

4,4-Oxydianiline – Comments of Environmental Defense

(Submitted via Internet 2/4/02)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for 4,4-Oxydianiline.

The test plan produced by duPont de Nemours is an accurate and well-written description of the available data on 4,4-oxydianiline. This substance reacts completely in the chemical processes for which it is used as an intermediate, so consumer exposure should not occur under normal conditions. It is transported to duPont facilities in closed containers so unless there is an accident, the risks are primarily to workers in duPont facilities. Strict safeguards are needed to insure worker protection as noted below.

The requirement for repeated dose studies is more than met by the existence of two lifetime bioassays; one a full-fledged NTP study using both rats and mice. 4,4-oxydianiline is a carcinogen, with pronounced increases in tumors at multiple sites in both rats and mice. It also possesses genetic toxicity in a number of assays so we already know that this is a hazardous agent for which strict safeguards need to be in place to prevent exposure.

The major knowledge gap identified in the test plan is the lack of an adequate developmental toxicity study. The sponsor appropriately proposes to conduct a developmental toxicity study and we concur. The sponsor also proposes to conduct additional biodegradation studies to fill knowledge gaps for environmental fate. We concur with this proposal as well.

Thank you for this opportunity to comment.

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