

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

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: 11/14/2018
Time Report Requested: 06:05:34
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						
	Treatment Groups (mg/kg)						
	0	1	10	30	100	300	800
Disposition Summary							
Animals Initially In Study	23	10	10	13	13	13	10
Scheduled sacrifice, interim							2
Early Deaths							
Euthanized, moribund							1
Found Dead							7
Survivors							
Scheduled sacrifice, terminal (SD 28 - 29)	23	10	10	13	13	13	
Animals Examined Microscopically	20	10	10	10	10	10	10

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	Male						
	Treatment Groups (mg/kg)						
	0	1	10	30	100	300	800
ALIMENTARY SYSTEM							
ESOPHAGUS	(20)	(2)	(0)	(1)	(1)	(10)	(10)
INFLAMMATION; CHRONIC	1 [1.0]	2 [1.0]		1 [1.0]	1 [1.0]	1 [1.0]	5 [1.0]
INFLAMMATION; CHRONIC-ACTIVE							1 [2.0]
INFLAMMATION; GRANULOMATOUS	1 [1.0]						
GALL BLADDER	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INTESTINE, LARGE, CECUM	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INTESTINE, LARGE, COLON	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INTESTINE, LARGE, RECTUM	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INTESTINE, SMALL, DUODENUM	(20)	(0)	(0)	(0)	(0)	(8)	(10)
INTESTINE, SMALL, ILEUM	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INTESTINE, SMALL, JEJUNUM	(20)	(0)	(0)	(0)	(0)	(10)	(10)
LIVER	(20)	(0)	(0)	(1)	(1)	(10)	(10)
HEPATOCYTE; DEGENERATION	1 [2.0]						
FIBROSIS	1 [1.0]						
BILE DUCT; HYPERPLASIA	2 [1.0]						
OVAL CELL; HYPERPLASIA	1 [1.0]						
MINERAL	1 [1.0]						
HEPATOCYTE; NECROSIS	5 [1.4]			1 [2.0]	1 [2.0]	2 [1.0]	1 [1.0]
PANCREAS	(20)	(0)	(0)	(0)	(0)	(10)	(10)
ACINAR CELL; VACUOLATION	1 [2.0]						
SALIVARY GLAND	(20)	(0)	(0)	(0)	(0)	(10)	(10)
LYMPHOCYTE; INFILTRATION, CELLULAR						1 [1.0]	
STOMACH, GLANDULAR	(20)	(0)	(0)	(0)	(0)	(10)	(10)
EROSION							1 [2.0]
NECROSIS							1 [2.0]

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Male							
	Treatment Groups (mg/kg)						
	0	1	10	30	100	300	800
CARDIOVASCULAR SYSTEM							
AORTA	(20)	(0)	(0)	(0)	(0)	(10)	(10)
HEART	(20)	(0)	(1)	(0)	(0)	(10)	(10)
CARDIOMYOPATHY	4 [1.0]						2 [1.0]
MYOCARDIUM; MINERAL							1 [1.0]
RHABDOMYOMATOSIS	5 [1.6]					3 [1.7]	2 [2.0]
ENDOCRINE SYSTEM							
ADRENAL GLAND	(20)	(0)	(0)	(0)	(0)	(10)	(10)
PARATHYROID GLAND	(12)	(0)	(0)	(0)	(0)	(5)	(7)
CYST; CONGENITAL							1
PITUITARY GLAND	(20)	(0)	(0)	(0)	(0)	(10)	(10)
PARS DISTALIS; CYST; MULTIPLE						2	
PARS DISTALIS; CYST	1					1	
THYROID GLAND	(20)	(0)	(0)	(0)	(0)	(10)	(10)
FOLLICLE; DILATION						1 [1.0]	
GENERAL BODY SYSTEM							
No Tissues/Organs Examined							
GENITAL SYSTEM							
EPIDIDYMIDIS	(20)	(0)	(0)	(0)	(0)	(10)	(10)
PROSTATE GLAND	(20)	(0)	(0)	(0)	(0)	(10)	(10)
SEMINAL VESICLE	(20)	(0)	(0)	(0)	(0)	(10)	(10)
TESTIS	(20)	(0)	(0)	(0)	(0)	(10)	(10)
GERM CELL; DEGENERATION						1 [2.0]	

