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Subject: Environmental Defense comments on the Quat Category

(Submitted via Internet 9/10/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and Bobf@regnet.com)

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

The Quat HPV Challenge Task Force, in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted robust summaries and a test plan describing available data to address SIDS elements required for the Quat Category. Our review of this submission indicates that these quaternary ammonium salts have similar properties and uses and are appropriately considered together as a category.

According to background information provided in the test plan, these chemicals are produced in closed systems and copolymerized with acrylamide or occasionally other monomers, or homopolymerized, to produce water-soluble polymers that are used exclusively in industrial applications. The test plan indicates there are no direct consumer uses of these chemicals. Environmental exposure is said to be limited by the fact that these chemicals are usually polymerized at the site of production, and the sponsor maintains (but has not provided any data to demonstrate) that the resulting polymers contain only trace levels of the monomers.

The chemical/physical properties and actual or predicted environmental fate of each of these four chemicals are not described in the test plan, but are provided in some detail in separate sections of the robust summaries; they should be also summarized in the test plan. Data describing the ecotoxicity are generally adequate for all four chemicals. Data addressing mammalian acute toxicity are limited to the methyl chloride salts, but we consider bridging from these data to predict the acute toxicity of the dimethylsulfate salts to be acceptable as well. Similarly, data are available to address the mutagenicity of only three of the four chemicals in this category, but these data are supplemented by data for each of the precursors of these chemicals and should be sufficient to predict negative mutagenicity for the fourth chemical.

Data are not available to address repeat dose toxicity or reproductive/developmental toxicity of any of the chemicals in this category. This lack of data, and the fact that data for the tertiary amine, dimethylaminoethyl acrylate, which is a precursor of two chemicals in this category, are described and used instead, are briefly mentioned only in the first paragraph of the section on repeated dose toxicity. This fact needs to be discussed again in the subsequent sections on reproductive/developmental toxicity. We also note that robust summaries of the studies of the precursor dimethylaminoethyl acrylate are not provided. Therefore, though we think it is appropriate to bridge data from the tertiary amine to predict the repeat dose and reproductive/developmental toxicity of the

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chemicals in this category, this submission should be significantly revised. The intention to fulfill the repeat dose and reproductive/developmental endpoints by bridging from data on the tertiary amine should be made more transparent in the test plan, and full robust summaries of the bridged data described in the test plan must be provided.

Thank you for this opportunity to comment.

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