Fact Sheet Date: JAN 0 2 1998

NEW YORK STATE
HUMAN HEALTH FACT SHEET

Ambient Water Quality Value for Protection of Sources of Potable Water

SUBSTANCE: Endothall **CAS REGISTRY NUMBER:** 145-73-3

AMBIENT WATER QUALITY VALUE: 50 micrograms/liter (50 µg/L)

BASIS: General Organic Guidance Value (6 NYCRR 702.15(a)(1)(ii))

INTRODUCTION

The physical, chemical, and toxicological properties of endothall have been reviewed (US EPA, 1988, 1990, 1992, 1995). 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 and 6 NYCRR 702.15(a)(1).

SPECIFIC MCL AND PRINCIPAL ORGANIC CONTAMINANT CLASS (702.3)

Endothall does not have a Specific MCL (maximum contaminant level) as defined in 6 NYCRR 700.1(a)(41) and is not in a principal organic contaminant class as defined in 6 NYCRR 700.1(a)(34). Therefore, a water quality value cannot be derived under 6 NYCRR 702.3.

ONCOGENIC EFFECTS (702.4)

One study performed to test the oncogenicity of endothall in laboratory animals was compromised by the small number of animals used and is inadequate to evaluate the oncogenic potential of endothall (US EPA, 1990).

NON-ONCOGENIC EFFECTS (702.5)

Endothall damages the stomach and small intestine and causes fetotoxicity in laboratory animals (US EPA, 1988, 1990). There are gaps in the toxicological data on the chronic toxicity of endothall. In 1986, the U.S. EPA established an oral reference dose (equivalent to an acceptable daily intake) of 20 micrograms per kilogram body weight per day (20 µg/kg/day) for endothall (Exhibit 1, taken from US EPA, 1995), using procedures consistent with those outlined in paragraphs (a) and (b) of 6 NYCRR 702.5. The reference dose was derived by application of a 100-fold uncertainty factor to a no-observed-effect level of 2,000 µg/kg/day for increased stomach and small intestine weights in dogs orally exposed for two years (US EPA, 1995). The uncertainty factor of 100 was used to account for variability among humans and differences between animals and humans. A value of 140 µg/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)).

AESTHETIC CONSIDERATIONS (702.6)

Data on the levels of endothall that would impair the aesthetic quality of water were not found.

CHEMICAL CORRELATION (702.7)

Although available data were not sufficient to evaluate endothall based on oncogenic effects (6 NYCRR 702.4) or aesthetic considerations (6 NYCRR 702.6), values based on chemical correlation were not derived because of insufficient data.

OTHER STANDARDS AND GUIDELINES

Under the New York State Department of Health regulations for drinking-water standards (10 NYCRR Part 5), endothall is an unspecified organic contaminant (UOC) and has a MCL of 50 µg/L. Under the Safe Drinking Water Act, the federal maximum contaminant level goal (MCLG) and the MCL for endothall are both 100 µg/L (rounded from 140 µg/L), assuming a 70-kg adult drinks 2 L/day and allocating 20% of the U.S. EPA reference dose (20 µg/kg/day) to drinking water (US EPA, 1990b, 1992a).

SELECTION OF VALUE

According to 6 NYCRR 702.15(a)(1), a guidance value may be derived for substances that do not have a standard in 6 NYCRR 703.5 and shall be the more stringent of the values derived using the procedures found in 6 NYCRR 702.3 through 702.7, or, in some cases, a general organic guidance value of 50 µg/L. Although applying the procedures of 6 NYCRR 702.5 to the available non-oncogenic data on endothall yields a value greater than 50 µg/L (i.e., 140 µg/L), the toxicological data base is limited, particularly with respect to chronic toxicity and oncogenic potential. Accordingly, there are not adequate and sufficient data available to justify a value greater than 50 µg/L, based on both oncogenic and non-oncogenic effects, as described in 6 NYCRR 702.15(a)(1)(ii). Thus, a guidance value of 50 µg/L (based on the organic guidance value) is selected as the water quality value for endothall.

