

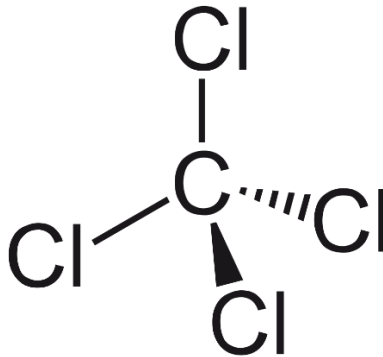


United States
Environmental Protection Agency

December 2022
EPA Document #740-S-22-002
Office of Chemical Safety and
Pollution Prevention

Non-Technical Summary of the Risk Evaluation for Carbon Tetrachloride (Methane, Tetrachloro-)

CASRN: 56-23-5



December 2022

BACKGROUND

- The TSCA risk evaluation for carbon tetrachloride was issued in November 2020.
- Uses for carbon tetrachloride include use as a feedstock in the production of hydrochlorofluorocarbons (HCFCs), hydrofluorocarbons (HFCs) and hydrofluoroolefins (HFOs). In addition, EPA has identified regulated use of carbon tetrachloride as a process agent in the manufacturing of petrochemicals-derived and agricultural products and other chlorinated compounds such as chlorinated paraffins, chlorinated rubber and others that may be used in the formulation of solvents for adhesives, asphalt, paints and coatings, and elimination of nitrogen trichloride in the production of chlorine and caustic soda. The use of carbon tetrachloride for non-feedstock uses (*i.e.*, process agent, laboratory chemical) is regulated in accordance with the Montreal Protocol and Title VI of the Clean Air Act (CAA) Amendments of 1990. In addition, the Consumer Product Safety Commission (CPSC) banned the use of carbon tetrachloride in consumer products (excluding unavoidable residues not exceeding 10 ppm atmospheric concentration) in 1970.
- The total annual production volume reported for carbon tetrachloride under the Chemical Data Reporting (CDR) rule was between 100 and 250 million pounds during the 2016 to 2019 period (per the 2020 CDR reporting cycle).

ACTION

- EPA is releasing a final revision to the risk determination on carbon tetrachloride with an order withdrawing the TSCA section 6(i)(1) order previously included in the November 2020 risk evaluation. This action follows issuance of a draft revised risk determination that EPA issued for comment in August 2022 (87 FR 52766). EPA has determined that carbon tetrachloride presents an unreasonable risk of injury to health under its conditions of use.
- This final risk evaluation, which includes the 2020 risk evaluation and a 2022 final revised unreasonable risk determination, is conducted pursuant to the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which requires EPA to prioritize and evaluate the risk of existing chemicals to determine whether a chemical presents an unreasonable risk of injury to health or the environment under the conditions of use. Under TSCA, if a chemical is determined to present an unreasonable risk, then EPA will propose risk management regulatory action to the extent necessary so that carbon tetrachloride no longer presents an unreasonable risk.
- The 2020 risk evaluation, supplemental materials, 2022 revised unreasonable risk determination and corresponding response to public comments can be found in dockets EPA-HQ-OPPT-2019-0499 and EPA-HQ-OPPT-2016-0733 on www.regulations.gov.
- Carbon tetrachloride was selected in 2016 as one of the first 10 chemicals for risk evaluation under section 6 of TSCA.

KEY POINTS

- Unreasonable risks include cancer and liver toxicity from chronic inhalation and dermal exposures and liver toxicity from acute dermal exposures. Cancer risks were assessed using two approaches: linear low-dose extrapolation and threshold. This is based on considerations for the modes of action for the different cancers evaluated.
- Public comments and external scientific peer review informed the development of the carbon tetrachloride final risk evaluation. EPA published the carbon tetrachloride final revised unreasonable risk determination in December 2022, the carbon tetrachloride draft revised

unreasonable risk determination in August 2022, the carbon tetrachloride risk evaluation in November 2020, the carbon tetrachloride draft risk evaluation in January 2020 (for a 60-day public comment period), the carbon tetrachloride problem formulation document in May 2018, and the scope document in June 2017.

