

Experiment Number: A86637

Test Type: Genetic Toxicology - Micronucleus

Route: Dosed-Water

Species/Strain: Mouse/B6C3F1

**G04: In Vivo Micronucleus Summary Data**

Test Compound: Urethane

CAS Number: 51-79-6

Date Report Requested: 09/21/2018

Time Report Requested: 08:18:27

**NTP Study Number:**

A86637

**Study Duration:**

90 Days

**Study Methodology:**

Slide Scoring

**Male Study Result:**

Positive

**Female Study Result:**

Positive

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Test Compound: Urethane

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Tissue: Blood; Sex: Male; Number of Treatments: 45; Time interval between final treatment and cell sampling: 24 h

Dose (mg/mL)	N	MN PCE/1000		MN NCE/1000		
		Mean ± SEM	p-Value	N	Mean ± SEM	p-Value
Vehicle Control <sup>1</sup>	12	2.41 ± 0.26		12	1.78 ± 0.16	
0.05	8	4.11 ± 0.72	0.0146	8	2.79 ± 0.26	0.0236
0.2	8	4.92 ± 1.01	0.0010 *	8	4.56 ± 0.42	< 0.001 *
0.75	8	8.08 ± 1.07	< 0.001 *	8	9.18 ± 0.76	< 0.001 *
2.0	8	17.87 ± 2.39	< 0.001 *	8	19.29 ± 2.15	< 0.001 *
Trend p-Value		< 0.001 *			< 0.001 *	

Trial Summary: Positive

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Tissue: Blood; Sex: Male; Number of Treatments: 90; Time interval between final treatment and cell sampling: 24 h

Dose (mg/mL)	N	MN PCE/1000		MN NCE/1000	
		Mean ± SEM	p-Value	Mean ± SEM	p-Value
Vehicle Control <sup>1</sup>	12	3.26 ± 0.44		2.04 ± 0.10	
0.05	8	4.14 ± 0.60	0.2150	2.83 ± 0.28	0.0866
0.2	8	4.63 ± 0.88	0.1129	4.07 ± 0.23	< 0.001 *
0.75	8	9.97 ± 1.91	< 0.001 *	10.33 ± 1.42	< 0.001 *
2.0	8	22.68 ± 2.74	< 0.001 *	21.87 ± 2.16	< 0.001 *
Trend p-Value		< 0.001 *		< 0.001 *	

Trial Summary: Positive

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**Tissue: Blood; Sex: Female; Number of Treatments: 45; Time interval between final treatment and cell sampling: 24 h**

Dose (mg/mL)	N	MN PCE/1000		MN NCE/1000		
		Mean ± SEM	p-Value	N	Mean ± SEM	p-Value
Vehicle Control <sup>1</sup>	12	2.34 ± 0.29		12	1.30 ± 0.08	
0.05	8	1.82 ± 0.21	0.7890	8	1.86 ± 0.19	0.0121
0.2	8	4.27 ± 0.50	0.0073	8	4.22 ± 0.22	< 0.001 *
0.75	8	10.72 ± 1.56	< 0.001 *	8	9.27 ± 0.50	< 0.001 *
2.0	8	21.00 ± 2.60	< 0.001 *	8	17.34 ± 1.09	< 0.001 *
Trend p-Value		< 0.001 *			< 0.001 *	

Trial Summary: Positive

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**Tissue: Blood; Sex: Female; Number of Treatments: 90; Time interval between final treatment and cell sampling: 24 h**

Dose (mg/mL)	N	MN PCE/1000		MN NCE/1000		
		Mean ± SEM	p-Value	N	Mean ± SEM	p-Value
Vehicle Control <sup>1</sup>	12	1.93 ± 0.33		12	1.56 ± 0.09	
0.05	8	2.39 ± 0.38	0.2377	8	2.02 ± 0.15	0.0591
0.2	8	3.48 ± 0.65	0.0138	8	4.20 ± 0.39	< 0.001 *
0.75	8	9.11 ± 0.95	< 0.001 *	8	9.95 ± 0.57	< 0.001 *
2.0	8	23.00 ± 1.76	< 0.001 *	8	22.69 ± 1.28	< 0.001 *
Trend p-Value		< 0.001 *			< 0.001 *	

Trial Summary: Positive

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Tissue: Bone marrow; Sex: Male; Number of Treatments: 90; Time interval between final treatment and cell sampling: 24 h

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<b>MN PCE/1000</b>			
<b>Dose (mg/mL)</b>	<b>N</b>	<b>Mean ± SEM</b>	<b>p-Value</b>
Vehicle Control <sup>1</sup>	12	2.33 ± 0.28	
0.05	8	3.13 ± 0.44	0.1430
0.2	8	4.38 ± 0.50	0.0058 *
0.75	8	10.75 ± 1.13	< 0.001 *
2.0	8	27.50 ± 3.94	< 0.001 *
Trend p-Value		< 0.001 *	

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Trial Summary: Positive

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Tissue: Bone marrow; Sex: Female; Number of Treatments: 90; Time interval between final treatment and cell sampling: 24 h

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<b>MN PCE/1000</b>			
<b>Dose (mg/mL)</b>	<b>N</b>	<b>Mean ± SEM</b>	<b>p-Value</b>
Vehicle Control <sup>1</sup>	12	2.00 ± 0.39	
0.05	8	2.88 ± 0.35	0.1053
0.2	8	4.50 ± 0.60	< 0.001 *
0.75	8	10.88 ± 0.81	< 0.001 *
2.0	8	23.75 ± 1.87	< 0.001 *
Trend p-Value		< 0.001 *	

Trial Summary: Positive

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LEGEND

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MN = micronucleated, PCE = polychromatic erythrocyte, NCE = normochromatic erythrocyte

CAS Number = Chemical Abstracts Service registry number

N = Number of subjects

Values given as Mean or Mean  $\pm$  Standard Error Mean

Results were tabulated as the mean of the pooled results from all animals within a treatment group, plus or minus the standard error of the mean

Pairwise comparison to the concurrent control, dosed groups significant at  $p = 0.025/\text{number of treatment groups}$ ; positive control value is significant at  $p = 0.05$

Cochran-Armitage trend test, significant at  $p = 0.025$

\* Statistically significant pairwise or trend test

1: Vehicle Control: Water

**\*\* END OF REPORT \*\***