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)

This document is based on screening-level characterizations done by EPA on the environmental fate, hazard, and exposure of the listed chemical. The information used by EPA includes data submitted under the HPV Challenge Program[1] and the 2006 Inventory Update Reporting (IUR)[2], and data publicly available through other selected sources[3]. This screening-level prioritization presents EPA's initial thinking regarding the potential risks presented by this chemical and future possible actions that may be needed. 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. Rather, they are interim evaluations. Recommended actions may be considered by EPA in the future based on a relative judgment regarding this chemical in comparison with others evaluated under this program, and in light of the uncertainties presented by gaps in the available data that may be determined to exist. These evaluations contribute to meeting U.S. commitments under the chemicals cooperation work being done in North America[4] through the EPA Chemical Assessment and Management Program (ChAMP)[5].

This chemical was considered in 2003 to have met the HPV Challenge Program guidance for a closed-system intermediate, a chemical manufactured and processed only in closed systems to produce other chemicals. Because closed-system intermediates have a limited potential for exposure generally attributable only to isolated accidental releases, toxicity testing elements in the HPV Challenge Program were reduced for those chemicals, and consisted of the Screening Information Data Set (SIDS) minus the tests for repeated dose toxicity and reproductive toxicity, but including a developmental toxicity test[6]. The sponsor did not provide all of the elements of this reduced data set for this chemical.

Hazard and Fate Summary:

- Human Health: The potential hazard of this chemical could not be determined based on the available data. Acute oral and inhalation toxicity in rats is 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. No data were submitted for developmental toxicity. *In vitro* studies were negative for mutagenic potential. No *in vitro* data were submitted for chromosomal aberration potential.
- Environment: The potential hazard of this chemical to aquatic organisms could not be assessed because of data gaps.

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[1] US EPA, HPV Challenge Program information: http://epa.gov/hpv/.
[2] US EPA, IUR information: http://www.epa.gov/oppt/iur/index.htm.
[3] US EPA, Information on additional public databases used: http://www.epa.gov/hpvis/pubdtsum.htm.
[4] US EPA, U.S. Commitments to North American Chemicals Cooperation: http://www.epa.gov/hpv/pubs/general/sppframework.htm.
[5] US EPA, ChAMP information: http://www.epa.gov/champ/.
[6] US EPA, Guidance for Testing Closed System Intermediates: http://www.epa.gov/chemrtk/pubs/general/closed9.htm.

- Persistence and Bioaccumulation:
  - Available data suggest that this chemical has high persistence.
  - Available data indicate that this chemical has moderate bioaccumulation potential.

Exposure Summary:

- Both Confidential Business Information (CBI) and non-confidential information from IUR and other sources are used in developing initial prioritizations.
- Production Volume: No IUR reports were submitted on this chemical in either the 2002 or 2006 reporting years, so the current production volume is unknown. It was included in the HPV Challenge Program because it was reported at HPV levels in earlier years.
- Uses: In 2003, the Agency reviewed the information in the HPV Challenge Program submission and determined that this chemical met the guidance for a closed-system intermediate.
- General Population and Environment: EPA identifies a low potential that the general population and the environment might be exposed to this chemical.
- Workers: EPA identifies a low potential for worker exposure.
- Consumers: EPA identifies a low potential that consumers might be exposed.
- Children: EPA identifies a low potential that children might be exposed.

Risk Characterization Summary:

EPA reviewed the information in the HPV Challenge Program submission for this chemical in 2003 and determined that it met the guidance for a closed-system intermediate. While there is a low concern for potential exposure to aquatic organisms, workers, consumers, children, and the general population from environmental releases, because of the lack of hazard data, EPA cannot identify an accurate level of risk for these populations.

- Potential Risk to Aquatic Organisms from Environmental Releases: *LOW CONCERN.*
- Potential Risk to the General Population from Environmental Releases: *LOW CONCERN.*
- Potential Risk to Workers: *LOW CONCERN.*
- Potential Risk to Consumers from Known Uses: *LOW CONCERN.*
- Potential Risk to Children: *LOW CONCERN.*

Regulatory and Related Information Summary:

- This chemical is listed on the TSCA Inventory. It is not otherwise regulated under TSCA.

Assumptions and Uncertainties:

- EPA assumes that potential exposures are very limited, based on the reported use. Given the absence of recent reporting, however, this information is not current.
- The HPV Challenge Program allowed for a reduced set of testing for chemicals that met the guidance for closed-system intermediates, reflecting the information needed to evaluate the hazards in the event of an accident. That reduced set of data was not fully provided on this chemical, however, and the potential hazard to health and the environment cannot be determined on the basis of the available data.

- The lack of any IUR reporting on this chemical in the 2002 and 2006 reporting cycles indicates that the production volume for this chemical in the individual years covered by those reporting cycles was below 10,000 pounds (2002) and 25,000 pounds (2006) per site.

Rationale Leading To Prioritization Decision:

- The manufacture and processing of this chemical only as an intermediate to produce other chemicals in systems that may significantly reduce the potential for worker exposure and environmental releases lead to a generally low concern for risk because exposures are unlikely.
- Accidental releases, however, remain an uncharacterized potential concern because the potential hazards have not been determined. The potential that an accidental release may occur cannot be determined from the available information.
- The absence of 2006 IUR reports on this chemical suggests that its current production and importation volume is low.

Prioritization Decision:

- LOW PRIORITY – No further action suggested at this time.
- This decision is based on the very low perceived potential for exposure to all populations, despite the lack of characterization on potential hazards. The voluntary completion of the outstanding, unsatisfied HPV Challenge Program data elements to permit the characterization of these hazards, or the voluntary submission of information documenting the low production volume suggested by the absence of IUR reports during the last two IUR cycles, could further resolve these potential concerns.
- EPA may consider revisiting this prioritization decision if future IUR reports indicate an increase in production or importation volume.

Supporting Documentation:

Screening-Level Risk Characterization: September 2008
Screening-Level Hazard Characterization: September 2008
Screening-Level Exposure Characterization: September 2008