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Subject: Environmental Defense comments on the Fatty Nitrogen Derived Nitriles Category

(Submitted via Internet 6/22/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and sonny_maher@americanchemistry.com)

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

The test plan and robust summaries for the proposed category of fatty nitrogen derived nitriles (FNDN) were submitted by the Nitriles Task Group of the American Chemistry Council. The proposed category covers 14 CAS numbers and the sponsor claims that all 14 substances are used as closed system intermediates. No information appears to be provided on the identity of downstream end products either in the test plan or in the several-hundred-page robust summaries. Based on the information contained in the FNDN submittal, we do not concur at this time with either the category proposal or the sponsor's conclusion that the existing and proposed studies are adequate to meet requirements of the HPV program. We also found the justification for considering FNDN members as closed system intermediates to be inadequate.

In regard to the claim of closed system intermediate status, the sponsor admits that the amount of FNDN is not measured in either the unidentified end products or waste streams arising from the chemical syntheses. The sponsor states that if it were present, they could be detected by smell, but no odor detection limits are provided. The sponsor also states, in the closed-system intermediate justification, that FNDN members are non-toxic. This statement is both wrong and an irrelevant justification for claiming a substance as a closed-system intermediate. Some FNDN members, according to the robust summaries, are very toxic to aquatic species, and there are few or no data on repeat dose, developmental or reproductive endpoints.

The category justification has two problems. The most serious one is that some of the proposed members contain unsaturated alkyl elements close to the nitrile moiety. This could substantially alter the toxic properties of the chemicals in question. The sponsor needs to provide some metabolism and toxicity data in support of the proposed category before we can support it. The sponsor may also wish to provide global gene array data to demonstrate that all members behave the same way in biological systems.

A second problem is that the chemical structures of coco, tallow and soya are not indicated, so we cannot determine the full structures of four of the CAS numbers: 61789-53-5, 61790-28-1, 61790-29-2 and 68514-67-0. Also Table 1 of the test plan does not contain viewable chemical structures and it printed out as gibberish. We had to go to the test plan on the companion ether nitriles submission to see some of the structures contained in the FNDN submission. If soya, coco and tallow simply refer to differences in alkyl chain length, then they may belong in this category provided that the

issue of unsaturated alkyl chains is resolved in favor of the category proposal. Readable chemical structures for all of the category members need to be provided.

We, recommend, for the reasons presented in the above paragraphs, that the sponsor conduct a combined repeat dose/reproductive/ developmental toxicity study on 9-octadecenenitrile (112-91-4) and dodecanenitrile (2437-25-4). We also recommend that genetic toxicity tests be conducted on both substances. This will address our concern regarding the unsaturated alkyl issue. Additional studies will be warranted if the chemical structures of soya, coco and tallow contain additional functional groups other than an alkyl chain. Existing data on other SIDS endpoints such as ecotoxicity and environmental fate appear to be adequate to address our category concerns.

Thank you for this opportunity to comment.

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