

Summary of Initial Risk Assessment Report

1,2-Dichloroethane CAS No : 107-06-2

PRTR No of Japan: 116

This substance is assessed based on Guideline for Initial Risk Assessment Version 1.0

1. General Information

1.1 Physico-chemical properties

Appearance	Colorless liquid
Melting point	-35.7 degC
Boiling point	83-84 degC
Water solubility	8.6 g/L (25 degC)
Henry's constant	120 Pa*m ³ /mol (1.18*10 ⁻³ tm*m ³ /mol) (23degC, measured)
Octanol/water partition coefficient (log Kow)	1.48 (measured), 1.83 (calculated)
Soil adsorption coefficient	Koc = 44 (estimated)

1.2 Environmental fate

Bioaccumulation	Not or low bioaccumulative Bioconcentration factor (BCF) : 2.0 (<i>Lepomis macrochirus</i>)
Biodegradation	1,2-Dichloroethane is generally considered non-biodegradable; however, it is expected to be biodegradable in specific conditions involving acclimatized microorganisms.
Stability in the environment	(In air) Reaction with OH radical: Reaction rate constant is 2.48*10 ⁻¹³ cm ³ /molecule-sec. (25 degC, measured) The half-life is 1-2 months, given OH radical concentration of 5*10 ⁵ -1*10 ⁶ molecule/cm ³ . Reaction with ozone: No data Reaction with nitrate radical: No data (In water) 1,2-Dichloroethane is not expected to be hydrolyzed in the general aquatic environment.
Environmental fate	If released into water, 1,2-dichloroethane is expected to be removed mainly by volatilization.

2. Sources of release to the environment

2.1 Annual production, import, export and domestic supply in 2001 (ton/year)

Production	Import	Export	Domestic supply	Remarks
3,274,975	383,448	20,548	3,637,875	

2.2 Uses

Mainly used as raw materials for polyvinyl chloride monomers, ethylenediamines, polyamino resins, and ion exchange resins. It is also used for film washing agents, solvents for organic syntheses, vitamin extraction, insecticides, and fumigants.

2.3 Release from the industries within the scope of PRTR system (in 2001)

Release sources		Air (ton)	Waters (ton)	Soil (ton)	Remarks
Listed industries	Reported release	915	4	0	Release to rivers: 1.7 tons
	Release outside notification	10	< 0.5	0	
Release outside notification from non listed industry		--	--	--	
Households		--	--	--	
Mobile sources		--	--	--	
Total		925	4	0	

2.4 Releases from other sources

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2.5 Main release route

1,2-Dichloroethane is expected to be released into air mainly during use of 1,2-dichloroethane or products containing it.

3. Exposure Assessment

3.1 Measured environmental concentration

Media	No. of points detected / No. of points measured	No. of samples detected / No. of samples measured	Detection range	95th percentile	Detection limit	Year of investigation, Institution
Air (microg/m ³)	-- /335	-- /3690	0.0075 -2.7 ¹⁾	--	--	2000 Ministry of the Environment
River water (microg/L)	13 /2,113	25 /5,147	nd-0.8 ¹⁾	--	0.4-1.0	2001 National Institute for Environmental Studies
Drinking water (microg/L)	-- /5,519	--	nd	--	0.4	2000 Japan Water Works Association
Food (microg/g-wet)	--	-/72	nd	--	0.001	1999 Ministry of the Environment

nd: Not detected

1) annual average

3.2 Estimated environmental concentration

Media	Estimated concentration	Description
Air (microg/m ³)	2.9	Calculated by mathematical model / Atmospheric Dispersion Model for Exposure and Risk Assessment ver.1.0 (AIST-ADMER)
River water (microg/L)	0.72	Calculated by mathematical model / Integrated River Model to predict the distribution of chemical concentration (IRM1)

3.3 Estimated environmental concentration in water (EEC)

EEC(microg/L)	0.8
	Measured concentration of 0.8 microg/L surveyed by the National Institute for Environmental Studies was used for EEC ¹⁾ .

