

June 17, 2002

William F. Gentit
Manager, Regulatory Affairs
Akzo Nobel Functional Chemicals LLC
5 Livingstone Avenue
Dobbs Ferry, NY 10522-3407

Dear Mr. Gentit:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Phosphoryl chloride, polymer with resorcinol, phenyl ester, posted on the ChemRTK HPV Challenge Program Web site on December 6, 2001. I commend Akzo Nobel Functional Chemicals LLC 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 HPV 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 will post this letter and the attached Comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Akzo Nobel Functional Chemicals LLC advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

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 HPV Challenge Program Web site Submit Technical Questions button 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

Attachment

cc: W. Sanders
A. Abramson
C. Auer
M. E. Weber

**EPA Comments on Chemical RTK HPV Challenge Submission:
Phosphoryl Chloride, Polymer with Resorcinol, Phenyl Ester**

SUMMARY OF EPA COMMENTS

The sponsor, Akzo Nobel Functional Chemicals LLC, submitted a test plan and robust summaries to EPA for phosphoryl chloride, polymer with resorcinol, phenyl ester (CAS No. 125997-21-9) dated August 28, 2001. EPA posted the submission on the ChemRTK HPV Challenge Web site on December 6, 2001.

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

1. Identity and Relevance of Test Chemical. The submitter needs to clearly identify the test substances. Most of the data were generated on resorcinol bis(diphenylphosphate) (RDP), Fyrolflex RDP, or CR 733-S. However, according to the CAS registry, all of these are synonyms of a different substance: phosphoric acid, 1,3-phenylene tetraphenyl ester (CAS No. 57583-54-7). The submitter needs to explain why the tested chemical is an acceptable analog.
2. Physicochemical and Environmental Fate Data. The submitter needs to provide measured data on vapor pressure and water solubility.
3. Health Effects. All appropriate SIDS-level tests have been performed on material referred to as Fyrolflex RDP, resorcinol bis(diphenylphosphate), or CR 733-S. As stated above, the submitter needs to provide more information to confirm that the tested substance is phosphoryl chloride, polymer with resorcinol, phenyl ester (CAS No. 125997-21-9) or needs to provide a justification for using the tested material as an analog for the title substance. The submitter also needs to address several deficiencies in the robust summaries.
4. Ecological Effects. Adequate data exist for acute toxicity in invertebrates. However, EPA reserves judgement on the adequacy of the acute toxicity data for fish and algae. The submitter needs to address two issues to facilitate a full assessment of the existing data. The submitter also needs to provide missing study details in the robust summaries.

EPA requests that the Submitter advise the Agency within 60 days of any modifications to its submission.

**EPA COMMENTS ON THE PHOSPHORYL CHLORIDE, POLYMER WITH RESORCINOL, PHENYL
ESTER CHALLENGE SUBMISSION**

Chemical identity

The chemical identity of the polymeric title substance, phosphoryl chloride, polymer with resorcinol, phenyl ester (95-99% wt%), is not the same as the substance, resorcinol bis(diphenyl phosphate), listed as a synonym of the title substance in Section 1.2 of the IUCLID summary. Also, the substance referred in many study summaries as Fyrolflex RDP, is a synonym of resorcinol bis(diphenyl phosphate) with a discrete chemical formula and different CAS number; therefore, it cannot be unambiguously linked to the title substance.

Thus, the title substance is not consistently described in Section 1.2 of the IUCLID summaries or in the body of the test description in many of the IUCLID summaries. If the test substance was not phosphoryl chloride, polymer with resorcinol, phenyl ester, the submitter needs to discuss why the tested substance is an acceptable analog of the title substance for the purpose of toxicity assessment.

On page two, the test chemical is named as an ether instead of an ester.

EPA also notes that the required comma after the word resorcinol in the title substance was lacking in

the submission, changing the meaning of the name.

Test Plan

Chemistry (melting point, boiling point, vapor pressure, water solubility, and partition coefficient).

In the test plan table the submitter indicates that testing is required for boiling point and partition coefficient. EPA agrees that test data need to be submitted for these endpoints. The submitter also needs to provide measured data for vapor pressure and water solubility.

Vapor Pressure. The submitter provides a vapor pressure value of < 0.1 hPa (<0.075 torr) at 38 °C. Because this value may exceed the threshold for determining this endpoint, the submitter needs to provide a discrete measured value for this endpoint, including method used, preferably following OECD guidelines.

Water Solubility. The submitter provides a water solubility value of <10 mg/L at 25 °C. Because this value may exceed the threshold for determining this endpoint, the submitter needs to provide a discrete measured value for this endpoint, including method used, preferably following OECD guidelines.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity).

EPA can not assess the adequacy of the environmental fate data until the submitter provides clarification on the identity of the tested chemical. In the test plan table the submitter indicates that testing is required for photodegradation and fugacity. EPA agrees that data need to be submitted for these endpoints.

Health Effects (acute toxicity, repeat dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

Assuming that the submitter will clarify the identity of the test substance, adequate data are available for these endpoints for Fyrolflex RDP, resorcinol bis(diphenylphosphate), or CR 733-S. However, the submitter has not shown that these data are relevant to the title substance. In addition, the submitter needs to enhance robust summaries by providing more information (See Specific Comments on Robust Summaries).

Ecotoxicity (fish, invertebrate, and algae).

The submitter proposed no additional ecotoxicity testing. With the assumption that the submitter will provide the missing study details, existing studies are adequate for acute toxicity to aquatic invertebrates. The existing data may also suffice for acute toxicity to fish and algae, but cannot be evaluated because the robust summaries did not provide sufficient information on the identity of the test substance Fyrolflex RDP or the means by which testing was performed at concentrations that exceeded the reported water solubility (see Section 2.6.1 of the IUCLID Data Set). The submitted information for acute toxicity to fish and algae may be acceptable if the sponsor can provide an adequate discussion and resolution of these issues and, in addition, can provide the missing study details. The submitter needs to consider chronic toxicity testing for hydrophobic chemicals with log P greater than 4.2.

Specific Comments on the Robust Summaries

Health Effects.

Reproductive Toxicity. Information missing from the robust summary includes: the magnitude, duration, and dose-response relationships for effects on food consumption, body weight, delayed reproductive development in females, and data for a pair-fed group, if available.

Ecotoxicity.

Fish and Algae: Test concentration. The three highest concentrations tested in the acute studies on fish and algae exceeded the water solubility of <10 mg/L that was reported in Section 2.6.1 of the IUCLID Data Set. Maximum nominal test concentrations were 71.2 mg/L in fish and 48.64 mg/L in algae. The robust summaries provided no indication that a solubilizing agent was used. Thus, the submitter needs to provide an explanation of how the higher test concentrations were achieved.

Fish. Water hardness, statistical methods, number of deaths per dose, signs of toxicity per dose, percent chemical purity, measured or nominal concentrations reported, and 95% confidence limits were not indicated in the robust summary.

Invertebrates. Statistical methods, number of deaths per dose, measured or nominal concentrations reported, percent purity, and signs of toxicity per dose were not indicated in the robust summary.

Algae. The robust summary did not provide the culture conditions, approximate percent inhibition observed at the highest dose, or percent purity of the compound. EPA will defer determining data adequacy for this endpoint until the missing critical elements are provided.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.