

201-14851

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To: NCIC HPV@EPA

11/20/2003 01:26 PM

cc:

Subject: Environmental Defense comments on Phosgene (CAS# 75-44-5)

----- Forwarded by Anh Nguyen/DC/USEPA/US on 11/20/2003 01:33 PM -----



Richard_Denison@environmentaldefense.org on 11/20/2003 12:00:21 PM

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Subject: Environmental Defense comments on Phosgene (CAS# 75-44-5)

(Submitted via Internet 11/20/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucieryg@msn.com and anne_lehuray@americanchemistry.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Phosgene (CAS# 75-44-5).

The test plan and robust summaries for phosgene were submitted by the Phosgene Panel of the American Chemistry Council, which is comprised of 10 member companies. Phosgene, a highly reactive gas, is used in the United States as a raw material in the production of isocyanates, polycarbonate plastics and a number of other chemicals, such as agricultural chemicals and pharmaceuticals. It was produced in Europe as a chemical warfare agent during World War I.

The sponsor claims that existing data are adequate to fulfill requirements of the HPV program, although for some SIDS endpoints there are no existing data (all three aquatic toxicity endpoints, fugacity, biodegradation and the reproductive and developmental toxicology endpoints). The sponsor argues that in those cases, studies would not be practical because phosgene is very unstable in water and is rapidly degraded to hydrochloric acid and carbon dioxide. Also, the test plan states that reproductive and developmental studies are not needed because when phosgene interacts with respiratory tract tissues it is degraded and not available to other tissues.

While we agree that aquatic toxicology studies would not be practical, we do recommend that more precise data be provided to support the statement that the acid released into water upon hydrolysis of phosgene would be insufficient to alter the pH of aquatic environments. Moreover, we recommend that the sponsor consider a combined reproductive/developmental toxicity study on phosgene because of the potential for secondary toxicity arising from reactivity in the lung. Specific comments are as follows:

1. Biodegradation of phosgene is indeed very rapid in water, with a half-life of 0.026 seconds. However, the atmospheric half-life can be quite long. The test plan states that the presence of phosgene in the troposphere is a consequence of atmospheric conversion of chlorinated molecules to phosgene and that the phosgene emitted from the 10 member companies of the sponsoring consortium has a negligible impact on tropospheric phosgene concentrations. We recommend that more details be provided to substantiate this contention.

2. Phosgene is a potent acute toxin so worker safety issues are paramount. While we presume that appropriate measures are in place to prevent significant worker exposure, a those procedures and practices should be

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discussed and documented in the test plan.

3. Two repeat dose studies are alluded to in the test plan, yet only one was presented in the robust summaries. The one that is presented examine only lung tissues and reported lung damage at all exposure levels examined, the lowest being 0.1 ppm. The study not presented in the robust summaries apparently evaluated numerous other tissues including the reproductive tracts; however, it is stated that this study found no lung lesions although doses were as high as 1 ppm. This poorly explained discrepancy raises the question that there might have been serious flaws in the no-effect study involving delivery of phosgene to the experimental animals and/or other methodological problems. A robust summary of the second study needs to be provided, along with a better discussion of the differences seen.

4. Since the robust summaries do not contain reliable data on the potential effects of phosgene on reproductive tract tissues, we recommend that a combined reproductive/developmental study be conducted using a valid chemical delivery method. The sponsor argues in the test plan that the high reactivity of phosgene would prevent it from reaching other tissues. While this may be true, data to support the contention should be provided if available; in any case, the actions of phosgene in the lung may cause secondary toxicity to the reproductive tract or other tissues or organs through hormonal or other mechanisms.

Thank you for this opportunity to comment.

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