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Subject Environmental Defense comments on the Sulfanilic Acids Category

Submitted via Internet 12/28/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and tadams@therobertsgroup.net)

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

The International Association of Color Manufacturers (IACM), in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted robust summaries and a test plan describing available data for sulfanilic acid and O-toluene sulfonic acid, 4-amino-5-methoxy- (p-cresidine sulfonic acid), with the proposal that they be considered a chemical category. The chemicals in this proposed category have similar chemical structures and are used in the synthesis of more complex chemicals that are used as dyes. Other possible uses of these chemicals are not mentioned, so we assume their use in the synthesis of dyes constitutes their primary or exclusive use. If this is the case, we agree that their consideration as a chemical category is appropriate.

Our review of this submission indicates that actual data for the subject chemicals are limited. Data requirements for the physicochemical properties, environmental fate and ecotoxicity endpoints of these chemical are provided primarily through model calculations and bridging data from more complex chemical dyes that are said to be metabolized or otherwise degraded to yield these chemicals. Similarly, data requirements addressing human health endpoints are addressed almost exclusively by bridging data developed for the more complex dyes. Studies confirming the metabolism of dyes synthesized using these chemicals to reform the chemicals in this category are limited and old, and would not be considered adequate by today's standards; however, more recent studies of similar dyes to yield similar chemicals indicate the metabolic and chemical processes proposed are valid. Therefore, we consider the bridging of data developed for dyes based on these chemicals to predict their fate and toxicity to be appropriate.

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All of the data described for the dyes indicate that they, and most probably the chemicals in this category, have low potential for environmental or human toxicity. Whereas many of these studies are somewhat dated and may not have been conducted under GLP, they appear to be carefully designed and sufficient to address the SIDS elements. They are also well-described in the thorough and well-organized robust summaries and test plan that describe extensive animal studies, including both repeated and chronic studies. In summary, this submission presents a strong argument for no further study, with which we concur. Additional information that is not required, but would be desirable in this submission, includes descriptions of other possible uses of these chemicals as well as methods of synthesis and modes of transport and use that might result in environmental or human exposure.

Minor points:

1. The unreferenced first paragraph on page 3 infers that acetylation of these chemicals may have occurred in the gastrointestinal tract because the acetylated products have been detected in the feces. That is not necessarily the case. These metabolites may have been formed internally and excreted in the bile and subsequently in the feces.
2. An interesting typo on page indicates that the study was conducted using mice weighing 20 to 25 "kg"!!!

Thank you for this opportunity to comment.

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