Summary of Initial Risk Assessment Report

Glutaraldehyde CAS No : 111-30-8

PRTR No of Japan: 66

This substance is assessed based on Guideline for Initial Risk Assessment Version 2.0

1. General Information

1.1 Physico-chemical properties

Appearance	Colorless liquid
Melting point	-14 (degC)
Boiling point	187-189 (degC)
Water solubility	Miscible
Henry's constant	$1.11*10^{-2}$ Pa*m^3/mol ($1.10*10^{-7}$ atm*m^3/mol) (25degC, estimated)
Octanol/water partition coefficient (log Kow)	-0.33 (measured), -0.18 (estimated)
Soil adsorption coefficient	Koc = 380 (measured), 1 (estimated)

1.2 Environmental fate

Bioaccumulation	Low bioaccumulative Bioconcentration factor (BCF): 3.2 (calculated using logKow of -0.33)
Biodegradation	Readily biodegradable Considered to be biodegradable under both aerobic and anaerobic conditions.
Stability in the environment	(In air) Reaction with OH radical: Reaction rate constant is $8.40*10^{-121}$ cm^3/molecule-sec. (25degC, measured value) The half-life is 8-20 hours, given OH radical concentration of $5*10^5$ – $1*10^6$ molecule/cm^3. Reaction with ozone: The data is not available. Reaction with nitrate radical: The data is not available. (In water) Glutaraldehyde is expected to be hydrolyzed easily in basic water, and also has the possibility to be oxidized by dissolved oxygen to produce glutaric acid.
Environmental fate	If released into water, glutaraldehyde is expected to be removed by biodegradation mainly under aerobic conditions. Under anaerobic conditions, only primary degradation may occur.

2. Sources of release to the environment

2.1 Annual production, import, export and domestic supply in 2002 (ton/year)

Production	Import	Export	Domestic supply	Remarks
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2.2 Uses

Sterilizers (disinfectants), algicides (60%), developer of photographs (40%). Other uses are reagents, cross-linking agents and tanning agents

2.3 Release from the industries within the scope of PRTR system (in 2004)

Release sources		Air (ton)	Waters (ton)	Soil (ton)	Remarks
Listed industries	Reported release	0.14	0.24	0	Release to river: 1 ton
	Release outside notification	0.54	0.90	0	
Release outside notification from non listed industry		--	--	--	
Households		--	--	--	
Mobile sources		--	--	--	
Total		0.68	1.1	0	

2.4 Releases from other sources

No information about the substance is available.

2.5 Main release route

Glutaraldehyde is expected to be released into aquatic environments mainly during use of reagents or disinfectants by universities or research institutes.

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	--	--	--	--	--	--
River water (microg/L)	2/59	2/59	nd-0.4	0.15	0.3	2000 Ministry of the Environment
Sea water (microg/L)	0/11	0/11	nd	--	0.3	2000 Ministry of the Environment
Drinking water (microg/L)(as ground water)	0/15	0/15	nd	-	0.3	2000 Ministry of the Environment
Food	--	--	--	--	--	--

nd: Not detected.

In calculation of 95 percentile, data less than detection limit are replaced to the value of one half of detection limit.

3.2 Estimated environmental concentration

Media	Estimated concentration	Description
Air (microg/m^3)	0.0026	Calculated by mathematical model / Atmospheric Dispersion Model for Exposure and Risk Assessment (AIST-ADMER) Ver.1.5
River water (microg/L)	0.090	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)	0.15
	The measured concentration in river water was used for the risk assessment, since the value was higher than the estimated concentration. [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	0.0026 (microg/m^3)	0.052	0.001
		Estimated concentration in the air ($2.6*10^{-3}$ microg/ m^3) was used, since no measured concentration is available.		
Oral	Drinking water	0.15 (microg/L)	0.30	0.006
		-Concentration in ground water was used, since no measured concentration in drinking water was available. -The value equal to 1/2 of detection limit was used, since glutaraldehyde was not detected in any samples.		
	Food	0.00048 (microg/g)	0.058	0.00116
		-Data of intake from food was not available. -Concentration in fish was estimated as a product of a concentration in seawater and BCF. -The value equal to 1/2 of detection limit was used for concentration in seawater, since glutaraldehyde was not detected in any samples in the survey by the Ministry of the Environment in 2000.		
	Subtotal	--	0.358	0.0072
Total route		--	0.41	0.0082

