Fact Sheet Date: June 1998

NEW YORK STATE
- HUMAN HEALTH FACT SHEET -

Ambient Water Quality Value for
Protection of Sources of Potable Water

SUBSTANCE: 2,4-Dimethylphenol **CAS REGISTRY NUMBER:** 105-67-9

AMBIENT WATER QUALITY VALUE: 50 ug/L

BASIS: General Organic Guidance Value

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 702.15) require that the water quality value be the more stringent of the values derived using the procedures in sections 702.3 through 702.7, or a "general organic guidance value" of 50 ug/L. Potential water quality values are derived below, and the value of 50 ug/L selected for 2,4-dimethylphenol as described under "Selection of Value."

PRINCIPAL ORGANIC CONTAMINANT CLASSES AND SPECIFIC MCL (702.3)

A. Discussion

2,4-Dimethylphenol does not have a Specific MCL for New York State as defined in 700.1. It is not in a principal organic contaminant class as defined in 700.1.

B. Derivation of Water Quality Value

Because 2,4-dimethylphenol does not have a Specific MCL and is not in a principal organic contaminant class, no water quality value can be derived based on 702.3.

ONCOGENIC EFFECTS (702.4)

U.S. EPA (1995) conducted a comprehensive evaluation of the oncogenic effects of 2,4-dimethylphenol 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 does not consider 2,4-dimethylphenol to be carcinogenic. The Department concludes that 2,4-dimethylphenol does not meet New York's definition of an oncogen in 6 NYCRR 700.1. Therefore, a value based on oncogenic effects is not derived.

NON-ONCOGENIC EFFECTS (702.5)

U.S. EPA (1995) also conducted a comprehensive review of toxicological data on non-oncogenic effects for 2,4-dimethylphenol as part of criteria development under GLI. The Department reviewed the toxicological basis for EPA's non-oncogenic criteria and concludes it is appropriate for the derivation of a statewide value. Exhibit I, excerpted from U.S. EPA (1995), provides the scientific basis for their non-oncogenic criteria. These data will be used to develop a water quality value for protection from non-oncogenic effects using New York State procedures as described below.

U.S. EPA (1995) selected the results of the study by U.S. EPA (1989) as the most appropriate for deriving a water quality value based on non-oncogenic effects. From these, they calculated an acceptable daily exposure (ADE) of 16.7 ug/(kg · day), equivalent to an acceptable daily intake (ADI) developed under NYS procedures (702.5).

A potential water quality value is calculated from the ADI, above, based on a 70 kg adult consuming 2 liters of water per day and allocating 20% of the ADI to drinking water, as follows:

$$\text{Water Quality Value} = \frac{[16.7\ \text{ug/(kg} \cdot \text{day)}]\ [70\ \text{kg}]\ [0.2]}{[2\ \text{L/day}]}$$

$$= 117\ \text{ug/L, rounded to } 100\ \text{ug/L}$$

The results of a recent 90-day study of 2,4-dimethylphenol in rats (Daniel et al., 1993) support the value derived by U.S. EPA. A no-observed-effect level (NOEL) of 60 mg/kg/day was identified from this study.

CHEMICAL CORRELATION (702.7)

A value based on chemical correlation is not applicable because data are sufficient to evaluate 2,4-dimethylphenol based on section 702.5 and insufficient information was found upon which to derive a value based on chemical correlation to section 702.4.

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 702.15) require that the value be the most stringent of the values derived using the procedures found in sections 702.3 through 702.7, or a "general organic guidance value" of 50 ug/L.

The data on non-oncogenic effects do yield a value of 100 ug/L (6 NYCRR 702.5). However, there is a lack of data on the chronic, reproductive and developmental effects of 2,4-dimethylphenol. Accordingly, there are not adequate and sufficient data to justify a value greater than 50 ug/L as described in 702.15. Thus, the appropriate H(WS) ambient water quality guidance value for 2,4-dimethylphenol is the general organic guidance value of 50 ug/L.

REFERENCES

Daniel, F.B., M. Robinson, G.R. Olson, R.G. York, and L.W. Condie. 1993. Ten and ninety-day toxicity studies of 2,4-dimethylphenol in Sprague-Dawley rats. Drug and Chemical Toxicology 16(4): 351-368.

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). 1989. Ninety day Gavage Study in Albino Mice Using 2,4-Dimethylphenol. Study No. 410-2831, prepared by Dynamac Corporation, Rockville, MD for the Office of Solid Waste and Emergency Response, Washington, D.C.

