

Adopted as Rule: November 2023

# **Toxicological Summary for: 1,1-Dichloroethylene**

CAS: **75-35-4** 

Synonyms: Vinylidene chloride, 1,1-Dichloroethene

Acute Non-Cancer Health Risk Limit (nHRL<sub>Acute</sub>) = Not Derived (Insufficient Data)

Short-term Non-Cancer Health Risk Limit (nHRL<sub>Short-term</sub>) = Not Derived (Insufficient Data)

Subchronic Non-Cancer Health Risk Limit (nHRL<sub>Subchronic</sub>) = 200 µg/L

(Reference Dose, mg/kg-d) x (Relative Source Contribution) x (Conversion Factor)
(Subchronic Intake Rate, L/kg-d)

=  $(0.069 \text{ mg/kg-d}) \times (0.2)^* \times (1000 \text{ µg/mg})$  $(0.074 \text{ L/kg-d})^{**}$ 

= 186 rounded to 200  $\mu$ g/L

Reference Dose/Concentration: HED/Total UF = 2.07/30 = 0.069 mg/kg-d (Sprague Dawley

Rat)

Source of toxicity value: Determined by MDH in 2019

Point of Departure (POD): 9 mg/kg-d (NOAEL, Nitschke et al. 1983 supported by

Quast et al. 1977)

Dose Adjustment Factor (DAF): 0.23, Body weight scaling, default (USEPA, 2011) (MDH,

2017)

Human Equivalent Dose (HED): POD x DAF = 9 mg/kg-d x 0.23 = 2.07 mg/kg-d

Total uncertainty factor (UF): 30

Uncertainty factor allocation: 3 for interspecies differences (for toxicodynamics), 10 for

intraspecies variability

Critical effect(s): Fatty changes in the liver

Co-critical effect(s): None

Additivity endpoint(s): Hepatic (liver) system

<sup>\*</sup>Relative Source Contribution: MDH 2008, Section IV.E.1.

<sup>\*\*</sup>Intake Rate: MDH 2008, Section IV.E.1. and US EPA 2019, Exposure Factors Handbook, Tables 3-1, 3-3 and 3-5

#### Chronic Non-Cancer Health Risk Limit (nHRL<sub>Chronic</sub>) = 200 μg/L

# (Reference Dose, mg/kg-d) x (Relative Source Contribution) x (Conversion Factor) (Chronic Intake Rate, L/kg-d)

# = $(0.040 \text{ mg/kg-d}) \times (0.2)^* \times (1000 \text{ µg/mg})$ $(0.045 \text{ L/kg-d})^{**}$

### = 177 rounded to 200 μg/L

Reference Dose/Concentration: HED/Total UF = 1.20/30 = 0.040 mg/kg-d (Sprague Dawley

Rat)

Source of toxicity value: Determined by MDH in 2019

Point of Departure (POD): 4.6 mg/kg-d (BMDL<sub>10</sub>, Quast et al. 1983 as calculated by

USEPA, 2002)

Dose Adjustment Factor (DAF): 0.26, Body weight scaling, default (USEPA, 2011) (MDH,

2017)

Human Equivalent Dose (HED): POD x DAF = 4.6 mg/kg-d x 0.26 = 1.20 mg/kg-d

Total uncertainty factor (UF): 30

Uncertainty factor allocation: 3 for interspecies differences (for toxicodynamics), 10 for

intraspecies variability

Critical effect(s): Fatty changes in the liver Co-critical effect(s): Fatty changes in the liver Additivity endpoint(s): Hepatic (liver) system

#### Cancer Health Risk Limit (cHRL) = Not Applicable

Cancer classification: Data are inadequate for an assessment of human

carcinogenic potential (oral route); Suggestive evidence of

carcinogenicity, but not sufficient to assess human carcinogenic potential (inhalation route) (USEPA, 2002)

Slope factor (SF): Not Applicable

Source of cancer slope factor (SF): Not Applicable

Tumor site(s): Not Applicable

**Volatile:** Yes (high)

#### **Summary of Guidance Value History:**

A non-cancer Health Risk Limit (HRL) of 6  $\mu$ g/L was promulgated in 1993/1994. Subchronic and chronic health-based values (HBV) of 200  $\mu$ g/L were derived in 2009 and were promulgated as Health Risk Limits (HRL) in 2011. In 2019, MDH re-evaluated the noncancer HRLs using the most recent risk assessment methodology, resulting in no changes to the subchronic and chronic guidance values. In

<sup>\*</sup>Relative Source Contribution: MDH 2008, Section IV.E.1.

<sup>\*\*</sup>Intake Rate: MDH 2008, Section IV.E.1. and US EPA 2019, Exposure Factors Handbook, Tables 3-1, 3-3 and 3-5

2020 MDH incorporated updated intake rates (US EPA 2019). Use of the updated intake rates did not result in any changes to the guidance values. In November 2023, the guidance values were adopted into Minnesota Rules, 4717.7860, as Health Risk Limits (HRLs).

#### Summary of toxicity testing for health effects identified in the Health Standards Statute (144.0751):

Even if testing for a specific health effect was not conducted for this chemical, information about that effect might be available from studies conducted for other purposes. MDH has considered the following information in developing health protective guidance.

	Endocrine	Immunotoxicity	Development	Reproductive	Neurotoxicity
Tested for specific effect?	No	No	Yes	Yes	No
Effects observed?	-	-	Yes <sup>1</sup>	Yes <sup>2</sup>	_3

#### Comments on extent of testing or effects:

<sup>1</sup>Two developmental studies with oral exposure have been conducted in laboratory animals. No developmental effects were observed at doses up to 100 times higher than the subchronic reference dose. Developmental effects were tested and observed in inhalation studies, however, maternal toxicity was evident at levels that resulted in developmental toxicity.

<sup>2</sup>One multi-generation reproductive study with oral exposure has been conducted in laboratory animals. No reproductive effects were observed at doses up to 100 times higher than the subchronic reference dose. No reproductive effects were observed in developmental inhalation studies in laboratory animals.

<sup>3</sup>Neurotoxicity of 1,1-dichloroethylene has not been studied. However, neurotoxicity endpoints were included in a developmental inhalation study in laboratory animals. No evidence of developmental neurotoxicity was observed up to the highest dose tested.

## **Resources Consulted During Review:**

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