

Experiment Number: 029483

Test Type: Genetic Toxicology - Micronucleus

Route: Intraperitoneal Injection

Species/Strain: Mouse/B6C3F1

G04: In Vivo Micronucleus Summary Data

Test Compound: FD & C Yellow No. 6

CAS Number: 2783-94-0

Date Report Requested: 09/19/2018

Time Report Requested: 11:45:56

NTP Study Number:

029483

Study Duration:

96 Hours

Study Methodology:

Slide Scoring

Male Study Result:

Negative

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Tissue: Blood; 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 | 5 | 3.90 ± 0.62 | | 3.60 ± 0.33 |
| 1500.0 | 5 | 4.10 ± 0.60 | 0.4114 | 4.70 ± 0.37 |
| 2000.0 | 5 | 3.80 ± 0.58 | 0.5455 | 4.60 ± 0.29 |
| Trend p-Value | | 0.5070 | | |

Trial Summary: Negative

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Tissue: Blood; 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 | 2.60 ± 0.29 | | 3.58 ± 0.27 |
| 500.0 | 5 | 3.00 ± 0.45 | 0.2962 | 4.66 ± 0.76 |
| 1000.0 | 5 | 3.80 ± 0.73 | 0.0665 | 4.72 ± 0.51 |
| 2000.0 | 5 | 3.60 ± 0.75 | 0.1017 | 4.68 ± 0.41 |
| Trend p-Value | | 0.0910 | | |
| Positive Control ² | 5 | 8.20 ± 0.87 | < 0.001 * | 3.04 ± 0.31 |

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 | 2.20 ± 0.30 | | 64.80 ± 1.49 |
| 500.0 | 5 | 2.40 ± 0.37 | 0.3839 | 64.70 ± 2.47 |
| 1000.0 | 5 | 3.60 ± 0.91 | 0.0328 | 64.20 ± 5.10 |
| 2000.0 | 5 | 4.60 ± 0.89 | 0.0018 * | 71.00 ± 3.28 |
| Trend p-Value | | < 0.001 * | | |
| Positive Control ² | 5 | 7.30 ± 0.98 | < 0.001 * | 60.10 ± 3.77 |

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 | 3.00 ± 0.35 | | 59.60 ± 1.83 |
| 500.0 | 3 | 2.50 ± 1.00 | 0.7184 | 61.00 ± 8.69 |
| 1000.0 | 4 | 2.50 ± 0.54 | 0.7367 | 58.25 ± 2.79 |
| 2000.0 | 5 | 3.00 ± 0.22 | 0.5000 | 65.80 ± 1.69 |
| Trend p-Value | | 0.4540 | | |
| Positive Control ² | 5 | 8.30 ± 2.02 | < 0.001 * | 54.60 ± 4.62 |

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 | 2.70 ± 0.72 | | 60.40 ± 3.89 |
| 2000.0 | 5 | 2.40 ± 0.19 | 0.6630 | 61.60 ± 2.16 |
| 2500.0 | 5 | 2.10 ± 0.43 | 0.8070 | 69.90 ± 1.98 |
| 3000.0 | 4 | 3.13 ± 0.13 | 0.2988 | 65.13 ± 2.67 |
| Trend p-Value | | 0.5220 | | |
| Positive Control ² | 5 | 6.90 ± 1.19 | < 0.001 * | 60.50 ± 3.64 |

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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: 0.2 mg/kg Mitomycin-C

**** END OF REPORT ****