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NCIC HPV
Sent by: Mary-Beth Weaver

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To: NCIC HPV, moran.matthew@epa.gov
cc:
cc:
Subject: Environmental Defense comments on the Keto Acid Category

Richard_Denison@environmentaldefense.org on 09/09/2003 02:17:04 PM

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Subject: Environmental Defense comments on the Keto Acid Category

(Submitted via Internet 9/9/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and Bkatje@escocompany.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for the Keto Acid Category.

The ESCO Company Limited Partnership, in response to the Environmental Protection Agency's High Production (HPV) Challenge, has submitted a Robust Summary/Test Plan to describe available data and testing needs for the HPV chemical, benzoic acid, 2-{4-diethylamino)-2-hydroxybenzyl], CAS# 5809-23-4 (EtKeto Acid). This Robust Summary/Test Pan also describes available data for a structurally similar chemical, benzoic acid, 2-{4-dibutylamino) -2-hydroxybenzyl], CAS #54574-82-2 (BuKeto Acid), with the proposal that these two chemicals be considered together as a category. BuKeto Acid is not an HPV chemical.

Data available for EtKeto Acid are inadequate to address the requested SIDS elements for the HPV program, whereas data for BuKeto Acid are marginally sufficient. Only six of the 21 requested SIDS elements for EtKeto Acid are addressed by actual measured data. The remainder of the data for EtKeto Acid are calculated bridging from studies of BuKeto Acid. Given the very similar chemical structures and properties of these two chemicals, we support the category and with some reservation (see below) do not request additional testing of EtKeto Acid.

Specific comments on the Test Plan:

1. No common names or synonyms are listed for these chemicals. If there are none, that should be stated.

2. Section 4.4 Ecotoxicity: It is stated that BuKeto Acid is mildly toxic to fish and mildly inhibitory to algal growth. However, the data presented indicate that it is more than mildly toxic. It also has significant toxicity to aquatic invertebrates, as shown in Table 4. Further, given the low solubility of BuKeto and its failure to biodegrade, as shown in Table 3, it could well be that a significant hazard would be posed by a release of either Keto Acid into a large body of water where more of it would be solubilized and could have a more widespread effect. We note that both PCBs and many halogenated insecticides are less soluble than these chemicals.

3. Sections 4.5 & 5, Toxicology & Test Plan Conclusion: The test plan's claims that "The data provided for acute oral toxicity are consistent for the keto acids" and "The keto acids in this category show a clear pattern of low toxicological concern, so no further toxicological testing is planned for the keto acid category" are considerable overstatements. The only such data available for EtKeto Acid are from a single acute toxicity test obtained with a single dose. Further, the single high dose was dissolved in corn oil and, as noted on page 59 of the Robust Summary, was probably not absorbed from the gastrointestinal tract. These conclusions do not appear to be sufficiently supported in light of the fact that only one keto acid has been adequately tested. We defer to the EPA to determine the need for additional studies of EtKeto Acid.

4. Section 5, Test Plan Conclusion: The sponsor states that it uses both of these chemicals are used as closed system intermediates. The Test Plan does not, however, provide sufficient information, as specified in EPA's guidance, to establish this status. Nor does it provide any information regarding the production and use of these chemicals by other companies, the potential for occupational exposure, or other uses that might result in human and/or environmental exposure.

Specific comments on the Robust Summary:
1. A single "Best Study" is presented to address each SIDS element for BuKeto Acid. Much of the data presented is unreferenced and when references are available they are limited to contract reports that are unavailable to the public, precluding a meaningful independent public review of the cited data. (Hopefully they are available to the EPA.)

2. It is interesting that the ESCO Company Limited Partnership did not comment on the quality of the studies of BuKeto Acid that were apparently performed for them on contract.

3. It is noted that there is a very significant difference in the "Nominal Concentrations" and the "Measured Concentrations" of BuKeto Acid in many of the aquatic toxicity studies. In some cases these differences are as great as ten-fold. What is the sponsor's explanation for this? Is it a reflection of differences in the quality of the data?

Summary:
This is a rather poorly prepared Robust Summary/Test Plan that extrapolates from a minimally sufficient set of data addressing the requested SIDS elements for a non-HPV chemical, BuKeto Acid, to predict the requested SIDS elements for the HPV chemical, EtKeto Acid. Given the fact that these chemicals have very similar structures and properties, including ? based on the very limited data available for the HPV ? apparently relatively low mammalian toxicity, this may be marginally adequate, although we would prefer to see more measured data generated for the HPV chemical. In addition, we feel this report should also include additional information regarding synthesis, transport and other possible uses of these chemicals so that the potential for human and environmental exposure might be more adequately assessed.

Thank you for this opportunity to comment.

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