March 17, 2003

James P. McBriarty, CIH
Director or Regulatory Affairs
AmeriBrom, Inc.
2115 Linwood Avenue
Fort Lee, NJ 07024

Dear Mr. McBriarty:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 2,2-bis(bromomethyl)-1,3-propanediol posted on the ChemRTK HPV Challenge Program Web site on November 18, 2002. I commend AmeriBrom, Inc. 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 AmeriBrom, Inc. 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 "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: C. Auer
A. Abramson
W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
2,2-Bis(bromomethyl)-1,3-propanediol

SUMMARY OF EPA COMMENTS

The sponsor, AmeriBrom Inc., submitted a test plan and robust summaries to EPA for 2,2-bis(bromomethyl)-1,3-propanediol (CAS No. 3296-90-0) dated October 24, 2002. EPA posted the submission on the ChemRTK HPV Challenge Web site on November 18, 2002.

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

1. Physicochemical Properties. The submitter proposes testing for boiling point and water solubility, which appear to adequately address these endpoints. However, EPA disagrees that vapor pressure has been adequately addressed and recommends testing for this endpoint.

2. Environmental Fate and Pathways. EPA agrees with the submitter's test plan for these endpoints.

3. Health Effects. EPA agrees with the submitter's test plan for these endpoints.

4. Ecological Effects. EPA agrees with the submitter's test plan for these endpoints.

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

EPA COMMENTS ON THE 2,2-BIS(BROMOMETHYL)-1,3-PROPANEDIOL CHALLENGE SUBMISSION

Test Plan

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

The submitted data for melting point is adequate for the purposes of the HPV Challenge program. EPA agrees with the submitter's proposal to measure the boiling point and water solubility. However, EPA disagrees with the submitter's assessment for vapor pressure.

Vapor Pressure. The submitter states that a vapor pressure estimate using MPBPWIN adequately addresses this endpoint. However, according to OECD TG 104, vapor pressure calculations are only acceptable if the calculated value is less than $1x10^{-5}$ Pa ($8x10^{-8}$ mm Hg). Since the submitted calculated value of $1.3x10^{-5}$ mm Hg is greater, testing needs to be conducted.

Octanol-Water Partition Coefficient. The submitter proposes no testing. The value presented in the Test Plan was 2.29, but EPA located a literature value of 1.06 (Hansch et al., 1995) that appears acceptable and is more in line with an EPIWIN estimate of 0.85; EPA recommends that these additional data be added to the robust summary. EPA agrees that available data satisfy this endpoint.

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

EPA agrees with the submitter's proposal to test for stability in water and estimate photodegradation and fugacity.

Photodegradation. The submitter suggests using the Mackay Level III Fugacity Model to estimate photodegradation, but EPA assumes the submitter is referring to the AOPWIN model.

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

EPA agrees with the submitter's proposal to test for developmental toxicity.

Ecotoxicity (fish, invertebrates, and algae).

EPA agrees with the submitter's proposal to conduct acute toxicity tests on fish, daphnids, and algae.

Specific Comments on the Robust Summaries

Environmental Fate

Biodegradation. The submitter should provide the following information if available: temperature, dosing procedure, sampling frequency, controls, and analytical methods.

Health Effects

Acute Toxicity. Provide the percentage of CAS No. 32960-90-0 in the Dynol used in the acute (including irritation) studies.

Repeated-Dose Toxicity. Study No. 16.1 - Under Method, the bullet for Post Exposure Observation Period, note that there was such a period and state its length.

Genetic Toxicity. Study No. 14.3 - Clarify that the doses listed represent concentrations in feed (not mg/kg/bw) and provide actual dose levels in mg/kg/bw (as was done in the summaries on the repeated dose and reproduction studies). Studies 15.4, 15.5, and 15.6 - Provide the purity of the test substance.

Followup Activity

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

References

Hansch, C., A. Leo, and D. Hoekman. 1995. *Exploring QSAR. Hydrophobic, Electronic, and Steric Constants.* ACS Professional Reference Book. Washington, DC: American Chemical Society.