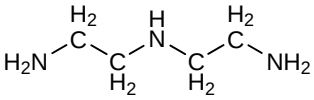
3	CAS No.: 111-40-0	Substance: *N*-(2-aminoethyl)-1,2-ethanediamine

Chemical Substances Control Law Reference No.: 2-159

PRTR Law Cabinet Order No.:

Molecular Formula: $C_4H_{13}N_3$ Structural Formula:

Molecular Weight: 103.17



1. General information

This substance is freely miscible with water, the partition coefficient (1-octanol/water) (log K_{ow}) is -2.1 (calculated value), and the vapor pressure is 0.23 mmHg (=30 Pa) (25℃). Biodegradability (aerobic degradation) is characterized by a BOD degradation rate of 0%, and bioaccumulation is judged to be non-existent or low.

The main uses of this substance are raw materials for wet paper-strengthening agents, epoxy resin curing agents, chelating agents, ion exchange resins, fiber processing agents (wrinkle prevention agents and dye fixing agents), and surfactants. The production and import quantity in fiscal 2010 was 20,000 t.

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2. Exposure assessment

This substance was classified as a Class 1 Designated Chemical Substance prior to revision of substances regulated by the PRTR Law. Total release to the environment in fiscal 2009 under the PRTR Law was approximately 86 t, of which approximately 86 t or more than 99% of overall releases were reported. The major destination of reported releases was public freshwater bodies. In addition, approximately 4.3 t was transferred to waste materials, and 0.034 t was transferred to sewage. The main source of reported releases was the chemical industry. The largest release among releases to the environment including those unreported was to water bodies. A multi-media model used to predict the proportions distributed to individual media in the environment indicated that in regions where the largest estimated releases were to the environment overall, or the atmosphere or public water bodies in particular, the proportion distributed to public water bodies was 98.3% in all cases.

The maximum expected concentration of exposure to humans via inhalation could not be obtained. The mean annual value for atmospheric concentration in fiscal 2009 was calculated by using a plume-puff model on the basis of reported releases to the atmosphere according to the PRTR Law; this model predicted a maximum level of 0.24 μg/m^3. The maximum expected oral exposure was estimated to be generally less than 0.08 μg/kg/day on the basis of calculations from data for public freshwater bodies. When reported releases to public freshwater bodies in fiscal 2010 according to the PRTR Law were divided by the ordinary water discharge of the national river channel structure database, estimating the concentration in rivers taking into consideration only dilution gave a maximum value of 3 μg/L. Using this estimated concentration for rivers to calculate oral exposure gave 0.12 μg/kg/day. The risk of exposure to this substance by intake from an environmental medium via food is considered slight, based on estimates of oral exposure obtained by using estimated concentrations in fish species.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was generally less than 2 μg/L for public freshwater bodies and around less than 2 μg/L for seawater. The maximum river concentration was estimated to be 3 μg/L from reported releases to public freshwater bodies under the PRTR Law.

3.Initial assessment of health risk

This substance may cause corrosion to eyes, skin and respiratory tract. Exposure to the substance through ingestion may also cause corrosion. Pulmonary edema may be caused by inhalation of vapors of the substance.

Symptoms of poisoning by its inhalation include sore throat, coughing, burning sensation and labored breathing, while those through ingestion include a burning sensation, abdominal pain, and even shock and collapse. Contact of the substance with the skin may cause pain or severe skin burns, while its contact with eyes may cause pain, severe eye burns or even vision loss.

As sufficient information was not available to evaluate carcinogenic potential 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, a NOAEL of 41 mg/kg/day (for increased mean corpuscular volume/hemoglobin concentration), obtained from its mid-term and long-term toxicity tests on rats, was divided by a factor of 10 due to their short test periods. 4.1 mg/kg/day was identified to be the reliable lowest dose as its 'non-toxic level*'. With regard to inhalation exposure, its 'non-toxic level*' could not be identified.

With regard to oral exposure to the substance, its maximum exposure concentration was estimated to be below 0.08 μg/kg/day, when its intakes through freshwater from public water bodies were assumed. The MOE (Margin of Exposure) would be above 5,100 when calculated from the 'non-toxic level*' of 4.1 mg/kg/day and the maximum exposure concentration predicted from animal experiments and divided by a factor of 10 to convert animal data to human. The maximum exposure level was calculated to be 0.12 μg/kg/day from concentrations of the substance in river water with effluents from operators discharging high concentrations of the substance, reported in FY 2010 under the PRTR Law. The MOE would be 3,400 when calculated from this value as its reference. As exposure to the substance in the environment through food intakes would be limited, the MOE would not change significantly even when this exposure is included. Therefore, no further action would be required at this moment to assess health risk from its oral exposure.

With regard to inhalation exposure to the substance, its health risk could not be assessed as its 'non-toxic level*' was not identified and its exposure concentrations were not known. If 100 % absorption were assumed, the 'non-toxic level*' for its oral exposure would be converted to a 'non-toxic level*' of 14 mg/m^3 for its inhalation exposure. The MOE would be 5,800 when calculated from this value as its reference. In addition, the maximum (annual mean) concentration of the substance in the ambient air near the operators discharging high concentrations of the substance was calculated to be 0.24 μg/m^3 from its emissions reported in FY 2010 under the PRTR Law. Therefore, collection of further information would not be required to assess health risk from its inhalation in the 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* 4.1 mg/kg/day	Rat	Increased mean corpuscular volume/ hemoglobin concentration	Drinking water	— μg/kg/day	MOE	—	×	○
				Freshwater	< 0.08 μg/kg/day	MOE	> 5,100	○	
Inhalation	'Non-toxic level*' — mg/m^3	—	—	Ambient air	26 μg/m^3	MOE	—	×	(○)
				Indoor air	200 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 96-h EC_{50} of 345,600 μg/L for growth inhibition in the green alga *Pseudokirchneriella subcapitata*, a 48-h EC_{50} of 53,500 μg/L for swimming inhibition in the crustacean *Daphnia magna*, and a 96-h LC_{50} of 430,000 μg/L for the fish species *Poecilia*

reticulata (guppy). Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 540 µg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC 10,200 µg/L for growth inhibition in the green alga *P. subcapitata*, and a 21-d NOEC of 5,600 µg/L for reproductive inhibition in the crustacean *D. magna*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a PNEC of 56 µg/L was obtained.

The value of 56 µg/L obtained from the chronic toxicity to the crustacean was used as the PNEC for this substance.

The PEC/PNEC ratio was less than 0.04 for both freshwater bodies and seawater. In addition, the maximum river concentration was estimated to be 3 µg/L from reported releases under the PRTR Law. The ratio of this value to the PNEC is less than 0.1; accordingly, further work on this substance 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	Judgment based on PEC/PNEC ratio	Assessment result
Species	Acute/ chronic	Endpoint			Water body	Predicted environmental concentration PEC (µg/L)			
Crustacean *Daphnia magna*	Chronic	NOEC Reproductive inhibition	100	56	Freshwater	<2	<0.04	○	○
					Seawater	<2	<0.04		

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need for further work.	○
	Inhalation exposure	Although risk to human health could not be confirmed, collection of further information would not be required.	(○)
Ecological risk	No need of further work at present.		○

［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.