

201-14481



Solutia Inc  
575 Maryville Centre Drive  
St. Louis, Missouri 63141

P.O. Box 66760  
St. Louis, Missouri 63166-6760  
Tel 314-674-1000

May 20, 2003

Christine Todd Whitman, Administrator  
US Environmental Protection Agency  
P.O. Box 1473  
Merrifield, VA 22116

Attn: Chemical Right-to-Know Program

In re: HPV Challenge Program – Response to EPA Comments: SN 154 (032003)  
AR-201  
4,5,6,7-Tetrachloro-1,3-Isobenzofurandione  
CAS Number 117-08-8

Dear Ms. Whitman:

I am pleased to forward to you our response to EPA's comments received on our referenced HPV submission, which you will find attached. In consideration of these comments, Solutia, Inc. (Registration no. ) has modified our Test Plan and Robust Summary Dossier originally submitted. Thus, I am pleased to forward to you under cover of this letter a diskette containing our Revised Test Plan and Revised Robust Summary for this HPV chemical. An electronic submission to the EPA website, containing the above information, will be made as of this date, as well.

Please contact me directly (314-674-8815) should there be any further questions related to this submission.

Sincerely,

Frederick R. Johannsen  
HPV Coordinator

attachment

RECEIVED  
OPPT/CBIC  
2003 MAY 22 PM 2:20

Solutia, Inc. Response to EPA Comments (SN 154; 032003) on RTK HPV Challenge Submission for: CAS No. 117-08-8; 4,5,6,7-Tetrachloro-1,3-isobenzofurandione (Tetrachlorophthalic anhydride)

#### Comments Pertaining to the Test Plan

##### 1. Environmental Fate – Stability in Water

Solutia agrees to provide measured stability of the referenced chemical (TCPA) in water (hydrolysis) following OECD Test Guideline 111. Recognizing the limited solubility of this chemical, we plan to provide a “best effort” without guarantee that measured solubility will be achieved. Should that not be the case, we would urge the Agency to rethink their initial conclusions as to the adequacy of information already presented. The Test Plan has been revised to indicate a Data Need and agreement to conduct this test.

##### 2. Environmental Fate - Photodegradation

Additional discussion regarding direct photolysis and its impact on fate pathway for TCPA has been included in the Revised Test Plan.

##### 3. Environmental Fate – Fugacity

While Solutia recognizes that the anticipated hydrolysis product of TCPA, the tetrachlorophthalic acid [CAS No. 632-58-6], is not an HPV chemical for which we volunteered, we consent to provide an estimation of transport and distribution for this chemical; an analysis has been included as a second data input within the Revised Robust Summary for TCPA itself.

##### 4. Health Effects – Repeated-Dose Toxicity

Citations in Table 5, page 13 of the Revised Test Plan have been modified to read “LOAEL (lowest dose tested)”, as recommended.

##### 5. Health Effects – Reproductive Toxicity

We have modified the Test Plan section summarizing the Reproductive Toxicity Endpoint, as suggested by the reviewer. A clear statement regarding the lack of reproductive organ toxicity in ovaries and testes/epididymides has been included.

##### 6. Ecological Effects –

We agree with the Agency that final determination of the nature of additional aquatic toxicity testing, if any, should await completion of the aqueous hydrolysis study to be conducted, as noted above. Thus, we reserve the right to again stipulate the acceptance of available data on the HPV chemical, pending the delineation of aqueous hydrolysis of tetrachlorophthalic anhydride.

##### 7. Comments Pertaining to the Robust Summaries

- a. Acute Oral Toxicity – Incidence of clinical signs organized by dose and sex are not available in the original report and thus cannot be included in the Revised Robust Summary.

- b. Genetic Toxicity (Gene Mutations) - Criteria for judging the experimental outcome has been added to the appropriate Revised Robust Summary.
- c. Partition Coefficient reference – Further details on the reference used supporting a log partition coefficient value of 3.57 is not available. We have contacted Dr. Leo directly who has indicated that the information was “hand calculated”; raw data forming that estimate are no longer available. Dr. Leo did incorporate Tetrachlorophthalic anhydride into the latest version of CLOGP which produced an estimated log P (oct) value of 4.21; similarly, he used the same methodology for Tetrachlorophthalic acid, which had a log P (oct) estimated value of 2.45. We have added both pieces of information into the Robust Summary section of this revised submission.

05/03