

July 12, 2004

Dr. Mark A. Thomson
Manager, Toxicology & International Product
Registration
Crompton Corporation
Middlebury, CT 06749

Dear Dr. Thomson:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 2,4,8,10-Tetraoxa-3,9-diphosphaspiro[5.5]undecane, 3,9-bis[2,4-bis(1,1-dimethylethyl)phenoxy]- posted on the ChemRTK HPV Challenge Program Web site on February 17, 2004. I commend the Crompton Corporation 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. Physicochemical Properties and Environmental Fate. EPA agrees with the test plan for these endpoints. The submitter needs to correct Table 1 by indicating that information is not available for hydrolysis and inserting the correct Cas No.
2. Health Effects. Adequate data are available for the acute, repeated-dose, and genetic toxicity endpoints for the purposes of the HPV Challenge Program. The oral feed studies need to report results on a mg/kg-bw basis. The reproductive toxicity endpoint is not adequately addressed in the test plan. Data from the 90-day study in rats may be more appropriate to use than the 2-year bioassay data because it is not clear from the robust summary when the reproductive organs were examined during the course of the study. A robust summary needs to be prepared for the reproductive

toxicity endpoint that clearly presents the data the submitter believes are available to address this endpoint. The developmental data are not adequate due to a lack of study details (the submitter assigned a Klimisch category of 4—not assignable). Unless additional study details are made available to judge data adequacy, EPA recommends that an OECD TG 421 study be conducted, which will also address the reproductive toxicity endpoint in greater detail.

3. Ecological Effects. Due to the high log Kow and the very low water solubility no ecological effects testing is recommended.

EPA will post this letter on the HPV Challenge Web site within the next few days. We ask that the Crompton Corporation 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 and chem.rtk@epa.gov.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. 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.

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

Enclosure

cc: W. Penberthy
M. E. Weber