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: Trichloroethene **CAS REGISTRY NUMBER:** 79-01-6

AMBIENT WATER QUALITY VALUE: 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)

I INTRODUCTION

The ambient water quality value applies to the water column and is designed to protect humans from the effects of contaminants in sources of drinking water; it is referred to as a Health (Water Source) or H(WS) value.

Regulations (6 NYCRR 702.2) require that the water quality value be based on the procedures in sections 702.3 through 702.7. Potential water quality values are derived below, and the value of 5 ug/L is selected for trichloroethene as described under "Selection of Value."

II PRINCIPAL ORGANIC CONTAMINANT CLASSES AND SPECIFIC MCL (702.3)

A. Discussion

Trichloroethene does not have a Specific MCL as defined in 700.1. However, trichloroethene is in principal organic contaminant class v as defined in 700.1.

The U.S. Environmental Protection Agency has established a maximum contaminant level goal (MCLG) of zero ug/L and a MCL of 5 ug/L for drinking water for trichloroethene.

Under the State Sanitary Code (10 NYCRR Part 5, Public Water Supplies), the New York State Department of Health has established a general maximum contaminant level of 5 ug/L for principal organic contaminants such as trichloroethene in drinking water.

B. Derivation of Water Quality Value

Because trichloroethene is in a principal organic contaminant class and has no Specific MCL, regulations require that the water quality value not exceed 5 ug/L.

III ONCOGENIC EFFECTS (702.4)

U.S. EPA (1995) conducted a comprehensive evaluation of the oncogenic effects of trichloroethene as part of its criteria development for the Great Lakes Water Quality Initiative (GLI). The GLI was a joint undertaking by U.S. EPA and the Great Lakes States and included representatives of interest groups. Its final regulations and the criteria document for this substance received extensive public review in a formal rule making process. U.S. EPA's documentation for their oncogenic criteria has been reviewed. The Department concludes that trichloroethene is an oncogen under New York's definition in 6 NYCRR 700.1 and that U.S. EPA's toxicological basis is appropriate for derivation of a statewide value.

Exhibit I, excerpted from U.S. EPA (1995), provides U.S. EPA's scientific basis for their criteria. These data will be used to calculate a water quality value for protection from oncogenic effects using New York State procedures as described below.

U.S. EPA (1995) selected the results of the NTP (1982) and NCI (1976) bioassays as the most appropriate dose-response data for deriving a water quality value. A summary of the data sets showing statistically and biologically significant increases in tumor response is presented in Exhibit I. U.S. EPA derived an oral cancer slope factor of 1.1×10^{-2} $[mg/(kg \cdot day)]^{-1}$ from the geometric mean of four slopes from data from the above key studies.

This slope factor was calculated by U.S. EPA using an interspecies scaling of doses based on the 2/3 power of relative body weights. Proposed New York State regulations call for such scaling to be done on the basis of the 3/4 power of relative body weights. An adjustment to U.S. EPA's slope is needed to account for the different scaling methods.

The adjustment factor for mouse data (body weight of 0.030 kg) is a multiplication factor of 0.52, which results in a slope of 5.72×10^{-3} $[mg/(kg \cdot day)]^{-1}$.

This slope factor is converted to a human dose, at a lifetime risk level of one-in-one million as shown below.

$$\text{Human dose} = \frac{\text{risk}}{\text{slope}} = \frac{10^{-6}}{5.72 \times 10^{-3}\ [mg/(kg \cdot day)]^{-1}}$$

$$= 1.75 \times 10^{-4}\ mg/(kg \cdot day) \equiv 0.175\ ug/(kg \cdot day)$$

The human dose above is converted to a potential water quality value based on a 70 kg adult consuming 2 liters of water per day as follows:

$$\text{Water Quality Value} = \frac{[0.175\ ug/(kg \cdot day)]\ [70\ kg]}{[2\ L/day]} = 6.12\ ug/L,$$ rounded to 6 ug/L

IV NON-ONCOGENIC EFFECTS (702.5)

U.S. EPA (1995) did not develop a GLI Tier I human noncancer criterion (Exhibit II) because there is no U.S. EPA verified RfD. The Department made no further pursuit of a non-oncogenic value because it is not likely to be more stringent than an oncogenic value for trichloroethene.

