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rdenison@environmentaldefense.org
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To: NCIC OPPT@EPA, ChemRTK HPV@EPA, Rtk Chem@EPA, NCIC HPV@EPA, Karen Boswell/DC/USEPA/US@EPA, rhenrich@glcc.com
cc: MTC@mchsi.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org
Subject: Environmental Defense comments on 1,3-Isobenzofurandione, 4,5,6,7-tetrabromo- (CAS# 632-79-1)

(Submitted via Internet 7/13/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and rhenrich@glcc.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for 1,3-Isobenzofurandione, 4,5,6,7-tetrabromo- (CAS# 632-79-1).

Great Lakes Chemical Corporation and Albemarle Corporation, in response to EPA's High Production Volume (HPV) Chemical Challenge, have submitted robust summaries and a test plan describing limited data to address SIDS elements required for 1,3-Isobenzofurandione, 4,5,6,7-tetrabromo-. According to the test plan, this chemical is used as a flame retardant in the production of unsaturated polyester resins. It is also stated that "Its derivatives are also used as flame retardants in rigid polyols, wire coatings and wool." However, the test plan fails to explain if or in what way these derivatives may differ from 1,3-Isobenzofurandione, 4,5,6,7-tetrabromo-.

The test plan contains no background information regarding the production, transport or possible use(s) in consumer products, e.g., wool, that might result in human or environmental exposure.

Review of the studies summarized in the test plan indicates that data on 1,3-Isobenzofurandione, 4,5,6,7-tetrabromo- are limited, but one or more studies are provided to address most of the required SIDS elements. Additional studies are proposed to provide better data on the partition coefficient and water solubility of this compound. The test plan points out that more accurate determinations of the water solubility of this compound may impact the interpretation of other studies. We request that, if results of the water solubility studies provide data significantly different from those currently available, EPA and the public be notified and other relevant studies, e.g. those for environmental toxicity, be reevaluated.

On review of the test plan we note that, according to section 4.2.2, the stability of 1,3-Isobenzofurandione, 4,5,6,7-tetrabromo- in water has not been determined and it is proposed that it will not be determined because the water solubility of this chemical is so low. However, section 4.3.4 states that the anhydride was rapidly hydrolyzed to the acid when placed in moist soil. These data seem inconsistent; therefore, we think the stability of this chemical in water should be determined. If it indeed rapidly hydrolyzes to form the acid, the solubility of the acid should be determined as well. Further, if 1,3-Isobenzofurandione, 4,5,6,7-tetrabromo- does hydrolyze rapidly in water, then the environmental toxicity of the acid should be determined.

Review of the robust summaries indicates that the studies used to address the SIDS elements for environmental and mammalian toxicity were not conducted under GLP, and in each case they failed to indicate the purity of the test chemical. Whereas we do not wish to request unnecessary animal testing, we do not think these studies should be considered acceptable to fulfill the requirements of the SIDS elements required by the EPA HPV Challenge.

Additional comments:
1. A minor point, but the structural formula of 1,3-Isobenzofurandione, 4,5,6,7-tetrabromo- shown on page 4 of the test plan is missing one bond on the anhydride oxygen.
2. The descriptions of toxicity to fish and invertebrates, sections 4.3.1 and 4.3.2, indicate that the studies were conducted at concentrations of 1,3-Isobenzofurandione, 4,5,6,7-tetrabromo- that are several orders of magnitude greater than the reported water solubility of this compound. Please clarify whether this is an error or the values represent nominal concentrations.
3. In the robust summaries, one of the studies with rats provided no data except the numbers for an LD50, but is still considered by the sponsors to be a valid study. We do not think that is acceptable.
4. A number of the studies described in the robust summaries reference a review compiled for the NTP, but fail to provide some critical data, e.g. purity of the test compound or, in some cases, even the chemical tested, etc. This review should go to the original source in an effort to provide more complete data.
5. On page 20 of the robust summaries, the test substance is given as "no data". This cannot be considered a valid study.

In summary, this submission describes limited data on a relatively data-poor chemical. Those data that are available appear to be old and of generally poor quality. Data describing the stability of1,3-Isobenzofurandione, 4,5,6,7-tetrabromo- in water are lacking. Unless the purity of the chemical tested can be determined in each case, the respective studies should not be considered acceptable to address the corresponding SIDS elements. Thus, we consider this submission unacceptable.

Thank you for this opportunity to comment.

Hazel B. Matthews, Ph.D.
Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.
Senior Scientist, Environmental Defense