Supporting Documents for Initial Risk-Based Prioritization of High Production Volume Chemicals

Methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate (CASRN 64667-33-0) (9th CI and CA Index Name: Hexanoic acid, 4,6,6,6-tetrachloro-3,3-dimethyl-, methyl ester)

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BACKGROUND

Screening-level hazard, exposure and risk characterizations for high production volume chemicals (HPV) are important contributions to the chemicals cooperation work being done in North America¹ through the EPA Chemical Assessment and Management Program (ChAMP)². These screening-level characterizations are developed by EPA for individual chemicals or chemical categories to support initial Risk-Based Prioritizations (RBPs) for HPV chemicals. These screening-level characterizations are technical documents intended primarily to inform the Agency's internal decision-making process. Accordingly, they are written for assessment professionals and assume a degree of technical understanding. Each of the support documents is described below.

The Risk-Based Prioritizations are found in an accompanying document and are written for a general audience. They present EPA's initial thinking regarding the potential risks presented by these chemicals and future possible actions that may be needed.

Hazard Characterizations for HPV Chemicals

EPA's screening-level hazard characterizations are based primarily on the review of the summaries of studies and other information submitted by the chemical sponsor(s) under the HPV Challenge Program³. These studies included in the scope of the HPV Challenge comprise the Screening Information Data Set (SIDS) of the Organization for Economic Cooperation and Development (OECD)⁴, an internationally recognized battery of tests that provides the basic data necessary to make an initial evaluation of a chemical's hazards and fate. In preparing the initial hazard characterizations, EPA also consulted a variety of reliable sources⁵ for additional relevant information and 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. In order to determine whether any new hazard information was developed since the time of an HPV submission, EPA also searched publicly available databases⁶ for information entered from one year prior to the HPV submission through May 2008. The screening-level hazard characterization is performed according to established EPA guidance⁷. A more detailed description of the hazard characterization process is available on the EPA website⁸.

With respect to chemicals for which internationally-accepted OECD SIDS Initial Assessment Profiles (SIAP) and Initial Assessment Reports (SIAR) were available, EPA did not generate its own screening-level hazard characterization, but did check for and incorporate updated information in the risk characterization.

Exposure Characterizations for HPV Chemicals

EPA recently received exposure-related data on chemicals submitted in accordance with the requirements of Inventory Update Reporting (IUR)⁹. The 2006 IUR submissions pertain to chemicals manufactured in

¹ U.S. EPA – U.S. Commitments to North American Chemicals Cooperation: http://www.epa.gov/hpv/pubs/general/sppframework.htm.

² U.S. EPA – ChAMP information: http://www.epa.gov/champ/.

³ U.S. EPA – HPV Challenge Program information: http://www.epa.gov/hpv.

⁴ U.S. EPA – Technical Guidance Document, OECD SIDS Manual Sections 3.4 and 3.5: http://www.epa.gov/chemrtk/pubs/general/sidsappb.htm.

⁵ U.S. EPA – Public Database Hazard Information: http://www.epa.gov/hpvis/hazardinfo.htm.

⁶ U.S. EPA – Public Database Update Information: http://www.epa.gov/chemrtk/hpvis/updateinfo.htm.

⁷ U.S. EPA – Risk Assessment Guidelines: http://cfpub.epa.gov/ncea/raf/rafguid.cfm.

⁸ U.S. EPA – About HPV Chemical Hazard Characterizations: http://www.epa.gov/hpvis/abouthc.htm.

⁹ U.S. EPA – Basic IUR Information: http://www.epa.gov/opptintr/iur/pubs/guidance/basic-information.htm.

(including imported into) the U.S. during calendar year 2005 in quantities of 25,000 pounds or more at a single site. The reports include the identity, the quantity, and the physical form of the chemical manufactured or imported, and the number of workers reasonably likely to be exposed during manufacture of the chemical. For chemicals manufactured or imported in quantities of 300,000 pounds or more at a single site, additional reported information includes: the industrial processing and uses of the chemical; the number of industrial processing sites and workers reasonably likely to be exposed to the chemical at those sites; the consumer and commercial uses of the chemical; and an indication whether the chemical was used in products intended for use by children under 14 years of age.