1) This substance is assessed based on the Guideline for Initial Risk Assessment Version2.0. Under Version 2.0, a measured concentration and an estimated concentration (calculated by mathematical model) are compared and the larger of two concentrations is used for risk assessment.

4. Hazard assessment

4.1 Effects on organisms in the environment

	Acute or Chronic	Species	Endpoint	Concentration
Algae	Acute	*Selenastrum capricornutum*	96 hours EC_{50} Growth inhibition Biomass	3.9 (mg/L)
Crustacea	Acute	*Daphnia magna*	48 hours LC_{50}	16.3 (mg/L)
Fish	Acute	*Oncorhynchus Mykiss*	96hours LC_{50}	10 (mg/L)
Key study		Data of algae (*Selenastrum capricornutum*) 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 (converted)
Repeated dose toxicity	Inhalation	Mouse	13 weeks	Reduced body weight gains, inflammation of nasal vestibule, hyperplasia, squamous metaplasia, inflammation, and erosion of respiratory epithelium on nasoturbinates, dyspnea, tachypnea, hypoactivity, ruffled fur, abdominal posture, squamous metaplasia and necrosis of laryngeal epithelium	LOAEL: 0.0625 ppm (0.26 mg/m^3) (equivalent to 0.077mg/kg/day)
	Oral	Rat	104 weeks Drinking water	Decreased food and drinking water consumption, reduced body weight gains, increased absolute and relative weight of kidneys, hyperplasia of bone marrow, renal tubular pigmentation, gastritis, edema and squamous epithelial hyperplasia of forestomach	LOAEL:50 ppm (equivalent to 6 mg/kg/day)
	Dermal	SD Rat	35 days	Thymic atrophy in female, increase in liver relative weight in male	NOAEL: 1 mg/kg/day
Reproductive and developmental toxicity	(Reproductive toxicity) Oral	Rat	Study for two generations	Decreased feed consumption, decreased weight gain of brood	No influence on the reproduction by 1000ppm of the highest dose (69.1-99.6 mg/kg/day)
	(Developmental toxicity) Oral	Rabbit	Developmental toxicity study, administered by oral gavage on GD 7-19	fetus deformity	decrease in body weight, no deformity in child animal's at 45mg/kg/day of the highest dose
Carcinogenicity	Evaluation by IARC : This substance has not been evaluated by IARC.				
Genotoxicity	Unable to determine genotoxicity				

5. Risk Assessment

5.1 Environmental organisms

Risk characterization	EEC (microg/L)	NOEC * (mg/L)	MOE (NOEC * /EEC)	Product of uncertainty factors	Conclusion
	0.15	EC_{50}: 3.9	26,000	1000	No immediate concern.
	Product of uncertainty factors (UF): Extrapolation from laboratory test (10) *Extrapolation from the result of acute toxicity test (100) = 1,000				
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	0.001	LOAEL: 0.077	77,000	5,000	No immediate concern
Oral	0.0072	LOAEL: 6.0	830,000	5,000	No immediate concern
Total	--	--	--	--	--
Product of uncertainty factors (UF): Inhalation/Oral: Interspecies (10) * Intraspecies (10) * Using of LOAEL(10) * Duration of test (5) = 5,000					

5.2.2 Reproductive and developmental toxicity

Since NOAEL of reproductive and developmental toxicity is larger than NOAEL of repeated dose toxicity, risk characterization of reproductive and developmental toxicity was not conducted.

5.2.3 Carcinogenicity

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5.2.4. Recommendation for Human Health

The substance is considered to be of no immediate concern for the moment, and low priority for further work.

6. Supplement

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