

Study Number: C11054-03
Test Type: TOX
Route: Oral Gavage
Species/Strain: Guinea Pig/Hartley

PA10X: Statistical Analysis of Non-Neoplastic Lesions
Test Compound: Sulfolane
CAS Number: 126-33-0

Date Report Requested: 11/16/2018
Time Report Requested: 08:51:26
Lab: Battelle

C Number:

C11054-03

Study Gender:

Both

PWG Approval Date

See web page for date of PWG Approval

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Male : Male Core

Treatment Groups (mg/kg)

	0	1	10	30	100	300	800
Disposition Summary							
Animals Initially In Study	20	10	10	10	10	10	10
Scheduled sacrifice, interim							2
Early Deaths							
Euthanized, moribund							1
Found Dead							7
Scheduled Deaths							
Scheduled sacrifice, terminal (SD 29)	20	10	10	10	10	10	
Number of Animals Examined	20	10	10	10	10	10	10

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	0	1	10	30	100	300	800
ALIMENTARY SYSTEM							
ESOPHAGUS	(20)	(2)	(0)	(1)	(1)	(10)	(10)
INFLAMMATION; CHRONIC	1 (5%) **	2 (100%)		1 (100%)	1 (100%)	1 (10%)	5 (50%) **
INFLAMMATION; CHRONIC-ACTIVE							1 (10%)
INFLAMMATION; GRANULOMATOUS	1 (5%)						
LIVER	(20)	(0)	(0)	(1)	(1)	(10)	(10)
HEPATOCYTE; DEGENERATION	1 (5%)						
FIBROSIS	1 (5%)						
BILE DUCT; HYPERPLASIA	2 (10%)						
OVAL CELL; HYPERPLASIA	1 (5%)						
MINERAL	1 (5%)						
HEPATOCYTE; NECROSIS	5 (25%)			1 (100%)	1 (100%)	2 (20%)	1 (10%)
PANCREAS	(20)	(0)	(0)	(0)	(0)	(10)	(10)
ACINAR CELL; VACUOLATION	1 (5%)						
SALIVARY GLAND	(20)	(0)	(0)	(0)	(0)	(10)	(10)
LYMPHOCYTE; INFILTRATION, CELLULAR						1 (10%)	
STOMACH, GLANDULAR	(20)	(0)	(0)	(0)	(0)	(10)	(10)
EROSION							1 (10%)
NECROSIS							1 (10%)
CARDIOVASCULAR SYSTEM							
HEART	(20)	(0)	(1)	(0)	(0)	(10)	(10)
CARDIOMYOPATHY	4 (20%)						2 (20%)
MYOCARDIUM; MINERAL							1 (10%)
RHABDOMYOMATOSIS	5 (25%)					3 (30%)	2 (20%)

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	0	1	10	30	100	300	800
ENDOCRINE SYSTEM							
PARATHYROID GLAND	(12)	(0)	(0)	(0)	(0)	(5)	(7)
CYST; CONGENITAL							1 (14.3%)
PITUITARY GLAND	(20)	(0)	(0)	(0)	(0)	(10)	(10)
PARS DISTALIS; CYST; MULTIPLE						2 (20%)	
PARS DISTALIS; CYST	1 (5%)					1 (10%)	
THYROID GLAND	(20)	(0)	(0)	(0)	(0)	(10)	(10)
FOLLICLE; DILATION						1 (10%)	
GENERAL BODY SYSTEM							
None							
GENITAL SYSTEM							
TESTIS	(20)	(0)	(0)	(0)	(0)	(10)	(10)
GERM CELL; DEGENERATION						1 (10%)	
HEMATOPOIETIC SYSTEM							
THYMUS	(20)	(0)	(0)	(0)	(0)	(10)	(10)
NECROSIS							1 (10%)
INTEGUMENTARY SYSTEM							
None							
LYMPHOID SYSTEM							
None							
MUSCULOSKELETAL SYSTEM							
None							

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	0	1	10	30	100	300	800
NERVOUS SYSTEM							
None							
RESPIRATORY SYSTEM							
LUNGS	(20)	(0)	(0)	(0)	(0)	(10)	(10)
CONGESTION							1 (10%)
FOREIGN BODY	4 (20%)					1 (10%)	2 (20%)
HEMORRHAGE	0 *						2 (20%)
INFILTRATION, CELLULAR; HISTIOCYTE INFLAMMATION; CHRONIC	1 (5%)					1 (10%)	
NOSE	(20)	(0)	(0)	(0)	(0)	(10)	(10)
FOREIGN BODY	0 *						2 (20%)
INFLAMMATION; CHRONIC-ACTIVE	9 (45%) *					6 (60%)	9 (90%) *
TRACHEA	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INFLAMMATION	1 (5%)						
SPECIAL SENSES SYSTEM							
HARDERIAN GLAND	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INFLAMMATION; CHRONIC-ACTIVE	7 (35%)					7 (70%)	2 (20%)
URINARY SYSTEM							
KIDNEY	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INFARCTION	1 (5%)						
RENAL TUBULE; REGENERATION	10 (50%)					5 (50%)	4 (40%)

