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US EPA Office of Pollution Prevention and Toxics
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SUBJECT: TSCA 8(e) Notice

8EHQ-0410-17927A

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Dear TSCA Section 8(e) Coordinator:

On behalf of the study sponsors named below I am submitting un-audited draft results for an *in vitro* mammalian cell gene mutation test (HPRT Assay, OECD 476) with tert-Butylperoxy-2-ethylhexanoate (CAS# 3006-82-4). The study sponsors include United Initiators GmbH & Co. KG, Arkema France, Pergan GmbH, and Akzo Nobel Polymer Chemicals bv.

Study details
Reference: report study Code: 522.734.2019 Performed by TOXI-COOP ZRT, Hungary

Study summary:
The test item, tert-butylperoxy-2-ethylhexanoate (TBPEH), was tested in a Mammalian Gene Mutation Test in V79 cells. The test item was dissolved in DMSO and the following concentrations were selected on the basis of cytotoxicity investigations made in a preliminary study (without and with metabolic activation using S9 mix).

Two independent main experiments (both run in duplicate) were performed at the concentrations and treatment intervals given below:
Experiment 1 (3-hour treatment period without and with S9 mix): 19.53, 39.06, 78.12, 156.37, 234.37, 312.50 µg/mL
Experiment 2 (20-hour treatment period without S9 mix): 19.53, 39.06, 78.12, 156.37, 234.37, 312.50 µg/mL
Experiment 2 (3-hour treatment period with S9 mix): 19.53, 39.06, 78.12, 156.37, 234.37, 312.50 µg/mL

In Experiment 1, there were no biologically or statistically significant increases in mutation frequency at any concentration without S9 mix. Three-hour treatment in the presence of S9 mix caused dose- related increases in mutant frequency. These increases were statistically significant at concentrations of 156.37, 234.37, 312.50 µg/mL.

In Experiment 2, the mutant frequency showed dose- associated statistically significant increases compared to the concurrent control without S9 mix over a prolonged treatment period of 20 hours. In this experiment, a 3- hour treatment in the presence of S9 mix caused statistically significant dose- related increases in mutant frequency, further indicating that findings in Experiment 1 were out of normal biological variation.

The sensitivity of the tests and the efficicacy of the S9 mix were demonstrated by large increases in mutation frequency in the positive control cultures.

tert-butylperoxy-2-ethylhexanoate (TBPEH) tested in both without and with metabolic activation (S9 mix), induced increases in mutant frequency in this test in Chinese hamster lung cells. Therefore, TBPEH was mutagenic in this *in vitro* mammalian cell gene mutation test performed with V79 cells.

This submission is not considered to be confidential. The item of concern is on the public list. Please contact me at (440)326-2419 if you have any questions regarding this letter.

Sincerely,

Mark King
Technical Director

DCN: 88100000256

Cc: Akzo Nobel Polymer Chemicals bv
Arkema France
Pergan GmbH
United Initiators GmbH & Co. KG

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