

January 29, 2002

DuPont SHE Excellence Center
Attn: Edwin L. Mongan III
1007 Market Street
Wilmington, DE 19898

Dear Mr. Mongan:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Glycolic acid, posted on the ChemRTK Web Site on August 17, 2001. I commend DuPont 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 Chemical RTK HPV Challenge Program website 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 Chemical RTK web site within the next few days. As noted in the comments, we ask that DuPont advise the Agency, within 60 days of the posting on the Chemical RTK website, 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 general questions about the HPV Challenge Program through the Chemical RTK web site comment 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 HPV Challenge Submission:
Glycolic Acid**

SUMMARY OF EPA COMMENTS

The sponsor, E.I. du Pont de Nemours & Co., Inc., submitted a Test Plan and Robust Summaries to EPA, dated July 17, 2001, for Glycolic acid (CAS # 79-14-1). EPA posted the submission on the ChemRTK HPV Challenge Web site on August 17, 2001.

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

1. Physicochemical and Environmental Fate Data. EPA agrees with the Test Plan for these endpoints. The submitter needs to provide more input data in its Robust Summary covering Transport between Environmental Compartments (Fugacity) (see Specific Comments on Robust Summaries).
2. Health Endpoints. Data are adequate for the purposes of the HPV Challenge Program. However, some Robust Summaries need to be enhanced (see Specific Comments on Robust Summaries).
3. Ecological effects. EPA considers the aquatic studies for fish and daphnia adequate. EPA disagrees with the submitter that the algal study is adequate (see below).

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

EPA COMMENTS ON THE Glycolic Acid CHALLENGE SUBMISSION

Test Plan

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

The submitter's approach to these endpoints is acceptable for the purposes of the HPV Challenge Program.

Environmental Fate (photodegradation, stability in water, biodegradation, transport/distribution fugacity)

The submitter's approach to these endpoints is acceptable for the purposes of the HPV Challenge Program.

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

Data are adequate for the purposes of the HPV Challenge Program. However, some Robust Summaries need to be enhanced (see Specific Comments on Robust Summaries).

Ecotoxicity

Adequate existing data are available for fish and daphnia. EPA considers the algal study to be inadequate to allow an evaluation because the algal test was done in a closed system using growth medium not containing sodium bicarbonate as an oxygen source. Algal tests done in this manner are not recommended by OECD Guidelines.

SPECIFIC COMMENTS ON ROBUST SUMMARIES

Environmental Fate

Transport between Environmental Compartments (Fugacity)

The submitter needs to provide half-life input data in its Robust Summary for Transport between Environmental Compartments (Fugacity).

Health Effects

Although the Robust Summaries are generally well-written and contain sufficient test information to independently assess the studies, they lack the following information: clinical signs (severity, duration, and time of onset), statistical methods used, and guideline followed (if any).

Followup Activity

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