

Background Information

EPA’s reassessment of vinyl chloride toxicity concludes that higher cancer risks results from exposure to vinyl chloride early in life compared to exposure during adulthood. Two cancer slope factors are in IRIS with one used to evaluate adult cancer risks and the second used to evaluate the increased susceptibility to cancer of children from vinyl chloride exposures.

The IRIS file for vinyl chloride is extracted below:

II.B.1. Summary of Risk Estimates

II.B.1.1. Oral Slope Factor	(a) LMS method (per mg/kg-day)	(b) LED 10/linear method (per mg/kg-day)
Continuous lifetime exposure during adulthood	7.2E-1	7.5E-1
Continuous lifetime exposure from birth	1.4	1.5

II.B.1.2. Drinking Water Unit Risk	(a) LMS method (per µg/L)	(b) LED 10/linear method (per µg/L)
Continuous lifetime exposure during adulthood	2.1E-5	2.1E-5
Continuous lifetime exposure from birth	4.2E-5	4.2E-5

Quantitative Estimate of Carcinogenic Risk from Inhalation Exposure

Air Unit Risk(s)	Extrapolation Method
4.4x10 ⁻³ per mg/m ³ (Continuous lifetime exposure during adulthood)	LMS method
4.4x10 ⁻³ per mg/m ³ (Continuous lifetime exposure during adulthood)	LED 10/ linear method
8.8x10 ⁻³ per mg/m ³ (Continuous lifetime exposure from birth)	LMS method
8.8x10 ⁻³ per mg/m ³ (Continuous lifetime exposure from birth)	LED 10/ linear method

On March 29, 2005 EPA published final, revised Guidelines for Carcinogen Risk Assessment, superseding all previous versions of the Guidelines. Pursuant to those Guidelines, the basic default is to assume linearity and use a linear default approach when the mode of action information is supportive of linearity or mode of action is not understood. Therefore, the LED10/linear method is preferred over EPA’s previous default, which was the linearized multistage (LMS) method. In this case, the slope factors derived from both methods are virtually identical.

For MTCA direct contact cleanup level equations, the slope factor (cancer potency factor) of 0.75 per mg/kg-day is used to calculate media cleanup levels for an industrial setting where children are not expected to be exposed. For exposure scenarios with the reasonable expectation that children may be potentially exposed (e.g., residential soils, ground water, surface water, air) then the slope factor (cancer potency factor) of 1.5 per mg/kg-day is used to calculate media cleanup levels. The tables below summarize MTCA direct contact cleanup levels for vinyl chloride that take into account the use of the two different cancer potency factors.

It should be noted that a more accurate way to calculate risks and cleanup levels, as explained in EPA’s “Toxicological Review for Vinyl Chloride In Support of Summary Information on the Integrated Risk Information System (IRIS),”¹ would be to include a separate cleanup level equation for early-life exposure that is not limited by exposure duration and frequency. This would effectively lower cleanup levels. EPA considers it to be an appropriate way to deal with vinyl chloride’s special ability to increase the lifetime cancer risk when exposure occurs during an undefined period of development in early life when the infant or child is particularly vulnerable to the chemical. This specific risk appears to be independent of, and in additive to, the more traditionally defined risk that is believed to be directly relative to exposure duration and frequency. However, MTCA regulations must be formally revised in order to accommodate this special way of calculating cleanup levels for vinyl chloride. In the meantime, use of the higher slope factor should be used to account for risks due to early-life exposures, as the only method currently available under MTCA.

¹ EPA/635R-00/004, May 2000. Available on the World Wide Web at <http://www.epa.gov/iris/toxreviews/1001-tr.pdf>

Vinyl Chloride Cleanup Levels – MTCA Direct Contact for carcinogenicity	
Soils	
Unrestricted Land Use – children may be exposed	Industrial Land Use – adult only exposure assumed
Standard Method B	Standard Method C
Eqn. 740-2,	Eqn. 745-2
Target risk level: 10^{-6}	Target risk level: 10^{-5}
CPF: 1.5 per mg/kg-day	CPF: 1.5 per mg/kg-day (see Note)
Soil cleanup level: 0.67 mg/kg	Industrial soil cleanup level: 87.5 mg/kg
Note: Use CPF: 0.75 per mg/kg-day only where a site-specific reasonable maximum exposure (RME) is determined where neither a child nor a pregnant woman may be potentially exposed to vinyl chloride contaminated industrial soils; the resulting cleanup level is 175 mg/kg.	

Vinyl Chloride Cleanup Levels – MTCA Direct Contact for carcinogenicity			
Ground Water (GW)		Surface Water (SW)	
Standard Method B – children may be exposed	Standard Method C – children may be exposed	Standard Method B – children may be exposed	Standard Method C – children may be exposed
Eqn. 720-2	Using Equation 720-2	Eqn. 730-2	Using Equation 730-2
Target risk: 10^{-6}	Target risk: 10^{-5}	Target risk: 10^{-6}	Target risk: 10^{-5}
CPF: 1.5 per mg/kg-day	CPF: 1.5 per mg/kg-day	CPF: 1.5 per mg/kg-day	CPF: 1.5 per mg/kg-day
GW Cleanup level: 0.029 µg/l	GW Cleanup level: 0.29 µg/l	SW Cleanup level: 3.7 µg/l	SW Cleanup level: 92.3 µg/l
INH = 2	Note: In the unlikely event that a site specific RME is determined to be exclusively for non-pregnant adults, consider using CPF: 0.75 per mg/kg-day.	BCF: 1.17 l/kg	Note: In the unlikely event that a site specific RME is determined to be exclusively for non-pregnant adults, consider using CPF: 0.75 per mg/kg-day.
Ambient water quality criteria has been revised for vinyl chloride (EPA-822-F-03-012)			
SW criteria based on default freshwater/estuarine fish consumption rate of 17.5 grams/day	Human Health Criteria for Consumption of:		
	Vinyl Chloride	Water + Organisms / Freshwaters (µg/L)	Organisms only / Marine waters (µg/L)
		0.025	2.4
Federal drinking Water – for potable GW	MCL = 2 µg/L		

Vinyl Chloride Cleanup Levels – MTCA Direct Contact for carcinogenicity	
Air	
Standard Method B	Standard Method C
Eqn. 750-2,	Using Eqn. 750-2
Target risk: 10^{-6}	Target risk: 10^{-5} Adult
CPF 3.1E-02 per mg/kg-day; Air unit risk 8.8E-03 per mg/m ³ X day/20 m ³ X 70 kg = 3.1E-02 per mg/kg-day	CPF 3.1E-02 per mg/kg-day (see Note)
Air Method B Cleanup Level: 0.28 ug/m ³	Air Method C Cleanup Level: 2.8 ug/m ³
Note: CPF 1.6E-02 per mg/kg-day [air unit risk 4.4E-03 per mg/m ³ X day/20 m ³ X 70 kg = 1.6E-02 per mg/kg-day] may be used only if it is determined that children and pregnant women will not be exposed.	