATIONS**

* Kidney		Nephropathy	Minimal
* Liver		Inflammation	Chronic, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 1-10 ]			

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**PRIMARY CAUSE OF DEATH**

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 245

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901965

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Salivary Glands	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

**MISSING**

\* Lymph Node, Mandibular

**OBSERVATIONS**

* Kidney		Nephropathy	Minimal
* Liver		Eosinophilic Focus Inflammation	Chronic, Minimal
[ Eosinophilic Focus TGLS = 3-4 ]			
* Lung	Alveolar Epith	Alveolar/Bronchiolar Adenoma Hyperplasia	Mild
[ Alveolar/Bronchiolar Adenoma TGLS = 1-3 ]			
[ Hyperplasia TGLS = 2-3 ]			
* Ovary		Cyst	Mild
* Pituitary Gland		Hyperplasia	Mild

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 246

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901966

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

Harderian Gland

**INSUFFICIENT TISSUE**

\* Ovary

**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Minimal
* Liver		Eosinophilic Focus	
		Hematopoietic Cell Proliferation	Moderate
		Inflammation	Chronic, Minimal
Note: TGL 5, "nodules, 1x1x1mm, 3x2x2mm, two, white" noted at necropsy, were not apparent microscopically. [ Eosinophilic Focus TGLS = 3,4-10+4 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 7-12 ]			
* Skin	Subcut Tiss	Sarcoma	
[ Sarcoma TGLS = 1-11 ]			
* Spleen		Hematopoietic Cell Proliferation	Marked
[ Hematopoietic Cell Proliferation TGLS = 2-4 ]			
* Uterus		Hydrometra	Moderate
[ Hydrometra TGLS = 6-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 247

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901967

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

\* Pituitary Gland

**INSUFFICIENT TISSUE**

\* Gallbladder

**OBSERVATIONS**

* Liver		Inflammation	Chronic, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2,3-10+11 ]			
* Uterus		Hydrometra	Moderate
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 248

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 0 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901968

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Pituitary Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**INSUFFICIENT TISSUE**

\* Parathyroid Gland

**OBSERVATIONS**

* Clitoral Gland [ Inflammation TGLS = 1-7 ]		Inflammation	Chronic Active, Minimal
* Kidney		Nephropathy	Minimal
* Liver		Inflammation	Chronic, Minimal
Mesentery [ Necrosis TGLS = 3-10 ]	Fat	Necrosis	Mild
* Uterus [ Hydrometra TGLS = 2-8 ]		Hydrometra	Mild

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 249

**TRT#:** 2  
**DOSE:** 0 MG/KG

**SEX:** Female  
**DISP:** Terminal Sacrifice

**DAY ON TEST:** 729  
**HISTO:** 9901969

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Clitoral Gland	* Parathyroid Gland
------------------	---------------------

**OBSERVATIONS**

* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Inflammation	Chronic, Minimal
[ Basophilic Focus TGLS = 2-10 ]			
* Pituitary Gland	Pars Distalis	Adenoma	
* Uterus		Hydrometra	Mild
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 250

**TRT#:** 2

**SEX:** Female

**DAY ON TEST:** 636

**DOSE:** 0 MG/KG

**DISP:** Natural Death

**HISTO:** 9901970

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Clitoral Gland	* Esophagus	Harderian Gland	* Intestine Large, Colon
* Intestine Large, Rectum	* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Skin	* Spleen	* Thyroid Gland

**MISSING**

* Lymph Node, Mandibular	* Pituitary Gland	* Salivary Glands	* Thymus
* Urinary Bladder			

**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Trachea		

**OBSERVATIONS**

Blood Vessel	Aorta	Mineralization	Mild
* Brain		Oligodendroglioma Benign	
* Heart		Mineralization	Minimal
* Kidney		Nephropathy	Mild
* Liver		Fatty Change	Marked
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-10 ]			
* Stomach, Forestomach		Ulcer	Mild
* Stomach, Glandular		Mineralization	Mild
* Uterus		Hyperplasia	Cystic, Mild
[ Hyperplasia TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

- Brain Oligodendroglioma Benign

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 251

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901971

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Pancreas	* Parathyroid Gland	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Thymus

**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Mild
* Gallbladder		Degeneration	Hyaline, Moderate
* Liver		Inflammation	Chronic, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 1-10 ]			
* Ovary		Cyst	Mild
* Pituitary Gland	Pars Distalis	Hyperplasia	Moderate
* Uterus		Hyperplasia	Cystic, Mild

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 252

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901972

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Mammary Gland	* Nose
* Ovary	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

**MISSING**

* Lymph Node, Mandibular	* Thymus
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**OBSERVATIONS**

* Kidney	Nephropathy	Minimal
* Liver	Basophilic Focus	
	Clear Cell Focus	
	Hematopoietic Cell Proliferation	Minimal
	Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Minimal
* Pancreas	Lipomatosis	Marked

[ Lipomatosis TGLS = 1-4 ]

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 253

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901973

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Esophagus	* Gallbladder	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Ovary	* Pancreas
* Pituitary Gland	* Salivary Glands	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Parathyroid Gland	* Thymus
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**INSUFFICIENT TISSUE**

\* Clitoral Gland

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
Harderian Gland		Adenoma	
[ Adenoma TGLS = 1-11 ]			
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Inflammation	Chronic, Minimal
Note: TGL 3, "cyst, 1x2mm" noted at trim, was not apparent microscopically.			
* Lung		Alveolar/Bronchiolar Adenoma	
[ Alveolar/Bronchiolar Adenoma TGLS = 2-3 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 4-10 ]			
* Nose	Olfactory Epi	Metaplasia	Minimal
* Uterus		Polyp Stromal	

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 254	<b>TRT#:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9901974

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Mammary Gland
* Nose	* Pancreas	* Parathyroid Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

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**OBSERVATIONS**

* Kidney	Transit Epithe	Carcinoma	
		Lymphoma Malignant	
* Liver		Basophilic Focus	
		Hepatocellular Adenoma	
		Inflammation	Chronic, Minimal
[ Basophilic Focus TGLS = 2-4 ]			
[ Hepatocellular Adenoma TGLS = 1-4 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
* Ovary		Cystadenoma	
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Lymphoma Malignant	

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 255

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 703

**DOSE:** 56 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9901975

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Salivary Glands	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Lymph Node, Mandibular	* Parathyroid Gland
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**OBSERVATIONS**

Harderian Gland		Hyperplasia	Minimal
* Heart		Inflammation	Suppurative, Mild
Note: There were bacterial colonies in the area of inflammation.			
* Kidney		Infarct	Mild
		Nephropathy	Minimal
		Sarcoma	Metastatic (Skin)
* Liver		Hematopoietic Cell Proliferation	Mild
		Inflammation	Chronic, Minimal
* Lung		Sarcoma	Metastatic (Skin)
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 4-11 ]			
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Skin	Subcut Tiss	Sarcoma	
[ Sarcoma TGLS = 3-10 ]			
* Spleen		Hematopoietic Cell Proliferation	Marked
[ Hematopoietic Cell Proliferation TGLS = 2-4 ]			
* Uterus		Hydrometra	Moderate
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH** - Skin Subcut Tiss Sarcoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 256

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901976

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Clitoral Gland	* Parathyroid Gland
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**OBSERVATIONS**

* Intestine Small, Duodenum [ Polyp Adenomatous TGLS = 3-10 ]		Polyp Adenomatous	
* Kidney		Nephropathy	Minimal
* Liver		Inflammation	Chronic, Minimal
Mesentery [ Necrosis TGLS = 4-11 ]	Fat	Necrosis	Moderate
* Ovary [ Cyst TGLS = 1-7 ]		Cyst	Moderate
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Uterus [ Hydrometra TGLS = 2-8 ]		Hydrometra	Minimal

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 257

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901977

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Lymph Node, Mandibular

**OBSERVATIONS**

* Kidney		Nephropathy	Minimal
* Liver		Eosinophilic Focus Inflammation	Chronic, Minimal
[ Eosinophilic Focus TGLS = 2-10 ]			
* Lung		Alveolar/Bronchiolar Adenoma	
[ Alveolar/Bronchiolar Adenoma TGLS = 3-3 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 4-11 ]			
* Uterus		Hydrometra	Minimal
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 258

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901978

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**OBSERVATIONS**

Harderian Gland		Hyperplasia	Moderate
* Liver		Inflammation	Chronic, Mild
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
* Ovary			
Note: TGL 1, "cyst, 3 mm3" noted at necropsy, was not apparent microscopically.			
* Uterus		Hyperplasia	Cystic, Mild
[ Hyperplasia TGLS = 2-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 259

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901979

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Lymph Node, Mandibular

**OBSERVATIONS**

Harderian Gland [ Adenoma TGLS = 1-10 ]		Adenoma	
* Liver		Inflammation	Chronic, Minimal
* Lung		Inflammation	Chronic Active, Minimal
Mesentery [ Necrosis TGLS = 4-11 ]	Fat	Necrosis	Mild
* Ovary [ Cyst TGLS = 3-7 ]		Cyst	Mild
* Uterus [ Hydrometra TGLS = 2-8 ]		Hydrometra	Mild

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 260

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901980

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Spleen	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

**MISSING**

\* Thymus

**OBSERVATIONS**

Harderian Gland [ Adenoma TGLS = 1-10 ]		Adenoma	
* Liver [ Basophilic Focus TGLS = 2-11 ]		Basophilic Focus Inflammation Tension Lipidosis	Chronic, Minimal
Mesentery [ Necrosis TGLS = 3-12 ]	Fat	Necrosis	Mild
* Stomach, Forestomach		Hyperplasia	Squamous, Minimal

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 261

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901981

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Liver	* Lung	* Mammary Gland
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Lymph Node, Mandibular

**OBSERVATIONS**

* Intestine Small, Duodenum [ Polyp Adenomatous TGLS = 4-10 ]	Polyp Adenomatous	
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Minimal
* Ovary [ Cyst TGLS = 3-7 ]	Cyst	Mild
* Spleen [ Hematopoietic Cell Proliferation TGLS = 1-4 ]	Hematopoietic Cell Proliferation	Marked
* Uterus [ Hydrometra TGLS = 2-8 ]	Hydrometra	Mild

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 262

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901982

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Thymus

**OBSERVATIONS**

* Liver	Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Minimal
* Ovary	Cyst	Mild
* Spleen	Hematopoietic Cell Proliferation	Minimal
* Uterus	Hyperplasia	Cystic, Minimal

[ Hyperplasia TGLS = 1-8 ]

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 263

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901983

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	Tissue NOS	* Trachea
* Urinary Bladder			

**MISSING**

\* Thymus

**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Mild
* Gallbladder		Cyst	Minimal
Harderian Gland		Atrophy	Mild
* Kidney		Nephropathy	Minimal
* Liver		Inflammation	Chronic, Minimal
Lymph Node	Bronchial	Hyperplasia	Lymphoid, Marked
	Mediastinal	Hyperplasia	Lymphoid, Marked
	Renal	Hyperplasia	Lymphoid, Marked
[ Hyperplasia TGLS = 5-10 ]			
[ Hyperplasia TGLS = 4-2 ]			
* Lymph Node, Mandibular		Hyperplasia	Lymphoid, Marked
* Lymph Node, Mesenteric		Hyperplasia	Lymphoid, Marked
[ Hyperplasia TGLS = 3-6 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 6-12 ]			
* Spleen		Hyperplasia	Lymphoid, Mild
* Uterus		Hydrometra	Moderate
		Hyperplasia	Cystic, Marked
[ Hydrometra TGLS = 1-8 ]			

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 263

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901983

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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[ Hyperplasia TGLS = 2-11 ]

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PRIMARY CAUSE OF DEATH

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 264

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901984

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Pituitary Gland	* Salivary Glands	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

**MISSING**

\* Parathyroid Gland

**OBSERVATIONS**

* Liver	Eosinophilic Focus	
	Inflammation	Chronic, Minimal
* Ovary	Cyst	Mild
[ Cyst TGLS = 1-7 ]		

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 265

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901985

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

\* Lymph Node, Mandibular

**OBSERVATIONS**

* Kidney		Nephropathy	Minimal
* Liver		Hematopoietic Cell Proliferation	Mild
		Inflammation	Chronic, Moderate
	[ Hematopoietic Cell Proliferation TGLS = 3-4 ]		
* Lung		Infiltration Cellular	Lymphocyte, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
Mesentery	Fat	Necrosis	Mild
	[ Necrosis TGLS = 4-10 ]		
* Ovary		Cyst	Minimal
* Spleen		Congestion	Moderate
		Hematopoietic Cell Proliferation	Minimal
		Hyperplasia	Lymphoid, Mild
	[ Congestion TGLS = 2-4 ]		
* Uterus		Hydrometra	Moderate
	[ Hydrometra TGLS = 1-8 ]		

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 266

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901986

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mandibular	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Trachea	* Urinary Bladder	* Uterus

**INSUFFICIENT TISSUE**

\* Ovary

**OBSERVATIONS**

* Kidney		Nephropathy	Minimal
* Liver		Inflammation	Chronic, Minimal
* Lung	Alveolar Epith	Hyperplasia	Mild
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 1-10 ]			
* Thyroid Gland	Follicular Cel	Hyperplasia	Mild

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 267

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 681

**DOSE:** 56 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9901987

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Clitoral Gland
* Esophagus	* Gallbladder	Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Pituitary Gland

**OBSERVATIONS**

* Bone Marrow		Histiocytic Sarcoma	
* Brain		Histiocytic Sarcoma	
* Heart		Cardiomyopathy	Minimal
* Kidney	Renal Tubule	Histiocytic Sarcoma	
		Accumulation, Hyaline Droplet	Moderate
		Histiocytic Sarcoma	
		Nephropathy	Minimal
* Liver		Histiocytic Sarcoma	
		[ Histiocytic Sarcoma TGLS = 3,4-10+11 ]	
* Lung		Histiocytic Sarcoma	
* Lymph Node, Mesenteric		Histiocytic Sarcoma	
Mesentery	Fat	Necrosis	Mild
		[ Necrosis TGLS = 6-13 ]	
* Spleen		Hematopoietic Cell Proliferation	Moderate
* Stomach, Glandular		Necrosis	Mild
		[ Necrosis TGLS = 5-12 ]	
* Uterus		Histiocytic Sarcoma	
		Hydrometra	Mild
		[ Histiocytic Sarcoma TGLS = 1-8 ]	
		[ Hydrometra TGLS = 2-8 ]	

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 267

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 681

**DOSE:** 56 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9901987

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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PRIMARY CAUSE OF DEATH

- Liver Histiocytic Sarcoma

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\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 268

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901988

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Mammary Gland
* Pancreas	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Thymus	* Trachea	* Urinary Bladder

**MISSING**

* Gallbladder	* Parathyroid Gland	* Thyroid Gland
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**OBSERVATIONS**

* Liver		Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-10 ]			
* Nose	Olfactory Epi	Atrophy	Minimal
* Ovary		Cyst	Minimal
* Spleen		Hyperplasia	Lymphoid, Moderate
		Infiltration Cellular	Histiocyte, Minimal
[ Hyperplasia TGLS = 1-4 ]			
* Stomach, Glandular		Hyperplasia	Mild
[ Hyperplasia TGLS = 3-11 ]			
* Uterus		Hydrometra	Mild

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 269

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901989

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Parathyroid Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

**MISSING**

\* Gallbladder

**OBSERVATIONS**

* Liver		Hepatocellular Carcinoma Inflammation	Chronic, Minimal
[ Hepatocellular Carcinoma TGLS = 2-10 ]			
* Pancreas		Basophilic Focus	
* Pituitary Gland	Pars Distalis	Adenoma	
[ Adenoma TGLS = 1-8 ]			

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 270

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 681

**DOSE:** 56 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9901990

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

**MISSING**

\* Thymus

**OBSERVATIONS**

* Clitoral Gland [ Cyst TGLS = 1-7 ]		Cyst	Mild
* Intestine Large, Rectum		Myxomatous Change	Minimal
* Kidney		Mineralization	Mild
* Liver		Hematopoietic Cell Proliferation	Mild
		Inflammation	Chronic, Minimal
* Lung		Sarcoma	Metastatic (Skin)
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
Mesentery	Fat	Necrosis	Minimal
		Sarcoma	Metastatic (Skin)
[ Necrosis TGLS = 3-11 ]			
* Ovary		Cyst	Mild
Skel Muscle			
Note: TGL 2, "mass, 28x28x15mm, mottled" noted at necropsy, was diagnosed under skin (subcutaneous).			
* Skin	Subcut Tiss	Sarcoma	
[ Sarcoma TGLS = 2-10 ]			
* Spleen		Hematopoietic Cell Proliferation	Marked

**PRIMARY CAUSE OF DEATH**

- Skin Subcut Tiss Sarcoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 271

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901991

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Pituitary Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

