

201-15753

# BPD/BPA Coalition

## BPD/BPA Coalition

1850 M Street, NW, Suite 700, Washington, DC 20036  
(202) 721-4142 – (202) 296-8120 fax

September 3, 2004

Dr. Oscar Hernandez, Director  
Risk Assessment Division  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

Re: BPD/BPA Coalition Revised Test Plan for Benzene Phosphorous Dichloride (CAS No. 644-97-3) and Phenylphosphinic Acid (CAS No. 1779-48-2) under the HPV Program.

Dear Dr. Hernandez;

On November 29, 2003, the BPD/BPA Coalition submitted a test plan and robust summaries for Benzene Phosphorous Dichloride (BPD – CAS No. 644-97-3) and Phenylphosphinic Acid (BPA – CAS No. 1779-48-2). On May 28, 2004, the BPD/BPA Coalition received comments from EPA regarding the test plan and summaries. The BPD/BPA Coalition thanks the EPA and several public commenters for thoughtful suggestions, which we believe have strengthened our test plan.

The BPD/BPA Coalition has revised the test plan and robust summaries as follows:

### General:

- Worker protection - A public commenter asked how workers are protected from the effects of BPA. Because of the well-known acid properties of BPA, established industrial hygiene standards and procedures are followed and appropriate personnel protective equipment is used.
- Consumer exposure - A public commenter asked whether there are opportunities for consumer exposures to BPD or BPA. Virtually all BPD is used to make BPA and virtually all BPA ends up reacted into a nylon polymer. We do not believe that BPA can be released from the nylon polymer and we are unaware of any evidence that would indicate that BPA was released from the nylon polymer.
- Incorrect references - EPA noted that some of the references do not always correlate to the citations in the test plan. We have corrected a typographical error and two cross-references to the wrong endnote in the test plan.
- Data discrepancies - EPA indicated that there are discrepancies between data described in the test plan and in the robust summaries, and that there are errors in the reference listings. We believe these discrepancies have been resolved in the revised test plan and robust summaries. An issue with two cross-references to an endnote also been corrected (see above comment).

### Physicochemical properties:

- Boiling point - We will follow OECD Test Guideline 103.
- Melting point - The test plan was revised to remove determination of melting point because data submitted in the test plan were considered adequate by EPA.

### Environmental Fate:

- Stability in water - The final report confirmed the stability data in the test plan and robust summary.
- Biodegradation - OECD Test Guideline 301 will be followed.

RECEIVED  
OPPT CRJF  
04 DEC 30 PM 1:10

- Fugacity – EPA noted that all physicochemical input values need to be incorporated into the fugacity robust summaries. We plan to incorporate these data in the final HPV Dossier, when all testing has been completed.

Ecological effects - A public commenter suggested that we continue avoidance of animal experiments and use *in vitro* methods for fish toxicity. We are not able to avoid an *in vivo* testing method for the fish toxicity because ECOSAR predicts some toxicity to fish. We need to test according to OECD Test Guideline 203 to clarify the status of BPA. Because BPA is not liberated into the environment, once reacted into nylon products, our primary concern is the period, including transportation and storage, between manufacture of BPA and its consumption in the manufacturing of nylon.

#### Health Effects:

- Category – A public commenter agreed that our data supported the BPD/BPA category and suggested using BPD data to estimate BPA toxicity. Although BPA is appropriate for estimating the toxicity of BPD, the converse is not true. BPD has three hydrolysis products, the ratio of which depends on the conditions of hydrolysis. Industrially, the hydrolysis of BPD to BPA is controlled to give a yield of 99% BPA or greater. In an OECD 111 study, the mass percentages for BPD hydrolysis products was approximately 40% CI, 30% PPOA, 25% BPA and 5% phenylphosphine. The physicochemical and acute toxicity properties of BPA and PPOA are similar, but those of phenylphosphine are not. Use of BPD for the test material in either mammalian or aquatic toxicity tests would involve uncontrolled hydrolysis and the test would be of a mixture of chemicals with different properties and not representative of the BPA/BPD category as the materials are actually used commercially.
- Mutagenicity – A public commenter suggested using BPD in an *in vivo* Mutagenicity study. We have concluded that it is not meaningful to use BPD as the test material (see above response) and we believe it is not appropriate to dose animals with BPA. We plan, therefore, to do *in vitro* mutagenicity testing using BPA as originally planned.
- Repeat Dose Reproductive/Developmental Toxicity Study – EPA and one public commenter suggested we do a repeat dose (OECD 422) study, but for different reasons and with different test articles. We have discovered that an adequate 4-week repeated dose study with BPA was added to PubMed after the closing date of our original literature searches. This study meets the requirements of the repeated dose endpoint. In addition, we have discovered that there is reproductive/developmental information available for a veterinary pharmaceutical, toldimfos, which is structurally related to BPA. Toldimfos (CAS No. 575-75-7) is BPA with an ortho methyl group and a para dimethylamino group. Together, these two studies provide adequate information on repeated-dose and reproductive/developmental toxicity and obviate the need for an OECD 422 study. The test plan and robust summary have been revised to include this new information.

In preparing this test plan, the BPD/BPA Coalition gave careful consideration to the principles contained in the letter EPA sent to all HPV Challenge Program participants on October 14, 1999. As requested by EPA, in that letter, the BPD/BPA Coalition has sought to maximize the use of scientifically appropriate categories of related chemicals and of structure-activity relationships and to minimize the use of laboratory animals. Additionally, and also as requested by EPA's letter, the BPD/BPA Coalition has conducted a thoughtful, qualitative analysis rather than use a rote checklist approach. The BPD/BPA Coalition has taken the same thoughtful approach when developing this revised test plan.

If there are any questions regarding our test plan, please contact me at by e-mail at [william.smock@verizon.net](mailto:william.smock@verizon.net).

Sincerely,

William H. Smock  
Executive Director