May 20, 2010

Mr. David Hay
Regulatory Compliance Specialist
Huntsman Petrochemical Corporation
10003 Woodloch Forest Drive
The Woodlands, TX 77380

Dear Mr. Hay:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for oxirane, reaction products with ammonia, distillation residue, posted on the ChemRTK HPV Challenge Program Web site on January 4, 2010.

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.

Upon receiving this submission, EPA asked Huntsman for additional substance identification information, specifically on the roughly 20% of the material not attributable to triethanolamine. EPA anticipated that lack of this information could significantly hamper evaluation of the submission, and delayed posting the submission on its Challenge Program Web site pending a fuller description. Huntsman provided a target date for an update but EPA received nothing further. After periodic followup requests were unsuccessful, EPA posted the original submission and proceeded to the review. EPA's comments reflect the incompleteness of the substance identity information.

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 Huntsman 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 me at 202-564-8617. 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/

Mark W. Townsend, Chief
HPV Chemicals Branch

Enclosure

cc: O. Hernandez
R. Lee
J. Willis

EPA Comments on Chemical RTK HPV Challenge Submission:
Oxirane, reaction products with ammonia, distillation residue

Summary of EPA Comments

The sponsor, Huntsman Petrochemical Corporation, submitted a test plan and robust summaries to EPA for Oxirane, reaction products with ammonia, distillation residue (CAS No. 68953-70-8), dated April 27, 2006. EPA posted the submission on the ChemRTK HPV Challenge Website on September 3, 2009.

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

1. General. The submitter has not identified ~20% of the sponsored substance. Without a better description of the "higher boiling amine reaction products", EPA cannot determine the adequacy of available data for this portion of the sponsored substance, and therefore, cannot evaluate its contribution to the toxicity of the sponsored substance for the purposes of the HPV Challenge Program.

2. Analog Justification. EPA reserves judgment on the proposed use of data for triethanolamine (TEA; CAS No. 102-71-6) to characterize the sponsored substance. About twenty percent of the sponsored substance is characterized as 'higher boiling amine reaction products' for which TEA may not be an appropriate analog.

3. Physicochemical Properties. Adequate data for these endpoints are available for the purposes of the HPV Challenge Program. However, some robust summaries are inadequate and need to be enhanced.

4. Environmental Fate. Adequate data for most endpoints are available for the purposes of the HPV Challenge Program. However, some robust summaries are inadequate and need to be enhanced.

5. Health Effects. Adequate data were submitted for the acute and genetic toxicity endpoints for the purposes of the HPV Challenge Program. Data submitted for the repeated-dose, reproductive and developmental toxicity endpoints are inadequate for the purposes of the HPV Challenge Program.

6. Ecological Effects. EPA reserves judgment on data adequacy for these endpoints pending receipt of adequate substance identification. Some TEA robust summaries are not adequate (see details below).

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

EPA Comments on the Oxirane, Reaction Products with Ammonia, Distillation Residue Challenge Submission

General

1) EPA delayed the posting of this submission in anticipation of receiving requested additional information on the composition of the sponsored substance from the submitter. This information has not been received as of May 19, 2010. 2) The test plan frequently mentions the proposed analog triethanolamine without ever stating its CAS number. The document needs to include that information.

Analog Justification

The sponsored substance is the distillation residue from alkanolamines production and "typically contains at least 80% triethanolamine" (TEA), with <1% of diethanolamine (DEA). The submitter states that this relatively high percentage of TEA would result in the toxicity of the sponsored substance being very similar to that of commercial TEA, and proposes the use of data for TEA to characterize the toxicity of the sponsored substance (TEA and DEA have been assessed in the OECD HPV program and the data

can be reviewed at http://www.oecd.org/document/63/0,3343,en_2649_34379_1897983_1_1_1_1,00.html). However, the test plan does not identify the remaining ~20% except as "higher boiling amine reaction products." Without more detailed information on substance identity, EPA believes that the toxicity of TEA may not represent that of the sponsored substance, and EPA reserves judgment on the sole use of TEA data to characterize biodegradation and toxicity endpoints for the sponsored substance.

Test Plan

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

Adequate data for these endpoints are available for the sponsored substance for the purposes of the HPV Challenge Program. However, some robust summaries are inadequate and need to be enhanced.