**MISSING**

\* Parathyroid Gland

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
* Liver		Eosinophilic Focus Inflammation	Chronic, Minimal
[ Eosinophilic Focus TGLS = 1-10 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-11 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

<b>ANIMAL ID:</b> 272	<b>TRT#:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 722
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 9901992

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Bone	* Esophagus	Harderian Gland	* Mammary Gland
* Nose	* Ovary	* Skin	

**MISSING**

* Brain	* Clitoral Gland	* Lymph Node, Mandibular	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Thymus	* Thyroid Gland

**AUTO PRECLUDES DIAG.**

* Adrenal Cortex	* Adrenal Medulla	* Bone Marrow	* Gallbladder
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Pancreas	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Trachea	* Urinary Bladder	* Uterus	

**OBSERVATIONS**

* Heart	Pericardium	Alveolar/Bronchiolar Carcinoma	Metastatic (Lung)
	Pericardium	Sarcoma	
	[ Alveolar/Bronchiolar Carcinoma TGLS = 5-13 ]		
	[ Sarcoma TGLS = 5-13 ]		
* Kidney		Histiocytic Sarcoma	
* Liver		Hepatocellular Carcinoma	
	[ Hepatocellular Carcinoma TGLS = 1-10 ]		
* Lung		Alveolar/Bronchiolar Carcinoma	
		Sarcoma	
	[ Alveolar/Bronchiolar Carcinoma TGLS = 7-3 ]		
	[ Sarcoma TGLS = 6,7-3 ]		
Lymph Node	Bronchial	Histiocytic Sarcoma	
	Mediastinal	Histiocytic Sarcoma	
Mesentery	Fat	Necrosis	Mild
	[ Necrosis TGLS = 2-11 ]		
Pleura		Sarcoma	Metastatic (Lung)
	[ Sarcoma TGLS = 4-12 ]		

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 272

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 722

**DOSE:** 56 MG/KG

**DISP:** Natural Death

**HISTO:** 9901992

---

**ORGAN AND ACCOUNTABLE SITE STATUS**

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PRIMARY CAUSE OF DEATH

- Liver Hepatocellular Carcinoma

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 273

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901993

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Clitoral Gland
* Esophagus	* Gallbladder	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Mammary Gland	* Ovary	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Pituitary Gland

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
* Brain		Sarcoma	
[ Sarcoma TGLS = 2-1 ]			
* Kidney		Nephropathy	Minimal
* Liver		Inflammation	Chronic, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
* Nose	Olfactory Epi	Metaplasia	Moderate
* Uterus		Hydrometra	Minimal
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 274

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901994

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Lymph Node, Mandibular

**OBSERVATIONS**

\* Int Sm Jejunum

Note: TGL 2, "Peyer's patch, enlarged, 3x, two" noted at necropsy, was within normal limits microscopically.

\* Liver

Inflammation

Chronic, Minimal

\* Lym Node Mesen

Note: TGL 3, "enlarged, 2x" noted at necropsy, was within normal limits microscopically.

Mesentery

Fat

Necrosis

Minimal

[ Necrosis TGLS = 4-11 ]

\* Uterus

Hyperplasia

Cystic, Mild

[ Hyperplasia TGLS = 1-8 ]

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 275      **TRT#:** 4      **SEX:** Female      **DAY ON TEST:** 730  
**DOSE:** 56 MG/KG      **DISP:** Terminal Sacrifice      **HISTO:** 9901995

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**OBSERVATIONS**

* Intestine Small, Jejunum [ Lymphoma Malignant TGLS = 2-10 ]		Lymphoma Malignant	
* Liver [ Basophilic Focus TGLS = 1-4 ]		Basophilic Focus Inflammation	Chronic, Minimal
Lymph Node	Pancreatic	Lymphoma Malignant	
* Lymph Node, Mesenteric [ Lymphoma Malignant TGLS = 3-6 ]		Lymphoma Malignant	
Mesentery [ Necrosis TGLS = 4-11 ]	Fat	Necrosis	Moderate
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Uterus		Hydrometra	Mild

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 276

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901996

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Mammary Gland
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**OBSERVATIONS**

* Bone		Fibrous Osteodystrophy	Mild
* Heart		Inflammation	Chronic Active, Minimal
* Kidney		Lymphoma Malignant	
* Liver	Bile Duct	Hyperplasia	Minimal
		Lymphoma Malignant	
* Lung		Lymphoma Malignant	
Lymph Node	Bronchial	Lymphoma Malignant	
	Pancreatic	Lymphoma Malignant	
		[ Lymphoma Malignant TGLS = 2-4 ]	
* Lymph Node, Mandibular		Lymphoma Malignant	
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
		Lymphoma Malignant	
* Ovary		Lymphoma Malignant	
* Spleen		Lymphoma Malignant	
		[ Lymphoma Malignant TGLS = 1-4 ]	
* Uterus		Hyperplasia	Cystic, Mild
		[ Hyperplasia TGLS = 3-8 ]	

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 277

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901997

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Pituitary Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Urinary Bladder

**MISSING**

\* Parathyroid Gland

**OBSERVATIONS**

* Kidney		Cyst	Mild
* Liver		Hepatocellular Adenoma	Multiple
		Inflammation	Chronic, Minimal
[ Hepatocellular Adenoma TGLS = 1,2-4 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 4-10 ]			
* Spleen		Hematopoietic Cell Proliferation	Mild
* Trachea		Metaplasia	Squamous, Minimal
* Uterus		Angiectasis	Mild
		Hyperplasia	Cystic, Moderate
[ Hyperplasia TGLS = 3-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 278

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901998

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Mammary Gland
* Nose	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

**OBSERVATIONS**

* Liver		Eosinophilic Focus Inflammation	Chronic, Minimal
[ Eosinophilic Focus TGLS = 2-10 ]			
* Lymph Node, Mandibular		Lymphoma Malignant	
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-11 ]			
* Ovary		Cyst	Mild
* Spleen		Lymphoma Malignant	
* Thymus		Lymphoma Malignant	
* Uterus		Hydrometra	Moderate
[ Hydrometra TGLS = 1-8 ]			

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 279

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9901999

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Mammary Gland
* Nose	* Pancreas	* Parathyroid Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**OBSERVATIONS**

* Gallbladder		Cyst	Minimal
* Liver		Clear Cell Focus	
		Inflammation	Chronic, Minimal
[ Clear Cell Focus TGLS = 3-4 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 4-10 ]			
* Ovary		Luteoma	
[ Luteoma TGLS = 2-7 ]			
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Infiltration Cellular	Histiocyte, Minimal
* Uterus		Hydrometra	Mild
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 280

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 555

**DOSE:** 56 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9902000

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Mild
* Kidney		Nephropathy	Mild
* Liver		Hematopoietic Cell Proliferation	Minimal
		Tension Lipidosis	
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
* Skin	Subcut Tiss	Sarcoma	
	[ Sarcoma TGLS = 1-10 ]		
* Spleen		Hematopoietic Cell Proliferation	Moderate
	[ Hematopoietic Cell Proliferation TGLS = 2-4 ]		

**PRIMARY CAUSE OF DEATH**

- Skin Subcut Tiss Sarcoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 281

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 485

**DOSE:** 56 MG/KG

**DISP:** Natural Death

**HISTO:** 9902001

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Esophagus	Harderian Gland	* Heart
* Lymph Node, Mandibular	* Mammary Gland	* Nose	* Ovary
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder
* Uterus			

**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Liver	* Lymph Node, Mesenteric	* Pancreas
* Stomach, Forestomach	* Stomach, Glandular		

**OBSERVATIONS**

* Clitoral Gland		Inflammation	Chronic Active, Moderate
* Liver			
Note: TGL 3, "discoloration, pale" noted at necropsy, was obscured by post mortem autolysis.			
* Lung		Lymphoma Malignant	
Lymph Node	Bronchial	Lymphoma Malignant	
* Spleen		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 2-4 ]			

**PRIMARY CAUSE OF DEATH**

- Spleen Lymphoma Malignant

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 282

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Natural Death

**HISTO:** 9902002

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	Harderian Gland
* Lymph Node, Mandibular	* Mammary Gland	* Nose	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Stomach, Forestomach	* Thyroid Gland
* Trachea			

**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Ovary	* Pancreas	* Stomach, Glandular
* Thymus	* Urinary Bladder		

**OBSERVATIONS**

\* Clitoral GI

Note: TGL 1, "discolored, dark" noted at necropsy, was not apparent microscopically.

* Heart		Mineralization	Minimal
* Kidney		Histiocytic Sarcoma	
* Liver		Histiocytic Sarcoma	
[ Histiocytic Sarcoma TGLS = 5-4+10 ]			
* Lung		Histiocytic Sarcoma	
Lymph Node	Mediastinal	Histiocytic Sarcoma	
Mesentery	Fat	Necrosis	Minimal
* Skin	Subcut Tiss	Necrosis	Fatty, Mild
[ Necrosis TGLS = 2-11 ]			
* Spleen		Histiocytic Sarcoma	
[ Histiocytic Sarcoma TGLS = 4-4 ]			
* Uterus		Hydrometra	Moderate
[ Hydrometra TGLS = 3-8 ]			

**PRIMARY CAUSE OF DEATH** - Liver Histiocytic Sarcoma

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 283

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 18

**DOSE:** 56 MG/KG

**DISP:** Dosing Accident

**HISTO:** 9902003

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Gallbladder	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney
* Liver	* Lymph Node, Mandibular	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Pituitary Gland	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Trachea	* Urinary Bladder	* Uterus	

**MISSING**

* Clitoral Gland	* Parathyroid Gland
------------------	---------------------

**OBSERVATIONS**

* Esophagus [ Necrosis TGLS = 1-2 ]		Necrosis	Moderate
* Lung	Mediastinum	Inflammation	Acute, Marked
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
* Thymus		Necrosis	Moderate
* Thyroid Gland		Necrosis	Moderate

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 284

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902004

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Islets, Pancreatic	* Kidney
* Liver	* Lung	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Lymph Node, Mandibular

**OBSERVATIONS**

Harderian Gland		Carcinoma	
		Hyperplasia	Moderate
		Hyperplasia	Lymphoid, Mild
* Intestine Small, Jejunum [ Hyperplasia TGLS = 2-10 ]			
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Uterus [ Hydrometra TGLS = 1-8 ]		Hydrometra	Marked

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 285

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902005

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

**MISSING**

\* Lymph Node, Mandibular

**OBSERVATIONS**

* Liver		Hepatocellular Adenoma Inflammation	Multiple Chronic, Minimal
Note: TGL 3, "nodule, 3x3x2mm, tan" noted at necropsy, was not apparent microscopically. [ Hepatocellular Adenoma TGLS = 1,2-4 ]			
* Lymph Node, Mesenteric Mesentery	Fat	Infiltration Cellular Necrosis	Histiocyte, Mild Mild
[ Necrosis TGLS = 4-11 ]			
* Spleen		Hematopoietic Cell Proliferation	Minimal

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 286

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902006

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

**OBSERVATIONS**

* Kidney		Nephropathy	Minimal
* Liver		Hepatocellular Adenoma	
		Inflammation	Chronic, Minimal
[ Hepatocellular Adenoma TGLS = 1-4 ]			
Mesentery	Fat	Necrosis	Moderate
[ Necrosis TGLS = 2-10 ]			
* Spleen		Hematopoietic Cell Proliferation	Minimal

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 287

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902007

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

\* Lymph Node, Mandibular

**OBSERVATIONS**

* Liver	Inflammation	Chronic, Minimal
* Spleen	Hematopoietic Cell Proliferation	Minimal
* Uterus	Hydrometra	Minimal

[ Hydrometra TGLS = 1-8 ]

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 288

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902008

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**OBSERVATIONS**

* Bone Marrow		Hemangiosarcoma	
* Clitoral GI			
Note: TGL 1, "discoloration, green" noted at necropsy, was not apparent microscopically.			
* Intestine Large, Rectum		Myxomatous Change	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Hemangiosarcoma	
		Inflammation	Chronic, Mild
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 4-10 ]			
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Hemangiosarcoma	
[ Hemangiosarcoma TGLS = 2-4 ]			
* Uterus		Hyperplasia	Cystic, Mild
[ Hyperplasia TGLS = 3-8 ]			

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 289

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 541

**DOSE:** 56 MG/KG

**DISP:** Natural Death

**HISTO:** 9902009

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Clitoral Gland
* Esophagus	Harderian Gland	* Heart	* Intestine Large, Rectum
* Islets, Pancreatic	* Mammary Gland	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Lymph Node, Mesenteric

**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum		

**OBSERVATIONS**

* Adrenal Cortex		Histiocytic Sarcoma	
* Brain		Histiocytic Sarcoma	
* Kidney		Histiocytic Sarcoma	
* Liver		Histiocytic Sarcoma	
[ Histiocytic Sarcoma TGLS = 4-4 ]			
* Lung		Alveolar/Bronchiolar Adenoma	Multiple
		Histiocytic Sarcoma	
Lymph Node	Bronchial	Histiocytic Sarcoma	
	Lumbar	Histiocytic Sarcoma	
[ Histiocytic Sarcoma TGLS = 5-10 ]			
* Lymph Node, Mandibular		Histiocytic Sarcoma	
Mesentery		Histiocytic Sarcoma	
* Nose		Histiocytic Sarcoma	
* Ovary		Histiocytic Sarcoma	
[ Histiocytic Sarcoma TGLS = 3-7 ]			
* Salivary Glands		Basophilic Focus	
* Skin	Subcut Tiss	Histiocytic Sarcoma	
* Spleen		Hematopoietic Cell Proliferation	Mild
[ Hematopoietic Cell Proliferation TGLS = 1-4 ]			

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 289

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 541

**DOSE:** 56 MG/KG

**DISP:** Natural Death

**HISTO:** 9902009

---

**ORGAN AND ACCOUNTABLE SITE STATUS**

---

\* Uterus

Histiocytic Sarcoma

[ Histiocytic Sarcoma TGLS = 2-8 ]

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PRIMARY CAUSE OF DEATH

- Liver Histiocytic Sarcoma

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\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 290	<b>TRT#:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 281
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 9902010

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**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Bone	* Clitoral Gland	* Esophagus	* Heart
* Mammary Gland	* Nose	* Ovary	* Pituitary Gland
* Salivary Glands	* Skin	Urethra	* Uterus

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**MISSING**

\* Parathyroid Gland

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**AUTO PRECLUDES DIAG.**

* Bone Marrow	* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Pancreas
* Stomach, Glandular	* Thyroid Gland	* Trachea	Ureter
* Urinary Bladder			

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**OBSERVATIONS**

* Adrenal Cortex		Lymphoma Malignant	
* Adrenal Medulla		Lymphoma Malignant	
* Brain		Lymphoma Malignant	
Harderian Gland		Lymphoma Malignant	
* Kidney		Lymphoma Malignant	
* Liver		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 2-4+10 ]			
* Lung		Lymphoma Malignant	
Lymph Node	Bronchial	Lymphoma Malignant	
Note: TGL 3, "bilateral renal, enlarged, 2x" noted at necropsy, was obscured by post mortem autolysis.			
* Spleen		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 1-4 ]			
* Stomach, Forestomach		Inflammation	Acute, Minimal
* Thymus		Lymphoma Malignant	

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**PRIMARY CAUSE OF DEATH** - Liver Lymphoma Malignant

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

<b>ANIMAL ID:</b> 291	<b>TRT#:</b> 4	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 56 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9902011

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Esophagus	* Gallbladder	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Pituitary Gland
* Salivary Glands	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

**MISSING**

* Clitoral Gland	Harderian Gland	* Parathyroid Gland	* Thymus
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**OBSERVATIONS**

* Adrenal Cortex		Sarcoma	Metastatic (Skin)
* Kidney		Nephropathy	Minimal
* Liver		Hematopoietic Cell Proliferation	Minimal
		Inflammation	Chronic, Minimal
* Lung	Alveolar Epith	Hyperplasia	Mild
		Sarcoma	Metastatic (Skin)
		Thrombosis	Mild
[ Hyperplasia TGLS = 2-3 ]			
Lymph Node	Renal	Sarcoma	Metastatic (Skin)
[ Sarcoma TGLS = 3-11 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
* Mammary GI			
Note: TGL 1, "mass, 35x22x20mm, mottled" noted at necropsy, was actually subcutaneous mass (skin).			
Mesentery	Fat	Necrosis	Mild
		Sarcoma	Metastatic (Skin)
[ Necrosis TGLS = 4-12 ]			
[ Sarcoma TGLS = 4-12 ]			
* Skin	Subcut Tiss	Sarcoma	
[ Sarcoma TGLS = 1-10 ]			
* Spleen		Hematopoietic Cell Proliferation	Mild

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 291

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902011

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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PRIMARY CAUSE OF DEATH

