

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 1,1-Difluoroethane, posted on the ChemRTK Web Site on August 22, 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: 1,1-Difluoroethane

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 1,1-Difluoroethane (CAS #75-37-6). EPA posted the submission on the ChemRTK HPV Challenge Web site on August 22, 2001.

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

1. Physicochemical and Environmental Fate Data. EPA agrees with the Test Plan and Robust Summaries for these endpoints.
2. Health Effects. 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. The Test Plan presented SAR predictions for fish, invertebrate, and algal endpoints. For the fish and invertebrate endpoints, the SAR values were supported by an analog, HFC-134a (1,1,1,2-tetrafluoro-ethane). The Submitter needs to provide Robust Summaries for these tests using the analog chemical in order for the ECOSAR values to be considered adequate. In the case of algae, only an SAR value was presented. The Submitter needs to provide an analog to support the SAR-predicted endpoint. For more on these topics see "Guidance on Developing Robust Summaries" and "The Use of Structure-Activity Relationships (SAR) in the High Production Volume Chemicals Challenge Program" at (<http://www.epa.gov/opptintr/chemrtk/guidocs.htm>).

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

EPA COMMENTS ON THE 1,1-DIFLUOROETHANE 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)

The submitter's approach to photodegradation, stability in water, and transport/distribution (fugacity) is acceptable for the purposes of the HPV Challenge Program.

Biodegradation

If the submitter means by "further evaluation" (in Test Plan table) that it will undertake testing for Biodegradation, then EPA agrees with the approach for this endpoint.

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

EPA agrees with the submitter that no further testing is necessary, however, some Robust Summaries need to be enhanced (see Specific Comments on Robust Summaries).

Ecological Effects (fish, daphnia and algal toxicity)

The Test Plan presented SAR predictions for fish, invertebrate, and algal endpoints. The Test Plan also presented experimental data for a structural analog, HFC-134a (1,1,1,2-tetrafluoroethane) for fish and invertebrate endpoints; however, no Robust Summaries were provided. The submitter needs to provide Robust Summaries for these endpoints.

In the case of algal toxicity, the predicted value in the Test Plan was 419 mg/L (96-h EC50). The HPV Challenge Program guidance for the use of structure-activity relationships states that "some measured data must be available [for the endpoint] to strengthen the use of ECOSAR." Therefore, the submitter needs to test or provide a study (on a closely related analog) addressing the algal toxicity of 1,1-difluoroethane.

Specific Comments on Robust Summaries

Health Effects

Some studies were not GLP-compliant and in most Robust Summaries the specific guideline followed was not indicated. Also, repeated-dose and genetic toxicity studies did not indicate the statistical method, and the repeated-dose study did not indicate the number of animals per dose group that displayed the observed signs of toxicity.

Followup Activity

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