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 Carbon Tetrachloride

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EPA has developed an 8-hour existing chemical exposure limit (ECEL) in support of risk management efforts on Carbon Tetrachloride under TSCA section 6(a), 15 U.S.C. §2605. EPA calculated the ECEL to be 0.03 ppm (30 ppb, 0.2 mg/m^3) for inhalation exposures to carbon tetrachloride as an 8-hour time-weighted average (TWA) and for use in workplace settings (see Appendix A). The value is based on the point of departure for liver cancer. This is the concentration at which an adult human would be unlikely to suffer adverse effects if exposed for a working lifetime, including susceptible subpopulations. 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 from occupational inhalation exposures for conditions of use identified as presenting unreasonable risk under TSCA.

At the cancer ECEL of 0.03 ppm (30 ppb), EPA expects that a worker also would be protected against Central Nervous System (CNS) depression from acute occupational exposure as well as non-cancer liver toxicity resulting from chronic exposures, and against excess risk of cancer above the 1×10^{-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 and an acceptable ceiling concentration for carbon tetrachloride (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 However, as noted on OSHA's website, "OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health.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 Carbon Tetrachloride. 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.

The ECEL is within the limits of detection (LOD) of some of the published NIOSH/OSHA/EPA 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 Carbon Tetrachloride (RE) (U.S. EPA, 2020).

Chronic Liver 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. The ECEL is based on an endpoint that is part of the basis for the TSCA unreasonable risk determination (cancer effects). The ECEL was calculated using the liver cancer point of departure (POD) for continuous exposures and the benchmark margin of exposure (MOE) and adjusted for exposure duration with the following equation:

$$\mathrm{ECEL}_{\mathrm{inhal,\ occupational}} = \frac{POD_{cancer}}{Benchmark\ MOE_{cancer}} * \frac{\mathrm{AT}_{\mathrm{POD\ cancer}}}{ED * EF * WY} = \frac{6\,\frac{\mathrm{mg}}{\mathrm{m}^3}}{300} * \frac{24h/d * 365d/y * 78\ y}{8h/d * 250d/y * 40\ y}$$

$$= 0.2\,\frac{\mathrm{mg}}{\mathrm{m}^3}$$

$$ECEL\ (ppm) = \frac{ECEL\ \frac{\mathrm{mg}}{\mathrm{m}^3} * Molar\ Volume}{MW} = \frac{0.2\ \frac{\mathrm{mg}}{\mathrm{m}^3} * 24.3\ \frac{L}{mol}}{153.8\,\frac{g}{mol}} = 0.03\ \mathrm{ppm}$$

Where:

Molar Volume = 24.3 L/mol at 1 atm and 23 °C, based on experimental conditions used in animal study used to derive $\mathrm{POD}_{\mathrm{cancer}}$ (RE section 3.2.5.2.6).

MW = Molecular weight of Carbon Tetrachloride (153.8 g/mole)

The above equation is based on average daily exposure averaged over 40 years for a worker, representative of chronic exposure duration which EPA defines as greater than 10 percent (7.8 years) of a lifetime (U.S. EPA, 2002).

Acute Non-Cancer Exposure Limit

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

$$\mathrm{EL}_{\mathrm{acute}} = \frac{\mathrm{POD}_{\mathrm{acute\ occupational}}}{Benchmark\ MOE_{acute}} = \frac{360\,\frac{\mathrm{mg}}{\mathrm{m}^3}}{10} = 36\,\frac{\mathrm{mg}}{\mathrm{m}^3} = 6\ \mathrm{ppm}$$

Chronic Non-Cancer Exposure Limit

The chronic occupational exposure limit ($\mathrm{EL}_{\mathrm{chronic}}$) was calculated from the 8-hour point of departure (POD) for non-cancer effects (liver toxicity from chronic exposure) and adjusted for exposure duration with the following equation:

$$\mathrm{EL}_{\mathrm{chronic}} = \frac{\mathrm{HEC}_{chronic\ occupational}}{Benchmark\ MOE_{chronic}} * \frac{\mathrm{AT}_{\mathrm{POD\ chronic}}}{ED * EF * WY} = \frac{31.1\,\frac{\mathrm{mg}}{\mathrm{m}^3}}{30} * \frac{8h/d * 250d/y * 40\ y}{8h/d * 250d/y * 40\ y}$$

$$= 1\,\frac{\mathrm{mg}}{\mathrm{m}^3} = 0.2\ \mathrm{ppm}$$

The above equation assumes that the health effects from chronic exposure would be observed after 40 years for a worker, representative of chronic exposure duration which EPA defines as greater than 10 percent (7.8 years) of a lifetime (U.S. EPA, 2002).

