

May 28, 2004

James A. Deyo, D.V.M., Ph.D., D.A.B.T.  
Product Safety & Health Toxicology Team Leader  
Eastman Chemical Company  
100 North Eastman Road  
Kingsport, TN 37662

Dear Dr. Deyo:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for N-Ethyl-N-(3-Methylphenyl)aminoacetonitrile posted on the ChemRTK HPV Challenge Program Web site on January 13, 2004. I commend Eastman Chemical Company 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 Eastman 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](mailto:oppt.ncic@epa.gov) and [chem.rtk@epa.gov](mailto:chem.rtk@epa.gov).

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 [tsca-hotline@epa.gov](mailto: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: W. Penberthy  
M. E. Weber

**EPA Comments on Chemical RTK HPV Challenge Submission:  
N-Ethyl-N-(3-Methylphenyl)aminoacetonitrile**

**Summary of EPA Comments**

The sponsor, Eastman Chemical Company, submitted a test plan and robust summaries to EPA for *N*-ethyl-*N*-(3-methylphenyl)aminoacetonitrile, CAS# 63133-74-4, dated December 9, 2003. EPA posted the submission on the ChemRTK HPV Challenge Website on January 13, 2004.

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

1. Physicochemical Properties. The submitter needs to provide measured vapor pressure and water solubility data.
2. Environmental Fate. The submitter needs to recalculate its fugacity values using measured physicochemical values.
3. Health Effects. The submitted data on acute toxicity and gene/chromosomal toxicity endpoints are adequate for the purposes of the HPV Challenge Program. The submitter did not fully support its proposal for reduced health endpoint testing, based on a closed-system intermediate (CSI) claim. Therefore, EPA reserves judgment for the repeated-dose and reproductive toxicity endpoints pending receipt of additional data. The submitter proposal to meet the developmental toxicity endpoint is acceptable and does not depend on the resolution of the CSI claim.
4. Ecological Effects. EPA agrees that adequate data exists for all ecological endpoints (i.e., fish, aquatic invertebrate and aquatic plants).

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

**EPA Comments on N-Ethyl-N-(3-Methylphenyl)aminoacetonitrile Challenge Submission**

General

EPA cannot fully evaluate the submitter's claim (Appendix 1 of the submission) that the sponsored chemical is a CSI and thus eligible for the reduced testing rationale in the HPV Challenge Program. The submitter did not include monitoring data showing that the chemical is not detected in any environmental medium after treatment or, in the absence of monitoring data, the basis for believing that the chemical has not been released. Specifically, the submitter states that all aqueous waste containing the sponsored chemical is directed to an on-site wastewater treatment (WWT) facility. Furthermore, at least 12 pounds of the chemical per batch (12,000 pounds/year) is discharged to the WWT facility. The submitter needs to supply information on the quantities measured or estimated to be in the final effluent, sludge or other wastes from the WWT facility, or in the absence of such data, the basis for believing that the chemical has not been released following wastewater treatment and that exposure does not occur.

Upon receipt of this information, EPA will re-evaluate the CSI claim and proposal for reduced testing.

Test Plan

The submitter needs to correct the chemical structure in the test plan on p. 2 by adding an ethyl group.

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

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

*Boiling Point.* The submitter provided a boiling point of >250 °C (highest temperature on thermometer) at 1013 hPa (Eastman Chemical Company, Unpublished data). No further data were provided by the submitter. EPA estimated boiling points of 296.21 °C (MPBPWIN v1.40) and 291.1 °C at 760 mm Hg (McEntee 1987; calculated using a boiling point of 107 °C at 1 mm Hg [Bent et al. 1951]). According to HPV Challenge Program guidelines, boiling points expected to be <300 °C should be measured, but the calculated values are very close so the data for this endpoint are adequate.

*Vapor Pressure.* The submitter provided a calculated vapor pressure value of 0.027 hPa (0.021 mm hg) at 25 °C. Estimated values over 10<sup>-5</sup> Pa are not adequate for the purposes of the HPV Challenge Program. The submitter needs to provide measured vapor pressure data for this chemical, following OECD guidelines.

*Water Solubility.* The submitter provided a calculated water solubility of value of 252 mg/L at 25 °C. Estimated values over 1 µg/L are not adequate for the purposes of the HPV Challenge Program. 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 biodegradation are adequate for the purposes of the HPV Challenge Program.

*Fugacity.* The submitter needs to recalculate its fugacity estimation using measured physicochemical values as noted above under Physicochemical Properties.

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

The data provided by the submitter for acute toxicity and genotoxicity are adequate for the purposes of the HPV Challenge Program. In addition, a separate submission to EPA, suggests that the submitter has completed an OECD TG 421 study (see below).

*Repeated-Dose and Reproductive Toxicity.* EPA has requested information to support the CSI claim for reduced testing. EPA reserves judgement on testing for these endpoints pending receipt of the requested information.

*Developmental Toxicity.* EPA recently received a TSCA 8(e) notice (8EHQ-0204-15524) stating that the OECD TG 421 study proposed to address this endpoint has been completed. EPA notes that any proposed testing should be conducted after the public and EPA have had an opportunity to comment. The submitter needs to provide a robust summary for this study.

Ecological Effects (fish, invertebrates, and algae)

EPA agrees with the sponsor that all ecological end points (i.e., fish, daphnia, and green algae) have been addressed for the purposes of the HPV Challenge Program.

**Specific Comments on the Robust Summaries**

None.

**Followup Activity**

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