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 Methylene Chloride

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EPA has developed an 8-hour existing chemical exposure limit (ECEL) in support of potential risk management action on methylene chloride under TSCA section 6(a), 15 U.S.C. §2605. EPA calculated the ECEL to be 2 ppm (8 mg/m^3) for inhalation exposures to methylene chloride as an 8-hour time-weighted average (TWA) and for use in workplace settings (see appendix A). The value is based on the chronic non-cancer human equivalent concentration (HEC) for liver toxicity. 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 any unreasonable risk of injury to health.

EPA has also developed a short-term ECEL of 16 ppm (57 mg/m^3) as a 15-minute TWA. This short-term limit is based on the non-cancer endpoint of central nervous system (CNS) depression resulting from acute exposures.

At the 8-hour ECEL of 2 ppm, EPA expects that a worker would be protected against CNS depression as well as liver toxicity resulting from an acute (8-hour) exposure if ambient exposures are kept below this ECEL. The incremental individual cancer risk at the 8-hr ECEL is 5.1 x 10^{-6}, which is lower than the occupational benchmark for cancer risk of 1 x 10^{-4} cited in the Risk Evaluation for Methylene Chloride and the National Institute for Occupational Safety and Health (NIOSH) Chemical Carcinogen Policy (https://www.cdc.gov/niosh/docs/2017-100/default.html).

The Occupational Safety and Health Administration (OSHA) set a permissible exposure limit (PEL) as an 8-hour TWA and a short-term exposure limit (STEL) as a 15-minute TWA for methylene chloride (https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1052). However, as noted on OSHA's website, "OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health.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 Methylene Chloride. 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 above the limits of detection or quantification, which generally range from about 0.2 to 0.4 ppm (see Appendix B "Summary of Workplace Air Monitoring Methods for Methylene Chloride").

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Appendix A: ECEL and Other Exposure Limit Calculations

This appendix presents the equation used to estimate the ECEL as well as other comparison equations. The resulting ECEL value was rounded. The values used in the equations are included in the final methylene chloride risk evaluation (RE) (U.S. EPA, 2020).

Chronic non-cancer ECEL

The 8-hour exposure concentration at which the margin of exposure (MOE) would indicate negligible concerns for human health effects for chronic exposures was calculated from the 24-hour point of departure (POD) and adjusted for exposure duration with the following equation for the endpoint that is the basis for the TSCA unreasonable risk determination (liver toxicity from chronic exposure):

$$EC_{\text{MOEchronic 8hrTWA}} = \frac{HEC_{\text{1st \%ile}}}{MOE_{benchmk\_chronic}} * \frac{AT_{\text{MOE chronic}}}{ED * EF * WY} = \frac{17.2\,\frac{\text{mg}}{\text{m}^3}}{10} * \frac{24h/d * 365d/y * 40\,y}{8h/d * 250d/y * 40\,y}$$

$$= 7.5\,\frac{\text{mg}}{\text{m}^3} = 2.2\text{ ppm}$$

The above equation assumes that the health effects from chronic exposure would be observed after 40 years for a worker even though the toxicity study was a lifetime study in animals, which is equivalent to 78 years in humans. This assumption is reasonable based on the definition of chronic duration as greater than 10 percent (7.8 years) of a lifetime (U.S. EPA, 2002).

EPA then rounded the final ECEL to 2 ppm (and 8 mg/m^3).

Acute non-cancer exposure limit (15-minute TWA)

The 15-minute exposure concentration at which the MOE would equal the benchmark MOE for acute exposures was calculated from the 15-minute point of departure and benchmark MOE with the following equation:

$$EC_{\text{MOEacute 15minTWA}} = \frac{POD_{\text{15min}}}{MOE_{benchmk\_acute}} = \frac{1706\,\frac{\text{mg}}{\text{m}^3}}{30} = 57\,\frac{\text{mg}}{\text{m}^3} = 16\text{ ppm}$$

Cancer risk at the ECEL

The cancer risks at the 8-hr ECEL of 2 ppm (8 mg/m^3) were calculated for as follows:

$$\text{Cancer Risk} = 1.38 \times 10^{-6}\ per\,\frac{\text{mg}}{\text{m}^3} * 8\,\frac{\text{mg}}{\text{m}^3} * \frac{8\text{h/d} * 250\text{d/y} * 40\text{y}}{8\text{ h/d} * 260\text{d/y} * 78\text{y}} = 5.4 \text{ x } 10^{-6}$$

Where:

$AT_{MOEchronic}$	=	Averaging time for the non-cancer chronic health endpoint (hrs), based on HEC conditions (24 hrs/day for 365 days/yr) (RE Table 3-21) and assuming the number of years matches the high-end WY (40 yrs) for a worker (RE Equation 2-5).
AT_{IUR}	=	Averaging time for the cancer health endpoint (hrs), based on IUR conditions (8 hrs/day for 250 days/yr) (RE Table 3-21) and using a lifetime exposure (78 yrs) appropriate for evaluating the cancer endpoint (RE Equation 2-5).
Cancer risk	=	Incremental individual lifetime cancer risk