EPA's screening-level exposure characterizations are based largely on the information submitted under the IUR reporting, although other exposure information submitted to the Agency (for example, in HPV submissions) or readily available through a limited set of publicly accessible databases¹⁰ was also considered. The screening-level exposure characterizations identify a potential (high, medium, or low) that each of five populations – the environment, the general population, workers, consumers, and children – might be exposed to the chemical. In most cases, this potential doesn't address the quantity, frequency, or duration of exposure, but refers only to the likelihood that an exposure could occur.

In many instances EPA is not able to fully disclose to the public all the IUR exposure-related data reviewed or relied upon in the development of the screening-level documents because some of the material was claimed as confidential business information (CBI) when it was submitted to the Agency. These CBI claims do limit the Agency's ability to be completely transparent in presenting some underlying exposure and use data for chemicals in public documents. EPA does consider all data, including data considered to be CBI, in the screening-level exposure and risk characterization process, and endeavors whenever possible to broadly characterize supporting materials claimed as confidential in ways that do not disclose actual CBI.

Risk Characterizations for HPV Chemicals

EPA combines the information from the screening-level exposure characterization with the screening-level hazard characterization to develop a qualitative screening-level risk characterization, as described in the Agency's guidance on drafting risk characterizations¹¹. These screening-level risk characterizations are technical documents intended to support subsequent priority-setting decisions and actions by OPPT. The purpose of the qualitative screening-level risk characterization is two-fold: to support initial risk-based decisions to prioritize chemicals, identify potential concerns, and inform risk management options; and to identify data needs for individual chemicals or chemical categories.

These initial characterization and prioritization documents do not constitute a final Agency determination as to risk, nor do they determine whether sufficient data are available to characterize risk. Recommended actions reflect EPA's relative judgment regarding this chemical or chemical category in comparison with others evaluated under this program, as well as the uncertainties presented by gaps that may exist in the available data.

¹⁰ U.S. EPA – Summary of Public Databases Routinely Searched: http://www.epa.gov/chemrtk/hpvis/pubdtsum.htm.

¹¹ U.S. EPA – Risk Characterization Program: http://www.epa.gov/osa/spc/2riskchr.htm.

QUALITATIVE SCREENING-LEVEL RISK CHARACTERIZATION OF HIGH PRODUCTION VOLUME CHEMICALS

SPONSORED CHEMICAL

Methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate (CAS No. 64667-33-0) [9th CI Name: Hexanoic acid, 4,6,6,6-tetrachloro-3,3-dimethyl-, methyl ester]

September 2008

Prepared by

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QUALITATIVE SCREENING-LEVEL RISK CHARACTERIZATION FOR Methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate (CAS No. 64667-33-0)

1. Physical-Chemical Properties and Environmental Fate

Methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate is a clear, colorless liquid at room temperature. It has moderate vapor pressure. The water solubility is considered moderate, based on an estimated value. It has moderate mobility in soil and moderate volatility. Hydrolysis is considered negligible under environmental conditions. Ready biodegradability data for methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate are not available but it is assumed to be persistent in the environment (P3). Methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate bioaccumulation potential is estimated to be moderate (B2).

2. Hazard Characterization

Aquatic Organism Toxicity. The potential hazard of methyl 4,6,6,6,-tetrachloro-3,3-dimethylhexanoate to aquatic organisms could not be assessed because of data gaps.

Human Health Toxicity. Acute oral and inhalation toxicity of methyl 4, 6,6,6,-tetrachloro-3,3-dimethylhexanoate in rats are low. Acute dermal toxicity in rabbits may be low but there is uncertainty because the highest concentration tested is below the limit dose generally used for such tests. Repeated-dose and reproductive data were not required for the HPV Challenge Program because methyl 4, 6,6,6,-tetrachloro-3,3-dimethylhexanoate is a closed-system intermediate. No data was submitted for developmental toxicity. *In vitro* studies were negative for mutagenic potential of methyl 4, 6,6,6,-tetrachloro-3,3-dimethylhexanoate. Data for chromosomal aberrations were not submitted. The potential health hazard of methyl 4, 6,6,6,-tetrachloro-3,3-dimethylhexanoate could not be determined.