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.

US EPA (U.S. Environmental Protection Agency). 1988. Endothall: Health Advisory. Washington, DC: Office of Drinking Water.

US EPA (U.S. Environmental Protection Agency). 1990. National Primary Drinking Water Regulations; Synthetic Organic Chemicals and Inorganic Chemicals; Proposed Rule. Fed. Register. **55**:30370-30448.

US EPA (U.S. Environmental Protection Agency). 1992. National Primary Drinking Water Regulations; Synthetic Organic Chemicals and Inorganic Chemicals; Final Rule. Fed. Register. **57**:31776-31849.

US EPA (U.S. Environmental Protection Agency). 1995. Endothall. On-Line as of May 1. Integrated Risk Information System (IRIS). Cincinnati, OH: Office of Research and Development, Environmental Criteria and Assessment Office.

SEARCH STRATEGY: ON-LINE TOXICOLOGIC DATABASE

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

Bureau of Toxic Substance Assessment/kgb02
New York State Department of Health
May, 1995

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Exhibit 1: Oral Reference Dose Summary for Endothall (CAS Registry Number 145-73-3) Taken from the On-Line Integrated Risk Information System (IRIS) of the U.S. Environmental Protection Agency (as of May 1, 1995).

REFERENCE DOSE FOR CHRONIC ORAL EXPOSURE (RfD)

Substance Name: Endothall
CASRN: 145-73-3

RfD ASSESSMENT SUMMARY TABLE

Crit. Dose: 2 mg/kg-day [Study 1 NOAEL(adj)]
UF: 100 MF: 1 RfD: 2E-2 mg/kg-day Confidence: Medium

Crit Effect: (1) Increased absolute and relative weights of stomach and small intestine

	NOAEL (Study 1)	LOAEL (Study 1)
Reported	100 ppm (diet)	300 ppm (diet)
ADJ	2 mg/kg-day	6 mg/kg-day
Study Type	Two-Year Feeding Study in Dogs	Two-Year Feeding Study in Dogs
Reference	Pennwalt Agchem., 1965	Pennwalt Agchem., 1965

1) Pennwalt Agchem., 1965
Two-Year Feeding Study in Dogs

Critical Effect: Increased absolute and relative weights of stomach and small intestine

Defined Dose Levels:
NOAEL= 100 ppm (diet)
NOAEL(ADJ)= 2 mg/kg-day
LOAEL= 300 ppm (diet)
LOAEL(ADJ)= 6 mg/kg-day

Conversion Factors: Dose adjusted for assumed dog food consumption (2.5% bw/day) and expressed as endothall ion.

DISCUSSION OF PRINCIPAL AND SUPPORTING STUDIES

Pennwalt Agchem. 1965. MRID No. 00101735. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Three male and 3 female dogs were administered diets that initially contained 0, 100, 300 or 800 ppm of disodium endothall. The concentration in the high-dose group was gradually increased over months 19-22 to a final concentration of 2000 ppm. The doses were calculated on the basis of the amount of endothall ion in the diet, and the standard equivalence factor for dogs (0.025 kg of diet/kg of bw/day). No effect on weight gain, hematology, BSP clearance, SGOT or urinalysis was noted. At necropsy, increased absolute and relative weights of stomach and small intestine were noted in intermediate and high-dose dogs. Increased "mucosal gland activity" was noted in the stomachs of high-dose dogs, along with slight edema of the pyloric region.

UNCERTAINTY AND MODIFYING FACTORS

UNCERTAINTY FACTORS:

An uncertainty factor of 100 was used to account for inter- and intraspecies differences.

CONFIDENCE IN THE RfD

Study: Medium Data Base: Medium RfD: Medium

The critical study appears to be of fair quality and is given a medium confidence rating. The data base is generally supportive but since there is a data gap existing for endothall, the data base is also given a medium confidence rating. Medium confidence in the RfD follows.