

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

**P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS
ABRIDGED) (a)**

Test Compound: Elmiron (sodium pentosanpolysulfate)
CAS Number: 37319-17-8

Date Report Requested: 10/19/2014
Time Report Requested: 16:06:18
First Dose M/F: NA / NA
Lab: BAT

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

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First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat MALE	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Disposition Summary						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Dosing Accident		1			1	2
Survivors						
Terminal Sacrifice	10	9	10	10	9	8
Animals Examined Microscopically	10	10	10	10	10	10
ALIMENTARY SYSTEM						
Esophagus	(10)	(1)	(0)	(0)	(2)	(10)
Intestine Large, Cecum	(10)	(1)	(0)	(0)	(1)	(10)
Intestine Large, Colon	(10)	(1)	(0)	(0)	(1)	(10)
Intestine Large, Rectum	(10)	(10)	(10)	(10)	(10)	(9)
Intestine Small, Duodenum	(10)	(1)	(0)	(0)	(1)	(10)
Intestine Small, Ileum	(10)	(1)	(0)	(0)	(1)	(10)
Intestine Small, Jejunum	(10)	(1)	(0)	(0)	(1)	(10)
Liver	(10)	(2)	(2)	(10)	(10)	(10)
Pancreas	(10)	(1)	(0)	(0)	(1)	(10)
Salivary Glands	(10)	(1)	(0)	(0)	(1)	(10)
Stomach, Forestomach	(10)	(1)	(0)	(0)	(1)	(10)
Stomach, Glandular	(10)	(1)	(0)	(0)	(1)	(9)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(1)	(0)	(0)	(1)	(10)
Heart	(10)	(1)	(0)	(0)	(1)	(10)
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(1)	(0)	(0)	(1)	(10)
Adrenal Medulla	(10)	(1)	(0)	(0)	(1)	(10)

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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Islets, Pancreatic	(10)	(1)	(0)	(0)	(1)	(10)
Parathyroid Gland	(9)	(1)	(0)	(0)	(1)	(8)
Pituitary Gland	(9)	(1)	(0)	(0)	(0)	(10)
Thyroid Gland	(10)	(1)	(0)	(0)	(1)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Epididymis	(10)	(1)	(0)	(0)	(1)	(10)
Preputial Gland	(10)	(1)	(0)	(0)	(1)	(10)
Prostate	(10)	(1)	(0)	(0)	(1)	(10)
Seminal Vesicle	(10)	(1)	(0)	(0)	(1)	(10)
Testes	(10)	(1)	(0)	(0)	(1)	(10)
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(1)	(0)	(0)	(1)	(10)
Lymph Node, Mandibular	(10)	(1)	(10)	(10)	(10)	(10)
Lymph Node, Mesenteric	(10)	(1)	(10)	(10)	(10)	(9)
Spleen	(10)	(1)	(0)	(10)	(10)	(10)
Thymus	(10)	(1)	(0)	(0)	(1)	(10)
INTEGUMENTARY SYSTEM						
Mammary Gland	(6)	(1)	(0)	(0)	(1)	(7)
Skin	(10)	(1)	(0)	(0)	(1)	(10)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(1)	(0)	(0)	(1)	(10)
NERVOUS SYSTEM						
Brain	(10)	(1)	(0)	(0)	(1)	(10)
Peripheral Nerve	(0)	(1)	(0)	(0)	(0)	(0)

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Lab: BAT

F 344/N Rat MALE	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Spinal Cord	(0)	(1)	(0)	(0)	(0)	(0)
RESPIRATORY SYSTEM						
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Nose	(10)	(1)	(0)	(0)	(1)	(10)
Trachea	(10)	(1)	(0)	(0)	(1)	(10)
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
Kidney	(10)	(1)	(0)	(0)	(10)	(9)
Urinary Bladder	(10)	(1)	(0)	(0)	(1)	(10)

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Lab: BAT

F 344/N Rat MALE

0 MG/KG

63 MG/KG

125 MG/KG

250 MG/KG

500 MG/KG

1000 MG/KG

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

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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First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat FEMALE	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Disposition Summary						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Survivors						
Terminal Sacrifice	10	10	10	10	10	10
Animals Examined Microscopically	10	10	10	10	10	10
ALIMENTARY SYSTEM						
Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(1)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(10)	(10)	(10)	(10)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(0)	(10)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
Heart	(10)	(0)	(0)	(0)	(0)	(10)
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)

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

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Parathyroid Gland	(10)	(0)	(0)	(0)	(0)	(9)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(9)	(0)	(0)	(0)	(0)	(10)
Ovary	(10)	(0)	(0)	(1)	(0)	(10)
Uterus	(10)	(0)	(0)	(0)	(0)	(10)
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mandibular	(10)	(1)	(2)	(10)	(10)	(10)
Lymph Node, Mesenteric	(10)	(2)	(5)	(7)	(10)	(10)
Spleen	(10)	(0)	(0)	(0)	(10)	(10)
Thymus	(10)	(0)	(0)	(0)	(0)	(10)
INTEGUMENTARY SYSTEM						
Mammary Gland	(9)	(0)	(0)	(0)	(0)	(10)
Skin	(10)	(0)	(0)	(0)	(0)	(10)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(0)	(10)
RESPIRATORY SYSTEM						
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Nose	(10)	(0)	(0)	(0)	(0)	(10)

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Trachea	(10)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(0)	(10)	(10)
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

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First Dose M/F: NA / NA
Lab: BAT

F 344/N Rat FEMALE

0 MG/KG

63 MG/KG

125 MG/KG

250 MG/KG

500 MG/KG

1000 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

**** 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