

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

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October 30, 2009

Via Federal Express

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency, ICC Building
1201 Constitution Ave., NW
Washington, DC 20004



Dear 8(e) Coordinator:

1,3-Benzenediamine
108-45-2
(2,4-phenylenediamine)

This letter is to inform you of the results of a 1982 *in vitro* mutagenicity study, which we recently became aware of through REACH SIEF activity, with the test substance referenced above. Below is the translation of the report summary.

The hair dye 2,4-phenylenediamine was tested with and without metabolism by rat liver microsomes in human whole blood cultures for increase in sister chromatid exchanges (SCEs) in lymphocytes. On the assumption that the total quantity of the substance penetrates through the scalp and reaches the bloodstream, the highest concentration with 120 µg of 2,4-phenylenediamine per mL of blood culture was selected. The other concentrations were 4 µg/mL and 0.12 µg/mL, 30 and 1000 times less, respectively.

The investigations showed that the test substance produces a dose-dependent increase of the SCE frequencies both with and without metabolism. A comparison with a known mutagenic substance, mitomycin C, indicates that this increase, despite [its] significance, is small.

This information is submitted in accordance with current guidance issued by EPA indicating EPA's interpretation of Section 8(e) of the Toxic Substances Control Act or, where it is not clear that reporting criteria have been met, it is submitted as a precautionary measure and because it is information in which EPA may have an interest.

Sincerely,

A. Michael Kaplan, Ph.D.
Director - Regulatory Affairs

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CONTAINS NO CR

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