

May 28, 2003

Natalie Rutherford
Global Regulatory Manager
FMC Corporation
1735 Market Street
Philadelphia, PA 19103

Dear Ms. Rutherford:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Methyl 4,6,6,6-Tetrachloro-3,3-dimethylhexanoate posted on the ChemRTK HPV Challenge Program Web site on January 28, 2003. I commend FMC 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 will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that FMC Corporation 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 Heffer, 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: A. Abramson
W. Penberthy
M. E. Weber

**EPA Comments on Chemical RTK HPV Challenge Submission:
Methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate**

SUMMARY OF EPA COMMENTS

The sponsor, FMC Corporation, submitted a test plan and robust summaries to EPA for methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate (CAS No. 64667-33-0) dated December 30, 2002. EPA posted the submission on the ChemRTK HPV Challenge Web site on January 28, 2003.

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.
2. Health Effects. EPA agrees with the submitter's plan to conduct a chromosomal aberrations and a combined reproduction/developmental screening test. EPA also agrees that the submitter has adequately supported the "closed system intermediate" claim for the substance.
3. Ecological Effects. The submitted data for acute fish toxicity are inadequate. However, because of the chemical's estimated low water solubility and high log Kow, only a chronic daphnia test needs to be performed.

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

**EPA COMMENTS ON THE METHYL 4,6,6,6-TETRACHLORO-3,3-DIMETHYLHEXANOATE
CHALLENGE SUBMISSION**

Test Plan

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

EPA agrees with the test plan for these endpoints.

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

EPA agrees with the test plan for these endpoints. However, the submitter will need to provide revised estimations based on the measured physicochemical properties.

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

Adequate data are available for acute toxicity and gene mutation endpoints for the purposes of the HPV Challenge Program. EPA agrees with the submitter's test plan to conduct a combined reproduction/developmental toxicity screening test (OECD TG 421) to address the developmental toxicity endpoint and recommends that the chromosomal aberrations test be done using OECD TG 473.

Repeated-Dose and Reproductive Toxicity. No data were submitted for these endpoints and no testing is proposed, based on the submitter's assertion that methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate is a closed-system intermediate.

The Guidance for Testing Closed System Intermediates for the Challenge Program at <http://www.epa.gov/chemrtk/guidocs.htm> allows for a reduced testing protocol provided certain criteria are met. The information required to judge a “closed system intermediate” claim must address the following:

- I. Site information
 - A. Number of sites.
 - B. Basis for “closed process” conclusion at each site.
 - 1) Process description.
 - 2) Monitoring data showing no detection.
 - 3) In the absence of monitoring data, the basis for believing that releases do not occur.
 - C. Data on “presence in distributed products.”
- II. Information on transport (mode, volume, controls, etc)
- III. A data search showing that the chemical is not present in other end products.

Closed System Intermediate Review.

EPA believes that information provided by the submitter is adequate to meet the criteria for claiming methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate as a closed-system intermediate.

I. Site information

A. Number of sites.

The test plan does not discuss the number of sites manufacturing or processing this chemical. However, the Inventory Updates for 1990, 1994, and 1998 list only the site identified in the test plan as reporting for this chemical.

B. Basis for “closed process” conclusion at each site.

1) Process description.

The subject chemical is manufactured in a closed vessel from precursor chemicals.

All transfers of the chemical from the vessel in which it is produced into storage and from storage into a vessel for subsequent reaction is through closed piping systems.

Following manufacture, the chemical undergoes further deliberate reaction at the same site to produce another chemical substance.

The test plan states that the entire system used to manufacture and subsequently react the chemical is closed.

2) Monitoring data showing no detection.

Wastewater from the manufacturing facility is monitored for the chemical. In 2001, the average concentration of the chemical the wastewater stream was 14.8 ppm. The limitation on discharges to carbon adsorption beds is 25 ppm.

Workplace air monitoring was conducted in 1985 and 1988. The chemical was not present in air samples at concentrations above the level of detection. The limit of detection at the time of sampling was 0.1 mg/m³.

C. Data on “presence in distributed products.”

The test plan states that the chemical is not present in any finished goods products manufactured from the chemical intermediate. No basis is provided for this statement.

II. Information on transport (mode, volume, controls, etc)

The chemical is manufactured at the site identified in the test plan and is reacted at this site to produce another chemical substance. The test plan states that the chemical is not transported from the site identified in the test plan.

III. A data search showing that the chemical is not present in other end products.

Results from a search of the Chemical Abstracts On-Line Database indicate that the chemical is not present in any end-products.

The chemical is not included in any Confidential Statement of Formula for the technical materials which use chemicals produced from the chemical at the identified site.

Ecological Effects (fish, invertebrates, and algae).

EPA disagrees that the the acute fish data are adequate. The test was conducted above the chemical's estimated water solubility and no analytical monitoring was performed. However, because of the estimated low water solubility and a high log Kow value (4.7), only a chronic daphnia test is needed. If the planned physicochemical tests indicate otherwise, then the three acute endpoints are needed.

Specific Comments on the Robust Summaries

Health Effects.

Genetic Toxicity (Gene Mutations). The omitted information included the positive and negative controls used in the study and their respective results, and the criteria for positive and negative results.

Followup Activity

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