

Hexamethyleneimine - Comments of Environmental Defense

(Submitted via Internet 1/16/03)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Hexamethyleneimine.

Hexamethyleneimine (HMI) is sponsored by Dupont. The test plan and robust summaries are well-written, objective and they justify the need for additional testing. We concur fully with the test plan including the proposals to conduct ecotoxicity and mammalian toxicity studies. In the case of mammalian toxicity, studies are available but, as the sponsor points out in the test plan and robust summaries, they suffer from significant flaws that preclude them from satisfying the requirements of the HPV program. For example, the purity of the HMI used in several of the studies was not available and this may confound the results because HMI impurities appear to possess significant toxicity. We agree that a combined repeat dose/developmental/reproduction study (OECD 422) is appropriate here and will be sufficient to fulfill HPV requirements; using a combined protocol, as proposed, is highly desirable in order to minimize the number of test animals.

We also agree that no additional acute toxicity studies are needed although the existing studies are flawed. We believe that the range finding component of OECD 422 will provide adequate high dose toxicity data for this chemical. The proposal to conduct an in vitro chromosomal aberration study in human blood cells will complete the requirements for genetic toxicity testing.

HMI is used as an intermediate in pesticide synthesis. This chemical clearly possesses toxic properties and it can produce sensitization reactions as well thereby posing a potential threat to workers. In DuPont's case, this threat appears to be minimized based on Dupont's description of its worker safety program and Responsible Care practices as summarized in its submission. Although not required under the HPV program, the sponsor provided exposure data under various workplace situations and they put the exposure data into the context of 8 hr TWA acceptable exposure limits. This information is much appreciated.

DuPont's submission does not indicate whether there are additional producers of HMI and whether the practices it uses to limit worker exposure are also used by other producers; hence no conclusions can be drawn about exposure potential beyond that from DuPont's facilities.

Thank you for this opportunity to comment.

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