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 292

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902012

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

Harderian Gland

**OBSERVATIONS**

* Clitoral GI			
Note: TGL 2, "discolored, dark" noted at necropsy, was not apparent microscopically.			
* Liver		Eosinophilic Focus Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-10 ]			
* Uterus		Hydrometra	Mild
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 293

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902013

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Bone	* Bone Marrow	* Brain
* Esophagus	* Gallbladder	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Clitoral Gland	Harderian Gland
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**OBSERVATIONS**

* Adrenal Medulla		Pheochromocytoma Benign	
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Hepatocellular Adenoma	
		Inflammation	Chronic, Minimal
[ Basophilic Focus TGLS = 4-10 ]			
[ Hepatocellular Adenoma TGLS = 1-4 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-11 ]			
* Pancreas		Basophilic Focus	
* Uterus		Hydrometra	Mild
[ Hydrometra TGLS = 3-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 294

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902014

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

Harderian Gland

**OBSERVATIONS**

* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-11 ]			
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Infiltration Cellular	Histiocyte, Minimal
* Uterus		Hydrometra	Marked
[ Hydrometra TGLS = 1-10 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 295

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902015

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

\* Thymus

**OBSERVATIONS**

Harderian Gland [ Carcinoma TGLS = 1-10 ]		Carcinoma	
* Kidney		Nephropathy	Minimal
* Liver		Inflammation	Chronic, Minimal
* Lymph Node, Mandibular [ Infiltration Cellular TGLS = 4-7 ]		Infiltration Cellular	Plasma Cell, Moderate
* Lymph Node, Mesenteric Mesentery [ Necrosis TGLS = 5-11 ]	Fat	Infiltration Cellular Necrosis	Histiocyte, Minimal Moderate
* Ovary [ Cyst TGLS = 2-7 ]		Cyst	Mild
* Uterus [ Hydrometra TGLS = 3-8 ]		Hydrometra Hyperplasia	Moderate Cystic, Mild

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 296

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 711

**DOSE:** 56 MG/KG

**DISP:** Natural Death

**HISTO:** 9902016

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Heart
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Mammary Gland
* Nose	* Pancreas	* Pituitary Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

**MISSING**

Harderian Gland

**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Parathyroid Gland
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**OBSERVATIONS**

* Kidney		Mineralization	Minimal
		Sarcoma	Metastatic (Mesentery)
* Liver		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 1-11 ]			
Lymph Node	Mediastinal	Lymphoma Malignant	
	Pancreatic	Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 6-4 ]			
[ Lymphoma Malignant TGLS = 5-12 ]			
* Lymph Node, Mandibular		Lymphoma Malignant	
* Lymph Node, Mesenteric		Sarcoma	Metastatic (Mesentery)
[ Sarcoma TGLS = 3-10 ]			
Mesentery	Fat	Necrosis	Moderate
		Sarcoma	
[ Necrosis TGLS = 4,7-13+14 ]			
[ Sarcoma TGLS = 3,4-10+13 ]			
* Ovary		Sarcoma	Metastatic (Mesentery)
* Spleen		Hematopoietic Cell Proliferation	Mild
		Lymphoma Malignant	

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 296

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 711

**DOSE:** 56 MG/KG

**DISP:** Natural Death

**HISTO:** 9902016

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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[ Lymphoma Malignant TGLS = 2-4 ]

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PRIMARY CAUSE OF DEATH

- Mesentery Sarcoma

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 297

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 642

**DOSE:** 56 MG/KG

**DISP:** Natural Death

**HISTO:** 9902017

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Heart
* Kidney	* Lung	* Lymph Node, Mandibular	* Mammary Gland
* Nose	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Thymus	* Thyroid Gland	* Trachea
* Uterus			

**MISSING**

Harderian Gland

**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Ovary	* Pancreas	* Spleen
* Stomach, Glandular	* Urinary Bladder		

**OBSERVATIONS**

* Liver	Fatty Change	Minimal
[ Fatty Change TGLS = 1-4 ]		
* Stomach, Forestomach	Hyperplasia	Squamous, Mild

**PRIMARY CAUSE OF DEATH**

- UNCERTAIN

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 298

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902018

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Islets, Pancreatic	* Kidney
* Lung	* Lymph Node, Mandibular	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

**MISSING**

Harderian Gland

**OBSERVATIONS**

* Intestine Small, Jejunum [ Lymphoma Malignant TGLS = 3-11 ]		Lymphoma Malignant	
* Liver		Hematopoietic Cell Proliferation Inflammation	Minimal Chronic, Minimal
* Lymph Node, Mesenteric [ Lymphoma Malignant TGLS = 2-10 ]		Lymphoma Malignant	
Mesentery [ Necrosis TGLS = 4-12 ]	Fat	Necrosis	Mild
* Ovary		Thrombosis	Moderate
* Pituitary Gland [ Adenoma TGLS = 1-8 ]	Pars Distalis	Adenoma	
* Spleen		Hematopoietic Cell Proliferation	Minimal

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 299      **TRT#:** 4      **SEX:** Female      **DAY ON TEST:** 703  
**DOSE:** 56 MG/KG      **DISP:** Moribund Sacrifice      **HISTO:** 9902019

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Salivary Glands	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

\* Gallbladder      Harderian Gland

**OBSERVATIONS**

* Heart		Inflammation	Chronic Active, Mild
* Liver		Angiectasis	Moderate
		Clear Cell Focus	
		Cyst	Mild
		Inflammation	Chronic, Mild
[ Clear Cell Focus TGLS = 3-10 ]			
[ Cyst TGLS = 2-4, 4-11 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 5,7-12+14 ]			
* Ovary		Cyst	Mild
* Pituitary Gland	Pars Distalis	Adenoma	
* Skin		Edema	Moderate
		Inflammation	Chronic Active, Moderate
[ Edema TGLS = 6-13 ]			
[ Inflammation TGLS = 6-13 ]			
* Uterus		Hydrometra	Mild
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**      - Skin Inflammation

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 300

**TRT#:** 4

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 56 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902020

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

**MISSING**

Harderian Gland \* Thymus

**INSUFFICIENT TISSUE**

\* Ovary

**OBSERVATIONS**

* Intestine Large, Rectum		Myxomatous Change	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Fatty Change	Minimal
		Hepatocellular Carcinoma	
		Inflammation	Chronic, Minimal
[ Hepatocellular Carcinoma TGLS = 1-10 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-11 ]			
* Spleen		Hematopoietic Cell Proliferation	Minimal

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 301

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902021

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Mammary Gland	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

**MISSING**

\* Lymph Node, Mandibular

**OBSERVATIONS**

Harderian Gland [ Adenoma TGLS = 1-11 ]		Adenoma	
* Liver [ Eosinophilic Focus TGLS = 4-4 ]		Eosinophilic Focus Hematopoietic Cell Proliferation Inflammation	Minimal Chronic, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Moderate
* Nose	Olfactory Epi	Atrophy	Mild
* Ovary [ Cyst TGLS = 3-7 ] [ Cystadenoma TGLS = 2-10 ]		Cyst Cystadenoma	Marked
* Spleen		Hematopoietic Cell Proliferation	Minimal

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 302      **TRT#:** 6      **SEX:** Female      **DAY ON TEST:** 729  
**DOSE:** 168 MG/KG      **DISP:** Terminal Sacrifice      **HISTO:** 9902022

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Clitoral Gland	* Parathyroid Gland
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**OBSERVATIONS**

Eye [ Degeneration TGLS = 3-10 ]		Degeneration	Marked
Harderian Gland [ Adenoma TGLS = 4-10 ]		Adenoma	
* Kidney		Infiltration Cellular	Lymphocyte, Mild
* Liver		Angiectasis	Minimal
		Hematopoietic Cell Proliferation	Minimal
		Inflammation	Chronic, Minimal
Lymph Node	Mediastinal	Hyperplasia	Lymphoid, Moderate
* Lymph Node, Mandibular [ Hyperplasia TGLS = 5-7 ]		Hyperplasia	Lymphoid, Marked
* Lymph Node, Mesenteric		Hyperplasia	Lymphoid, Marked
		Infiltration Cellular	Histiocyte, Mild
* Pituitary Gland	Pars Distalis	Adenoma	
* Salivary Glands		Infiltration Cellular	Lymphocyte, Mild
* Spleen [ Hematopoietic Cell Proliferation TGLS = 2-4 ]		Hematopoietic Cell Proliferation	Minimal
* Stom Forestom			
Note: TGL 6, "mass, 6mm dia, pale" noted at trim, was not apparent microscopically.			
* Uterus		Hydrometra	Moderate

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 302

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902022

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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[ Hydrometra TGLS = 1-8 ]

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE



Experiment Number: 88122-07  
Test Type: CHRONIC  
Route: GAVAGE  
Species/Strain: Mouse/B6C3F1

P14: INDIVIDUAL ANIMAL PATHOLOGY DATA  
Test Compound: Elmiron (sodium pentosanpolysulfate)  
CAS Number: 37319-17-8

Date Report Requested: 10/16/2014  
Time Report Requested: 12:23:17  
First Dose M/F: NA / NA  
Lab: BAT

ANIMAL ID: 303

TRT#: 6  
DOSE: 168 MG/KG

SEX: Female  
DISP: Moribund Sacrifice

DAY ON TEST: 313  
HISTO: 9902023

ORGAN AND ACCOUNTABLE SITE STATUS

NORMAL

- \* Adrenal Cortex
- \* Brain
- \* Heart
- \* Intestine Small, Duodenum
- \* Kidney
- \* Nose
- \* Pituitary Gland
- \* Stomach, Forestomach
- \* Trachea

- \* Adrenal Medulla
- \* Esophagus
- \* Intestine Large, Cecum
- \* Intestine Small, Ileum
- \* Lung
- \* Ovary
- \* Salivary Glands
- \* Stomach, Glandular
- \* Urinary Bladder

- \* Bone
- \* Gallbladder
- \* Intestine Large, Colon
- \* Intestine Small, Jejunum
- \* Lymph Node, Mesenteric
- \* Pancreas
- \* Skin
- \* Thymus
- \* Uterus

- \* Bone Marrow
- \* Harderian Gland
- \* Intestine Large, Rectum
- \* Islets, Pancreatic
- \* Mammary Gland
- \* Parathyroid Gland
- \* Spleen
- \* Thyroid Gland

MISSING

- \* Lymph Node, Mandibular

INSUFFICIENT TISSUE

- \* Clitoral Gland

OBSERVATIONS

\* Liver Inflammation Chronic, Mild

PRIMARY CAUSE OF DEATH - UNCERTAIN

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 304

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902024

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder
* Uterus			

**MISSING**

\* Lymph Node, Mandibular

**OBSERVATIONS**

* Kidney		Nephropathy	Minimal
* Liver		Inflammation	Chronic, Minimal
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Ovary		Cyst	Moderate

[ Cyst TGLS = 1-7 ]

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 305

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902025

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**OBSERVATIONS**

* Intestine Large, Rectum		Myxomatous Change	Minimal
* Liver		Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Uterus		Hydrometra	Moderate
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 306

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902026

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney
* Lung	* Lymph Node, Mandibular	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Minimal
* Intestine Large, Rectum		Myxomatous Change	Minimal
* Liver		Inflammation	Chronic, Minimal
Note: TGL 3, "focus, 2mm dia, pale" noted at trim, was not apparent microscopically.			
* Lymph Node, Mesenteric		Hemorrhage	Minimal
		Infiltration Cellular	Histiocyte, Minimal
[ Hemorrhage TGLS = 2-6 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 4-10 ]			
* Pituitary Gland	Pars Distalis	Adenoma	
[ Adenoma TGLS = 1-8 ]			
* Spleen		Infiltration Cellular	Histiocyte, Minimal

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

<b>ANIMAL ID:</b> 307	<b>TRT#:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 638
	<b>DOSE:</b> 168 MG/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 9902027

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Esophagus	Harderian Gland	* Heart
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Nose	* Ovary	* Pancreas	* Salivary Glands
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Clitoral Gland	* Mammary Gland	* Thymus
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**AUTO PRECLUDES DIAG.**

* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mesenteric	

**INSUFFICIENT TISSUE**

\* Parathyroid Gland

**OBSERVATIONS**

* Gallbladder		Sarcoma	Metastatic (Uterus)
* Liver	Centrilobular	Degeneration	Mild
		Inflammation	Chronic, Mild
		Sarcoma	Metastatic (Uterus)
Mesentery		Sarcoma	Metastatic (Uterus)
[ Sarcoma TGLS = 3-12 ]			
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Skin		Sarcoma	Metastatic (Uterus)
[ Sarcoma TGLS = 2-11 ]			
* Spleen		Hematopoietic Cell Proliferation	Mild
* Uterus		Sarcoma	
[ Sarcoma TGLS = 1-10 ]			

**PRIMARY CAUSE OF DEATH**

- Uterus Sarcoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 308

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902028

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**OBSERVATIONS**

* Intestine Large, Rectum		Myxomatous Change	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Inflammation	Chronic, Minimal
[ Basophilic Focus TGLS = 1-11 ]			
[ Eosinophilic Focus TGLS = 2-10 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Moderate
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-12 ]			
* Uterus		Polyp Stromal	

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 309

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902029

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**OBSERVATIONS**

* Intestine Large, Rectum		Myxomatous Change	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Inflammation	Chronic, Minimal
		Tension Lipidosis	
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Infiltration Cellular	Histiocyte, Minimal
* Uterus		Hydrometra	Marked

[ Hydrometra TGLS = 1-8 ]

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 310      **TRT#:** 6      **SEX:** Female      **DAY ON TEST:** 730  
**DOSE:** 168 MG/KG      **DISP:** Terminal Sacrifice      **HISTO:** 9902030

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

**MISSING**

\* Gallbladder

**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Minimal
Harderian Gland		Hyperplasia	Moderate
* Intestine Large, Rectum		Myxomatous Change	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Hemangiosarcoma	
		Inflammation	Chronic, Minimal
[ Basophilic Focus TGLS = 3-4 ]			
[ Hemangiosarcoma TGLS = 4-10 ]			
* Lymph Node, Mandibular		Hyperplasia	Lymphoid, Marked
[ Hyperplasia TGLS = 1-7 ]			
* Lymph Node, Mesenteric		Hyperplasia	Lymphoid, Marked
[ Hyperplasia TGLS = 5-6 ]			
Mesentery	Fat	Necrosis	Moderate
[ Necrosis TGLS = 2-11 ]			
* Spleen		Infiltration Cellular	Histiocyte, Minimal

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 311

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902031

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney
* Lung	* Lymph Node, Mandibular	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
* Intestine Large, Cecum	Inflammation	Granulomatous, Mild
* Liver	Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Minimal
* Uterus	Hydrometra	Minimal

[ Hydrometra TGLS = 1-8 ]

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 312

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902032

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone Marrow	* Brain	* Clitoral Gland
* Esophagus	* Gallbladder	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

\* Parathyroid Gland

**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Minimal
* Bone	Fibrous Osteodystrophy	Mild
* Clitoral GI		
Note: TGL 2, "discolored, dark" noted at necropsy, was not apparent microscopically.		
* Kidney	Nephropathy	Minimal
* Liver	Eosinophilic Focus	
	Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Mild
* Spleen	Infiltration Cellular	Histiocyte, Minimal
* Uterus	Hyperplasia	Cystic, Moderate

[ Hyperplasia TGLS = 1-8 ]

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 313

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 481

**DOSE:** 168 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9902033

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

**MISSING**

\* Lymph Node, Mesenteric

**INSUFFICIENT TISSUE**

\* Clitoral Gland

**OBSERVATIONS**

* Kidney	Nephropathy	Mild
* Liver	Hematopoietic Cell Proliferation	Minimal
* Lung	Alveolar/Bronchiolar Carcinoma	
[ Alveolar/Bronchiolar Carcinoma TGLS = 1-10 ]		
* Spleen	Infiltration Cellular	Histiocyte, Minimal

**PRIMARY CAUSE OF DEATH**

- Lung Alveolar/Bronchiolar Carcinoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 314

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902034

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney
* Lung	* Lymph Node, Mandibular	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Pituitary Gland	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Gallbladder	* Parathyroid Gland
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**OBSERVATIONS**

* Bone		Fibrous Osteodystrophy	Mild
* Liver		Basophilic Focus	
		Inflammation	Chronic, Minimal
[ Basophilic Focus TGLS = 2-4 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-10 ]			
* Uterus		Hydrometra	Marked
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 315

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902035

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Thymus

**INSUFFICIENT TISSUE**

\* Parathyroid Gland

**OBSERVATIONS**

* Intestine Large, Rectum		Myxomatous Change	Minimal
* Liver		Fatty Change	Minimal
		Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-10 ]			
* Pituitary Gland	Pars Distalis	Adenoma	
* Uterus		Hydrometra	Mild
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 316

