

December 16, 2004

Edwin L. Mongan, III
Manager, Environmental Stewardship
E.I. du Pont de Nemours & Company, Inc.
Safety, Health & Environmental Excellence Center
1007 Market Street, DuPont 6082
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 Fluoroethylene posted on the ChemRTK HPV Challenge Program Web site on February 18, 2004. I commend E.I. du Pont de Nemours & Company, Inc. 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 duPont advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Donald Rodier, Acting Chief of the HPV Chemicals Branch, at 202-564-7633. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages 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

Enclosure

cc: W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission: Fluoroethylene

Summary of EPA Comments

The sponsor, E.I. du Pont de Nemours & Company, Inc., submitted a test plan and robust summaries to EPA for Fluoroethylene (CAS No. 75-02-5) dated December 31, 2003. EPA posted the submission on the ChemRTK HPV Challenge Web site on February 18, 2004.

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

1. Analog Justification. The information provided for vinyl chloride supporting its use as an analog for ecological effects is acceptable. However, information supporting its use for health effects is insufficient.
2. Physicochemical Properties. The data provided by the submitter for these endpoints are adequate for the purposes of the HPV Challenge Program.
3. Environmental Fate. The data provided by the submitter for photodegradation, stability in water, and fugacity are adequate for the purposes of the HPV Challenge Program. EPA agrees with the submitter's plan to test for biodegradation. Because this chemical is a gas, EPA recommends special precautions in conducting this test.
4. Health Effects. Data are adequate for acute toxicity, repeated-dose toxicity, genetic toxicity and reproductive effects. Information on developmental effects is needed.
5. Ecological Effects. The data provided for fish and algae are adequate. Adequate measured data are needed for the invertebrate endpoint.

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

EPA Comments on the Fluoroethylene Challenge Submission

Test Plan

Analog Justification

Although the discussion is minimal, the information provided for vinyl chloride supports its use as an analog for ecological effects in fish and algae. The invertebrate analog data are inadequate because the available study was only of 24 hours' duration.

With respect to developmental effects, no comparative information was provided for vinyl chloride. A summary similar to the one provided for ecological effects, with appropriate discussion, is needed. Comparative information on metabolism and the metabolic end products should be included if available.

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

The data provided by the submitter for these endpoints are adequate for the purposes of the HPV Challenge Program.

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

The data provided by the submitter for photodegradation, stability in water and fugacity are adequate for the purposes of the HPV Challenge Program.

Biodegradation. EPA agrees with the submitter's plan to test for biodegradation following OECD Guideline 301 D (closed bottle test). Because vinyl fluoride is a gas at room temperature, EPA recommends that the submitter follow stringent precautions when conducting this test (e.g., carefully inject the test substance through a gas-tight septum directly into the liquid phase of the test medium in the bottle).

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

Data are adequate for acute toxicity, repeated-dose toxicity, genetic toxicity and reproductive effects. Additional information on the developmental effects of the proposed analog, vinyl chloride, may be sufficient to address this endpoint. However, EPA reserves judgement as to its adequacy pending receipt of additional information as discussed under "Analog Justification."

Ecological Effects (fish, invertebrates, and algae)

Data are adequate for fish and algae.

Invertebrates. A 48-hour test using daphnia is needed to address the invertebrate endpoint. The 24-hour test data submitted for the proposed analog, vinyl chloride, are not adequate for the purposes of the HPV Challenge Program. A 48-hour test using OECD guidelines is needed.

Specific Comments on Robust Summaries

Health Effects

A specific listing of the parameters examined should be included in the robust summaries. Organs and tissues selected for weighing and gross and microscopic examination should be identified; clinical and hematological tests should be listed, even if no effects were observed.

Followup Activity

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