

October 8, 2002

Richard Henrich
Manager, Regulatory Affairs
Great Lakes Chemical Corporation
Highway 52 N.W.
West Lafayette, IN 47996

Dear Mr. Henrich:

The Office of Pollution Prevention and Toxics (OPPT) is transmitting EPA's comments on the robust summaries and test plan for Ethane, 1,2-dibromo, posted on the ChemRTK HPV Challenge Program Web site on February 5, 2002. I commend Great Lakes Chemical Corporation 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.

I am sure you are aware that Ethane, 1,2 -bromo is a chemical that is included, but not yet sponsored, in the Voluntary Children's Chemical Evaluation Program (VCCEP) which OPPT also manages. Given that human health-related HPV Challenge Program studies are included in VCCEP's first tier of information needs, you may want to consider sponsoring this chemical now in VCCEP. Detailed information on VCCEP, including how to sponsor a chemical, can be found at <http://www.epa.gov/opptintr/chemrtk/childhlt.htm>.

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 Great Lakes Chemical Corporation 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 HPV Challenge Program Web site "Submit Technical Questions" button 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: C. Auer
W. Penberthy

A. Abramson
M. E. Weber

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

SUMMARY OF EPA COMMENTS

The sponsor, Great Lakes Chemical Corp., submitted the test plan and robust summaries to EPA for 1,2-dibromoethane, CAS No. 106-93-4 dated December 28, 2001. EPA posted the submission on the ChemRTK HPV Challenge Web site on February 5, 2002.

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

1. Physicochemical Properties and Environmental Fate. The submitter needs to provide the fugacity calculation. All other appropriate SIDS-level endpoints have been addressed for the purposes of the HPV Challenge Program.
2. Health Effects. A chromosomal aberration test is needed. Adequate data are available for all other appropriate SIDS-level endpoints.
3. Ecological Effects. Acute toxicity data submitted for fish, invertebrates and algae are inadequate.

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

EPA COMMENTS ON THE 1,2-DIBROMOETHANE CHALLENGE SUBMISSION

Test Plan

Chemistry (melting point, boiling point, vapor pressure, partition coefficient and water solubility).

All appropriate SIDS-level endpoints have been addressed for the purposes of the HPV Challenge Program.

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

EPA agrees that the submitter's approach to these endpoints, except for fugacity, is acceptable for the purposes of the HPV Challenge Program.

Fugacity. The submitter indicated in the test plan that data are available for fugacity but did not submit the data. EPA recommends that the submitter provide transport/distribution model results, preferably using a Level III fugacity model.

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

Genotoxicity (chromosomal aberrations). EPA disagrees with the submitter's test plan that no further testing is required for this endpoint. Although nine genetic toxicity studies were submitted, no chromosomal aberration studies were included. Therefore, testing is needed for this endpoint.

Ecological Effects.

EPA disagrees with the submitter that no ecological testing is needed. The studies submitted for fish are inadequate because the test duration was shorter than the standard 96 hours. Invertebrate and algae studies were done using unacceptable (*Hydra* and *Octopus*) or unidentified species, respectively. In addition, the algal study measured photosynthesis rate which is not an acceptable algal endpoint. EPA suggests that the submitter conduct all three tests according to OECD TG's 201, 202, and 203. Studies should be conducted using mean-measured concentrations, closed systems and no head space.

Specific Comments on Robust Summaries

Health Effects.

Acute toxicity. For the two oral studies, dose levels and number of doses are not given and the number of male and females in each test group is not indicated. For the acute inhalation study, the number of males and females in each test group is not indicated, and only a limited number of LC₅₀ values are listed and it is unclear to which species they pertain. Reference to "rabbits" needs to be deleted from sections "Species" and "Method" in the Robust Summary because there is no other indication that rabbits were tested. For the dermal study, the sex of the animals in each test group is not specified, and an LD₅₀ is not calculated.

Followup Activity

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