

Experiment Number: A40595

Test Type: Genetic Toxicology - Micronucleus

Route: Gavage

Species/Strain: Mouse/B6C3F1

G04: In Vivo Micronucleus Summary Data

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 09/20/2018

Time Report Requested: 12:50:42

NTP Study Number:

A40595

Study Duration:

72 Hours

Study Methodology:

Slide Scoring

Male Study Result:

Negative

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Tissue: Bone marrow; Sex: Male; Number of Treatments: 3; Time interval between final treatment and cell sampling: 24 h

Dose (mg/kg)	N	MN PCE/1000		N	MN NCE/1000		% PCE
		Mean ± SEM	p-Value		Mean ± SEM	p-Value	Mean ± SEM
Vehicle Control ¹	5	1.20 ± 0.34		5	0.00 ± 0.00		40.42 ± 1.84
156.25	5	1.20 ± 0.12	0.5000	4	0.00 ± 0.00	0.5000	43.55 ± 4.13
312.5	5	1.50 ± 0.39	0.2817	4	0.00 ± 0.00	0.5000	45.78 ± 1.10
625.0	5	1.10 ± 0.33	0.5826	3	0.00 ± 0.00	0.5000	47.87 ± 0.63
1250.0	5	0.90 ± 0.40	0.7438	3	0.00 ± 0.00	0.5000	47.53 ± 1.13
2500.0	5	1.50 ± 0.35	0.2817	4	0.00 ± 0.00	0.5000	46.38 ± 1.33
Trend p-Value		0.3700					
Positive Control ²	5	29.00 ± 0.77	< 0.001 *	5	0.00 ± 0.00	0.5000	26.96 ± 1.91

Trial Summary: Negative

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LEGEND

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: Phosphate Buffered Saline

2: 50.0 mg/kg Cyclophosphamide

**** END OF REPORT ****