EC	=	Exposure concentration in air (mg/m^3 or ppm)
$EC_{MOEacute8hrTWA}$	=	EC based on CNS depression (8-hr TWA)
$EC_{MOEacute15\text{-}minTWA}$	=	EC based on CNS depression (15-min TWA)
$EC_{MOEchronic8hrTWA}$	=	EC based on liver toxicity (8-hr TWA)
$EC_{IUR8hrTWA}$	=	EC based on cancer (8-hr TWA)
ED	=	Exposure duration (hrs/day), RE Equation 2-5
EF	=	Exposure frequency (days/yr), RE Equation 2-5
WY	=	Working years per lifetime at the 95th percentile (40 yrs), RE Equation 2-5
$HEC_{1st\%ile}$	=	Human equivalent concentration at 1st percentile[1] for continuous exposure (mg/m^3), RE Table 3-21
IUR	=	Inhalation unit risk (per mg/m^3), RE Table 3-21
$MOE_{benchmk\_acute}$	=	Acute non-cancer benchmark margin of exposure, based on the total uncertainty factor of 30 in RE Table 3-21
$MOE_{benchmk\_chronic}$	=	Chronic non-cancer benchmark margin of exposure, based on the total uncertainty factor of 10 in RE Table 3-21
POD_{8hrs}	=	Point of departure for CNS depressant effects for an 8-hour exposure (mg/m^3), RE Table 3-21
POD_{15min}	=	Point of departure for CNS depressant effects for a 15-min exposure (mg/m^3), RE Table 3-21

Unit conversion:

1 ppm = 3.47 mg/m^3 (conversion is *not* explicitly shown in above equations, in which final mg/m^3 values were converted to ppm values)

References

U.S. Environmental Protection Agency. 2020. Risk Evaluation for Methylene Chloride (Dichloromethane, DCM) CASRN: 75-09-2. EPA-740-R1-8010. Office of Chemical Safety and Pollution Prevention. June 2020. Available at: EPA-HQ-OPPT-2019-0437-0107.

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.

[1] EPA used the 1st percentile to account for susceptibility from the toxicokinetic variability among humans related to differences in metabolism. Using the 1st percentile, EPA reduced the intraspecies uncertainty factor (UF_H) from 10 to 3. The remaining UF_H of 3 accounts for any toxicodynamic differences among humans.

Appendix B: Summary of Current Workplace Air Monitoring Methods for Methylene Chloride

This summary provides associated limits of detection or quantification, which generally range from about 0.2 to 0.4 ppm.

EPA conducted a web search to identify the most-current, state of the art methods used to monitor the presence of MC in workplace air. The sources used for the search included:

- NIOSH Manual of Analytical Methods (NMAM); 5th Edition (April 2016) (https://www.cdc.gov/niosh/nmam/default.html)
- NIOSH NMAM 4th Edition (January 1998) (https://www.cdc.gov/niosh/docs/2003-154/default.html)
- OSHA Index of Sampling and Analytical Methods (https://www.osha.gov/dts/sltc/methods/)
- PubMed (https://pubmed.ncbi.nlm.nih.gov/)
- PubChem (https://pubchem.ncbi.nlm.nih.gov/)

From these authoritative sources, EPA gathered information on multiple monitoring and analytical methods for MC, which are shown in Table 1.

Table 1: Sources of Identified Monitoring Methods

Source	Method	Published Year	Method Sheet
NIOSH MAM (4th Ed.), PubChem	NIOSH 1005	1998 (Issue 3)	https://www.cdc.gov/niosh/docs/2003-154/pdfs/1005.pdf
NIOSH MAM (4th Ed.), PubChem	NIOSH 2549	1996 (Issue 1)	https://www.cdc.gov/niosh/docs/2003-154/pdfs/2549.pdf
NIOSH MAM (5th Ed.)	NIOSH 3800	2016 (Issue 2)	https://www.cdc.gov/niosh/docs/2014-151/pdfs/methods/3800.pdf
NIOSH MAM (5th Ed.)	NIOSH 3900	2018	https://www.cdc.gov/niosh/nmam/pdf/3900.pdf
OSHA, PubChem	OSHA 80	1990	https://www.osha.gov/dts/sltc/methods/organic/org080/org080.html

Note that NIOSH method 3800 is a direct-reading instrument, and direct-reading methods may have the lower accuracy compared to the other collection methods.

A summary of the methods found in the search is shown in Table 2, which includes sampling media, equipment, analytical instruments, LOD/LOQs and sampling volume and flow rate.

