

Study Number: C11054-01

Test Type: TOX

Route: Oral Gavage

Species/Strain: Rat/Harlan Sprague Dawley

C Number:

Study Gender:

PWG Approval Date

PA41: Clinical Chemistry Summary

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: 15:22:52

Lab: Battelle

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Lab: Battelle

Male: Male Core

	Phase Day	Treatment Groups (mg/kg)				
		0	1	10	30	100
Urea Nitrogen (mg/dL)	SD 29	16.8 ± 0.8 (10)	16.0 ± 0.4 (10)	17.6 ± 0.5 (10)	17.2 ± 0.6 (10)	17.7 ± 1.0 (10)
Percent of Control			95.0	105.0	102.0	105.0
Creatinine (mg/dL)	SD 29	0.75 ± 0.02 (10)	0.71 ± 0.01 (10)	0.75 ± 0.02 (10)	0.72 ± 0.01 (10)	0.73 ± 0.02 (10)
Percent of Control			95.00	100.00	96.00	97.00
Glucose (mg/dL)	SD 29	130.3 ± 2.9 (10)	128.9 ± 4.6 (10)	129.8 ± 3.4 (10)	127.7 ± 1.4 (10)	127.7 ± 2.5 (10)
Percent of Control			99.0	100.0	98.0	98.0
Total Protein (g/dL)	SD 29	6.48 ± 0.07 (10)	6.44 ± 0.10 (10)	6.67 ± 0.07 (10)	6.51 ± 0.12 (10)	6.50 ± 0.06 (10)
Percent of Control			99.00	103.00	100.00	100.00
Albumin (g/dL)	SD 29	4.37 ± 0.04 (10)	4.28 ± 0.04 (10)	4.42 ± 0.04 (10)	4.32 ± 0.06 (10)	4.29 ± 0.02 (10)
Percent of Control			98.00	101.00	99.00	98.00
Cholesterol (mg/dL)	SD 29	115.2 ± 4.3 (10)	118.4 ± 2.7 (10)	116.9 ± 3.5 (10)	126.3 ± 3.8 (10)	119.0 ± 3.9 (10)
Percent of Control			103.0	101.0	110.0	103.0
Triglyceride (mg/dL)	SD 29	78.1 ± 5.2 (10) **	83.8 ± 8.1 (10)	88.5 ± 7.0 (10)	111.4 ± 9.8 (10)	88.9 ± 7.4 (10)
Percent of Control			107.0	113.0	143.0	114.0
Alanine Aminotransferase (IU/L)	SD 29	52.20 ± 2.54 (10) **	50.00 ± 2.48 (10)	53.30 ± 1.22 (10)	50.70 ± 2.11 (10)	47.00 ± 1.81 (10)
Percent of Control			96.00	102.00	97.00	90.00
Alkaline Phosphatase (IU/L)	SD 29	227.3 ± 4.6 (10)	204.3 ± 8.3 (10)	227.5 ± 11.2 (10)	226.2 ± 9.5 (10)	214.2 ± 6.7 (10)
Percent of Control			90.0	100.0	100.0	94.0
Creatine Kinase (IU/L)	SD 29	193.4 ± 18.0 (10)	389.9 ± 105.2 (10)	260.5 ± 28.2 (10)	322.4 ± 57.1 (10)	254.9 ± 57.4 (9)
Percent of Control			202.0	135.0	167.0	132.0
Sorbitol Dehydrogenase (IU/L)	SD 29	12.6 ± 0.5 (10) **	11.9 ± 0.7 (10)	10.6 ± 0.7 (10)	11.2 ± 1.0 (10)	10.8 ± 0.7 (10)
Percent of Control			94.0	84.0	89.0	86.0

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Lab: Battelle

Male: Male Core

		Treatment Groups (mg/kg)				
	Phase Day	0	1	10	30	100
Bile salt/acids ($\mu\text{mol/L}$)	SD 29	25.4 \pm 5.5 (10)	18.7 \pm 2.7 (10)	26.3 \pm 4.9 (10)	16.9 \pm 2.3 (10)	13.0 \pm 2.6 (10)
Percent of Control			74.0	104.0	67.0	51.0

