



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

SUBJECT: Existing Chemical Exposure Limit (ECEL) for Occupational Use of Perchloroethylene

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EPA has developed an 8-hour existing chemical exposure limit (ECEL) in support of risk management efforts on perchloroethylene under TSCA section 6(a), 15 U.S.C. §2605. EPA calculated the ECEL to be 0.14 ppm (0.98 mg/m³) for inhalation exposures to perchloroethylene as an 8-hour time-weighted average (TWA) and for use in workplace settings (see Appendix A) based on the occupational chronic, non-cancer human equivalent concentration (HEC) for neurotoxicity (CNS). EPA has determined, as a matter of risk management policy, that ensuring exposures remain at or below the ECEL will eliminate the unreasonable risk of injury to health resulting from inhalation exposures in an occupational setting for those conditions of use identified as presenting unreasonable risk in the Risk Evaluation for perchloroethylene ([U.S. EPA, 2020](#)) under TSCA.

EPA expects that at the chronic non-cancer ECEL of 0.14 ppm (0.98 mg/m³) a worker also is protected against neurotoxicity resulting from acute occupational exposure. In addition, this ECEL protects against excess risk of cancer above the 1x10⁻⁴ benchmark resulting from lifetime exposure if ambient exposures are kept below this ECEL.

The Occupational Safety and Health Administration (OSHA) set a permissible exposure limit (PEL) as an 8-hour TWA for perchloroethylene (<https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1000TABLEZ2>). However, as noted on OSHA's website, "OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970 and have not been updated since that time." EPA's ECEL is a lower value and is based on newer information and analysis, from the 2020 Risk Evaluation for Perchloroethylene ([U.S. EPA, 2020](#)). In addition, OSHA's PEL must undergo both risk assessment and feasibility assessment analyses before selecting a level that will substantially reduce risk under the Occupational Safety and Health Act.

Published NIOSH/OSHA/EPA methods were identified and the ECEL is within the limit of detection (LOD) of some of the methods identified in Appendix B.

Appendix A: ECEL and Other Exposure Limit Calculations

This appendix presents the calculations used to estimate the ECEL and other exposure limits used for comparison. The resulting ECEL value was rounded. The values used in the equations are included in the Final Risk Evaluation for Perchloroethylene ([U.S. EPA, 2020](#)).

Chronic Non-Cancer ECEL

The 8-hour ECEL is the concentration that EPA determined would indicate no unreasonable risk of injury to human health from chronic inhalation exposures in an occupational setting for the endpoints that are the basis for the TSCA unreasonable risk determination. The ECEL was calculated for the occupational chronic, non-cancer human equivalent concentration for neurotoxicity (CNS) as the concentration at which the chronic margin of exposure (MOE) would equal the benchmark MOE for chronic occupational exposures with the following equation:

$$\begin{aligned} ECEL_{\text{inhal,occupational}} &= \frac{HEC_{\text{chronic,occupational}}}{\text{Benchmark } MOE_{\text{chronic}}} * \frac{AT_{\text{POD chronic}}}{ED * EF * WY} \\ &= \frac{14.5 \text{ ppm}}{100} * \frac{8h/d * 250d/y * 40 y}{8h/d * 250d/y * 40 y} = 0.14 \text{ ppm} \end{aligned}$$

$$ECEL \left(\frac{\text{mg}}{\text{m}^3} \right) = \frac{ECEL \text{ ppm} * MW}{\text{Molar Volume}} = \frac{0.14 \text{ ppm} * 165.83 \frac{\text{g}}{\text{mol}}}{24.45 \frac{\text{L}}{\text{mol}}} = 0.98 \frac{\text{mg}}{\text{m}^3}$$

Where:

Molar Volume = 24.45 L/mol, the volume of a mole of gas at 1 atm and 25 °C
 MW = Molecular weight of PCE (165.83 g/mole)

Acute Non-Cancer Exposure Limit

The acute occupational exposure limit (EL_{acute}) was calculated as the concentration at which the acute MOE would equal the benchmark MOE for acute occupational exposures using the following equation:

$$EL_{\text{acute}} = \frac{HEC_{\text{acute,occupational}}}{\text{Benchmark } MOE_{\text{acute}}} * \frac{AT_{\text{PODacute}}}{ED} = \frac{5.0 \text{ ppm}}{10} * \frac{\frac{8h}{d}}{\frac{8h}{d}} = 0.50 \text{ ppm} = 3.4 \frac{\text{mg}}{\text{m}^3}$$