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902036

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

**OBSERVATIONS**

* Bone Marrow	Histiocytic Sarcoma	
* Intestine Large, Rectum	Myxomatous Change	Minimal
* Kidney	Histiocytic Sarcoma	
	Nephropathy	Minimal
* Liver	Eosinophilic Focus	
	Histiocytic Sarcoma	
[ Eosinophilic Focus TGLS = 2-4 ]		
[ Histiocytic Sarcoma TGLS = 1-4 ]		
* Lung	Histiocytic Sarcoma	
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Minimal
* Spleen	Hematopoietic Cell Proliferation	Mild
	Histiocytic Sarcoma	
[ Histiocytic Sarcoma TGLS = 3-4 ]		

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 317

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 638

**DOSE:** 168 MG/KG

**DISP:** Natural Death

**HISTO:** 9902037

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

\* Adrenal Cortex  
\* Clitoral Gland  
\* Kidney  
\* Ovary  
\* Stomach, Forestomach  
\* Urinary Bladder

\* Bone  
\* Esophagus  
\* Lung  
\* Parathyroid Gland  
\* Thymus

\* Bone Marrow  
\* Harderian Gland  
\* Mammary Gland  
\* Salivary Glands  
\* Thyroid Gland

\* Brain  
\* Heart  
\* Nose  
\* Skin  
\* Trachea

**MISSING**

\* Adrenal Medulla

\* Lymph Node, Mandibular

**AUTO PRECLUDES DIAG.**

\* Gallbladder  
\* Intestine Small, Duodenum  
\* Lymph Node, Mesenteric

\* Intestine Large, Cecum  
\* Intestine Small, Ileum  
\* Pancreas

\* Intestine Large, Colon  
\* Intestine Small, Jejunum  
\* Spleen

\* Intestine Large, Rectum  
\* Islets, Pancreatic  
\* Stomach, Glandular

**INSUFFICIENT TISSUE**

\* Pituitary Gland

**OBSERVATIONS**

\* Liver  
Mesentery  
[ Necrosis TGLS = 2-10 ]  
\* Uterus  
[ Hydrometra TGLS = 1-8 ]

Fat

Inflammation  
Necrosis

Hydrometra

Chronic, Minimal  
Mild

Moderate

**PRIMARY CAUSE OF DEATH**

- UNCERTAIN

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 318

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902038

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

**MISSING**

* Gallbladder	* Thymus
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**OBSERVATIONS**

* Kidney		Nephropathy	Minimal
* Liver		Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 1-10 ]			
* Ovary		Cyst	Mild

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

<b>ANIMAL ID:</b> 319	<b>TRT#:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 717
	<b>DOSE:</b> 168 MG/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 9902039

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	Harderian Gland	* Heart
* Mammary Gland	* Nose	* Salivary Glands	* Thyroid Gland

**MISSING**

* Adrenal Medulla	* Lymph Node, Mandibular	* Parathyroid Gland
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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lymph Node, Mesenteric	* Ovary	* Pituitary Gland
* Stomach, Glandular	* Thymus	* Trachea	* Urinary Bladder

**OBSERVATIONS**

* Liver		Sarcoma	Metastatic (Skin)
* Lung		Sarcoma	Metastatic (Skin)
Mesentery	Fat	Necrosis	Mild
		Sarcoma	Metastatic (Skin)
[ Necrosis TGLS = 2-10 ]			
* Pancreas		Sarcoma	Metastatic (Skin)
[ Sarcoma TGLS = 3-12 ]			
Peritoneum		Sarcoma	Metastatic (Skin)
Skel Muscle			
Note: TGL 4, "mass, 25x23x14mm, tan" noted at necropsy, was diagnosed under skin (subcutaneous).			
* Skin	Subcut Tiss	Sarcoma	
[ Sarcoma TGLS = 4-11 ]			
* Spleen		Hematopoietic Cell Proliferation	Mild
* Stomach, Forestomach		Sarcoma	Metastatic (Skin)
* Uterus		Hydrometra	Mild
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH** - Skin Subcut Tiss Sarcoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 320

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902040

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder
* Uterus			

**MISSING**

\* Clitoral Gland

**INSUFFICIENT TISSUE**

\* Thymus

**OBSERVATIONS**

* Intestine Small, Jejunum [ Lymphoma Malignant TGLS = 7-12 ]		Lymphoma Malignant	
* Kidney Note: TGL 5, "discolored, pale" noted at necropsy, was not apparent microscopically.		Nephropathy	Minimal
* Liver  Note: TGL 6, "discolored, pale" noted at necropsy, was not apparent microscopically. [ Hepatocellular Adenoma TGLS = 2,3-4+10 ]		Hepatocellular Adenoma Inflammation Sarcoma	Multiple Chronic, Minimal Metastatic (Skin)
* Lung [ Sarcoma TGLS = 8-3 ]		Sarcoma	Metastatic (Skin)
Mesentery  [ Necrosis TGLS = 9-13 ]	Fat	Necrosis Sarcoma	Mild Metastatic (Skin)
* Ovary [ Cyst TGLS = 4-7 ]		Cyst	Moderate
* Skin	Subcut Tiss	Sarcoma	

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 320

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902040

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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[ Sarcoma TGLS = 1-11 ]

\* Spleen

Hematopoietic Cell Proliferation

Mild

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 321

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902041

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**OBSERVATIONS**

* Liver		Basophilic Focus Inflammation	Chronic, Mild
[ Basophilic Focus TGLS = 1,2-10+11 ]			
* Lymph Node, Mesenteric		Infiltration Cellular Necrosis	Histiocyte, Minimal Mild
Mesentery	Fat		
[ Necrosis TGLS = 4-12 ]			
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Hematopoietic Cell Proliferation Infiltration Cellular	Minimal Histiocyte, Minimal
* Uterus		Hyperplasia	Cystic, Minimal
[ Hyperplasia TGLS = 3-8 ]			

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 322

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 603

**DOSE:** 168 MG/KG

**DISP:** Natural Death

**HISTO:** 9902042

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Bone	* Bone Marrow	* Brain	* Clitoral Gland
* Esophagus	Harderian Gland	* Heart	* Liver
* Lung	* Lymph Node, Mandibular	* Mammary Gland	* Nose
* Ovary	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Thyroid Gland	* Uterus	

**MISSING**

\* Parathyroid Gland

**AUTO PRECLUDES DIAG.**

* Adrenal Cortex	* Adrenal Medulla	* Gallbladder	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lymph Node, Mesenteric	* Pancreas
* Stomach, Glandular	* Thymus	* Trachea	* Urinary Bladder

**OBSERVATIONS**

* Intestine Large, Cecum [ Necrosis TGLS = 1-10 ]		Necrosis	Marked
Mesentery [ Necrosis TGLS = 2-11 ]	Fat	Necrosis	Moderate
* Spleen		Hematopoietic Cell Proliferation	Mild

**PRIMARY CAUSE OF DEATH**

- Intestine Large, Cecum Necrosis

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 323

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902043

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney
* Lung	* Lymph Node, Mandibular	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
* Heart		Inflammation	Chronic Active, Minimal
* Liver		Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Minimal
[ Necrosis TGLS = 2-10 ]			
* Uterus		Hyperplasia	Cystic, Minimal
[ Hyperplasia TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 324

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902044

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Pituitary Gland	* Salivary Glands	* Skin	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Lymph Node, Mandibular	* Parathyroid Gland
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**OBSERVATIONS**

* Intestine Large, Rectum		Myxomatous Change	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
		Hepatocellular Carcinoma	
		Inflammation	Chronic, Minimal
[ Hepatocellular Carcinoma TGLS = 2-10 ]			
* Lung		Hepatocellular Carcinoma	Metastatic (Liver)
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 4-12 ]			
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Stomach, Forestomach		Hyperplasia	Squamous, Mild
[ Hyperplasia TGLS = 3-11 ]			
* Uterus		Hydrometra	Mild
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 325

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902045

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**OBSERVATIONS**

* Clitoral GI			
Note: TGL 2, "discolored, dark" noted at necropsy, was not apparent microscopically.			
* Liver		Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Moderate
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-10 ]			
* Uterus		Hydrometra	Minimal
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 326

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902046

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Mammary Gland	* Nose	* Pancreas	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Parathyroid Gland

**OBSERVATIONS**

* Gallbladder		Degeneration	Hyaline, Moderate
* Intestine Large, Rectum		Myxomatous Change	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Hepatocellular Carcinoma	
		Inflammation	Chronic, Minimal
[ Hepatocellular Carcinoma TGLS = 3-10 ]			
* Lymph Node, Mandibular		Hyperplasia	Lymphoid, Mild
[ Hyperplasia TGLS = 2-7 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Moderate
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 4-11 ]			
* Ovary		Cyst	Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Infiltration Cellular	Histiocyte, Minimal
* Uterus		Hyperplasia	Cystic, Minimal
[ Hyperplasia TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 327      **TRT#:** 6      **SEX:** Female      **DAY ON TEST:** 509  
**DOSE:** 168 MG/KG      **DISP:** Natural Death      **HISTO:** 9902047

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Brain
* Esophagus	Harderian Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mandibular	* Mammary Gland	* Parathyroid Gland
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

**MISSING**

\* Clitoral Gland

**INSUFFICIENT TISSUE**

\* Pituitary Gland

**OBSERVATIONS**

* Bone Marrow		Lymphoma Malignant	
* Gallbladder		Lymphoma Malignant	
* Intestine Large, Rectum		Infiltration Cellular	Histiocyte, Minimal
		Myxomatous Change	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Lymphoma Malignant	
* Lung		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 4-3 ]			
Lymph Node	Mediastinal	Lymphoma Malignant	
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
		Lymphoma Malignant	
* Nose		Inflammation	Suppurative, Mild
		Lymphoma Malignant	
* Ovary		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 3-7 ]			
* Pancreas		Lymphoma Malignant	
* Salivary Glands		Infiltration Cellular	Lymphocyte, Mild
* Skin	Subcut Tiss	Hemangiosarcoma	

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 327

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 509

**DOSE:** 168 MG/KG

**DISP:** Natural Death

**HISTO:** 9902047

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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[ Hemangiosarcoma TGLS = 1-10 ]

\* Spleen

Lymphoma Malignant

[ Lymphoma Malignant TGLS = 2-11 ]

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**PRIMARY CAUSE OF DEATH**

- Spleen Lymphoma Malignant

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 328

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902048

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Parathyroid Gland

**OBSERVATIONS**

* Liver		Basophilic Focus Inflammation Infiltration Cellular Necrosis	Chronic, Mild Histiocyte, Mild Mild
* Lymph Node, Mesenteric Mesentery [ Necrosis TGLS = 3-10 ]	Fat		
* Pituitary Gland	Pars Distalis	Hyperplasia Angiectasis Hydrometra	Minimal Moderate Moderate
* Uterus  [ Angiectasis TGLS = 2-8 ] [ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 329	<b>TRT#:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 647
	<b>DOSE:</b> 168 MG/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 9902049

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Colon	* Intestine Large, Rectum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea		

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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Urinary Bladder		

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**INSUFFICIENT TISSUE**

\* Pituitary Gland

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**OBSERVATIONS**

* Kidney		Nephropathy	Minimal
* Liver		Hepatocellular Adenoma	
[ Hepatocellular Adenoma TGLS = 1-10 ]			
* Lymph Node, Mesenteric		Hyperplasia	Lymphoid, Marked
[ Hyperplasia TGLS = 2-6 ]			
Mesentery	Fat	Necrosis	Moderate
[ Necrosis TGLS = 3-11 ]			
* Salivary Glands		Atrophy	Mild
* Uterus		Hydrometra	Minimal

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**PRIMARY CAUSE OF DEATH** - Liver Hepatocellular Adenoma

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 330

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902050

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**INSUFFICIENT TISSUE**

\* Gallbladder

**OBSERVATIONS**

* Liver		Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-10 ]			
* Uterus		Hydrometra	Moderate
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 331

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902051

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Pituitary Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

**MISSING**

* Lymph Node, Mandibular	* Parathyroid Gland
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**OBSERVATIONS**

* Liver		Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 1,2-11+10 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 332

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902052

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

\* Pituitary Gland

**OBSERVATIONS**

* Intestine Large, Rectum		Myxomatous Change	Minimal
* Liver		Inflammation	Chronic, Minimal
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Lymph Node, Mandibular		Infiltration Cellular	Plasma Cell, Mild
[ Infiltration Cellular TGLS = 1-7 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Plasma Cell, Marked
[ Infiltration Cellular TGLS = 3-6 ]		Infiltration Cellular	Histiocyte, Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Uterus		Hydrometra	Mild
[ Hydrometra TGLS = 2-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 333

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902053

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**OBSERVATIONS**

* Gallbladder		Degeneration	Hyaline, Mild
* Kidney		Nephropathy	Minimal
* Liver		Hepatocellular Carcinoma	
		Inflammation	Chronic, Minimal
[ Hepatocellular Carcinoma TGLS = 2-10 ]			
* Lung		Hepatocellular Carcinoma	Metastatic (Liver)
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-11 ]			
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Uterus		Hyperplasia	Cystic, Mild
[ Hyperplasia TGLS = 1-8 ]			

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 334

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902054

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney
* Lung	* Lymph Node, Mandibular	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**OBSERVATIONS**

* Bone Harderian Gland [ Adenoma TGLS = 5-11 ]		Fibrous Osteodystrophy Adenoma	Mild
* Liver  Note: TGL 3, "nodule, 3x2x2mm, tan" noted at necropsy, was not apparent microscopically. [ Basophilic Focus TGLS = 4-10 ]		Basophilic Focus Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
* Ovary [ Hemangiosarcoma TGLS = 2-7 ]		Hemangiosarcoma	
* Uterus [ Hydrometra TGLS = 1-8 ]		Hydrometra	Moderate

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 335

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 589

**DOSE:** 168 MG/KG

**DISP:** Natural Death

**HISTO:** 9902055

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder
* Uterus			

**MISSING**

\* Gallbladder

**OBSERVATIONS**

* Intestine Large, Rectum		Myxomatous Change	Mild
* Kidney		Nephropathy	Minimal
* Liver		Hematopoietic Cell Proliferation	Minimal
* Lung	Mediastinum	Osteosarcoma	Metastatic (Uncertain Primary Site)
		Osteosarcoma	Metastatic (Uncertain Primary Site)
		Osteosarcoma	Metastatic (Uncertain Primary Site)
Lymph Node	Bronchial	Osteosarcoma	Metastatic (Uncertain Primary Site)
	Mediastinal	Osteosarcoma	Metastatic (Uncertain Primary Site)
[ Osteosarcoma TGLS = 2-2 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-10 ]			
* Ovary		Cyst	Mild
Skeletal Muscle		Osteosarcoma	Metastatic (Uncertain Primary Site)
[ Osteosarcoma TGLS = 4-11 ]			
* Spleen		Hematopoietic Cell Proliferation	Moderate
[ Hematopoietic Cell Proliferation TGLS = 1-4 ]			
* Thymus		Osteosarcoma	Metastatic (Uncertain Primary Site)
[ Osteosarcoma TGLS = 2-2 ]			

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 335

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 589

**DOSE:** 168 MG/KG

**DISP:** Natural Death

**HISTO:** 9902055

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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PRIMARY CAUSE OF DEATH

- Lymph Node Mediastinal Osteosarcoma Uncertain Primary Site

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 336      **TRT#:** 6      **SEX:** Female      **DAY ON TEST:** 730  
**DOSE:** 168 MG/KG      **DISP:** Terminal Sacrifice      **HISTO:** 9902056

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

* Clitoral Gland	* Lymph Node, Mandibular
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**OBSERVATIONS**

* Intestine Large, Rectum		Myxomatous Change	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Hepatocellular Adenoma	
		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 2-4 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
		Lymphoma Malignant	
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-10 ]			
* Pituitary Gland	Pars Intermed	Adenoma	
* Skin	Subcut Tiss	Lymphoma Malignant	
* Spleen		Infiltration Cellular	Histiocyte, Minimal
* Uterus		Hydrometra	Moderate
		Polyp Stromal	
[ Hydrometra TGLS = 1-8 ]			

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 337

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902057

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Lymph Node, Mesenteric

**OBSERVATIONS**

Harderian Gland		Hyperplasia	Mild
* Intestine Large, Rectum		Myxomatous Change	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Inflammation	Chronic, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-10 ]			
* Spleen		Infiltration Cellular	Histiocyte, Minimal
* Uterus		Hydrometra	Mild
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 338

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 667

**DOSE:** 168 MG/KG

**DISP:** Natural Death

**HISTO:** 9902058

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	Harderian Gland
* Heart	* Liver	* Lung	* Lymph Node, Mandibular
* Mammary Gland	* Nose	* Pituitary Gland	* Salivary Glands
* Skin	* Thymus	* Thyroid Gland	