3. Exposure Characterization

There were no 2002 or 2006 IUR reports for Methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate (CAS # 64667-33-0). No information on commercial/consumer uses were found in the IUR or any other sources.

Potential Exposures to Humans and the Environment:

Based on the information considered (including information from the HPV Challenge Program) and in combination with the Agency's professional judgment, EPA identifies, for the purposes of risk-based prioritization, a low relative ranking for each of the potentially exposed groups (including workers, general population, consumers and children) and the environment. In 2003, the Agency reviewed the information in the HPV submission and test plan and determined that the information satisfies the guidance to demonstrate that the chemical is a closed system intermediate. The chemical was determined to be manufactured and processed in systems which are expected to reduce the potential for worker exposure and environmental releases that could lead to other human and environmental exposure.

4. Risk Characterization

The statements and rationale provided below are intended solely for the purpose of this screening-level and qualitative risk characterization and will be used for prioritizing substances for future work in the Chemical Assessment and Management Program (ChAMP).

Risk Statement and Rationale

The Agency reviewed the information in the HPV submission and test plan and determined that the HPV chemical satisfied the guidance to demonstrate that the chemical is a closed-system intermediate. Methyl 4, 6,6,6,-tetrachloro-3,3-dimethylhexanoate was determined to be manufactured and processed in closed systems which are expected to reduce the potential for worker exposure and environmental releases that could lead to other human and environmental exposure. Therefore, there is a low concern for potential risks to aquatic organisms and the general population from environmental releases, and also to workers, consumers, and children.

SCREENING-LEVEL HAZARD CHARACTERIZATION OF HIGH PRODUCTION VOLUME CHEMICALS

SPONSORED CHEMICAL

Methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate (CAS No. 64667-33-0) [9th CI Name: Hexanoic acid, 4,6,6,6-tetrachloro-3,3-dimethyl-, methyl ester]

September 2008

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SCREENING-LEVEL HAZARD CHARACTERIZATION OF HIGH PRODUCTION VOLUME CHEMICALS

SCREENING-LEVEL HAZARD CHARACTERIZATION Methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate (CAS No. 64667-33-0)

Introduction

The sponsor, the 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; 9th CI name: hexanoic acid, 4,6,6,6-tetrachloro-3,3-dimethyl-, methyl ester) on December 30, 2002. EPA posted the submission on the ChemRTK HPV Challenge website on January 28, 2003 (http://www.epa.gov/chemrtk/pubs/summaries/methyl46/c14189tc.htm). EPA comments on the original submission were posted to the website on June 3, 2002. Public comments were also received and posted to the website. The sponsor submitted updated/revised documents on July 30, 2003, which were posted to the ChemRTK website on September 5, 2003.

The sponsor proposed reduced health testing, claiming that methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate is a closed-system intermediate (CSI). EPA's evaluation of the original and revised/updated information indicated that the sponsor adequately supported the "closed system intermediate" claim for the substance. Therefore, EPA has determined that the chemical qualifies for reduced testing – waiving of repeated-dose and reproductive toxicity testing.

On July 1, 2004, the sponsor informed EPA that they no longer manufactured or imported methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate and had no plans to in the future. The sponsor stated that for this reason, they do not believe conducting the additional tests identified in their test plans would be an appropriate allocation of human, animal and financial resources and that EPA should consider their submission based on existing data to be final.

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. In order to determine whether any new hazard information was developed since the time of the HPV submission, a search of the following databases was made from 2004 to May 2008: the NLM databases (ChemID to locate available data sources including Medline/PubMed, Toxline, HSDB, IRIS, NTP, ATSDR, EXTOXNET, EPA SRS, etc.), STN/CAS online databases (Registry file for locators, ChemAbs for toxicology data, RTECS, Merck, etc.) and Science Direct. 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 effects is based largely on SIDS endpoints and is described according to established EPA or OECD effect level definitions and hazard assessment practices.

