VALUE(S) ADDED 7-24-85

FACT SHEET REVISED _____

VALUE(S) REMOVED _____

AMBIENT SURFACE WATER QUALITY STANDARDS DOCUMENTATION

CHEMICAL: 1,1-Dichloroethylene

CAS NO.(s): 75-35-4

BASIS (Human/Aquatic): Human

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

STANDARD: 0.07 ug/l Note A

REMARKS:

SUMMARY INFORMATION:

The toxicologic data base for this compound has been reviewed.[1-3] It is an animal oncogen as defined in Part 701.1(p). Chronic exposure of laboratory animals to inhaled doses of this compound has resulted in a significant increase in the incidence of kidney tumors in male mice and perhaps mammary gland tumors in female mice and rats.[4] It has also shown genotoxic activity in short-term tests.[2] Although the oncogenicity of inhaled 1,1-dichloroethylene has not been confirmed by other studies using oral or inhalation doses,[2,3] these studies did not meet the criteria for a well-designed and well-conducted oncogenic bioassay; specifically, exposures were too short and/or doses too low to maximize the probability of inducing and detecting tumors.

STANDARD DERIVATION:

Dose-response data from the Maltoni et al.[4,5] carcinogenesis bioassay were used for extrapolation. Using the protocol in Part 701.4 and a linearized multistage extrapolation procedure (GLOBAL82)[5], a 1,1-dichloroethylene concentration of 0.07 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 1,1-dichloroethylene is 0.07 ug/l.

Calculations:

1. Maltoni et al. Bioassay Data

The incidence of kidney tumors in male mice exposed to 1,1-dichloroethylene concentrations in air of 0, 10 and 25 ppm for 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 and sex, occurring at a statistically significant level.

2. Average Daily Intake (for animals)*

Average Daily Intake During Lifetime
0 mg/kg/day
2.42 mg/kg/day
6.05 mg/kg/day

*The dose received by the mice during their exposure to air concentrations of 1,1-dichloroethylene can be calculated from the following equation:

$$D = (R \times h \times c \times a)/W$$

where D = mg/kg/day on treatment days,

R = m^3 of air respired per mouse per day ($R = 0.0345\ (W/0.025)^{2/3}\ m^3/day$)[6],

W = body weight of mouse (0.03 kg),

h = proportion of day exposed (4h/24h = 0.17),

c = air concentration of 1,1-dichloroethylene in mg/m^3 (1 ppm = 3.97 mg/m^3),

a = proportion of inhaled 1,1-dichloroethylene absorbed (1.0)

Exposure was only for 4-5 days a week; therefore, calculated doses on treatment days were multiplied by 4.5/7 to calculate average daily doses during the exposure period. In addition, mice lived an additional 69 weeks without exposure after being exposed for 52 weeks; therefore, average daily doses during exposure were multiplied by 0.43 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	126
2.42	0	25
6.05	28	119

4. GLOBAL82 Result (for animals)

The lower 95% confidence limit value of the 1,1-dichloroethylene dose corresponding to an increased lifetime cancer risk of 1×10^{-6} for the experimental animals was 0.027 ug/kg/day.

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

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

$$0.027 \text{ ug/kg/day} \times \left(\frac{0.03 \text{ kg}}{70 \text{ kg}}\right)^{0.33} = 0.0021 \text{ ug/kg/day}$$

6. Calculation of the 1,1-dichloroethylene 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.

$$\frac{0.0021 \text{ ug/kg/day} \times 70 \text{ kg}}{2 \text{ l/day}} = 0.074 \text{ ug/l}$$

REFERENCES:

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

(2) International Agency for Research on Cancer. 1979. IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. 19: 439-459.

(3) U.S. Environmental Protection Agency. 1980. Ambient water quality criteria for dichloroethylenes. NTIS No. PB81-117525.

(4) Maltoni, C. et al. 1977. Carcinogenicity bioassays of vinylidene chloride. Research plans and early results. Med. Lav. 68: 242-262.

(5) U.S. Environmental Protection Agency. 1983. Health assessment document for vinylidene chloride (review draft). EPA-600/8-83-031A.

(6) U.S. Environmental Protection Agency. 1980. Water quality criteria documents; availability. Fed. Register. 79318-79378.

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

KB/pb DEC 1 8 1984