Table 2: Summary of Workplace Air Monitoring Methods

Method	Sampling Media and Equipment	Analytical Instrument	Per-Sample Analytical LOD, LOQ	Concentration LOD, LOQ (dependent on air volume sampled)	Sampling Volume and Flow Rate
NIOSH 1005 (Rev. 1998)	Charcoal sampling sorbent tubes; personal sampling pump	GC + FID analysis	LOD: 0.4 µg per sample (estimated)	Working range: 0.4 to 749 ppm (1.4 to 2600 mg/m^3) for a 1-L air sample. Accuracy: +/- 15.8% Precision: 0.076	Volume: 0.5-2.5 L Flow Rate: 0.01-0.2 L/min.
NIOSH 1005 (Rev. 1998) Alternate analytical equipment	Charcoal sampling sorbent tubes; personal sampling pump	GC + electron capture detector (ECD) desorbed with toluene	LOD: 0.002 µg per sample (estimated)	Extrapolated working range 200 times lower than GC+FID: 0.0002 to 3.7 ppm Accuracy: +/- 15.8% Precision: 0.05 at 320 µg.	Volume: 0.5-2.5 L Flow Rate: 0.01-0.2 L/min
NIOSH 2549 (1996)	Thermal Desorption Tube (multi-sorbent tubes containing graphitized carbons and carbon molecular sieve sorbents)	Thermal desorption + GC + MS	LOD: 100 ng per tube or less	Not applicable	Volume: 1-6 L Flow Rate: 0.01-0.05 L/min
NIOSH 3800 (2003)	Portable direct-reading instrument (with filter, if required)	Extractive Fourier Transform Infrared (FTIR) Spectrometry	LOD: 0.31 ppm at a 10-meter absorption path length	Working range: 0.31-150 ppm at a 10-meter absorption path length	Flow Rate: ~0.1-~20 L/min (system-dependent)
NIOSH 3900 (2018)	Fused-Silica Lined Stainless Steel Canister	GC+MS	LOD: 0.2 (ppb levels) or 0.4 (ppm levels) per sample	Working range: 0.26-20.8 (ppb levels) or 0.15-1.9 (ppm levels) Precision: 0.049 (ppb levels) or	Volume: 6 L, 450 mL, or 400 mL Flow Rate: 0.06-50 mL/min.

Method	Sampling Media and Equipment	Analytical Instrument	Per-Sample Analytical LOD, LOQ	Concentration LOD, LOQ (dependent on air volume sampled)	Sampling Volume and Flow Rate
				0.099 (ppm levels)	
OSHA Method 80 (1990)	Carbosieve S-III; personal sampling pump	GC + FID analysis	LOD and LOQ identical: 2.09 µg per sample	LOD, LOQ: 0.201 ppm (0.697 mg/m^3) for 3-L air sample. Reliable quantitation limit is 2.41 ppm (8.36 mg/m^3) when 0.25 L air is collected (5 minute sample). Standard errors of estimate: 5.8% at 10 ppm, 6.5% at 500 ppm (OSHA methods developed to have less than 25% error overall).	Volume: 3 L Flow Rate: 0.05 L/min

ECD – Electron capture detector
FID – Flame ionization detector
GC – Gas chromatography
MS – Mass Spectrometry
LOD – Limit of detection
LOQ – Limit of quantification
Note: Precision in NIOSH methods 1005 and 3900 is given as relative standard deviation.

References

OSHA (Occupational Safety and Health Administration). 1990. *Method 80: Methylene Chloride. Sampling and Analytical Methods.* OSHA Salt Lake Technical Center, Sandy, UT. https://www.osha.gov/dts/sltc/methods/organic/org080/org080.html

NIOSH (National Institute for Occupational Safety and Health). 1998. *Method 1005, Issue 3: Dichloromethane (in Methylene Chloride)*. NIOSH Manual of Analytical Methods (NMAM), 4th Edition. http://www.cdc.gov/niosh/docs/2003-154/pdfs/1005.pdf

NIOSH (National Institute for Occupational Safety and Health). 1996. *Method 2549, Issue 1: Dichloromethane (in VOLATILE ORGANIC COMPOUNDS (SCREENING))*. NIOSH Manual of Analytical Methods (NMAM), 4th Edition. https://www.cdc.gov/niosh/docs/2003-154/pdfs/2549.pdf

NIOSH (National Institute for Occupational Safety and Health). 2003. *Method 3800, Issue 2: Dichloromethane* (in *ORGANIC AND INORGANIC GASES by Extractive FTIR Spectrometry)*. NIOSH Manual of Analytical Methods **(NMAM),** 5th Edition. https://www.cdc.gov/niosh/docs/2014-151/pdfs/methods/3800.pdf

NIOSH (National Institute for Occupational Safety and Health). 2018. *Method 3900, Issue 1: Dichloromethane (in Volatile Organic Compounds, C1 to C10, Canister Method)*. NIOSH Manual of Analytical Methods (NMAM), 5th Edition. https://www.cdc.gov/niosh/nmam/pdf/3900.pdf