

**FMC RESPONSE TO EPA COMMENTS ON THE
METHYL 4,6,6,6-TETRACHLORO-3,3-DIMETHYLHEXANOATE TEST PLAN**

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

EPA Comment

EPA agrees with the test plan for these endpoints.

FMC Response

No additional comments.

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

EPA Comment

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

FMC Response

Revised estimations based on the measured physicochemical properties will be provided.

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

EPA Comment

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.

FMC Response

The test plan has been revised to specify that the chromosomal aberrations test will be done using OECD TG 473.

EPA Comment

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.

FMC Response

No additional comments.

Ecological Effects (fish, invertebrates, and algae).

EPA Comment

EPA disagrees that 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.

FMC Response

The acute sheepshead minnow test with methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate was conducted using an acetone carrier, one of EPA's recommended solvents for testing compounds that are not very soluble in water. The concentration of methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate was not measured analytically, therefore the EPA classified the study as inadequate.

Our test plan for methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate includes physicochemical testing. The results of these tests will be evaluated and used to determine the potential aquatic toxicity of this substance and the aquatic toxicity testing needed. The test plan has been noted accordingly.

FMC RESPONSE TO EPA COMMENTS ON THE METHYL 4,6,6,6-TETRACHLORO-3,3-DIMETHYLHEXANOATE ROBUST SUMMARIES

Health Effects.

EPA Comment

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.

FMC Response

This information has been added to the robust summary.

DV Ester Step II (methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate), FMC 30099
CAS No. 64667-33-0

Study	Information (Y/N)	EPA/OECD Guideline (Y/N)	GLP (Y/N)	Other Study (Y/N)	Estimation Method (Y/N)	Acceptable (Y/N)	SIDS Testing Required (Y/N)
Physical and Chemical Data							
Melting Point	No	No	No	No	No	No	Yes
Boiling Point	Yes	No	No	No	No	No	Yes
Vapor Pressure	Yes	No	No	No	No	No	Yes
Partition Coefficient	No	No	No	No	No	No	Yes
Water Solubility	No	No	No	No	No	No	Yes
Environmental Fate and Pathways							
Photodegradation	Yes	No	No	No	Yes	Yes	No
Stability in Water (Hydrolysis)	Yes	No	No	No	Yes	Yes	No
Transport/Distribution	Yes	No	No	No	Yes	Yes	No
Biodegradation	No	No	No	No	No	No	Yes
Ecotoxicity							
Acute/Prolonged Toxicity to Fish	Yes	Yes	No	No	No	Yes	1
Acute Toxicity to Aquatic Invertebrates (Daphnia)	No	No	No	No	No	No	1
Acute Toxicity to Aquatic Plants (Algae)	No	No	No	No	No	No	1
Toxicity							
Acute Oral	Yes	Yes	Yes	No	No	Yes	No
Acute Dermal	Yes	No	Yes	No	No	Yes	No
Acute Inhalation	Yes	No	Yes	No	No	Yes	No
Repeated Dose	No	No	No	No	No	No	No
Genetic - Gene Mutation	Yes	No	Yes	No	No	Yes	No
Genetic – Chromosomal Aberration (OECD 473)	No	No	No	No	No	No	Yes
Reproduction/Developmental Screen (OECD 421) ¹	No	No	No	No	No	No	Yes
Reproduction	No	No	No	No	No	No	No
Developmental/Teratogenicity	No	No	No	No	No	No	No

¹ Ecotoxicity testing will be determined based on the physical and chemical testing results.

² Acceptable for satisfying Developmental Toxicity requirement for closed-system intermediates.