

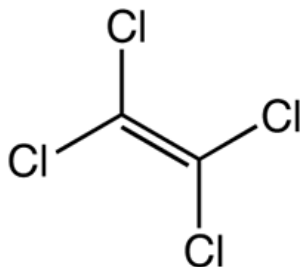


United States
Environmental Protection Agency

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Office of Chemical Safety and
Pollution Prevention

Non-Technical Summary of the Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro-)

CASRN: 127-18-4



December 2022

BACKGROUND

- The TSCA risk evaluation for perchloroethylene (PCE) was issued in December 2020.
- Uses for PCE include use in production of fluorinated compounds and as a solvent in dry cleaning and vapor degreasing. A variety of consumer and commercial products use PCE, such as adhesives (arts and crafts, as well as light repairs), aerosol degreasers, brake cleaners, aerosol lubricants, sealants, stone polish, stainless steel polish, and wipe cleaners.
- The total aggregate production volume reported for PCE under the Chemical Data Reporting rule ranged from 250 million to 500 million pounds between 2016 and 2019.

ACTION

- EPA is releasing a final revision to the risk determination on PCE with an order withdrawing the TSCA section 6(i)(1) order previously included in the December 2020 risk evaluation. This action follows issuance of a draft revised risk determination that EPA issued for comment in June 2022 (87 FR 39085). EPA has determined that PCE 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 PCE 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-2019-0502 and EPA-HQ-OPPT-2016-0732 on www.regulations.gov.
- PCE was selected in 2016 as one of the first 10 chemicals for risk evaluation under section 6 of TSCA.

KEY POINTS

- EPA has identified risks for non-cancer adverse effects from acute and chronic inhalation and dermal exposures to PCE, and for cancer from chronic inhalation and dermal exposures to PCE.
- Public comments and external scientific peer review informed the development of the PCE final risk evaluation. EPA published the PCE final revised unreasonable risk determination in December 2022, the PCE draft revised unreasonable risk determination in June 2022, the PCE risk evaluation in December 2020, the PCE draft risk evaluation in April 2020 (for a 60-day public comment period), the PCE 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 PCE on May 26-29, 2020.
- In the revised unreasonable risk determination for PCE, EPA is making an unreasonable risk determination for PCE as a whole chemical substance, rather than a condition of use-specific approach. The whole chemical approach is appropriate PCE because there are benchmark exceedances for a substantial number of conditions of use for human health, and there are severe health effects associated with PCE exposures.

- After evaluating 61 conditions of use, EPA determined that PCE presents an unreasonable risk to human health under its conditions of use based on risk of injury to health of workers, occupational non-users (ONUs), consumers, and bystanders.
- 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 PCE would mean that: one condition of use in addition to the original 59 conditions of use drives the unreasonable risk for PCE; an additional route of exposure (*i.e.*, inhalation) is also identified as driving the unreasonable risk to workers in many of those 59 conditions of use; and additional risks for acute non-cancer effects and cancer from inhalation and dermal exposures also drive the unreasonable risk in many of those 59 conditions of use (where previously those conditions of use were identified as presenting unreasonable risk only for chronic non-cancer effects or for chronic non-cancer effects and cancer).
- Overall, 60 of the 61 conditions of use evaluated drive the PCE 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 and incorporation into a formulation, mixture or reaction product; repackaging and recycling; a variety of industrial and commercial uses, including several types of degreasing uses, lubricants, adhesives, paints and coatings, automotive care products, metal and stone polishes, welding, textile processing, use in wood furniture manufacturing, foundry application, and various dry cleaning-related uses; and all consumer uses including exposure to certain recently dry cleaned articles.
- The condition of use that does not drive EPA's unreasonable risk determination for PCE is distribution in commerce.
- For PCE, the exposure pathways that were or could be regulated under another EPA-administered statute were excluded from the December 2020 PCE Risk Evaluation. This resulted in the surface water, drinking water, and ambient air pathways for PCE not being assessed for human health exposures or the general population. EPA is conducting a screening approach to assess risks from the air and water pathways for several of the first 10 chemicals, including PCE. 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 PCE 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 PCE.
- EPA did not identify risks of injury to the environment that drive the unreasonable risk determination for PCE.
- 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 December 2020 risk evaluation. EPA is also releasing a document with response to public comments received on the draft revised risk determination for PCE published in June 2022.