Melting point. Although this mixture will not have a sharp melting point, the robust summary should discuss this endpoint and not be left blank. It should also include the measured value for TEA as a reference point.

Boiling point. The submitter provided a boiling point of ca. 372 °C. This is reasonable for a distillation residue containing 80% TEA, which has reported boiling points ranging to 361 °C. According to HPV Guidelines, boiling points above 300 °C do not need to be measured,

Vapor pressure. The submitter provided a measured vapor pressure of <0.1 hPa (<10 Pa). Open range values are not adequate for purposes of the HPV Challenge program. The submitter needs to provide measured data for vapor pressure values above 7.5×10^{-8} mm Hg. However, because this substance is a distillation residue containing 80% TEA, the value for TEA will adequately represent the mixture in this case. A measured TEA value of 3.59×10^{-6} mm Hg/25 °C (4.79×10^{-4} Pa) is reported in the EPIWIN database. The submitter needs to incorporate this value in the test plan and robust summary.

Partition coefficient. The robust summary was blank. It should contain data or a discussion of this endpoint and not be left blank. Data for water-miscible TEA would satisfy this endpoint.

Water solubility. TEA is miscible with water (EPIWIN) and the submitter's report (from MSDS, no details) that the sponsored substance is "completely soluble" in water is reasonable.

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

Data are adequate for photodegradation, stability in water, and fugacity for the purposes of the HPV Challenge Program.

Photodegradation. Given the low vapor pressure and high water solubility of TEA and the rest of the sponsored distillation residue, data for this endpoint are not necessary. However, the robust summary was left blank. The summary needs a brief discussion or a calculated value (AOPWIN).

Biodegradation. The OECD reviewed a range of available TEA studies (see Analog Justification for link) and concluded that "triethanolamine is readily biodegradable, possibly after a short acclimation period and that extensive removal due to biodegradation is to be expected in sewage treatment plants." For reasons discussed above, it is uncertain whether the non-TEA portion of the sponsored substance will be readily biodegradable. EPA reserves judgment on this endpoint pending submission of better substance identification. The submitter also needs to add a description of the OECD's TEA conclusion to the robust summary.

Stability in water. Even if the 20% of unidentified substance contains some water-sensitive material, overall the sponsored substance will reflect the inability of TEA to react with water. The robust summary should make that point.

Fugacity. TEA data are adequate for this endpoint.

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

Adequate data on the sponsored substance were submitted for the acute and genetic toxicity endpoints for the purposes of the HPV Challenge Program. Inadequate data (see Analog Justification) were submitted for the repeated-dose, reproductive and developmental toxicity endpoints.

Ecological Effects (fish, invertebrates, and algae)

EPA reserves judgment on data adequacy for these endpoints for the sponsored substance pending receipt of adequate substance identification and/or adequate studies on that substance. The comments below address data and robust summary adequacy for the proposed analog, TEA.

Fish. The referenced TEA fish data (Geiger, et al.) appear adequate. However, the robust summary for the sponsored substance is blank. The summary either needs to be complete, or point to a publicly available adequate robust summary (see below, Specific Comments on the Robust Summaries).

Invertebrates. EPA reserves judgment on data adequacy for the submitted TEA study (Warne and Schifko (1999)) until the submitter provides an adequate robust summary; the submitted summary lacked adequate detail (see EPA guidance at http://www.epa.gov/hpv/pubs/general/robsumgd.htm).

Algae. EPA reserves judgment on data adequacy for the submitted TEA 96/72-h studies for the neutralized and non-neutralized forms until the submitter provides an adequate robust summary; the summary provided lacked adequate detail.

The algal study EC50 quoted on p. 4 of the test plan differs from the robust summary value. The discrepancy needs to be corrected.

Specific Comments on the Robust Summaries

Some summaries were left blank. Summaries must contain data or a discussion, or a pointer to a robust summary in another publicly available source such as an OECD Dossier or another HPV Challenge submission. Where data are for an analog, that substance and its CAS number also need to be clearly stated in the summary.

Ecological Effects

Algae. The summary refers to a 48-hour study. The study appears identical to one cited elsewhere as 72 hours. The submitter needs to check the apparent discrepancy. A 48-hour study is not considered adequate for this endpoint.

Followup Activity

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