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Male							
	Treatment Groups (mg/kg)						
	0	1	10	30	100	300	800
HEMATOPOIETIC SYSTEM							
BONE MARROW	(20)	(0)	(0)	(0)	(0)	(10)	(10)
LYMPH NODE, MANDIBULAR	(20)	(0)	(0)	(0)	(0)	(10)	(10)
LYMPH NODE, MESENTERIC	(20)	(0)	(0)	(0)	(0)	(10)	(10)
SPLEEN	(20)	(10)	(10)	(10)	(10)	(10)	(10)
THYMUS	(20)	(0)	(0)	(0)	(0)	(10)	(10)
NECROSIS							1 [2.0]
INTEGUMENTARY SYSTEM							
MAMMARY GLAND	(19)	(0)	(0)	(0)	(0)	(10)	(5)
LYMPHOID SYSTEM							
No Tissues/Organs Examined							
MUSCULOSKELETAL SYSTEM							
BONE, FEMUR	(20)	(0)	(0)	(0)	(0)	(10)	(10)
NERVOUS SYSTEM							
BRAIN	(20)	(0)	(0)	(0)	(0)	(10)	(10)
RESPIRATORY SYSTEM							
LUNGS	(20)	(0)	(0)	(0)	(0)	(10)	(10)
CONGESTION							1 [3.0]
FOREIGN BODY	4					1	2
HEMORRHAGE							2 [2.0]
INFILTRATION, CELLULAR; HISTIOCYTE	1 [1.0]					1 [1.0]	
INFLAMMATION; CHRONIC	1 [1.0]						
NOSE	(20)	(0)	(0)	(0)	(0)	(10)	(10)
FOREIGN BODY							2
INFLAMMATION; CHRONIC-ACTIVE	9 [1.7]					6 [1.7]	9 [1.6]
TRACHEA	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INFLAMMATION	1 [1.0]						

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Male							
	Treatment Groups (mg/kg)						
	0	1	10	30	100	300	800
SPECIAL SENSES SYSTEM							
EYE	(20)	(0)	(0)	(0)	(0)	(10)	(10)
HARDERIAN GLAND	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INFLAMMATION; CHRONIC-ACTIVE	7 [1.4]					7 [1.6]	2 [1.0]
URINARY SYSTEM							
KIDNEY	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INFARCTION	1 [2.0]						
RENAL TUBULE; REGENERATION	10 [1.2]					5 [1.0]	4 [1.0]
URINARY BLADDER	(20)	(0)	(0)	(0)	(0)	(10)	(10)

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Female							
	Treatment Groups (mg/kg)						
	0	1	10	30	100	300	800
Disposition Summary							
Animals Initially In Study	23	10	10	13	13	13	10
Scheduled sacrifice, interim							7
Early Deaths							
Found Dead							3
Survivors							
Scheduled sacrifice, terminal (SD 28 - 29)	23	10	10	13	13	13	
Animals Examined Microscopically	20	10	10	10	10	10	10
ALIMENTARY SYSTEM							
ESOPHAGUS	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INFLAMMATION; CHRONIC							5 [1.0]
GALL BLADDER	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INTESTINE, LARGE, CECUM	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INTESTINE, LARGE, COLON	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INTESTINE, LARGE, RECTUM	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INTESTINE, SMALL, DUODENUM	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INTESTINE, SMALL, ILEUM	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INTESTINE, SMALL, JEJUNUM	(20)	(0)	(0)	(0)	(0)	(10)	(10)
CONGESTION							1 [2.0]
LIVER	(20)	(3)	(6)	(3)	(1)	(10)	(10)
HEPATOCYTE; NECROSIS	9 [1.2]	2 [1.5]	6 [1.2]	3 [1.0]	1 [1.0]	2 [1.0]	3 [1.3]
PANCREAS	(20)	(0)	(0)	(0)	(0)	(10)	(10)
SALIVARY GLAND	(20)	(0)	(0)	(0)	(0)	(10)	(10)
STOMACH, GLANDULAR	(20)	(0)	(0)	(0)	(0)	(10)	(10)

