

September 27, 2006

Ms. Gail M. Hartwell
Dow AgroSciences LLC
EH&S Improvement Specialist
9330 Zionsville Road
Indianapolis, IN 46268

Dear Ms. Hartwell:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the Dow AgroSciences test plan and robust summaries for the Chlorinated Pyridine category. The submission was posted on the ChemRTK HPV Challenge Program Web site on January 26, 2006. The category includes the following chemicals:

- 1) 2,3,4,5,6-pentachloropyridine (CAS No. 2176-62-7);
- 2) 3,4,5,6-tetrachloro-2-pyridine carbonitrile (CAS No. 17824-83-8);
- 3) 3,6-dichloro-2-trichloromethylpyridine (CAS No. 1817-13-6);
- 4) 2-chloro-5-trichloromethylpyridine (CAS No. 69045-78-9);
- 5) chloropyridine derivatives (CAS No. 68412-40-8);
- 6) methyl chloropyridine derivatives (CAS No. 70024-85-0); and
- 7) 2,3,5,6-tetrachloropyridine (CAS No. 2402-79-1) (supporting chemical)

EPA reviews test plans and robust summaries to determine whether they provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for preparing test plans and determining the adequacy of data used to prioritize chemicals for further work.

Category Justification

EPA concludes that the proposed Chlorinated Pyridines Category is inadequate for the purposes of the HPV Challenge Program for the reasons outlined below. Previously, the submitter provided individual submissions for the above-listed category members and EPA concluded that each of those submissions was significantly deficient and inadequate for the purposes of the HPV Challenge Program.

The main problems with the category submission are: (1) The submitter has provided little justification to support grouping these chemicals in a category, and the test plan as submitted does not include a specific strategy for using a category read-across approach to fulfill data gaps for most of the category members. (2) Given the differences in structure and potential reactivity, the proposed category members should not be grouped together, and most do not even fit the submitter's description of the category as being composed only of chlorinated pyridines with varying degrees of chlorination. (3) The submitter has failed to address adequately all of the concerns already outlined in the various Agency comments on the previous individual submissions of these chemicals. Given these shortcomings, the Agency can not continue review of this category.

Specific comments:

3,6-Dichloro-2-trichloromethylpyridine and 2-chloro-5-trichloromethylpyridine. These two chemicals have structural similarities but may differ significantly from other chloropyridines owing to the presence of the potentially reactive trichloromethyl group. Therefore, these two substituted pyridines should not be grouped with any of the other proposed category members, and data for pentachloropyridine cannot be used as a surrogate for these chemicals. Also note that estimated data are not adequate for several of the physicochemical and fate endpoints for the purposes of the HPV Challenge Program.

2,3,4,5,6-Pentachloropyridine. In the previous submission for this chemical EPA raised concerns about the adequacy of the submitted vapor pressure and water solubility data and also requested measured ready biodegradation data (EPA comments dated 8/28/03). The submitter has not addressed these concerns nor provided additional data for pentachloropyridine in this submission.

3,4,5,6-Tetrachloro-2-pyridinecarbonitrile. The submitter has not provided an adequate justification for including this substance in this category. The addition of a functional group not shared by the rest of the proposed category members would need specific justification. EPA previously stated that using data for pentachloropyridine as an analog for this substance is inappropriate. EPA requested measured data (comments posted on 8/24/04) for physicochemical properties, stability in water, and ready biodegradability. These data have not been provided in this submission for most of these properties.

Chloropyridine Derivatives. This is a complex reaction mixture and its inclusion in the category is unsupported. The submitter proposes using data for pentachloropyridine to read across to this substance. However, the sample composition of this mixture shows only 3.3% pentachloropyridine. Given the complexity of this mixture and the low levels of pentachloropyridine present, there is no justification for using pentachloropyridine as an analog. The submitter needs to devise a different strategy for fulfilling the data requirements of this mixture.

Methyl chloropyridine derivatives. This chemical is also a complex reaction mixture and should not be included in a category with the other chemicals. The submitter proposes using data for pentachloropyridine to read across to this chemical. However, pentachloropyridine is not a

major component of the mixture and thus is an inappropriate data source. The submitter needs to devise a different strategy for fulfilling the data requirements of this mixture.

In conclusion, this category is poorly designed and cannot be reviewed as submitted. Category analysis and supporting statements are at a superficial level. Pentachloropyridine was not shown to be an adequate supporting chemical for any of the other substances, and no support for using data on 2,3,5,6-tetrachloropyridine was provided. Data needs previously identified by EPA remain largely unsatisfied.

Closed system intermediate (CSI) claim

The CSI claims in the test plan (referred to there as “site-limited intermediate”) are inadequate on the basis of the information submitted.

1. There is no description of the manufacturing process documenting the use of closed reactors.
2. There is no information provided nor a reasonable basis included to demonstrate that chloropyridines are not present in the air, solid wastes, or waste water leaving the manufacturing sites.
3. There is no information provided to document that unreacted chloropyridines do not remain in chemicals manufactured using these chemicals or in other end products.

As indicated in EPA’s March 31, 2005 comments on the chlorinated pyridines and methyl chlorinated pyridines, descriptions are missing of all major unit operations from manufacturing through processing, storage and disposal; information on potential releases during operations; worker exposure; monitoring data showing no detection of methyl chloropyridine derivatives or chloropyridine derivatives in any medium; information on transport from the production site (for chloropyridine derivatives); data on the presence or absence of these streams in distributed products; and supporting evidence that these streams are not present in other end products. For a more complete description of the CSI criteria, please refer to “The Guidance for Testing Closed System Intermediates for the Challenge Program”

(<http://www.epa.gov/chemrtk/pubs/general/guidocs.htm>). Unless Dow can support these CSI claims with additional documentation, test data will be needed for the repeated dose and reproductive toxicity endpoints, as well as for the acute, genetic, and developmental toxicity endpoints.

EPA will post this letter on the HPV Challenge Web site within the next few days. We ask that Dow Agrosiences advise the Agency, within 90 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 there are any questions about this response, please contact Mark Townsend, Chief of the HPV Chemicals Branch, 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.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

cc: R. Lee
J. Willis