

Study Number: C11054-01

Test Type: TOX

Route: Oral Gavage

Species/Strain: Rat/Harlan Sprague Dawley

C Number:

Study Gender:

PWG Approval Date

PA10X: Statistical Analysis of Non-Neoplastic Lesions

Test Compound: Sulfolane

CAS Number: 126-33-0

C11054-01

Both

See web page for date of PWG Approval

Date Report Requested: 11/16/2018

Time Report Requested: 08:22:52

Lab: Battelle

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Lab: Battelle

Male : Male Core

Treatment Groups (mg/kg)

	0	1	10	30	100	300	800
Disposition Summary							
Animals Initially In Study	10	10	10	10	10	10	10
Early Deaths							
Scheduled Deaths							
Scheduled sacrifice, terminal (SD 29)	10	10	10	10	10	10	10
Number of Animals Examined	10	10	10	10	10	10	10
ALIMENTARY SYSTEM							
LIVER	(10)	(0)	(0)	(1)	(0)	(0)	(10)
EXTRAMEDULLARY HEMATOPOEISIS	2 (20%)						
HEPATODIAPHRAGMATIC NODULE	1 (10%)			1 (100%)			
CARDIOVASCULAR SYSTEM							
HEART	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INFLAMMATION; CHRONIC	2 (20%)						
ENDOCRINE SYSTEM							
PARATHYROID GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(8)
HYPERPLASIA; DIFFUSE							1 (12.5%)
GENERAL BODY SYSTEM							
None							
GENITAL SYSTEM							
PREPUTIAL GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INFLAMMATION; CHRONIC-ACTIVE	1 (10%)						3 (30%)
HEMATOPOIETIC SYSTEM							
None							

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Treatment Groups (mg/kg)

0 1 10 30 100 300 800

INTEGUMENTARY SYSTEM

None

LYMPHOID SYSTEM

None

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

BRAIN	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(10)
EDEMA; INTRAMYELINIC	1 (10%)							

RESPIRATORY SYSTEM

LUNGS	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(10)
INFILTRATION, CELLULAR; HISTIOCYTE	5 (50%)							1 (10%)
NOSE	(10)	(0)	(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%)

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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%)						
URINARY SYSTEM							
KIDNEY	(10)	(10)	(10)	(10)	(10)	(10)	(10)
RENAL TUBULE; ACCUMULATION; HYALINE DROPLET	0 **	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%)

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Lab: Battelle

Species/Strain: Rat/Harlan Sprague Dawley

Female : Female Core

Treatment Groups (mg/kg)

	0	1	10	30	100	300	800
Disposition Summary							
Animals Initially In Study	10	10	10	10	10	10	10
Early Deaths							
Scheduled Deaths							
Scheduled sacrifice, terminal (SD 29)	10	10	10	10	10	10	10
Number of Animals Examined	10	10	10	10	10	10	10
ALIMENTARY SYSTEM							
INTESTINE, LARGE, RECTUM	(10)	(0)	(0)	(0)	(0)	(0)	(10)
FOREIGN BODY							1 (10%)
INFLAMMATION; ACUTE							1 (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%)
CARDIOVASCULAR SYSTEM							
HEART	(10)	(0)	(0)	(0)	(0)	(0)	(10)
CARDIOMYOPATHY							2 (20%)
ENDOCRINE SYSTEM							
PITUITARY GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(10)
PARS DISTALIS; CYST	1 (10%)						
RATHKES CLEFT; DILATION							2 (20%)
GENERAL BODY SYSTEM							
None							

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Female : Female Core

Treatment Groups (mg/kg)

	0	1	10	30	100	300	800
GENITAL SYSTEM							
CLITORAL GLAND	(10)	(0)	(0)	(0)	(0)	(0)	(10)
INFLAMMATION; CHRONIC-ACTIVE	2 (20%)						1 (10%)
UTERUS	(10)	(0)	(0)	(1)	(0)	(0)	(10)
ANGIECTASIS							1 (10%)
CYST				1 (100%)			

HEMATOPOIETIC SYSTEM

None

INTEGUMENTARY SYSTEM

None

LYMPHOID SYSTEM

None

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

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Treatment Groups (mg/kg)

	0	1	10	30	100	300	800
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;							
INFLAMMATION; CHRONIC	1 (10%)						
RESPIRATORY EPITHELIUM;							
INFLAMMATION; SUBACUTE	4 (40%)						2 (20%)
TRANSITIONAL EPITHELIUM;							
INFLAMMATION; SUBACUTE	3 (30%)						3 (30%)
SPECIAL SENSES SYSTEM							
None							
URINARY SYSTEM							
KIDNEY	(10)	(0)	(0)	(0)	(0)	(0)	(10)
NEPHROPATHY; CHRONIC-PROGRESSIVE	5 (50%)						8 (80%)

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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. The exception to this is if statistical analysis is performed for a lesion and the control group has no animals with the lesion then a 0 is included for the control group on the table for that lesion.

Number of animals with observation reported with percent incidence in parentheses

Statistical analysis performed by Cochran-Armitage (trend) and Fisher Exact (pairwise) tests.

Trend p-values are reported only for those organs that were fully examined in the control group plus two or more other dose groups. For organs that were fully examined in just the control and one other dose group, only the pairwise p-values are reported.

Statistical significance for the control group indicates a significant trend test

Statistical significance for a treatment group indicates a significant pairwise test compared to the vehicle control group

All trend and pairwise p-values are reported as one-sided.

* Statistically significant at $P \leq 0.05$

** Statistically significant at $P \leq 0.01$

**** END OF REPORT ****