Lifetime Cancer Exposure Limit

The EL_{cancer} is the concentration at which the extra cancer risk is equivalent to the benchmark cancer risk of 1×10^{-4} :

$$\begin{aligned} EL_{\text{cancer}} &= \frac{\text{Benchmark}_{\text{Cancer}}}{IUR} * \frac{AT_{IUR}}{ED * EF * WY} = \frac{1 \times 10^{-4}}{1.8 \times 10^{-3} \text{ per ppm}} * \frac{24 \frac{h}{d} * \frac{365d}{y} * 78y}{8 \frac{h}{d} * \frac{250d}{y} * 40y} = \\ &= 0.47 \text{ ppm} = 3.2 \frac{\text{mg}}{\text{m}^3} \end{aligned}$$

Where:

| | | |
|---|---|---|
| AT _{PODchronic} | = | Averaging time for the POD/HEC used for evaluating non-cancer, chronic occupational risk, based on study conditions and/or HEC adjustments (8 hrs/day for 250 days/yr) and assuming the number of years matches the high-end working years (WY, 40 yrs) for a worker (RE Section 4.2.2.1) |
| AT _{PODacute} | = | Averaging time for the POD/HEC used for evaluating non-cancer, acute occupational risk, based on study conditions and/or any HEC adjustments (8hrs/day) |
| AT _{IUR} | = | Averaging time for the cancer IUR, based on study conditions and any adjustments (24 hrs/day for 365 days/yr) and averaged over a lifetime (78 yrs) (Supplemental File: Releases and Occupational Exposure Assessment; Appendix B). |
| Benchmark MOE _{acute} | = | Acute non-cancer benchmark margin of exposure, based on the total uncertainty factor of 10 (RE Table 3-7) |
| Benchmark MOE _{chronic} | = | Chronic non-cancer benchmark margin of exposure, based on the total uncertainty factor of 100 (RE Table 3-8) |
| Benchmark _{Cancer} | = | Benchmark for excess lifetime cancer risk |
| ECEL | = | Existing chemical exposure limit (mg/m ³) |
| EL _{acute} | = | Exposure limit based on acute neurotoxicity (CNS) |
| EL _{cancer} | = | Exposure limit based on excess cancer risk |
| ED | = | Exposure duration (8 hrs/day) (RE Table 3-8) |
| EF | = | Exposure frequency (250 days/yr), (RE Section 4.2.2.1) |
| HEC _{acute or chronic, occupational} | = | Human equivalent concentration for acute or chronic occupational exposure scenarios (RE Tables 3-7 and 3-8) |
| IUR | = | Inhalation unit risk (per ppm) (RE Table 3-6) |
| WY | = | Working years per lifetime at the 95 th percentile (40 yrs) (Supplemental File: Releases and Occupational Exposure Assessment; Appendix B) |

Unit conversion:

1 ppm = 6.78 mg/m³ (based on molecular weight of 165.83 g/mol for PCE and molar volume of 24.45 L/mol at 25°C and 1 atm pressure)

$$ECEL \left(\frac{\text{mg}}{\text{m}^3} \right) = \frac{ECEL \text{ ppm} * MW}{\text{Molar Volume}}$$

References

U.S. Environmental Protection Agency. 2020. Final Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro-) (CASRN 127-18-4). EPA-740-R1-8011. Office of Chemical Safety and Pollution Prevention. June 2020. Available at: EPA-HQ-OPPT-2019-0502-0058.

U.S. Environmental Protection Agency. 2002. A Review of the Reference Dose and Reference Concentration Processes. Final Report. EPA/630/P-02/002F. Prepared for the Risk Assessment Forum. December.