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.

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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.

EXHIBIT I

GREAT LAKES WATER QUALITY INITIATIVE
TIER 1 HUMAN HEALTH CRITERIA FOR
2,4-DIMETHYLPHENOL
CAS NO. 105-67-9

Tier 1 Human Noncancer Criterion

A review of the available literature indicates that HNV derivation for 2,4-dimethylphenol (2,4-DMP) is most appropriately based on the subchronic oral mouse study conducted by EPA (1989). Groups consisting of 30 male and 30 female albino mice were administered 2,4-DMP by gavage at dose levels of 0, 5, 50 or 250 mg/kg/day for 90 days. At day 30, an interim sacrifice was performed on at least 8 males and 9 females from each group. Effects examined included mortality, clinical signs, body weights, food consumption, ophthalmology, hematology, clinical chemistry, organ weights, and gross histopathology. Toxicologically relevant clinical signs observed only after week 6 at 250 mg/kg/day in both sexes included squinting, lethargy, prostration, and ataxia, with onset shortly after dosing. Statistically significant lower mean corpuscular volume and mean corpuscular hemoglobin concentrations were observed in female mice at 250 mg/kg/day during the final but not during the interim sacrifice. At interim sacrifice, the blood urea nitrogen (BUN) levels for females at 50 and 250 mg/kg/day were significantly lower than the vehicle controls, while at the final sacrifice, the BUN levels for females at 50 mg/kg/day were significantly higher than the vehicle control group. For only the low-dose (5 mg/kg/day) males at the interim sacrifice, cholesterol levels were significantly higher than the vehicle control group. Increased adrenal weights were observed in low-dose (5 mg/kg/day) but not mid- to high-dose females when compared to vehicle control animals. Since the reported changes in BUN, serum cholesterol and adrenal weights were not dose- or time-dependent, they may be interpreted to be spurious findings. The NOAEL and LOAEL for this study were 50 and 250 mg/kg/day, respectively, based on clinical signs and hematological changes.

The database is judged to be sufficient for Tier 1 HNC derivation because the key study (EPA, 1989) provides a subchronic NOAEL. However, there is a paucity of supplemental and supportive data. No useful chronic, reproductive or developmental studies are available. The overall findings from the 90-day study (EPA, 1989) compare favorably with the results of a 14-day mice gavage study (EPA, 1987; as cited in EPA, 1989; EPA, 1990) conducted at the same laboratory. In the 14-day study, the only toxicological signs observed in males and females administered 250 mg/kg/day were lethargy, prostration, and ataxia. This is the same dose at which critical effects were found in the 90-day study (EPA, 1989).

The HNV is derived from the NOAEL dose of 50 mg/kg/day from the 90-day gavage mouse study by EPA (1989) with an uncertainty factor of 3000. This approach is consistent with the derivation of the oral RfD for 2,4-DMP by EPA (1990).

$$ADE = \frac{NOAEL}{UF} = \frac{50\ mg/kg/d}{3000} = 1.67 \times 10^{-2}\ mg/kg/d$$

Where: Uncertainty Factor = 3000, composed of:

10x for interspecies variability
10x for intraspecies differences
10x for subchronic exposure duration
3x for substantial gaps in the database

References:

U.S. Environmental Protection Agency (EPA). 1990. Integrated Risk Information System (IRIS database). Chemical file for 2,4-dimethylphenol (105-67-9). Verification Date 2/21/90. Last Reviewed 2/21/90.

U.S. Environmental Protection Agency (EPA). 1989. Ninety-Day Gavage Study in Albino Mice Using 2,4-Dimethylphenol. Study No. 410-2831, prepared by Dynamac Corporation, Rockville, MD, for the Office of Solid Waste and Emergency Response, Washington, DC.

U.S. Environmental Protection Agency (EPA). 1987. Fourteen-Day Gavage Study in Albino Mice Using 2,4-Dimethylphenol. Study No. 410-2830, prepared by Dynamac Corporation, Rockville, MD, for the Office of Solid Waste and Emergency Response, Washington, DC. As cited in EPA (1989, 1990).

U.S. Environmental Protection Agency (EPA). 1980. Ambient Water Quality Criteria for 2,4-Dimethylphenol. Office of Water Regulations and Standards, Criteria and Standards Division, Washington, DC. EPA 440/5-80-044. PB81-117558.