201-15318

Anh Nguyen
06/02/2004 12:15 PM

To: NCIC HPV@EPA
cc:
Subject: Fw: Environmental Defense comments on Benzoic acid, 2-Hydoxy-, Mono-C14-C18 Alkyl Derivatives, Calcium salts (CAS# 114959-46-5)

----- Forwarded by Anh Nguyen/DC/USEPA/US on 06/02/2004 12:15 PM -----

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06/02/2004 11:03 AM

To: NCIC OPPT@EPA, ChemRTK HPV@EPA, Rtk Chem@EPA, Karen Boswell/DC/USEPA/US@EPA, Sarah_McLallen@americanchemistry.com
cc: lucierg@msn.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org
Subject: Environmental Defense comments on Benzoic acid, 2-Hydoxy-, Mono-C14-C18 Alkyl Derivatives, Calcium salts (CAS# 114959-46-5)

(Submitted via Internet 6/2/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and Sarah_McLallen@americanchemistry.com)

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Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Benzoic acid, 2-Hydoxy-, Mono-C14-C18 Alkyl Derivatives, Calcium salts (CAS# 114959-46-5).

The test plan and robust summaries for benzoic acid, 2-hydroxy-, mono-C14-C18 alkyl derivatives, calcium salts (hereafter calcium alkyl salicylates) was submitted by the Petroleum Additives Panel of the American Chemistry Council. This is a clearly written and objective test plan, and the robust summaries contain sufficient detail to permit an evaluation of the available studies relevant to the HPV program.

The calcium alkyl salicylates are used as detergent additives in gasoline and diesel engine oils. These substances also function to minimize sludge formation and they act as anti-oxidants and to prevent rust.

The sponsor states that two representative calcium alkyl salicylate mixtures have been used to conduct studies of SIDS endpoints. The two mixtures are AI-43 (43% calcium alkyl salicylates, 48% refined lubricating base oil and 9% calcium salts) and AI-28 (28% calcium alkyl salicylates, 51% refined lubricating base oil and 21% calcium salts). The sponsor proposes to address these two substances essentially as a category, so results of one test mixture would be relevant to the other.

This seems like a reasonable approach, although we are troubled by the finding that the toxicity to aquatic invertebrates is at least 100 times higher for AI-43 than for AI-28. This difference cannot be accounted for by differences in amounts of calcium alkyl salicylates, lubricating base oil or calcium salts. Are there qualitative differences in compositions of AI-43 and AI-28 that could lead to differing sensitivities of aquatic organisms? Based on information contained in the robust summaries, the difference does not appear to be related to water temperature, pH or water hardness. This difference between the two test substances needs to be understood and explained if the category approach is to be viable.

Data are not available for several SIDS endpoints, so the sponsor proposes a number of studies to fill the identified screening-level data gaps. We agree with the sponsor's proposals indicated in the test plan, with one

exception and one recommendation on the selection of test substances. The exception is that we recommend that a fish toxicity study be conducted on AI-43. Fish toxicity data are available for AI-28, which has an LD50 of >1000 mg/kg, but given the finding that Daphnia are 100 times more sensitive (measured by immobilization) to AI-43 than to AI-28, it seems prudent to determine if fish are also more sensitive to AI-43. The sponsor also proposes a combined repeat dose/reproductive/developmental toxicity study, as no data are available on these endpoints. We agree with this proposal but recommend that, for the reasons indicated above, AI-43 should be used as the test substance.

Other comments are as follows:

1. Are data available concerning environmental or human exposures to the calcium alkyl salicylates? Although this is not required under the HPV program, such information is useful for evaluating potential environmental or health concerns.

2. The calcium alkyl salts do not appear to be mutagenic in vitro, but no in vivo studies are available, so we agree with the proposal to conduct a chromosome aberration study provided that AI-43 is used as the test substance.

Thank you for this opportunity to comment.

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