Appendix B: Summary of Air Sampling Analytical Methods Identified

EPA conducted a search to identify relevant NIOSH/OSHA/EPA analytical methods used to monitor for the presence of perchloroethylene in air (see **Error! Reference source not found.**). The sources used for the search included the following:

- 1) NIOSH Manual of Analytical Methods (NMAM); 5th Edition
 - URL: <https://www.cdc.gov/niosh/nmam/default.html>
- 2) NIOSH NMAM 4th Edition
 - URL: <https://www.cdc.gov/niosh/docs/2003-154/default.html>
- 3) OSHA Index of Sampling and Analytical Methods
 - URL: <https://www.osha.gov/dts/sltc/methods/>
- 4) EPA Environmental Test Method and Monitoring Information
 - <https://www.epa.gov/emc/epa-websites-environmental-test-method-and-monitoring-information>

Table 1: Limit of detection (LOD) summary for air sampling analytical methods identified.

| Air Sampling Analytical Methods | Year Published | LOD ^a | Notes | Source |
|--|----------------|------------------|--|---|
| OSHA Method 1001 https://www.osha.gov/dts/sltc/methods/mdt/mdt1001/1001.html | 1999 | 4.3 or 31 ppb | Method reports LOD of overall procedure as 4.3 ppb for charcoal tubes and 31 ppb for SKC 575-002 Samplers. | OSHA Index of Sampling and Analytical Methods https://www.osha.gov/dts/sltc/methods/ |
| OSHA PV2120 https://www.osha.gov/dts/sltc/methods/partial/pv2120/pv2120.html | 2003 | 0.4 ppb | This method is only partially validated. Estimated LOD based on 100 mL injected sample volume and two-fold dilution (Section 4.1). | OSHA Index of Sampling and Analytical Methods https://www.osha.gov/dts/sltc/methods/ |
| NIOSH 1003, Issue 3 https://www.cdc.gov/niosh/docs/2003-154/pdfs/1003.pdf | 2003 | 9 ppm | Modifications of NIOSH Method 1003 may offer lower LODs. ^b | NIOSH NMAM 4th Edition https://www.cdc.gov/niosh/docs/2003-154/default.html |
| NIOSH 2549, Issue 1 https://www.cdc.gov/niosh/docs/2003-154/pdfs/2549.pdf | 1996 | N/A | This method can only be used to detect the presence of PCE but cannot quantify the concentration. | NIOSH NMAM 4th Edition https://www.cdc.gov/niosh/docs/2003-154/default.html |
| NIOSH 3704, Issue 1 https://www.cdc.gov/niosh/docs/2003-154/pdfs/3704.pdf | 1998 | 0.1 ppm | Method is designed for detecting PCE in exhaled breath and is likely highly inconvenient for use in workplace sampling. | NIOSH NMAM 4th Edition https://www.cdc.gov/niosh/docs/2003-154/default.html |

| Air Sampling Analytical Methods | Year Published | LOD ^a | Notes | Source |
|--|----------------|------------------|---|--|
| EPA Method TO-15 https://www3.epa.gov/ttn/amtic/files/ambient/airtox/to-15r.pdf | 1999 | ≤0.5 ppb | To qualify under Compendium Method TO-15, the method detection limit must ≤0.5 ppbv. This method uses ppbv, but LODs for other methods listed here are also understood to be on a volume basis. For consistency, the LOD for this method is listed as ≤0.5 ppb. | EPA Air Toxics – Monitoring Methods https://www3.epa.gov/ttn/amtic/airtox.html |
| EPA Method TO-17 https://www.epa.gov/sites/production/files/2019-11/documents/to-17r.pdf | 1999 | ≤0.5 ppb | To qualify under Compendium Method TO-17, the method detection limit must be ≤0.5 ppb. | EPA Air Toxics – Monitoring Methods https://www3.epa.gov/ttn/amtic/airtox.html |
| <p>ppm = parts per million; ppb = parts per billion; ppt = parts per trillion</p> <p>^a These sources cover a range of LOD including both below and above the ECEL value.</p> <p>^b It is common for laboratories to acquire updated equipment from that used by NIOSH to develop Method 1003 and for the modern equipment to offer dramatically greater performance than the equipment available when NIOSH 1003 was published resulting in significantly lower LOQ/LODs. However, NIOSH does not necessarily continually update the method since the labs are using the same general procedures with just modified/better equipment. Therefore, the lab is permitted to report their method as “modified NIOSH Method 1003”. The lab will include a record of how it modifies the method in their results.</p> | | | | |