

Study Number: C11054-01

Test Type: TOX

Route: Oral Gavage

Species/Strain: Rat/Harlan Sprague Dawley

C Number:

Study Gender:

PWG Approval Date

PA03: Non-Neoplastic Lesion Summary with Percent Incidence

Test Compound: Sulfolane

CAS Number: 126-33-0

C11054-01

Both

See web page for date of PWG Approval

Date Report Requested: 11/13/2018

Time Report Requested: 14:49:02

Lab: Battelle

Study Number: C11054-01

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Lab: Battelle

Species/Strain: Rat/Harlan Sprague Dawley

Male							
	Treatment Groups (mg/kg)						
	0	1	10	30	100	300	800
Disposition Summary							
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
ALIMENTARY SYSTEM							
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 (20%)						
HEPATODIAPHRAGMATIC NODULE	1 (10%)			1 (100%)			
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)
CARDIOVASCULAR SYSTEM							
AORTA	(10)	(0)	(0)	(0)	(0)	(0)	(10)
HEART	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INFLAMMATION; CHRONIC	2 (20%)						

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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 (13%)
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 (10%)						3 (30%)
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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Species/Strain: Rat/Harlan Sprague Dawley

	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 (10%)						
RESPIRATORY SYSTEM							
LUNGS	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INFILTRATION, CELLULAR; HISTIOCYTE	5 (50%)						1 (10%)
NOSE	(10)	(0)	(0)	(0)	(0)	(0)	(10)
RESPIRATORY EPITHELIUM; GOBLET CELL; HYPERPLASIA							1 (10%)
NASOLACRIMAL DUCT; INFLAMMATION; SUBACUTE							1 (10%)
RESPIRATORY EPITHELIUM; INFLAMMATION; CHRONIC	2 (20%)						1 (10%)
RESPIRATORY EPITHELIUM; INFLAMMATION; SUBACUTE	2 (20%)						1 (10%)
TRANSITIONAL EPITHELIUM; INFLAMMATION; CHRONIC	1 (10%)						1 (10%)
TRANSITIONAL EPITHELIUM; INFLAMMATION; SUBACUTE	2 (20%)						1 (10%)
TRACHEA	(10)	(0)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM							
EYE	(10)	(0)	(0)	(0)	(0)	(0)	(10)
RETINA; DYSPLASIA	1 (10%)						
HARDERIAN GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(10)
HYPERPLASIA	1 (10%)						

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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 (60%)	8 (80%)	10 (100%)	9 (90%)	10 (100%)	10 (100%)
RENAL TUBULE; HYPERPLASIA; ATYPICAL	1 (10%)						
NEPHROPATHY; CHRONIC-PROGRESSIVE	8 (80%)	7 (70%)	9 (90%)	9 (90%)	9 (90%)	9 (90%)	10 (100%)
URINARY BLADDER	(10)	(0)	(0)	(0)	(0)	(0)	(10)

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Species/Strain: Rat/Harlan Sprague Dawley

Female

Treatment Groups (mg/kg)

	0	1	10	30	100	300	800
Disposition Summary							
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
ALIMENTARY SYSTEM							
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 (10%)
INFLAMMATION; ACUTE							1 (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)	(0)	(0)	(1)	(10)
EXTRAMEDULLARY HEMATOPOEISIS	3 (30%)						3 (30%)
FATTY CHANGE; FOCAL	2 (20%)						
HEPATODIAPHRAGMATIC NODULE						1 (100%)	
MINERAL							1 (10%)
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
CARDIOVASCULAR SYSTEM							
AORTA	(10)	(0)	(0)	(0)	(0)	(0)	(10)
HEART	(10)	(0)	(0)	(0)	(0)	(0)	(10)
CARDIOMYOPATHY							2 (20%)
ENDOCRINE SYSTEM							
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 (10%)						
RATHKES CLEFT; DILATION							2 (20%)
THYROID GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(10)
GENERAL BODY SYSTEM							
No Tissues/Organs Examined							
GENITAL SYSTEM							
CERVIX	(10)	(0)	(0)	(0)	(0)	(0)	(10)
CLITORAL GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INFLAMMATION; CHRONIC-ACTIVE	2 (20%)						1 (10%)
OVARY	(10)	(0)	(0)	(0)	(0)	(0)	(10)
UTERUS	(10)	(0)	(0)	(1)	(0)	(0)	(10)
ANGIECTASIS							1 (10%)
CYST				1 (100%)			
VAGINA	(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)

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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 (20%)						
METAPLASIA; OSSEOUS	2 (20%)						
NOSE	(10)	(0)	(0)	(0)	(0)	(0)	(10)
RESPIRATORY EPITHELIUM;	1 (10%)						
INFLAMMATION; CHRONIC							
RESPIRATORY EPITHELIUM;	4 (40%)						2 (20%)
INFLAMMATION; SUBACUTE							
TRANSITIONAL EPITHELIUM;	3 (30%)						3 (30%)
INFLAMMATION; SUBACUTE							
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 (50%)						8 (80%)
URINARY BLADDER	(10)	(0)	(0)	(0)	(0)	(0)	(10)

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LEGEND

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.

Number of animals with observation reported with percent incidence in parentheses

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

SD – Study Day

**** END OF REPORT ****