Cancer risk for other tumor types (e.g., adrenal glands) at the ECEL

The cancer risks at the 8-hr ECEL of 0.03 ppm (0.2 mg/m^3) were calculated for as follows:

$$\text{Cancer Risk} = IUR * ECEL * \frac{8\text{h/d} * 250\text{d/y} * 40\text{y}}{24\ h/d * 365 d/y * 78y} =$$

$$= 6 \times 10^{-3}\ per\ \frac{\text{mg}}{\text{m}^3} * 0.2 \frac{\text{mg}}{\text{m}^3} * \frac{8\text{h/d}*250\text{d/y}*40\text{y}}{24\ \text{h/d}*365\text{d/y}*78\text{y}} = 1 \times 10^{-4}$$

Where:

$AT_{PODcancer}$	=	Averaging time for the liver cancer POD used for evaluating cancer (chronic) occupational risk based on study conditions and POD adjustments (24 hrs/day for 365 days/yr) (RE Section 3.2.5.2.6) and averaged over a lifetime exposure (78 years) (RE Equation 2-2)
$AT_{PODchronic}$	=	Averaging time for the POD/HEC used for evaluating non-cancer, chronic occupational risk based on study conditions and HEC adjustments (8 hrs/day for 250 days/yr) (RE Table 3-6 and RE equation 2-2) and assuming the number of years matches the high-end working years (WY,40 yrs) for a worker (RE equation 2-2).
Benchmark MOE_{acute}	=	Acute non-cancer benchmark margin of exposure, based on the total uncertainty factor of 10 (RE Table 3-5)
Benchmark MOE_{cancer}	=	Cancer benchmark margin of exposure based on the total uncertainty factor of 300 (RE Section 3.2.5.2.6)
Benchmark $MOE_{chronic}$	=	Chronic non-cancer benchmark margin of exposure, based on the total uncertainty factor of 30 (RE Table 3-6)
Cancer risk	=	Incremental individual lifetime cancer risk
ECEL	=	Existing chemical exposure limit (mg/m^3 or ppm)
EL_{acute}	=	Exposure limit based on CNS depression
$EL_{chronic}$	=	Exposure limit based on liver toxicity
ED	=	Exposure duration (8 hrs/day) (RE Equation 2-2)
EF	=	Exposure frequency (250 days/yr) (RE Equation 2-2)
$HEC_{chronic\ occupational}$	=	Human equivalent concentration for non-cancer effects for chronic occupational exposures scenarios (RE Table 3-6)
POD_{cancer}	=	Point of departure for cancer for chronic occupational exposures (RE Section 3.2.5.2.6)
IUR	=	Inhalation unit risk (per mg/m^3) (RE Table 3-12)
$POD_{acute\ occupational}$	=	Point of departure for acute occupational exposure scenarios (RE Table 3-5)
WY	=	Working years per lifetime at the 95th percentile (40 yrs), (RE Equation 2-2)

Unit conversion:

1 ppm = 6.3 mg/m^3 (based on molecular weight of 153.8 g/mol for carbon tetrachloride and molar volume of 24.3 L/mol at 23 °C and 1 atm pressure)(RE section 3.2.5.2.6) $ECEL\ \left(\frac{\text{mg}}{\text{m}^3}\right) = \frac{ECEL\ ppm * MW}{Molar\ Volume}$

References

U.S. Environmental Protection Agency. 2020. Risk Evaluation for Carbon Tetrachloride (Methane, Tetrachloro-) CASRN: 56-23-5. EPA-740-R1-8014. Office of Chemical Safety and Pollution Prevention. October 2020. Available at: EPA-HQ-OPPT-2019-0499-0047.

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 web search to identify relevant NIOSH/OSHA/EPA analytical methods used to monitor for the presence of carbon tetrachloride 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
   - URL: https://www.epa.gov/emc/epa-websites-environmental-test-method-and-monitoring-information

Table 1: LOD summary for air sampling analytical methods identified.

Air Sampling Analytical Methods	Year Published	Limit of Detection (LOD)	Notes	Source
NIOSH 1003 Hydrocarbons, Halogenated	2003 (Issue 3)	LOD: 4 µg per sample	LOD is for carbon tetrachloride	https://www.cdc.gov/niosh/docs/2003-154/pdfs/1003.pdf
OSHA Occupational Safety and Health Guidance Manual for Hazardous Waste Site Activities (Site Air Monitoring for Organics)	Not specified	LOD 10 λg for organics per sample	LOD is applicable to all organics in the sample, not only carbon tetrachloride	https://www.osha.gov/Publications/complinks/OSHG-HazWaste/7-8.pdf See Table 7-3
EPA Method 325 b (method for VOCs)	2019 (updated)	Not Specified	LOD depends upon the analytical conditions selected	https://www.epa.gov/emc/method-325b-volatile-organic-compounds-fugitive-and-area-sources-sampler-preparation-and

GC= gas chromatography; CLMD = chemiluminescence detection; VOC –volatile organic compound