**MISSING**

\* Parathyroid Gland

**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mesenteric	* Ovary	* Pancreas	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Trachea	

**OBSERVATIONS**

* Kidney		Nephropathy	Minimal
* Lung			
Note: TGL 2, "nodule, 2x2x1mm, white" noted at necropsy, actually involved bronchial lymph node, not lung.			
Lymph Node	Bronchial	Lymphoma Malignant	
	Mediastinal	Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 2-3 ]			
* Urinary Bladder		Lymphoma Malignant	
* Uterus		Hyperplasia	Cystic, Mild
[ Hyperplasia TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

- Lymph Node Mediastinal Lymphoma Malignant

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 339      **TRT#:** 6      **SEX:** Female      **DAY ON TEST:** 677  
**DOSE:** 168 MG/KG      **DISP:** Natural Death      **HISTO:** 9902059

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Heart	* Kidney
* Mammary Gland	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Urinary Bladder	

**MISSING**

* Islets, Pancreatic	* Lymph Node, Mandibular	* Pancreas	* Spleen
* Thymus			

**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Lymph Node, Mesenteric
* Stomach, Glandular	* Thyroid Gland	* Trachea	

**OBSERVATIONS**

* Bone		Carcinoma	Metastatic (Harderian Gland)
		Fibrous Osteodystrophy	Mild
Harderian Gland		Carcinoma	
[ Carcinoma TGLS = 1-10 ]			
* Liver		Basophilic Focus	
		Inflammation	Chronic, Minimal
[ Basophilic Focus TGLS = 3-4 ]			
* Lung		Carcinoma	Metastatic (Harderian Gland)
[ Carcinoma TGLS = 4,5-3 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 6-11 ]			
* Nose		Inflammation	Suppurative, Mild
* Ovary		Cyst	Mild
* Uterus		Hydrometra	Mild
[ Hydrometra TGLS = 2-8 ]			

**PRIMARY CAUSE OF DEATH**      - Harderian Gland    Carcinoma

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 340

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902060

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Parathyroid Gland

**INSUFFICIENT TISSUE**

\* Clitoral Gland

**OBSERVATIONS**

Harderian Gland [ Carcinoma TGLS = 2-10 ]		Carcinoma	
* Kidney		Nephropathy	Minimal
* Liver		Inflammation	Chronic, Mild
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery [ Necrosis TGLS = 3-11 ]	Fat	Necrosis	Mild
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Infiltration Cellular	Histiocyte, Minimal
* Uterus [ Hydrometra TGLS = 1-8 ]		Hydrometra	Moderate

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 341

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902061

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney
* Lung	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

\* Lymph Node, Mandibular

**OBSERVATIONS**

* Bone		Fibrous Osteodystrophy	Minimal
* Intestine Large, Rectum		Myxomatous Change	Minimal
* Liver		Hepatocellular Carcinoma	
		Inflammation	Chronic, Minimal
[ Hepatocellular Carcinoma TGLS = 2-4 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
		Lymphoma Malignant	
Mesentery	Fat	Necrosis	Moderate
[ Necrosis TGLS = 3-10 ]			
* Thymus		Lymphoma Malignant	
* Uterus		Hydrometra	Moderate
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 342      **TRT#:** 6      **SEX:** Female      **DAY ON TEST:** 730  
**DOSE:** 168 MG/KG      **DISP:** Terminal Sacrifice      **HISTO:** 9902062

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney
* Lung	* Lymph Node, Mandibular	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Salivary Glands	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**OBSERVATIONS**

Harderian Gland [ Adenoma TGLS = 1-10 ]		Adenoma	
* Intestine Large, Rectum		Myxomatous Change	Minimal
* Liver		Inflammation	Chronic, Minimal
* Lym Node Mand Note: TGL 5, "enlarged, 3x" noted at necropsy, was not apparent microscopically.			
* Lymph Node, Mesenteric Mesentery [ Necrosis TGLS = 6-11 ]	Fat	Infiltration Cellular Necrosis	Histiocyte, Mild Mild
* Ovary [ Cyst TGLS = 3-7 ]		Cyst	Moderate
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Uterus Note: TGL 4, "nodule, 3x3x2mm, red" noted at necropsy, was not apparent microscopically. [ Hydrometra TGLS = 2-8 ]		Hydrometra	Mild

PRIMARY CAUSE OF DEATH -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 343	<b>TRT#:</b> 6	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 168 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9902063

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder
* Uterus			

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**OBSERVATIONS**

* Kidney		Nephropathy	Minimal
* Liver		Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 1-10 ]			
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Stomach, Forestomach		Hyperplasia	Squamous, Mild

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 344      **TRT#:** 6      **SEX:** Female      **DAY ON TEST:** 653  
**DOSE:** 168 MG/KG      **DISP:** Moribund Sacrifice      **HISTO:** 9902064

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Brain
* Clitoral Gland	* Esophagus	Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Mammary Gland
* Nose	* Pancreas	* Parathyroid Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**OBSERVATIONS**

* Bone Marrow		Necrosis	Marked
* Gallbladder		Cyst	Minimal
* Heart		Cardiomyopathy	Mild
* Intestine Large, Rectum		Inflammation	Chronic Active, Marked
		Necrosis	Marked
* Kidney		Infarct	Moderate
		Nephropathy	Moderate
* Liver		Hematopoietic Cell Proliferation	Minimal
		Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
* Ovary		Cystadenoma	
[ Cystadenoma TGLS = 2-7 ]			
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
Skeletal Muscle		Degeneration	Moderate
		Mineralization	Moderate
* Spleen		Hematopoietic Cell Proliferation	Moderate
* Uterus		Hydrometra	Marked
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**      - Skeletal Muscle    Degeneration

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 345

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902065

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

**OBSERVATIONS**

* Intestine Large, Rectum		Myxomatous Change	Minimal
* Liver		Hepatocellular Carcinoma	
		Inflammation	Chronic, Minimal
[ Hepatocellular Carcinoma TGLS = 1-10 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-11 ]			
* Pituitary Gland	Pars Distalis	Adenoma	

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 346

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902066

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Pancreas	* Parathyroid Gland	* Salivary Glands
* Skin	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Lymph Node, Mandibular

**INSUFFICIENT TISSUE**

\* Ovary

**OBSERVATIONS**

* Intestine Large, Rectum		Myxomatous Change	Minimal
* Liver		Inflammation	Chronic, Minimal
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Uterus		Hydrometra	Mild

[ Hydrometra TGLS = 1-8 ]

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 347

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902067

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Spleen	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**OBSERVATIONS**

* Gallbladder	Degeneration	Hyaline, Moderate
* Intestine Large, Rectum	Inflammation	Chronic Active, Minimal
	Metaplasia	Squamous, Mild
	Myxomatous Change	Minimal
* Kidney	Nephropathy	Minimal
* Liver	Clear Cell Focus	
	Inflammation	Chronic, Minimal
[ Clear Cell Focus TGLS = 2-10 ]		
* Lung	Alveolar/Bronchiolar Adenoma	
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Mild
* Uterus	Hyperplasia	Cystic, Mild
[ Hyperplasia TGLS = 1-8 ]		

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 348      **TRT#:** 6      **SEX:** Female      **DAY ON TEST:** 621  
**DOSE:** 168 MG/KG      **DISP:** Natural Death      **HISTO:** 9902068

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	Harderian Gland
* Intestine Large, Cecum	* Intestine Large, Colon	* Islets, Pancreatic	* Lung
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Lymph Node, Mandibular

**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Stomach, Glandular			

**OBSERVATIONS**

* Heart		Mineralization	Mild
* Intestine Large, Rectum		Infiltration Cellular	Histiocyte, Minimal
		Myxomatous Change	Mild
* Kidney		Nephropathy	Minimal
* Liver		Lymphoma Malignant	
		Mineralization	Mild
[ Lymphoma Malignant TGLS = 5,6-4 ]			
Lymph Node	Bronchial	Lymphoma Malignant	
	Renal	Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 2-10 ]			
[ Lymphoma Malignant TGLS = 4-3 ]			
* Lymph Node, Mesenteric		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 7-11 ]			
* Spleen		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 1-4 ]			
* Thymus		Lymphoma Malignant	
* Uterus		Hydrometra	Mild
[ Hydrometra TGLS = 3-8 ]			

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 348

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 621

**DOSE:** 168 MG/KG

**DISP:** Natural Death

**HISTO:** 9902068

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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PRIMARY CAUSE OF DEATH

- Lymph Node, Mesenteric Lymphoma Malignant

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:17  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 349

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902069

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mandibular
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**OBSERVATIONS**

* Brain	Meninges	Infiltration Cellular	Mononuclear CI, Minimal
* Intestine Large, Rectum		Myxomatous Change	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Hepatocellular Adenoma	Multiple
		Inflammation	Chronic, Minimal
Note: TGL 3, "deformity, 2x2mm" noted at necropsy, was not apparent microscopically.			
			[ Eosinophilic Focus TGLS = 2-4 ]
			[ Hepatocellular Adenoma TGLS = 1,4-4+10 ]
* Lung	Alveolar Epith	Alveolar/Bronchiolar Adenoma	
		Hyperplasia	Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
			[ Necrosis TGLS = 6-11 ]
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Infiltration Cellular	Histiocyte, Minimal
* Uterus		Hydrometra	Mild
		Hyperplasia	Cystic, Minimal
			[ Hydrometra TGLS = 5-8 ]
			[ Hyperplasia TGLS = 5-8 ]

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 349

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902069

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 350

**TRT#:** 6

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 168 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902070

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder
* Uterus			

**MISSING**

\* Lymph Node, Mandibular

**OBSERVATIONS**

* Adrenal Cortex	Subcapsular	Carcinoma	
* Liver		Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 1-10 ]			
* Spleen		Infiltration Cellular	Histiocyte, Minimal

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 351

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 517

**DOSE:** 504 MG/KG

**DISP:** Natural Death

**HISTO:** 9902071

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Colon	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Mammary Gland	* Nose	* Ovary	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Small, Duodenum	* Intestine Small, Ileum
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**INSUFFICIENT TISSUE**

\* Intestine Large, Rectum

**OBSERVATIONS**

* Adrenal Cortex	Hypertrophy	Mild
* Kidney	Nephropathy	Minimal
* Liver	Fatty Change	Minimal
	Hepatocellular Adenoma	
	Inflammation	Chronic, Mild
[ Hepatocellular Adenoma TGLS = 1-4 ]		
* Lymph Node, Mandibular	Infiltration Cellular	Histiocyte, Minimal
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Moderate
* Pancreas	Atrophy	Minimal
* Spleen	Infiltration Cellular	Histiocyte, Minimal

**PRIMARY CAUSE OF DEATH**

- Liver Hepatocellular Adenoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 352

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902072

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney	* Lung
* Lymph Node, Mandibular	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Mild
Harderian Gland		Adenoma	
[ Adenoma TGLS = 1-11 ]			
* Int Sm Jejunum			
Note: TGL 2, "enlarged, 3x, white" noted at necropsy, was within normal limits microscopically.			
* Intestine Large, Rectum		Inflammation	Chronic Active, Minimal
		Myxomatous Change	Mild
* Liver		Clear Cell Focus	
		Inflammation	Chronic, Moderate
[ Clear Cell Focus TGLS = 3-4 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Minimal
[ Necrosis TGLS = 4-10 ]			
* Pituitary Gland	Pars Distalis	Hyperplasia	Moderate
* Spleen		Infiltration Cellular	Histiocyte, Minimal

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 353      **TRT#:** 8      **SEX:** Female      **DAY ON TEST:** 703  
**DOSE:** 504 MG/KG      **DISP:** Moribund Sacrifice      **HISTO:** 9902073

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Brain
* Esophagus	* Gallbladder	* Heart	* Intestine Large, Cecum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

**MISSING**

* Clitoral Gland	Harderian Gland	* Thymus
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**OBSERVATIONS**

* Bone Marrow		Histiocytic Sarcoma	
* Intestine Large, Colon		Necrosis	Minimal
* Intestine Large, Rectum		Inflammation	Chronic Active, Minimal
		Metaplasia	Squamous, Mild
		Myxomatous Change	Moderate
* Kidney		Nephropathy	Minimal
* Liver		Histiocytic Sarcoma	
[ Histiocytic Sarcoma TGLS = 2,3,4-4 ]			
* Lung		Histiocytic Sarcoma	
	Alveolus	Infiltration Cellular	Histiocyte, Minimal
* Lymph Node, Mandibular		Infiltration Cellular	Histiocyte, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
		Infiltration Cellular	Plasma Cell, Mild
[ Infiltration Cellular TGLS = 5-6 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 6-10 ]			
* Spleen		Histiocytic Sarcoma	
[ Histiocytic Sarcoma TGLS = 1-4 ]			

**PRIMARY CAUSE OF DEATH** - Liver Histiocytic Sarcoma

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

<b>ANIMAL ID:</b> 354	<b>TRT#:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 660
	<b>DOSE:</b> 504 MG/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 9902074

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Bone	* Bone Marrow	* Brain
* Esophagus	* Heart	* Kidney	* Mammary Gland
* Nose	* Ovary	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Stomach, Forestomach	* Thyroid Gland	* Trachea
* Uterus			

**MISSING**

* Adrenal Medulla	Harderian Gland	* Lymph Node, Mandibular	
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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lymph Node, Mesenteric
* Pancreas	* Spleen	* Stomach, Glandular	* Thymus
* Urinary Bladder			

**INSUFFICIENT TISSUE**

\* Clitoral Gland

**OBSERVATIONS**

* Intestine Large, Rectum		Inflammation	Chronic Active, Minimal
		Metaplasia	Squamous, Moderate
		Myxomatous Change	Mild
		Necrosis	Mild
* Liver		Hepatocellular Carcinoma	
[ Hepatocellular Carcinoma TGLS = 4-10 ]			
* Lung		Hepatocellular Carcinoma	Metastatic (Liver)
Lymph Node	Iliac	Lymphoma Malignant	
	Renal	Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 3-13 ]			
Mesentery	Fat	Necrosis	Moderate
[ Necrosis TGLS = 5-11 ]			
* Skin	Subcut Tiss	Hemangioma	
[ Hemangioma TGLS = 1-12 ]			

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 354

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 660

**DOSE:** 504 MG/KG

**DISP:** Natural Death

**HISTO:** 9902074

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* Spleen

Note: TGL 2, "enlarged 31x6x4mm" noted at necropsy, was obscured by post mortem autolysis and not apparent microscopically.