V CHEMICAL CORRELATION (702.7)

A value based on chemical correlation for oncogenic or non-oncogenic effects is not applicable because data are sufficient to evaluate these effects.

VI SELECTION OF VALUE

The H(WS) value is designed to protect humans from oncogenic and non-oncogenic effects from contaminants in sources of drinking water. To protect for these effects, regulations (6 NYCRR 702.2(b)) require that the value be the most stringent of the values derived using the procedures found in sections 702.3 through 702.7. The principal organic contaminant class value of 5 ug/L (6 NYCRR 702.3(b)) is the most stringent value derived by these procedures and is the ambient water quality value for trichloroethene.

The principal organic contaminant (POC) groundwater standard of 5 ug/L (6 NYCRR 703.5) applies to trichloroethene. This standard became effective on January 9, 1989 by reference to 10 NYCRR Subpart 5-1 standards. The basis and derivation of the POC standard are described in a separate fact sheet.

VII REFERENCES

6 NYCRR (New York State Codes, Rules and Regulations). Water Quality Regulations, Surface Water and Groundwater Classifications and Standards: Title 6 NYCRR, Chapter X, Parts 700-705. Albany, NY: New York State Department of Environmental Conservation.

10 NYCRR (New York State Codes, Rules and Regulations). Public Water Systems: Title 10 NYCRR, Chapter 1, State Sanitary Code, Subpart 5-1. Albany, NY: New York State Department of Health, Bureau of Public Water Supply Protection.

U.S. EPA (Environmental Protection Agency). 1995. Great Lakes Water Quality Initiative Criteria Documents for the Protection of Human Health. Washington, D.C.: Office of Water. EPA-820-B-95-006.

New York State Department of Environmental Conservation
Division of Water
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EXHIBIT I
(From U.S. EPA,1995)

GREAT LAKES WATER QUALITY INITIATIVE
TIER 1 HUMAN HEALTH CRITERIA FOR TRICHLOROETHYLENE
CAS NO. 79-01-6

Tier 1 Human Cancer Criterion

Six epidemiologic studies have been performed to investigate the carcinogenicity of trichloroethylene (TCE) in exposed workers (Axelson et al., 1978; Hardell et al., 1981; Malek et al., 1979; Novotna et al., 1979; Paddle, 1983; Tola et al, 1980). Results of those studies were inadequate to attribute cancer incidence to TCE exposure. However, because they suffer from various limitations and deficiencies, they also fail to provide adequate evidence that TCE is not a human carcinogen (EPA, 1985).

Based on weight of evidence, EPA (1985, 1987, 1988) classified TCE in Group B2- Probable Human Carcinogen. The evidence reviewed by EPA (1985) for carcinogenicity of TCE in experimental animals includes increased incidence of hepatocellular carcinomas in male and female B6C3F1 mice (NCI, 1976; NTP, 1982, 1986) by gavage, malignant lymphomas in female Han:NMRI mice by inhalation (Henschler et al., 1980); and renal adenocarcinomas in male Fischer 344 rats by gavage (NTP, 1982, 1986). Evidence presented in EPA (1987) markedly strengthened the B2 classification by showing that inhalation is a second exposure route that results in carcinogenic activity in rats and mice, and by identifying diverse tumor sites (EPA, 1987).

EPA (1985) developed a quantitative cancer risk assessment based on four sets of gavage bioassay data that show hepatocellular carcinomas in male and female mice (NTP, 1982; NCI, 1976). The NCI bioassay involved exposure by gavage to B6C3F1 mice. Although rats were also tested, excessive mortality in all groups cast doubt on the adequacy of those results. Mice were dosed in groups of 50 animals per sex, 5 days/week for 78 weeks. Surviving animals were sacrificed at 90 weeks and subjected to complete necropsy and histopathological examination. The time-weighted-average (TWA) doses for male mice were 1,169 and 2,339 mg/kg, and for the female mice they were 869 and 1,739 mg/kg. The study included 20 matched vehicle control animals of each sex. It was concluded that TCE induced a statistically significant ($p < 0.05$) increase in the incidence of hepatocellular carcinoma in both male and female B6C3F1 mice. A reduction in the time-to-tumor response was also reported among male mice at the high dose level. The presence of the trace contaminant epichlorohydrin (0.09%) in the test material for this bioassay could be a cause for concern. However, it has been determined that any potential contribution of epichlorohydrin to the overall carcinogenic potency of TCE in the bioassay was negligible (EPA, 1985).