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Lab: Battelle

Male: Male Core

	Phase Day	Treatment Groups (mg/kg)	
		300	800
Urea Nitrogen (mg/dL)	SD 29	21.2 ± 1.8 (10)	14.8 ± 0.5 (10)
Percent of Control		126.0	88.0
Creatinine (mg/dL)	SD 29	0.75 ± 0.02 (10)	0.72 ± 0.01 (10)
Percent of Control		100.00	96.00
Glucose (mg/dL)	SD 29	137.9 ± 10.0 (10)	141.4 ± 3.7 (10)
Percent of Control		106.0	109.0
Total Protein (g/dL)	SD 29	6.75 ± 0.19 (10)	6.37 ± 0.08 (10)
Percent of Control		104.00	98.00
Albumin (g/dL)	SD 29	4.42 ± 0.11 (10)	4.29 ± 0.04 (10)
Percent of Control		101.00	98.00
Cholesterol (mg/dL)	SD 29	130.5 ± 5.1 (10)	120.2 ± 3.8 (10)
Percent of Control		113.0	104.0
Triglyceride (mg/dL)	SD 29	75.5 ± 10.3 (10)	144.7 ± 11.9 (10) **
Percent of Control		97.0	185.0
Alanine Aminotransferase (IU/L)	SD 29	55.10 ± 1.71 (10)	74.50 ± 1.54 (10) **
Percent of Control		106.00	143.00
Alkaline Phosphatase (IU/L)	SD 29	207.2 ± 7.3 (10)	245.8 ± 10.6 (10)
Percent of Control		91.0	108.0
Creatine Kinase (IU/L)	SD 29	356.9 ± 48.7 (10)	318.9 ± 77.1 (10)
Percent of Control		185.0	165.0
Sorbitol Dehydrogenase (IU/L)	SD 29	11.3 ± 0.7 (10)	9.5 ± 0.4 (10) **
Percent of Control		90.0	75.0

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Lab: Battelle

Male: Male Core

	Phase Day	Treatment Groups (mg/kg)	
		300	800
Bile salt/acids ($\mu\text{mol/L}$)	SD 29	15.2 \pm 3.2 (10)	19.8 \pm 3.0 (10)
Percent of Control		60.0	78.0

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Lab: Battelle

Female: Female Core

	Phase Day	Treatment Groups (mg/kg)				
		0	1	10	30	100
Urea Nitrogen (mg/dL)	SD 29	15.6 ± 0.8 (10)	15.2 ± 0.6 (10)	17.1 ± 0.6 (10)	14.8 ± 0.5 (10)	15.4 ± 0.6 (10)
Percent of Control			97.0	110.0	95.0	99.0
Creatinine (mg/dL)	SD 29	0.74 ± 0.02 (10)	0.75 ± 0.02 (10)	0.77 ± 0.02 (10)	0.73 ± 0.02 (10)	0.76 ± 0.02 (10)
Percent of Control			101.00	104.00	99.00	103.00
Glucose (mg/dL)	SD 29	129.5 ± 4.2 (10)	123.8 ± 4.7 (10)	128.0 ± 7.0 (10)	124.5 ± 5.9 (10)	124.7 ± 3.3 (10)
Percent of Control			96.0	99.0	96.0	96.0
Total Protein (g/dL)	SD 29	6.48 ± 0.09 (10)	6.49 ± 0.10 (10)	6.53 ± 0.10 (10)	6.51 ± 0.07 (10)	6.47 ± 0.12 (10)
Percent of Control			100.00	101.00	100.00	100.00
Albumin (g/dL)	SD 29	4.53 ± 0.05 (10) *	4.59 ± 0.08 (10)	4.60 ± 0.09 (10)	4.56 ± 0.05 (10)	4.55 ± 0.08 (10)
Percent of Control			101.00	102.00	101.00	100.00
Cholesterol (mg/dL)	SD 29	114.1 ± 4.7 (10)	103.8 ± 3.9 (10)	102.2 ± 4.6 (10)	106.6 ± 3.7 (10)	102.4 ± 4.6 (10)
Percent of Control			91.0	90.0	93.0	90.0
Triglyceride (mg/dL)	SD 29	50.4 ± 4.6 (10) *	56.9 ± 4.6 (10)	67.7 ± 4.0 (10)	61.1 ± 7.4 (10)	56.7 ± 6.6 (10)
Percent of Control			113.0	134.0	121.0	113.0
Alanine Aminotransferase (IU/L)	SD 29	49.40 ± 1.05 (10) **	46.80 ± 2.03 (10)	49.70 ± 3.26 (10)	48.40 ± 1.78 (10)	46.50 ± 1.28 (10)
Percent of Control			95.00	101.00	98.00	94.00
Alkaline Phosphatase (IU/L)	SD 29	179.4 ± 9.3 (10)	164.6 ± 10.2 (10)	192.5 ± 10.7 (10)	187.1 ± 6.2 (10)	170.4 ± 11.3 (10)
Percent of Control			92.0	107.0	104.0	95.0
Creatine Kinase (IU/L)	SD 29	277.5 ± 37.1 (10)	259.3 ± 32.4 (9)	302.0 ± 41.0 (10)	264.7 ± 26.2 (10)	471.7 ± 131.1 (10)
Percent of Control			93.0	109.0	95.0	170.0
Sorbitol Dehydrogenase (IU/L)	SD 29	11.4 ± 1.1 (10)	11.9 ± 0.9 (10)	10.8 ± 1.0 (10)	12.0 ± 1.1 (10)	12.3 ± 0.8 (10)
Percent of Control			104.0	95.0	105.0	108.0

