

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

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)**

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

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

**Date Report Requested:** 10/19/2014

**Time Report Requested:** 16:06:10

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

**Lab:** BAT

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

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Species/Strain: Rat/F 344/N

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
<b>Disposition Summary</b>						
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
<b>ALIMENTARY SYSTEM</b>						
Esophagus	(10)	(1)	(0)	(0)	(2)	(10)
Muscularis, Inflammation, Chronic Ulcer	4 (40%)				1 (50%)	7 (70%)
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)
Infiltration Cellular, Histiocyte			3 (30%)	7 (70%)	9 (90%)	8 (89%)
Inflammation, Chronic Active			2 (20%)	7 (70%)	8 (80%)	8 (89%)
Ulcer, Chronic			1 (10%)	3 (30%)	7 (70%)	7 (78%)
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)
Hepatodiaphragmatic Nodule		2 (100%)	2 (100%)		1 (10%)	4 (40%)
Inflammation	2 (20%)			1 (10%)	1 (10%)	
Inflammation, Granulomatous					4 (40%)	6 (60%)
Midzonal, Vacuolization Cytoplasmic		1 (50%)			4 (40%)	8 (80%)
Pancreas	(10)	(1)	(0)	(0)	(1)	(10)
Acinus, Atrophy						2 (20%)
Atrophy, Acute	1 (10%)					
Hemorrhage					1 (100%)	

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

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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
Salivary Glands	(10)	(1)	(0)	(0)	(1)	(10)
Stomach, Forestomach	(10)	(1)	(0)	(0)	(1)	(10)
Hemorrhage					1 (100%)	
Stomach, Glandular	(10)	(1)	(0)	(0)	(1)	(9)
<b>CARDIOVASCULAR SYSTEM</b>						
Blood Vessel	(10)	(1)	(0)	(0)	(1)	(10)
Heart	(10)	(1)	(0)	(0)	(1)	(10)
Myocardium, Degeneration	8 (80%)					7 (70%)
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(1)	(0)	(0)	(1)	(10)
Adrenal Medulla	(10)	(1)	(0)	(0)	(1)	(10)
Islets, Pancreatic	(10)	(1)	(0)	(0)	(1)	(10)
Parathyroid Gland	(9)	(1)	(0)	(0)	(1)	(8)
Pituitary Gland	(9)	(1)	(0)	(0)	(0)	(10)
Pars Distalis, Hyperplasia, Focal						1 (10%)
Thyroid Gland	(10)	(1)	(0)	(0)	(1)	(10)
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Epididymis	(10)	(1)	(0)	(0)	(1)	(10)
Inflammation, Chronic						1 (10%)
Preputial Gland	(10)	(1)	(0)	(0)	(1)	(10)
Prostate	(10)	(1)	(0)	(0)	(1)	(10)
Inflammation, Chronic						1 (10%)
Seminal Vesicle	(10)	(1)	(0)	(0)	(1)	(10)
Inflammation, Chronic						1 (10%)
Testes	(10)	(1)	(0)	(0)	(1)	(10)
<b>HEMATOPOIETIC SYSTEM</b>						

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Bone Marrow	(10)	(1)	(0)	(0)	(1)	(10)
Lymph Node, Mandibular	(10)	(1)	(10)	(10)	(10)	(10)
Infiltration Cellular, Histiocyte				3 (30%)	8 (80%)	7 (70%)
Lymph Node, Mesenteric	(10)	(1)	(10)	(10)	(10)	(9)
Infiltration Cellular, Histiocyte				6 (60%)	8 (80%)	8 (89%)
Spleen	(10)	(1)	(0)	(10)	(10)	(10)
Lymph Follic, Depletion Cellular					1 (10%)	1 (10%)
Thymus	(10)	(1)	(0)	(0)	(1)	(10)
Atrophy					1 (100%)	
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)
Spinal Cord	(0)	(1)	(0)	(0)	(0)	(0)
RESPIRATORY SYSTEM						
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Alveolus, Infiltration Cellular, Histiocyte		2 (20%)	5 (50%)	6 (60%)	10 (100%)	8 (80%)
Congestion						1 (10%)
Hemorrhage						1 (10%)
Inflammation, Acute					1 (10%)	
Interstitial, Edema		1 (10%)				2 (20%)
Interstitial, Inflammation, Chronic					1 (10%)	3 (30%)
Nose	(10)	(1)	(0)	(0)	(1)	(10)
Trachea	(10)	(1)	(0)	(0)	(1)	(10)