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PRIMARY CAUSE OF DEATH

- Liver Hepatocellular Carcinoma

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 355

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902075

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Mammary Gland
* Nose	* Pancreas	* Pituitary Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Parathyroid Gland	* Thymus
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Moderate
Harderian Gland		Hyperplasia	Minimal
* Intestine Large, Rectum		Inflammation	Chronic Active, Mild
		Metaplasia	Squamous, Minimal
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
		Hepatocellular Adenoma	
		Inflammation	Chronic, Moderate
[ Basophilic Focus TGLS = 2-4 ]			
[ Clear Cell Focus TGLS = 5-12 ]			
[ Eosinophilic Focus TGLS = 3-11 ]			
[ Hepatocellular Adenoma TGLS = 4-10 ]			
* Lymph Node, Mandibular		Lymphoma Malignant	
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Minimal
[ Necrosis TGLS = 6-13 ]			
* Ovary		Cyst	Mild
* Spleen		Infiltration Cellular	Histiocyte, Minimal

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 355

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902075

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* Uterus

Hydrometra

Minimal

[ Hydrometra TGLS = 1-8 ]

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 356

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902076

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Brain
* Clitoral Gland	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Gallbladder	* Parathyroid Gland	* Thymus
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**OBSERVATIONS**

* Bone Marrow		Lymphoma Malignant	
* Intestine Large, Rectum		Inflammation	Chronic Active, Moderate
		Metaplasia	Squamous, Mild
		Myxomatous Change	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Eosinophilic Focus	
		Hematopoietic Cell Proliferation	Mild
		Hepatocellular Adenoma	
		Inflammation	Chronic, Minimal
		Lymphoma Malignant	
[ Basophilic Focus TGLS = 3-10 ]			
[ Clear Cell Focus TGLS = 3,6,7-10+4+11 ]			
[ Eosinophilic Focus TGLS = 9-12 ]			
[ Hepatocellular Adenoma TGLS = 5-4 ]			
[ Lymphoma Malignant TGLS = 4-4 ]			
Lymph Node	Mediastinal	Lymphoma Malignant	
	Pancreatic	Lymphoma Malignant	
	Renal	Lymphoma Malignant	

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 356	<b>TRT#:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 504 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9902076

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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[ Lymphoma Malignant TGLS = 11-13 ]			
[ Lymphoma Malignant TGLS = 8-4 ]			
* Lymph Node, Mandibular		Infiltration Cellular	Plasma Cell, Marked
[ Infiltration Cellular TGLS = 10-7 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Plasma Cell, Marked
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 12-14 ]			
* Spleen		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 1-4 ]			
* Uterus		Hydrometra	Moderate
[ Hydrometra TGLS = 2-8 ]			

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 357

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902077

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**OBSERVATIONS**

* Bone		Fibrous Osteodystrophy	Minimal
* Intestine Large, Rectum		Inflammation	Chronic Active, Moderate
		Metaplasia	Squamous, Moderate
* Liver		Clear Cell Focus	
		Hepatocellular Adenoma	Multiple
		Inflammation	Chronic, Moderate
[ Clear Cell Focus TGLS = 3,6-4+11 ]			
[ Hepatocellular Adenoma TGLS = 4,5-4+10 ]			
* Lung		Inflammation	Chronic Active, Minimal
* Lymph Node, Mandibular		Infiltration Cellular	Histiocyte, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 7-12 ]			
* Spleen		Infiltration Cellular	Histiocyte, Minimal
		Metaplasia	Osseous, Mild
[ Metaplasia TGLS = 2-4 ]			
* Uterus		Polyp Stromal	
[ Polyp Stromal TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 358

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902078

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney
* Lung	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Thymus

**OBSERVATIONS**

* Intestine Large, Cecum		Leiomyoma	
* Intestine Large, Rectum		Infiltration Cellular	Histiocyte, Minimal
		Inflammation	Chronic Active, Mild
		Metaplasia	Squamous, Minimal
		Myxomatous Change	Mild
		Necrosis	Mild
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Inflammation	Chronic, Mild
		Lymphoma Malignant	
[ Clear Cell Focus TGLS = 4-10 ]			
[ Lymphoma Malignant TGLS = 3-4+10 ]			
Lymph Node	Mediastinal	Lymphoma Malignant	
* Lymph Node, Mandibular		Lymphoma Malignant	
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
		Lymphoma Malignant	
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 6-12 ]			
* Salivary Glands		Lymphoma Malignant	

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 358	<b>TRT#:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 504 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9902078

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Spleen [ Lymphoma Malignant TGLS = 1,2-4+11 ]	Infiltration Cellular Lymphoma Malignant	Histiocyte, Minimal
* Uterus [ Hydrometra TGLS = 5-8 ]	Hydrometra	Moderate

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PRIMARY CAUSE OF DEATH -

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 359

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902079

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lung	* Lymph Node, Mandibular	* Mammary Gland
* Ovary	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Inflammation	Chronic, Mild
[ Clear Cell Focus TGLS = 2-4+10 ]			
[ Eosinophilic Focus TGLS = 4-12 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
Mesentery	Fat	Necrosis	Moderate
[ Necrosis TGLS = 5-13 ]			
* Nose	Olfactory Epi	Metaplasia	Mild
* Spleen		Hematopoietic Cell Proliferation	Mild
		Infiltration Cellular	Histiocyte, Minimal
[ Hematopoietic Cell Proliferation TGLS = 1-4 ]			
* Uterus		Hydrometra	Minimal

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

<b>ANIMAL ID:</b> 360	<b>TRT#:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 504 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9902080

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Esophagus	* Gallbladder	Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Mammary Gland	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Clitoral Gland	* Thymus
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
* Heart		Cardiomyopathy	Minimal
* Intestine Large, Rectum		Infiltration Cellular	Histiocyte, Minimal
		Inflammation	Chronic Active, Minimal
		Metaplasia	Squamous, Mild
		Myxomatous Change	Mild
		Necrosis	Mild
* Kidney		Mineralization	Minimal
		Nephropathy	Minimal
* Liver		Basophilic Focus	
[ Basophilic Focus TGLS = 3-10 ]			
* Lung		Liposarcoma	Metastatic (Skin)
* Lymph Node, Mandibular		Infiltration Cellular	Plasma Cell, Moderate
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 4-12 ]			
* Nose		Inflammation	Suppurative, Mild
* Ovary		Cyst	Mild
Skel Muscle			
Note: TGL 1, "mass, 35x24x26mm" noted at necropsy, was diagnosed under skin (subcutaneous tissue).			
* Skin	Subcut Tiss	Liposarcoma	

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 360	<b>TRT#:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 504 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9902080

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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[ Liposarcoma TGLS = 1-11 ]		
* Spleen	Infiltration Cellular	Histiocyte, Minimal
	Lymphoma Malignant	
* Uterus	Hydrometra	Moderate
[ Hydrometra TGLS = 2-8 ]		

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 361

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 708

**DOSE:** 504 MG/KG

**DISP:** Natural Death

**HISTO:** 9902081

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Bone	* Brain	* Clitoral Gland	* Esophagus
* Heart	* Mammary Gland	* Nose	* Parathyroid Gland
* Pituitary Gland	* Stomach, Forestomach	* Thymus	* Trachea
* Uterus			

**MISSING**

* Lymph Node, Mandibular	* Salivary Glands
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**AUTO PRECLUDES DIAG.**

* Adrenal Cortex	* Adrenal Medulla	* Gallbladder	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney	* Liver
Lymph Node	* Lymph Node, Mesenteric	* Pancreas	* Spleen
* Stomach, Glandular	* Thyroid Gland	* Urinary Bladder	

**OBSERVATIONS**

* Bone Marrow		Histiocytic Sarcoma	
Harderian Gland		Inflammation	Chronic, Mild
* Lung		Histiocytic Sarcoma	
Mesentery		Histiocytic Sarcoma	
	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-10 ]			
* Ovary		Histiocytic Sarcoma	
* Skin	Subcut Tiss	Histiocytic Sarcoma	

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 362

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902082

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**OBSERVATIONS**

* Intestine Large, Rectum		Myxomatous Change	Minimal
* Kidney		Nephropathy	Minimal
* Liver		Hepatocellular Adenoma	Multiple
		Inflammation	Chronic, Mild
[ Hepatocellular Adenoma TGLS = 2,3,4-4+10+11+12 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 6-14 ]			
* Skin	Subcut Tiss	Myxoma	
Note: The subcutaneous mass was myxomatous.			
[ Myxoma TGLS = 5-13 ]			
* Spleen		Infiltration Cellular	Histiocyte, Minimal
* Uterus		Hydrometra	Moderate
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 363

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 717

**DOSE:** 504 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9902083

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone Marrow	* Brain	* Esophagus
* Gallbladder	Harderian Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mandibular	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Clitoral Gland

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Mild
* Bone		Osteosarcoma	
[ Osteosarcoma TGLS = 3,4-10+11 ]			
* Intestine Large, Rectum		Inflammation	Chronic Active, Minimal
		Metaplasia	Squamous, Minimal
		Myxomatous Change	Moderate
		Necrosis	Moderate
* Kidney		Nephropathy	Minimal
* Liver		Eosinophilic Focus	
		Hematopoietic Cell Proliferation	Mild
		Inflammation	Chronic, Minimal
* Lung	Alveolar Epith	Hyperplasia	Minimal
* Lymph Node, Mesenteric		Hemorrhage	Mild
[ Hemorrhage TGLS = 5-6 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 6-12 ]			
* Spleen		Hematopoietic Cell Proliferation	Moderate
		Infiltration Cellular	Histiocyte, Minimal
[ Hematopoietic Cell Proliferation TGLS = 2-4 ]			
* Uterus		Hydrometra	Mild

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 363

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 717

**DOSE:** 504 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9902083

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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[ Hydrometra TGLS = 1-8 ]

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PRIMARY CAUSE OF DEATH

- Bone Osteosarcoma

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\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 364

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902084

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Parathyroid Gland

**OBSERVATIONS**

* Bone		Fibrous Osteodystrophy	Mild
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Fatty Change	Minimal
		Hemangiosarcoma	
		Lymphoma Malignant	
[ Basophilic Focus TGLS = 5-11 ]			
[ Clear Cell Focus TGLS = 6,7-12+4 ]			
[ Hemangiosarcoma TGLS = 4-10 ]			
* Lymph Node, Mandibular		Lymphoma Malignant	
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 1,9-13+14 ]			
* Ovary		Hemangioma	
[ Hemangioma TGLS = 3-7 ]			
* Spleen		Infiltration Cellular	Histiocyte, Minimal
		Metaplasia	Osseous, Mild
[ Metaplasia TGLS = 8-4 ]			
* Thymus		Lymphoma Malignant	

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 364

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902084

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* Uterus

Hyperplasia

Cystic, Mild

[ Hyperplasia TGLS = 2-8 ]

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 365

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 661

**DOSE:** 504 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9902085

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Lymph Node, Mesenteric

**OBSERVATIONS**

* Intestine Large, Rectum		Infiltration Cellular Inflammation Metaplasia Myxomatous Change Necrosis	Histiocyte, Minimal Chronic Active, Moderate Squamous, Moderate Mild
* Kidney		Nephropathy	Mild
* Liver		Fatty Change Hematopoietic Cell Proliferation Hepatocellular Adenoma Inflammation	Mild Moderate Chronic, Minimal
[ Hepatocellular Adenoma TGLS = 3-10 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 4-11 ]			
* Spleen		Hematopoietic Cell Proliferation	Moderate
[ Hematopoietic Cell Proliferation TGLS = 2-4 ]			
* Uterus		Hyperplasia	Cystic, Moderate
[ Hyperplasia TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH** - Liver Hepatocellular Adenoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 366

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902086

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Esophagus	* Gallbladder	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

\* Clitoral Gland

**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Moderate
		Hypertrophy	Mild
Harderian Gland		Hyperplasia	Marked
* Int Sm Jejunum			
Note: TGL 5, "Peyers patch, enlarged, 2x" noted at necropsy, was within normal limits microscopically.			
* Kidney		Metaplasia	Osseous, Minimal
		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Inflammation	Chronic, Moderate
[ Clear Cell Focus TGLS = 3-10 ]			
* Lym Node Mand			
Note: TGL 4, "enlarged, 2x" noted at necropsy, was within normal limits microscopically.			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-11 ]			
* Spleen		Infiltration Cellular	Histiocyte, Minimal
* Uterus		Hydrometra	Minimal
		Polyp Stromal	

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 366

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902086

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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[ Hydrometra TGLS = 1-8 ]

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 367

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902087

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

**MISSING**

\* Gallbladder

**OBSERVATIONS**

* Esophagus		Inflammation	Chronic Active, Mild
Harderian Gland		Hyperplasia	Marked
* Intestine Large, Rectum		Inflammation	Chronic Active, Mild
		Metaplasia	Squamous, Moderate
		Myxomatous Change	Minimal
		Necrosis	Mild
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Clear Cell Focus	
		Inflammation	Chronic, Mild
[ Clear Cell Focus TGLS = 2-10 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-11 ]			
* Spleen		Infiltration Cellular	Histiocyte, Minimal
* Uterus			

Note: TGL 1, "dilated, 2x" noted at necropsy, was not apparent microscopically.

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 368      **TRT#:** 8      **SEX:** Female      **DAY ON TEST:** 729  
**DOSE:** 504 MG/KG      **DISP:** Terminal Sacrifice      **HISTO:** 9902088

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Clitoral Gland
* Esophagus	* Gallbladder	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder	* Uterus		

**OBSERVATIONS**

* Bone Marrow		Atrophy	Mild
* Brain	Meninges	Inflammation	Chronic, Mild
* Intestine Large, Rectum		Infiltration Cellular	Histiocyte, Minimal
		Inflammation	Chronic Active, Minimal
		Metaplasia	Squamous, Minimal
		Myxomatous Change	Mild
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Inflammation	Chronic, Mild
[ Basophilic Focus TGLS = 1-4 ]			
* Lymph Node, Mesenteric		Hemorrhage	Minimal
[ Hemorrhage TGLS = 2-6 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-10 ]			
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Infiltration Cellular	Histiocyte, Minimal

PRIMARY CAUSE OF DEATH -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 369

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902089

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**OBSERVATIONS**

* Bone Marrow		Histiocytic Sarcoma	
* Intestine Large, Rectum		Inflammation	Chronic Active, Minimal
		Metaplasia	Squamous, Moderate
* Kidney		Histiocytic Sarcoma	
		Nephropathy	Minimal
	[ Histiocytic Sarcoma TGLS = 5-5 ]		
* Liver		Hematopoietic Cell Proliferation	Minimal
		Hepatocellular Adenoma	Multiple
		Histiocytic Sarcoma	
		Inflammation	Chronic, Minimal
	[ Hepatocellular Adenoma TGLS = 3,4-4+11 ]		
	[ Histiocytic Sarcoma TGLS = 7-10 ]		
Lymph Node	Pancreatic	Lymphoma Malignant	
* Lymph Node, Mandibular		Lymphoma Malignant	
* Lymph Node, Mesenteric		Histiocytic Sarcoma	
		Lymphoma Malignant	
	[ Lymphoma Malignant TGLS = 6-12 ]		
Mesentery	Fat	Necrosis	Mild
	[ Necrosis TGLS = 8-13 ]		
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Hematopoietic Cell Proliferation	Mild

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 369

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902089

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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[ Lymphoma Malignant TGLS = 1-4 ]

Lymphoma Malignant

\* Uterus

[ Hydrometra TGLS = 2-8 ]

Hydrometra

Mild

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PRIMARY CAUSE OF DEATH

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 370

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 723

**DOSE:** 504 MG/KG

**DISP:** Natural Death

**HISTO:** 9902090

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

\* Adrenal Cortex  
\* Brain  
\* Mammary Gland  
\* Urinary Bladder

\* Adrenal Medulla  
\* Esophagus  
\* Nose  
\* Uterus

\* Bone  
\* Harderian Gland  
\* Salivary Glands

\* Bone Marrow  
\* Heart  
\* Skin

**MISSING**

\* Clitoral Gland

\* Thymus

**AUTO PRECLUDES DIAG.**

\* Gallbladder  
\* Intestine Small, Duodenum  
\* Kidney  
\* Parathyroid Gland  
\* Stomach, Glandular

\* Intestine Large, Cecum  
\* Intestine Small, Ileum  
\* Lymph Node, Mesenteric  
\* Pituitary Gland  
\* Thyroid Gland

\* Intestine Large, Colon  
\* Intestine Small, Jejunum  
\* Ovary  
\* Spleen  
\* Trachea

\* Intestine Large, Rectum  
\* Islets, Pancreatic  
\* Pancreas  
\* Stomach, Forestomach

**INSUFFICIENT TISSUE**

\* Lymph Node, Mandibular

**OBSERVATIONS**

\* Liver  
[ Hepatocellular Carcinoma TGLS = 1-10 ]  
\* Lung  
Mesentery Fat  
[ Necrosis TGLS = 3-11 ]  
\* Spleen

Hepatocellular Carcinoma

Hepatocellular Carcinoma  
Necrosis

Metastatic (Liver)  
Mild

Note: TGL 2, "enlarged, 2x" noted at necropsy, was obscured by post mortem autolysis.