NTP (1982) conducted a carcinogenicity bioassay on TCE in B6C3F1 mice and F344/N rats.

The rats experienced reduced survival when compared to controls, and the results were therefore invalidated. Male and female mice were dosed by gavage at 1,000 mg/kg, 5 days/week for 103 weeks. Survival was significantly lower ($p < 0.004$) in treated males whereas survival in treated females was lower after 95 weeks, but the overall difference between vehicle controls and treated females was not significant. Male and female mice had a statistically significant increase in the incidence of hepatocellular carcinoma ($p \leq 0.002$) and hepatocellular adenoma ($p \leq 0.05$) over corresponding vehicle controls. The TCE test material for that bioassay was not contaminated with detectable amounts of epichlorohydrin. The potency of TCE with regard to the induction of hepatocellular carcinomas in mice has been determined to be very similar in the NTP (1982) bioassay and the NCI (1976) bioassay (EPA, 1985).

Additional studies were reviewed by EPA (1987) identifying positive findings by inhalation exposure in rats and mice. Maltoni et l. (1986) conducted bioassays of Sprague-Dawley rats exposed to 0, 100, 300 and 600 ppm of TCE 7 hours/day, 5 days/week for 104 weeks. Necropsy was performed on all animals. Male rats demonstrated increased incidence of renal tubuli megalonucleocytosis and renal adenocarcinomas, and a slight increase in leukemias, particularly immunoblastic lymphosarcomas. Maltoni et al. (1986) also conducted bioassays on Swiss mice and B6C3F1 mice (90 mice/strain/sex/group) exposed to 0, 100, 300, and 600 ppm TCE for 78 weeks. Statistically significant increases in hepatomas were noted among male Swiss mice at the high concentration, and significant increases in pulmonary tumors were observed among male Swiss mice at high and medium exposures. Among the B6C3F1 mice, there were increases in hepatomas in males and females, pulmonary tumors in females, and in the total number of tumors among females at all concentrations.

Fukuda et al., (1983) reported the results of bioassays with female ICR mice and Sprague-Dawley rats (49-50 per group) exposed to airborne concentrations of 0, 50, 150, and 450 ppm of TCE for 7 hours/day, 5 days/week for 107 weeks. There were no statistically significant increases in tumors among rats, however a statistically significant increase in lung adenocarcinomas was found among the mice.

Using the mice liver tumor data sets from NTP (1982) and NCI (1976), EPA (1985) calculated human slope estimates of 1.9×10^{-2}, 8.0×10^{-3}, 1.8×10^{-2}, and 5.8×10^{-3} $(mg/kg/day)^{-1}$. Because the slope estimates from these four data sets were found to be comparable, their geometric mean was used to derive the recommended slope factor of 1.1×10^{-2} $(mg/kg/day)^{-1}$. EPA (1987) also developed slope factors from the inhalation studies of Maltoni et al. (1986) and Fukuda et al. (1983). These slope factors were found to be comparable to the q_1* developed earlier from the gavage studies (EPA, 1987).

EPA is currently reviewing the carcinogenicity data for trichloroethylene. Based on this review EPA may change the carcinogenicity characterization for trichloroethylene. However, until this review is completed the previously verified oral slope factor of 1.1×10^{-2} $(mg/kg/day)^{-1}$ will be used.

References:

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EXHIBIT II
(From U.S. EPA, 1995)

GREAT LAKES WATER QUALITY INITIATIVE
TIER 1 HUMAN HEALTH CRITERIA FOR TRICHLOROETHYLENE
CAS NO. 79-01-6

Tier 1 Human Noncancer Criterion

EPA is currently reviewing the RfD for trichloroethylene. Because there is no EPA verified RfD that can be used for derivation of a Tier I human noncancer, the final Guidance does [not] include a noncancer criterion for trichloroethylene.