April 27, 2009

Richard E. Opatick
4-VCH Group Director
4-Vinylcyclohexene Group
1850 M Street, NW
Suite 700
Washington, DC 20036

Dear Mr. Opatick:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 4-Vinylcyclohexene, posted on the ChemRTK HPV Challenge Program Web site on December 7, 2006. I commend the 4-Vinylcyclohexene Group 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 the Group advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. EPA has moved energetically from the HPV Challenge Program to the Chemical Assessment and Management Program, or ChAMP (www.epa.gov/champ), and is relying on Challenge chemical sponsors to provide, as expeditiously as possible, the data that are the key to this effort.

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:
4-Vinylcyclohexene

Summary of EPA Comments

The sponsor, the Synthetic Organic Chemical Manufacturers Association (SOCMA) 4-Vinylcyclohexene Work Group, submitted a test plan and robust summaries to EPA for 4-Vinylcyclohexene (4-VCH; CAS No. 100-40-3), dated October 30, 2006. EPA posted the submission on the ChemRTK HPV Challenge Website on December 7, 2006.

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

1. Physicochemical Properties. Adequate data are available for these endpoints for the purposes of the HPV Challenge Program.

2. Environmental Fate. Adequate data are available for these endpoints for the purposes of the HPV Challenge Program.

3. Health Effects. Data for all health effects endpoints are adequate for the purposes of the HPV Challenge Program. The submitter needs to address deficiencies in the robust summaries.

4. Ecological Effects. EPA reserves judgment on the fish and invertebrate endpoints until all missing critical elements have been provided. Algal testing needs to be conducted at appropriate concentrations.

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

EPA Comments on the 4-Vinylcyclohexene Challenge Submission

Test Plan

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

Adequate data are available for these endpoints for the purposes of the HPV Challenge Program.

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

Adequate data are available for these endpoints for the purposes of the HPV Challenge Program.

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

Data for these endpoints are adequate for the purposes of the HPV Challenge Program. The submitter needs to address deficiencies in the robust summaries.

Ecological Effects (fish, invertebrates, and algae)

Fish and invertebrates. EPA reserves judgment on these endpoints. Although most studies were conducted following OECD guidelines and GLPs, relevant information and method details for each of these studies need to be included in the robust summaries.

Algae. The reported EC50 of > 4 mg/L is not adequate. Testing up to a concentration of at least 100 mg/L is necessary to adequately characterize hazard. The submitter needs to provide such measured data on the sponsored chemical, or on a suitable analog with ECOSAR-modeled data on the sponsored chemical, to characterize this end point.

Specific Comments on the Robust Summaries

Health Effects

Reproductive/developmental toxicity. The submitter needs to clarify the statement, on pages 79-80, about the statistical significance of weight reduction observed at 77 weeks and 117 weeks, "This may be attributable to the different statistical method employed at this stage of the study", or remove this statement from the robust summary. "Spargue" on p 82 should be "Sprague."

Ecological Effects

Fish. Details missing from the summaries include test substance purity, concentrations tested, measurement of test concentrations (nominal/measured), statistical methods used and confidence limits, photoperiod, water chemistry parameters (temperature, pH, hardness, dissolved oxygen, TOC), loading rate, number of animals per concentration, number of replicates per concentration, control use and response, mean length and weight, and specific mortality results at each dose level.

Invertebrates. Details missing from the summaries include GLP compliance, controls and control response, age of the daphnids, test substance purity, test guideline used, concentrations tested, number of replicates and daphnids per replicate, statistical methods, confidence limits, photoperiod, and water parameters (pH, temperature, dissolved oxygen, TOC).

Followup Activity

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