- Additionally, EPA held a peer review meeting of the Science Advisory Committee on Chemicals (SACC) on the draft risk evaluation of carbon tetrachloride on February 25-26, 2020.
- In the revised unreasonable risk determination for carbon tetrachloride, EPA is making an unreasonable risk determination for carbon tetrachloride as a whole chemical substance, rather than a condition of use-specific approach. The whole chemical approach is appropriate for carbon tetrachloride because there are benchmark exceedances for a substantial number of conditions of use for human health, and the severity of the health effects associated with carbon tetrachloride exposures.
- After evaluating 15 conditions of use, EPA determined that carbon tetrachloride presents an unreasonable risk to human health under its conditions of use based on risk of injury to health of workers and occupational non-users (ONUs).
- In addition, EPA is revising the assumption that workers always and properly use personal protective equipment (PPE), although EPA does not question public comments received regarding the occupational safety practices often followed by industry. Information on the use of PPE as a means of mitigating risk will be considered during the risk management phase. Removing the assumption that workers wear PPE in making the whole chemical risk determination for carbon tetrachloride did not alter the conditions of use that drive the unreasonable risk. However, without the assumed use of PPE, inhalation exposures to workers now also drive the unreasonable risk and, in addition to there being risks of cancer effects from dermal exposures, risks of non-cancer effects (specifically liver toxicity) from dermal exposures are now also driving the unreasonable risk. In addition, the November 2020 Risk Evaluation contained a typographical error in the acute dermal point of departure (POD). This error was corrected in a memorandum made available to the public in the docket July 2022 and the changes to the risk estimates for acute dermal exposures are reflected in the revision to the risk determination. The corrections do not alter the conditions of use that drive the unreasonable risk determination for carbon tetrachloride.
- Overall, 13 of the 15 conditions of use evaluated drive the carbon tetrachloride whole chemical unreasonable risk determination due to risks identified for human health. These conditions of use include but are not limited to: domestic manufacturing and import; processing as a reactant or intermediate; processing in the incorporation into formulation, mixtures or reaction products in the manufacturing of petrochemicals-derived products, agricultural products, and other basic organic and inorganic chemicals; laboratory uses; recycling; industrial and commercial uses including as a processing aid and additive; and disposal.
- The conditions of use that do not drive EPA's unreasonable risk determination for carbon tetrachloride are processing as a reactant in reactive ion etching (i.e., semiconductor manufacturing) and distribution in commerce.
- For carbon tetrachloride the exposure pathways that were or could be regulated under other EPA-administered statutes were excluded from the November 2020 carbon tetrachloride risk evaluation. This resulted in the ambient air and ambient water pathways for carbon tetrachloride not being assessed. EPA is conducting a screening approach to assess risks from the air and water pathways for several of the first 10 chemicals, including carbon tetrachloride.

The goal of the recently-developed screening approach is to remedy this exclusion and to determine if there may be risks that were unaccounted for in the carbon tetrachloride risk evaluation. While this analysis is underway, EPA is not incorporating the screening-level approach into this revised unreasonable risk determination. EPA expects to describe its findings regarding the chemical-specific application of this screening-level approach in the forthcoming proposed rule under TSCA section 6(a) for carbon tetrachloride.

- EPA did not identify risks of injury to the environment that drive the unreasonable risk determination for carbon tetrachloride.
- As noted above, EPA is releasing a final revision to the unreasonable risk determination with an order withdrawing the TSCA section 6(i)(1) order previously included in the November 2020 risk evaluation. EPA is also releasing a document with response to public comments received on the draft revised risk determination for carbon tetrachloride published in August 2022.

NEXT STEPS

- EPA has issued the final risk evaluation (2020 risk evaluation and 2022 revised risk determination) for carbon tetrachloride, meeting the requirements set forth in TSCA section 6(b) for chemical risk evaluations. EPA is now initiating the process to address the unreasonable risk identified. Following the issuance of the final risk evaluation, EPA will address, by rule, the unreasonable risk identified. The public will have an opportunity to comment on a proposed rule before EPA issues a final rule.

SUMMARY OF UNREASONABLE RISK DETERMINATION

EPA has determined that carbon tetrachloride presents an unreasonable risk of injury to human health under the conditions of use.

EPA's unreasonable risk determination for carbon tetrachloride is driven by risks associated with the following conditions of use, considered singularly or in combination with other exposures:

- Manufacturing (Domestic Manufacture);
- Manufacturing (Import);
- Processing as a reactant in the production of hydrochlorofluorocarbon, hydrofluorocarbon, hydrofluoroolefin, and perchloroethylene;
- Processing: Incorporation into formulation, mixtures or reaction products (petrochemicals-derived manufacturing; agricultural products manufacturing; other basic organic and inorganic chemical manufacturing);
- Processing: Repackaging for use as a laboratory chemical;
- Processing: Recycling;
- Industrial/commercial use as an industrial processing aid in the manufacture of petrochemicals-derived products and agricultural products;
- Industrial/commercial use in the manufacture of other basic chemicals (including chlorinated compounds used in solvents, adhesives, asphalt, paints and coatings, and elimination of nitrogen trichloride in the production of chlorine and caustic soda);
- Industrial/commercial use in metal recovery;
- Industrial/commercial use as an additive;
- Industrial/commercial use in specialty uses by the Department of Defense;

- Industrial/commercial use as a laboratory chemical; and
- Disposal.

The following conditions of use do not drive EPA's unreasonable risk determination for carbon tetrachloride:

- Processing as a reactant/intermediate in reactive ion etching; and
- Distribution in commerce.

EPA is not making condition of use-specific risk determinations for these conditions of use, is not issuing a final order under TSCA section 6(i)(1) for these conditions of use, and does not consider the revised risk determination for carbon tetrachloride to constitute a final agency action at this point in time.

Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management regulatory action to the extent necessary so that carbon tetrachloride no longer presents an unreasonable risk. EPA expects to focus its risk management action on the conditions of use that drive the unreasonable risk. However, it should be noted that, under TSCA section 6(a), EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management requirements in section 6(a) related to manufacture (including import), processing, distribution in commerce, commercial use, and disposal as part of its regulatory options to address the unreasonable risk. As a general example, EPA may regulate upstream activities (e.g., processing, distribution in commerce) to address downstream activities (e.g., commercial uses) driving unreasonable risk, even if the upstream activities do not drive the unreasonable risk.