

September 16, 2002

Emily Clark
Product Regulatory Specialist
Velsicol Chemical Corporation
10400 W. Higgins Rd.
Suite 600
Rosemont, IL 60018-3713

Dear Ms. Clark:

The Office of Pollution and Toxics is transmitting EPA's comments on the robust summaries and test plan for Chlorendic Anhydride, posted on the ChemRTK HPV Challenge Program Web site on February 20, 2002. I commend Velsicol 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.

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 Velsicol 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
A. Abramson
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission: Chlorendic Anhydride

SUMMARY OF EPA COMMENTS

The sponsor, the Velsicol Chemical Corporation, submitted a test plan and robust summaries to EPA for chlorendic anhydride (CAS No. 115-27-5) dated December 21, 2002. EPA posted the submission on the ChemRTK HPV Challenge Website on February 20, 2002.

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

1. Physicochemical Properties and Environmental Fate. All appropriate SIDS-level tests/estimations have been performed.
2. Health Effects. All appropriate SIDS-level tests have been performed. The submitter needs to address a few deficiencies in the robust summaries.
3. Ecological Effects. All appropriate SIDS-level tests have been performed. The submitter needs to address a few deficiencies in the robust summaries.

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

EPA COMMENTS ON THE CHLORENDIC ANHYDRIDE CHALLENGE SUBMISSION

Test Plan

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

The submitter's test plan for these endpoints is adequate for the purposes of the HPV Challenge Program.

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

The submitter's test plan for these endpoints is adequate for the purposes of the HPV Challenge Program.

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

Adequate test data are available for all health endpoints for the purposes of the HPV Challenge Program. However, the submitter needs to supply a robust summary for the reproductive toxicity endpoint. HPV Challenge Program guidance indicates that when a study addresses multiple endpoints, a robust summary is needed for each endpoint. In addition, the submitter needs to address a few deficiencies in the robust summaries.

Reproductive Toxicity. HPV Challenge Program guidance allows the use of adequate data from a 90-day repeated-dose study where the reproductive organs have been examined to address the reproductive toxicity endpoint. An adequate repeated-dose study with examination of the reproductive organs showing no effects is available to address the reproductive toxicity endpoint. However, as indicated above, a separate summary is needed to address this endpoint.

Ecological Effects (fish, invertebrates, and algae). Adequate data are available for these endpoints. However, the submitter needs to supply a number of data elements missing from the robust summaries.

Specific Comments on the Robust Summaries

Health Effects.

In the repeated-dose and developmental toxicity robust summaries, the submitter did not indicate the NOAEL's (NOEL's) and LOAEL's (LOEL's).

Ecological Effects.

Fish. Missing data element is dissolved oxygen.

Invertebrate. Missing data element is concentration of acetone used as solvent.

Algae. Missing data element is pH.

Followup Activity

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