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Female							
	Treatment Groups (mg/kg)						
	0	1	10	30	100	300	800
CARDIOVASCULAR SYSTEM							
AORTA	(20)	(0)	(0)	(0)	(0)	(10)	(10)
HEART	(20)	(0)	(0)	(0)	(0)	(10)	(10)
CARDIOMYOPATHY	5 [1.0]					1 [1.0]	2 [1.0]
ENDOCARDIUM; HYPERPLASIA; ENDOTHELIAL							1 [1.0]
INFLAMMATION; ACUTE							1 [1.0]
RHABDOMYOMATOSIS	7 [1.2]						2 [2.0]
ENDOCRINE SYSTEM							
ADRENAL GLAND	(20)	(0)	(0)	(0)	(0)	(10)	(10)
CORTEX; CYST							1
CORTEX; HYPERPLASIA; FOCAL	1 [1.0]						
PARATHYROID GLAND	(10)	(0)	(0)	(0)	(0)	(5)	(8)
CYST; CONGENITAL	1						
PITUITARY GLAND	(20)	(0)	(0)	(0)	(0)	(10)	(10)
PARS DISTALIS; CYST; MULTIPLE							1
PARS DISTALIS; CYST	1					1	
PARS INTERMEDIA; CYST						2	
THYROID GLAND	(20)	(0)	(0)	(0)	(0)	(10)	(10)
FOLLICLE; DILATION							1 [1.0]
INFLAMMATION; CHRONIC						1 [1.0]	
GENERAL BODY SYSTEM							
No Tissues/Organs Examined							

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Female							
	Treatment Groups (mg/kg)						
	0	1	10	30	100	300	800
GENITAL SYSTEM							
CERVIX	(20)	(0)	(0)	(0)	(0)	(10)	(10)
ANGIECTASIS; FOCAL						1 [3.0]	
OVARY	(20)	(0)	(0)	(0)	(0)	(10)	(10)
UTERUS	(20)	(0)	(0)	(0)	(0)	(10)	(10)
VAGINA	(20)	(0)	(0)	(0)	(0)	(10)	(10)
HEMATOPOIETIC SYSTEM							
BONE MARROW	(20)	(0)	(0)	(0)	(0)	(10)	(10)
LYMPH NODE, MANDIBULAR	(20)	(0)	(0)	(0)	(0)	(10)	(10)
LYMPH NODE, MESENTERIC	(20)	(0)	(0)	(0)	(0)	(10)	(10)
SPLEEN	(20)	(10)	(10)	(10)	(10)	(10)	(10)
THYMUS	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INTEGUMENTARY SYSTEM							
MAMMARY GLAND	(20)	(0)	(0)	(0)	(0)	(8)	(9)
LYMPHOID SYSTEM							
No Tissues/Organs Examined							
MUSCULOSKELETAL SYSTEM							
BONE, FEMUR	(20)	(0)	(0)	(0)	(0)	(10)	(10)
NERVOUS SYSTEM							
BRAIN	(20)	(0)	(0)	(0)	(0)	(10)	(10)

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Female							
	Treatment Groups (mg/kg)						
	0	1	10	30	100	300	800
RESPIRATORY SYSTEM							
CAVITY, NASAL	(0)	(0)	(0)	(0)	(1)	(0)	(0)
LUNGS	(20)	(0)	(0)	(0)	(0)	(10)	(10)
FOREIGN BODY	5					2	
HEMORRHAGE							2 [2.5]
ALVEOLAR EPITHELIUM; HYPERPLASIA	1 [1.0]						
INFILTRATION, CELLULAR; HISTIOCYTE						1 [1.0]	
INFLAMMATION; CHRONIC	3 [1.0]					2 [1.5]	2 [1.0]
NOSE	(20)	(10)	(10)	(10)	(10)	(10)	(10)
INFLAMMATION; CHRONIC-ACTIVE	20 [1.8]	10 [1.9]	10 [1.9]	10 [2.0]	10 [1.8]	10 [1.7]	10 [1.9]
TRACHEA	(20)	(0)	(0)	(0)	(0)	(10)	(10)
SPECIAL SENSES SYSTEM							
EYE	(20)	(0)	(0)	(0)	(0)	(10)	(10)
HARDERIAN GLAND	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INFLAMMATION; CHRONIC-ACTIVE	1 [1.0]						1 [1.0]
URINARY SYSTEM							
KIDNEY	(20)	(0)	(1)	(0)	(0)	(10)	(10)
PELVIS; DILATION			1 [2.0]				
RENAL TUBULE; REGENERATION	17 [1.4]					7 [1.0]	7 [1.0]
URINARY BLADDER	(20)	(0)	(0)	(0)	(0)	(10)	(10)

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LEGEND

[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 ****