NEXT STEPS

- EPA has issued the final risk evaluation (2020 risk evaluation and 2022 revised risk determination) for PCE, 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 PCE presents an unreasonable risk of injury to human health under the conditions of use.

EPA's unreasonable risk determination for PCE 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/intermediate;
- Processing into formulation, mixture or reaction product for cleaning and degreasing products;
- Processing into formulation, mixture or reaction product for adhesive and sealant products;
- Processing into formulation, mixture or reaction product for paint and coating products;
- Processing into formulation, mixture or reaction product for other chemical products and preparations;
- Processing by repackaging;
- Recycling;
- Industrial and commercial use as solvent for open-top batch vapor degreasing;
- Industrial and commercial use as solvent for closed-loop batch vapor degreasing;
- Industrial and commercial use as solvent for in-line conveyORIZED vapor degreasing;
- Industrial and commercial use as solvent for in-line web cleaner vapor degreasing;
- Industrial and commercial use as solvent for cold cleaning;
- Industrial and commercial use as solvent for aerosol spray degreaser/cleaner;
- Industrial and commercial use as a solvent for aerosol lubricants;
- Industrial and commercial use as a solvent for penetrating lubricants and cutting tool coolants.
- Industrial and commercial use in solvent-based adhesives and sealants;
- Industrial and commercial use in solvent-based paints and coatings;
- Industrial and commercial use in maskants for chemical milling;
- Industrial and commercial use as a processing aid in pesticide, fertilizer and other agricultural chemical manufacturing;
- Industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing;
- Industrial and commercial use in wipe cleaning;
- Industrial and commercial use in other spot cleaning and spot removers, including carpet cleaning;

- Industrial and commercial use in mold release;
- Industrial and commercial use in dry cleaning and spot cleaning post-2006 dry cleaning;
- Industrial and commercial use in dry cleaning and spot cleaning 4th/5th gen only dry cleaning;
- Industrial and commercial use in automotive care products (*e.g.*, engine degreaser and brake cleaner);
- Industrial and commercial use in non-aerosol cleaner;
- Industrial and commercial use in metal (*e.g.*, stainless steel) and stone polishes;
- Industrial and commercial use in laboratory chemicals;
- Industrial and commercial use in welding;
- Industrial and commercial use in other textile processing;
- Industrial and commercial use in wood furniture manufacturing;
- Industrial and commercial use in foundry applications;
- Industrial and commercial use in specialty Department of Defense uses (oil analysis and water pipe repair);
- Commercial use in inks and ink removal products (based on printing);
- Commercial use in inks and ink removal products (based on photocopying);
- Commercial use for photographic film;
- Commercial use in mold cleaning, release and protectant products;
- Consumer use in cleaners and degreasers (other);
- Consumer use as a dry cleaning solvent;
- Consumer use in automotive care products (brake cleaner);
- Consumer use in automotive care products (parts cleaner);
- Consumer use in aerosol cleaner (vandalism mark and stain remover);
- Consumer use in non-aerosol cleaner (*e.g.*, marble and stone polish);
- Consumer use in lubricants and greases (cutting fluid);
- Consumer use in lubricants and greases (lubricants and penetrating oils);
- Consumer use in adhesives for arts and crafts (including industrial adhesive, arts and crafts adhesive, gun ammunition sealant);
- Consumer use in adhesives for arts and crafts (livestock grooming adhesive);
- Consumer use in adhesives for arts and crafts (column adhesive, caulk and sealant);
- Consumer use in solvent-based paints and coatings (outdoor water shield (liquid));
- Consumer use in solvent-based paints and coatings (coatings and primers (aerosol));
- Consumer use in solvent-based paints and coatings (rust primer and sealant (liquid));
- Consumer use in solvent-based paints and coatings (metallic overglaze);
- Consumer use in metal (*e.g.*, stainless steel) and stone polishes;
- Consumer use in inks and ink removal products;
- Consumer use in welding;
- Consumer use in mold cleaning, release and protectant products; and
- Disposal.

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

- Distribution in commerce

EPA is not making a condition of use-specific risk determination for this condition of use, is not issuing a final order under TSCA section 6(i)(1) for this condition of use, and does not consider the revised risk determination for PCE 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 PCE 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., consumer uses) driving unreasonable risk, even if the upstream activities do not drive the unreasonable risk.