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PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

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Stephen Johnson, Administrator
U.S. Environmental Protection Agency
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1200 Pennsylvania Ave., N.W.
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Subject: Public Comments on the HPV Challenge Program test plans for sodium cocoyl isethionate (CAS# 61789-32-0) and sodium isethionate (CAS# 1562-00-1) by the Sodium Ethyl Sulfonates Coalition.

The following comments on the HPV Challenge Program test plans for sodium cocoyl isethionate and sodium isethionate by the Sodium Ethyl Sulfonates Coalition (SESC) are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal and environmental protection organizations have a combined membership of more than ten million Americans.

Sodium cocoyl isethionate (SCI) and sodium isethionate (SI) are mild foaming and cleansing agents used in synthetic and combination detergent bars. SI is also an intermediate in the production of SCI. The SESC proposes no additional testing for SCI and SI. These exemplary test plans appropriately employ the first principle listed by the EPA in its October, 1999 Letter to Manufacturers/Importers regarding animal welfare considerations. Having performed a thoughtful, qualitative analysis, the SESC concludes that there is sufficient data, given the totality of what is known about SCI and SI, including human experience, that certain endpoints need not be tested.

Existing data are available for acute fish toxicity and indicate that SCI is slightly toxic, while SI is not toxic, to fish. Existing data for acute mammalian toxicity demonstrate no acute toxicity for either SCI or SI. SCI was also not toxic in repeated dose studies via dermal or oral routes of exposure and causes neither gene mutations nor chromosomal aberrations *in vitro*, while SI is not mutagenic *in vitro*. Although no data for reproductive toxicity are summarized, sex organs were examined in a repeated dose study for SCI. These results show that even at very high doses (1000 mg/kg bw/day) SCI does not affect the histology of the sex or accessory organs.

While no existing data are summarized for developmental toxicity for SCI or SI, or for repeated dose, reproductive toxicity or chromosomal aberrations for SI, the SESC notes that these two compounds are closely related, differing only in the addition of a coconut fatty acid moiety in SCI. SCI is produced by reacting SI with the fatty acid mixture from coconut oil or the corresponding chlorides, and ADME studies indicate that SCI is metabolized to SI by hydrolysis of the ester bond in SCI. The SESC therefore appropriately suggests that read across from the SCI data set could address some

endpoints for SI, in particular repeated dose and reproductive toxicity and chromosomal aberrations.

The SESC also argues convincingly on the basis of the first principle in the EPA letter mentioned above that the developmental toxicity endpoint need not be tested for SCI and SI. The SESC observes that the success of SCI and SI in consumer products is due largely to their mildness to the skin relative to soaps and other surfactants. Also, in addition to a well established long history of safe use, many studies have been conducted in which SCI-containing products were applied to the skin of volunteers. Since some SI is also present in final products that use SCI as the primary ingredient, several of these studies were conducted on products that contain up to 15% SI. Several Repeat Insult Patch Tests (RIPT) have also been conducted for products containing both SCI and SI. Results demonstrate that SCI and SI are only minimally irritating to the skin. In addition, the potential for worker exposure during manufacturing and distribution is limited by operational controls including the use of closed reactors and local exhaust ventilation. Engineering controls are also in place to minimize releases to the environment.

Since no toxicity has been observed in any of the available studies, the SESC appropriately concludes, given the totality of what is known about SCI and SI, that no new testing is warranted. This thoughtful, qualitative analysis of existing data, including human exposure data, is consistent with the HPV Challenge Program's goal of obtaining screening level hazard information as elucidated in the EPA's October, 1999 Letter to Manufacturers/Importers. This approach saves animals' lives by avoiding duplicative tests.

Thank you for your attention to these comments. I may be reached at 610-586-3975, or via e-mail at josephm@peta.org.

Sincerely,

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Research & Investigations