July 14, 2003

James A. Barter, Ph.D., DABT
Director, Environmental Health Sciences & Toxicology
PPG Industries, Inc.
One PPG Place
Pittsburgh, PA 15272

Dear Dr. Barter:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for trans-1,2-Dichloroethylene posted on the ChemRTK HPV Challenge Program Web site on March 20, 2003. I commend PPG Industries, 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 PPG Industries, Inc. advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. 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,

*-S-*

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber

**EPA Comments on Chemical RTK HPV Challenge Submission:**
**trans-1,2-Dichloroethylene**

## Summary of EPA Comments

The sponsor, PPG Industries, Inc., submitted a test plan and robust summaries to EPA for trans-1,2-Dichloroethylene (CAS No. 156-60-5) dated March 6, 2003. EPA posted the submission on the ChemRTK HPV Challenge Website on March 20, 2003.

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

1. Physicochemical Properties. Available data for all endpoints are adequate for the purposes of the HPV Challenge Program.

2. Environmental Fate. The submitter needs to provide biodegradation data following OECD guidelines and address some deficiencies in the robust summaries.

3. Health Effects. Available data for all endpoints are adequate for the purposes of the HPV Challenge Program. The submitter needs to include a separate robust summary of the reproductive organs evaluations from the 90-day studies and address deficiencies in the robust summaries.

4. Ecological Effects. EPA reserves judgement on the adequacy of all aquatic endpoints pending submission of a rationale for using 1,1-dichloroethylene as an analog and key robust summaries. The submitter needs to provide missing critical details in the robust summary of the fish toxicity study.

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

## EPA Comments on the trans-1,2-Dichloroethylene Challenge Submission

### Test Plan

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

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

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

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

*Biodegradation.* The submitted data are not adequate for the purposes of the HPV Challenge Program. The method used is inappropriate because it used subcultures and yeast extract creating favorable conditions for biodegradation to occur, and allowed volatilization (26-33%) of the test substance. EPA located a literature reference that indicated 0% BOD in 28 days (Chemicals Inspection and Testing Institute; Biodegradation and Bioaccumulation Data of Existing Chemicals Based on the CSCL Japan; Japan Chemical Industry Ecology-Toxicology and Information Center, ISBN 4-89-74-101-1 p. 2-24 (1992)). This study was apparently conducted following OECD TG 301D - Closed bottle test. EPA reserves judgement on the adequacy of this endpoint pending submission of an adequate robust summary of this test or a new study according to OECD TG 301D.

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

Available data are adequate for all endpoints for the purposes of the HPV Challenge Program. The submitter needs to address deficiencies in the robust summaries.

Ecological Effects (fish, invertebrates, and algae)

EPA reserves judgement on the adequacy of all aquatic endpoints pending submission of a rationale for using 1,1-dichloroethylene as an analog, that compares the physicochemical properties of 1,1-dichloroethylene and the subject chemical 1,2-dichloroethylene and discusses their significance. The submitter also needs to provide robust summaries for all key studies before a determination of data adequacy can be made. The submitter needs to address deficiencies in the one robust summary submitted (fish toxicity).

**Specific Comments on the Robust Summaries**

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

*Fugacity.* The submitter needs to incorporate in the robust summary the values used as inputs to the Level III fugacity model.

Health Effects

In all robust summaries the submitter needs to include the test substance name.

*Acute Toxicity*. The submitter needs to provide the following information, if available, in the robust summary: purity of the test substance, observed clinical signs, body weight data, deaths per group and time of death, doses tested (rather than a range).

*Reproduction Toxicity*. Include a separate robust summary of the reproductive organ evaluations from the 90-day studies in this section.

Ecological Effects

*Fish*. Missing critical data elements are water temperature, water hardness, dissolved oxygen, pH, chemical purity, and whether the concentrations were measured or nominal.

**Followup Activity**

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