Summary of Initial Risk Assessment Report

Dichloromethane; methylene dichloride CAS No : 75-09-2

PRTR No of Japan: 145

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	-95 degC
Boiling point	39.75 degC
Water solubility	13 g/L (20 degC)
Henry's constant	329 Pa*m^3/mol (3.25 *10^{-3}atm*m^3/mol) (25degC, measured)
Octanol/water partition coefficient (log Kow)	1.25 (measured), 1.34 (estimated)
Soil adsorption coefficient	Koc = 24 (estimated)

1.2 Environmental fate

Bioaccumulation	Exhibits little to no bioaccumulation Bioconcentration factor (BCF) : 2.0-5.4 (0.25 mg/L), < 6.4-40 (0.025 mg/L) (carp) (measured)
Biodegradation	Dichloromethane 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 1.42*10^{-13} cm^3/molecule-sec. (25 degC, measured) The half-life is 2-4 months, given OH radical concentration of 5*10^5-1*10^6 molecule/cm^3. Reaction with ozone: No data Reaction with nitrate radical: Reaction rate constant is 1.66*10^{-17} cm^3/molecule-sec. (25 degC, measured) The half-life is 0.6-6 years, given nitrate radical concentration of 2.4*10^8-2.4*10^9 molecule/cm^3 (10-100 ppt). Dichloromethane is not expected to be directly photolyzed. (In water) Dichloromethane is not readily hydrolyzed in water.
Environmental fate	If released into water, dichloromethane is expected to be rapidly removed to air by volatilization due to its high volatility.

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
70,022	10,751	3,089	77,684	

2.2 Uses

Washing agent (print circuit boards, metal degreasing) (50%), solvent for medical products/agricultural chemicals (16%), aerosol propellant, paint remover (9%), reaction solvent of polycarbonate (6%), foaming auxiliary agent for urethane foam (5%), fiber/film solvent (5%), adhesive (4%), other solvent (5%)

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	27,116	19	< 0.5	Release to rivers: 56 tons
	Release outside notification	56,593	40	< 0.5	
Release outside notification from non listed industry		--	--	--	
Households		--	--	--	
Mobile sources		--	--	--	
Total		83,709	59	< 0.5	

2.4 Releases from other sources

No information about the substance is available.

2.5 Main release route

Dichloromethane is expected to be released into air mainly during use of dichloromethane and 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)	Unspecified /307	Unspecified /3,685	0.17-20[1)]	--	--	2001 Ministry of the Environment
River water (microg/L)	42/2,118	343/5,617	nd-6[1)]	--	0.2-10	2001 National Institute for Environmental Studies
Sea water (microg/L)	8/688	36/1382	nd-4[1)]	--	0.2-10	2001 National Institute for Environmental Studies
Drinking water (microg/L)	5,703[2)]	--	nd	--	2	1999 Japan Water Works Association
Food (microg/g)	--	0/45	nd	--	0.05	1997 Japan Food Research Laboratories

nd: Not detected.

1) Annual average

2) number of water purification plants in Japan

3.2 Estimated environmental concentration

Media	Estimated concentration	Description
Air (microg/m^3)	22	Calculated by mathematical model / Atmospheric Dispersion Model for Exposure and Risk Assessment ver.1.0 (AIST-ADMER)
River water (microg/L)	3.6	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)	6
	Maximum of annual average of measured concentrations in river water (6 microg/L)[1] was used for the risk assessment.

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	20 (microg/m^3)	400	8.0
		Maximum of annual average concentration in the survey by the Ministry of the Environment ,20 microg/m^3, was used for the risk assessment.		
Oral	Drinking water	1 (microg/L)	2	0.04
		The value (1 microg/L) equal to 1/2 of the detection limit of survey by Japan Water Works Association in 1999 was used for the risk asssessment.		
	Food	0.16 (microg/g)	19	0.38
		-Dichloromethane was not detected in any of the meal samplers of 45 households in a duplicate diet study conducted by the Japan Food Research Laboratories. -The detection limit of the survey was too high. Using a value equal to 1/2 of the detection limit may result in overestimation of human intake via food. -Therefore, the concentration in food was estimated using the concentration in fish. The concentration in fish was calculated as a product of the concentration in seawater and a BCF. 4 (microg/L) * 40 (L/kg) = 0.16 (microg/g)		
	Subtotal	--	21	0.42
Total route		--	420	8.4

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	Acute	*Selenastrumapricornutum* *Skeletonema costatum*	96 hours EC_{50} Growth inhibition	> 662 (mg/L)
Crustacea	Acute	*Daphnia magna*	48 hours LC_{50}	136 (mg/L)
Fish	Chronic	*Oncorhynchus mykiss*	27 days LC_{50}	13.2 (mg/L)
Key study		The data of fish (*oncorhynchus mykiss*) 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 Mouse	100 days (24 hours)	hepatocellular vacuolation, fat stain positive hepatocytes	LOAEL: 25 ppm (88 mg/m^3) (equivalent to 65.4 mg/kg/day)
	Oral	Rat (F344)	104 weeks Drinking water	Increased Hct, Hgb and RBC, increased incidence of foci and areas of hepatocellular alteration, reduced body weight gain, decreased ALP, Crn, BUN, TP, and T-Cho	NOAEL: 5 mg/kg/day
	Dermal	--	--	--	--
Reproductive and developmental toxicity	--	--	--	--	--
Carcinogenicity	Evaluation by IARC : Group 2B (possibly carcinogenic to humans)				
Genotoxicity	Dichloromethane gave positive results in gene mutation assays using bacteria and yeast with and without S9-mix. Likewise, it showed positive results in alkaline elution methods using cultured mammalian cells and mammals, and in chromosomal aberration tests using mammals at higher exposure concentrations, although it did mostly negative results in gene mutation assays and chromosomal aberration tests using cultured mammalian cells. Dichloromethane is known for its potential to induce gene damage in organisms and individuals expressing GSTT1 gene.				

5. Risk Assessment

5.1 Environmental organisms

	EEC (microg/L)	NOEC * (mg/L)	MOE (NOEC * /EEC)	Product of uncertainty factors	Conclusion
Risk character -ization	6	LC_{50}: 13.2	2,200	200	No immediate concern
	Product of uncertainty factors (UF): Extrapolation from laboratory test (10) * Toxicity data on one nutritional stage (10) * Additional factor (2)* = 200 *Using of LC_{50} instead of NOEC				
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, EC_{50}, 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	8	LOAEL: 65	8,100	5,000	No immediate concern
Oral	0.42	5	12,000	100	No immediate concern
Total	8.4	5 (Oral)	600	100	No immediate concern
Product of uncertainty factors (UF): Inhalation: Interspecies (10) * Intraspecies (10) * Using of LOAEL (10) * Duration of test (5) = 5,000 Oral/Total: Interspecies (10) * Intraspecies (10) = 100					

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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