

201-16262



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05/25/2006 04:14 PM

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EPA/OPPT/OPIC

2006 MAY 30 10:17:39

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Subject: Environmental Defense comments on the Chlorinated
Pyridine Category

(Submitted via Internet 5/25/06 to _____
_____ MTC@mchsi.com, and
aaarvin@dow.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for the **Chlorinated Pyridine Category**.

The Dow Chemical Company, in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted extensive documents describing available data for a number of chlorinated pyridines and related chemicals, with the proposal that they be considered together as the Chlorinated Pyridine Category. Members of the proposed category include the chlorinated pyridine derivative stream, methyl chlorinated pyridine derivatives, **2-chloro-5-trimethylchloropyridine**, **3,6-dichloro-2-trichloromethylpyridine**, pentachloropyridine, and **3,4,5,6-tetrachloro-2-pyridine carbonitrile**. Information describing studies for **2,3,5,6-tetrachloropyridine** are also included in order to "enrich the database for the category," although it is not clear as to whether this chemical is considered a member of the category.

General Comments:

Most of these chemicals and/or groups of chemicals have been considered individually in previous submissions for the HPV Challenge. In each case, we considered those submissions inadequate to meet data requirements as defined by the HPV Challenge guidelines.

Our review of the present submission indicates that additional work has been done to address information requested in the earlier reviews of pentachloropyridine, and that information provided for this chemical is now minimally adequate to meet the requirements of the HPV Challenge. However, little or nothing has been done to address the data gaps for most of the other chemicals in this newly proposed category. Rather, as was done previously, pentachloropyridine is proposed to be used as a surrogate to address most of the missing data elements for other chemicals in the proposed category. Whereas this might be acceptable for some elements and for some of these chemicals, it is clearly not acceptable for others. Clear explanations as to why data developed for pentachloropyridine are not acceptable surrogates to address data requirements for a number of the chemicals in this proposed category have been provided in previous letters from Dr. Hernandez of EPA to Dow Chemical posted on the EPA [website](#). If data developed for pentachloropyridine were not acceptable surrogates when these chemicals were considered individually, then the same data cannot be considered acceptable when these same chemicals are considered as a group. Barring further data development on them, those chemicals for which pentachloropyridine has been deemed not to be an appropriate surrogate must be eliminated from this proposed category before the remaining chemicals can be considered together as a category. Further, additional work should be done on those chemicals that can be considered members of this category in order to address the required **SIDS** elements before any submission describing these chemicals can be considered acceptable to meet the HPV Challenge.

Specific Comments:

1. The robust summaries for this submission consist largely of a voluminous compilation (296 pages!) of documents that have been previously submitted as IUCLID files to the European Risk Assessment Program on Existing Substances. They contain numerous blank pages and dozens of headings without data. Moreover, they provide no consistent argument for the consideration of these chemicals as a category. We are not opposed to the use of these reports to address HPV requirements, but they should comport with the HPV guidelines.
2. The test plan should be revised to systematically discuss the chemical relationships that the sponsor believes permit the consideration of the chemicals as a category. It also needs to clearly outline the data gaps for each and propose the necessary work to address these data gaps.
3. Most of the IUCLID documents submitted as robust summaries for the proposed category members actually include little data for the chemical in question, but rather data developed for pentachloropyridine, which is proposed as a surrogate for multiple members of the proposed category. This results in extensive redundancies while still failing to provide a convincing argument for the proposal to consider these chemicals as a category.

4. The test plan states that, with exception of pentachloropyridine, these chemicals should be considered closed-system intermediates, but it provides little evidence to support this claim. As noted above, it is not clear whether the sponsor considers **2,3,5,6-tetrachloropyridine** a member of the proposed category, but **2,3,5,6-tetrachloropyridine** is said to be produced in two plants and shipped to another for the production of chloropyrifos – clearly not features of a closed-system intermediate. Minimal information is provided on how the other chemicals in the proposed category are produced and used, or whether they are present in waste streams or as impurities in finished products, and hence is insufficient to support the status claim.
5. Many of the studies described are old and were not conducted under GLP, and some utilized too few animals and/or too few doses. A number of the **IUCLID** reports describe the test substance as “no data”. Such inadequate studies serve no purpose other than to bulk up the robust summaries and should be eliminated from this submission.
6. It is stated in the test plan that data for pentachloropyridine is proposed as a surrogate for the chloropyridine derivatives (**CAS68142-40-8**) because pentachloropyridine is a primary component of this chemical stream. However, on page 7 we see that an analysis of this chemical stream provided by Dow indicates that pentachloropyridine accounts for only 3.3% of the mixture. Other chemicals, the chemical structures of which differ sufficiently from pentachloropyridine to preclude the use of pentachloropyridine as a surrogate, are actually the major constituents of the mixture. Thus, it appears that this analysis of the chloropyridine stream presents a good argument as to why pentachloropyridine is not an appropriate surrogate for the chloropyridine derivatives.

In summary, most of the individual reports used to make up this submission were not acceptable when first submitted to support the individual chemicals; submitting them as a large package and calling it a chemical category with no real justification has only served to decrease the quality of the submission. With the exception of that for pentachloropyridine, the quality of these submissions has not been significantly improved, and a number of these chemicals obviously cannot be considered to be in the same chemical category. Thus, we recommend that EPA require, as necessary, additional studies to address **the data** gaps for those chemicals that do not fit the category. Further, for those that might be considered members of a category we recommend the test plan and IUCLID documents be completely revised to provide a coherent discussion of their chemical relationships and the specific data that address the respective HPV data requirements.

Thank you for this opportunity to comment.

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