

Study Number: C05051-01

Test Type: TOX

Route: Dosing in Water

Species/Strain: Rat/Harlan Sprague Dawley

C Number:

Study Gender:

PWG Approval Date

PA41: Clinical Chemistry Summary

Test Compound: 1-Butyl-1-Methylpyrrolidinium Chloride

CAS Number: 479500-35-1

C05051-01

Both

See web page for date of PWG Approval

Date Report Requested: 04/21/2020

Time Report Requested: 13:48:03

Lab: NTP

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Male

	Phase Day	Treatment Groups (mg/mL)			
		0	0.3	1	3
Urea Nitrogen (mg/dL)	SD 92	16.4 ± 0.6 (10)	18.4 ± 1.0 (10)	16.2 ± 0.6 (10)	17.6 ± 0.3 (10)
Percent of Control			112.2	98.8	107.3
Creatinine (mg/dL)	SD 92	0.69 ± 0.02 (10)	0.72 ± 0.01 (10)	0.72 ± 0.01 (10)	0.71 ± 0.01 (10)
Percent of Control			104.3	104.3	102.9
Glucose (mg/dL)	SD 92	124.6 ± 3.1 (10)	132.2 ± 5.5 (10)	136.8 ± 6.1 (10)	138.4 ± 7.1 (10)
Percent of Control			106.1	109.8	111.1
Total Protein (g/dL)	SD 92	7.28 ± 0.06 (10)	7.35 ± 0.08 (10)	7.37 ± 0.04 (10)	7.36 ± 0.09 (10)
Percent of Control			101.0	101.2	101.1
Globulin (g/dL)	SD 92	3.01 ± 0.05 (10)	3.10 ± 0.09 (10)	3.08 ± 0.04 (10)	3.10 ± 0.08 (10)
Percent of Control			103.0	102.3	103.0
Globulin (g/dL)	SD 92	3.01 ± 0.05 (10)	3.10 ± 0.09 (10)	3.08 ± 0.04 (10)	3.10 ± 0.08 (10)
Percent of Control			103.0	102.3	103.0
A/G Ratio	SD 92	1.42 ± 0.03 (10)	1.38 ± 0.04 (10)	1.40 ± 0.03 (10)	1.38 ± 0.04 (10)
Percent of Control			97.1	98.1	97.2
Albumin (g/dL)	SD 92	4.27 ± 0.03 (10)	4.25 ± 0.04 (10)	4.29 ± 0.04 (10)	4.26 ± 0.04 (10)
Percent of Control			99.5	100.5	99.8
Cholesterol (mg/dL)	SD 92	133.9 ± 6.2 (10)	132.1 ± 2.5 (10)	127.6 ± 4.3 (10)	128.7 ± 6.2 (10)
Percent of Control			98.7	95.3	96.1
Triglyceride (mg/dL)	SD 92	112.1 ± 16.3 (10)	107.2 ± 11.1 (10)	100.2 ± 8.8 (10)	121.1 ± 17.9 (10)
Percent of Control			95.6	89.4	108.0
Alanine Aminotransferase (IU/L)	SD 92	59.7 ± 4.3 (10)	70.7 ± 9.3 (10)	74.6 ± 20.4 (10)	55.0 ± 2.8 (10)
Percent of Control			118.4	125.0	92.1

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	Phase Day	Treatment Groups (mg/mL)			
		0	0.3	1	3
Alkaline Phosphatase (IU/L) Percent of Control	SD 92	176.9 ± 8.3 (10) *	186.7 ± 4.3 (10) 105.5	197.0 ± 10.8 (10) 111.4	198.9 ± 8.5 (10) 112.4
Creatine Kinase (IU/L) Percent of Control	SD 92	227.5 ± 41.6 (10)	276.0 ± 58.7 (10) 121.3	317.5 ± 57.7 (10) 139.6	225.0 ± 33.0 (10) 98.9
Sorbitol Dehydrogenase (IU/L) Percent of Control	SD 92	18.9 ± 2.5 (10)	25.0 ± 7.0 (10) 132.3	34.1 ± 18.6 (10) 180.4	14.6 ± 1.7 (10) 77.2
Bile salt/acids (umol/L) Percent of Control	SD 92	22.5 ± 2.7 (10)	26.4 ± 2.4 (10) 117.3	18.1 ± 3.2 (10) 80.4	16.8 ± 2.9 (10) 74.7