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Female: Female Core

		Treatment Groups (mg/kg)				
	Phase Day	0	1	10	30	100
Bile salt/acids (µmol/L)	SD 29	21.3 ± 3.6 (10)	13.5 ± 2.1 (10)	28.4 ± 5.5 (10)	16.2 ± 4.1 (10)	20.1 ± 5.3 (10)
Percent of Control			63.0	133.0	76.0	94.0

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Lab: Battelle

Female: Female Core

	Phase Day	Treatment Groups (mg/kg)	
		300	800
Urea Nitrogen (mg/dL)	SD 29	15.0 ± 0.4 (10)	15.9 ± 0.7 (10)
Percent of Control		96.0	102.0
Creatinine (mg/dL)	SD 29	0.75 ± 0.02 (10)	0.70 ± 0.02 (10)
Percent of Control		101.00	95.00
Glucose (mg/dL)	SD 29	131.7 ± 6.4 (10)	137.2 ± 4.7 (10)
Percent of Control		102.0	106.0
Total Protein (g/dL)	SD 29	6.49 ± 0.10 (10)	6.33 ± 0.11 (10)
Percent of Control		100.00	98.00
Albumin (g/dL)	SD 29	4.52 ± 0.08 (10)	4.31 ± 0.06 (10)
Percent of Control		100.00	95.00
Cholesterol (mg/dL)	SD 29	119.8 ± 4.2 (10)	117.2 ± 5.0 (10)
Percent of Control		105.0	103.0
Triglyceride (mg/dL)	SD 29	66.7 ± 6.9 (10)	90.6 ± 18.1 (10)
Percent of Control		132.0	180.0
Alanine Aminotransferase (IU/L)	SD 29	52.00 ± 1.35 (10)	70.80 ± 3.00 (10) **
Percent of Control		105.00	143.00
Alkaline Phosphatase (IU/L)	SD 29	174.8 ± 8.9 (10)	199.7 ± 12.5 (10)
Percent of Control		97.0	111.0
Creatine Kinase (IU/L)	SD 29	310.9 ± 96.2 (10)	358.7 ± 66.8 (10)
Percent of Control		112.0	129.0
Sorbitol Dehydrogenase (IU/L)	SD 29	11.4 ± 1.1 (10)	11.7 ± 1.0 (10)
Percent of Control		100.0	103.0

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Lab: Battelle

Female: Female Core

	Phase Day	Treatment Groups (mg/kg)	
		300	800
Bile salt/acids ($\mu\text{mol/L}$)	SD 29	23.2 \pm 4.0 (10)	30.4 \pm 5.2 (10)
Percent of Control		109.0	143.0

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LEGEND

Values given as mean \pm SEM (N) with Percent of Control calculated by (dosed group mean / control group mean) x 100

SD – Study Day

Statistical analysis performed by Jonckheere (trend) and Shirley or Dunn (pairwise) tests (unless otherwise noted).

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

* Statistically significant at $P \leq 0.05$

** Statistically significant at $P \leq 0.01$

Decrease in N for Creatine Kinase in the 100 mg/kg group is due to one male's value being excluded because it was an outlier.

Decrease in N for Creatine Kinase in the 1 mg/kg group is due to one female's value being excluded because it was an outlier.

**** END OF REPORT ****