

January 5, 2006

Marian K. Stanley
Technical Contact
American Chemistry Council
Brominated Phthalates Panel
1300 Wilson Boulevard
Arlington, VA 22209

Dear Ms. Stanley:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Tetrabromophthalic acid bis(2-ethylhexyl) ester posted on the ChemRTK HPV Challenge Program Web site on September 2, 2004. I commend the ACC Brominated Phthalates Panel 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 Panel 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 Mark Townsend, Chief of the HPV Chemicals Branch, at 202-564-8617. 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,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: N. Patel
J. Willis

**EPA Comments on Chemical RTK HPV Challenge Submission:
Tetrabromophthalic Acid bis(2-Ethylhexyl) Ester**

Summary of EPA Comments

The sponsor, the Brominated Phthalates Panel of the American Chemistry Council, submitted a test plan and robust summaries to EPA for tetrabromophthalic acid, bis(2-ethylhexyl) ester (CAS No. 26040-51-7) dated July 23, 2004. EPA posted the submission on the ChemRTK HPV Challenge Web site on September 2, 2004.

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

1. Physicochemical Properties. The submitter needs to provide measured melting point data.
2. Environmental Fate. The submitted data are adequate for the purposes of the HPV Challenge Program. The submitter needs to address deficiencies in the robust summaries.
3. Health Effects. Adequate data were submitted for all endpoints except reproductive and developmental toxicity. The submitter needs to provide data for these endpoints.
4. Ecological Effects. Although the submitted data are not adequate, for the purposes of the HPV Challenge Program, EPA agrees with the submitter's proposal that testing is not needed because of the chemical's high octanol-water partition coefficient and low water solubility.

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

EPA Comments on the Tetrabromophthalic Acid Bis(2-ethylhexyl) Ester Challenge Submission

General

The sponsored substance is named inconsistently in the test plan, and the abbreviated version used most often, "phthalic acid tetrabromo ester", is misleading.

Test Plan

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

The data for boiling point, vapor pressure, partition coefficient, and water solubility are adequate for the purposes of the HPV Challenge Program.

Melting point. The submitter needs to provide measured melting point data following OECD TG 102 or from a published source. According to HPV guidelines, melting points above 0 °C need to be measured. Not only are estimated melting points unreliable, but the description of this chemical as a liquid in the test plan and robust summary (as well as standard reference sources) is a signal that the high calculated melting point (229 °C) is incorrect.

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

The submitted data are adequate for the purposes of the HPV Challenge Program.

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

Adequate data were submitted for the acute, repeated-dose and genetic toxicity endpoints.

Reproductive/Developmental toxicity. The submitter claimed a waiver for the developmental toxicity endpoint based on low acute and repeated-dose toxicity. The reproductive organs were evaluated in the 28-day repeated-dose toxicity study. For the purposes of the HPV Challenge Program, for the reproductive toxicity endpoint the evaluation of reproductive organs from a 90-day repeated-dose study plus negative findings from an existing developmental toxicity study are adequate. Because no developmental toxicity data were provided for this substance, and the reproductive organs were evaluated in a 28-day study, EPA does not consider these two endpoints adequately addressed. EPA suggests that the submitter provide data from a combined reproductive/ developmental toxicity screening test (OECD TG 421) using the sponsored substance.

Ecological Effects (fish, invertebrates, and algae)

No adequate data were submitted for the ecological effects endpoints. However, given the EPIWIN-predicted low water solubility value of 1.983×10^{-9} mg/L and the high log K_{ow} value of 12, EPA agrees with the submitter's proposal not to conduct further ecotoxicity testing.

Fish. As indicated in the test plan, the submitted study is unreliable because it employed a range of test concentrations that exceeds the estimated water solubility of this chemical.

Invertebrates. The data are inadequate because the study reported an EC_{50} above the water solubility limit.

Specific Comments on the Robust Summaries

Environmental Fate

Photodegradation. The submitter needs to incorporate the atmospheric oxidation data from page 5 in the test plan into the photodegradation section of the robust summary.

Followup Activity

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