

June 12, 2003

Elmer Rauckman, Ph.D., DABT  
Consulting Toxicologist  
BPPB Consortium  
1201 Anise Court  
Freeburg, IL 62243

Dear Dr. Rauckman:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 2-Butene-1,4-diol posted on the ChemRTK HPV Challenge Program Web site on January 31, 2003. I commend The BPPB Consortium on behalf of the 2-Butene-1,4-diol Consortium 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 BPPB Consortium on behalf of the 2-Butene-1,4-diol Consortium 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](mailto: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:  
2-Butene-1,4-Diol**

**Summary of EPA Comments**

The sponsor, the 2-Butene-1,4-diol Consortium, submitted a test plan and robust summaries to EPA for 2-butene-1,4-diol (CAS No. 110-64-5) dated December 30, 2002. EPA posted the submission on the ChemRTK HPV Challenge Web site on January 31, 2003.

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

1. Physicochemical Properties and Environmental Fate. Adequate data are available for all endpoints except biodegradation. The submitter needs to conduct a ready biodegradation test.
2. Health Effects. EPA agrees with the submitter's plan to conduct a screening-level repeated-dose/reproductive/developmental toxicity test.
3. Ecological Effects. EPA disagrees with the submitter that the data submitted for fish are adequate.

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

**EPA Comments on the 2-butene-1,4-diol Challenge Submission**

**Test Plan**

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

Adequate data are available for these endpoints for the purposes of the HPV Challenge Program.

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

*Biodegradation.* EPA disagrees that the submitted data are adequate for this endpoint. The data provided by the submitter are inadequate to determine if the test substance would pass a ready biodegradation test. This is because the BASF study is for inherent biodegradation and the adaptation of the inoculum in the Huls study was not reported. Only negative results are definitive in inherent biodegradability tests. Positive results in such tests indicate only that a substance is not persistent, but are not sufficient to characterize biodegradation in the environment. Therefore, the submitter needs to provide additional data on adaptation for the Huls study or conduct a ready biodegradation study according to the OECD TG 301 series.

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

EPA agrees with the submitter's plan to conduct a repeated-dose/reproductive/developmental toxicity screening test according to OECD TG 422.

*Genetic Toxicity.* The gene mutation endpoint is adequately addressed. Although the BASF, 1989 study used only four bacterial strains, these strains were adequate according to the protocol available when the tests were conducted (1983).

Ecological Effects (fish, invertebrates, and algae)

Adequate data are available for aquatic invertebrates and algae for the purposes of the HPV Challenge Program. The data submitted for fish are inadequate.

*Fish.* The duration of the submitted study is inadequate. The submitter needs to conduct a 96-hour LC50 acute toxicity study following recommended HPV Challenge Program test guidelines.

### **Specific Comments on the Robust Summaries**

#### **General Comment**

A number of the submitted robust summaries for acute mammalian toxicity provided limited details. The submitter is encouraged to review the guidance on developing robust summaries (available at: <http://www.epa.gov/chemrtk/robsumgd.htm> ) and consider revising the robust summaries if additional data are available.

#### **Followup Activity**

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