Hazard Characterization

Methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate is a clear, colorless liquid at room temperature. It has moderate vapor pressure. The water solubility is considered moderate, based on an estimated value. It has moderate mobility in soil and moderate volatility. Hydrolysis is considered negligible under environmental conditions. Ready biodegradability data for methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate are not available but it is assumed to be persistent in the environment (P3). Methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate bioaccumulation potential is estimated to be moderate (B2).

The potential hazard of methyl 4,6,6,6,-tetrachloro-3,3-dimethylhexanoate to aquatic organisms could not be assessed because of data gaps.

Acute oral and inhalation toxicity of methyl 4,6,6,6,-tetrachloro-3,3-dimethylhexanoate in rats are low. Acute dermal toxicity in rabbits may be low but there is uncertainty because the highest concentration tested is below the limit dose generally used for such tests. Repeated-dose and reproductive data were waived for the HPV Challenge Program because methyl 4,6,6,6,-tetrachloro-3,3-dimethylhexanoate is a closed-system intermediate. No data was submitted for developmental toxicity. *In vitro* studies were negative for mutagenic potential of methyl 4, 6,6,6,-tetrachloro-3,3-dimethylhexanoate. Data for chromosomal aberrations were not submitted. The potential health hazard of methyl 4,6,6,6,-tetrachloro-3,3-dimethylhexanoate could not be determined.

Ready biodegradation, toxicity to aquatic organisms, developmental toxicity and chromosomal aberrations were identified as data gaps under the HPV Challenge Program.

1. Physical-Chemical Properties and Environmental Fate

The physical-chemical properties of methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate are summarized in Table 1a, while its environmental fate properties are given in Table 1b. The structure of the compound is provided in the Appendix.

Physical-Chemical Properties Characterization

Methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate is a clear, colorless liquid at room temperature. It has moderate vapor pressure. The water solubility is considered moderate, based on an estimated value.

Table 1a. Physical-Chemical Properties of Methyl 4,6,6,6-tetrachloro-3,3dimethylhexanoate ¹	
Property	Value
CAS No.	64667-33-0
Molecular Weight	296
Physical State	Liquid
Melting Point	Unavailable, liquid at room temperature
Boiling Point	110-114°C at 0.7 mm Hg (measured)
	101-103°C at 0.1 mm Hg (measured)
Vapor Pressure	0.6 mm Hg at 100°C (measured)
	0.05 mm Hg at 25°C (estimated) ²
Henry's Law Constant	1.48×10^{-5} atm-m ³ /mol (estimated) ²
Water Solubility	1.149mg/L (estimated) ²
Log K _{ow}	$4.74 \text{ (estimated)}^2$

¹FMC. 2002. Robust Summary for methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate.

http://www.epa.gov/chemrtk/pubs/summaries/methyl46/c14189rr.pdf.

http://www.epa.gov/opptintr/exposure/pubs/episuite.htm.

Environmental Fate Characterization

Methyl 4,6,6,6-tetrachloro-3,3,-dimethylhexanoate is expected to partition primarily to soil, according to a Level III fugacity model that assumes equal emissions to air, water, and soil. Based on its vapor pressure, methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate will exist in the vapor phase in the atmosphere. Vapor-phase methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate has an estimated half-life of 5.2 days due to photooxidation with hydroxyl radicals. Volatilization of methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate is considered moderate based on its Henry's Law constant. It has moderate mobility in soil. Hydrolysis is considered negligible under environmental conditions. Biodegradation data for methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate are not available; but it is estimated to be persistent (P3). Methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate bioaccumulation potential is ranked moderate (B2) based on an estimated log BCF of 3.0.

² US EPA. 2008. Estimation Programs Interface Suite [™] for Microsoft® Windows, v 3.20. United States Environmental Protection Agency, Washington, DC, USA.

