

Experiment Number: A76890

Test Type: Genetic Toxicology - Micronucleus

Route: Gavage

Species/Strain: Rat/Fischer 344

G04: In Vivo Micronucleus Summary Data

Test Compound: Elmiron (sodium pentosanpolysulfate)

CAS Number: 37319-17-8

Date Report Requested: 09/21/2018

Time Report Requested: 04:28:18

NTP Study Number:

A76890

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	p-Value	% PCE
		Mean ± SEM		Mean ± SEM
Vehicle Control ¹	5	1.00 ± 0.32		31.50 ± 3.16
156.25	5	1.30 ± 0.25	0.2657	33.80 ± 0.90
312.5	5	1.70 ± 0.20	0.0888	37.10 ± 0.76
625.0	5	2.30 ± 0.25	0.0118	49.10 ± 3.15
1250.0	5	1.90 ± 0.33	0.0472	37.60 ± 4.57
2500.0	5	2.30 ± 0.34	0.0118	43.90 ± 2.60
Trend p-Value		0.0190 *		
Positive Control ²	5	26.20 ± 2.03	< 0.001 *	34.40 ± 4.53

Trial Summary: Negative

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Dose (mg/kg)	N	MN PCE/1000	p-Value	% PCE
		Mean ± SEM		Mean ± SEM
Vehicle Control ¹	5	1.70 ± 0.37		44.70 ± 3.68
156.25	5	1.50 ± 0.32	0.6383	48.30 ± 2.96
312.5	5	1.50 ± 0.50	0.6383	39.40 ± 3.13
625.0	5	1.20 ± 0.25	0.8236	37.30 ± 1.57
1250.0	5	1.10 ± 0.29	0.8717	48.30 ± 2.67
2500.0	5	1.40 ± 0.33	0.7051	34.70 ± 1.83
Trend p-Value		0.7180		
Positive Control ²	5	18.50 ± 0.72	< 0.001 *	36.50 ± 3.26

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: 10.0 mg/kg Cyclophosphamide

**** END OF REPORT ****