

Experiment Number: 88122-04
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Mouse/B6C3F1

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

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/22/2014

Time Report Requested: 01:47:28

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

Experiment Number: 88122-04

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

Date Report Requested: 10/22/2014

Test Type: 90-DAY

Test Compound: Elmiron (sodium pentosanpolysulfate)

Time Report Requested: 01:47:28

Route: GAVAGE

CAS Number: 37319-17-8

First Dose M/F: NA / NA

Species/Strain: Mouse/B6C3F1

Lab: BAT

B6C3F1 Mouse 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						
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)	(9)
Inflammation, Focal	1 (10%)					1 (11%)
Gallbladder	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation	1 (10%)					
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Histiocyte				3 (30%)	3 (30%)	10 (100%)
Inflammation						8 (80%)
Ulcer						2 (20%)
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)	(2)	(0)	(10)	(10)	(10)
Clear Cell Focus					1 (10%)	1 (10%)
Inflammation	5 (50%)	2 (100%)		7 (70%)	6 (60%)	10 (100%)
Vacuolization Cytoplasmic					4 (40%)	9 (90%)
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)
Inflammation						1 (10%)

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

Experiment Number: 88122-04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Mouse/B6C3F1

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

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/22/2014

Time Report Requested: 01:47:28

First Dose M/F: NA / NA

Lab: BAT

B6C3F1 Mouse MALE	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
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)
Parathyroid Gland	(7)	(0)	(0)	(0)	(0)	(5)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(9)
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Epididymis	(10)	(0)	(0)	(0)	(0)	(10)
Preputial Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation						1 (10%)
Prostate	(10)	(0)	(0)	(0)	(0)	(10)
Seminal Vesicle	(10)	(0)	(0)	(0)	(0)	(10)
Testes	(10)	(0)	(0)	(0)	(0)	(10)
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mandibular	(10)	(8)	(10)	(10)	(10)	(10)
Infiltration Cellular, Histiocyte		1 (13%)	3 (30%)	9 (90%)	10 (100%)	8 (80%)
Inflammation, Suppurative				1 (10%)		
Lymph Node, Mesenteric	(10)	(10)	(10)	(10)	(10)	(10)
Ectasia				1 (10%)		
Infiltration Cellular, Histiocyte			4 (40%)	10 (100%)	10 (100%)	10 (100%)
Inflammation, Suppurative						1 (10%)

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

Experiment Number: 88122-04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Mouse/B6C3F1

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

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/22/2014

Time Report Requested: 01:47:28

First Dose M/F: NA / NA

Lab: BAT

B6C3F1 Mouse MALE	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Spleen	(10)	(0)	(0)	(0)	(10)	(10)
Infiltration Cellular, Histiocyte						9 (90%)
Thymus	(10)	(0)	(0)	(0)	(0)	(9)
INTEGUMENTARY SYSTEM						
Mammary Gland	(1)	(0)	(0)	(0)	(0)	(0)
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)	(0)	(0)	(0)	(0)	(10)
Inflammation						1 (10%)
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
Kidney	(10)	(1)	(1)	(0)	(0)	(10)
Nephropathy		1 (100%)	1 (100%)			2 (20%)
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

END OF MALE DATA

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

Experiment Number: 88122-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/B6C3F1

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)
 Test Compound: Elmiron (sodium pentosanpolysulfate)
 CAS Number: 37319-17-8

Date Report Requested: 10/22/2014
 Time Report Requested: 01:47:28
 First Dose M/F: NA / NA
 Lab: BAT

B6C3F1 Mouse 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						
Moribund Sacrifice				1		
Survivors						
Terminal Sacrifice	10	10	10	9	10	10
Animals Examined Microscopically	10	10	10	10	10	10
ALIMENTARY SYSTEM						
Esophagus	(10)	(0)	(0)	(1)	(0)	(10)
Inflammation, Focal	2 (20%)					4 (40%)
Gallbladder	(10)	(0)	(0)	(1)	(0)	(10)
Inflammation, Acute						1 (10%)
Intestine Large, Cecum	(10)	(0)	(0)	(1)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(1)	(0)	(10)
Intestine Large, Rectum	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Histiocyte					3 (30%)	10 (100%)
Inflammation					1 (10%)	7 (70%)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(1)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(1)	(0)	(10)
Liver	(10)	(5)	(5)	(8)	(10)	(10)
Inflammation	8 (80%)	5 (100%)	5 (100%)	7 (88%)	7 (70%)	9 (90%)
Necrosis				1 (13%)		1 (10%)
Vacuolization Cytoplasmic						2 (20%)
Pancreas	(10)	(0)	(0)	(1)	(0)	(10)
Salivary Glands	(10)	(0)	(0)	(1)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(1)	(0)	(10)
Stomach, Glandular	(10)	(0)	(0)	(1)	(0)	(10)

CARDIOVASCULAR SYSTEM

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

Experiment Number: 88122-04

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

Date Report Requested: 10/22/2014

Test Type: 90-DAY

Test Compound: Elmiron (sodium pentosanpolysulfate)

Time Report Requested: 01:47:28

Route: GAVAGE

CAS Number: 37319-17-8

First Dose M/F: NA / NA

Species/Strain: Mouse/B6C3F1

Lab: BAT

B6C3F1 Mouse FEMALE	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Blood Vessel	(10)	(0)	(0)	(1)	(0)	(10)
Heart	(10)	(0)	(0)	(1)	(0)	(10)
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(1)	(0)	(10)
Adrenal Medulla	(10)	(0)	(0)	(1)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(1)	(0)	(10)
Parathyroid Gland	(10)	(0)	(0)	(1)	(0)	(10)
Cyst						1 (10%)
Pituitary Gland	(10)	(0)	(0)	(1)	(0)	(10)
Thyroid Gland	(10)	(0)	(0)	(1)	(0)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(10)	(0)	(0)	(1)	(0)	(10)
Ovary	(10)	(0)	(0)	(1)	(0)	(10)
Uterus	(10)	(0)	(0)	(1)	(0)	(10)
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(0)	(0)	(1)	(0)	(10)
Lymph Node, Mandibular	(10)	(10)	(10)	(9)	(10)	(9)
Infiltration Cellular, Histiocyte			2 (20%)	7 (78%)	9 (90%)	9 (100%)
Lymph Node, Mesenteric	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Histiocyte			1 (10%)	10 (100%)	10 (100%)	10 (100%)
Spleen	(10)	(0)	(0)	(10)	(10)	(10)
Hematopoietic Cell Proliferation				2 (20%)		
Infiltration Cellular, Histiocyte					4 (40%)	10 (100%)
Lymph Follic, Atrophy				1 (10%)		
Thymus	(10)	(0)	(0)	(1)	(0)	(10)
Atrophy				1 (100%)		

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

Experiment Number: 88122-04

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Mouse/B6C3F1

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

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 10/22/2014

Time Report Requested: 01:47:28

First Dose M/F: NA / NA

Lab: BAT

B6C3F1 Mouse FEMALE	0 MG/KG	63 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
INTEGUMENTARY SYSTEM						
Mammary Gland	(10)	(0)	(0)	(1)	(0)	(9)
Skin	(10)	(0)	(0)	(1)	(0)	(10)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(1)	(0)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(1)	(0)	(10)
RESPIRATORY SYSTEM						
Lung	(10)	(0)	(0)	(1)	(0)	(10)
Interstitial, Inflammation						1 (10%)
Pigmentation, Hemosiderin						1 (10%)
Nose	(10)	(0)	(0)	(1)	(0)	(10)
Trachea	(10)	(0)	(0)	(1)	(0)	(10)
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(1)	(0)	(10)
Casts Protein				1 (100%)		
Nephropathy						1 (10%)
Renal Tubule, Accumulation, Hyaline Droplet				1 (100%)		
Urinary Bladder	(10)	(0)	(0)	(1)	(0)	(10)

** END OF REPORT **

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