

201-14815



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Subject: Environmental Defense comments on Carbamate Hydrochloride (CAS# 65206-90-8)

(Submitted via Internet 10/27/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, luciery@msn.com and Edwin.L.Mongan-1@usa.dupont.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Carbamate Hydrochloride (CAS# 65206-90-8).

The test plan and robust summaries for carbamate hydrochloride were prepared by DuPont. Although carbamate hydrochloride is a single chemical, it is apparently transported and used as part of a mixture (F3455.HCl) containing about 50% carbamate hydrochloride, water, trimethylguanidine hydrochloride and dimethylamine hydrochloride. The sponsor states that carbamate hydrochloride is manufactured at a single Dupont site and transported to a single other Dupont site, limiting opportunity for human exposure.

There are no available data on mammalian health endpoints except for acute toxicity and the ecological data provided by the sponsor were obtained from computer models. The sponsor proposes to conduct a developmental toxicity study and genetic toxicity tests, but the test plan does not include reproductive or repeat dose studies, with the presumption being that carbamate hydrochloride is a closed-system intermediate. However, the test plan does not actually state or document that carbamate hydrochloride is manufactured and used exclusively in closed systems, nor is information provided characterizing the potential for worker exposure at the two sites where the chemical is manufactured and used, although there are apparently a small number of employees at these sites. Moreover, there are apparently residues of carbamate hydrochloride in the finished product(s); the product or products are not identified, so we cannot evaluate the potential for consumer exposure to carbamate hydrochloride. For the above reasons, we cannot concur based on the information provided by the sponsor that repeat dose and reproductive toxicity studies are not needed. We would be glad to review a revised test plan that either provides for these studies to be conducted, or that provides adequate justification that carbamate hydrochloride qualifies as a closed system intermediate. Additional comments are as follows:

1. The data on physicochemical properties appears to have been obtained by unknown methods, and certainly were not from studies employing GLP. Therefore, we disagree that no new studies on physicochemical endpoints are needed and we recommend that new studies be conducted in all cases where these endpoints are not addressed by GLP studies.
2. The sponsor proposes to conduct new studies on the three ecological toxicity endpoints since the existing data were obtained by models in the absence of data for structural analogs. We agree with this proposal and

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recommend that the studies be conducted using the mixture F3455.HCl.

3. We agree that the existing data are sufficient to conclude that carbamate hydrochloride should not accumulate in the environment and that it has very low acute mammalian oral toxicity.

4.. We agree with the proposal to conduct gene mutation and chromosomal aberration studies and again we recommend that F3455.HCl be used as the test substance.

Thank you for this opportunity to comment.

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