

201-15315

Anh Nguyen
06/01/2004 02:39 PM

To: NCIC HPV@EPA
cc:
Subject: Fw: Environmental Defense comments on Sodium Lauryl Sulfoacetate (Acetic Acid, sulfo-, 1-dodecyl ester sodium salt) (CAS# 1847-58-1)

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06/01/2004 12:31 PM

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Subject: Environmental Defense comments on Sodium Lauryl Sulfoacetate (Acetic Acid, sulfo-,
1-dodecyl ester sodium salt) (CAS# 1847-58-1)

(Submitted via Internet 6/1/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and Ljovanovich@stephan.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Sodium Lauryl Sulfoacetate (Acetic Acid, sulfo-, 1-dodecyl ester sodium salt) (CAS# 1847-58-1).

NOTOX Safety and Environmental Research B.V., on behalf of Stepan Company and in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted robust summaries and a test plan describing available data for sodium lauryl sulfoacetate and proposing testing to address unfilled data gaps. Our review of this submission indicates it is somewhat cursory and provides minimal background information and data to address the required SIDS elements.

Other than a brief statement saying this chemical is used in personal care products the test plan provides no information regarding production, transport or the products in which it is used. We appreciate the fact that an expert panel has reviewed the data on sodium lauryl sulfoacetate and judged it to be safe for use in cosmetics; however, it should be possible to provide more data for a chemical that is used in personal care products by millions of people.

Our review of the brief test plan indicates most of the required SIDS elements are addressed by computer estimates or limited actual studies of the commercial product. Additional studies of reproductive and developmental toxicity are proposed to address these data gaps.

Data described in the test plan indicate sodium lauryl sulfoacetate has little acute toxicity unless administered at high concentrations. We do not question that use of sodium lauryl sulfoacetate in small quantities represents little risk. However, for a chemical used so widely in personal care products, our review of the robust summaries indicate that some of the studies of this chemical may not have been as rigorously designed, conducted and reported in this submission as would be desirable. The following are some examples of study design and reporting that we find questionable.

1. Table 3: Should list the species of fish tested.
2. Table 4: Should list the species of animal tested. It should also be

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made clear in the table that the repeated doses were administered by the dermal route.

3. Review of the robust summaries indicate that some of the studies were done with a commercial formulation of sodium lauryl sulfoacetate, Lanthol LAL powder, which contains approximately 75% sodium lauryl sulfoacetate. That fact is not usually mentioned in the test plan, but should be.

4. In the dermal studies using rats, a single group of five animals of each sex were treated with 2000 mg/kg. Of these treated groups, three of the males died and one of the females died. Based on those results an LD50 of >2000 is reported. It would seem more accurate to say the males appeared more sensitive and report the actual numbers.

5. In the dermal studies with rats, the purity of the test substance was reported as 65 ? 80%. This seems a rather vague characterization of a specific test substance. In other studies, e.g., some of the mutagenicity studies, the purity of the test substance is not listed at all, while in others the sodium lauryl sulfoacetate content is as low as 35%.

6. The 28-day repeat dose toxicity studies did not include reports of histological examinations; however, this deficiency was corrected in the 90-day repeat dose studies. We would not request additional repeat dose studies.

To summarize briefly, we find this a marginally acceptable submission, and encourage the EPA to carefully consider the quality of the studies described before accepting it for inclusion in the HPV Challenge Program.

Thank you for this opportunity to comment.

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