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Subject: Environmental Defense comments on Benzoyl Chloride (CAS# 98-88-4)

(Submitted via Internet 6/17/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and john_morris@americanchemistry.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Benzoyl Chloride (CAS# 98-88-4).

A consortium of companies, formed under the Benzoates Panel of the American Chemistry Council in response to EPA's High Production Chemical Challenge, has submitted robust summaries and a test plan describing available data and proposed testing to address SIDS elements required for benzoyl chloride.

Review of this submission indicates it is quite cursory. In addition the fact that it contains no information regarding synthesis, production, transport, potential for human and environmental exposure or even the uses of this chemical, the data described are minimal.

Data summarized in the test plan are limited but adequately address the chemical/physical properties of this chemical. It is stated that some parameters, e.g. solubility in water, etc., were not determined because benzoyl chloride hydrolyzes very rapidly on contact with water. It is concluded by the sponsor that adverse environmental effects should be limited to the immediate area of an accidental release or spill. However, the hydrolysis products, benzoic acid and hydrogen chloride, would be expected to account for much of the toxicity of benzoyl chloride and could well account for some risks associated with the use and production of this chemical.

With exception of toxicity to algae, SIDS elements required for environmental toxicity have been addressed and a study of the toxicity of benzoyl chloride to algae is proposed. Mammalian toxicity studies are limited to determinations of acute oral, dermal and inhalation toxicity in rats and rabbits. Studies of repeated dose toxicity and reproductive/developmental toxicity are proposed. Assays for mutagenicity are limited to tests in the Ames system and a micronucleus assay in mice. Most results of these tests indicate benzoyl chloride is not mutagenic; however one study described in the robust summaries indicates it is positive in the TA98 strain of bacteria. We note that the Data Matrix presented on page 7 of the test plan erroneously indicates benzoyl chloride is negative in the bacterial strain TA98 used in the Ames system. Description of data in the test plan should be consistent with results presented in the robust summaries. We also failed to see mention of the toxicity of benzoyl chloride, or the acids into which it degrades, to the test organisms used in the Ames system. Since an Ames assay cannot be positive if the bacteria are dead, this information should be included and discussed.

Review of the robust summaries indicates most of the studies are old, not conducted under GLP and poorly described. Further, the data described in the robust summaries appear to be of generally poor quality. For example, the purity of test compound is usually given as "not determined" and in a number of cases only the heading is given and no data are provided for the respective study. Several specific examples are the following:

1. It's probably a typo, but on page 20/40 it is stated that the LC50 is >2.3 mg/l, but in the methods it is stated that males were exposed to 2343 mg/l.
2. On page 23/40 the LD50 is given for rabbits as 750 mg/kg, but no details are provided other than to say that the purity of the test substance was not noted.
3. A study with mice described on page 26/40 failed to identify the sex studied and provided little other information except that the dose was administered under the skin and no de-pigmentation was noted.
4. The carcinogenicity study described using mice applied benzyl chloride in benzene, a known carcinogen.

We appreciate the information provided regarding the epidemiology studies that have been conducted and the mention that occupationally exposed humans have been observed to have an increased incidence of lung cancer.

In summary, assuming this submission is significantly revised per the comments above, and that it otherwise meets the requirements of the EPA HPV Challenge, we consider it minimally acceptable.

Thank you for this opportunity to comment.

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