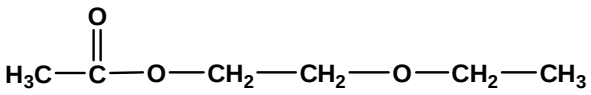
5	CAS No.: 111-15-9	Substance: 2-Ethoxyethyl acetate

Chemical Substances Control Law Reference No.: 2-740 (Acetate ester of ethylene glycol monoalkyl (C1-4) ether)
PRTR Law Cabinet Order No.: 1-101

Molecular Formula:
$C_6H_{12}O_3$
Molecular Weight: 132.16

Structural Formula:



1. General information

The aqueous solubility of this substance is 2.29 x 10^5-2.3 x 10^5 mg/L (20°C) and the partition coefficient (1-octanol/water) (log Kow) is 0.24. The vapor pressure is 2.34 mmHg (= 312 Pa) (25°C). This substance is determinated to be ready biodegradable.

This substance is a Class 1 Designated Chemical Substance under the Law concerning Reporting, etc. of Releases to the Environment of Specific Chemical Substances and Promoting Improvements in Their Management (PRTR Law). The substance is mainly used in paints for metal products and furniture and solvents for painting ink and electronic ink, and it is also contained in some manicure substances. The estimated domestic production, imports, and exports in FY 2005 were 5,000, 54, and 230 tons, respectively.

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2. Exposure assessment

Total release to the environment in FY2005 under the PRTR Law came to approximately 550 tons. Of this quantity, the amount reported came to approximately 460 tons (84% of the total). Most release to the atmosphere accounted for a large part of the reported release. In addition, the transfers to sewage and waste were 0.002 and approximately 200 tons, respectively. Industries that reported large releases to the atmosphere were transport equipment manufacturing, plastic product manufacturing, and metal product manufacturing industries. Only the chemical industry reported large releases to public water bodies.

When estimated releases are included, release to the atmosphere accounted for the greatest quantity of release to the environment. The distribution into each environmental medium predicted by means of a multimedia model was 47.2% for the atmosphere and 31.9% for water bodies in the case of the region in which the estimated release quantity to the environment and atmosphere was considered to be the maximum. In the case of the region in which the estimated release quantity to the public water bodies was considered to be the maximum, the distributions were 60.8% for water bodies and 28.9% for the atmosphere.

The highest predicted inhalation exposure concentration for human beings was approximately 7.0 μg/m^3 for indoor air. The highest oral predicted exposure was calculated to be approximately less than 0.002 μg/kg/day based on groundwater data. The risk of exposure to this substance through food in environmental media is considered to be low.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was estimated to be less than 0.05 μg/L for freshwater and approximately 0.05 μg/L for seawater public water bodies.

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3. Initial assessment of health risk

The vapor of this substance is mildly irritating to the eyes. The substance may cause effects on the blood, resulting in lesions of blood cells, anemia and kidney impairment at high levels. The substance may cause effects on the central nervous system, resulting in unconsciousness at high levels. Contact with eyes or skin may cause redness of eyes, and dry skin. By inhalation or ingestion, it may cause dizziness, drowsiness, headache, and unconsciousness. Additionally, by ingestion, it may cause nausea and vomiting. The substance absorbed into the body through the skin may cause the similar symptoms.

There was insufficient information regarding the carcinogenicity of the substance. For this reason, an initial assessment of the substance was conducted based on information of non-carcinogenic effects.

A no observed adverse effect level (NOAEL) of 500 mg/kg/day (decrease in weight of testis and seminal vesicle, decrease of sperm, etc) was obtained for oral exposure from the reproductive/developmental toxicity testing for mice.

A no observed adverse effect level (NOAEL) for the inhalation exposure of 25 ppm（low body weight of the fetus , retarded ossification, etc.）was obtained from the reproductive/developmental toxicity testing for rabbits. The NOAEL was adjusted to 6.3 ppm (34 mg/m^3) taking into account the exposure situations. The resulting value was derived as the 'Non-toxic level*'.

With regard to oral exposure, in case of intakes of groundwater, the predicted maximum exposure was approximately less than 0.002 μg/kg/day. The margin of exposure (MOE) of exceeding 25,000,000 was derived from the 'Non-toxic level*' of 500 mg/kg/day divided by the predicted maximum dose, and divided by 10, because the 'Non-toxic level*' was established by means of animal testing. As the exposure to this substance through food intakes was estimated minor, even when the exposure through groundwater and food are combined, it would not greatly affect the MOE values. Accordingly, further action for assessment of its health risk from oral exposure to this substance would not be required at present.

