

June 2, 2003

Alvaro J. DeCarvalho
Director of Environmental Safety
The TCC Consortium
The Soap and Detergent Association
1500 K. Street, N.W.
Suite 300
Washington, DC 20005

Dear Mr. DeCarvalho:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Triclocarban posted on the ChemRTK HPV Challenge Program Web site on January 27, 2003. I commend The TCC Consortium; The Soap and Detergent Association for their 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 TCC Consortium; The Soap and Detergent Association 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: W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission: Triclocarban

Summary of EPA Comments

The sponsor, the TTC Consortium, submitted a test plan and robust summaries to EPA for triclocarban dated December 27, 2002. EPA posted the submission on the ChemRTK HPV Challenge Web site on January 27, 2003. The sponsored chemical is triclocarban [N-(4-chlorophenyl)-N'-(3,4-dichlorophenyl) urea], CAS No. 101-20-2.

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

1. Physicochemical Properties. The data provided by the submitter for melting point, boiling point, partition coefficient, and water solubility are adequate for the purposes of the HPV Challenge Program. The submitter needs to provide a discrete value for vapor pressure.
2. Environmental Fate. The data provided by the submitter for photodegradation, stability in water, and fugacity are adequate for the purposes of the HPV Challenge Program. The submitter needs to clarify biodegradation and fugacity results and address some deficiencies in the robust summaries.
3. Health Effects. Adequate data are available for these endpoints for the purposes of the HPV Challenge Program. The submitter needs to address some deficiencies in the robust summaries.
4. Ecological Effects. Data for acute fish, daphnid, and algae in addition to the 21-day chronic toxicity study are tentatively acceptable pending receipt of adequately enhanced robust summaries.

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

EPA Comments on the Triclocarban Challenge Submission

Test Plan

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

Adequate data are available for all endpoints except vapor pressure.

Vapor Pressure. Presenting the vapor pressure as a range (< 1 hPa at 50 °C) is inadequate for the purposes of the HPV Challenge Program. The submitter needs to provide a discrete, quantitative value for this endpoint at an ambient temperature (25 °C).

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

Adequate data are available for these endpoints.

Biodegradation. Among the studies submitted, the data from the ready biodegradation test (OECD 301C) satisfy the needs of the HPV Challenge Program.

In Table 2.2 of the test plan (shake-flask method with adapted activated sludge), the submitter indicates that the parent compound undergoes 100% biodegradation after 10 hours, and has a 50% mineralization

rate, whereas the robust summary indicates 70% loss of the chemical. The submitter needs to resolve the discrepancy.

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

Adequate data are available for these endpoints.

Ecological Effects (fish, invertebrates, and algae)

Fish, invertebrates, and algae. The submitter needs to provide details in the robust summaries before adequacy of the data can be fully assessed. Also, there are several discrepancies between Table 2.3 (Environmental Toxicity Data) and Appendix B (Available Ecotoxicity Data for Triclocarban) of the test plan. For example, the NOEC in *C. dubia* was reported as a 21-day NOEC in Table 2.3 and a 7-day NOEC in Appendix B. Also, the 5-day NOEC in *N. pelliculosa* indicated in Table 2.3 was reported as a MAC in Appendix B. These discrepancies need to be addressed and the studies need to be included in the robust summaries.

Specific Comments on the Robust Summaries

Environmental Fate

Biodegradation. In the second test using activated/adapted sludge, the submitter concludes that this chemical is readily biodegradable. However, ready biodegradability cannot be determined from a test that uses adapted, activated sludge. The submitter needs to correct this error.

Fugacity. The submitter obtained, for a release scenario of 300 kg/hr to water, percent distributions of 0 (air), 71 (water), 0 (soil), and 29 (sediment). The submitter may have transposed the data for water and sediment, and needs to check its figures.

Health Effects

Acute Toxicity. A robust summary for a GLP-compliant acute oral toxicity study in rats provided only limited information; however, because the study was conducted under an EEC guideline, the data are acceptable.

Repeated-Dose Toxicity. If clinical chemistry and hematological parameters were evaluated in the 30-day study, the submitter needs to state this fact. In addition, the submitter needs to list the organs examined in the 24-month study and needs to supply a full reference for this study including the date of publication.

Reproductive Toxicity. The robust summary for a three-generation feeding bioassay in rats omitted details including the reproductive organs examined and whether implantation sites were recorded.

Ecological Effects

Fish. Details missing from the robust summaries include values of the concentrations evaluated, control use and response, water quality parameters, size of the test groups, statistical methods and analysis, mortality at each concentration, and whether the reported LC₅₀ values are based on nominal or measured concentrations. Also, the temperature ranges reported for the tests in *Oncorhynchus mykiss* and *Lepomis macrochirus* are outside of the OECD-recommended temperature ranges for these species.

Invertebrates. Details missing from the acute toxicity robust summaries include size and number of the test groups, concentrations evaluated, control use and response, statistical methods and analysis, nominal

concentrations, test system (e.g., static, flow-through), mortality at each concentration, and whether the reported LC₅₀ values are based on nominal or measured concentrations.

Robust summaries are also provided for seven chronic tests in aquatic invertebrates including a 21-day *Daphnia magna* study. Adequate data exist from the 21-day study to satisfy this endpoint. However, details missing from other robust summaries include test condition (e.g., flow-through, semi-static), size of the test groups, mortality at each concentration, statistical methods, use and response of controls, and water quality parameters need to be provided before data adequacy can be fully assessed.

Algae. Details missing from the robust summaries include initial and final cell densities, concentrations evaluated, statistical methods and analysis, water quality parameters, use and response of controls, and whether the reported EC₅₀ values are based on nominal or measured concentrations.

Followup Activity

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