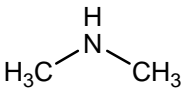| 5	CAS No.: 124-40-3	Substance: Dimethylamine

Chemical Substances Control Law Reference No.: 2-134

PRTR Law Cabinet Order No.: 1-218

Molecular Formula: C_2H_7N

Molecular Weight: 45.08

Structural Formula:

1. General information

The aqueous solubility of this substance is 1.63×10^6 mg/L (40°C), the partition coefficient (1-octanol/water) (log K_{ow}) is -0.27, and the vapor pressure is 1.3×10^3 mmHg (=1.7×10^5 Pa) (20°C). Biodegradability (aerobic degradation) is judged to be good. The substance does not have any hydrolyzable groups.

This substance is designated as a Priority Assessment Chemical Substance 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 use of this substance is as a raw material for vulcanizers, pesticides, bactericides, pharmaceuticals, surfactants, and solvents (dimethylformamide, dimethylacetoamide). The production and import quantity in fiscal 2011 was 20,096 t. The production and import category under the PRTR Law is more than 100 t.

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2. Exposure assessment

Total release to the environment in fiscal 2011 under the PRTR Law was approximately 50 t, of which approximately 49 t or 99% of overall releases were reported. The major destination of reported releases was public water bodies. In addition, approximately 34 t was transferred to waste materials, and 0.015 t was transferred to sewage. The industry type with large reported releases was the chemical industry for the atmosphere and public water bodies. 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 quantities were estimated to have been released to the environment overall or to public water bodies in particular, the predicted proportion distributed to water bodies was 98.4%. In regions where the largest estimated releases were to the atmosphere, the predicted proportions distributed to the atmosphere and water bodies were 77% and 13.9%, respectively.

The maximum expected concentration of exposure to humans via inhalation, based on general environmental atmospheric data, was around 0.034 μg/m^3. The mean annual value for atmospheric concentration in fiscal 2011 was calculated by using a plume-puff model on the basis of releases to the atmosphere reported according to the PRTR Law; this model predicted a maximum level of 0.99 μg/m^3. The maximum expected oral exposure was estimated to be around 7.6 μg/kg/day on the basis of calculations from data for public freshwater bodies. When releases to public freshwater bodies in fiscal 2011 reported according to the PRTR Law 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 0.12 μg/L. Using this estimated concentration for rivers to calculate oral exposure gave 0.0048 μg/kg/day. The risk of exposure to this substance by intake from an environmental medium via food is considered slight, based on this substance's physical properties.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was around 190 μg/L for public freshwater bodies and less than 4 μg/L for seawater. When releases to public freshwater bodies in fiscal 2011 reported according to the PRTR Law 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 0.12 μg/L.

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3. Initial assessment of health risk

This substance may cause irritation to eyes and respiratory tract. Pulmonary edema may occur when exposed to its vapors in high concentrations. Frostbites may occur when its liquid rapidly vaporizes on skin. Its aqueous solution may cause corrosion to eyes and skin. Its inhalation exposure may cause burning sensation, coughing, labored breathing, shortness of breath and sore throat, while its contact with eyes may cause redness, pain and blurred vision. Corrosion, abdominal pain, burning sensation, shock or collapse may occur when the substance is orally ingested.

As sufficient information was not available to evaluate 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 its inhalation exposure, a LOAEL of 10 ppm (for degenerated nasal tissue) obtained from its mid-term and long-term toxicity tests on rats and mice was adjusted for their durations to provide 1.8 ppm (3.3 mg/m^3) for its intermittent to continuous exposure, and divided by a factor of 10 for conservative use of the LOAEL. Outcome of 0.33 mg/m^3 was identified to be the reliable lowest dose and its 'non-toxic level*'.

With regard to oral exposure to the substance, its health risk could not be assessed as its 'non-toxic level*' could not be identified. Other than the direct effects (local effects on nasal cavity) on exposed parts, which are specific to its inhalation exposure, its effects on the body weight was observed for animals at 175 ppm, and its 'non-toxic level*' for inhalation exposure was obtained from this. If a NOAEL of 50 ppm were assumed for systemic effects, it would be adjusted for durations of the tests to provide 8.9 ppm (16 mg/m^3) for its intermittent to continuous exposure. If 100 % absorption were assumed, its 'non-toxic level*' for inhalation exposure would be converted to a 'non-toxic level*' of 4.8 mg/kg/day for its oral exposure. This is almost equivalent to the 'non-toxic level*' (4 mg/kg/day) of trimethylamine. The MOE would be 63 when calculated for reference from this level and the predicted maximum exposure concentration from animal experiments and divided by a factor of 10 to convert animal data to human data. In addition, its maximum exposure would be 0.0048 μg/kg/day when calculated from its concentrations in river water with effluents from operators discharging the substance in high concentrations, reported in FY 2011 under the PRTR Law. The MOE would be 100,000 when calculated from this level for 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 was included. Therefore, collection of further information would be required to assess health risk from its oral exposure.

As for inhalation exposure to the substance in the ambient air, its mean exposure concentration was below about 0.015 μg/m^3 while its maximum exposure concentration was predicted to be about 0.034 μg/m^3. The MOE would be 970 when calculated from its 'non-toxic level*' of 0.33 mg/m^3 and the maximum exposure concentration predicted from animal experiments and divided by a factor of 10 to convert animal data to human data. The maximum (annual mean) concentration in the ambient air near the operators discharging the substance in high concentrations would be 0.99 μg/m^3 when calculated from its emissions reported in FY 2011 under the PRTR Law. The MOE would be 33 when calculated from this for reference. Therefore, collection of further information would be required to assess health risk from its inhalation exposure 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*' mg/kg/day			Drinking water		µg/kg/day	MOE		×	
				Freshwater	7.6	µg/kg/day	MOE		×	
Inhalation	'Non-toxic level*' 0.33 mg/m^3	Rat & mouse	Degenerated nasal tissue	Ambient air	0.034	µg/m^3	MOE	970		
				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 96-h EC_{50} of 30,000 µg/L for growth inhibition in the green alga *Chlorella pyrenoidosa*, a 48-h LC_{50} of 50,000 µg/L for the crustacean *Daphnia magna*, and a 96-h LC_{50} 17,000 µg/L for the fish species *Oncorhynchus mykiss* (rainbow trout). Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 170 µg/L was obtained.

With regard to chronic toxicity, a 50-d NOEC of 1,000 µg/L for growth inhibition in the fish species *O.mykiss* (rainbow trout) was obtained as a reliable finding. Accordingly, based on this chronic toxicity value and an assessment factor of 100, a PNEC of 10 µg/L was obtained.

The value of 10 µg/L obtained from the chronic toxicity to the fish species was used as the PNEC for this substance.

The PEC/PNEC ratio was 19 for freshwater bodies and 0.12 for seawater. Accordingly, the substance is considered as a candidate for detailed assessment.

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)			
Fish (rainbow trout)	Chronic	NOEC Growth inhibition	100	10	Freshwater	190	19		
					Seawater	1.2	0.12		

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5. Conclusions

		Conclusions	Judgment
Health risk	Oral exposure	Collection of further information would be required.	
	Inhalation exposure	Collection of further information would be required.	
Ecological risk		Candidates for further work.	

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.