For the inhalation exposure to this substance in the ambient air, because the predicted maximum exposure concentrations have not been estimated, its health risk can not be identified.

For the inhalation exposure to this substance in the indoor air, the predicted maximum exposure concentration was approximately 7.0 μg/m^3. Accordingly, from the 'Non-toxic level*' of 34 mg/m^3 and the predicted maximum exposure concentration, the MOE of 490 was determined in the same way.

The total release of this substance to the environment was estimated to be approximately 550 t. Exceeding 99% of the release was into the atmosphere and it was estimated that a half of the substance released into the atmosphere was distributed in the atmosphere subsequently. The half-life of the substance in the atmosphere was estimated to be 4.9-49hrs. Therefore, it would be required to collect information on inhalation exposure to this substance in the ambient air.

Accordingly, it would be required to collect information for assessment of its health risk from inhalation exposure to this substance in the ambient air. On the other hand, further action would not be required at present for assessment of its health risk from inhalation exposure to this substance in the indoor air.

Information of toxicity				Exposure assessment		Result of risk assessment			Judgment
Exposure Path	Criteria for risk assessment	Animal	Criteria for diagnoses (endpoint)	Exposure medium	Predicted maximum exposure quantity and concentration				
Oral	'Non-toxic level*' 500 mg/kg/day	Mice	decrease in weight of testis and seminal vesicle, decrease of sperm, etc.	Drinking water	— μg/kg/day	MOE	—	×	○
				Groundwater	< 0.002 μg/kg/day	MOE	> 25,000,000	○	
Inhalation	'Non-toxic level*' 34 mg/m^3	Rabbits	low body weight of the fetus , retarded ossification, etc.	Ambient air	— μg/m^3	MOE	—	×	(▲)
				Indoor air	7.0 μg/m^3	MOE	490	○	○

Non-toxic level *

- When a LOAEL is available, it is divided by 10 to obtain a level equivalent to NOAEL.
- When an adverse effect level for the short-term exposure is available, it is divided by 10 to obtain a level equivalent to an adverse effect level for the long-term exposure.

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4. Initial assessment of ecological risk

With regard to acute toxicity, reliable information of a 72-hour median effective concentration (EC_{50}) growth inhibition value exceeding 1,000,000 μg/L was found for the algae *Pseudokirchneriella subcapitata*, a 48-hour EC_{50} immobilization value of 197,000 μg/L was found for the crustacea *Daphnia magna* (water flea), a 96-hour median

lethal concentration (LC_{50}) value of 41,000 μg/L was found for the fish *Lepomis macrochirus* (bluegill), and a 96-hour LC_{50} value of 65,200 μg/L was found for *Aplexa hypnorum* (snail). Accordingly, an assessment factor of 100 was used, and a predicted no effect concentration (PNEC) of 410 μg/L was obtained based on the acute toxicity values. With regard to chronic toxicity, reliable information of a 72-hour no observed effect concentration (NOEC) growth inhibition value of 1,000,000 μg/L was found for the algae *P. subcapitata*, and a 21-day NOEC reproduction value of 44,400 μg/L was found for the crustacean *D. magna*. Accordingly, an assessment factor of 100 was used, and a PNEC value of 440 μg/L was obtained based on the chronic toxicity values. As the PNEC for the substance, a value of 410 μg/L obtained from the acute toxicity for the fish was used.

The PEC/PNEC ratio was less than 0.0001 for freshwater bodies and 0.0001 for seawater bodies. Accordingly, further work is thought to be unnecessary at this time.

Hazard assessment (basis for PNEC)			Assessment factor	Predicted no effect concentration PNEC (μg/L)	Exposure assessment		PEC/ PNEC ratio	Result of assessment
Species	Acute / chronic	Endpoint			Water body	Predicted environmental concentration PEC (μg/L)		
Fish (bluegill)	Acute	LC_{50} mortality	100	410	Freshwater	<0.05	<0.0001	○
					Seawater	0.05	0.0001	

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need for further work.	○
	Inhalation exposure	Risk assessment for the ambient air is not feasible, but collection of information is required. No further action is required for the indoor air at the moment.	(▲)
Ecological risk	No need for further work.		○

［Risk judgments］ ○: No need for further work ▲: Requiring information collection

■: Candidates for further work ×: Impossibility of risk characterization

(○) : Though a risk characterization cannot be determined, there would be little necessity of collecting information.

(▲) : Further information collection would be required for risk characterization.