Fact Sheet Date: March 12, 1998

NEW YORK STATE HUMAN HEALTH FACT SHEET

Ambient Water Quality Value for Protection of Sources of Potable Water

SUBSTANCE: Methylene chloride CAS REGISTRY NUMBER: 75-09-2

AMBIENT WATER QUALITY VALUE: 5 micrograms/liter (5 ug/L)

BASIS: Surface Water: Principal Organic Contaminant Classes

Groundwater: Former Reference to 10 NYCRR Subpart 5-1 Principal

Organic Contaminant (POC) General Maximum

Contaminant Level (MCL)

INTRODUCTION

The physical, chemical and toxicological properties of methylene chloride (dichloromethane) have been reviewed (ATSDR, 1993; US EPA, 1985a,b, 1987, 1990, 1992). The following ambient water quality values were derived using these and other references and the procedures outlined in 6 NYCRR 702.2 through 702.7.

SPECIFIC MCL AND PRINCIPAL ORGANIC CONTAMINANT CLASS (702.3)

Methylene chloride does not have a Specific MCL (maximum contaminant level) as defined in 6 NYCRR 700.1 and is in principal organic contaminant class i as defined in 6 NYCRR 700.1. Therefore, a water quality value of 5 ug/L can be derived based on 6 NYCRR 702.3(b).

ONCOGENIC EFFECTS (702.4)

Methylene chloride induces liver tumors in mice and rats following oral exposure (Serota et

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al., 1986a,b; US EPA, 1995) and liver and lung tumors in mice and mammary gland tumors in rats following inhalation exposure (NTP, 1986; US EPA, 1995) and is an oncogen under 6 NYCRR 700.1. In 1985, the U.S. EPA evaluated the dose-response data for methylene chloride and calculated cancer potency factors of 1.2 x 10⁻² per milligram per kilogram body weight per day (1.2 x 10⁻² (mg/kg/day)⁻¹) for liver tumors in male mice exposed, via drinking water, for two years and 2.6 x 10⁻³ (mg/kg/day)⁻¹ for liver tumors in female mice exposed, via inhalation, 6 hours/day, 5 days/week for two years (Exhibit 1, taken from US EPA, 1995), using procedures consistent with those outlined in paragraphs (a) through (e) of 6 NYCRR 702.4, including the linearized multistage model (extra risk). These cancer potency factors were calculated by the U.S. EPA using a cross-species scaling factor for carcinogen risk assessment based on the assumption that lifetime cancer risks are equal when daily administered doses are in proportion to body weights raised to the 2/3 power (the surface area scaling factor). Proposed New York State regulations state that the scaling factor should be based on the assumption that lifetime cancer risks are equal when daily administered doses are in proportion to body weights raised to the 3/4 power. This change requires application of an adjustment factor to cancer potency factors calculated using a cross-species scaling factor based on surface area.

The water concentration corresponding to the lower bound estimate on the dose associated with an excess lifetime human cancer risk of one-in-one million is 6 ug/L. This value was derived using the adjusted cancer potency factor (6.2 x 10⁻³ (mg/kg/day)⁻¹) based on the most relevant route of exposure (i.e., via drinking water) and the procedure in paragraph (f) of 6 NYCRR 702.4. The adjusted cancer potency factor was calculated by multiplying the U.S. EPA cancer potency factor of 1.2 x 10⁻² (mg/kg/day)⁻¹ by 0.52 (the adjustment factor for a mouse body weight of 0.03 kg).

NON-ONCOGENIC EFFECTS (702.5)

Methylene chloride damages the liver, kidney and central nervous system of laboratory animals (ATSDR, 1993; US EPA, 1985a,b, 1987). In 1985, the U.S. EPA established an oral reference dose (equivalent to an acceptable daily intake) of 60 micrograms per kilogram body weight per day (60 ug/kg/day) for methylene chloride (Exhibit 2, taken from US EPA, 1995), using procedures consistent with those outlined in paragraphs (a) and (b) of 6 NYCRR 702.5. This reference dose was derived by application of a 100-fold uncertainty factor to a no-observed-effect level (NOEL) of 6,000 ug/kg/day for liver toxicity (histological lesions) in rats exposed, via drinking water, for two years (Serota et al., 1986a). A value of 420 ug/L is derived using the procedure outlined in paragraph (e) of 6 NYCRR 702.5 and allowing 20% of the acceptable daily intake to come from drinking water (6 NYCRR 702.5(c)).

CHEMICAL CORRELATION (702.7)

A value based on chemical correlation is not applicable because data are sufficient to evaluate methylene chloride based on both of the sections 6 NYCRR 702.4 and 702.5.

OTHER STANDARDS AND GUIDELINES

Under New York State Department of Health regulations for drinking-water standards (10 NYCRR Part 5), methylene chloride is a principal organic contaminant (POC) and has a MCL of 5 ug/L. Under the Safe Drinking Water Act, the federal maximum contaminant level goal (MCLG) for methylene chloride is zero and the MCL for methylene chloride is 5 ug/L, based on analytical considerations (US EPA, 1992).

The World Health Organization (WHO) calculated a tolerable daily intake of 6 ug/kg/day for methylene chloride by applying an uncertainty factor of 1,000 to a NOEL of 6 mg/kg/day for hepatotoxic effects in a two-year drinking-water study in rats. An uncertainty factor of 1,000 was used to account for human variability, differences between animals and humans and the concern about carcinogenic potential. The WHO derived a guideline value of 20 ug/L for methylene chloride in drinking water (rounded from the calculated value of 18 ug/L), assuming a 60-kg adult drinks 2 L/day and allocating 10% of the WHO reference dose (6 ug/kg/day) to drinking water (WHO, 1993).

SELECTION OF VALUE

According to 6 NYCRR 702.2(b), the selected ambient water quality value shall be the most stringent of the values derived using the procedures found in 6 NYCRR 702.3 through 702.7. This value is 5 ug/L (based on the principal organic contaminant class value) and is the value selected as the water quality value for methylene chloride.

It should be noted that the principal organic contaminant (POC) value of 5 ug/L became a standard for groundwater (6 NYCRR 703.5) effective on January 9, 1989 by inclusion by reference to 10 NYCRR Subpart 5-1 standards. The basis and derivation of this POC standard are described in a separate fact sheet.

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SEARCH STRATEGY: ON-LINE TOXICOLOGIC DATABASE

Toxline (1981 to June, 1995) was searched linking the CAS Registry Number of methylene chloride with the keyword "toxicity."

Bureau of Toxic Substance Assessment/kgb02 New York State Department of Health June, 1995; Revised January, 1997

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