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Anh Nguyen

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To: NCIC HPV@EPA

CC:

Subject: Fw: Environmental Defense comments on the Alkyl Nitriles Category

----- Forwarded by Anh Nguyen/DC/USEPA/US on 05/05/2004 02:38 PM -----



rdenison@environmentaldefense.org

05/05/2004 02:18 PM

To: oppt.ncic@epamail.epa.gov, hpv.chemrtk@epamail.epa.gov, chem.rtk@epamail.epa.gov, boswell.karen@epamail.epa.gov, r.gerwe2@verizon.net

cc: MTC@mchsi.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org

Subject: Environmental Defense comments on the Alkyl Nitriles Category

(Submitted via Internet 5/5/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and r.gerwe2@verizon.net)

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

Eastman Chemical Company and Solutia, Inc., in response to EPA's High Production Volume (HPV) Chemical Challenge, have submitted robust summaries and a test plan describing data to address the required SIDS elements for three alkyl nitriles, with the proposal that they be considered together as a category. These three chemicals, propionitrile (CAS# 107-12-0), butyronitrile (CAS# 109-74-0) and isobutyronitrile (CAS# 78-82-0), have very similar chemical structures and properties and induce similar toxicities; thus, their consideration as a category is appropriate.

According to the test plan each of these chemicals is produced by a single producer and is used almost exclusively as an industrial chemical or chemical intermediate. According to the test plan: "There are no reported consumer uses in consumer products or formulations." They may be, however, present in wastes or otherwise emitted to the environment, and apparently are transported from their respective sites of production to the sites where they are further processed or used. Thus, some potential for environmental and human exposure is posed, including the possibility of a spill, and a discussion of the potential risks posed to the environment and human health would be helpful.

Our review of this submission indicates that these chemicals have appreciable mammalian toxicity as a result of their metabolism to cyanide, but they do not appear to be mutagenic and they should not be expected to persist in the environment. Of the SIDS elements required, all necessary chemical/physical data are available for each of the compounds, while most of the environmental fate data are proposed to be estimated. No data are available to address the hydrolysis of these three chemicals, but we consider it appropriate that data available for acetonitrile, which indicate very slow hydrolysis -- are bridged to address this element.

Aquatic toxicity data described for these chemicals appear to have significant limitations; the data described for butyronitrile and isobutyronitrile are based on toxicity studies that used only a single concentration of the test chemical. (Note: these studies are said to be based on OECD guidelines; however, OECD guidelines specify the use of five concentrations.) Repeated dose and reproductive toxicity studies are available only for propionitrile, but, given their common mechanism of action, it is acceptable that results of these studies are bridged to predict the corresponding toxicities for the other two members of the category. Studies of developmental toxicity indicate these chemicals would not be expected to be toxic to the developing fetus at doses below those that are toxic to the dams.

Data presented for chemicals in this category are reasonably well-described in the test plan and the tables therein, and are supported by relevant

references. The extensive robust summaries for this category are divided into three parts to address each of the three chemicals separately. Our review of the robust summaries indicates they are well-organized and that most studies are adequate. Some of the older studies and a few of the newer ones were not conducted under GLP, but they appear adequate. However, some of the ecotoxicity studies failed to provide the purity of the test compound. Given that these chemicals have appreciable aquatic toxicity, we do not consider those studies of aquatic toxicity to be adequate to address these SIDS elements. Unless adequate studies can be identified, new studies should be conducted for these endpoints.

In summary, this is not one of the stronger submissions we have reviewed, but if the additional aquatic toxicity studies are conducted, or adequate existing studies of aquatic toxicity using appropriate dose ranges are submitted, it could be rendered adequate. We would not recommend additional studies with mammals.

Thank you for this opportunity to comment.

Hazel B. Matthews, Ph.D.
Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.
Senior Scientist, Environmental Defense