

**Experiment Number:** 88122-01  
**Test Type:** 14-DAY  
**Route:** GAVAGE  
**Species/Strain:** Rat/F 344/N

**P02: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (a)**  
**Test Compound:** Elmiron (sodium pentosanpolysulfate)  
**CAS Number:** 37319-17-8

**Date Report Requested:** 10/18/2014  
**Time Report Requested:** 14:05:25  
**First Dose M/F:** NA / NA  
**Lab:** MBA

<b>C Number:</b>	C88122B
<b>Lock Date:</b>	08/21/1995
<b>Cage Range:</b>	All
<b>Date Range:</b>	All
<b>Reasons For Removal:</b>	All
<b>Removal Date Range:</b>	All
<b>Treatment Groups:</b>	All
<b>Study Gender:</b>	Both
<b>PWG Approval Date</b>	NONE

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Lab: MBA

F 344/N Rat MALE	0	MG/KG	33	MG/KG	111	MG/KG	333	MG/KG	1000	MG/KG	3000	MG/KG
<b>Disposition Summary</b>												
Animals Initially In Study	5		5		5		5		5		5	
Early Deaths												
Survivors												
Terminal Sacrifice	5		5		5		5		5		5	
Animals Examined Microscopically	5										5	
<b>ALIMENTARY SYSTEM</b>												
Liver	(5)		(0)		(0)		(0)		(0)		(5)	
Stomach, Forestomach	(5)		(0)		(0)		(0)		(0)		(5)	
<b>CARDIOVASCULAR SYSTEM</b>												
None												
<b>ENDOCRINE SYSTEM</b>												
None												
<b>GENERAL BODY SYSTEM</b>												
None												
<b>GENITAL SYSTEM</b>												
None												
<b>HEMATOPOIETIC SYSTEM</b>												
None												
<b>INTEGUMENTARY SYSTEM</b>												
None												
<b>MUSCULOSKELETAL SYSTEM</b>												
None												
<b>NERVOUS SYSTEM</b>												

a - Number of animals examined microscopically at site and number of animals with lesion

b - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically

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<b>F 344/N Rat MALE</b>	<b>0</b>	<b>MG/KG</b>	<b>33</b>	<b>MG/KG</b>	<b>111</b>	<b>MG/KG</b>	<b>333</b>	<b>MG/KG</b>	<b>1000</b>	<b>MG/KG</b>	<b>3000</b>	<b>MG/KG</b>
None												
RESPIRATORY SYSTEM												
None												
SPECIAL SENSES SYSTEM												
None												
URINARY SYSTEM												
Kidney	(5)		(0)		(0)		(0)		(0)		(5)	
Urinary Bladder	(5)		(0)		(0)		(0)		(0)		(5)	

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a - Number of animals examined microscopically at site and number of animals with lesion

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\* Number of animals with any tissue examined microscopically

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F 344/N Rat MALE	0	MG/KG	33	MG/KG	111	MG/KG	333	MG/KG	1000	MG/KG	3000	MG/KG
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**Tumor Summary for MALE**

**Total Animals with Primary Neoplasms (b)**

**Total Primary Neoplasms**

**Total Animals with Benign Neoplasms**

**Total Benign Neoplasms**

**Total Animals with Malignant Neoplasms**

**Total Malignant Neoplasms**

**Total Animals with Metastatic Neoplasms**

**Total Metastatic Neoplasms**

**Total Animals with Malignant Neoplasms**

**Uncertain Primary Site**

**Total Animals with Neoplasms Uncertain -**

**Benign or Malignant**

**Total Uncertain Neoplasms**

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

a - Number of animals examined microscopically at site and number of animals with lesion

b - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically

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Lab: MBA

F 344/N Rat FEMALE	0	MG/KG	33	MG/KG	111	MG/KG	333	MG/KG	1000	MG/KG	3000	MG/KG
<b>Disposition Summary</b>												
Animals Initially In Study	5		5		5		5		5		5	
Early Deaths												
Survivors												
Terminal Sacrifice	5		5		5		5		5		5	
Animals Examined Microscopically	5								5		5	
<b>ALIMENTARY SYSTEM</b>												
Liver	(5)		(0)		(0)		(0)		(5)		(5)	
Stomach, Forestomach	(5)		(0)		(0)		(0)		(0)		(5)	
<b>CARDIOVASCULAR SYSTEM</b>												
None												
<b>ENDOCRINE SYSTEM</b>												
None												
<b>GENERAL BODY SYSTEM</b>												
None												
<b>GENITAL SYSTEM</b>												
None												
<b>HEMATOPOIETIC SYSTEM</b>												
None												
<b>INTEGUMENTARY SYSTEM</b>												
None												
<b>MUSCULOSKELETAL SYSTEM</b>												
None												
<b>NERVOUS SYSTEM</b>												

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Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/18/2014

Time Report Requested: 14:05:26

First Dose M/F: NA / NA

Lab: MBA

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<b>F 344/N Rat FEMALE</b>	<b>0</b>	<b>MG/KG</b>	<b>33</b>	<b>MG/KG</b>	<b>111</b>	<b>MG/KG</b>	<b>333</b>	<b>MG/KG</b>	<b>1000</b>	<b>MG/KG</b>	<b>3000</b>	<b>MG/KG</b>
None												
RESPIRATORY SYSTEM												
None												
SPECIAL SENSES SYSTEM												
None												
URINARY SYSTEM												
Kidney	(5)		(0)		(0)		(0)		(0)		(5)	
Urinary Bladder	(5)		(0)		(0)		(0)		(0)		(5)	

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a - Number of animals examined microscopically at site and number of animals with lesion

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**Lab:** MBA

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**F 344/N Rat FEMALE**

**0 MG/KG**

**33 MG/KG**

**111 MG/KG**

**333 MG/KG**

**1000 MG/KG**

**3000 MG/KG**

---

**Tumor Summary for FEMALE**

**Total Animals with Primary Neoplasms (b)**

**Total Primary Neoplasms**

**Total Animals with Benign Neoplasms**

**Total Benign Neoplasms**

**Total Animals with Malignant Neoplasms**

**Total Malignant Neoplasms**

**Total Animals with Metastatic Neoplasms**

**Total Metastatic Neoplasms**

**Total Animals with Malignant Neoplasms**

**Uncertain Primary Site**

**Total Animals with Neoplasms Uncertain -**

**Benign or Malignant**

**Total Uncertain Neoplasms**

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

a - Number of animals examined microscopically at site and number of animals with lesion

b - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically