

**Study Number:** C11054-01

**Test Type:** TOX

**Route:** Oral Gavage

**Species/Strain:** Rat/Harlan Sprague Dawley

**C Number:**

**Study Gender:**

**PWG Approval Date**

**PA18: Incidence Rates of Non-Neoplastic Lesions by Anatomic Site [a] with Average Severity Grades [b]**

**Test Compound:** Sulfolane

**CAS Number:** 126-33-0

**Date Report Requested:** 11/13/2018

**Time Report Requested:** 13:58:19

**Lab:** Battelle

C11054-01

Both

See web page for date of PWG Approval

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Lab: Battelle

	Male						
	Treatment Groups (mg/kg)						
	0	1	10	30	100	300	800
<b>Disposition Summary</b>							
Animals Initially In Study	13	10	10	13	13	13	10
Early Deaths							
Survivors							
Scheduled sacrifice, terminal (SD 28 - 29)	13	10	10	13	13	13	10
Animals Examined Microscopically	10	10	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>							
ESOPHAGUS	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INTESTINE, LARGE, CECUM	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INTESTINE, LARGE, COLON	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INTESTINE, LARGE, RECTUM	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INTESTINE, SMALL, DUODENUM	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INTESTINE, SMALL, ILEUM	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INTESTINE, SMALL, JEJUNUM	(10)	(0)	(0)	(0)	(0)	(0)	(10)
LIVER	(10)	(0)	(0)	(1)	(0)	(0)	(10)
EXTRAMEDULLARY HEMATOPOEISIS	2 [1.0]						
HEPATODIAPHRAGMATIC NODULE	1			1			
PANCREAS	(10)	(0)	(0)	(0)	(0)	(0)	(10)
SALIVARY GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(10)
STOMACH, FORESTOMACH	(10)	(0)	(0)	(0)	(0)	(0)	(10)
STOMACH, GLANDULAR	(10)	(0)	(0)	(0)	(0)	(0)	(10)
<b>CARDIOVASCULAR SYSTEM</b>							
AORTA	(10)	(0)	(0)	(0)	(0)	(0)	(10)
HEART	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INFLAMMATION; CHRONIC	2 [1.0]						

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	Male						
	Treatment Groups (mg/kg)						
	0	1	10	30	100	300	800
ENDOCRINE SYSTEM							
ADRENAL GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(10)
PARATHYROID GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(8)
HYPERPLASIA; DIFFUSE							1 [1.0]
PITUITARY GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(10)
THYROID GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(10)
GENERAL BODY SYSTEM							
No Tissues/Organs Examined							
GENITAL SYSTEM							
EPIDIDYMIDIS	(10)	(0)	(0)	(0)	(0)	(0)	(10)
PREPUTIAL GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INFLAMMATION; CHRONIC-ACTIVE	1 [1.0]						3 [1.0]
PROSTATE GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(10)
SEMINAL VESICLE	(10)	(0)	(0)	(0)	(0)	(0)	(10)
TESTIS	(10)	(0)	(0)	(0)	(0)	(0)	(10)
HEMATOPOIETIC SYSTEM							
BONE MARROW	(10)	(0)	(0)	(0)	(0)	(0)	(10)
LYMPH NODE, MANDIBULAR	(10)	(0)	(0)	(0)	(0)	(0)	(10)
LYMPH NODE, MESENTERIC	(10)	(0)	(0)	(0)	(0)	(0)	(10)
SPLEEN	(10)	(10)	(10)	(10)	(10)	(10)	(10)
THYMUS	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INTEGUMENTARY SYSTEM							
MAMMARY GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(10)
SKIN	(10)	(0)	(0)	(0)	(0)	(0)	(10)
LYMPHOID SYSTEM							
No Tissues/Organs Examined							

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	Male						
	Treatment Groups (mg/kg)						
	0	1	10	30	100	300	800
MUSCULOSKELETAL SYSTEM							
BONE, FEMUR	(10)	(0)	(0)	(0)	(0)	(0)	(10)
NERVOUS SYSTEM							
BRAIN	(10)	(0)	(0)	(0)	(0)	(0)	(10)
EDEMA; INTRAMYELINIC	1 [1.0]						
RESPIRATORY SYSTEM							
LUNGS	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INFILTRATION, CELLULAR; HISTIOCYTE	5 [1.0]						1 [1.0]
NOSE	(10)	(0)	(0)	(0)	(0)	(0)	(10)
RESPIRATORY EPITHELIUM; GOBLET CELL; HYPERPLASIA							1 [2.0]
NASOLACRIMAL DUCT; INFLAMMATION; SUBACUTE							1 [1.0]
RESPIRATORY EPITHELIUM; INFLAMMATION; CHRONIC	2 [1.0]						1 [1.0]
RESPIRATORY EPITHELIUM; INFLAMMATION; SUBACUTE	2 [1.0]						1 [1.0]
TRANSITIONAL EPITHELIUM; INFLAMMATION; CHRONIC	1 [1.0]						1 [1.0]
TRANSITIONAL EPITHELIUM; INFLAMMATION; SUBACUTE	2 [1.0]						1 [1.0]
TRACHEA	(10)	(0)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM							
EYE	(10)	(0)	(0)	(0)	(0)	(0)	(10)
RETINA; DYSPLASIA	1						
HARDERIAN GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(10)
HYPERPLASIA	1 [1.0]						

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Lab: Battelle

Male

Treatment Groups (mg/kg)

	0	1	10	30	100	300	800
URINARY SYSTEM							
KIDNEY	(10)	(10)	(10)	(10)	(10)	(10)	(10)
RENAL TUBULE; ACCUMULATION; HYALINE DROPLET		6 [1.0]	8 [1.0]	10 [1.1]	9 [1.1]	10 [2.6]	10 [3.1]
RENAL TUBULE; HYPERPLASIA; ATYPICAL	1 [1.0]						
NEPHROPATHY; CHRONIC-PROGRESSIVE	8 [1.0]	7 [1.0]	9 [1.0]	9 [1.1]	9 [1.0]	9 [1.1]	10 [1.0]
URINARY BLADDER	(10)	(0)	(0)	(0)	(0)	(0)	(10)

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Lab: Battelle

Female							
	Treatment Groups (mg/kg)						
	0	1	10	30	100	300	800
<b>Disposition Summary</b>							
Animals Initially In Study	13	10	10	13	13	13	10
Early Deaths							
Survivors							
Scheduled sacrifice, terminal (SD 28 - 29)	13	10	10	13	13	13	10
Animals Examined Microscopically	10	10	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>							
ESOPHAGUS	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INTESTINE, LARGE, CECUM	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INTESTINE, LARGE, COLON	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INTESTINE, LARGE, RECTUM	(10)	(0)	(0)	(0)	(0)	(0)	(10)
FOREIGN BODY							1
INFLAMMATION; ACUTE							1 [2.0]
INTESTINE, SMALL, DUODENUM	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INTESTINE, SMALL, ILEUM	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INTESTINE, SMALL, JEJUNUM	(10)	(0)	(0)	(0)	(0)	(0)	(10)
LIVER	(10)	(0)	(0)	(0)	(0)	(1)	(10)
EXTRAMEDULLARY HEMATOPOEISIS	3 [1.0]						3 [1.0]
FATTY CHANGE; FOCAL	2 [1.0]						
HEPATODIAPHRAGMATIC NODULE						1	
MINERAL							1 [2.0]
PANCREAS	(10)	(0)	(0)	(0)	(0)	(0)	(10)
SALIVARY GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(10)
STOMACH, FORESTOMACH	(10)	(0)	(0)	(0)	(0)	(0)	(10)
STOMACH, GLANDULAR	(10)	(0)	(0)	(0)	(0)	(0)	(10)

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Female							
	Treatment Groups (mg/kg)						
	0	1	10	30	100	300	800
<b>CARDIOVASCULAR SYSTEM</b>							
AORTA	(10)	(0)	(0)	(0)	(0)	(0)	(10)
HEART	(10)	(0)	(0)	(0)	(0)	(0)	(10)
CARDIOMYOPATHY							2 [1.0]
<b>ENDOCRINE SYSTEM</b>							
ADRENAL GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(10)
PARATHYROID GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(9)
PITUITARY GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(10)
PARS DISTALIS; CYST	1						
RATHKES CLEFT; DILATION							2
THYROID GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(10)
<b>GENERAL BODY SYSTEM</b>							
No Tissues/Organs Examined							
<b>GENITAL SYSTEM</b>							
CERVIX	(10)	(0)	(0)	(0)	(0)	(0)	(10)
CLITORAL GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INFLAMMATION; CHRONIC-ACTIVE	2 [1.0]						1 [2.0]
OVARY	(10)	(0)	(0)	(0)	(0)	(0)	(10)
UTERUS	(10)	(0)	(0)	(1)	(0)	(0)	(10)
ANGIECTASIS							1 [1.0]
CYST				1			
VAGINA	(10)	(0)	(0)	(0)	(0)	(0)	(10)
<b>HEMATOPOIETIC SYSTEM</b>							
BONE MARROW	(10)	(0)	(0)	(0)	(0)	(0)	(10)
LYMPH NODE, MANDIBULAR	(10)	(0)	(0)	(0)	(0)	(0)	(10)
LYMPH NODE, MESENTERIC	(10)	(0)	(0)	(0)	(0)	(0)	(10)
SPLEEN	(10)	(10)	(10)	(10)	(10)	(10)	(10)
THYMUS	(10)	(0)	(0)	(0)	(0)	(0)	(10)

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Female							
	Treatment Groups (mg/kg)						
	0	1	10	30	100	300	800
INTEGUMENTARY SYSTEM							
MAMMARY GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(10)
SKIN	(10)	(0)	(0)	(0)	(0)	(0)	(10)
LYMPHOID SYSTEM							
No Tissues/Organs Examined							
MUSCULOSKELETAL SYSTEM							
BONE, FEMUR	(10)	(0)	(0)	(0)	(0)	(0)	(10)
NERVOUS SYSTEM							
BRAIN	(10)	(0)	(0)	(0)	(0)	(0)	(10)
RESPIRATORY SYSTEM							
LUNGS	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INFILTRATION, CELLULAR; HISTIOCYTE	2 [1.0]						
METAPLASIA; OSSEOUS	2						
NOSE	(10)	(0)	(0)	(0)	(0)	(0)	(10)
RESPIRATORY EPITHELIUM; INFLAMMATION; CHRONIC	1 [2.0]						
RESPIRATORY EPITHELIUM; INFLAMMATION; SUBACUTE	4 [1.5]						2 [1.0]
TRANSITIONAL EPITHELIUM; INFLAMMATION; SUBACUTE	3 [1.0]						3 [1.0]
TRACHEA	(10)	(0)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM							
EYE	(10)	(0)	(0)	(0)	(0)	(0)	(10)
HARDERIAN GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(10)
URINARY SYSTEM							
KIDNEY	(10)	(0)	(0)	(0)	(0)	(0)	(10)
NEPHROPATHY; CHRONIC-PROGRESSIVE	5 [1.0]						8 [1.0]
URINARY BLADDER	(10)	(0)	(0)	(0)	(0)	(0)	(10)



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## LEGEND

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[a] Number of animals examined given for each tissue. If none of the animals examined have the specific lesion then there is a blank for that dose group for that specific lesion.

[b] Mean severity grade denoted by 1 - minimal, 2 - mild, 3 - moderate, 4 - marked

Number of animals with observation reported with mean severity grade in square brackets

Phase day range of terminal sacrifice shown in parentheses in disposition summary

SD – Study Day

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