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F 344/N Rat MALE	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Hemorrhage					1 (100%)	
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
Kidney	(10)	(1)	(0)	(0)	(10)	(9)
Hemorrhage						1 (11%)
Infarct	1 (10%)					
Inflammation					1 (10%)	1 (11%)
Renal Tubule, Cyst	2 (20%)					
Renal Tubule, Necrosis					1 (10%)	
Renal Tubule, Vacuolization Cytoplasmic						8 (89%)
Urinary Bladder	(10)	(1)	(0)	(0)	(1)	(10)

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

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<b>Disposition Summary</b>						
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
<b>ALIMENTARY SYSTEM</b>						
Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Muscularis, Inflammation, Chronic	4 (40%)					7 (70%)
Intestine Large, Cecum	(10)	(0)	(0)	(1)	(0)	(10)
Infiltration Cellular, Histiocyte				1 (100%)		
Inflammation, Chronic Active						1 (10%)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Histiocyte		2 (20%)	1 (10%)	2 (20%)	10 (100%)	10 (100%)
Inflammation, Chronic Active					9 (90%)	10 (100%)
Ulcer, Chronic					6 (60%)	8 (80%)
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)
Hepatodiaphragmatic Nodule	1 (10%)			1 (10%)		1 (10%)
Inflammation, Granulomatous	9 (90%)	10 (100%)	10 (100%)	10 (100%)	9 (90%)	10 (100%)
Midzonal, Vacuolization Cytoplasmic						7 (70%)
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Acinus, Atrophy	2 (20%)					
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)

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F 344/N Rat FEMALE	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>CARDIOVASCULAR SYSTEM</b>						
Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Myocardium, Degeneration	2 (20%)					5 (50%)
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(10)	(0)	(0)	(0)	(0)	(9)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Clitoral Gland	(9)	(0)	(0)	(0)	(0)	(10)
Ovary	(10)	(0)	(0)	(1)	(0)	(10)
Cyst	1 (10%)			1 (100%)		1 (10%)
Uterus	(10)	(0)	(0)	(0)	(0)	(10)
Endometrium, Hyperplasia, Cystic	1 (10%)					
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mandibular	(10)	(1)	(2)	(10)	(10)	(10)
Infiltration Cellular, Histiocyte		1 (100%)	2 (100%)	3 (30%)	3 (30%)	10 (100%)
Lymph Node, Mesenteric	(10)	(2)	(5)	(7)	(10)	(10)
Infiltration Cellular, Histiocyte		2 (100%)	5 (100%)	7 (100%)	7 (70%)	10 (100%)
Spleen	(10)	(0)	(0)	(0)	(10)	(10)
Capsule, Inflammation, Focal						1 (10%)
Thymus	(10)	(0)	(0)	(0)	(0)	(10)

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F 344/N Rat FEMALE	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(9)	(0)	(0)	(0)	(0)	(10)
Skin	(10)	(0)	(0)	(0)	(0)	(10)
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
<b>NERVOUS SYSTEM</b>						
Brain	(10)	(0)	(0)	(0)	(0)	(10)
<b>RESPIRATORY SYSTEM</b>						
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Alveolus, Foreign Body					1 (10%)	
Alveolus, Infiltration Cellular, Histiocyte		7 (70%)	5 (50%)	6 (60%)	7 (70%)	9 (90%)
Bronchiole, Foreign Body		1 (10%)				
Hematopoietic Cell Proliferation						1 (10%)
Infiltration Cellular, Histiocyte				1 (10%)		
Interstitial, Inflammation, Chronic		1 (10%)		1 (10%)	3 (30%)	6 (60%)
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
<b>SPECIAL SENSES SYSTEM</b>						
None						
<b>URINARY SYSTEM</b>						
Kidney	(10)	(0)	(0)	(0)	(10)	(10)
Renal Tubule, Vacuolization Cytoplasmic						10 (100%)
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

\*\* END OF REPORT \*\*

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