SCREENING-LEVEL HAZARD CHARACTERIZATION OF HIGH PRODUCTION VOLUME CHEMICALS

SPONSORED CHEMICAL

Cyclic Neopentanetetrayl Diphenyl Phosphite (CAS No. 144-35-4)
[9th CI Name: 2,4,8,10-Tetraoxa-3,9-diphosphaspiro(5.5)undecane, 3,9-diphenoxy-]

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Prepared by

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The High Production Volume (HPV) Challenge Program[1] is a voluntary initiative aimed at developing and making publicly available screening-level health and environmental effects information on chemicals manufactured in or imported into the United States in quantities greater than one million pounds per year. In the Challenge Program, producers and importers of HPV chemicals voluntarily sponsor chemicals; sponsorship entails the identification and initial assessment of the adequacy of existing toxicity data/information, conducting new testing if adequate data do not exist, and making both new and existing data and information available to the public. Each complete data submission contains data on 18 internationally agreed to "SIDS" (Screening Information Data Set[1,2]) endpoints that are screening-level indicators of potential hazards (toxicity) for humans or the environment.

The Environmental Protection Agency's Office of Pollution Prevention and Toxics (OPPT) is evaluating the data submitted in the HPV Challenge Program on approximately 1400 sponsored chemicals. OPPT is using a hazard-based screening process to prioritize review of the submissions. The hazard-based screening process consists of two tiers described below briefly and in more detail on the Hazard Characterization website[3].

Tier 1 is a computerized sorting process whereby key elements of a submitted data set are compared to established criteria to "bin" chemicals/categories for OPPT review. This is an automated process performed on the data as submitted by the sponsor. It does not include evaluation of the quality or completeness of the data.

In Tier 2, a screening-level hazard characterization is developed by EPA that consists of an objective evaluation of the quality and completeness of the data set provided in the Challenge Program submissions. The evaluation is performed according to established EPA guidance[2,4] and is based primarily on hazard data provided by sponsors. EPA may also include additional or updated hazard information of which EPA, sponsors or other parties have become aware. The hazard characterization may also identify data gaps that will become the basis for a subsequent data needs assessment where deemed necessary. Under the HPV Challenge Program, chemicals that have similar chemical structures, properties and biological activities may be grouped together and their data shared across the resulting category. This approach often significantly reduces the need for conducting tests for all endpoints for all category members. As part of Tier 2, evaluation of chemical category rationale and composition and data extrapolation(s) among category members is performed in accord with established EPA[2] and OECD[5] guidance.

The screening-level hazard characterizations that emerge from Tier 2 are important contributors to OPPT's existing chemicals review process. These hazard characterizations are technical documents intended to support subsequent decisions and actions by OPPT. Accordingly, the documents are not written with the goal of informing the general public. However, they do provide a vehicle for public access to a concise assessment of the raw technical data on HPV chemicals and provide information previously not readily available to the public. The public, including sponsors, may offer comments on the hazard characterization documents.

The screening-level hazard characterizations, as the name indicates, do not evaluate the potential risks of a chemical or a chemical category, but will serve as a starting point for such reviews. In 2007, EPA received data on uses of and exposures to high-volume TSCA existing chemicals, submitted in accordance with the requirements of the Inventory Update Reporting (IUR) rule. For the chemicals in the HPV Challenge Program, EPA will review the IUR data to evaluate exposure potential. The resulting exposure information will then be combined with the screening-level hazard characterizations to develop screening-level risk characterizations[4,6]. The screening-level risk characterizations will inform EPA on the need for further work on individual chemicals or categories. Efforts are currently underway to consider how best to utilize these screening-level risk characterizations as part of a risk-based decision-making process on HPV chemicals which applies the results of the successful U.S. High Production Volume Challenge Program and the IUR to support judgments concerning the need, if any, for further action.

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[1] U.S. EPA. High Production Volume (HPV) Challenge Program; http://www.epa.gov/chemrtk/index.htm.
[2] U.S. EPA. HPV Challenge Program – Information Sources; http://www.epa.gov/chemrtk/pubs/general/guidocs.htm.
[3] U.S. EPA. HPV Chemicals Hazard Characterization website (http://www.epa.gov/hpvis/abouthc.html).
[4] U.S. EPA. Risk Assessment Guidelines; http://cfpub.epa.gov/ncea/raf/rafguid.cfm.
[5] OECD. Guidance on the Development and Use of Chemical Categories; http://www.oecd.org/dataoecd/60/47/1947509.pdf.
[6] U.S. EPA. Risk Characterization Program; http://www.epa.gov/osa/spc/2riskchr.htm.

SCREENING-LEVEL HAZARD CHARACTERIZATION
Cyclic Neopentanetetrayl Diphenyl Phosphite (CAS No. 144-35-4)

Introduction

The sponsor, GE Plastics Co., submitted a Test Plan and Robust Summaries to EPA for Cyclic neopentanetetrayl diphenyl phosphite (CAS No. 144-35-4; 9th CI name: 2,4,8,10-tetraoxa-3,9-diphosphaspiro(5.5)undecane, 3,9-diphenoxy-) on July 14, 2000. EPA posted the submission on the ChemRTK HPV Challenge website on June 13, 2000 (http://www.epa.gov/chemrtk/pubs/summaries/plastics/c12614tc.htm). EPA comments on the original submission were posted to the website on October 6, 2000. Public comments were also received and posted to the website.

