

January 15, 2003

Edwin L. Mongan, III
Manager, Environmental Stewardship
DuPont Safety, Health and Environmental Excellence Center
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 Hexamethyleneimine posted on the ChemRTK HPV Challenge Program Web site on September 19, 2002. 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 E.I. du Pont de Nemours & Company Inc. 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 "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: C. Auer
A. Abramson
W. Penberthy
M. E. Weber

**EPA COMMENTS ON CHEMICAL RTK HPV CHALLENGE SUBMISSION:
HEXAMETHYLENEIMINE**

SUMMARY OF EPA COMMENTS

The sponsor, E.I. du Pont de Nemours & Company, submitted a test plan and robust summaries to EPA for Hexamethyleneimine (CAS No. 111-49-9) on August 26, 2002. EPA posted the submission on the ChemRTK HPV Challenge Web site on September 19, 2002.

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

1. Physicochemical Properties and Environmental Fate. The submitter needs to provide measured partition coefficient, water solubility, and biodegradation data.
2. Health Effects. EPA agrees with the test plan for these endpoints.
3. Ecological Effects. EPA agrees with the test plan for these endpoints.

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

EPA COMMENTS ON THE HEXAMETHYLENEIMINE CHALLENGE SUBMISSION

Test Plan

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

The data provided by the submitter for melting point, boiling point and vapor pressure are adequate for the purposes of the HPV Challenge Program.

Partition coefficient. The submitter reported a log Kow for this compound that was estimated using EPIWIN software. While OECD allows for estimation of log Kow, in this case EPA strongly recommends that the submitter provide a measured value because the water solubility value is also questionable.

Water solubility. The submitter provided a water solubility value taken from a computerized database (HSDB). However, EPA notes that the value given in this reference is the activity coefficient, which was incorrectly used in HSDB as a water solubility value; thus, it has been incorrectly reported by the submitter. The DuPont MSDS for this material states that it is miscible with water. OECD guideline 105 requires that the water solubility be measured if it is greater than 1 : g/L. Because of these inconsistencies, the submitter needs to provide measured water solubility data for this chemical following OECD guidelines.

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. The submitter provided data showing an increase in cellular protein, and considered it a positive result for biodegradation. An increase in cellular protein is not a good indication of biodegradation because it does not provide a quantitative statement about the ultimate biodegradation of the chemical. Furthermore, the study does not provide data on the degradation of the chemical into carbon dioxide, nor does it provide data on the loss of dissolved organic carbon. Therefore, EPA considers the study inadequate for the purposes of the HPV Challenge Program. The submitter needs to provide measured ready biodegradation data following OECD Guideline 301.

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

The submitted data are adequate for acute toxicity and genetic testing for gene mutations. EPA agrees with the submitter that the following tests are needed: repeated-dose, developmental, reproductive and genetic testing for chromosomal aberrations. EPA recommends the use of OECD TG 422 and 473 for these endpoints.

Ecological Effects (fish, invertebrates, and algae).

EPA agrees with the submitter that testing is needed to assess acute toxicity in fish, invertebrates, and algae. All aquatic testing should be done using a flow-through system when possible, zero head space, with total organic carbon less than 2.0%, and analytically determined exposure concentrations.

Specific Comments on the Robust Summaries

Ecological Effects.

The submitter needs to supply the missing log Kow input value used to obtain the predicted values from the ECOSAR model so that an independent evaluation can be made.

Followup Activity

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