

June 4, 2009

Sam Kennedy
Technical Contact
Vertellus Performance Materials Inc.
2110 High Point Road
Greensboro, NC 27403

Dear Mr. Kennedy:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Dimethyl isophthalate (DMIP) posted on the ChemRTK HPV Challenge Program Web site on February 5, 2007. I commend Vertellus Performance Materials Inc. 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 Vertellus advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. EPA has moved energetically from the HPV Challenge Program to the Chemical Assessment and Management Program, or ChAMP (www.epa.gov/champ), and is relying on Challenge chemical sponsors to provide, as expeditiously as possible, the data that are the key to this effort.

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 me 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 tsca-hotline@epa.gov.

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

Sincerely,

Mark W. Townsend, Chief
HPV Chemicals Branch

Enclosure

cc: O. Hernandez
R. Lee
J. Willis

**EPA Comments on Chemical RTK HPV Challenge Submission:
Dimethyl Isophthalate**

SUMMARY OF EPA COMMENTS

The sponsor, Vertellus Performance Materials, Inc., submitted a test plan and robust summaries to EPA for dimethyl isophthalate (DMIP, CAS No. 1459-93-4) dated 11/10/2006. EPA posted the submission on the ChemRTK HPV Challenge Web site on 2/5/2007. The submitter also provided data on several proposed supporting chemicals: dimethyl terephthalate (DMTP; CAS No. 120-61-6), isophthalic acid (IPA; CAS No. 121-91-5) and terephthalic acid (TPA; CAS No. 100-21-0).

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

1. Analog Justification. EPA agrees that the use of analog data is adequately supported for the human health and ecological endpoints. For human health, prioritizing data use in the order IPA> DMTP> TPA is advisable; for the ecological hazard endpoints, only the analog DMTP is appropriate.
2. Physical Chemical Data. Existing data are adequate for these endpoints for the purposes of the HPV Challenge Program.
3. Environmental Fate and Pathways. Existing data are adequate for these endpoints for the purposes of the HPV Challenge Program.
4. Health Effects. Adequate data were submitted for all SIDS endpoints for the purposes of the HPV Challenge Program.
5. Ecological Effects. Adequate data were submitted for all SIDS endpoints for the purposes of the HPV Challenge Program.

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

EPA COMMENTS ON THE DIMETHYL ISOPHTHALATE CHALLENGE SUBMISSION

Analog Justification

The submitter proposes to satisfy various endpoints for DMIP using measured data for its metabolite isophthalic acid (IPA) as well as for a proposed structural analog, dimethyl terephthalate (DMTP) and its metabolite terephthalic acid (TPA).

EPA agrees that data for DMTP can be used to support the stability in water values for DMIP.

For the human health endpoints, the data for the metabolite IPA are appropriate and should be used in the first instance. Data for the structural analog and its metabolite, DMTP and TPA, respectively, are also adequate and can be used to address endpoints where data for IPA are not available.

For ecological effects, DMTP is an appropriate analog.

Test Plan

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

The submitter's measured data, and the estimated value for partition coefficient, are adequate for these endpoints for the purposes of the HPV Challenge Program.

Melting Point. The submitter's measured melting point of 67.5°C for dimethyl isophthalate appears to be from Lide (Lide DR, Milne GWA. Handbook of Data on Organic Compounds. Boca Raton: CRC Press. p.811 (1994)). The citation needs to be added to the robust summary.

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

Existing data are adequate for these endpoints for the purposes of the HPV Challenge Program.

Stability in Water. The submitter provided estimated hydrolysis half-lives of 35 and 352 days at pH 8 and 7, respectively, for dimethyl isophthalate, and noted that the structural analog dimethyl terephthalate has a hydrolytic half-life of 321 days in neutral waters (no source given). EPA located a measured half-life value of 46 weeks (322 days) at pH 7 and 25°C for the structural analog dimethyl terephthalate (Svirbey et al., *Can J Chem* 40, 1826 (1962); cited in Mabey, W and Mill, T *J Phys Chem Ref Data* 7, 383-415 (1978)); the submitter needs to add this citation to the robust summary. EPA agrees that the combination of estimated values and experimental analog data is adequate for this endpoint.

Health Effects

Adequate data were submitted for all SIDS endpoints for the purposes of the HPV Challenge Program.

Ecological effects

Adequate data were submitted for all SIDS endpoints for the purposes of the HPV Challenge Program.

Specific Comments on the Robust Summaries

Physical Chemical Properties

Vapor Pressure. The data summary 2.4(1) twice identifies the only submitted value as estimated when it is also cited as a literature value and supported by a reference. The submitter needs to eliminate the confusion.

Followup Activity

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