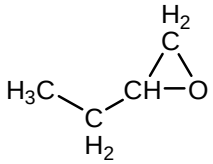
3	CAS No.: 106-88-7	Substance: 1,2-Epoxybutane

Chemical Substances Control Law Reference No.: 2-229 (butylene oxide)

PRTR Law Cabinet Order No.*: 1-66

Molecular Formula: C_4H_8O Structural formula:

Molecular Weight: 72.11



*Note: No. in Revised Cabinet Order enacted on October 1, 2009

1. General information

The aqueous solubility of this substance is 9.50×10^4 mg/L (25°C), the partition coefficient (1-octanol/water) (log K_{ow}) is 0.68 (25°C), and the vapor pressure is 238 mmHg (=3.17×10^4 Pa) (25°C). Biodegradability (aerobic degradation) is thought to be good. Furthermore, its half-life for hydrolysis is 156 hours (37°C, pH=7.4).

This substance is designated as a Type II Monitoring Chemical Substance under the Law Concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances, and 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 main uses are as a trichloroethane stabilizer, specialty solvent for PVC compounds, and raw material for pharmaceuticals, agricultural chemicals and surfactants. The production (shipments) and import quantity for butylene oxide in fiscal 2007 was 100 to <1,000 t/y. The production and import category under the PRTR Law was ≥100 t.

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2. Exposure assessment

Because this substance was not designated a Class 1 Designated Chemical Substance under the PRTR Law prior to its revision, release and transfer quantities could not be obtained. Predictions of distribution by medium using a Mackay-type level III fugacity model indicated that if equal quantities were released to the atmosphere, water bodies, and soil, the proportions distributed to soil and water bodies would be greater.

The predicted maximum exposure to humans via inhalation, based on general environmental atmospheric data, was generally 0.088 μg/m^3.

The predicted maximum oral exposure was estimated to be generally 0.000084 μg/kg/day based on calculations from data for public freshwater bodies. The risk of exposure to this substance by intake from an environmental medium via food is considered slight based on estimates of oral exposure using estimated concentrations in fish species.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, has been reported to be generally 0.0021 μg/L for public freshwater bodies and less than 0.0016 μg/L for seawater.

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3. Initial assessment of health risk

This substance is irritable to the eyes, skin and respiratory tract. Exposure to high concentration levels may cause lowering of consciousness. Symptoms of poisoning via the inhalation route include confusion, cough, dizziness, headache, laboured breathing, nausea, sore throat, and unconsciousness, while those via the oral route include abdominal pain as well. Contact with the substance causes redness and pain in the eyes or redness in the skin.

As sufficient information was not available on the carcinogenicity of the substance, an initial assessment was conducted on the basis of information on its non-carcinogenic effects.

With regard to oral exposure to the substance, its ‘non-toxic level*’ could not be identified. As for inhalation

exposure, a LOAEL of 50 ppm (for suppressed body weight increase and degenerated nasal tissues) was obtained from mid-term and long-term toxicity tests in mice. It was then adjusted to 8.9 ppm（26 mg/m^3） according to exposure conditions and was divided by 10 as is always the case with a LOAEL. 2.6 mg/m^3 derived was deemed as a plausible value for the lowest dose of the substance and was identified as its 'non-toxic level*'.

As for oral exposure, the absence of information available on 'non-toxic levels*' did not allow for a health risk assessment. For reference however,if 100% absorption was assumed, the substance's 'non-toxic level*' of the substance for inhalation exposure would be equivalent to its 'non-toxic level' of 0.78 mg/kg/day for oral exposure. The MOE derived would be 190,000 when calculated from this 'non-toxic level*' and the predicted maximum exposure of approximately 0.000084 μg/kg/day for oral exposure divided by 10 due to the need to convert the 'non-toxic level*' obtained from the animal experiments to a human equivalent dose. The value obtained was further divided by 5 due to the carcinogenicity of the substance. As the exposure to this substance through food intakes from the environment was estimated to be minor, remarkable changes in the MOE would not be likely. Collection of information on oral exposure to this substance, therefore, would not be required to assess health risk.

With regard to inhalation exposure to the substance, the maximum exposure concentration was estimated to be approximately 0.088 μg/m^3, when concentrations in the ambient air were considered. The MOE was 590 when calculated from the 'non-toxic level*' of 2.6 mg/m^3 and its predicted maximum exposure concentration divided by 10 due to the need to convert the 'non-toxic level*' obtained from the animal experiments to a human equivalent dose, and then divided again by 5 due to the carcinogenicity of the substance. Therefore, no further action would be required at the moment to assess health risk from inhalation exposure to this substance in the ambient air.

Information of toxicity				Exposure assessment		Result of risk Exposure 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 * ' — mg/kg/day	—	—	Drinking water	— μg/kg/day	MOE	—	×	(○)
				Freshwater	0.000084 μg/kg/day	MOE	—	×	
Inhalation	'Non-toxic level * ' 2.6 mg/m^3	Mice	Suppressed body weight increase, histopathology in the nasal tissues	Ambient air	0.088 μg/m^3	MOE	590	○	○
				Indoor air	— μg/m^3	MOE	—	×	×

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

A PNEC value could not be set for this substance because toxicity data applicable for an initial assessment could not be obtained. Accordingly, a judgment could not be made regarding ecological risk.

The 14-d LC_{50} value of 32,960 μg/L obtained from extended toxicity tests using the fish species *Poecilia reticulata* (guppy) is not adopted as the PNEC in this initial assessment

However, from this data the acute toxicity towards guppies is considered to be more than 32,960 μg/L, this value is divided by an assessment coefficient of 1,000 and a preliminary PNEC of more than 33 μg/L is obtained.

Based on a comparison of this value with the predicted environmental concentration (PEC), the ecological risk of this substance is thought to be sufficiently small. Accordingly, the need to collect further data for initial assessment of the ecological risk towards aquatic organisms is considered to be minimal.

Hazard assessment (basis for PNEC)			Assessment coefficient	Predicted no effect concentration PNEC (μg/L)	Exposure assessment		PEC/ PNEC ratio	Judgment based on PEC/PNEC ratio	Assessment result
Species	Acute/ chronic	End point			Water body	Predicted environmental concentration PEC (μg/L)			
–	–	–	–	–	Freshwater	0.0021	–	×	○
					Seawater	<0.0016	–		

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	Though a risk characterization cannot be determined, there would be little necessity of collecting information.	(○)
	Inhalation exposure	No need for further work.	○
Ecological risk	Minimal need to collect data.		○

［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.