

201-15061

Anh Nguyen
01/21/04 11:04 AM

To: NCIC HPV@EPA
CC:
Subject: Environmental Defense comments on 4,4'-oxydi(benzenesulfonylhydrazide) (CAS# 80-51-3)

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cc: lucieryg@msn.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org
Subject: Environmental Defense comments on 4,4'-oxydi(benzenesulfonylhydrazide) (CAS# 80-51-3)

(Submitted via Internet 1/21/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucieryg@msn.com and mark_thomson@cromptoncorp.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for 4,4'-oxydi(benzenesulfonylhydrazide) (CAS# 80-51-3).

The test plan and robust summaries for 4,4'-oxydibenzenesulfonylhydrazide (ODBSH) were prepared by Crompton Corporation. ODBSH is apparently used as a chemical blowing agent in the manufacture of foam rubber and unspecified plastic products. No information is provided on potential or actual environmental releases, levels in the environment, concentrations in consumer products or opportunities for workplace exposures. While environmental and human exposure data are not explicitly required by the HPV program, they are helpful in reviewing HPV submissions.

Inasmuch as there are no available reproductive and developmental toxicity studies, the sponsor proposes to conduct a combined reproductive/developmental study. We are also concerned with the adequacy of the repeat dose studies. They were not conducted according to GLP and were not considered to be valid studies. Therefore, we recommend that a combined repeat dose/reproductive/developmental study be conducted in lieu of the proposed reproductive/developmental study.

Other specific comments are as follows:

1. The Biowin model predicts that ODBSH is not biodegradable. This is somewhat surprising based on the structure; it seems likely that the phenyl ester linkage would be hydrolyzed to produce phenolic metabolites. Are any actual data available to validate the Biowin predictions for ODBSH?
2. ODBSH is moderately toxic to fish, plants and aquatic invertebrates based on ECOSAR predictions. We have some concerns regarding the ECOSAR predictions based on the above point and recommend including any available experimental data on aquatic toxicity in the robust summaries.
3. The available data indicate that ODBSH is mutagenic. This is to be expected based on the hydrazide structure. We agree that the available genetic toxicity data are adequate to fulfill HPV requirements.

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4. One of the repeat dose studies did not include full histological analysis, was not conducted under GLP and is not considered a valid study. The other repeat dose study did not indicate that any histological analysis were conducted, it employed only one dose and like the other repeat dose study it was not conducted under GLP and is not considered a valid study. For these reasons, we recommend, as stated earlier, that a repeat dose study be added to the reproductive/developmental study proposed by the sponsor.

Thank you for this opportunity to comment.

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