

Experiment Number: 754198

Test Type: Genetic Toxicology - Micronucleus

Route: Intraperitoneal Injection

Species/Strain: Mouse/B6C3F1

G04: In Vivo Micronucleus Summary Data

Test Compound: Primidone (primaclone)

CAS Number: 125-33-7

Date Report Requested: 09/19/2018

Time Report Requested: 20:00:27

NTP Study Number:

754198

Study Duration:

96 Hours

Study Methodology:

Slide Scoring

Male Study Result:

Negative

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Date Report Requested: 09/19/2018
Time Report Requested: 20:00:27

Tissue: Bone marrow; Sex: Male; Number of Treatments: 3; Time interval between final treatment and cell sampling: 48 h

| Dose (mg/kg) | N | MN PCE/1000 | p-Value | % PCE |
|------------------------------|---|-------------|---------|--------------|
| | | Mean ± SEM | | Mean ± SEM |
| Vehicle Control ¹ | 3 | 1.67 ± 0.88 | | 38.00 ± 3.56 |
| 100.0 | 3 | 2.00 ± 1.00 | 0.3927 | 46.03 ± 3.29 |
| 300.0 | 2 | 1.50 ± 0.50 | 0.5518 | 34.20 ± 9.70 |
| Trend p-Value | | 0.5620 | | |

Trial Summary: Negative

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Date Report Requested: 09/19/2018
Time Report Requested: 20:00:27

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

| | | MN PCE/1000 | | % PCE | |
|-------------------------------|---|-------------|-----------|--------------|--|
| Dose (mg/kg) | N | Mean ± SEM | p-Value | Mean ± SEM | |
| Vehicle Control ¹ | 5 | 0.60 ± 0.19 | | 44.70 ± 2.20 | |
| 87.5 | 5 | 0.40 ± 0.19 | 0.7365 | 47.90 ± 1.79 | |
| 175.0 | 5 | 0.90 ± 0.24 | 0.2192 | 43.52 ± 0.65 | |
| 300.0 | 2 | 1.25 ± 0.25 | 0.1075 | 45.10 ± 6.20 | |
| Trend p-Value | | 0.0610 | | | |
| Positive Control ² | 5 | 2.40 ± 0.29 | < 0.001 * | 37.30 ± 2.14 | |

Trial Summary: 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 | 0.60 ± 0.19 | | 44.52 ± 0.58 |
| 87.5 | 5 | 1.10 ± 0.29 | 0.1125 | 42.76 ± 3.14 |
| 175.0 | 5 | 1.10 ± 0.37 | 0.1125 | 34.70 ± 1.71 |
| 300.0 | 3 | 1.33 ± 0.33 | 0.0644 | 36.83 ± 0.32 |
| 350.0 | 3 | 1.50 ± 0.58 | 0.0359 | 23.53 ± 2.83 |
| Trend p-Value | | 0.0410 | | |
| Positive Control ² | 4 | 4.25 ± 1.49 | < 0.001 * | 30.90 ± 6.04 |

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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: Corn Oil

2: 12.5 mg/kg Dimethylbenzanthracene

**** END OF REPORT ****