

Experiment Number: A91531

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: 09/21/2018

Time Report Requested: 10:16:45

NTP Study Number:

A91531

Study Duration:

13 Weeks

Study Methodology:

Slide Scoring

Male Study Result:

Negative

Female Study Result:

Negative

Experiment Number: A91531
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: 09/21/2018
Time Report Requested: 10:16:45

Tissue: Blood; Sex: Male; Number of Treatments: 65; Time interval between final treatment and cell sampling: 24 h

MN NCE/1000			
Dose (mg/kg)	N	Mean ± SEM	p-Value
Vehicle Control ¹	5	0.40 ± 0.10	
63.0	5	0.50 ± 0.32	0.3694
125.0	5	0.50 ± 0.32	0.3694
250.0	5	0.40 ± 0.19	0.5000
500.0	5	0.10 ± 0.10	0.9102
1000.0	5	0.40 ± 0.19	0.5000
Trend p-Value		0.7260	

Trial Summary: Negative

Experiment Number: A91531
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: 09/21/2018
Time Report Requested: 10:16:45

Tissue: Blood; Sex: Female; Number of Treatments: 65; Time interval between final treatment and cell sampling: 24 h

MN NCE/1000			
Dose (mg/kg)	N	Mean ± SEM	p-Value
Vehicle Control ¹	5	0.10 ± 0.10	
63.0	5	0.50 ± 0.16	0.0512
125.0	5	0.40 ± 0.19	0.0898
250.0	5	0.20 ± 0.20	0.2818
500.0	5	0.70 ± 0.25	0.0169
1000.0	5	0.20 ± 0.12	0.2818
Trend p-Value		0.4920	

Trial Summary: Negative

Experiment Number: A91531

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: 09/21/2018

Time Report Requested: 10:16:45

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: Water

**** END OF REPORT ****