1	CAS No.: 122-60-1	Substance: 2,3-Epoxypropyl phenyl ether

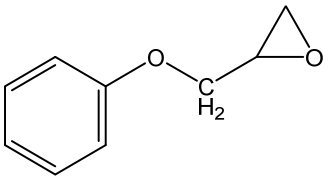
Chemical Substances Control Law Reference No.: 3-559

PRTR Law Cabinet Order No.: 1-69

Molecular Formula: $C_9H_{10}O_2$

Molecular Weight: 150.17

Structural formula:



1. General information

The aqueous solubility of this substance is 2.40×10^3 mg/L (25°C), the partition coefficient (1-octanol/water) (log K_{ow}) is 1.12, and the vapor pressure is 1.33 Pa (25°C). The biodegradability (aerobic degradation) is characterized by a BOD degradation rate of 51%, and biodegradability is judged to be good. Further, degradability screening tests indicated a residual ratio of 75.0% after 5 days (initial concentration: 55.4 μg/mL, pH: 7) for hydrolyzability.

This substance was classified as a Class 1 Designated Chemical Substance under the PRTR Law, but it was removed from the classification by the Cabinet Order partially revising the Enforcement Order for the Act on the Assessment of Releases of Specified Chemical Substances in the Environment and the Promotion of Management Improvement promulgated on October 20, 2021, which came into force on April 1, 2023.

The main uses of this substance are as a reactive diluent for epoxy and alkyd resins, a modifying agent for fibers, and a synthetic resin. The production and import quantity in fiscal 2020 was less than 1,000 t. The production and import category under the PRTR Law was more than 100 t.

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2. Exposure assessment

Total release to the environment in fiscal 2020 under the PRTR Law was 0.091 t, of which 0.086 t or 94% were notified releases. The largest notified releases to the atmosphere and public water bodies were to the atmosphere. In addition, 0.009 t was transferred to sewage and approximately 0.71 t was transferred to waste. The major source of notified releases to the atmosphere and public water bodies was the chemical industry. Including unnotified releases, the majority of releases to the environment were to the atmosphere. A multi-media model used to predict the proportions distributed to individual media in the environment indicated that in regions where the largest quantities were estimated to have been released to the environment overall or to the atmosphere in particular, the predicted proportion distributed to water bodies would be 75.6% and that distributed to soil would be 17.9%. Where the largest quantities were estimated to have been released to public water bodies, the predicted proportion distributed to water bodies would be 97.2%.

The maximum expected concentration of exposure to humans via inhalation could not be defined because ambient atmospheric and indoor air quality data could not be obtained. Further, the mean annual value for atmospheric concentration in fiscal 2020 was calculated by use of a plume-puff model on the basis of releases to the atmosphere reported under the PRTR Law: this model predicts a maximum level of 0.011 μg/m^3.

Data for potable water, groundwater, public freshwater bodies, food, and soil to assess oral exposure could not be obtained. However, while no releases to public freshwater bodies were notified in fiscal 2020 under the PRTR Law, transfer to sewage was reported. Accordingly, when releases to public freshwater bodies estimated from the reported transfer to sewage were divided by the ordinary water discharge of the national river channel structure database, estimating the concentration in rivers by taking into consideration only dilution gave a maximum value of 0.0094 μg/L. Calculating oral exposure based on this gives 0.00038 μg/kg/day. The exposure to this substance by intake from an environmental medium via food is considered slight, given the low bioaccumulation of the substance expected on the basis of its physicochemical properties.

Estimates of exposure to aquatic organisms could not be carried out. However, while no releases to public freshwater

bodies were notified in fiscal 2020 according to the PRTR Law, transfer to sewage was reported. Accordingly, when releases to public freshwater bodies estimated from the reported transfer to sewage were divided by the ordinary water discharge of the national river channel structure database, estimating the concentration in rivers by taking into consideration only dilution gave a maximum value of 0.0094 μg/L.

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3. Initial assessment of health risk

This substance irritates the eyes, the skin and the respiratory tract. Inhalation of this substance will cause a cough and sore throat. Contact with the skin or the eyes will cause redness and pain.

Since not enough information was available on the carcinogenicity of the substance, the initial assessment was conducted based on information on its non-carcinogenic effects.

The 'non-toxic level' for oral exposure could not be identified. The NOAEL of 6 mg/m^3 for inhalation exposure (based on epithelial hyperplasia and squamous metaplasia or dysplasia in the nasal cavity, etc.), determined from toxicity tests in rats, was adjusted according to exposure conditions. The obtained value of 1 mg/m^3 was deemed the lowest reliable concentration and was identified as the 'non-toxic level' of the substance for inhalation exposure.

