5	CAS No. 102-71-6	Substance: Triethanolamine

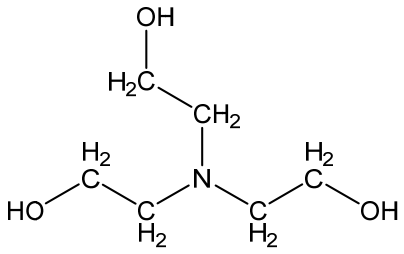
Chemical Substances Control Law Reference No.: 2-308

PRTR Law Cabinet Order No.:

Molecular Formula: $C_6H_{15}NO_3$

Molecular Weight: 149.19

Structural formula:



1.General information

The aqueous solubility of this substance is 1.00×10^6 mg/L, the partition coefficient (1-octanol/water) (log Kow) is -1.00 (pH = 9.0, buffered solution), and the vapor pressure is less than 10 Pa (25°C). The biodegradability (aerobic degradation) is characterized by a BOD degradation rate of 0%, and the substance is not judged to be highly bioaccumulative. Further, this substance does not contain any hydrolyzable groups and as such, it does not undergo hydrolysis under ambient environmental conditions.

From the perspective of human health effects, this substance is designated as a Priority Assessment Chemical under the Chemical Substances Control Law. The primary uses of this substance are as a surfactant and pharmaceutical raw material, polyurethane foaming agent, antifreeze rust inhibitor, pesticide solvent, gas absorbent, and quasi-drug additive (medicated soap, cosmetics, etc.). The production and import quantity in fiscal 2022 was 15,149 t.

2.Exposure assessment

Because this substance is not classified as a Class 1 Designated Chemical Substance under the PRTR Law, release and transfer quantities could not be obtained. Predictions of proportions distributed to individual media by use of a Mackay-type level III fugacity model indicate that if equal quantities were released to the atmosphere, water bodies, and soil, the proportion distributed to soil would be largest.

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.

Data for potable water, ground water, food, and soil to assess oral exposure could not be obtained. Thereupon, assuming ingestion solely from public freshwater bodies, an average daily exposure and maximum predicted daily exposure of around 0.11 μg/kg/day was obtained. Further, this substance is not judged to be highly bioaccumulative. Thus, exposure to this substance by intake from an environmental medium via food is considered slight.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was around 2.7 μg/L for public freshwater bodies, and around 0.49 μg/L for seawater. Further, albeit based on a survey for a limited area a maximum value of around 1.0 μg/L was reported for public seawater bodies.

---

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 eyes will cause redness, pain and severe deep burns. Contact with the skin will cause redness. Repeated or prolonged contact may cause skin sensitization.

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 LOAEL of 560 mg/kg/day for oral exposure (based on increase in the absolute and relative kidney weights and mineralization of the renal papilla in males), determined from chronic toxicity tests in rats, was divided by a factor of 10 to

account for uncertainty in using a LOAEL. The calculated value of 56 mg/kg/day was deemed the lowest reliable dose and was identified as the 'non-toxic level' of the substance for oral exposure. The LOAEL of 20 mg/m^3 for inhalation exposure (based on bloody crusts on the nasal edges and focal inflammation in the submucosa of the larynx), determined from toxicity tests in rats, was adjusted according to exposure conditions and subsequently divided by a factor of 10 to account for uncertainty in using a LOAEL, and by another factor of 10 to account for extrapolation to chronic exposure. The calculated value of 0.036 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, assuming that the substance is absorbed via public freshwater bodies, the predicted maximum exposure level was approximately 0.11 μg/kg/day. The MOE (Margin of Exposure) would be 51,000 which is calculated from the predicted maximum exposure level and the 'non-toxic level' of 56 mg/kg/day and subsequently divided by a factor of 10 to account for extrapolation from animals to humans. This would lead to the health risk judgment that no further work would be required at present. No data on the release and the transfer are available without specification of this substance as a "Class I Designated Chemical" under the PRTR Law. 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, no further work would be required at present.

Regarding inhalation exposure, due to the lack of identified exposure concentrations, the health risk could not be assessed. No data on the release and the transfer are available without specification of this substance as a "Class I Designated Chemical" under the PRTR Law. This substance is hazardous when inhaled and may be present in the air as a mist in unknown concentrations, although predictions of the multimedia fugacity model indicated that the proportion distributed to air was negligible. Therefore, as a comprehensive judgment, the collection of information would be required to assess the health risk of this substance via inhalation in ambient air, starting from the data on the concentrations in ambient air near the operators that are releasing a large amount of the substance.

Toxicity					Exposure assessment		Result of risk assessment		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'	56 mg/kg/day	Rats	Increase in the absolute and relative kidney weights and mineralization of the renal papilla in males	Drinking water	– μg/kg/day	MOE	–	○
					Freshwater	0.11 μg/kg/day	MOE	51,000	
Inhalation	'Non-toxic level'	0.036 mg/m^3	Rats	Bloody crusts on the nasal edges and focal inflammation in the submucosa of the larynx	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 were obtained: a 72-h EC_{50} of 204,000 μg/L for growth inhibition in the alga *Phaeodactylum tricornutum*, a 24-h EC_{50} of 577,000 μg/L for swimming inhibition in the crustacean *Artemia monica*, a 96-h LC_{50} of 11,800,000 μg/L for the fish *Pimephales promelas* (fathead minnow), and a 48-h EC_{50} of 112,000 μg/L for embryonic development abnormalities for the mussel *Mytilus galloprovincialis*. Accordingly, based on this acute toxicity value and an assessment factor of 100, a predicted no effect concentration (PNEC) of 2000 μg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of less than 28,000 μg/L for growth inhibition in the alga *P. tricornutum*, and a 21-d NOEC of 16,000 μg/L for reproductive inhibition in the crustacean *Daphnia magna*. Accordingly, based on this chronic toxicity value and an assessment factor of 100, a predicted no effect

concentration (PNEC) of 160 μg/L was obtained.

The value of 160 μg/L obtained from the chronic toxicity to the crustacean was used as the PNEC for this substance.

The PEC/PNEC ratio is 0.02 for freshwater bodies and 0.003 for seawater. Accordingly, efforts to collect data for determining ecological risk are considered unnecessary at this time.

Further, albeit based on a survey for a limited area, a maximum value for public seawater bodies of around 1.0 μg/L was reported. The ratio of this value to PNEC is 0.006.

Furthermore, although this substance has been detected at many water quality monitoring sites in public water bodies, its concentration in water was sufficiently below the PNEC. Accordingly, based on a comprehensive review of the above findings, further work is considered unnecessary at this time.

Hazard assessment (basis for PNEC)			Assessment coefficient	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)		
Crustacean *Daphnia magna*	Chronic	NOEC Reproductive inhibition	100	160	Freshwater	2.7	0.02	○
					Seawater	0.49	0.003	

---

5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need for further work	○
	Inhalation exposure	Requiring information collection	▲
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