Summary of Initial Risk Assessment Report

Formaldehyde CAS No : 50-00-0

PRTR No of Japan: 310

This substance is assessed based on Guideline for Initial Risk Assessment Version1.0

1. General Information

1.1 Physico-chemical properties

Appearance	Colorless gas
Melting point	-92 degC
Boiling point	-19.5 degC
Water solubility	55 %
Henry's constant	3.41 * 10^{-2} Pa*m^3/mol (3.37 * 10^{-7}atm*m^3/mol) (25degC ,measured)
Octanol/water partition coefficient (log Kow)	0.35 (measured), 0.35 (estimated)
Soil adsorption coefficient	Koc = 1 (estimated)

1.2 Environmental fate

Bioaccumulation	Low bioaccumulative Bioconcentration factor (BCF) : 3.2 (estimated)
Biodegradation	Readily biodegradable
Stability in the environment	(In air) Reaction with OH radical: The reaction rate constant is 9.4 * $10^{-12}$$cm^3$/molecule-sec (25degC, measured). The half-life is 20-40 hours, given OH radical concentration of 5 * 10^5-1 * 10^6 molecule/cm^3. Reaction with ozone: Formaldehyde does not react with ozone. Reaction with nitrate radical : The reaction rate constant is 5.8 * 10^{-16} cm^3/molecule-sec. (25degC, estimated) The half-life is 0.2-2 months, given nitrate radical concentration is 2.4 * 10^8-2.4 * 10^9 molecule/cm^3. Photodegradation: Formaldehyde can be photodegradated directly, since it absorbs light of length more than 360 nm. (In water) Formaldehyde may react with water to produce ethylene glycol and paraformaldehyde.
Environmental fate	Formaldehyde is expected to be removed mainly by biodegradation when released to the aquatic environment. Volatilization from water to air, adsorption to sediment and suspended matter in the aquatic environment are not important environmental fate processes.

2. Information of 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
1,063,047	2	885	1,062,164	

2.2 Uses

Raw materials for resins (polyacetal resin, urea resin, melamine resin, phenol resin)

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

Release		Air (ton)	Waters (ton)	Soil (ton)	Remarks
Listed industries	Reported release	549	83	< 0.5	Release to rivers: 1,010 tons
	Release outside notification	982	148	< 0.5	
Release outside notification from non listed industry		98	817	0	
Household		1	0	0	
Mobile sources		25,207	0	0	
Total		26,837	1,048	<0.5	

2.4 Releases from other sources

(Natural sources)

Oxidation of hydrocarbon by ozone and OH radical, growth of plants accompanied with terpene or isoprene, degradation by microorganisms

(Anthropogenic sources)

Vehicle exhaust gas, smoke of cigarette, combustion of fuel

(Indoor)

Smoke of cigarette, particleboard and plywood, furniture

2.5 Main release route

Formaldehyde is expected to be released mainly from vehicles. An important release to aquatic environments may be through the use of medical products. Formaldehyde residue in adhesives for household use may result in indoor air pollution.

3. Exposure Assessment

3.1 Measured environmental concentration

Media	No. of points detected / No. of points examined	No. of samples detected / No. of samples examined	Detection range	95th percentile	Detection limit	Year of investigation & institution
Air (microg/m^3)	--	Unspecified /103	2.8-569	140	Un-specified	2000-2001 The Tokyo Metropolitan Research Laboratory of Public Health
River water (microg/L)	35/90	--	nd-4	2.6	1	1999 Ministry of Environment
Drinking water (microg/L)	61/1,233	-	nd-76	-	8	2002 Japan Water Research Center
Food (microg/g)	--	44/45	nd-1.5	0.49	0.02	1999 Japan Food Research Laboratories

nd: not detected

For calculation of the 95th percentile, data less than the detection limit are replaced with a value equal to 1/2 of the detection limit**.**

