

Experiment Number: F27464

Test Type: Genetic Toxicology - Micronucleus

Route: Gavage

Species/Strain: Mouse/B6C3F1

**G04: In Vivo Micronucleus Summary Data**

Test Compound: Tenofovir

CAS Number: 147127-20-6

Date Report Requested: 09/21/2018

Time Report Requested: 15:44:14

**NTP Study Number:**

F27464

**Study Duration:**

4 Days

**Study Methodology:**

Flow Cytometry

**Male Study Result:**

Negative

**Female Study Result:**

Positive

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**Tissue: Blood; Sex: Male; Number of Treatments: 4; Time interval between final treatment and cell sampling: 28 h**

Dose (mg/kg)	N	MN PCE/1000		N	MN NCE/1000		% PCE	
		Mean ± SEM	p-Value		Mean ± SEM	p-Value	Mean ± SEM	p-Value
Vehicle Control <sup>1</sup>	5	2.900 ± 0.272		5	1.392 ± 0.037		1.905 ± 0.089	
500.0	5	2.900 ± 0.486	0.5424	5	1.423 ± 0.051	0.4590	1.966 ± 0.177	1.0000
1000.0	5	2.930 ± 0.260	0.6282	5	1.373 ± 0.021	0.5380	1.744 ± 0.070	0.3429
1500.0	5	2.690 ± 0.124	0.6646	5	1.399 ± 0.029	0.5635	1.698 ± 0.071	0.2100
Trend p-Value		0.6716			0.5771		0.0783	
Positive Control <sup>2</sup>	5	13.910 ± 0.576	< 0.001 *	5	1.700 ± 0.030	< 0.001 *	0.882 ± 0.084	< 0.001 *

Trial Summary: Negative

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Tissue: Blood; Sex: Female; Number of Treatments: 4; Time interval between final treatment and cell sampling: 28 h

Dose (mg/kg)	N	MN PCE/1000		N	MN NCE/1000		% PCE	
		Mean ± SEM	p-Value		Mean ± SEM	p-Value	Mean ± SEM	p-Value
Vehicle Control <sup>1</sup>	5	2.240 ± 0.201		5	1.001 ± 0.061		1.961 ± 0.244	
1500.0	5	3.090 ± 0.078	0.0023 *	5	1.054 ± 0.038	0.2391	2.124 ± 0.240	0.6189
Trend p-Value		0.0021 *			0.2381		0.6186	
Positive Control <sup>2</sup>	5	9.540 ± 0.421	0.0044 *	5	1.312 ± 0.035	0.0012 *	1.575 ± 0.113	0.2241

Trial Summary: Positive

Experiment Number: F27464

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CAS Number: 147127-20-6

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**Tissue: Blood; Sex: Female; Number of Treatments: 4; Time interval between final treatment and cell sampling: 28 h**

Dose (mg/kg)	N	MN PCE/1000		N	MN NCE/1000		% PCE	
		Mean ± SEM	p-Value		Mean ± SEM	p-Value	Mean ± SEM	p-Value
Vehicle Control <sup>1</sup>	5	2.030 ± 0.280		5	1.076 ± 0.095		1.277 ± 0.109	
1000.0	5	2.670 ± 0.300	0.0389	5	1.075 ± 0.032	0.5053	1.212 ± 0.144	0.6592
1500.0	5	3.260 ± 0.128	0.0041 *	5	1.118 ± 0.025	0.4110	1.049 ± 0.066	0.4846
2000.0	5	2.880 ± 0.214	0.0042 *	5	1.096 ± 0.026	0.4386	1.218 ± 0.136	0.5146
Trend p-Value		0.0037 *			0.3307		0.4469	
Positive Control <sup>2</sup>	5	15.220 ± 0.299	< 0.001 *	5	1.389 ± 0.055	0.0109 *	0.804 ± 0.111	0.0219 *

Trial Summary: Positive

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LEGEND

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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

Pairwise comparison with the control group; values are significant at  $P \leq 0.025$  by Williams or Dunn's test

Dose-related trend; significant at  $P \leq 0.025$  by linear regression or Jonckheere's test

\* Statistically significant pairwise or trend test

1: Vehicle Control: Corn Oil

2: 25.0 mg/kg Cyclophosphamide

**\*\* END OF REPORT \*\***