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bcc:
Subject: Environmental Defense comments on 2-Chloro-5-trichloromethylpyridine (CAS# 69045-78-9)

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(Submitted via Internet 1/18/05 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, / boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and ggarvin@dow.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for **2-Chloro-5-trichloromethylpyridine (CAS# 69045-78-9)**.

Dow AgroSciences, LLC, in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted a long-overdue set of robust summaries to accompany a test plan (submitted earlier) describing available data and a proposal to use QSAR calculations to address the SIDS elements required for 2-chloro-5-trichloromethylpyridine. It also has provided data for 2,3,4,5,6-pentachloropyridine, from which the Sponsor proposes to bridge data to the sponsored chemical, to address SIDS elements not otherwise addressed.

Our review of the test plan indicates that it contains a dearth of information and is not sufficient to meet the requirements of the HPV Challenge. Neither the Plain English Summary nor the Executive Summary provides information regarding 2-chloro-5-trichloromethylpyridine that would be informative to anyone. The body of the test plan provides no data to address the required SIDS elements and no comparison of available, calculated or bridged data to address the respective elements. Rather, the test plan consists primarily of a list of the required SIDS elements, as if the EPA or anyone familiar with the program needs to know what those elements are. The test plan proposes to generate necessary data to address the SIDS elements through "... the use of existing data and scientific judgment/analysis ...". However, the test plan contains no discussion of existing data or the scientific judgment to be used. No additional studies are proposed. The test plan does provide a brief description of the production and use of the chemical, with the proposal that it be considered a site-limited intermediate. We defer to EPA as to whether sufficient documentation to support such a claim has been provided by the Sponsor.

Our review of the robust summaries -- submitted many months after the test plan -- indicates that although it is extensive, most of the data describe the fate and toxicity not of the sponsored chemical but of 2,3,4,5,6-pentachloropyridine. Some data addressing the required SIDS elements for 2-chloro-5-trichloromethylpyridine are also available. All the studies are described in considerable detail and those descriptions are interspersed with numerous irrelevant sections containing headings, but no information. By wading through this confusing presentation, it is possible to determine that 2-chloro-5-trichloromethylpyridine appears to have little toxicity to fish and invertebrates, and moderate toxicity to mammals in acute and repeated oral dose studies. However, one study indicates that 2-chloro-5-trichloromethylpyridine is relatively toxic to mice when inhaled, whereas another study reported no toxicity when mice inhaled the same concentration. No comment is made as to why this discrepancy was found or which is the better study. No data were described for several SIDS elements, e.g., genetic, reproductive, or developmental toxicity and toxicity to algae.

2-Chloro-5-trichloromethylpyridine and 2,3,4,5,6-pentachloropyridine are both pyridines, but are otherwise sufficiently different that we do not consider it appropriate to bridge data from one to another. Our rationale is based on chemical structural differences. That is, 2-chloro-5-trichloromethylpyridine has adjacent unsubstituted carbon atoms in the ring portion of the molecule that will result in significantly different metabolism than can be expected for 2,3,4,5,6-pentachloropyridine, which does not have any unsubstituted carbon atoms. Furthermore, 2-chloro-5-trichloromethylpyridine contains a fully chlorinated methyl group that is not present in 2,3,4,5,6-pentachloropyridine. Each of these differences in their structures may account for significant differences in their metabolism, genotoxicity and mammalian toxicity.

Additional Comments:

1. The HPV instructions specifically request a structural formula for the compounds considered under the HPV Program. No structural formula is provided for 2-chloro-5-trichloromethylpyridine or for 2,3,4,5,6-pentachloropyridine from which data are proposed to be bridged.
2. The QSAR calculation provided for genetic toxicity reports that "mutagenicity is plausible". Given that structurally similar chemicals are mutagenic in the Ames System, we would expect a stronger statement.
3. An apparent typo on page 3/3 of the robust summaries for 2,3,4,5,6-pentachloropyridine indicates it is "inorganic".

In summary, we consider this is a poorly prepared and mostly uninformative submission. Further, we do not consider 2,3,4,5,6-pentachloropyridine an appropriate surrogate chemical from which data should be bridged to predict the fate and toxicity of 2-chloro-5-trichloromethylpyridine. Therefore, we recommend that EPA not accept this submission to address the HPV requirements for 2-chloro-5-trichloromethylpyridine.

Thank you for this opportunity to comment.

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