Table 1b. Environmental Fate Characteristics of Methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate ¹	
Property	Value ¹
Photodegradation Half-life	5.2 days (estimated) ²
Hydrolysis Half-life	54 years at pH 7 (estimated)
	5.4 years at pH 8 (estimated)
Biodegradation	No data – expected to be stable to biodegradation
Bioconcentration	$Log BCF = 3.0^2$
Log K _{oc}	$2.8 \text{ (estimated)}^2$
Fugacity	Air = 0.67%
(Level III Model)	Water = 9.71%
	Soil = 72%
	Sediment = 17.6%
Persistence ³	P3 (high)
Bioaccumulation ³	B2 (moderate)

¹FMC 2002. U.S. High Production Volume (HPV) Chemical Challenge Program. Robust Summary for methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate. http://www.epa.gov/chemrtk/pubs/summaries/methyl46/c14189rr.pdf
²US EPA. 2008. Estimation Programs Interface Suite for Microsoft® Windows, v 3.20. United States Environmental Protection Agency, Washington, DC, USA. http://www.epa.gov/opptintr/exposure/pubs/episuite.htm.

Conclusion: Methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate is a clear, colorless liquid at room temperature. It has moderate vapor pressure. The water solubility is considered moderate, based on an estimated value. It has moderate mobility in soil and moderate volatility. Hydrolysis is considered negligible under environmental conditions. Ready biodegradability data for methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate are not available but it is assumed to be persistent in the environment (P3). Methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate bioaccumulation potential is estimated to be moderate (B2).

2. Environmental Effects – Aquatic Toxicity

In comments on the original test plan, EPA indicated that because of the estimated low water solubility and high log K_{ow} of methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate only a chronic daphnia test needed to be performed, unless results of proposed physical-chemical properties and fate testing indicated the estimated properties were greatly different than predicted, in which case test data for all three acute aquatic toxicity endpoints would need to be provided.

Acute Toxicity to Fish

No adequate data were submitted.

Acute Toxicity to Aquatic Invertebrates

No data were submitted.

Toxicity to Aquatic Plants

No data were submitted.

Chronic Toxicity to Aquatic Invertebrates

No data were submitted.

³ FR. 1999. Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances. *Federal Register* 64, Number 213 (November 4, 1999) Page 60194-60204.

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Conclusion: The potential hazard of methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate to aquatic organisms could not be assessed because of data gaps.

3. Human Health Effects

Acute Oral Toxicity

Sprague-Dawley rats (5/sex) were administered methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate at 5000 mg/kg-bw and observed for up to 14 days following dosing. No mortality was observed. Clinical signs of toxicity included abdominogenital staining, diarrhea, exophthalmos, lacrimation, decreased locomotion, nasal discharge and oral discharge. There were no gross lesions in any animal at gross necropsy.

 $LD_{50} > 5000 \text{ mg/kg-bw}$

Acute Inhalation Toxicity

Sprague-Dawley rats (5/sex) were exposed (whole-body) to methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate at 5.5 ppm (~ 0.07 mg/L) for 6 hours and observed for up to 14 days following dosing. No mortality was observed. Clinical signs of toxicity included irregular breathing patterns during the first hour of treatment. One rat had red periocular fur around the left eye immediately following exposure. No gross lesions were noted at necropsy. $LC_{50} > 0.07$ mg/L

Acute Dermal Toxicity

New Zealand White rabbits (5/dose, sex not specified) were administered methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate dermally at 28.2 or 423 mg/kg-bw under occlusive conditions for 24 hours and observed for 14 days. No mortality or body weight change was observed. Slight erythema and desquamation were noted sporadically. No gross lesions were observed at necropsy.

 $LD_{50} > 423 \text{ mg/kg-bw}$

Repeated-Dose Toxicity

EPA indicated that the information provided by the sponsor was sufficient to meet the criteria for demonstrating that methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate is a closed-system intermediate. No repeated-dose toxicity data were submitted and the EPA agreed that testing was not required for this endpoint.

