

April 26, 2005

Stephen S. Dimond  
Toxicologist  
GE Advanced Materials, Plastics  
148 Powder Hill Road  
Bedford, N.H. 03110

Dear Mr. Dimond:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 5,5'-[(1-methylethylidene)bis(4,1-phenyleneoxy)]bis(1,3-isobenzofurandione) (bisphenol A dianhydride; BPA-DA) posted on the ChemRTK HPV Challenge Program Web site on March 2, 2004. I commend General Electric Company for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA has reviewed this submission and has reached the following conclusions:

1. It is unclear whether page 2 of the test plan was left blank intentionally.
2. Physicochemical Properties and Environmental Fate. EPA agrees with the test plan for these endpoints.
3. Health Effects. EPA agrees that repeated-dose, gene mutation and developmental toxicity data are adequate for the purposes of the HPV Challenge Program and agrees with the submitter's proposal to test for the chromosomal aberrations endpoint using OECD TG 473 and for the reproductive toxicity endpoint using OECD TG 421.

The robust summaries indicate that, prior to submission of BPA-DA information under the HPV Challenge Program, testing for chromosomal aberrations (OECD TG 473) and reproductive/developmental toxicity (OECD TG 421) was already in progress. If the testing was in response to the HPV Challenge Program, General Electric should have waited until the close of the public comment period before initiating any testing, in accordance with HPV Challenge Program guidance.

4. Ecological Effects. Because of the planned water solubility and other physicochemical property and environmental fate testing, EPA defers judgement on the need for aquatic testing until these data become available. Such data will determine what type of testing, if any, is appropriate.

EPA will post this letter on the HPV Challenge Web site within the next few days. We ask that General Electric advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses:

[oppt.ncic@epa.gov](mailto:oppt.ncic@epa.gov) and [chem.rtk@epa.gov](mailto:chem.rtk@epa.gov).

If you have any questions about his response, please contact Mark Townsend, Acting Chief of the HPV Chemicals Branch, at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at [tsca-hotline@epa.gov](mailto:tsca-hotline@epa.gov).

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director  
Risk Assessment Division

cc: M. E. Weber  
J. Willis