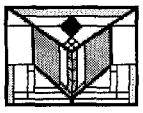
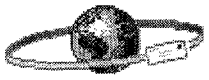
201-14731



Peter Wendolkowski

09/11/2003 10:57 AM

To: Peter Wendolkowski/DC/USEPA/US@EPA
cc:
cc:
Subject: Environmental Defense comments on the Color Former Category



Richard_Denison@environmentaldefense.org on 09/10/2003 01:27:04 PM

To: oppt.ncic@epamail.epa.gov, hpv.chemrtk@epamail.epa.gov, Rtk Chem/DC/USEPA/US@EPA, Karen Boswell/DC/USEPA/US@EPA, Bkatje@escocompany.com
cc: MTC@mchsi.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org

Subject: Environmental Defense comments on the Color Former Category

(Submitted via Internet 9/10/03 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 Color Former 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 an HPV chemical, spiro[isobenzofuran-1(3H),9'-[9H]xanthene]-3one, 6' -(diethylamino)-3'-methyl-2'-(2,4-dimethylphenylamino)-, CAS# 36431-22-8, also known as color former Black XV. This Robust Summary/Test Pan also describes available data for two non-HPV chemicals, color formers N-102 and ODB-2, that have very similar chemical structures. ESCO proposes that all three chemicals be considered together as a category. Given the fact that available data describing the requested SIDS elements for Black XV are already relatively complete, this approach is probably not necessary, but has the advantage of providing datasets on all three chemicals.

Our review of data presented for Black XV and the related chemicals indicates most SIDS elements have been addressed by recent studies, many of which were conducted under GLP. Results of these studies indicate each of these chemicals has very low water solubility and low chemical reactivity. Each chemical also has low ecotoxicity and acute mammalian toxicity. ODB-2 also exhibits low toxicity in repeated dose and studies of reproductive toxicity. All three chemicals were negative in studies of genotoxicity.

Specific comment on the Test Plan:

1. These chemicals have very low water solubility and tend to partition into the sediment, where they have long half-lives. Because these properties indicate likely persistence of these chemicals in the environment, some discussion in the Test Plan of their synthesis, uses and transport that could result in possible release into the environment would be helpful.

Specific comments on the Robust Summary:

1. When references are cited, they are limited to contract reports that are unavailable to the public. (Hopefully they are available to the EPA.)
2. Pages 32-34: A minor comment: these studies of toxicity to fish indicate the value for 100% mortality is the same as that for no mortality. We realize that no toxicity was observed, but these statements could be misleading or confusing to the public. We feel it would be better to state

that no toxicity was observed.
3. Studies in rainbow trout indicate significant potential for bioaccumulation and a long half-life in fish. We realize these are not SIDS elements, but this work does raise an additional flag regarding the potential for negative effects should these chemicals be released into the environment (see our comment 1 under Test Plan above).
4. Another minor comment: Black XV is sometimes referred to as Black 15; we realize these are the same, but the sponsor might wish to be consistent in their use of Roman or Arabic numerals.

Summary:

This Robust Summary/Test Plan describes available data to address most of the requested SIDS elements for the HPV chemical of interest, Black XV, and where studies are not available, appropriate data values are bridged from studies of two non-HPV chemicals. Given the fact that these chemicals have very similar structures and properties, including low mammalian and ecotoxicity, we consider this an adequate Robust Summary/Test Plan. However, we feel this report would be more complete and useful if it also included 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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