Ground Water Quality Standard for Chloroethane CASRN# 75-00-3

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NJDEP

Summary of Decision: In accordance with the <u>New Jersey Ground Water Quality</u> <u>Standards rules at N.J.A.C. 7:9C-1.7</u>, the Department of Environmental Protection (Department) has determined that insufficient information is available to develop a specific or interim specific ground water quality criterion for chloroethane at this time. Chloroethane is a synthetic organic chemical not listed in <u>Appendix Table 1</u>. The U.S. Environmental Protection Agency (USEPA) USEPA does not provide a Reference Dose or carcinogenicity assessment for chloroethane at this time; however, there is sufficient information to classify chloroethane as a likely carcinogen. Therefore, **the applicable constituent standard is the interim generic ground water quality criterion of 5 µg/L**. The basis for this criterion and PQL are discussed below.

> Chloroethane ethyl chloride Molecular Formula: C₂H₅Cl Molecular Structure:

Background: Chloroethane is a colorless gas at room temperature and pressure. It was formerly used in leaded gasoline, but is now used primarily in the production of cellulose, dyes, medicinal drugs, and other commercial products, and as a solvent and refrigerant. It is also used to numb the skin before medical procedures such as ear piercing and skin biopsies and as a treatment in sports injuries. Exposure to chloroethane can occur from breathing air or drinking water that contains this chemical (ATSDR, 2008).

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There is no Reference Dose or carcinogenicity assessment for chloroethane provided in the <u>USEPA IRIS database</u>, but an inhalation Reference Concentration (RfC) is provided under its synonym, ethyl chloride (USEPA, 1998). The USEPA National Center for Environmental Assessment (NCEA) evaluated the carcinogenic potential of chloroethane (USEPA, 1993) and developed an oral cancer slope factor of 0.029 (mg/kg/day)⁻¹ derived from a National Toxicology Program inhalation bioassay (NTP, 1989) that observed uterine tumors in female mice. NCEA emphasized the uncertainties in this oral slope factor because it was based on a single high dose exposure group and because there was no oral carcinogenicity data for chloroethane.

Reference Dose: NCEA derived a "Provisional Reference Dose" of 0.4 mg/kg/day for chloroethane (USEPA, 1996), based on extrapolation from the IRIS inhalation RfC. The RfC was based on delayed fetal ossification observed in a mouse developmental study (Scortichini et al., 1986). The No Observed Adverse Effect Level (NOAEL) was 4000 mg/m³ (1504 ppm) and the Lowest Observed Adverse Effect Level (LOAEL) was 13,000 mg/m³ (4946 ppm). A total uncertainty factor of 300 was used to develop the RfC of 10 mg/m³, including a factor of 10 for intraspecies variability, a factor of 3 (rather than 10)

for interspecies extrapolation (due to dosimetric adjustment of the inhaled concentration), and an uncertainy factor of 10 for database deficiencies (no multigeneration reproductive study and no definitive developmental toxicity studies). NCEA used the RfC as the basis for developing an oral RfD of 0.4 mg/kg/day for chloroethane. The inhalation NOAEL of 4000 mg/m³ was converted to a NOAEL dose of 1,143 mg/kg/day by assuming equal absorption orally and by inhalation, a human inhalation rate of 20 m³/day, and a 70 kg body weight. An uncertainty factor of 3000 was applied to the NOAEL, including the same factors totaling 300 mentioned above for the RfC and an additional uncertainty factor of 10 for route-to-route extrapolation, based on no oral toxicity data and sparse pharmacokinetic data.

Derivation of Ground Water Quality Criterion: The Department has determined that insufficient information exists to develop a specific or interim specific health-based ground water quality criterion for chloroethane at this time. The USEPA cancer slope factor (USEPA, 1993) is inadequate for quantitative risk assessment since it is based on the tumor incidence in a single high dose exposure group and there are no data on oral carcinogenicity of chloroethane. The Ground Water Quality Standards at N.J.A.C 7:9C-1.7(c)6 establish that for synthetic organic chemicals (SOC) not listed in Appendix Table 1, the interim generic ground water quality criterion of 5 μ g/L applies to SOCs with some evidence of carcinogenicity. Therefore, the interim generic ground water quality criterion of 5 μ g/L applies to this constituent.

Derivation of PQL: The method detection limit (MDL) and the practical quantitation level (PQL) are performance measures used to estimate the limits of performance of analytic chemistry methods for measuring contaminants. The MDL is defined as "the minimum concentration of a substance that can be measured and reported with 99 percent confidence that the analyte concentration is greater than zero" (40 CFR Part 136 Appendix B). USEPA recommends that the MDL be multiplied by a factor of five or 10 to account for the variability and uncertainty that can occur at the MDL. The Department uses a value of five as the median upper boundary of the inter-laboratory MDL distribution from the New Jersey certified laboratory community and multiplies the MDL by five to derive the PQL. Establishing the PQL at a level that is five times the MDL provides a reliable quantitation level that most laboratories can be expected to meet during day-to-day operations.

Chloroethane appears as a listed parameter in a published analytical method – "USEPA 524.2, VOCs in Water Using GCMS VOCs in Water Using GCMS". The limit of detection in the method is specified as 0.02 ppb. As explained above, a more conservative detection limit is established using a multiplier of five. 0.02 ppb x 5 = 0.1 ppb. However, the difference between this result and the theoretical detection limit is not statistically significant. Therefore, the Department has established a PQL of 0.5 ppb (μ g/L) for chloroethane.

Conclusion: Based on the information provided above (and cited below), the Department has determined that insufficient information is available to develop a specific or an interim specific ground water quality criterion for chloroethane at this time but that chloroethane is a likely carcinogen; therefore, the applicable constituent standard is the interim generic ground water quality criterion of 5 μ g/L for a carcinogen.

Technical Support Documents: Interim Specific Ground Water Quality Criterion

Recommendation Report for Chloroethane, Dr. Gloria Post, NJDEP, February 28, 2007; *Procedure for Describing Process for Development of Analytical Practical Quantitation Levels (PQLs) for Chloroethane*, R. Lee Lippincott, Ph.D., NJDEP, February 26, 2003.

References:

ATSDR (2008). Agency for Toxic Substances and Disease Registry. U.S. Department of Health and Human Services Web site (http://www.atsdr.cdc.gov/tfacts105.html February 11, 2008. Chloroethane.

NTP (1989). National Toxicology Program. Toxicology and carcinogenesis studies of chloroethane in F344/N and B6C3F1 mice. Inhalation studies. NTP Technical Report No. 346 (cited in USEPA, 1993).

Scortichini, B.H., K.A. Johnson, J.J. Momany-Pfruender and T.R. Hanley, Jr. 1986. Ethyl chloride: Inhalation teratology study in CF-1 mice. Dow Chemical Co. EPA Document #86-870002248 (cited in USEPA, 1996).

USEPA (1993). Risk assessment issue paper for derivation of oral slope factor for chloroethane (CASRN 75-00-3). 93-20/04-05-93.

USEPA (1996). Risk assessment issue paper for derivation of provisional RfD for chloroethane (ethyl chloride) (CASRN 75-00-3). 96-032/08-30-96.

USEPA (1998). United States Environmental Protection Agency. Integrated Risk Information System. Ethyl chloride (CASRN 75-00-3). Last updated 1/2/1998.



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