This screening-level hazard characterization is based primarily on the review of the test plan and robust summaries of studies submitted by the sponsor(s) under the HPV Challenge Program. In preparing the hazard characterization, EPA considered its own comments and public comments on the original submission as well as the sponsor's responses to comments and revisions made to the submission. A summary table of SIDS endpoint data with the structure(s) of the sponsored chemical(s) is included in the appendix. The screening-level hazard characterization for environmental and human health toxicity is based largely on SIDS endpoints and is described according to established EPA or OECD effect level definitions and hazard assessment practices.

Summary-Conclusion

The log K_{ow} value of phosphorus acid, cyclic neopentanetetrayl diphenyl phosphite indicates that its potential to bioaccumulate is expected to be low. Biodegradation data were not provided this substance.

No aquatic toxicity or human health effects data were provided for cyclic neopentanetetrayl diphenyl phosphite. Hazard assessment for these endpoints will be conducted following the receipt of results from the tests proposed by the sponsor.

Data gaps: Octanol-water partition coefficient, ready biodegradation test and the aquatic toxicity and human health endpoints.

1. Physical-Chemical Properties and Environmental Fate

Octanol-Water Partition Coefficient

Log K_{ow}: 3.26

Biodegradation

No data are available.

Conclusion: The log K_{ow} value of phosphorus acid, cyclic neopentanetetrayl diphenyl phosphite indicates that its potential to bioaccumulate is expected to be low. Biodegradation data are not available for this substance.

2. Environmental Effects- Aquatic Toxicity

Testing was proposed for all aquatic toxicity endpoints.

Conclusion: No aquatic toxicity data are available for cyclic neopentanetetrayl diphenyl phosphite. Hazard assessment for these endpoints will be conducted following the receipt of results from the tests proposed by the sponsor.

3. Human Health Effects

Testing proposed for all human health endpoints.

Conclusion: No human health effects data are available for cyclic neopentanetetrayl diphenyl phosphite. Hazard assessment for these endpoints will be conducted following the receipt of results from the tests proposed by the sponsor.

4. Hazard Characterization

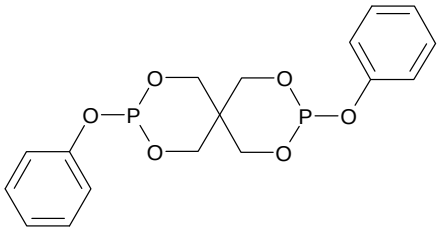
The log K_{ow} value of phosphorus acid, cyclic neopentanetetrayl diphenyl phosphite indicates that its potential to bioaccumulate is expected to be low. Biodegradation data are not available for this substance.

No aquatic toxicity or human health effects data are available for cyclic neopentanetetrayl diphenyl phosphite. Hazard assessment for these endpoints will be conducted following the receipt of results from the tests proposed by the sponsor.

5. Data Gaps

Octanol-water partition coefficient, ready biodegradation test and the aquatic toxicity and human health endpoints.

APPENDIX

Summary Table of the Screening Information Data Set as submitted under the U.S. HPV Challenge Program	
Endpoints	**SPONSORED CHEMICAL** **Cyclic neopentanetetrayl diphenyl phosphate** **(144-35-4)**
Structure	
Summary of Physical-Chemical Properties and Environmental Fate Data	
Melting Point (°C)	No data. Testing is proposed.
Boiling Point (°C)	> 300 (estimated)
Vapor Pressure **(hPa at 25°C)**	1.6×10^{-3} @ 20 °C
Log K_{ow}	No data. Testing is proposed.
Water Solubility **(mg/L at 25°C)**	No data. Testing is proposed.
Direct Photodegradation	—
Indirect (OH^-) Photodegradation **Half-life ($t_{1/2}$)**	1.3 h
Stability in Water (Hydrolysis) ($t_{1/2}$)	No data. Testing is proposed.
Fugacity **(Level III Model)** **Water (%)** **Sediment (%)** **Soil (%)** **Air (%)**	No data. Testing is proposed.
Biodegradation at 28 days (%)	No data. Testing is proposed.
Summary of Environmental Effects – Aquatic Toxicity Data	
Fish **96-h LC_{50} (mg/L)**	No data. Testing is proposed.
Aquatic Invertebrates **48-h EC_{50} (mg/L)**	No data. Testing is proposed.
Aquatic Plants **72-h EC_{50} (mg/L)** **(growth)** **(biomass)**	No data. Testing is proposed.
Chronic Toxicity to Invertebrates **21-day EC_{50} (mg/L)**	—

Summary Table of the Screening Information Data Set as submitted under the U.S. HPV Challenge Program	
Endpoints	**SPONSORED CHEMICAL Cyclic neopentanetetrayl diphenyl phosphate (144-35-4)**
Summary of Human Health Data	
Acute Oral Toxicity LD_{50} (mg/kg-bw)	No data. Testing is proposed.
Acute Dermal Toxicity LD_{50} (mg/kg-bw)	—
Acute Inhalation Toxicity LC_{50} (mg/L)	—
Repeated-Dose Toxicity (NOAEL/LOAEL) Oral (mg/kg-bw/day)	No data. Testing is proposed.
Reproductive Toxicity	No data. Testing is proposed.
Developmental Toxicity	No data. Testing is proposed.
Genetic Toxicity – Gene Mutation	No data. Testing is proposed.
Genetic Toxicity – Chromosomal Aberrations	No data. Testing is proposed.
Additional Information	—

– indicates endpoint was not addressed for this chemical