

201-14360



NCIC HPV
Sent by: Mary-Beth
Weaver

03/21/2003 10:38 AM

To: Matthew Moran/DC/USEPA/US@EPA, NCIC HPV
cc:
cc:
Subject: Environmental Defense comments on
4,5,6,7-Tetrachloro-1,3-isobenzofurandione (CAS 117-08-8)



Richard_Denison@environmentaldefense.org on 03/20/2003 03:27:14 PM

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

Subject: Environmental Defense comments on 4,5,6,7-Tetrachloro-1,3-isobenzofurandione (CAS 117-08-8)

(Submitted via Internet 3/20/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, and lucierg@msn.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for 4,5,6,7-Tetrachloro-1,3-isobenzofurandione (CAS 117-08-8).

The test plan for this chemical, also known as Tetrachlorophthalic anhydride (TCPA), was prepared by Solutia, Inc. Overall the test plan was informative and clearly written. However, we do not concur with the sponsor's conclusions that the available data are adequate to fulfill requirements of the HPV program. Specifically, we recommend additional ecotoxicity studies on the hydrolytic breakdown products of TCPA. Moreover, we are concerned that Solutia's airborne exposure guideline of 0.5 mg/m³ 8-hr TWA may not provide an adequate margin of safety in the workplace. Specific comments are as follows:

1. TCPA is used as a flame retardant in plastics and it is chemically bound to the plastics. The sponsor states that there are no known commercial uses of TCPA itself, although no information was given regarding its potential release from treated plastics over time and as a consequence of different conditions that the treated plastics might encounter in various uses.

2. From the information presented in the test plan, it appears that TCPA can be rapidly hydrolyzed to its acid form under a variety of environmental conditions. The sponsor states that no ecotoxicity studies are needed because TCPA is so water insoluble that reasonable studies could not be conducted. However, the acid breakdown product is readily formed, is water soluble and is stable in the environment. Therefore, we recommend that ecotoxicity and aquatic toxicity studies be conducted on the carboxylic acid breakdown product of TCPA.

3. There are some fish toxicity data available for the structural analog Tetrabromophthalic Anhydride (TBPA). We agree that these data can be used as surrogate data for TCPA because the physical and toxic properties of the two chemicals should be similar.

4. The NTP has conducted extensive studies on TCPA and these fulfill the requirements for repeat dose, reproductive, developmental and genetic toxicity endpoints.

5. Repeat dose studies using the inhalation route of exposure for TCPA did not achieve a NOEL in rats. The lowest dose used in those studies (0.5 mg/m³) resulted in histological changes in the lung, according to data

RECEIVED
OPPT/NCIC
2003 MAR 21 AM 10:55

presented in the robust summaries. In spite of this, the sponsor has established an airborne exposure guideline in the workplace of 0.5 mg/m³ as an 8-hr TWA. Because effects were still observed at this level in the repeat dose studies, we believe that the exposure guideline may not be protective and should be lowered by at least an order of magnitude.

Thank you for this opportunity to comment.

George Lucier, Ph.D.
Consulting Toxicologist, Environmental Defense

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