Reproductive/Developmental Toxicity

No data were submitted. Data Gap.

Genetic Toxicity - Gene Mutation

In vitro

Salmonella typhimurium strains TA1535, TA1537, TA1538, TA98 and TA100 were exposed to methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate at concentrations of 10 – 10,000 μg/plate in the presence and absence of metabolic activation. Positive and negative controls were used, but their responses were not provided. **Methyl 4,6,6-tetrachloro-3,3-dimethylhexanoate was not mutagenic in this assay.**

Genetic Toxicity - Chromosomal Aberrations

In vitro

No data were submitted. Data Gap.

Conclusion: Acute oral and inhalation toxicity of methyl 4, 6,6,6,-tetrachloro-3,3-dimethylhexanoate in rats are low. Acute dermal toxicity in rabbits may be low but there is uncertainty because the highest concentration tested is below the limit dose generally used for such tests. Repeated-dose and reproductive data were not required for the

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HPV Challenge Program because methyl 4, 6,6,6,-tetrachloro-3,3-dimethylhexanoate is a closed-system intermediate. No data was submitted for developmental toxicity. *In vitro* studies were negative for mutagenic potential of methyl 4, 6,6,6,-tetrachloro-3,3-dimethylhexanoate. Data for chromosomal aberrations were not submitted. The potential health hazard of methyl 4, 6,6,6,-tetrachloro-3,3-dimethylhexanoate could not be determined.

APPENDIX

Summary Table of the Screening Information Data Set as Submitted under the U.S. HPV Challenge Program	
Endpoints	SPONSORED CHEMICAL Methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate (CAS No. 64667-33-0)
Structure	CI CI CI CI
Summary of Environmental Effects – Aquatic Toxicity Data	
Fish 96-h LC ₅₀ (mg/L)	— Data Gap
Aquatic Invertebrates 48-h EC ₅₀ (mg/L)	— Data Gap
Aquatic Plants 72-h EC ₅₀ (mg/L)	— Data Gap
Chronic Toxicity to Invertebrates 21-day EC ₅₀ (mg/L)	— Data Gap
Summary of Human Health Data	
Acute Oral Toxicity LD ₅₀ (mg/kg-bw)	> 5000
Acute Inhalation Toxicity LC ₅₀ (mg/L)	> 0.07
Acute Dermal Toxicity LD ₅₀ (mg/kg-bw)	> 423
Developmental Toxicity NOAEL/LOAEL	— Data Gap
Genetic Toxicity – Gene Mutation In vitro	Negative
Genetic Toxicity – Chromosomal Aberrations In vitro	— Data Gap

[—] indicates that endpoint was not addressed for this chemical.

Screening Level Exposure Characterization for HPV Challenge Chemical

Methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate CAS # 64667-33-0

September 2008

Prepared by

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Screening Level Exposure Characterization Methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate (CAS # 64667-33-0)

Non-CBI Executive Summary

There were no 2002 or 2006 IUR reports for Methyl 4,6,6,6-tetrachloro-3,3-dimethylhexanoate (CAS # 64667-33-0).

Potential Exposures to Humans and the Environment:

Based on the information considered (including information from the HPV Challenge Program) and in combination with Agency's professional judgment, EPA identifies, for the purposes of risk-based prioritization, a low relative ranking for each of the potentially exposed groups (including workers, general population, consumers and children) and the environment. In 2003, the Agency reviewed the information in the HPV submission and test plan and determined that the information satisfies the guidance to demonstrate that the chemical is a closed system intermediate. The chemical was determined to be manufactured and processed in systems which are expected to reduce the potential for worker exposure and environmental releases that could lead to other human and environmental exposure. There are no 2002 or 2006 IUR reports for this chemical. No information on commercial/consumer uses were found in the IUR or any other sources.

¹² USEPA, 2003. EPA Comments on Chemical RTK HPV Challenge Submission. Letter dated May 28, 2003. Accessed June 16, 2008. http://www.epa.gov/chemrtk/pubs/summaries/methyl46/c14189rr.pdf.