3.2 Estimated environmental concentration

Media	Estimated concentration	Description
Air compartment (microg/m^3)	3.0	Calculated by mathematical model / Atmospheric Dispersion Model for Exposure and Risk Assessment (AIST-ADMER)
Water (microg/L)	4.3	Calculated by mathematical model / Integrated River Model to predict the distribution of chemical concentration ver.1 (IRM1)

3.3 Estimated environmental concentration in water (EEC) for risk assessment

EEC(microg/L)	2.6
	The 95th percentile of measured concentrations in river water was used for the risk assessment.[1)]

3.4 Estimated intake in human

Intake route		Concentrations used for estimation of intake	Estimated intake/ day (microg/ person/ day)	Estimated intake / body weight / day (microg/ kg-Bodyweight (BW)/ day)
Inhalation	Air	140 (microg/m^3)	2,800	56
		Observed concentrations of formaldehyde in indoor air were higher than those of outdoor air. Measured concentration in indoor air was used for the risk assessment.		
Oral	Drinking water	76 (microg/L)	150	3
		Maximum of measured concentration in tap water surveyed by Japan Water Research Center in 2002 was used for the risk assessment.		
	Foods	0.49 (microg/g)	980	19.6
		A duplicate diet study was performed on 45 households by Japan Food Research Laboratories in1999. The concentrations of formaldehyde were measured for each of the 45 household diets. The 95th percentile (0.49microg/g) is used.		
	Sub total	--	1,130	23
Total route		--	3,930	79

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 Environmental organisms toxicity

	Acute or Chronic	Species	Endpoint	Concentration
Algae	Acute	*Scenedesmus quadricauda*	24hours EC_{50} growth inhibition (growth rate)	14.7(mg/L)
Crustacea	Acute	*Daphnia pulex*	48 hours EC_{50} Immobilization	5.8(mg/L)
Fish	Acute	*moronesaxxatilis*	96 hours LC_{50}	6.7(mg/L)
Key study		Data of crustacea was chosen for the key study because effects were observed at the lowest concentration in the hazard assessment.		

4.2 Human health toxicity

	Exposure routes	Experiment-al animal	Dose term/ dose method	Toxic effects	NOAEL
Repeated dose toxicity	Inhalation	Monkey	26 weeks	Metaplasia of nasal turbinate mucosa	0.2 ppm (equivalent to 0.039 mg/kgBW/day)
	Oral	Rat	2 years drinking water	Hyperplasia of the glandular stomach, focal hyperkeratosis of forestomach, gastritis	260 mg/L (equivalent to 15 mg/kgBW/day)
Reproductive and developmental toxicity	No influence observed in offspring at a dose level without significant maternal toxicity in reproduction toxicity and/or teratology studies.				
Carcinogenicity	Evaluation by IARC : Group 1 (Carcinogenic to humans)				
Genotoxicity	Considered to be genotoxic				

5. Risk Assessment

5.1 Environmental organisms

	EEC (microg/L)	NOEC* (mg/L)	MOE (NOEC* / EEC)	Product of uncertainty factors	Conclusion
Risk characterization	2.6	EC_{50}:5.8	2,200	100	No immediate concern
	Product of uncertainty factors (UF):Extrapolation from laboratory test (10) * Acute toxicity (100) * Additional factor by assessor (0.1)** = 100 * * Data of three species representative three tropic levels including sensitive species are extensively available. In addition, a ratio of chronic toxicity data to acute toxicity data is assumed to be relatively small due to results of acute and chronic tests on fish and crustacea. An additional factor of 0.1 is adopted.				
Recommendation : The substance is considered to be of no immediate concern for the moment, and 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	56	0.039	0.70	200	Substance of concern
Oral	23	15	650	100	No immediate concern
Total	-	-	-	-	
Product of uncertainty factors (Inhalation): interspecies (10) * intraspecies (10) * test duration (2) = 200 Product of uncertainty factors (Oral): 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

The substance is considered to be of concern about effects and further investigation, analysis and assessment are necessary

6. Supplement

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