

201-14707



NCIC HPV
Sent by: Mary-Beth
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08/29/2003 09:25 AM

To: NCIC HPV, moran.matthew@epa.gov
cc:

Subject: Environmental Defense comments on 2,3,4,5,6-pentachloropyridine
(CAS# 2176-62-7)



Richard_Denison@environmentaldefense.org on 08/27/2003 03:18:36 PM

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Boswell/DC/USEPA/US@EPA, ggarvin@dow.com
cc: lucieryg@msn.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org

Subject: Environmental Defense comments on 2,3,4,5,6-pentachloropyridine (CAS# 2176-62-7)

(Submitted via Internet 8/27/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov,
boswell.karen@epa.gov, chem.rtk@epa.gov, lucieryg@msn.com and
ggarvin@dow.com)

Environmental Defense appreciates this opportunity to submit comments on
the robust summary/test plan for 2,3,4,5,6-pentachloropyridine (CAS#
2176-62-7).

The test plan and robust summaries for 2,3,4,5,6-pentachloropyridine (PCP)
were submitted by Dow Chemical Company. The sponsor appears to claim that
PCP qualifies as a closed-system intermediate used to produce precursors
(Symtet) of chlorinated pesticides, including chlorpyrifos and others. It
appears that 75% of PCP is used to synthesize Symtet in California, 24% is
shipped to California and a small amount sold to other customers for
unspecified uses. It is also stated that Symtet contains up to 0.6% PCP.
Although the sponsor states that there is no PCP remaining in chlorpyrifos,
another final product, N-serve, contains up to 0.4% PCP.

The test plan and robust summary do not provide sufficient information (as
specified in EPA guidance governing such claims) to support a claim of
closed-system intermediate status; hence, in our view, the chemical does
not qualify. The facts -- stated by the sponsor -- that some PCP is sold
to other customers for unspecified uses, and that it is present in end-use
products, also would appear to disqualify PCP from such a status.

The sponsor has identified HPV endpoints for which there are no available
data and studies are proposed for algal toxicity, genetic toxicity and
developmental toxicity. We agree with this proposal but we recommend that a
combined reproductive/developmental study be conducted instead of just a
developmental toxicity study. Specific comments are as follows:

1. The life cycle for PCP is complicated. It would be helpful if the
sponsor could provide an illustration which depicts how PCP is used,
transported and sold to other customers. This illustration should also
include the amount of PCP remaining in various products, especially those
for which there is opportunity for environmental release and human
exposure. This approach would help to satisfy "right to know" concerns.
2. Environmental fate data for PCP were generated using computer models.
While these models are acceptable to EPA, we recommend that the sponsor
also provide any available experimental data so that comparisons can be
made with the computer-generated data. This would be especially helpful for
chemical transport and distribution properties of PCP. Are any
environmental sampling data available for PCP in areas where it is

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synthesized and used?

3. PCP is moderately toxic to fish and aquatic invertebrates. Because of the absence of plant toxicity data, we support the sponsor's proposal to conduct an algal toxicity study.

4. PCP has irritant and sensitizing properties. The sponsor states that safe handling information is available, but no details are provided. We recommend that such information be added to the test plan. (The allowable level in the workplace indicated by the sponsor ? 7 mg/m³ ? appears high, given that PCP is an irritant and a sensitizer.)

5. The oral repeat dose study indicated that PCP causes liver, kidney and testicular toxicity. The sponsor indicates that they have discounted the testicular toxicity findings because a subsequent study was not able to reproduce those findings. However, the subsequent study was not included in the robust summaries so we have no way to evaluate its adequacy. Until the methods and results of this study are made available we must assume that PCP is a testicular toxicant.

6. The sponsor proposes to conduct a developmental toxicity study to satisfy this HPV endpoint. However, no reproductive toxicity data are available, and barring a showing that PCP qualifies as a closed-system intermediate, this is a required SIDS endpoint. Since repeat dose data indicate that PCP might be a testicular toxicant, PCP is handled in ways that could lead to worker exposure, and there is some PCP remaining in products from which there could be consumer exposure, we recommend that a combined reproductive/developmental toxicity test be conducted on PCP.

7. We agree that the proposal to conduct an Ames test and an in vitro lymphocyte cytogenetics assay will be sufficient to meet HPV requirements.

Thank you for this opportunity to comment.

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