

January 18, 2005

Elizabeth Hunt
Technical Contact
Diethyl Ether Producers Association
941 Rhonda Place SE
Leesburg, VA 20175

Dear Ms. Hunt:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for diethyl ether, posted on the ChemRTK HPV Challenge Program Web site on February 25, 2004. I commend the Diethyl Ether Producers Association for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that the Association advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Donald Rodier, Acting Chief of the HPV Chemicals Branch, at 202-564-7633. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsc-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission: Diethyl Ether

Summary of EPA Comments

The sponsor, the Diethyl Ether Producers Association (DEPA), submitted a test plan and robust summaries to EPA for Diethyl ether (1,1'-Oxybisethane; CAS No. 60-29-7) dated December 30, 2003. EPA posted the submission on the ChemRTK HPV Challenge Web site on February 25, 2004.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties. The data provided by the submitter for these endpoints are adequate for the purposes of the HPV Challenge Program.
2. Environmental Fate. The submitter needs to provide 28 day biodegradation data for this chemical.
3. Health Effects. EPA agrees with the submitter's plan to conduct a combined repeated-dose/reproductive/developmental toxicity screening test and a chromosomal aberration assay following OECD guidelines. The submitter needs to address deficiencies in the robust summaries.
4. Ecological Effects. EPA agrees with the submitter's plan to test algae, and with the adequacy of the data submitted on fish and invertebrates.

EPA Comments on the Diethyl Ether Challenge Submission

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, water solubility, and partition coefficient)

The data provided by the submitter for these endpoints are adequate for the purposes of the HPV Challenge Program.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

The data provided by the submitter for photodegradation, stability in water and fugacity are adequate for the purposes of the HPV Challenge Program.

Biodegradation. The submitter provided one biodegradation study similar to OECD Guideline 301C, in which it indicates that no biodegradation was observed after 10 days. This information is not sufficient to conclude that this chemical is not readily biodegradable. The submitter needs to provide 28-day test data following OECD Guideline 301 or from reliable published literature sources. EPA found biodegradation information for this chemical in the website for the Chemicals Evaluation and Research Institute, Japan (CERIJ), at: http://qsar.cerij.or.jp/cgi-bin/QSAR/e_r_text_query.cgi. EPA recommends that the submitter add this information into its biodegradation robust summary.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

EPA agrees that adequate data are available for acute toxicity for the purposes of the HPV Challenge Program but reserves judgement on the data submitted for gene mutations pending receipt of additional information. EPA agrees with the submitter's plan to conduct a combined repeated-dose/reproductive/

developmental toxicity screening test and a chromosomal aberration assay following OECD guidelines (OECD TGs 422 and 473, respectively).

Ecological Effects

EPA agrees with the submitter's plan to test in algae. The data submitted on fish and invertebrates are adequate.

Specific Comments on the Robust Summaries

Health Effects

Acute toxicity. A robust summary for an acute oral toxicity study in rats omitted the identity and purity of the test substance.

Genetic toxicity (gene mutations). Details missing in a robust summary for an Ames test include the purity of the test material, concentrations tested, cytotoxic concentration, number of colonies counted per concentration, information on positive and negative controls and the statistical methods.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.