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NCIC HPV
Sent by: Mary-Beth
Weaver

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

Subject: Environmental Defense comments on Trans-1,2-Dichloroethylene
(CAS# 156-60-5)



Richard_Denison@environmentaldefense.org on 06/25/2003 10:16:45 AM

To: oppt.ncic@epamail.epa.gov, hpv.chemrtk@epamail.epa.gov, Rtk Chem/DC/USEPA/US@EPA, Karen
Boswell/DC/USEPA/US@EPA, barter@ppg.com
cc: lucieryg@msn.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org

Subject: Environmental Defense comments on Trans-1,2-Dichloroethylene (CAS# 156-60-5)

(Submitted via Internet 6/25/03 oppt.ncic@epa.gov, hpv.chemrtk@epa.gov,
boswell.karen@epa.gov, chem.rtk@epa.gov, lucieryg@msn.com and barter@ppg.com
)

Environmental Defense appreciates this opportunity to submit comments on
the robust summary/test plan for Trans-1,2-Dichloroethylene (CAS# 156-60-5)

The test plan and robust summaries for trans-1,2-dichloroethylene (1,2-DCE)
were prepared by PPG Industries. The submissions were clearly written and
informative. 1,2-DCE is used primarily in industry as a precision cleaning
agent, as a component in aerosol blends for precision cleaning and as a
source of HCl for silicon etching. Based on these uses, there is
opportunity for workplace exposures; however, no information was provided
on the magnitude of those exposures. Likewise, no information was provided
on environmental releases in water and air from the facilities which use
this substance. It is unclear from the test plan whether there is
opportunity for consumer exposure to 1,2-DCE. Although these kinds of
exposure data are not explicitly required by the HPV Program, they are
helpful in assessing adequacy of data and they are also informative to the
public.

The sponsor concludes that existing data are adequate for all HPV endpoints
and that no additional testing is needed. While we agree that the database
for mammalian health endpoints is complete, we reserve judgment at this
time as to whether additional ecotoxicity studies are needed. The sponsor
plans to use data from a surrogate chemical, 1,1-dichloroethylene, to meet
the requirements for aquatic invertebrate and plant toxicity studies.
However, the surrogate data are not presented in the robust summaries and
the justification provided for considering 1,1-dichloroethylene
sufficiently analogous to serve as a surrogate chemical for 1,2-DCE is
inadequate. We do, however, recognize that the sponsor may easily be able
to supply the additional data and justification, and we certainly are
willing to reevaluate the adequacy of the ecotoxicity data for 1,2-DCE in a
revised test plan and robust summary.

Other comments are as follows:

1. Acute toxicity testing and repeat dose studies indicate that 1,2-DCE has
very low mammalian toxicity. In an inhalation repeat dose study, the
highest dose was the NOAEL and in a microencapsulation study, a maximum
tolerated dose was not achieved although high doses were used. In the
microencapsulation study, which was conducted by the NTP, the histological
examinations were complete and clinical chemistry data were negative even

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at very high doses. Repeat dose data are available for studies in multiple species using multiple routes of exposure.

2. Genetic toxicity data are available from multiple in vitro and in vivo studies, and clearly demonstrate that 1,2-DCE does not possess genetic toxicity.

3. Reproductive studies are not available for 1,2-DCE, but since multiple and well-conducted repeat dose studies are negative and developmental toxicity studies are also negative, we agree with the sponsor's conclusion that a reproductive study is not needed. Moreover, histology specimens from the NTP study are available in the NTP Archives for any individual or group wishing further review of the reproductive organs using traditional methods or newer molecular pathology techniques.

Thank you for this opportunity to comment.

George Lucier, Ph.D.
Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.
Senior Scientist, Environmental Defense