

November 28, 2005

Adrienne L. Kiley
RegNet Environmental Services
P.O. Box 955
8 Vreeland Road
Florham Park, NJ 07932

Dear Ms. Kiley:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 2-(hydroxymethylamino)ethanol, posted on the ChemRTK HPV Challenge Program Web site on March 30, 2005. I commend Troy 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 Troy Chemical 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 Mark Townsend, Acting Chief of the HPV Chemicals Branch, 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 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: N. Patel
J. Willis

**EPA Comments on Chemical RTK HPV Challenge Submission:
2-(Hydroxymethylamino)ethanol**

Summary of EPA Comments

The sponsor, Troy Chemical Company, submitted robust summaries to EPA for 2-(hydroxymethylamino)-ethanol (CAS No. 34375-28-5) dated February 21, 2005. EPA posted the submission on the ChemRTK HPV Challenge Web site on March 30, 2005.

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

1. General. The submitter needs to include a test plan in this submission such as a summary table of existing data, data gaps, and what testing is or is not proposed.
2. Physicochemical Properties. The submitted data for water solubility are adequate for the purposes of the HPV Challenge Program. The submitter needs to clarify issues related to boiling point and vapor pressure, and adequately address the melting point and partition coefficient endpoints.
3. Environmental Fate. The stability in water data are adequate for the purposes of the HPV Challenge Program. The submitter needs to address the biodegradation, photodegradation and fugacity endpoints.
4. Health Effects. The submitted data are adequate for the purposes of the HPV Challenge Program, except for reproductive toxicity. The submitter needs to address this endpoint.
5. Ecological Effects. EPA agrees that data are adequate for fish and invertebrates for the purposes of the HPV Challenge Program. The submitter needs to provide data for acute toxicity to algae.

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

EPA Comments on the 2-(Hydroxymethylamino)ethanol Challenge Submission

Test Plan

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

The submitted data for water solubility are adequate for the purposes of the HPV Challenge Program. The submitter needs to provide data for melting point, clarify issues related to boiling point and vapor pressure, and address the partition coefficient endpoints.

Melting Point. The submitter concluded that testing for melting point is not needed because the chemical is a liquid at room temperature. However, for the purposes of the HPV Challenge Program, measured melting point data are needed unless the melting point of the substance is below 0 °C.

Boiling Point. The submitter provided an experimental boiling point of 110 °C. This seems extremely low, as the closest homolog, diethanolamine, boils at 268.8 °C, while replacing the N-hydroxymethyl group with a much less polar methyl group (2-(methylamino)ethanol) results in a *higher* boiling point of 158 °C. The estimated boiling point of 213°C for the sponsored compound (EPIWIN) is consistent with these analog data. While the sample purity is given as nearly 99%, the submitter needs to discuss whether an impurity, or possibly decomposition, could explain the anomalous results. The identity of any known impurities should be stated. As a measurement pressure was not recorded, it is also possible that the value of 110°C was determined at a reduced pressure. A new measurement on a purer sample or under more rigorous conditions may be necessary. Finally, the relevant OECD guideline is 103, not 102 as stated.

Vapor Pressure. The submitter provided calculated vapor pressure values of 1585 Pa (11.89 mm Hg) at 20 °C and 2116 Pa (15.87 mm Hg) at 25 °C, extrapolated from experimental values determined at a temperature range of 24.6 to 46.9 °C. These values are high in comparison with those of similar chemicals (e.g., diethanolamine, 2.80E-04 mm Hg); *cf.* comments above under Boiling Point. No sample purity was reported nor were impurities identified. The summary did not state whether atmospheric moisture, which could react with the sample to produce more volatile products, was excluded during sample handling. The submitter needs to discuss whether an impurity or some other factor could explain the anomalous results. The identity of any known impurities should be stated.

Partition Coefficient. No data were provided for this endpoint. The submitter needs to provide an estimated value for log Kow or an explanation in the robust summary that log Kow values are not relevant because the chemical hydrolyzes rapidly.

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

The data for stability in water are adequate for the purposes of the HPV Challenge Program. The submitter needs to address the biodegradation, photodegradation and fugacity endpoints.

Biodegradation. The submitter did not provide ready biodegradation test data. However, biodegradation testing of 2-(hydroxymethylamino)ethanol itself is probably obviated by rapid hydrolysis. If this is the case, the submitter needs to provide biodegradation data for the hydrolysis products.

Photodegradation. The submitter did not provide photodegradation data. The submitter needs to provide estimated data for photodegradation or explain in the test plan and robust summary if data are not appropriate for this substance.

Fugacity. The submitter did not provide fugacity values. The rapid hydrolysis of this substance suggests that fugacity modeling of 2-(hydroxymethylamino)ethanol will not be useful. Instead, the submitter needs to provide Level III fugacity model data on the hydrolysis products.

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

The submitted data for acute, genetic, repeated-dose and developmental toxicity are adequate for the purposes of the HPV Challenge Program. The submitter needs to address the reproductive toxicity endpoint.

Reproductive Toxicity. The submitter did not provide data for this endpoint. Because this chemical hydrolyzes very rapidly to formaldehyde and ethanolamine, the submitter may provide available reproductive toxicity data on the hydrolysis products in lieu of conducting a reproductive toxicity study.

Ecological Effects (fish, invertebrates, and algae)

EPA agrees with the submitter that there are adequate data for the fish and invertebrate acute toxicity endpoints for the purposes of the HPV Challenge Program. The submitter needs to provide acute toxicity data for algae using the sponsored chemical according to OECD TG 201 to address this endpoint or provide available data on its hydrolysis products.

Followup Activity

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