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SOCMA

Society of Chemical Manufacturers & Affiliates

July 2, 2009

Mark W. Townsend, Chief
HPV Chemicals Branch

By Email: oppt.ncic@epa.gov
Chem..rtk@epa.gov

RE: EPA Comments on Chemical RTK HPV Challenge Submission: 4-Vinylcycloxene

Dear Mr. Townsend:

On behalf of the members of SOCMA's 4-vinylcyclohexene (4-VCH) work group, I am responding to your letter of May 1, 2009 containing EPA's comments on our HPV Challenge submission. The 4-VCH work group has given careful consideration to your letter and appreciates the opportunity to address EPA's concerns.

The EPA pointed out certain editorial changes that should be made in the health effects section of the robust summaries. These changes have been made accordingly and are contained in the revised robust summaries which are attached.

EPA also requested that select details be added to some of the ecological effects robust summaries, namely the fish and invertebrates summaries. The data submitted in those summaries were taken from the following online database search for CAS# 100-40-3:

http://www.safe.nite.go.jp/data/sougou/pkc_e_search_frm.html

This online database provides a reference for the data but it is in Japanese and, therefore, the sponsors did not review these references but instead represented the data as coming from a reliable government source. The 4-VCH work group will determine if the requested technical details are available in the translated reference document and add what is available to the relevant summaries and submit them as soon as that effort is completed. The work group anticipates that this effort can be completed this year.

Lastly, EPA asks for a new algal EC_{50} study at test concentrations up to 100 mg/L to complete the environmental endpoints. This study is not needed because sufficient data exist from the available aquatic toxicity studies and modeled data (ECOSAR) to characterize the aquatic hazard with regard to the alga toxicity endpoint of 4-VCH. Although the alga study results included with the 4-VCH test plan did not identify a specific EC_{50} value, the study did determine a NOEC value. Therefore, the 4-VCH work group believes that a new study is not needed for the following reasons:

- The modeled alga data can be used for the 96-hour EC50 and NOEC values.
- The ECOSAR model is appropriate for use with non-polar narcotic chemicals like 4-VCH as evidenced by the good agreement between the modeled fish/invertebrate data and the measured fish/invertebrate data.
- The modeled alga data are more conservative than the measured alga data and provide EC50 and ChV values that would be appropriate for use in a hazard assessment for this endpoint.
- There is also a chronic 21-day invertebrate reproduction study included with the test plan that provides measured lethal and sublethal endpoint values, of which the NOEC value is consistent with modeled algae and fish ChV values; a measured NOEC of 0.23 mg/L versus calculated ChV values of 0.32 and 0.22 mg/L.

Thank you for this opportunity to respond to EPA's comments on the 4-VCH submission. The 4-VCH work group is committed to responsible manufacture, testing, and safe use of its member company products. As evidence of this commitment, the 4-VCH work group agreed to develop study summaries and hazard testing plans for 4-VCH and continues to participate in the U.S. Environmental Protection Agency HPV program. Please contact me directly if you have any questions or further comment about our submission.

Sincerely,

C. Tucker Helmes, Ph.D.
Executive Director
4-Vinylcyclohexene Work Group