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

SUBJECT: Second Existing Chemical Exposure Limit (ECEL) (Developmental Toxicity) for Occupational Use of Trichloroethylene

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On February 22, 2021, EPA developed an 8-hour existing chemical exposure limit (ECEL) for trichloroethylene based on the immunotoxicity endpoint (4.0 ppb (0.021 mg/m^3)) characterized in the November 2020 TSCA Risk Evaluation for Trichloroethylene. In addition, EPA has developed an 8-hour ECEL for the most sensitive acute and chronic non-cancer health endpoint (developmental toxicity) in support of risk management efforts on trichloroethylene under TSCA section 6(a), 15 U.S.C. §2605. EPA calculated the ECEL to be 1.1 ppb (0.0059 mg/m^3) for inhalation exposures to trichloroethylene as an 8-hour time-weighted average (TWA) and for use in workplace settings (see Appendix A) based on the acute non-cancer occupational human equivalent concentration (HEC99) for congenital heart defects.

EPA expects that at the acute non-cancer ECEL of 1.1 ppb (0.0059 mg/m^3) a worker or occupational non-user (ONU) is also protected against congenital heart defects resulting from chronic 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 both an 8-hour TWA and an acceptable ceiling concentration for trichloroethylene (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 However, as noted on OSHA's website, "OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health.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 Trichloroethylene.

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 Trichloroethylene (U.S. EPA, 2020).

Acute Non-Cancer ECEL

This 8-hour ECEL is the concentration that EPA calculated for (the acute non-cancer occupational human equivalent concentration (HEC99) for congenital heart defects) the concentration at which the acute MOE would equal the benchmark MOE for acute occupational exposures with the following equation:

$$\mathrm{EL}_{\mathrm{acute}} = \frac{\mathrm{HEC}_{\mathrm{acute,occupational}}}{Benchmark\ MOE_{acute}} * \frac{\mathrm{AT}_{\mathrm{PODacute}}}{ED} = \frac{0.0037\ \mathrm{ppm}}{10} * \frac{\frac{24h}{d}}{\frac{8h}{d}} = 0.0011\ \mathrm{ppm} = 1.1\ \mathrm{ppb}$$

$$ECEL\ \left(\frac{\mathrm{mg}}{\mathrm{m}^3}\right) = \frac{ECEL\ ppm * MW}{Molar\ Volume} = \frac{0.0011\ \mathrm{ppm} * 131.39 \frac{g}{mol}}{24.45\ \frac{L}{mol}} = 0.0059\ \frac{\mathrm{mg}}{\mathrm{m}^3}$$

Where:

Molar Volume	=	24.45 L/mol, the volume of a mole of gas at 1 atm and 25 °C
MW	=	Molecular weight of TCE (131.39 g/mole)

Chronic Non-Cancer Exposure Limit

The chronic occupational exposure limit ($\mathrm{EL}_{\mathrm{chronic}}$) was calculated as the concentration at which the chronic MOE would equal the benchmark MOE for chronic occupational exposures using the following equation:

$$\mathrm{ECEL}_{\mathrm{inhal,occupational}} = \frac{\mathrm{HEC}_{\mathrm{chronic,occupational}}}{Benchmark\ MOE_{chronic}} * \frac{\mathrm{AT}_{\mathrm{POD\ chronic}}}{ED * EF * WY} =$$

$$\frac{0.0037\ \mathrm{ppm}}{10} * \frac{24h/d * 365d/y * 40\ y}{8h/d * 250d/y * 40\ y} = 0.0016\ \mathrm{ppm} = 1.6\ \mathrm{ppb} = 0.0086\ \frac{\mathrm{mg}}{\mathrm{m}^3}$$

Lifetime Cancer Exposure Limit

The $\mathrm{EL}_{\mathrm{cancer}}$ is the concentration at which the extra cancer risk is equivalent to the benchmark cancer risk of $1x10^{-4}$:

$$\mathrm{EL}_{\mathrm{cancer}} = \frac{Benchmark_{Cancer}}{IUR} * \frac{AT_{IUR}}{ED * EF * WY} = \frac{1X10^{-4}}{2.2 \times 10^{-2}\ per\ ppm} * \frac{24h/d * 365d/y * 78y}{8h/d * 250d/y * 40y} =$$

$$0.039\ \mathrm{ppm} = 0.21\ \frac{\mathrm{mg}}{\mathrm{m}^3}$$

Where:

