

August 14, 2002

James A. Deyo, D.V.M., Ph.D., D.A.B.T.
Technical Associate
Eastman Chemical Company
P.O. Box 511
Kingsport, TN 37662

Dear Dr. Deyo:

The Office of Pollution and Toxics is transmitting EPA's comments on the robust summaries and test plan for 2,2,4-Trimethylpentane-1,3-diol posted on the ChemRTK HPV Challenge Program Web site on April 19, 2002. 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 Chemical Company 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 HPV Challenge Program Web site "Submit Technical Questions" button 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. Sanders
A. Abramson
C. Auer
M. E. Weber

**EPA Comments on Chemical RTK HPV Challenge Submission:
2,2,4-Trimethylpentane-1,3-diol (TMPD)**

SUMMARY OF EPA COMMENTS

The Sponsor, Eastman Chemical Company, submitted a test plan and robust summaries to EPA for 2,2,4-Trimethylpentane-1,3-diol (CAS No. 144-19-4; TMPD) dated March 26, 2002. EPA posted the submission on the ChemRTK HPV Challenge Web site on April 19, 2002.

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

1. Physicochemical and Environmental Fate Data. All appropriate SIDS-level tests/estimations have been performed. However, the fugacity model should have been run using the available measured data.
2. Health Effects. All appropriate SIDS-level tests have been performed.
3. Ecological Effects. The submitted ecotoxicity data are adequate and no further testing is required.

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

EPA COMMENTS ON THE 2,2,4-TRIMETHYLPENTANE-1,3-DIOL (TMPD) CHALLENGE SUBMISSION

Test Plan

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

The submitter's approach to these endpoints is acceptable for the purposes of the HPV Challenge Program.

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

The submitter's approach to these endpoints is acceptable for the purposes of the HPV Challenge Program. However, the fugacity calculation should have been done with the measured physicochemical data that are available for TMPD instead of relying on the model default values. The submitter supplied a technical discussion that TMPD would not be subject to hydrolysis because it does not contain the necessary functional groups. EPA agrees with the submitter that a stability in water test is not needed.

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

Adequate test data are available for all health endpoints for the purposes of the HPV Challenge Program. However, the submitter needs to supply a robust summary for the reproductive toxicity endpoint. HPV Challenge Program guidance indicates that when a study addresses multiple endpoints, robust summaries are needed for each endpoint.

Acute Toxicity. Although a number of the acute toxicity studies are inadequate, the results reported in the five submitted robust summaries are generally consistent among the species tested (rats, mice, and guinea pigs); thus, based on the weight of the evidence, additional acute toxicity testing is not needed.

Ecotoxicity (fish, invertebrates, and algae). Adequate data are available for these endpoints for the purposes of the HPV Challenge Program.

Specific Comments on the Robust Summaries

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

Fugacity. The input values used in the fugacity calculation need to be added to the robust summary.

Health Effects.

Acute Toxicity. Information missing from the robust summary includes the purity of the tested material and sex of the test animals.

Repeated-Dose Toxicity. The submitter needs to define the specific tissues that were examined histopathologically because it is stated as "selected organs". The purity of the tested chemical is also missing.

Genetic Toxicity (in vitro). In both summaries, the submitter needs to list concentrations that were tested. The submitter also needs to provide the number of replicate plates per concentration for the reverse mutation in bacteria study and the number of metaphases per concentration that were examined for the chromosomal aberration assay.

Followup Activity

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