

November 14, 2007

Wendy H. Koch, Ph.D.
Epona Associates, LLC
156 River Road, Studio 3
Willington, CT 06279

Dear Dr. Koch:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Dimethylolpropionic acid (DMPA), posted on the ChemRTK HPV Challenge Program Web site on February 27, 2007. I commend GEO Specialty Chemicals 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 GEO Specialty Chemicals 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 tsc hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Mark Townsend, Chief
HPV Chemicals Branch

Enclosure

cc: O. Hernandez
R. Lee
J. Willis

EPA Comments on Chemical RTK HPV Challenge Submission: Dimethylolpropionic acid

Summary of EPA Comments

The sponsor, GEO Specialty Chemicals, submitted a test plan and robust summaries to EPA for Dimethylolpropionic acid (DMPA, CAS No. 4767-03-7), dated January 10, 2007. EPA posted the submission on the ChemRTK HPV Challenge Website on February 27, 2007.

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

1. Physical Chemical Properties. Adequate data are available for these end points for the purposes of the HPV Challenge Program pending confirmation by the submitter of the water solubility value.
2. Environmental Fate. Adequate data are available for these end points for the purposes of the HPV Challenge Program.
3. Health Effects. EPA agrees with the submitter's proposed testing for the repeated-dose and reproductive/developmental toxicity endpoints. The submitter needs to address deficiencies in the robust summaries.
4. Ecological Effects. EPA agrees with the submitter's proposed testing for these three endpoints.

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

EPA Comments on the Dimethylolpropionic Acid Challenge Submission

Test Plan

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

EPA agrees with the submitter that there are sufficient data for these end points, pending confirmation of the correct value for water solubility (see below).

Water Solubility. The submitter reported a measured water solubility of 11 mg/L. EPA located a water solubility of 11 g/100g at 25 °C (1.1×10^5 mg/L) from another document published by the submitter (A complete guide to DMPA brand of dimethylolpropionic acid. GEO Specialty Chemicals Trimet Products Group, Allentown, PA). This value is more in keeping with the polar structure of the sponsored substance. The submitter needs to confirm the correct value and update the robust summary accordingly.

Fugacity. The parameter employed by the submitter for the log K_{ow} was incorrectly input as 0.95, rather than -0.95; using the correct input to the model, EPA obtained similar results.

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

EPA agrees that there are sufficient data for these end points.

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

Adequate data were submitted for the acute and genetic toxicity endpoints. The submitter needs to address deficiencies in the robust summaries.

No data were submitted for the repeated-dose and reproductive/developmental toxicity endpoints. EPA agrees with the submitter's proposed testing for these endpoints using the combined repeated-dose/reproductive/developmental toxicity screening test according to OECD TG 422.

Ecological Effects (fish, invertebrates, and algae)

EPA agrees with the submitter's proposed testing for these three endpoints according to OECD TGs 203, 202 and 201.

Specific Comments on the Robust Summaries

Health Effects

Acute toxicity. If known, the submitter needs to indicate whether male and female rats were tested and describe any clinical findings during the post-exposure observation period.

Followup Activity

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