

**AMBIENT SURFACE WATER QUALITY
STANDARDS DOCUMENTATION****CHEMICAL:** Dyphylline**CAS NO.(s):** 479-18-5**BASIS (Human/Aquatic):** Human**WATER CLASSIFICATION:** AA; AA-s; A; A-s**STANDARD:** 50 ug/l **Note** D**REMARKS:****SUMMARY INFORMATION:**

Dyphylline, a smooth muscle relaxant, is a neutral theophylline derivative having the same pharmacologic actions, uses and adverse reactions as theophylline.^{1,2} Adequate information necessary to establish a guideline based on the aesthetic effects of dyphylline is unavailable. Dyphylline has not been adequately tested to determine its oncogenic potential. A four-month study in adults of the toxicity of the parent compound, theophylline, indicates that a daily oral dose of 6 mg/kg may be expected to produce low serum theophylline concentrations (<3 ug/ml) and no toxic effects in most individuals.³ Using the oral dose of 6 mg/kg and an uncertainty factor of 1000, an acceptable daily intake (ADI) of 6 ug/kg/day can be calculated for theophylline.

STANDARD DERIVATION:

Based on the estimated ADI of 6 ug/kg/day for theophylline and assuming that a 70 kg adult ingests 20% of the ADI by drinking 2 liters of water/day, a guideline of 40 ug/l can be calculated for theophylline, the parent compound of dyphylline. Dyphylline is approximately 71% theophylline moiety by weight. In the absence of adequate data on subchronic or chronic toxicity, the recommended ambient water quality standard for dyphylline is 50 ug/l based on its chemical similarity to theophylline.

REFERENCES:

- (1) Timson, J. 1975. Mutation Res. 32, 169-178.
- (2) Rudolph, B.M. 1977. J. Tenn. Med. Assoc. 70, 171-174.
- (3) Jacobs, M.H., et al. 1976. JAMA, 2.35, 1983-1986.

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