Regarding oral exposure, due to the lack of identified 'non-toxic level' and exposure levels, the health risk could not be assessed. In consideration of the fact that the systemic health effects were observed in mid-term and long-term toxicity tests for inhalation exposure of this substance, the tentative 'non-toxic level' for oral exposure was derived from the conversion of the 'non-toxic level' for inhalation exposure based on the epithelial lesion in the nasal cavity, which is highly sensitive health effects, to make a conservative assessment. Assuming that 100% of the ingested substance is absorbed, the tentative 'non-toxic level' for oral exposure would be 0.3 mg/kg/day. The maximum exposure level would be estimated to be 0.00038 μg/kg/day according to the concentration in effluents based on the transfers to the sewage system, reported in FY 2020 under the PRTR Law. The MOE (Margin of Exposure) for reference would be 16,000 which is calculated from the tentative 'non-toxic level' of 0.3 mg/kg/day and the estimated maximum exposure level of 0.00038 μg/kg/day, and subsequently divided by a factor of 10 to account for extrapolation from animals to humans, and by another factor of 5 to take into consideration the carcinogenicity. Since exposure to the substance in environmental media via food is presumed to be limited, despite the lack of exposure level via food, including it in the calculation would not change the MOE significantly. Therefore, as a comprehensive judgment, the collection of further information would not be required to assess the health risk of this substance via oral exposure.

Regarding inhalation exposure, due to the lack of identified exposure concentrations, the health risk could not be assessed. However, the maximum concentration (annual mean) in ambient air near the operators that are releasing a large amount of the substance was estimated to be 0.011 μg/m^3, based on the releases to air reported in FY 2020 under the PRTR Law. The MOE for reference would be 1,800 which is calculated from the estimated concentration in ambient air and the 'non-toxic level' of 1 mg/m^3, and subsequently divided by a factor of 10 to account for extrapolation from animals to humans and by another factor of 5 to take into consideration the carcinogenicity. Therefore, as a comprehensive judgment, the collection of further information would not be required to assess the health risk of this substance via inhalation in ambient air.

Toxicity				Exposure assessment		MOE		Comprehensive judgment
Exposure Path	Criteria for risk assessment	Animal	Criteria for diagnoses (endpoint)	Exposure medium	Predicted maximum exposure dose and concentration			
Oral	'Non-toxic level*' - mg/kg/day	-	-	Drinking water	- μg/kg/day	MOE	-	○
				Groundwater	- μg/kg/day	MOE	-	
Inhalation	'Non-toxic level*' 1 mg/m^3	Rats	Epithelial hyperplasia and squamous metaplasia or dysplasia in the nasal cavity, etc.	Ambient air	- μg/m^3	MOE	-	○
				Indoor air	- μg/m^3	MOE	-	×

Non-toxic level *

・When a LOAEL is available, it is divided by 10 to obtain a NOAEL-equivalent level.

・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.

4.Initial assessment of ecological risk

With regard to acute toxicity, the following reliable data was obtained: a 96-hour LC_{50} of 43,000 μg/L for the fish *Carassius auratus* (goldfish). Accordingly, based on this acute toxicity value and an assessment factor of 1,000, a predicted no effect concentration (PNEC) of 43 μg/L was obtained. The value of 43 μg/L obtained from the acute toxicity to the fish was used as the PNEC for this substance.

The predicted environmental concentration (PEC) could not be set for this substance because data could not be obtained. Accordingly, a judgment regarding ecological risk could not be made.

When releases to public freshwater bodies estimated from the reported transfer to sewage were divided by the ordinary water discharge of the national river channel structure database, estimating the concentration in rivers by taking into consideration only dilution gave a maximum value of 0.0094 μg/L. The ratio of this value and PNEC was 0.0002.

Further, based on QSAR and other methods, dibromocresyl glycidyl ether, which is highly similar to this substance in terms of chemical structure, was considered to be more toxic than this substance due to its increased log K_{ow} based on its chemical structure.

As an analogy to the toxicity value of this substance, the minimum acute toxicity value of dibromocresyl glycidyl ether (610 μg/L) for three groups of organisms was divided by an assessment factor of 100 to yield 6.1 μg/L as a reliable data for this substance. The ratio of this value and the river concentration estimated from discharges to public water bodies (0.0094 μg/L) was 0.002.

Based on a comprehensive review of the above findings, further work is considered unnecessary at this time.

Hazard Assessment（Basis for PNEC）			Assessment factor	Predicted no effect concentration PNEC (μg/L)	Exposure Assessment		PEC/ PNEC ratio	Comprehensive judgment
Species	Acute/ chronic	Endpoint			Water body	Predicted environmental concentration PEC (μg/L)		
Fish *Carassius auratus*	Acute	LC_{50} Mortality	1,000	43	Freshwater	—	—	○
					Seawater	—	—	

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need for further work.	○
	Inhalation exposure	No need for further work.	○
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