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Female

	Phase Day	Treatment Groups (mg/mL)			
		0	1	3	6
Urea Nitrogen (mg/dL)	SD 92	16.2 ± 0.4 (10)	16.1 ± 0.6 (10)	17.8 ± 0.7 (10)	16.8 ± 0.6 (10)
Percent of Control			99.4	109.9	103.7
Creatinine (mg/dL)	SD 92	0.80 ± 0.01 (10)	0.79 ± 0.02 (10)	0.77 ± 0.02 (10)	0.77 ± 0.02 (10)
Percent of Control			98.8	96.3	96.3
Glucose (mg/dL)	SD 92	135.6 ± 5.0 (10)	139.6 ± 7.7 (10)	134.0 ± 3.5 (10)	150.1 ± 6.6 (10)
Percent of Control			102.9	98.8	110.7
Total Protein (g/dL)	SD 92	7.38 ± 0.15 (10)	7.22 ± 0.14 (10)	7.15 ± 0.15 (10)	7.24 ± 0.15 (10)
Percent of Control			97.8	96.9	98.1
Globulin (g/dL)	SD 92	2.58 ± 0.15 (10)	2.51 ± 0.09 (10)	2.48 ± 0.11 (10)	2.62 ± 0.09 (10)
Percent of Control			97.3	96.1	101.6
Globulin (g/dL)	SD 92	2.58 ± 0.15 (10)	2.51 ± 0.09 (10)	2.48 ± 0.11 (10)	2.62 ± 0.09 (10)
Percent of Control			97.3	96.1	101.6
A/G Ratio	SD 92	1.93 ± 0.14 (10)	1.90 ± 0.08 (10)	1.92 ± 0.10 (10)	1.78 ± 0.04 (10)
Percent of Control			98.5	99.4	91.9
Albumin (g/dL)	SD 92	4.80 ± 0.05 (10)	4.71 ± 0.07 (10)	4.67 ± 0.06 (10)	4.62 ± 0.07 (10)
Percent of Control			98.1	97.3	96.3
Cholesterol (mg/dL)	SD 92	115.8 ± 5.4 (10)	117.1 ± 7.5 (10)	115.7 ± 4.3 (10)	109.5 ± 4.0 (10)
Percent of Control			101.1	99.9	94.6
Triglyceride (mg/dL)	SD 92	65.9 ± 4.7 (10)	58.2 ± 4.0 (10)	68.1 ± 5.9 (10)	52.0 ± 5.5 (10)
Percent of Control			88.3	103.3	78.9
Alanine Aminotransferase (IU/L)	SD 92	46.6 ± 2.2 (10) **	46.4 ± 2.1 (10)	42.5 ± 2.3 (10)	38.0 ± 1.3 (10) **
Percent of Control			99.6	91.2	81.5

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	Phase Day	Treatment Groups (mg/mL)			
		0	1	3	6
Alkaline Phosphatase (IU/L) Percent of Control	SD 92	143.6 ± 7.4 (10)	158.6 ± 10.0 (10) 110.4	156.6 ± 8.8 (10) 109.1	138.6 ± 8.6 (10) 96.5
Creatine Kinase (IU/L) Percent of Control	SD 92	301.6 ± 86.9 (10)	306.3 ± 101.0 (10) 101.6	442.8 ± 164.1 (10) 146.8	276.7 ± 66.4 (10) 91.7
Sorbitol Dehydrogenase (IU/L) Percent of Control	SD 92	10.9 ± 0.5 (10)	11.6 ± 0.9 (10) 106.4	11.0 ± 1.1 (10) 100.9	11.2 ± 0.4 (9) 103.0
Bile salt/acids (umol/L) Percent of Control	SD 92	13.1 ± 1.6 (10)	21.5 ± 3.0 (10) 164.1	14.6 ± 3.0 (10) 111.5	9.3 ± 1.6 (10) 71.0

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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.

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 $P \leq 0.01$

**** END OF REPORT ****