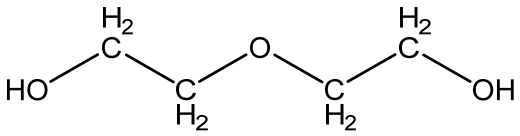
4	CAS No.: 111-46-6	Substance: Diethylene glycol

Chemical Substances Control Law Reference No.: 2-415

PRTR Law Cabinet Order No.:

Molecular Formula: $C_4H_{10}O_3$ Structural Formula:

Molecular Weight: 106.12



1.General information

The aqueous solubility of this substance is 1.00×10^6 mg/L (25°C), the partition coefficient (1-octanol/water) (log K_{ow}) is –1.98, and the vapor pressure is 7.5×10^{-3} mmHg (=1 Pa) (25°C). The biodegradability (aerobic degradation) is characterized by a BOD degradation rate of 90%.

The main uses of this substance are in plastics (alkyds, polyesters, polyurethanes), printing inks, soluble oils, textile adhesives, brake fluids, plasticizers, Udex process extraction solvents, gas dehydration, cellophane softeners, and cement admixtures. The production and import quantity in fiscal 2016 was 100,000 t.

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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 indicates that if equal quantities were released to the atmosphere, water bodies, and soil, the proportion distributed to soil and water bodies would be largest.

The maximum expected concentration of exposure to humans via inhalation, based on general environmental atmospheric data, was generally 0.043 μg/m^3.

Data for potable water, ground water, public freshwater bodies, food and soil to determine oral exposure could not be obtained. The risk of 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.

Data for setting the predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, could not be obtained.

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3. Initial assessment of health risk

Ingestion of this substance causes abdominal pain, nausea, vomiting, diarrhea, dizziness, drowsiness, confusion and unconsciousness. The substance may cause effects on the kidneys, central nervous system and liver.

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

The NOAEL of 105 mg/kg/day for oral exposure (based on crystal nephropathy and changes in renal function), determined from medium-term toxicity tests in rats, was divided by a factor of 10 to account for extrapolation to chronic exposure. The calculated value of 11 mg/kg/day was deemed to be the lowest reliable dose and was identified as the ‘non-toxic level*’ of the substance for oral exposure. The NOAEL of 3,000 mg/m^3 for inhalation exposure (based on parameter changes in hematology and blood chemistry), determined from medium-term toxicity tests in rats, was adjusted according to exposure conditions to obtain 536 mg/m^3 , and subsequently divided by a factor of 10 to account for extrapolation to

chronic exposure. The calculated value of 54 mg/m^3 was deemed to be the lowest reliable dose and was identified as the 'non-toxic level*' of the substance for inhalation exposure.

With regard to oral exposure, owing to the lack of identified exposure levels, the health risk could not be assessed. As the substance is produced in high volume and can be freely mixed with water, it is predicted that when released to water bodies, it would almost entirely be distributed to water. Therefore, collection of information would be required to assess the health risk of this substance via oral exposure, starting from data on concentrations in public freshwater bodies based on the current releases.

With regard to inhalation exposure, the predicted maximum exposure concentration in ambient air was 0.043 μg/m^3, approximately. The MOE would be 130,000, when calculated from the predicted maximum exposure concentration and the 'non-toxic level*'of 54 mg/m^3, and subsequently divided by a factor of 10 to account for extrapolation from animals to humans. Therefore, collection of further information would not be required to assess the health risk of this substance via inhalation in ambient air.

Toxicity				Exposure assessment		Result of risk assessment		Judgment
Exposure Path	Criteria for risk assessment	Animal	Criteria for diagnoses (endpoint)	Exposure medium	Predicted maximum exposure dose and concentration			
Oral	'Non-toxic level*' 11 mg/kg/day	Rats	Crystal nephropathy and changes in renal function	Drinking water	- μg/kg/day	MOE	-	(▲)
				Public freshwater bodies	- μg/kg/day	MOE	-	
Inhalation	'Non-toxic level*' 54 mg/m^3	Rats	Parameter changes in hematology and blood chemistry	Ambient air	0.043 μg/m^3	MOE	130,000	○
				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.

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4. Initial assessment of ecological risk

With regard to acute toxicity, the following reliable data were obtained: a 72-h EC_{50} of 57,400,000 μg/L for growth inhibition in the diatom species *Phaeodactylum tricornutum*, a 96-h LC_{50} exceeding 5,900,000 μg/L in the crustacean *Tigriopus fulvus*, a 96-h LC_{50} exceeding 100,000 μg/L for the fish species *Cyprinus carpio* (carp), and a 48-h LC_{50} of 3,065,000 μg/L for the African clawed frog *Xenopus laevis*. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 59,000 μg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 5,000,000 μg/L for growth inhibition in the diatom species *P. Tricornutum*. Accordingly, based on this chronic toxicity value and an assessment factor of 100, a PNEC of 50,000 μg/L was obtained.

The value of 50,000 μg/L obtained from the acute toxicity to the diatom species was used as the PNEC for this substance.

Data to determine the predicted environmental concentration (PEC) of this substance could not be obtained. Accordingly, ecological risk could not be determined. The production and import quantity in fiscal 2016 was 100,000 t, and a multi-media model used to predict the proportions distributed to individual media in the environment indicates that when this substance is released to water bodies, the majority will be distributed to water bodies. However, taking into consideration this substance's biodegradability and the PNEC value (50,000 μg/L), it is unlikely that it exists in public

water bodies at concentrations likely to harm aquatic organisms based on normal release conditions; accordingly, there is little need to collect new data regarding this substance.

Hazard assessment (basis for PNEC)			Assessment coefficient	Predicted no effect concentration PNEC (μg/L)	Exposure assessment		PEC/ PNEC ratio	Assessment result
Species	Acute/ chronic	Endpoint			Water body	Predicted environmental concentration PEC (μg/L)		
Diatom	Chronic	NOEC Growth inhibition	100	50,000	Freshwater	—	—	○
					Seawater	—	—	

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	Further efforts to collect data required based on comprehensive review of existing relevant data.	(▲)
	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

（▲）: Further efforts to collect data required based on comprehensive review of existing relevant data

（■）: Candidate for further work based on comprehensive review of existing data