Experiment Number: 695078

Test Type: Genetic Toxicology - Micronucleus

Route: Gavage

Species/Strain: Mouse/B6C3F1

NTP Study Number:

G04: In Vivo Micronucleus Summary Data

Test Compound: Cytarabine hydrochloride

CAS Number: 69-74-9

Date Report Requested: 09/19/2018
Time Report Requested: 19:16:07

695078

Study Duration: 72 Hours

Study Methodology: Slide Scoring

Male Study Result: Positive

G04: In Vivo Micronucleus Summary Data

Test Compound: Cytarabine hydrochloride

CAS Number: 69-74-9

Date Report Requested: 09/19/2018
Time Report Requested: 19:16:07

Route: Gavage

Species/Strain: Mouse/B6C3F1

Test Type: Genetic Toxicology - Micronucleus

Experiment Number: 695078

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 | 1.80 ± 0.62 | | 57.70 ± 1.91 |
| 40.0 | 5 | 21.10 ± 1.91 | < 0.001 * | 57.00 ± 2.13 |
| 80.0 | 5 | 27.80 ± 0.75 | < 0.001 * | 53.50 ± 1.40 |
| 160.0 | 5 | 29.50 ± 2.32 | < 0.001 * | 42.30 ± 3.59 |
| Trend p-Value | | < 0.001 * | | |
| Positive Control ² | 4 | 2.88 ± 0.43 | 0.0664 | 60.25 ± 2.24 |
| Trial Summary: Positive | | | | |

G04: In Vivo Micronucleus Summary Data

Test Compound: Cytarabine hydrochloride

CAS Number: 69-74-9

Date Report Requested: 09/19/2018
Time Report Requested: 19:16:07

Route: Gavage

Species/Strain: Mouse/B6C3F1

Test Type: Genetic Toxicology - Micronucleus

Experiment Number: 695078

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 | 2.00 ± 0.16 | | 58.30 ± 2.19 |
| 40.0 | 5 | 18.70 ± 1.95 | < 0.001 * | 53.60 ± 1.13 |
| 80.0 | 5 | 31.60 ± 2.60 | < 0.001 * | 48.30 ± 3.33 |
| 160.0 | 5 | 36.80 ± 3.18 | < 0.001 * | 49.20 ± 1.07 |
| Trend p-Value | | < 0.001 * | | |
| Positive Control ³ | 4 | 4.13 ± 0.66 | 0.0045 * | 57.13 ± 2.10 |
| Trial Summary: Positive | | | | |

Experiment Number: 695078 G04: In Vivo Micronucleus Summary Data

Test Compound: Cytarabine hydrochloride

Date Report Requested: 09/19/2018

Time Report Requested: 19:16:07

CAS Number: 69-74-9

Test Type: Genetic Toxicology - Micronucleus

Species/Strain: Mouse/B6C3F1

Route: Gavage

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 ± 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/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
- 3: 0.6 mg/kg Mitomycin-C

** END OF REPORT **