

May 21, 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)-1,2-ethanediamine 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 and 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.

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)-1,2-ethanediamine**

Summary of EPA Comments

The sponsor, Eastman Chemical Company, submitted a test plan and robust summaries to EPA for N-ethyl-N-(3-methylphenyl)-1,2-ethanediamine (EMPE, CAS No. 19248-13-6) dated December 8, 2003. EPA posted the submission on the ChemRTK HPV Challenge Web site on January 13, 2004.

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

1. Physicochemical Properties. The submitter needs to provide measured melting point, boiling point, vapor pressure, and water solubility data for this chemical.
2. Environmental Fate. The submitter needs to recalculate its fugacity values using measured physicochemical values.
3. Health Effects. EPA believes that information provided by the submitter is sufficient to meet the criteria for claiming EMPE as a closed-system intermediate. EPA agrees with the submitter's plan to conduct a developmental toxicity study.
4. Ecological Effects. EPA agrees that there are adequate data for all ecological endpoints.

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

EPA Comments on the N-ethyl-n-(3-methylphenyl)-1,2-ethanediamine Challenge Submission

Test Plan

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

The data provided by the submitter for partition coefficient are adequate for the purposes of the HPV Challenge Program.

Melting Point. The submitter provided a melting point value of < 0 °C. Open range values are not adequate for the purposes of the HPV Challenge Program. The submitter needs to provide a measured value for this endpoint. For values under 0 °C, calculated values are adequate for the purposes of the HPV challenge Program.

Boiling Point. The submitter provided a boiling point value of > 250 °C. Open range values are not adequate for the purposes of the HPV Challenge Program. The submitter needs to provide a measured value for this endpoint, or a temperature at which it starts decomposing if boiling is not achieved. For values over 300 °C, calculated values are adequate for the purposes of the HPV Challenge Program.

Vapor Pressure. The submitter provided a calculated vapor pressure value of 0.036 hPa (0.027 mm hg) at 25 °C. Estimated values over 10^{-5} 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 12,090 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)

Adequate data are available for the acute and genetic toxicity endpoints for the purposes of the HPV Challenge Program. The submitter plans to conduct a test for developmental toxicity following OECD TG 421. The submitter requests an exemption from repeated-dose toxicity testing based on EPA's guidelines for closed-system intermediates.

Repeated-Dose Toxicity. No data were submitted for this endpoint, and no testing is proposed based on the submitter's assertion that EMPE is a closed-system intermediate. As discussed below, EPA believes that the closed-system intermediate criteria have been met.

The Guidance for Testing Closed System Intermediates for the Challenge Program <http://www.epa.gov/chemrtk/guidocs.htm> allows for a reduced testing protocol provided certain criteria are met. The information required to judge a "closed-system intermediate" claim must address the following:

- I. Site information
 - A. Number of sites.
 - B. Basis for "closed process" conclusion at each site.
 - 1) Process description.
 - 2) Monitoring data showing no detection.
 - 3) In the absence of monitoring data, the basis for believing that releases do not occur.
 - C. Data on "presence in distributed products."
- II. Information on transport (mode, volume, controls, etc.)
- III. A data search showing that the chemical is not present in other end products.

EPA believes that the information provided by the submitter is sufficient to satisfy the requirements for classification as a closed-system intermediate.

I. Site information

- A. Number of sites.

The test plan indicates that EMPE is manufactured at a single site located in Kingsport, Tennessee and is consumed at that site as an intermediate. A check of Inventory Update Rule information submitted for the years 1998 and 2002 indicated that EMPE was manufactured only by this submitter at a single site.

- B. Basis for "closed process" conclusion at each site.

- 1) Process description.

The test plan provides a process flow diagram and description of all steps in the manufacture and subsequent purification and use of EMPE as an intermediate. EMPE is manufactured by hydrogenation of an isopropyl alcohol solution of a precursor chemical over a noble metal catalyst. The crude EMPE is filtered and stored in a closed tank. The crude EMPE is distilled to remove the isopropyl alcohol and stored in a closed tank. The stripped EPME is distilled under vacuum to remove unconsumed reactants and volatile impurities and stored in a closed tank. EPME is consumed by reaction with methane sulfonyl chloride. The resulting chemical substance is further converted by a series of reactions to the distributed product, color developer CD-3.

2) Monitoring data showing no detection.

The test plan states that on average, approximately 4 pounds of EMPE per batch are discharged during filtration equipment rinsing and is sent to a hazardous waste disposal facility. An additional 4 pounds of EMPE are contained in catalyst sent for reclamation after manufacturing approximately 125 batches of EMPE. Isopropyl alcohol recovered during stripping of the crude reaction product contains no EMPE. The reaction product manufactured by consumption of EMPE may contain as much as 0.4% of the reactant; subsequent reactions consume any residual EMPE and the chemical is not detected in any distributed product.

With one exception, the test plan confirms that EMPE is not released to the air through reactor process vents, distillation process vents, or storage tank vents. The exception is the crude EMPE stripping process vents which release 0.0138 pounds per day of EMPE.

Residual tars from the distillation of EMPE are discharged via a tar dilution tank to hazardous waste disposal.

C. Data on "presence in distributed products."

EMPE is consumed by onsite chemical reactions subsequent to its manufacture. Residual EMPE in the reaction product averages 0.03% with occasional batches as high as 0.4%. A subsequent reaction removes all traces of EMPE. The chemical has never been detected in the distributed product despite extensive characterization of the impurity profile at ppm levels.

II. Information on transport (mode, volume, controls, etc.)

The submitter notes that EMPE is manufactured and consumed at the single site operated by the submitter.

III. A data search showing that the chemical is not present in other end products.

The submitter states that EMPE is manufactured for the sole purpose of producing the distributed product on site. EMPE is not marketed by the submitter, nor is the submitter aware of any other use for the chemical.

Ecological Effects (fish, invertebrates, and algae)

EPA agrees that adequate data are available for the fish, daphnia, and green algae endpoints for the purposes of the HPV Challenge Program.

Followup Activity

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