VALUE(S) ADDED 7-24-85

FACT SHEET REVISED _____

VALUE(S) REMOVED _____

AMBIENT SURFACE WATER QUALITY STANDARDS DOCUMENTATION

CHEMICAL: Vinyl chloride

CAS NO.(s): 75-01-4

BASIS (Human/Aquatic): Human

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

STANDARD: 0.3 ug/l Note A

REMARKS:

SUMMARY INFORMATION:

The toxicologic data base for this compound has been reviewed.[1-5,7] It is a human and animal oncogen as defined in Part 701.1(p). Chronic exposure of laboratory animals to gavage or inhalation doses of this compound has resulted in a significant increase in the incidence of tumors at numerous sites in rats, mice and hamsters, including tumors of the liver (angiosarcomas), lung, mammary gland and brain. Vinyl chloride has also been demonstrated to be a transplacental carcinogen in rats. This compound has been found to be mutagenic in a variety of biological test systems and the preponderance of evidence supports a conclusion that it is mutagenic in humans. Several independent but mutually confirmatory epidemiological studies have shown that workplace exposure to vinyl chloride results in an increased carcinogenic risk involving the liver (angiosarcomas), brain, lungs, and hemo-lymphopoietic system.

STANDARD DERIVATION:

Dose-response data from a Maltoni et al.[6] carcinogenesis bioassay (oral administration to rats) were used for extrapolation. Using the protocol in Part 701.4 and a linearized multistage extrapolation procedure (GLOBAL82)[8], a vinyl chloride concentration of 0.3 ug/l in water was calculated to correspond to an increased human cancer risk of 1×10^{-6} over a lifetime (see calculations below). The recommended ambient water quality standard for vinyl chloride is 0.3 ug/l.

Calculations:

1. Maltoni et al. Bioassay Data

The incidence of liver angiosarcomas in female and male rats given doses of 0, 3.3 and 16.65 and 50.0 mg/kg of vinyl chloride via gavage on 4-5 days each week during the exposure period is the dose-response data for the most sensitive tumor type in the most sensitive species, occurring at a statistically significant level. Separate data on male and female rats were not available.

2. Average Daily Intake (for animals)*

Average Daily Intake During Lifetime
0 mg/kg/day
1.06 mg/kg/day
5.35 mg/kg/day
16.07 mg/kg/day

*Exposure was only for 4-5 days a week; therefore, doses on treatment days were multiplied by 4.5/7 to calculate average daily doses during the exposure period. In addition, rats were assumed to live an additional 52 weeks without exposure after being exposed for 52 weeks; therefore, average daily doses during exposure were multiplied by 0.50 to calculate average daily doses during lifetime.

3. Data Input for GLOBAL82 Computer Program

Dose (mg/kg/day)	Number of animals with tumors	Number of experimental animals
0	0	80
1.06	0	80
5.35	9	80
16.07	16	80

4. GLOBAL82 Result (for animals)

The lower 95% confidence limit value of the vinyl chloride dose corresponding to an increased lifetime cancer risk of 1×10^{-6} for the experimental animals was 0.048 ug/kg/day.

5. Conversion of the animal dose (ug/kg/day) to a human dose using surface area conversion rule

$$\text{rodent dose (ug/kg/day)} \times \left(\frac{\text{animal body wt. (kg)}}{\text{human body wt. (kg)}}\right)^{0.33} = \text{human dose (ug/kg/day)}$$

$$0.048 \text{ ug/kg/day} \times \left(\frac{0.30 \text{ kg}}{70 \text{ kg}}\right)^{0.33} = 0.0079 \text{ ug/kg/day}$$

6. Calculation of the vinyl chloride level in water corresponding to an increased cancer risk of 1×10^{-6} for a 70 kg human ingesting 2 liters of contaminated water per day over a lifetime.

$$\frac{0.0079 \text{ ug/kg/day} \times 70 \text{ kg}}{2 \text{ l/day}} = 0.28 \text{ ug/l}$$

REFERENCES:

(1) National Academy of Sciences. 1977. Drinking Water and Health, Vol. 1. National Academy of Sciences. Washington, D.C.

(2) National Academy of Sciences. 1983. Drinking Water and Health, Vol. 5. National Academy Press. Washington, D.C.

(3) International Agency for Research on Cancer. 1979. IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. 19: 377-438.

(4) U.S. Environmental Protection Agency. 1980. Ambient water quality criteria for vinyl chloride. NTIS No. PB81-117889.

(5) U.S. National Institute of Environmental Health Services. 1981. Conference to reevaluate the toxicity of vinyl chloride monomer, poly(vinyl chloride), and structural analogs. Envir. Hlth. Persp. 41: 1-231.

(6) Maltoni, C. et al. 1977. Vinyl chloride carcinogenicity: an experimental model for carcinogenesis studies. In: Hiatt, H.H. et al. (eds.). Origins of Human Cancer, Book A. Cold Spring Harbor Laboratory. Cold Spring Harbor, N.Y. pp. 119-146.

(7) Barlow, S.M. and F.M. Sullivan. 1982. Reproductive Hazards of Industrial Chemicals. Academic Press, N.Y.

(8) Howe, R.B. and K.S. Crump. 1982. GLOBAL82 Computer Program. Science Research Systems, Inc., Ruston, LA.

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