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Treatment Groups (mg/kg)

	0	1	10	30	100	300	800
Disposition Summary							
Animals Initially In Study	20	10	10	10	10	10	10
Scheduled sacrifice, interim							7
Early Deaths							
Found Dead							3
Scheduled Deaths							
Scheduled sacrifice, terminal (SD 29)	20	10	10	10	10	10	
Number of Animals Examined	20	10	10	10	10	10	10
ALIMENTARY SYSTEM							
ESOPHAGUS	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INFLAMMATION; CHRONIC	0 **						5 (50%) **
INTESTINE, SMALL, JEJUNUM	(20)	(0)	(0)	(0)	(0)	(10)	(10)
CONGESTION							1 (10%)
LIVER	(20)	(3)	(6)	(3)	(1)	(10)	(10)
HEPATOCYTE; NECROSIS	9 (45%)	2 (66.7%)	6 (100%)	3 (100%)	1 (100%)	2 (20%)	3 (30%)
CARDIOVASCULAR SYSTEM							
HEART	(20)	(0)	(0)	(0)	(0)	(10)	(10)
CARDIOMYOPATHY	5 (25%)					1 (10%)	2 (20%)
ENDOCARDIUM; HYPERPLASIA; ENDOTHELIAL							1 (10%)
INFLAMMATION; ACUTE							1 (10%)
RHABDOMYOMATOSIS	7 (35%)					0 *	2 (20%)

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	0	1	10	30	100	300	800
ENDOCRINE SYSTEM							
ADRENAL GLAND	(20)	(0)	(0)	(0)	(0)	(10)	(10)
CORTEX; CYST							1 (10%)
CORTEX; HYPERPLASIA; FOCAL	1 (5%)						
PARATHYROID GLAND	(10)	(0)	(0)	(0)	(0)	(5)	(8)
CYST; CONGENITAL	1 (10%)						
PITUITARY GLAND	(20)	(0)	(0)	(0)	(0)	(10)	(10)
PARS DISTALIS; CYST; MULTIPLE							1 (10%)
PARS DISTALIS; CYST	1 (5%)					1 (10%)	
PARS INTERMEDIA; CYST						2 (20%)	
THYROID GLAND	(20)	(0)	(0)	(0)	(0)	(10)	(10)
FOLLICLE; DILATION							1 (10%)
INFLAMMATION; CHRONIC						1 (10%)	
GENERAL BODY SYSTEM							
None							
GENITAL SYSTEM							
CERVIX	(20)	(0)	(0)	(0)	(0)	(10)	(10)
ANGIECTASIS; FOCAL						1 (10%)	
HEMATOPOIETIC SYSTEM							
None							
INTEGUMENTARY SYSTEM							
None							
LYMPHOID SYSTEM							
None							

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0 1 10 30 100 300 800

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

	0	1	10	30	100	300	800
LUNGS	(20)	(0)	(0)	(0)	(0)	(10)	(10)
FOREIGN BODY	5 (25%)					2 (20%)	
HEMORRHAGE	0 *						2 (20%)
ALVEOLAR EPITHELIUM; HYPERPLASIA	1 (5%)						
INFILTRATION, CELLULAR; HISTIOCYTE						1 (10%)	
INFLAMMATION; CHRONIC	3 (15%)					2 (20%)	2 (20%)
NOSE	(20)	(10)	(10)	(10)	(10)	(10)	(10)
INFLAMMATION; CHRONIC-ACTIVE	20 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)

SPECIAL SENSES SYSTEM

	0	1	10	30	100	300	800
HARDERIAN GLAND	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INFLAMMATION; CHRONIC-ACTIVE	1 (5%)						1 (10%)

URINARY SYSTEM

	0	1	10	30	100	300	800
KIDNEY	(20)	(0)	(1)	(0)	(0)	(10)	(10)
PELVIS; DILATION			1 (100%)				
RENAL TUBULE; REGENERATION	17 (85%)					7 (70%)	7 (70%)

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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 ****