

**New York State Department of Health
Inhalation Cancer Toxicity Value**

Summary of Available Inhalation Unit Risk Values for Trichloroethene

Agency	Risk Specific Air Concentration ¹ (mcg/m ³)	Unit Risk (mcg/m ³) ⁻¹	Extrapolation Methods		Summary
			High to Low Dose	Animal to Human	
Cal EPA (2002)	0.5	2×10^{-6}	linearized multistage model, extra risk	Metabolized dose from PBPK ² modeling; also mentions interspecies adjustment based on surface area scaling ³ but not clear how scaling was used	Based on the incidence of lung and liver tumors and lymphomas in male and female mice in several chronic inhalation studies. A best estimate of the unit risk was obtained by taking the geometric mean of the unit risks from four inhalation studies.
Health Canada (1993)	8.2×10^4 reported as a TC ₀₅ ⁴ ; a linear extrapolation to 10 ⁻⁶ risk would yield: 1.6	-- ⁵	--	Derivation includes an adjustment based on the relative inhalation volume to body weight for rats vs. humans aged 5-11 years	Based on the increased incidence of leydig cell tumors in male rats exposed via inhalation for 104 weeks.
WHO (2000)	2.3	4.3×10^{-7}	linearized multistage model	inhaled dose	Based on the same data set used by Health Canada.

¹The air concentration associated with an increased lifetime cancer risk of one-in-one million (i.e., 1×10^{-6} dose), where 1×10^{-6} air concentration = 1×10^{-6} / unit risk.

²PBPK: Physiologically-based pharmacokinetic

³Factor for dose adjustment from animal to humans is (animal body weight/human body weight)^{0.25}.

⁴TC₀₅: the concentration in air associated with a 5% increase in mean tumor incidence (not a lower-bound estimate)

⁵No unit risk was derived.

References for Summary Table

Cal EPA (California Environmental Protection Agency). 2002. Air Toxics Hot Spots Program Risk Assessment Guidelines: Part II Technical Support Document for Describing Available Cancer Potency Factors. Sacramento, CA.

http://www.oehha.ca.gov/air/cancer_guide/TSD2.html

Health Canada. 1993. Priority Substances List Assessment Report: Trichloroethylene. Ottawa: Environment Canada, Ministry of Public Works and Government Services.

<http://www.hc-sc.gc.ca/hecs-sesc/exsd/psl2.htm>

WHO (World Health Organization). 2000. Air Quality Guidelines (2nd Ed.), Chapter 5.15, Trichloroethylene. World Health Organization, Copenhagen, Denmark.

http://www.euro.who.int/air/Activities/20020620_1

New York State Department of Health
Oral Cancer Toxicity Value

Summary of Available Oral Cancer Potency Values for Trichloroethene

Agency	Risk Specific Dose ¹ (mg/kg/day)	Cancer Potency Factor (mg/kg/day) ⁻¹	Extrapolation Methods		Summary
			High to Low Dose	Animal to Human	
NYS DEC (1997)	1.75×10^{-4}	5.72×10^{-3}	linearized multistage model, extra risk	BW ^{3/4} 2	Based on the geometric mean of four gavage data sets showing hepatocellular carcinomas in male and female mice exposed for five days per week for 78 or 103 weeks.
Health Canada (1993)	Reported Range: 200 – 600 (TD ₀₅ ³)	-- ³	linearized multistage model, extra risk	body weight ⁴	Based on testicular tumors in rats exposed orally and lung tumors in mice exposed via inhalation
Cal EPA (2002)	7.7×10^{-5}	1.3×10^{-2}	linear extrapol. from the LED ₁₀ based on PBPK dose metrics ⁵	BW ^{3/4} 2	Geometric mean of six potency estimates based on liver tumors in orally exposed mice and liver and lung tumors in mice exposed via inhalation.
US EPA ODW (2004)	8.6×10^{-5}	0.0117			Information on derivation not available.
US EPA Region 3 (2003)	2.5×10^{-6}	0.4	--	--	Based on increased risk for non-Hodgkin's lymphoma in female residents exposed to trichloroethene and other chemicals in a 75-town epidemiology study.

¹The dose associated with an increased lifetime cancer risk of one-in-one million (i.e., 1×10^{-6} dose), where 1×10^{-6} dose = 1×10^{-6} / cancer potency factor.

²Factor for dose adjustment from animal to humans is (animal body weight/human body weight)^{0.25}.

³No cancer potency factor was derived. A range of risk-specific doses was reported as the modeled TD₀₅ (= 200 - 600 mg/kg/day), the dose associated with a 5% increase in mean tumor incidence (not a lower-bound estimate). TERA (2004) convention for converting this estimate to a risk-specific dose at 10⁻⁵ lifetime risk would be to divide the lowest TD₀₅ by 5000; this would imply a 10⁻⁶ risk specific dose of 4×10^{-3} mg/kg/day (not a lower bound estimate).

⁴Factor for dose adjustment from animal to humans is 1.

⁵PBPK: Physiologically-based pharmacokinetic. LED₁₀: The lower bound on the dose associated with a 10% increase in tumor incidence.

References for Summary Table

Cal EPA (California Environmental Protection Agency). 2002. Public Health Goal for Trichloroethylene In Drinking Water. Office of Environmental Health Hazard Assessment.
<http://www.oehha.ca.gov/water/phg/allphgs.html>

Health Canada. 1993. Priority Substances List Assessment Report: Trichloroethylene. Ottawa: Environment Canada, Health Canada.
<http://www.hc-sc.gc.ca/hecs-sesc/exsd/psl1.htm>

NYS DEC (New York State Department of Environmental Conservation). 1997. Combined Regulatory Impact and Draft Environmental Impact Statement; Human Health Fact Sheet for Trichloroethene. Albany, NY: Division of Water.

Toxicology Excellence for Risk Assessment (TERA). 2004. International toxicity estimates for risk database.
<http://www.tera.org/iter/>

US EPA IRIS (United States Environmental Protection Agency Integrated Risk Information System). 2004. Office of Research and Development, National Center for Environmental Assessment.
<http://www.epa.gov/iris/subst/index.html>

US EPA NCEA (United States Environmental Protection Agency National Center for Environmental Assessment). 2001. Trichloroethylene Health Risk Assessment: Synthesis and Characterization. External Review Draft. EPA /600/P-01/002A. Office of Research and Development. Washington DC.
<http://cfpub2.epa.gov/ncea/cfm/nceapubtopics.cfm?ActType=PublicationTopics>

US EPA ODW (Office of Drinking Water). 2004. 2004 Edition of the Drinking Water Standards and Health Advisories. EPA 822-R-04-005. Office of Water. U.S. Environmental Protection Agency. Washington, DC
<http://www.epa.gov/waterscience/drinking/>

US EPA Region 3 (United States Environmental Protection Agency Region 3). 2003. Risk-based Concentration Table. Superfund Technical Support Section.
<http://www.epa.gov/reg3hwmd/risk/human/index.htm>