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To: NCIC HPV@EPA

cc:

Subject: Fw: Environmental Defense comments on the Fatty Nitrogen Derived Ether Amines Category (revised category)

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Subject: Environmental Defense comments on the Fatty Nitrogen Derived Ether Amines Category (revised category)

(Submitted via Internet 6/2/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and Miriam_Azimi-Osman@americanchemistry.com)

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

The Fatty Nitrogen Derivatives Panel of the American Chemistry Council, in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted robust summaries and a test plan describing available data for the Fatty Nitrogen Derived (FND) Ether Amines Category. This chemical category is composed of four propaneamine and two propanediamine derivatives of long chain fatty molecules, derived primarily from tallow, coconut oil, etc.

The Introduction to the test plan briefly mentions that these chemicals find uses as industrial surfactants or in the synthesis of surfactants used in industry. As such they find extensive use in chemical mixtures or in the processing of other chemicals, and it is inferred but not stated there are few applications in which consumers are directly exposed. The test plan provides very little specific information as to the uses of chemicals in this category or their potential for human and environmental exposure. No information is provided regarding their transport and end uses, either of the chemicals themselves or regarding specific products in which they are used, or their potential for release from these products. Most important, there is no mention of potential human and environmental exposure as a result of their intended uses or as byproducts of their use, e.g., in wastewater, etc. While not strictly required, such information is useful in increasing understanding of the potential for health and environmental effects to occur; see below.

Our review of this submission indicates that the six chemicals in the FND ether amines category have similar molecular structures and share very similar properties. Further, they share most of these properties with a large number of other surfactants that are suggested as sources of read-across or bridged data to address the SIDS elements called for under EPA's HPV Challenge; thus, it is appropriate that they be considered a chemical category.

A summary of all of these data are presented in a well-organized and

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well-written test plan that is supported by numerous references and further summarized in a series of tables. Each of the referenced studies is described in considerably more detail in the extensive(669-page) robust summary. Our review of the robust summary indicates it too is well-organized and very thorough. Many of the studies are recent and were conducted under GLP. The older studies appear to have been carefully designed and conducted.

Data described in the robust summaries and summarized in the test plan indicate chemicals in the FND ether amines category are degraded in the environment, have low acute toxicity, are not mutagenic and have little reproductive or developmental toxicity. Their low acute toxicity may well be attributable to the fact that they have limited water solubility, so that most of an oral or dermal dose may not have been absorbed. This speculation is supported by the observation that they are toxic when administered at relatively low repeated doses. They also have significant aquatic toxicity and are dermal irritants. These potentially adverse effects can most probably be attributed to the surfactant properties of these molecules.

Aquatic toxicity and/or repeated dose toxicity could result from long-term, low-level release of these chemicals from products in which they are used, but the significance of such a scenario is not discussed. Dermal irritation is likely to be limited to occupational exposures, but measures to prevent such exposures by adherence to appropriate industrial hygiene practices are not described.

In summary, we are aware that ? in contrast to most chemicals considered in these HPV reviews ? surfactants exert both their intended use effects and their biological effects through their physical rather than their chemical properties. Thus, many of the required SIDS elements do not characterize the potential for adverse effects from these chemicals as well as they do for most other chemicals considered under this initiative. Therefore, we agree that additional studies are not necessary. However, whereas we compliment the sponsor on the compilation and review of an extensive data on the chemicals in this category, we think this submission would be far more useful, given the potential toxicity of FND ether amines to aquatic organisms, and to mammals on repeated exposure, were it to provide a more thorough description of the potential for human and environmental exposure as a result of their production and use.

Thank you for this opportunity to comment.

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