

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

**PA03: Non-Neoplastic Lesion Summary with Percent Incidence**

**Test Compound:** Sulfolane  
**CAS Number:** 126-33-0

**Date Report Requested:** 11/14/2018  
**Time Report Requested:** 06:05:41  
**Lab:** Battelle

**C Number:**

C11054-03

**Study Gender:**

Both

**PWG Approval Date**

See web page for date of PWG Approval

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	<b>Male</b>						
	<b>Treatment Groups (mg/kg)</b>						
	<b>0</b>	<b>1</b>	<b>10</b>	<b>30</b>	<b>100</b>	<b>300</b>	<b>800</b>
<b>Disposition Summary</b>							
<b>Animals Initially In Study</b>	<b>23</b>	<b>10</b>	<b>10</b>	<b>13</b>	<b>13</b>	<b>13</b>	<b>10</b>
<b>Scheduled sacrifice, interim</b>							<b>2</b>
<b>Early Deaths</b>							
<b>Euthanized, moribund</b>							<b>1</b>
<b>Found Dead</b>							<b>7</b>
<b>Survivors</b>							
<b>Scheduled sacrifice, terminal (SD 28 - 29)</b>	<b>23</b>	<b>10</b>	<b>10</b>	<b>13</b>	<b>13</b>	<b>13</b>	
<b>Animals Examined Microscopically</b>	<b>20</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>	<b>10</b>

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Lab: Battelle

Species/Strain: Guinea Pig/Hartley

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 (5%)	2 (100%)		1 (100%)	1 (100%)	1 (10%)	5 (50%)
INFLAMMATION; CHRONIC-ACTIVE							1 (10%)
INFLAMMATION; GRANULOMATOUS	1 (5%)						
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 (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%)

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Male							
	Treatment Groups (mg/kg)						
	0	1	10	30	100	300	800
<b>CARDIOVASCULAR SYSTEM</b>							
AORTA	(20)	(0)	(0)	(0)	(0)	(10)	(10)
HEART	(20)	(0)	(1)	(0)	(0)	(10)	(10)
CARDIOMYOPATHY	4 (20%)						2 (20%)
MYOCARDIUM; MINERAL							1 (10%)
RHABDOMYOMATOSIS	5 (25%)					3 (30%)	2 (20%)
<b>ENDOCRINE SYSTEM</b>							
ADRENAL GLAND	(20)	(0)	(0)	(0)	(0)	(10)	(10)
PARATHYROID GLAND	(12)	(0)	(0)	(0)	(0)	(5)	(7)
CYST; CONGENITAL							1 (14%)
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%)	
<b>GENERAL BODY SYSTEM</b>							
No Tissues/Organs Examined							
<b>GENITAL SYSTEM</b>							
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 (10%)	

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Route: Oral Gavage

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Lab: Battelle

Species/Strain: Guinea Pig/Hartley

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 (10%)
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 (10%)
FOREIGN BODY	4 (20%)					1 (10%)	2 (20%)
HEMORRHAGE							2 (20%)
INFILTRATION, CELLULAR; HISTIOCYTE	1 (5%)					1 (10%)	
INFLAMMATION; CHRONIC	1 (5%)						
NOSE	(20)	(0)	(0)	(0)	(0)	(10)	(10)
FOREIGN BODY							2 (20%)
INFLAMMATION; CHRONIC-ACTIVE	9 (45%)					6 (60%)	9 (90%)
TRACHEA	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INFLAMMATION	1 (5%)						

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<b>Male</b>							
<b>Treatment Groups (mg/kg)</b>							
	<b>0</b>	<b>1</b>	<b>10</b>	<b>30</b>	<b>100</b>	<b>300</b>	<b>800</b>
<b>SPECIAL SENSES SYSTEM</b>							
EYE	(20)	(0)	(0)	(0)	(0)	(10)	(10)
HARDERIAN GLAND	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INFLAMMATION; CHRONIC-ACTIVE	7 (35%)					7 (70%)	2 (20%)
<b>URINARY SYSTEM</b>							
KIDNEY	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INFARCTION	1 (5%)						
RENAL TUBULE; REGENERATION	10 (50%)					5 (50%)	4 (40%)
URINARY BLADDER	(20)	(0)	(0)	(0)	(0)	(10)	(10)

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Lab: Battelle

Species/Strain: Guinea Pig/Hartley

Female							
	Treatment Groups (mg/kg)						
	0	1	10	30	100	300	800
<b>Disposition Summary</b>							
Animals Initially In Study	23	10	10	13	13	13	10
Scheduled sacrifice, interim							7
<b>Early Deaths</b>							
Found Dead							3
<b>Survivors</b>							
Scheduled sacrifice, terminal (SD 28 - 29)	23	10	10	13	13	13	
Animals Examined Microscopically	20	10	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>							
ESOPHAGUS	(20)	(0)	(0)	(0)	(0)	(10)	(10)
INFLAMMATION; CHRONIC							5 (50%)
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 (10%)
LIVER	(20)	(3)	(6)	(3)	(1)	(10)	(10)
HEPATOCYTE; NECROSIS	9 (45%)	2 (67%)	6 (100%)	3 (100%)	1 (100%)	2 (20%)	3 (30%)
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 (25%)					1 (10%)	2 (20%)
ENDOCARDIUM; HYPERPLASIA; ENDOTHELIAL							1 (10%)
INFLAMMATION; ACUTE							1 (10%)
RHABDOMYOMATOSIS	7 (35%)						2 (20%)
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							
No Tissues/Organs Examined							



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Female							
	Treatment Groups (mg/kg)						
	0	1	10	30	100	300	800
<b>GENITAL SYSTEM</b>							
CERVIX	(20)	(0)	(0)	(0)	(0)	(10)	(10)
ANGIECTASIS; FOCAL						1 (10%)	
OVARY	(20)	(0)	(0)	(0)	(0)	(10)	(10)
UTERUS	(20)	(0)	(0)	(0)	(0)	(10)	(10)
VAGINA	(20)	(0)	(0)	(0)	(0)	(10)	(10)
<b>HEMATOPOIETIC SYSTEM</b>							
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)
<b>INTEGUMENTARY SYSTEM</b>							
MAMMARY GLAND	(20)	(0)	(0)	(0)	(0)	(8)	(9)
<b>LYMPHOID SYSTEM</b>							
No Tissues/Organs Examined							
<b>MUSCULOSKELETAL SYSTEM</b>							
BONE, FEMUR	(20)	(0)	(0)	(0)	(0)	(10)	(10)
<b>NERVOUS SYSTEM</b>							
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 (25%)					2 (20%)	
HEMORRHAGE							2 (20%)
ALVEOLAR EPITHELIUM; HYPERPLASIA	1 (5%)					1 (10%)	
INFILTRATION, CELLULAR; HISTIOCYTE						2 (20%)	2 (20%)
INFLAMMATION; CHRONIC	3 (15%)						
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%)
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 (5%)						1 (10%)
URINARY SYSTEM							
KIDNEY	(20)	(0)	(1)	(0)	(0)	(10)	(10)
PELVIS; DILATION			1 (100%)				
RENAL TUBULE; REGENERATION	17 (85%)					7 (70%)	7 (70%)
URINARY BLADDER	(20)	(0)	(0)	(0)	(0)	(10)	(10)

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LEGEND

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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 \*\***