**PRIMARY CAUSE OF DEATH**

- Liver Hepatocellular Carcinoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 371

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 401

**DOSE:** 504 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9902091

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
Spinal Cord	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

**MISSING**

* Intestine Small, Duodenum	* Thymus
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**INSUFFICIENT TISSUE**

\* Clitoral Gland

**OBSERVATIONS**

Harderian Gland [ Adenoma TGLS = 1-10 ]	Adenoma	
* Intestine Large, Rectum	Infiltration Cellular Inflammation Metaplasia Myxomatous Change Necrosis	Histiocyte, Minimal Chronic Active, Mild Squamous, Minimal Minimal Minimal
* Liver	Clear Cell Focus Fatty Change Inflammation	Minimal Minimal Chronic, Minimal
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Moderate
Peripheral Nerve	Infiltration Cellular	Mast Cell, Minimal
* Spleen	Infiltration Cellular	Histiocyte, Minimal

**PRIMARY CAUSE OF DEATH**

- UNCERTAIN

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 372

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 509

**DOSE:** 504 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9902092

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Esophagus	* Gallbladder	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

**MISSING**

\* Clitoral Gland

**OBSERVATIONS**

* Adrenal Cortex	Necrosis	Mild
* Intestine Large, Rectum	Myxomatous Change	Minimal
* Kidney	Nephropathy	Marked
[ Nephropathy TGLS = 1-5 ]		
* Liver	Hematopoietic Cell Proliferation	Minimal
	Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Mild
* Spleen	Hematopoietic Cell Proliferation	Mild

**PRIMARY CAUSE OF DEATH**

- Kidney Nephropathy

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 373

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902093

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Lymph Node, Mandibular

**OBSERVATIONS**

* Gallbladder	Degeneration	Hyaline, Moderate
Harderian Gland	Adenoma	
* Intestine Large, Rectum	Infiltration Cellular	Histiocyte, Minimal
	Inflammation	Chronic Active, Moderate
	Metaplasia	Squamous, Minimal
	Myxomatous Change	Mild
	Necrosis	Moderate
* Kidney	Nephropathy	Minimal
* Liver	Basophilic Focus	
	Clear Cell Focus	
	Eosinophilic Focus	
	Fatty Change	Minimal
	Inflammation	Chronic, Mild
[ Basophilic Focus TGLS = 3-4 ]		
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Mild
* Spleen	Hematopoietic Cell Proliferation	Minimal
[ Hematopoietic Cell Proliferation TGLS = 2-4 ]		
* Uterus	Hydrometra	Mild
[ Hydrometra TGLS = 1-8 ]		

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 373

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902093

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 374                      **TRT#:** 8                      **SEX:** Female                      **DAY ON TEST:** 621  
**DOSE:** 504 MG/KG                      **DISP:** Moribund Sacrifice                      **HISTO:** 9902094

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Bone	* Brain	* Clitoral Gland	* Esophagus
* Gallbladder	Harderian Gland	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Mammary Gland	* Parathyroid Gland	* Skin	* Stomach, Glandular
* Thyroid Gland	* Trachea		

**OBSERVATIONS**

* Adrenal Cortex		Lymphoma Malignant	
* Adrenal Medulla		Lymphoma Malignant	
* Bone Marrow		Lymphoma Malignant	
* Heart		Lymphoma Malignant	
* Intestine Large, Rectum		Infiltration Cellular	Histiocyte, Minimal
		Inflammation	Chronic Active, Mild
		Myxomatous Change	Mild
		Necrosis	Mild
* Kidney		Lymphoma Malignant	
		Nephropathy	Minimal
* Liver		Hepatocellular Adenoma	
		Lymphoma Malignant	
	[ Hepatocellular Adenoma TGLS = 3-10 ]		
	[ Lymphoma Malignant TGLS = 4-4 ]		
* Lung		Lymphoma Malignant	
Lymph Node	Bronchial	Lymphoma Malignant	
* Lymph Node, Mandibular		Lymphoma Malignant	
* Lymph Node, Mesenteric		Lymphoma Malignant	
Mesentery	Fat	Necrosis	Mild
	[ Necrosis TGLS = 5-11 ]		
* Nose		Lymphoma Malignant	
* Ovary		Lymphoma Malignant	
* Pancreas		Lymphoma Malignant	
* Pituitary Gland		Lymphoma Malignant	

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 374	<b>TRT#:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 621
	<b>DOSE:</b> 504 MG/KG	<b>DISP:</b> Moribund Sacrifice	<b>HISTO:</b> 9902094

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Salivary Glands	Lymphoma Malignant
* Spleen [ Lymphoma Malignant TGLS = 1-4 ]	Lymphoma Malignant
* Stomach, Forestomach	Lymphoma Malignant
* Thymus [ Lymphoma Malignant TGLS = 2-2 ]	Lymphoma Malignant
* Urinary Bladder	Lymphoma Malignant
* Uterus	Lymphoma Malignant

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PRIMARY CAUSE OF DEATH      - Lymph Node, Mesenteric    Lymphoma Malignant

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\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 375

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902095

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
* Intestine Large, Rectum		Inflammation	Chronic Active, Moderate
		Myxomatous Change	Mild
		Necrosis	Mild
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus	
		Hepatocellular Adenoma	
		Inflammation	Chronic, Mild
Note: TGL 3, "focus, 1x1mm, white" noted at necropsy, was not apparent microscopically.			
[ Basophilic Focus TGLS = 4-4 ]			
[ Hepatocellular Adenoma TGLS = 2-4 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 5-10 ]			
* Spleen		Infiltration Cellular	Histiocyte, Minimal
* Uterus		Hyperplasia	Cystic, Mild
[ Hyperplasia TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 376

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 652

**DOSE:** 504 MG/KG

**DISP:** Natural Death

**HISTO:** 9902096

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Colon	* Islets, Pancreatic	* Lung	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Spleen
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

**MISSING**

* Clitoral Gland	* Lymph Node, Mandibular
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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Kidney		

**OBSERVATIONS**

* Intestine Large, Rectum	Inflammation	Chronic Active, Minimal
	Metaplasia	Squamous, Minimal
	Myxomatous Change	Mild
	Necrosis	Mild
* Liver	Fatty Change	Mild
	Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Mild

**PRIMARY CAUSE OF DEATH**

- UNCERTAIN

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 377

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902097

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Kidney	* Lung	* Lymph Node, Mandibular
* Mammary Gland	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Spleen	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**OBSERVATIONS**

* Adrenal Cortex		Hyperplasia	Minimal
* Intestine Large, Rectum		Inflammation	Chronic Active, Moderate
		Metaplasia	Squamous, Marked
* Intestine Small, Ileum		Infiltration Cellular	Mixed Cell, Moderate
* Liver		Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Moderate
* Nose	Olfactory Epi	Atrophy	Mild
* Ovary		Cyst	Mild
* Uterus		Hyperplasia	Cystic, Mild

[ Hyperplasia TGLS = 1-8 ]

**PRIMARY CAUSE OF DEATH**

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 378

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902098

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	* Heart
* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Mammary Gland	* Nose	* Pancreas
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea

**MISSING**

\* Urinary Bladder

**OBSERVATIONS**

* Bone	Fibrous Osteodystrophy	Mild
* Intestine Large, Cecum	Lymphoma Malignant	
* Intestine Large, Rectum	Inflammation	Chronic Active, Mild
	Metaplasia	Squamous, Minimal
	Myxomatous Change	Mild
	Necrosis	Minimal
* Kidney	Lymphoma Malignant	
* Liver	Basophilic Focus	
	Clear Cell Focus	
	Eosinophilic Focus	
	Fatty Change	Minimal
	Hepatocellular Adenoma	
	Lymphoma Malignant	
[ Basophilic Focus TGLS = 4-11 ]		
[ Hepatocellular Adenoma TGLS = 3-10 ]		
* Lung	Lymphoma Malignant	
* Lymph Node, Mandibular	Lymphoma Malignant	
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Mild
	Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 5-6 ]		
* Ovary	Lymphoma Malignant	

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 378	<b>TRT#:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 504 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9902098

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Hematopoietic Cell Proliferation	Minimal
	[ Lymphoma Malignant TGLS = 2-4 ]	Lymphoma Malignant	
* Uterus		Hydrometra	Mild
	[ Hydrometra TGLS = 1-8 ]		

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 379

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 701

**DOSE:** 504 MG/KG

**DISP:** Natural Death

**HISTO:** 9902099

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	Harderian Gland	* Intestine Large, Cecum
* Intestine Large, Colon	* Islets, Pancreatic	* Kidney	* Lymph Node, Mandibular
* Nose	* Ovary	* Pancreas	* Salivary Glands
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Mammary Gland	* Parathyroid Gland
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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Small, Ileum	* Intestine Small, Jejunum
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**OBSERVATIONS**

* Adrenal Cortex	Sarcoma	Metastatic (Skin)
* Heart	Mineralization	Mild
* Intestine Large, Rectum	Inflammation	Chronic Active, Minimal
	Metaplasia	Squamous, Marked
	Necrosis	Minimal
* Intestine Small, Duodenum	Polyp Adenomatous	
[ Polyp Adenomatous TGLS = 4-6 ]		
* Liver	Eosinophilic Focus	
	Hematopoietic Cell Proliferation	Marked
	Hepatocellular Adenoma	
* Lung	Sarcoma	Metastatic (Skin)
	Thrombosis	Minimal
* Lymph Node, Mesenteric	Infiltration Cellular	Histiocyte, Moderate
* Mammary GI		
Note: TGL 1, "mass, 45x35x25mm, mottled" noted at necropsy, actually involved the skin (subcutaneous tissue).		
Mesentery	Fat	Mild
	Necrosis	Metastatic (Skin)
	Sarcoma	
[ Necrosis TGLS = 5-11 ]		
* Pituitary Gland	Pars Distalis	Mild
	Hyperplasia	

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 379	<b>TRT#:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 701
	<b>DOSE:</b> 504 MG/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 9902099

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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* Skin [ Sarcoma TGLS = 1-10 ]	Subcut Tiss	Sarcoma	
* Spleen [ Hematopoietic Cell Proliferation TGLS = 3-4 ]		Hematopoietic Cell Proliferation	Moderate
* Thymus		Sarcoma	Metastatic (Skin)
* Uterus [ Hydrometra TGLS = 2-8 ]		Hydrometra	Marked

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PRIMARY CAUSE OF DEATH - Skin Subcut Tiss Sarcoma

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 380

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 683

**DOSE:** 504 MG/KG

**DISP:** Natural Death

**HISTO:** 9902100

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Islets, Pancreatic	* Kidney
* Lung	Lymph Node	* Lymph Node, Mandibular	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Clitoral Gland

**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
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**OBSERVATIONS**

* Intestine Large, Rectum		Myxomatous Change	Minimal
* Liver	Centrilobular	Degeneration	Mild
		Fatty Change	Mild
		Hematopoietic Cell Proliferation	Minimal
	Centrilobular	Necrosis	Mild
Note: TGL 4, "nodule, 1x1x1mm, white" noted at necropsy, was not apparent microscopically. [ Necrosis TGLS = 5-4 ]			
* Lym Node Mand			
Note: TGL 6, "enlarged, 2x, red" noted at necropsy, was not apparent microscopically.			
Lymph Node			
Note: TGL 7, "mediastinal, enlarged, 2x, red" noted at necropsy, was not apparent microscopically.			
* Lymph Node, Mesenteric		Hemorrhage	Moderate
[ Hemorrhage TGLS = 8-6 ]			
Mesentery	Fat	Necrosis	Mild
		Thrombosis	Moderate
[ Necrosis TGLS = 9-10 ]			
* Pituitary Gland	Pars Distalis	Adenoma	
* Spleen		Hematopoietic Cell Proliferation	Marked

\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 380	<b>TRT#:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 683
	<b>DOSE:</b> 504 MG/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 9902100

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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[ Hematopoietic Cell Proliferation TGLS = 3-4 ]	Infiltration Cellular	Histiocyte, Minimal
* Uterus	Hydrometra	Minimal
[ Hydrometra TGLS = 2-8 ]		

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**PRIMARY CAUSE OF DEATH** - Pituitary Gland Pars Distalis Adenoma

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 381

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902101

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

\* Lymph Node, Mandibular

**INSUFFICIENT TISSUE**

\* Thymus

**OBSERVATIONS**

* Bone Marrow		Lymphoma Malignant	
* Intestine Large, Rectum		Infiltration Cellular	Histiocyte, Minimal
		Inflammation	Chronic Active, Mild
		Metaplasia	Squamous, Minimal
		Myxomatous Change	Minimal
		Necrosis	Minimal
* Liver		Basophilic Focus	
		Eosinophilic Focus	
		Inflammation	Chronic, Mild
[ Basophilic Focus TGLS = 1-4 ]			
* Lung	Alveolus	Infiltration Cellular	Histiocyte, Mild
Lymph Node	Pancreatic	Hyperplasia	Lymphoid, Marked
	Renal	Lymphoma Malignant	
Mesentery		Inflammation	Chronic Active, Mild
	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-10 ]			
* Spleen		Lymphoma Malignant	

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 381

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902101

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* Uterus

Hydrometra

Mild

[ Hydrometra TGLS = 2-8 ]

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 382

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 579

**DOSE:** 504 MG/KG

**DISP:** Moribund Sacrifice

**HISTO:** 9902102

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular
* Lymph Node, Mesenteric	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	* Uterus

**OBSERVATIONS**

* Brain		Meningioma Malignant	
[ Meningioma Malignant TGLS = 1-1 ]			
* Intestine Large, Cecum		Ulcer	Minimal
* Intestine Large, Rectum		Inflammation	Chronic Active, Mild
		Metaplasia	Squamous, Mild
		Myxomatous Change	Moderate
		Necrosis	Marked
* Kidney	Renal Tubule	Vacuolization Cytoplasmic	Moderate
Note: Vacuoles were most likely fat.			
[ Vacuolization Cytoplasmic TGLS = 4-5 ]			
* Liver		Fatty Change	Marked
		Inflammation	Chronic, Minimal
[ Fatty Change TGLS = 3-4 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-10 ]			
* Spleen		Hematopoietic Cell Proliferation	Mild
		Infiltration Cellular	Histiocyte, Minimal

**PRIMARY CAUSE OF DEATH**

- Brain Meningioma Malignant

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 383

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902103

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Mammary Gland	* Nose	* Ovary	* Parathyroid Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Lymph Node, Mandibular

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Mild
* Intestine Large, Rectum		Myxomatous Change	Minimal
* Kidney		Lymphoma Malignant	
		Metaplasia	Osseous, Minimal
* Liver		Lymphoma Malignant	
Note: TGL 4, "focus, 1x1mm, tan" noted at necropsy, was not apparent microscopically.			
[ Lymphoma Malignant TGLS = 5-4 ]			
* Lym Node Mand			
Note: TGL 6, "enlarged, 2x" noted at necropsy, was not apparent microscopically.			
Lymph Node	Renal	Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 7-11 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 1-12 ]			
* Pancreas		Lymphoma Malignant	
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Infiltration Cellular	Histiocyte, Minimal
		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 2-4 ]			
* Uterus		Hydrometra	Mild

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 383

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902103

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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[ Hydrometra TGLS = 3-8 ]

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 384

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902104

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney
* Lung	* Lymph Node, Mandibular	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**OBSERVATIONS**

* Bone		Fibrous Osteodystrophy	Mild
* Intestine Large, Rectum		Myxomatous Change	Minimal
* Liver		Clear Cell Focus	
		Inflammation	Chronic, Minimal
Note: TGL 3, "focus, 1mm dia, dark" noted at trim, was normal vein filled with blood.			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
	[ Necrosis TGLS = 4-11 ]		
* Ovary		Angiectasis	Mild
	[ Hemangioma TGLS = 2-7 ]	Hemangioma	
* Spleen		Infiltration Cellular	Histiocyte, Minimal
* Uterus		Hyperplasia	Cystic, Mild
	[ Hyperplasia TGLS = 1-8 ]		

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 385

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902105

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Islets, Pancreatic	* Kidney	* Lung
* Lymph Node, Mandibular	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

**OBSERVATIONS**

* Gallbladder		Degeneration	Hyaline, Marked
* Intestine Large, Rectum		Myxomatous Change	Minimal
* Intestine Small, Jejunum		Inflammation	Acute, Mild
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Inflammation	Chronic, Minimal
[ Clear Cell Focus TGLS = 2-4 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Moderate
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-10 ]			
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Infiltration Cellular	Histiocyte, Minimal
* Uterus			

Note: TGL 1, "dilated, 1.5x" noted at necropsy, was within normal limits microscopically.