$AT_{PODacute}$	=	Averaging time for the POD/HEC used for evaluating non-cancer, acute occupational risk, based on study conditions and/or any HEC adjustments (24hrs/day)
$AT_{PODchronic}$	=	Averaging time for the POD/HEC used for evaluating non-cancer, chronic occupational risk, based on study conditions and/or HEC adjustments (24 hrs/day for 365 days/yr) and assuming the number of years matches the high-end working years (WY, 40 yrs) for a worker (RE Section 2.3.1.2.4 and Table 2-17).
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) (RE Section 2.3.1.2.4 and Table 2-17)
Benchmark MOE_{acute}	=	Acute non-cancer benchmark margin of exposure, based on the total uncertainty factor (UF) of 10 (RE Table 3-13)
Benchmark $MOE_{chronic}$	=	Chronic non-cancer benchmark margin of exposure, based on the total uncertainty factor (UF) of 10 (RE Table 3-14)
$Benchmark_{Cancer}$	=	Benchmark for excess lifetime cancer risk ($1x10^{-4}$)
ECEL	=	Existing chemical exposure limit (mg/m^3 or ppm)
$EL_{chronic}$	=	Exposure limit based on congenital heart defects from chronic exposure
EL_{cancer}	=	Exposure limit based on excess cancer risk
ED	=	Exposure duration (8 hrs/day), (RE Table 2-17 and Appendix M)
EF	=	Exposure frequency (250 days/yr), (RE Table 2-17 and Appendix M)
$HEC_{acute\ or\ chronic,\ occupational}$	=	Human equivalent concentration for acute or chronic occupational exposure scenarios (RE Table 3-13 and 3-14)
IUR	=	Inhalation unit risk (per ppm) (RE Table 3-15)
WY	=	Working years per lifetime at the 95th percentile (40 yrs) (RE Table 2-17)

Unit conversion:

1 ppm = 5.37 mg/m^3 (based on molecular weight of 131.39.8 g/mol for TCE and molar volume of 24.45 L/mol at 25°C and 1 atm pressure) $ECEL\ \left(\frac{\text{mg}}{\text{m}^3}\right) = \frac{ECEL\ ppm * MW}{Molar\ Volume}$

References

U.S. Environmental Protection Agency. 2020. Risk Evaluation for Trichloroethylene (TCE) CASRN: 79-01-6. EPA-740-R1-8008. Office of Chemical Safety and Pollution Prevention. November 2020. Available at: EPA-HQ-OPPT-2019-0500-0113.

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 trichloroethylene in air (see Table 1). 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
NIOSH Method 8300 https://www.cdc.gov/niosh/docs/2014-151/pdfs/methods/3800.pdf	2016	0.43 ppm	Method reports approximate LOD for an absorption length of 10 m.	NIOSH Manual of Analytical Methods (NMAM); 5th Edition https://www.cdc.gov/niosh/nmam/default.html
NIOSH Method 1022, Issue 2 https://www.cdc.gov/niosh/docs/2003-154/pdfs/1022.pdf	1994	60 ppb	Method reports estimated LOD as 0.01 mg per sample, with a maximum sample of 30 L.	NIOSH NMAM 4th Edition https://www.cdc.gov/niosh/docs/2003-154/default.html
NIOSH Method 3701, Issue 2 https://www.cdc.gov/niosh/docs/2003-154/pdfs/3701.pdf	1994	0.1 ppm	Method reports estimated LOD as 0.1 ppm for a 1 mL injection.	NIOSH NMAM 4th Edition https://www.cdc.gov/niosh/docs/2003-154/default.html
OSHA Method 1001 https://www.osha.gov/dts/sltc/methods/mdt/mdt1001/1001.html	1999	3.7 or 18 ppb	Method reports LOD of overall procedure as 3.7 ppb for charcoal tubes and 18 ppb for SKC 575-002 Samplers.	OSHA Index of Sampling and Analytical Methods https://www.osha.gov/dts/sltc/methods/
EPA Method TO-14A https://www3.epa.gov/ttn/amtic/files/ambient/airtox/to-14ar.pdf	1999	14 ppb	Estimated LOD based on 1 microliter sample volume (Table B-1).	EPA Air Toxics – Monitoring Methods https://www3.epa.gov/ttn/amtic/airtox.html
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	EPA Air Toxics – Monitoring Methods https://www3.epa.gov/ttn/amtic/airtox.html

Air Sampling Analytical Methods	Year Published	LOD[a]	Notes	Source
			for this method is listed as ≤0.5 ppb.	
EPA Method TO-17	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

ppm = parts per million; ppb = parts per billion; ppt = parts per trillion
[a] EPA has included all relevant NIOSH/OSHA/EPA methods that it identified, including those methods with an LOD above the ECEL.