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VALUE (S) ADDED

| FACT | SHEET | REVISED |  |
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VALUE(S) REMOVED

## AMBIENT SURFACE WATER QUALITY STANDARDS DOCUMENTATION

CHEMICAL: Niacinamide

CAS NO.(s): 98-92-0

BASIS (Human/Aquatic): Human

WATER CLASSIFICATION: AA; AA-s; A; A-s

STANDARD: 500 ug/l Note B

REMARKS:

## **SUMMARY INFORMATION:**

Niacinamide is a water-soluble, B complex vitamin which is widely-distributed in body tissues, required for normal body metabolism and used to treat niacin deficiency (pellagra). 1,2 Niacinamide is the physiologically active form of niacin (nicotinic acid) in humans, being a component of two important coenzymes that are required for tissue respiration, lipid metabolism, and energy transfer in glycolysis. In normal individuals, the niacinamide required is converted from niacin in vivo and from some dietary tryptophan (an amino acid) oxidized in vivo to niacin. Tryptophan and niacin occur in many foods.

The recommended daily allowance (RDA) for niacin or niacinamide is 5-9 mg for children under 4 years old and 12-20 mg for adults and children over 4 years old. Dietary sources can provide a more than adequate supply of niacin to prevent deficiency in most people. The average diet provides about 16 to 33 mg of niacin daily. Supplemental multivitamin preparations may reasonably add another 6 to 30 mg/day of niacinamide. Oral doses of niacinamide greatly exceeding the physiologic requirement have been associated with abnormalities in liver function, jaundice, chronic liver damage, abnormal prothrombin time, and hypoalbuminemia.

The available information is inadequate to establish a guideline based on aesthetic effects (niacinamide has a bitter taste). Niacinamide has not been adequately tested to determine its oncogenic potential. The results of a subchronic 28-day study of the effects of niacinamide on the growth of rats indicate that the minimal-effect-level (5% growth reduction) occurred at 72 mg/kg/day; 3 at higher levels, a dose-related inhibition of growth was observed.

## STANDARD DERIVATION:

A subchronic 28-day study in rats provides a minimal-effect-level of 72 mg/kg/day. Based on this minimal-effect-level and an uncertainty factor of 1000, an acceptable daily intake (ADI) of 72 ug/kg can be calculated. Using a body weight of 70 kg and consumption of 2 liters of water per day, a guideline value of 500 ug/l would provide a daily dose corresponding to 20% of the calculated ADI and 5% to 10% of the RDA for niacinamide. In the absence of appropriate studies on the chronic ingestion, the value of 500 ug/l is recommended as the ambient water quality standard for niacinamide. This level, however, if found in drinking water would be indicative of unnatural contamination.

## REFERENCES:

- (1) American Medical Association, 1980, AMA Drug Evaluations, 4th Edition, pp. 829-930.
- (2) Brazda, F.G. and R.A. Coulson, 1946, Toxicity of nicotinic acid and some of its derivatives, Proc. Soc. Exp. Biol. Med. <u>62</u>, 19-20.
- (3) Handler, P. and W. J. Dann, 1942, The inhibition of rat growth by nicotinamide, J. Biol. Chem. 146, 357-368.

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