

June 12, 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 is transmitting EPA's comments on the robust summaries and test plan for Carbonic Acid, Oxydiethylene Diallyl Ester, posted on the ChemRTK HPV Challenge Program Web site on January 15, 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 HPV 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 attached 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 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

Attachment

cc: W. Sanders
A. Abramson
C. Auer
M. E. Weber

EPA Comments on Chemical RTK Challenger Submission:

Carbonic acid, oxydiethylene diallyl ester

SUMMARY OF EPA COMMENTS

The sponsor, Great Lakes Chemical Corporation, submitted a Test Plan and Robust Study Summaries to EPA on December 20, 2001. EPA posted the cover letter, Test Plan and Robust Study Summaries on the Chem RTK Web site on January 15, 2002. The proposed information gathering plan is for Carbonic acid, oxydiethylene diallyl ester (CAS No. 142-22-3).

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

1. Physicochemical Properties and Environmental Fate. The submitter needs to provide measured vapor pressure and water solubility data.
2. Health Effects. EPA agrees with the submitter that data need to be generated to address repeated-dose toxicity, reproduction toxicity and chromosomal aberration endpoints. However, EPA disagrees with the submitter's proposal to conduct an assessment of toxicity to reproductive organs in its proposed 90-day repeated-dose toxicity study to address the reproductive toxicity endpoint. EPA recommends conducting a Combined Repeated-dose Toxicity Study with the Reproduction/Developmental Toxicity Screen (OECD 422).
1. Ecotoxicity: Algae. (a) The submitter needs to explain use of a solvent in the algal toxicity studies. (b) The submitter needs to provide an EC₅₀ value based on number of cells/mL. If an adequate explanation for using the solvent is not provided and an algal EC₅₀ value cannot be calculated, the submitter needs to conduct an algal toxicity test without the use of a solvent.

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

EPA COMMENTS ON THE CARBONIC ACID, OXYDIETHYLENE DIALLYL ESTER CHALLENGE SUBMISSION

Test Plan

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

Adequate data are available for melting point, boiling point, and partition coefficient for the purposes of the HPV Challenge Program.

The submitter needs to provide measured vapor pressure data because the estimated value of ca. 1.46×10^{-4} kPa at 25 °C is higher than 10^{-5} kPa, the SIDS threshold for vapor pressure testing.

The submitter provided a water solubility value of < 0.1 g/l at 20 °C. Qualitative values are not adequate for the purposes of the HPV Challenge Program. The submitter needs to provide a discrete measured water solubility value for this chemical.