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

<b>ANIMAL ID:</b> 386	<b>TRT#:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 504 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9902106

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**OBSERVATIONS**

Eye [ Inflammation TGLS = 1-10 ]	Cornea	Inflammation	Chronic, Mild
Harderian Gland [ Carcinoma TGLS = 2-10 ]		Carcinoma Hyperplasia	Mild
* Kidney		Infarct	Minimal
* Liver		Clear Cell Focus Inflammation	Chronic, Moderate
* Lung [ Carcinoma TGLS = 6-3 ]		Carcinoma	Metastatic (Harderian Gland)
* Ovary [ Cyst TGLS = 5-7 ]		Cyst	Mild
* Pituitary Gland [ Adenoma TGLS = 3-8 ]	Pars Distalis	Adenoma	
* Spleen		Hematopoietic Cell Proliferation	Minimal
* Stom Forestom			
Note: TGL 7, "lesion, 2x4mm, pale" noted at trim, was not apparent microscopically.			
* Uterus [ Hyperplasia TGLS = 4-8 ]		Hyperplasia	Cystic, Mild

PRIMARY CAUSE OF DEATH -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 387

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902107

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

**MISSING**

\* Lymph Node, Mandibular

**OBSERVATIONS**

* Intestine Large, Rectum	Inflammation	Chronic Active, Mild
	Metaplasia	Squamous, Minimal
	Necrosis	Mild
* Kidney	Nephropathy	Minimal
* Liver	Hemangiosarcoma	
	Inflammation	Chronic, Mild
[ Hemangiosarcoma TGLS = 3-4 ]		
Mesentery	Hemangiosarcoma	
[ Hemangiosarcoma TGLS = 4-10 ]		
* Spleen	Hematopoietic Cell Proliferation	Mild
[ Hematopoietic Cell Proliferation TGLS = 2-4 ]		
* Uterus	Hyperplasia	Cystic, Mild
[ Hyperplasia TGLS = 1-8 ]		

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 388

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902108

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

* Clitoral Gland	* Lymph Node, Mandibular
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**OBSERVATIONS**

* Gallbladder		Cyst	Mild
* Int Lg Cecum			
Note: TGL 5, "nodule, 3mm dia, pale" noted at trim, was normal Peyer's patch.			
* Intestine Large, Rectum		Myxomatous Change	Minimal
* Kidney		Nephropathy	Mild
* Liver		Inflammation	Chronic, Minimal
Note: TGL 4, "focus, 2mm dia, pale" noted at trim, was not apparent microscopically.			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 6-12 ]			
* Ovary		Cyst	Moderate
[ Cyst TGLS = 2-7 ]			
* Spleen		Hematopoietic Cell Proliferation	Mild
		Infiltration Cellular	Histiocyte, Minimal
[ Hematopoietic Cell Proliferation TGLS = 3-4 ]			
* Uterus		Angiectasis	Marked
[ Angiectasis TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 389

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 698

**DOSE:** 504 MG/KG

**DISP:** Natural Death

**HISTO:** 9902109

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Colon	* Intestine Large, Rectum	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Islets, Pancreatic	* Lung	* Lymph Node, Mandibular	* Lymph Node, Mesenteric
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Pituitary Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thyroid Gland	* Trachea	* Urinary Bladder
* Uterus			

**MISSING**

* Clitoral Gland	* Parathyroid Gland	* Thymus
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**AUTO PRECLUDES DIAG.**

* Gallbladder	* Intestine Large, Cecum	* Intestine Small, Jejunum
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**OBSERVATIONS**

* Kidney		Nephropathy	Minimal
* Liver		Hemangiosarcoma	
		Hepatocellular Carcinoma	
		Inflammation	Chronic, Minimal
[ Hemangiosarcoma TGLS = 3-11 ]			
[ Hepatocellular Carcinoma TGLS = 2-10 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 4-12 ]			
* Spleen		Hematopoietic Cell Proliferation	Moderate
[ Hematopoietic Cell Proliferation TGLS = 1-4 ]			

**PRIMARY CAUSE OF DEATH**

- Liver Hepatocellular Carcinoma

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 390

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902110

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Mammary Gland	* Nose
* Ovary	* Pancreas	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

\* Gallbladder

**OBSERVATIONS**

* Adrenal Cortex		Lymphoma Malignant	
* Intestine Large, Rectum		Inflammation	Chronic Active, Mild
		Metaplasia	Squamous, Mild
		Myxomatous Change	Mild
		Necrosis	Mild
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Fatty Change	Mild
		Hepatocellular Adenoma	Multiple
		Inflammation	Chronic, Minimal
[ Clear Cell Focus TGLS = 8-4 ]			
[ Hepatocellular Adenoma TGLS = 2,3,4,5-4+11+10+12 ]			
* Lung		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 7-3 ]			
Lymph Node	Mediastinal	Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 6-2 ]			
* Lymph Node, Mandibular		Lymphoma Malignant	
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
		Lymphoma Malignant	

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 390	<b>TRT#:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 729
	<b>DOSE:</b> 504 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9902110

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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Mesentery		Lymphoma Malignant	
	Fat	Necrosis	Mild
[ Necrosis TGLS = 9-13 ]			
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Infiltration Cellular	Histiocyte, Minimal
* Stomach, Forestomach		Lymphoma Malignant	
* Stomach, Glandular		Lymphoma Malignant	
* Uterus		Hydrometra	Minimal
[ Hydrometra TGLS = 1-8 ]			

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 391      **TRT#:** 8      **SEX:** Female      **DAY ON TEST:** 729  
**DOSE:** 504 MG/KG      **DISP:** Terminal Sacrifice      **HISTO:** 9902111

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Esophagus	* Gallbladder	* Heart	* Intestine Large, Cecum
* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum
* Islets, Pancreatic	* Lymph Node, Mandibular	* Lymph Node, Mesenteric	* Mammary Gland
* Nose	* Ovary	* Pancreas	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland
* Trachea	* Urinary Bladder		

**MISSING**

* Clitoral Gland	* Parathyroid Gland	* Thymus
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**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
Eye	Cornea	Inflammation	Acute, Marked
[ Inflammation TGLS = 1-10 ]			
Harderian Gland		Carcinoma	
[ Carcinoma TGLS = 2-10 ]			
* Intestine Large, Rectum		Myxomatous Change	Mild
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Inflammation	Chronic, Mild
* Lung		Carcinoma	Metastatic (Harderian Gland)
[ Carcinoma TGLS = 3-3 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 5-11 ]			
* Pituitary Gland	Pars Distalis	Hyperplasia	Minimal
* Spleen		Hematopoietic Cell Proliferation	Minimal
		Infiltration Cellular	Histiocyte, Minimal
* Uterus		Hydrometra	Moderate
[ Hydrometra TGLS = 4-8 ]			

PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 391

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902111

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

<b>ANIMAL ID:</b> 392	<b>TRT#:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 730
	<b>DOSE:</b> 504 MG/KG	<b>DISP:</b> Terminal Sacrifice	<b>HISTO:</b> 9902112

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Mammary Gland	* Nose	* Ovary	* Pancreas
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thyroid Gland	* Trachea	* Urinary Bladder	

**MISSING**

* Lymph Node, Mandibular	* Parathyroid Gland	* Thymus
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**OBSERVATIONS**

* Intestine Large, Rectum		Inflammation Metaplasia Myxomatous Change Necrosis	Chronic Active, Mild Squamous, Minimal Mild
* Kidney		Nephropathy	Minimal
* Liver		Basophilic Focus Inflammation	Chronic, Mild
[ Basophilic Focus TGLS = 3-4 ]			
* Lung		Alveolar/Bronchiolar Adenoma	
[ Alveolar/Bronchiolar Adenoma TGLS = 4-3 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 6-10 ]			
* Pituitary Gland	Pars Intermed	Adenoma	
[ Adenoma TGLS = 5-8 ]			
* Spleen		Congestion Infiltration Cellular	Mild Histiocyte, Minimal
[ Congestion TGLS = 2-4 ]			
* Uterus		Hyperplasia	Cystic, Moderate
[ Hyperplasia TGLS = 1-8 ]			

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 392

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902112

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 393

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902113

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mesenteric	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**OBSERVATIONS**

* Intestine Large, Rectum		Inflammation	Chronic Active, Moderate
		Metaplasia	Squamous, Mild
		Myxomatous Change	Mild
		Necrosis	Moderate
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Fatty Change	Minimal
		Hepatocellular Adenoma	Multiple
		Inflammation	Chronic, Mild
[ Clear Cell Focus TGLS = 4,5-10+4 ]			
[ Hepatocellular Adenoma TGLS = 2,3-4+11 ]			
* Lymph Node, Mandibular		Lymphoma Malignant	
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 6-12 ]			
* Ovary		Lymphoma Malignant	
* Spleen		Infiltration Cellular	Histiocyte, Minimal
* Uterus		Hyperplasia	Cystic, Mild
[ Hyperplasia TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH** -

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 394      **TRT#:** 8      **SEX:** Female      **DAY ON TEST:** 729  
**DOSE:** 504 MG/KG      **DISP:** Terminal Sacrifice      **HISTO:** 9902114

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney
* Lung	* Lymph Node, Mandibular	* Mammary Gland	* Nose
* Pancreas	* Parathyroid Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thymus	* Thyroid Gland
* Trachea	* Urinary Bladder	* Uterus	

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Minimal
* Clitoral GI			
Note: TGL 3, "focus, 2x2mm, dark" noted at necropsy, was not apparent microscopically.			
* Intestine Large, Rectum		Myxomatous Change	Minimal
* Liver		Clear Cell Focus	
		Inflammation	Chronic, Mild
Note: TGL 5, "focus, 1-2mm dia, two, pale" noted at trim, was not apparent microscopically.			
[ Clear Cell Focus TGLS = 4-4 ]			
* Lymph Node, Mesenteric		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 6-6 ]			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 7-11 ]			
* Ovary		Angiectasis	Marked
[ Angiectasis TGLS = 2-7 ]			
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 1-4 ]			

PRIMARY CAUSE OF DEATH

-

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>ANIMAL ID:</b> 395	<b>TRT#:</b> 8	<b>SEX:</b> Female	<b>DAY ON TEST:</b> 645
	<b>DOSE:</b> 504 MG/KG	<b>DISP:</b> Natural Death	<b>HISTO:</b> 9902115

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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**NORMAL**

* Bone	* Brain	Harderian Gland	* Heart
* Lung	* Mammary Gland	* Nose	* Skin
* Uterus			

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**MISSING**

* Clitoral Gland	* Lymph Node, Mandibular	* Ovary	* Salivary Glands
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**AUTO PRECLUDES DIAG.**

* Adrenal Cortex	* Adrenal Medulla	* Bone Marrow	* Esophagus
* Gallbladder	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Large, Rectum
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Kidney	* Lymph Node, Mesenteric	* Pancreas	* Parathyroid Gland
* Pituitary Gland	* Spleen	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder

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**OBSERVATIONS**

* Liver		Hemangiosarcoma	
Note: TGL 1, "small, 0.7x" noted at necropsy, was not apparent microscopically.			
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2-10 ]			

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**PRIMARY CAUSE OF DEATH** - Liver Hemangiosarcoma

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 396

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902116

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Kidney
* Lung	* Lymph Node, Mandibular	* Mammary Gland	* Pancreas
* Parathyroid Gland	* Pituitary Gland	* Salivary Glands	* Skin
* Stomach, Forestomach	* Stomach, Glandular	* Thyroid Gland	* Trachea
* Urinary Bladder			

**MISSING**

\* Thymus

**OBSERVATIONS**

* Bone		Fibrous Osteodystrophy	Mild
* Intestine Large, Rectum		Inflammation	Chronic Active, Moderate
		Necrosis	Moderate
* Liver		Inflammation	Chronic, Minimal
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Minimal
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 3-10 ]			
* Nose		Inflammation	Suppurative, Minimal
* Ovary		Cyst	Mild
* Spleen		Hematopoietic Cell Proliferation	Mild
[ Hematopoietic Cell Proliferation TGLS = 2-4 ]			
* Uterus		Hydrometra	Mild
[ Hydrometra TGLS = 1-8 ]			

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 397

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902117

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Brain
* Esophagus	* Gallbladder	Harderian Gland	* Heart
* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum	* Intestine Small, Ileum
* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung	* Mammary Gland
* Nose	* Ovary	* Parathyroid Gland	* Pituitary Gland
* Salivary Glands	* Skin	* Stomach, Forestomach	* Stomach, Glandular
* Thymus	* Thyroid Gland	* Trachea	* Urinary Bladder
* Uterus			

**INSUFFICIENT TISSUE**

\* Clitoral Gland

**OBSERVATIONS**

* Bone Marrow		Lymphoma Malignant	
* Intestine Large, Rectum		Inflammation	Chronic Active, Mild
		Myxomatous Change	Mild
		Necrosis	Mild
* Kidney		Nephropathy	Minimal
* Liver		Clear Cell Focus	
		Eosinophilic Focus	
		Inflammation	Chronic, Minimal
		Lymphoma Malignant	
[ Clear Cell Focus TGLS = 5-10 ]			
Lymph Node	Bronchial	Lymphoma Malignant	
	Mediastinal	Lymphoma Malignant	
	Renal	Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 3-2 ]			
* Lymph Node, Mandibular		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 4-7 ]			
* Lymph Node, Mesenteric		Lymphoma Malignant	
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 2,6-11+12 ]			

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 397

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 730

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902117

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* Pancreas

Lymphoma Malignant

\* Spleen

Lymphoma Malignant

[ Lymphoma Malignant TGLS = 1-4 ]

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PRIMARY CAUSE OF DEATH

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\* PROTOCOL REQUIRED TISSUE



**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 398

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902118

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lung	* Lymph Node, Mandibular	* Mammary Gland	* Nose
* Parathyroid Gland	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Thyroid Gland	* Trachea
* Urinary Bladder			

**OBSERVATIONS**

* Intestine Large, Rectum		Infiltration Cellular Inflammation Necrosis	Histiocyte, Minimal Chronic Active, Moderate Mild
* Kidney		Nephropathy	Minimal
* Liver		Eosinophilic Focus Inflammation	Chronic, Mild
[ Eosinophilic Focus TGLS = 3-4 ]			
* Lymph Node, Mesenteric		Infiltration Cellular Necrosis	Histiocyte, Mild Moderate
Mesentery	Fat		
[ Necrosis TGLS = 4-10 ]			
* Ovary		Cyst	Mild
[ Cyst TGLS = 1-7 ]			
* Pancreas		Basophilic Focus	
* Pituitary Gland	Pars Distalis	Hyperplasia	Mild
* Spleen		Infiltration Cellular	Histiocyte, Minimal
* Uterus		Hydrometra	Minimal
[ Hydrometra TGLS = 2-8 ]			

**PRIMARY CAUSE OF DEATH**

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 399

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902119

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Cortex	* Adrenal Medulla	* Bone	* Bone Marrow
* Brain	* Clitoral Gland	* Esophagus	* Gallbladder
Harderian Gland	* Heart	* Intestine Large, Cecum	* Intestine Large, Colon
* Intestine Small, Duodenum	* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic
* Lymph Node, Mandibular	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Salivary Glands	* Skin	* Stomach, Forestomach
* Stomach, Glandular	* Thymus	* Trachea	* Urinary Bladder

**MISSING**

* Parathyroid Gland	* Thyroid Gland
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**OBSERVATIONS**

* Intestine Large, Rectum		Infiltration Cellular Inflammation Metaplasia Necrosis	Histiocyte, Minimal Chronic Active, Moderate Squamous, Marked Minimal
* Kidney		Metaplasia	Osseous, Minimal
* Liver		Basophilic Focus Clear Cell Focus Fatty Change Hepatocellular Adenoma Inflammation	Minimal Chronic, Moderate
[ Basophilic Focus TGLS = 7-4 ]			
[ Clear Cell Focus TGLS = 8-4 ]			
[ Hepatocellular Adenoma TGLS = 4-10 ]			
* Lung		Alveolar/Bronchiolar Carcinoma	
[ Alveolar/Bronchiolar Carcinoma TGLS = 6-3 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 5,9-12+11 ]			
* Pituitary Gland	Pars Distalis	Hyperplasia	Moderate
[ Hyperplasia TGLS = 3-8 ]			

\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**ANIMAL ID:** 399

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902119

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**ORGAN AND ACCOUNTABLE SITE STATUS**

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\* Spleen

Hematopoietic Cell Proliferation  
Infiltration Cellular

Mild  
Histiocyte, Minimal

[ Hematopoietic Cell Proliferation TGLS = 2-4 ]

\* Uterus

Hyperplasia

Cystic, Moderate

[ Hyperplasia TGLS = 1-8 ]

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PRIMARY CAUSE OF DEATH

-

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\* PROTOCOL REQUIRED TISSUE

**Experiment Number:** 88122-07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P14: INDIVIDUAL ANIMAL PATHOLOGY DATA**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 12:23:18  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**ANIMAL ID:** 400

**TRT#:** 8

**SEX:** Female

**DAY ON TEST:** 729

**DOSE:** 504 MG/KG

**DISP:** Terminal Sacrifice

**HISTO:** 9902120

**ORGAN AND ACCOUNTABLE SITE STATUS**

**NORMAL**

* Adrenal Medulla	* Bone	* Bone Marrow	* Brain
* Clitoral Gland	* Esophagus	* Gallbladder	Harderian Gland
* Heart	* Intestine Large, Cecum	* Intestine Large, Colon	* Intestine Small, Duodenum
* Intestine Small, Ileum	* Intestine Small, Jejunum	* Islets, Pancreatic	* Lung
* Lymph Node, Mandibular	* Mammary Gland	* Nose	* Ovary
* Pancreas	* Parathyroid Gland	* Pituitary Gland	* Salivary Glands
* Skin	* Stomach, Forestomach	* Stomach, Glandular	* Thymus
* Thyroid Gland	* Trachea	* Urinary Bladder	

**OBSERVATIONS**

* Adrenal Cortex		Hypertrophy	Mild
* Intestine Large, Rectum		Inflammation	Chronic Active, Marked
		Metaplasia	Squamous, Mild
		Necrosis	Moderate
* Kidney		Lymphoma Malignant	
		Nephropathy	Minimal
* Liver		Hepatocellular Adenoma	Multiple
		Inflammation	Chronic, Mild
[ Hepatocellular Adenoma TGLS = 3,4,5-10+11+12 ]			
* Lymph Node, Mesenteric		Infiltration Cellular	Histiocyte, Mild
Mesentery	Fat	Necrosis	Mild
[ Necrosis TGLS = 6-13 ]			
* Spleen		Infiltration Cellular	Histiocyte, Minimal
		Lymphoma Malignant	
[ Lymphoma Malignant TGLS = 2-4 ]			
* Uterus		Hydrometra	Moderate
[ Hydrometra TGLS = 1-8 ]			

PRIMARY CAUSE OF DEATH

-

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

\* PROTOCOL REQUIRED TISSUE