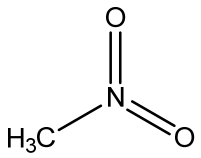
12	CAS No.: 75-52-5	Substance: Nitromethane

Chemical Substances Control Law Reference No.: 2-191

PRTR Law Cabinet Order No.: 1-317

Molecular Formula: CH_3NO_2 Structural formula:

Molecular Weight: 61.04



1. General information

The aqueous solubility of this substance is 1.11×10^5 mg/L (25°C), the partition coefficient (1-octanol/water) (log K_{ow}) is -0.35, and the vapor pressure is 35.8 mmHg (= 4.77×10^3 Pa) (25°C). Biodegradability (aerobic degradation) is characterized by BOD degradation rates of 4% (tested substance concentration: 2.0 mg/L) and 5% (tested substance concentration: 10.0 mg/L), and bioaccumulation is thought to be nonexistent or low. 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 solvents, combustion aids, surfactants, explosives, pharmaceuticals, pesticides, and bactericides. The production and import quantity in fiscal 2012 was 1,611 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 2012 under the PRTR Law was approximately 0.91 t, and all releases were reported. All reported releases were to the atmosphere. In addition, approximately 4.4 t was transferred to waste materials. The industry type with large reported releases was the chemical industry. 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 the atmosphere was 56.4%, and that distributed to water bodies was 37.4%.

The maximum expected concentration of exposure to humans via inhalation, based on ambient air, was around 0.12 μg/m^3. The mean annual value for atmospheric concentration in fiscal 2012 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 0.15 μg/m^3. The maximum expected oral exposure could not be obtained. However, albeit past data, one report estimated a maximum expected oral exposure of less than 0.04 μg/kg/day was calculated from public freshwater body data. The exposure level 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.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, could not be obtained. However, past data yielded values of less than 1 μg/L for freshwater bodies and around less than 1 μg/L for seawater.

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3. Initial assessment of health risk

This substance irritates the eyes, skin and respiratory tract and may possibly affect the central nervous system, resulting in decreased nervous system function. When inhaled or ingested, coughing, lethargy, headache,

nausea, sore throat, loss of consciousness and vomiting may occur. Contact of the substance with the skin may cause dry skin and redness, while contact with the eyes may cause redness.

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

With regard to the oral exposure to the substance, the 'non-toxic level*' could not be established. As for the inhalation exposure, the LOAEL of 94 ppm (based on kidney relative weight increase and hyaline droplet deposition in respiratory epithelium), resulting from mid-term and long-term toxicity tests on mice, was adjusted according to the test conditions to obtain an exposure of 16.8 ppm (0.42 mg/m^3) and was divided by a factor of 10 for the use as a LOAEL and further divided by a factor of 10 due to the short test periods. The outcome of 0.42 mg/m^3 was considered to be the reliable lowest dose of the substance and was identified as its 'non-toxic level*'.

Regarding the oral exposure, the health risk could not be assessed as its 'non-toxic level*' could not be established, nor the exposure concentrations. In addition, assuming a 100 % absorption, and converting the 'non-toxic level*' for oral exposure to the inhalation one, the 'non-toxic level*' would be 0.13 mg//kg/day. The MOE (Margin of Exposure) of more than 65 was derived from the substance's 'non-toxic level*' and the oral exposure level of below 0.04 μg/kg/day, calculated from public water bodies and freshwater maximum concentration as reported in 1986, and after the division by a factor of 10 to convert animal data to human data and further by a factor of 5 to take into account the carcinogenic properties. As exposure to the substance in the environment through diet is limited, the MOE would not change significantly even when this exposure is included. This substance's vapor pressure is relatively high, and the total amount of emissions into the environment (FY 2012) was approximately 0.91 t and the whole amount was discharged into the atmosphere. No detection in water bodies was reported, even if data are old. Therefore, collection of information would not be required to assess the health risk from the oral exposure to this substance.

Concerning the inhalation exposure to the substance, the predicted maximum exposure concentration in ambient air was approximately 0.12 μg/m^3. The MOE of 70 was derived from the substance's 'non-toxic level*' of 0.42 mg/m^3 and the predicted maximum exposure concentration and after the division by a factor of 10 to convert animal data to human data and further by a factor of 5 to take into account the carcinogenic properties. The atmospheric maximum concentration in the high discharging plants area was estimated to be 0.15 μg/m^3 (annual mean) from the reports of emissions into the environment reported in FY 2012 under the PRTR Law. The MOE would be 56 when calculated from this level. Therefore, collection of information would be required to assess the health risk for the inhalation exposure to this substance 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*' — mg/kg/day	—	—	Drinking water	— μg/kg/day	MOE	—	×	(○)
				Groundwater	— μg/kg/day	MOE	—	×	
Inhalation	'Non-toxic level*' 0.42 mg/m^3	Mouse	Kidney relative weight increase and hyaline droplet deposition in respiratory epithelium	Ambient air	0.12 μg/m^3	MOE	70	▲	▲
				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} exceeding 102,000 µg/L for growth inhibition in the green alga *Pseudokirchneriella subcapitata*, a 48-h EC_{50} exceeding 103,000 µg/L for swimming inhibition in the crustacean *Daphnia magna*, and a 96-h LC_{50} exceeding 659,200 µg/L for the fish species *Pimephales promelas* (fathead minnow). Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 1,020 µg/L was obtained.

With regard to chronic toxicity, the following reliable data was obtained: a 72-h NOEC of 3,010 µg/L for growth inhibition in the green alga *P. subcapitata*. Accordingly, based on this chronic toxicity value and an assessment factor of 100, a PNEC of 30 µg/L was obtained.

The value of 30 µg/L obtained from the chronic toxicity to the alga was used as the PNEC for this substance.

The PEC of this substance could not be obtained. As such, a judgment on ecological risk could not be made. The ratios of past public freshwater body and seawater concentrations (less than 1 µg/L) to the PNEC are less than 0.1. Furthermore, release to public water bodies in fiscal 2012 under the PRTR Law is 0 kg. Accordingly, the need to collect further data on this substance is considered to be minimal.

Hazard Assessment（Basis for PNEC）			Assessment Coefficient	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)			
Green algae	Chronic	NOEC growth inhibition	100	30	Freshwater	—	—	×	○
					Seawater	—	—		

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5. Conclusions

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

［Risk judgments］ ○: No need for further work ▲: Requiring information collection

■: Candidates for further work ×: Impossibility of risk characterization

（○）: Although risk to human health could not be confirmed, collection of further information would not be required.

（▲）: Further information collection would be required for risk characterization.