

Summary of Initial Risk Assessment Report

Ethylene oxide CAS No : 75-21-8

PRTR No of Japan: 42

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

1. General Information

1.1 Physico-chemical properties

Appearance	Colorless gas, Colorless liquid
Melting point	-111 (degC)
Boiling point	10.7 (degC)
Water solubility	Miscible
Henry's constant	15.0 Pa*m ³ /mol (1.48*10 ⁻⁴ atm*m ³ /mol) (25degC, measured)
Octanol/water partition coefficient (log Kow)	-0.30 (measured), -0.05 (estimated)
Soil adsorption coefficient	Koc = 1 (estimated)

1.2 Environmental fate

Bioaccumulation	Low bioaccumulative Bioconcentration factor (BCF): 3.2 (calculated using logKow of -0.30).
Biodegradation	Readily biodegradable Considered to be biodegradable also under anaerobic conditions.
Stability in the environment	(In air) Reaction with OH radical: Reaction rate constant is 7.6*10 ⁻¹⁴ cm ³ /molecule-sec. (25 degC, measured) The half-life is 4-7 months, given OH radical concentration of 5*10 ⁵ - 5*1*10 ⁶ molecule/cm ³ . Reaction with ozone: No data Reaction with nitrate radical: No data Ethylene oxide is not degraded directly by light (In water) Ethylene oxide has been reported that the hydrolysis half - life is 12 - 14 days in freshwater and 9 - 11 days in seawater. Ethylene oxide hydrolyzes slowly in fresh water and in salt water to give ethylene glycol and ethylene chlorohydrin. Ethylene oxide is hydrolyzed and generates ethylene glycol in fresh water, and ethylene glycol and ethylene chloropicrin are generated in salt water.
Environmental fate	If released into water, ethylene oxide is expected to be removed by volatilization to the atmosphere, and removed partially by biodegradation.

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
891,453	16	8	891,461	--

2.2 Uses

Intermediates of ethylene glycol, ethanol amine and others (74.2%), raw material for surface-active agents (19.8%), sterilizer for medical treatment tools (6%)

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	398	24	0	Release to rivers: 51 tons
	Release outside notification	456	28	0	
Release outside notification from non listed industry		--	--	--	
Households		--	--	--	
Mobile sources		--	--	--	
Total		854	52	0	

2.4 Releases from other sources

This substance, used as a raw material in surfactants, might be released with surfactants into the environment. However, the amount of the substance released is negligible. According to the Tokyo Metropolitan Research Institute for Environmental Protection, this substance is used for the sterilization of medical equipment and is released from sterilizers into the air or sewage. Based on 2002 PRTR "outside notification" release data, the amount of release of the substance as an "emission related to medicine" is estimated to be 185 tons per year.

2.5 Main release route

Ethylene oxide is expected to be released mainly during synthesis of various chemicals using ethylene oxide as a raw material. Natural sources are not considered here because release amounts could not be estimated.

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)	247/248	--/2,788	nd-0.67 (annual average)	--	0.00023- 1.0	2003 Ministry of the Environment
River water	--	--	--	--	--	
Drinking water	--	--	--	--	--	
Food (microg/g) (Fish)	0/8	0/24	nd	--	0.00023- 0.00194	2001 Ministry of the Environment

nd: Not detected

3.2 Estimated environmental concentration

Media	Estimated concentration	Description
Air (microg/m ³)	0.51	Calculated by mathematical model / Atmospheric Dispersion Model for Exposure and Risk Assessment (AIST-ADMER) ver.1.0
River water (microg/L)	2.1	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)	2.1
	The estimated value of 2.1 microg/L was used for the risk assessment, since no adequate measured data was available. 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	0.67 (microg/m ³)	13	0.26
	The measured concentrations in air in a survey by the Ministry of the Environment			
Oral	Drinking water	2.1 (microg/L)	4.2	0.084
	The estimated concentration of ethylene oxide in river water was used as a substitute, since concentration of ethylene oxide in drinking water was not available.			
	Food	0.00097 (microg/g)	0.12	0.0024
	-Data of intake via food were not available. -Ethylene oxide was not detected in any fish samples in the survey by the Ministry of the Environment. -The value (0.00097 microg/g-wet) equal to 1/2 of the highest detection limit (0.00194 microg/g-wet) in this survey was used for concentration in fish body.			
	Subtotal	--	4.3	0.086
Total route		--	17	0.35

1) This substance is assessed based on the Guideline for Initial Risk Assessment Version 1.0. 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	--	No adequate data		--
Crustacea	Acute	<i>Daphnia magna</i>	48 hours LC ₅₀	137-300 (mg/L)
Fish	Acute	<i>Pimephales Promelas</i>	96 hours LC ₅₀	84 (mg/L)
Key study		Data of fish (<i>Pimephamelas promelas</i>) is 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	Rat	2 years	<u>Reduced body weight gains,</u> increased mortality rates	NOAEL: 18.3 mg/m ³ (converted 2.4 mg/kg/day)
	Oral	--	--	--	--
	Dermal	--	--	--	--
Reproductive and developmental toxicity	Fetal toxicity, teratogenicity, developmental toxicity and testicular toxicity are noted.				
Carcinogenicity	Evaluation by IARC : Group 1(Carcinogenic to the humans)				
Genotoxicity	Considered to be genotoxic.				

5. Risk Assessment

5.1 Environmental organisms

Risk characterization	EEC (microg/L)	NOEC * (mg/L)	MOE (NOEC * /EEC)	Product of uncertainty factors	Conclusion
	2.1	LC ₅₀ : 84	40,000	1,000	No immediate concern
Product of uncertainty factors (UF): Extrapolation from laboratory test (10) * Acute toxicity test (100) = 1,000					
Recommendation : The substance is considered to be of no immediate concern for the moment, and low priority of 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	0.26	2.4	9,200	100	No immediate concern
Oral	0.086	No adequate data	Not calculated	Not calculated	--
Total	0.35	2.4 (Inhalation)	6,900	100	No immediate concern

Product of uncertainty factors (UF): Interspecies (10) * Intraspecies (10) = 100

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 carried out.

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

Although no adequate toxicity data for oral route, MOE of total route of inhalation and oral is larger than the product of uncertainty factor. Therefore, 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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