3.4 Estimated human intake

Intake route		Concentration used for estimation of intake	Estimated intake (microg/ person/ day)	Estimated intake (microg/ kg-Bodyweight (BW)/ day)
Inhalation	Air	2.7 (microg/m ³)	54	1.1
		Maximum (2.7 microg/m ³) of measured annual average concentration surveyed by the Ministry of the Environment wa used.		
Oral	Drinking water	0.2 (microg/L)	0.40	0.008
		The value (0.2 microg/L) equal to 1/2 of the detection limit (0.4 microg/L) was used, since 1,2-dichloroethane was not detected in any samples in the survey by Japan Water Works Association.		
	Food	0.0005 (microg/g)	1.0	0.02
		The value (0.0005 microg/g) equal to 1/2 of the detection limit (0.001 microg/g) was used, since 1,2-dichloroethane was not detected in the survey by the Ministry of the Environment in 1999.		
Subtotal	--	1.4	0.028	
Total route		--	55	1.1

1) This substance is assessed based on the Guideline for Initial Risk Assessment Version1.0. If adequate measured concentrations are available, they are given priority and used as values for risk assessment. If they are not available, an estimated value calculated using a mathematical model is used.

4. Hazard assessment

4.1 Effects on organisms in the environment

	Acute or Chronic	Species	Endpoint	Concentration
Algae	Chronic	<i>Selenastrum capricornutum</i>	72 hours NOEC Growth inhibition (biomass)	65.6 (mg/L)
Crustacea	Chronic	<i>Daphnia magna</i>	21 days NOEC Reproduction	1.02 (mg/L)
Fish	Chronic	<i>Pimephales promelas</i>	32 days NOEC Hatching, survival, growth	29 (mg/L)
Key study		Data of crustacea (<i>Daphnia magna</i>) was chosen for the key study because effects were observed at the lowest concentration in the hazard assessment.		

4.2 Human health toxicity

Toxicity	Exposure route	Species	Duration / Dose method	Toxic effects (Key study is underlined)	NOAEL or LOAEL
Repeated dose toxicity	Inhalation	Rat (SD)	12 months Inhalation exposure	<u>Increased ALT and uric acid, decreased T-Cho, increased gamma-GST in females,</u> increased Glu	NOAEL: 10 ppm (41.1 mg/m ³) (equivalent to 6.4 mg/kg/day)
	Oral	Rat (SD)	90 days Gavage administration	<u>Increased relative weight of kidneys and liver, decreased Hgb, increased Plt,</u> increased relative weight of brain, testes and adrenal in males, increased RBC and Hct in females	NOAEL: 37.5 mg/kg/day
	Dermal	--	--	--	--
Reproductive and developmental toxicity	--	Risk characterization of reproductive and developmental toxicity was not conducted, since no effects on offspring noted up to the highest dose level of 300 ppm, equivalent to 1,233 mg/m ³ /day in developmental toxicity study via inhalation in rat.			
Carcinogenicity	Evaluation by IARC : Group 2B (possibly carcinogenic to humans)				
Genotoxicity	Possibly genotoxic				

5. Risk Assessment

5.1 Environmental organisms

Risk characterization	EEC (microg/L)	NOEC * (mg/L)	MOE (NOEC * /EEC)	Product of uncertainty factors	Conclusion
	0.8	NOEC: 1.02	1,300	10	No immediate concern
Product of uncertainty factors (UF): Extrapolation from laboratory test (10) = 10					
Recommendation : The substance is considered to be of no immediate concern for the moment, and a low priority for further work.					

* NOEC means NOEC, LOEC, EC₅₀, etc.

5.2 Human health

5.2.1 Repeated dose toxicity

Exposure route	Intake (microg/kgBW/day)	NOAEL (mg/kgBW/day)	Risk characterization		
			MOE	Product of uncertainty factors	Conclusion
Inhalation	1.1	6.4	5,800	100	No immediate concern
Oral	0.028	37.5	1,300,000	500	No immediate concern
Total	--	--	--	--	--

Product of uncertainty factors (UF):
 Inhalation: Interspecies (10) * Intraspecies (10) = 100
 Oral: Interspecies (10) * Intraspecies (10) * Duration of test (5) = 500

5.2.2 Reproductive and developmental toxicity

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5.2.3 Carcinogenicity

Risk characterization of carcinogenicity of the substance was not carried out in this assessment.

5.2.4. Recommendation for Human Health

Though the substance is considered to be of no immediate concern for the moment and a low priority for further work, it should be noted that a carcinogenic risk characterization was not conducted. The possibility remains that this substance may be carcinogenic to humans.

6. Supplement

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