



LARKIN LABORATORY
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Oscar Hernandez, Director – OPPT Risk Assessment Division
Environmental Protection Agency

Richard Hefter, Chief – HPV Chemicals Branch
Environmental Protection Agency

Chemical Right-to-Know – HPV Challenge Program

Thank you for the comments provided on the HPV Test Plan and Robust Summaries for the Alkyl Diphenyl Oxide Disulfonates (ADPODS) Category. Provided below is the response of The Dow Chemical Company (Dow) to the Agency's comments. Further, as requested and referenced in our comments, the robust summaries for each of the compounds in the category have been updated. The revised IUCLID documents are included, as attachments, in this e-mail.

Dow Response to EPA Conclusions (noted in *italics*):

1. Category Justification. The data provided by the submitter generally support the category.

Response: *The sponsor appreciates the Agency's confirmation that the data support the category outlined.*

2. Physicochemical Properties. The data provided by the submitter for melting point, boiling point, vapor pressure and octanol/water partition coefficient are adequate for the purposes of the HPV Challenge Program. The submitter needs to provide water solubility data

Response: *The sponsor appreciates the Agency's confirmation that the majority of the data is adequate. With regards to water solubility, we understand the confusion in Appendix B of the test plan. An error was made in the notation that the water solubility values were determined using an ACD/LogD program. The water solubilities were determined based on product formulation. The sponsor is confident that the values provided are accurate, as there are no other components in the formulation that could contribute to the solubilization of the substance. Thus, the sponsor does not commit to generate any additional water solubility information.*

Note: *In response to comments in this area on the Robust Summaries, the IUCLID document for each compound has been updated.*

3. Environmental Fate. The submitter needs to incorporate the photodegradation and stability in water information in the robust summaries. The submitter needs to provide ready biodegradation data for the C12 linear salt. EPA recommends that the submitter provide transport and distribution (fugacity) data using a level III model.

Response: The sponsor has updated the robust summary for each compound to include both photodegradation and stability in water information.

With regards to the request to generate ready biodegradation data for the C12 linear salt, in light of the significant amount of biodegradation data available on compounds in this category (and on the C12 linear salt) and knowing that the C12 linear salt will not pass this test, the sponsor does not commit to conduct this test. Conducting the requested test would provide no new information.

The sponsor does agree to provide transport and distribution data using a level III model.

Note: In response to comments in this area on the Robust Summaries, the IUCLID document for each compound has been updated. Further, for the C16 linear, sodium salt, the sponsor has included two additional robust summaries on degradation work that was completed after the submittal of the Test Plan and Robust Summaries in Dec. 2002.

4. Health Effects. Adequate data are available for acute, repeated-dose and genetic toxicities for the purposes of the HPV Challenge Program. EPA agrees with the submitter's plan and recommends a combined reproduction/developmental screening tests on C6 and C16 linear sodium salts to define the category boundaries. The submitter needs to address the deficiencies in the robust summaries.

Response: The sponsor appreciates the confirmation that the majority of the health effects data are adequate to meet the SIDS-level endpoints.

The sponsor notes that the agency has requested that OECD TG 421 be utilized rather than the proposed OECD TG 422 for these studies. As there was time available in the Dow testing laboratory, the sponsor had already initiated the testing for the C16 linear sodium salt prior to receiving the Agency's comments. However, the sponsor agrees to conduct the testing on the C6 linear sodium salt using OECD TG 421.

Note: In response to comments in this area on the Robust Summaries, the IUCLID document for each compound has been updated.

5. Ecological Effects. The data for fish and invertebrates are adequate for the purposes of the HPV Challenge Program. The data for the algal studies are inadequate and further testing is necessary. EPA reserves judgement on the adequacy of the chronic daphnia reproduction studies pending submission of additional information.

Response: The sponsor appreciates the confirmation that the data for fish and invertebrates are adequate for the HPV Program. With this input, the sponsor will not conduct the testing on the C10 linear, acid and the C12 branched, acid that was originally proposed.

The sponsor does not understand the request for additional algal data. In light of the Agency's comment that there are no adequate data on the critical C10 and C12 category members, the sponsor went back and reviewed the study that was cited for the C12 linear, sodium salt. Our evaluation of the study noted that the Day 3 EC50 value was greater than the top measured dose level of 1010 mg/L and the effect endpoint was monitored using both cell number and cell

volume. Further, complete recovery of dose concentrations was noted, after 5 days of exposure, so the algal cells were exposed to 100% of their nominal dose levels after 3 days. After completing the additional assessment of the study, the sponsor continues to believe that this study is adequate and thus, does not agree to conduct an additional algal study.

In response to questions raised by the Agency on the chronic daphnia reproduction study, the sponsor has reviewed the study again and made significant revisions to the robust summary. While the sponsor expects this updated robust summary will address the Agency's questions, it should be noted that the chronic toxicity information was submitted to enhance the robust summaries. It is our understanding that this type of study is outside the requirements of the HPV Challenge Program.

Note: In response to comments in this area on the Robust Summaries, the IUCLID documents for each compound has been updated.

We do appreciate the time that you spent in review of our Robust Summaries and Test Plan. We hope that you find that the further information provided in our response above and in the updated robust summaries adequately addressed the issues that were identified.

Regards,

Industrial Chemicals
Global EH&S Manager
The Dow Chemical Company
Phone: (989) 636-6978
Fax: (989) 636-9899
E-mail: cldeford@dow.com

Attachments