

2-Amino-2,3-dimethylbutanenitrile – Comments of Environmental Defense

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Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for 2-amino-2,3-dimethylbutanenitrile (ADBN).

Cytec Industries have conducted a detailed review and assessment of the existing data on ADBN and they conclude that no additional testing is needed. Since ADBN is manufactured in a closed system and transported under strict guidelines to a single client, for use in pesticide manufacture, there is little opportunity for human exposure under normal conditions. There also appears to be essentially no release of ADBN to the environment based on convincing treatment and monitoring data provided by Cytec. Nevertheless, ADBN is a highly toxic chemical and we have some concerns regarding the adequacy of available data for assessing mammalian toxicity. These concerns are as follows:

1. The repeat dose study was conducted by a dermal application route. It seems that if worker exposures occurred a larger dose might be received via the inhalation route so we question selection of the dermal route for the repeat dose study. Was the ADBN absorbed through the skin in the dermal study and if so how much was found in internal organs?

2. Developmental toxicity studies have not been conducted on ADBN. Instead the sponsor proposes to use surrogate data from a series of teratogenic aliphatic nitriles to fulfill the developmental toxicology requirement. Unlike ADBM, however, none of the nine aliphatic nitriles used as surrogates for ADBN have an amino group. Accordingly, the use of the surrogate data is questionable. The sponsor also states that because of the high degree of acute toxicity strict safeguards are in place to prevent human exposure; accordingly, they conclude that developmental toxicology studies are not really needed. This argument is not consistent with the ground rules of the HPV program, which require developmental toxicity studies even for intermediates precisely because accidents can “and do” happen, potentially resulting in exposures to pregnant workers. See EPA Guidance for Testing Closed System Intermediates for the HPV Challenge Program, <http://www.epa.gov/chemrtk/closed9.htm>. As noted in the Guidance:

“For closed system intermediates a reduced test plan package reflecting the information needed to evaluate the hazards in case of an accident is considered the appropriate level of testing for screening purposes. This is because exposures resulting from chemical accidents are likely to be of relatively short versus chronic duration. The reduced testing consists of the Screening Information Data Set (SIDS) minus the tests for repeated dose toxicity and reproductive toxicity, but including a developmental toxicity test.”

By the same token, we agree with Cytec that reproductive studies are not necessary.

Thank you for this opportunity to comment.

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