8	CAS No.: 74-89-5	Substance: Methylamine

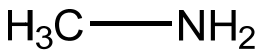
Chemical Substances Control Law Reference No.: 2-129

PRTR Law Cabinet Order No.: 1-423

Molecular Formula: CH_5N

Molecular Weight: 31.06

Structural formula:



1. General information

The aqueous solubility of this substance is 1.08×10^6 mg/L (25°C), the partition coefficient (1-octanol/water) (log K_{ow}) is −0.57, and the vapor pressure is 3.53×10^5 Pa (25°C). The biodegradability (aerobic degradation) is characterized by a BOD degradation rate of 84%. Further, this substance is believed to not hydrolyze under ambient environmental conditions because it does not possess any hydrolyzable groups.

This substance was classified as a Class 1 Designated Chemical Substance under the PRTR Law, but it was removed from the classification by the Cabinet Order partially revising the Enforcement Order for the Act on the Assessment of Releases of Specified Chemical Substances in the Environment and the Promotion of Management Improvement promulgated on October 20, 2021, which came into force on April 1, 2023.

The main use of this substance is as a raw material for agricultural chemicals, pharmaceuticals, dyes, and slurry explosives. The production and import category in fiscal 2019 was less than 9,854 t. The production and import category under the PRTR Law was more than 100 t.

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2. Exposure assessment

Total release to the environment in fiscal 2020 under the PRTR Law was 1.2 t, of which all were notified releases. The largest notified releases to the atmosphere and public water bodies were to the atmosphere. In addition, approximately 53 t was transferred to waste.

The major sources of notified releases to the atmosphere were the chemical and agricultural chemical manufacturing industries, while the chemical industry was the major source for public 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 would be 99.0%. Where the largest quantities were estimated to have been released to the atmosphere, the predicted proportion distributed to the atmosphere would be 80.1%.

The maximum expected concentration of exposure to humans via inhalation, based on ambient atmospheric data, was less than around 0.079 μg/m^3. Further, the mean annual value for atmospheric concentration in fiscal 2020 was calculated by use of a plume-puff model on the basis of releases to the atmosphere reported under the PRTR Law: this model predicts a maximum level of 0.11 μg/m^3.

Data for potable water, groundwater, public freshwater bodies, food, and soil to assess oral exposure could not be obtained. However, the concentration of this substance in public freshwater bodies is believed to be low given there were 0 kg of notified releases to in public freshwater bodies in fiscal 2020 under the PRTR Law.

Data capable of withstanding assessment for water quality could not be obtained and therefore, the predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, could not be set. However past data indicated a concentration for public freshwater bodies of generally less than 2 μg/L and a concentration for seawater of less than 2 μg/L.

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3. Initial assessment of health risk

This substance is corrosive to the eyes and the respiratory tract. Inhalation will cause a burning sensation, cough, headache, labored breathing, shortness of breath, and sore throat. Contact with the eyes will cause redness, pain, blurred

vision, and severe deep burns. Rapid evaporation of the liquid of this substance on the skin may cause frostbite.

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 NOAEL of 500 mg/kg/day for oral exposure to methylamine hydrochloride (based on suppression of body weight gain), determined from toxicity tests in rats, was converted to methylamine equivalent to obtain 230 mg/kg/day and subsequently divided by a factor of 10 to account for extrapolation to chronic exposure. The calculated value of 23 mg/kg/day was deemed the lowest reliable dose and was identified as the 'non-toxic level' of the substance for oral exposure. The NOAEL of 5 ppm for inhalation exposure (based on inflammation and hyperplasia of the transitional epithelium in the nasal cavity), determined from toxicity tests in mice, was adjusted according to exposure conditions. The obtained value of 0.89 ppm (1.1 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, due to the lack of identified exposure levels, the health risk could not be assessed. However, the MOE for reference would exceed 29,000 which is calculated from the 'non-toxic level' of 23 mg/m^3 and the maximum exposure level via public freshwater bodies of approximately less than 0.08 μg/kg/day, reported in 1986, and subsequently divided by a factor of 10 to account for extrapolation from animals to humans. In addition, since the release to public freshwater bodies was reported to be 0 kg in FY 2020 under the PRTR Law, the concentrations of the substance in public freshwater bodies would not be high. 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, the collection of further information would not be required to assess the health risk of this substance via oral exposure.

Regarding inhalation exposure, the predicted maximum exposure concentration in ambient air was approximately less than 0.079 μg/m^3. The MOE (Margin of Exposure) would exceed 1,400 which is calculated from the predicted maximum exposure concentration and the 'non-toxic level' of 1.1 mg/m^3 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. In addition, the MOE for reference would be 1,000 which is calculated from the maximum concentration (annual mean) of 0.11 μg/m^3 in ambient air near the operators that are releasing a large amount of the substance based on the releases to air reported in FY 2020 under the PRTR Law. Therefore, as a comprehensive judgment, the collection of further information would not be required to assess the health risk of this substance via inhalation in ambient air.

Toxicity				Exposure assessment		MOE		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*' 23 mg/kg/day	Rats	Suppression of body weight gain	Drinking water	- μg/kg/day	MOE	-	○
				Groundwater	- μg/kg/day	MOE	-	
Inhalation	'Non-toxic level*' 1.1 mg/m^3	Mice	Inflammation and hyperplasia of the transitional epithelium in the nasal cavity	Ambient air	<0.079 μg/m^3	MOE	>1,400	○
				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 281,800 μg/L for growth

inhibition in the green alga *Desmodesmus subspicatus*, a 48-h EC_{50} of 702,000 μg/L for swimming inhibition in the crustacean *Daphnia magna*, and a 48-h TLm of 1,000,000 μg/L for the fish *Oryzias latipes* (medaka). Accordingly, based on this acute toxicity value and an assessment factor of 100, a predicted no effect concentration (PNEC) of 2,800 μg/L was obtained.

With regard to chronic toxicity, the following reliable data was obtained: a 72-h NOEC of 8,900 μg/L for growth inhibition in the green alga *D. subspicatus*. Accordingly, based on this chronic toxicity value and an assessment factor of 100, a PNEC of 89 μg/L was obtained.

The value of 89 μg/L obtained from the acute toxicity to the alga was used as the PNEC for this substance.

The predicted environmental concentration (PEC) could not be set for this substance because data could not be obtained. Accordingly, a judgment regarding ecological risk could not be made.

Considering the fact that experts believe amines exhibit especially high chronic toxicities towards crustacean species compared with acute toxicities, a QSAR and other methods were used to conduct a review of chronic toxicities for crustacean species. The minimum value of an analog of this substance for chronic toxicity towards a crustacean species is 850 μg/L. This value was used as the chronic toxicity value for this substance towards crustacean species. An assessment factor of 100, considered appropriate when estimating reliable data for 1–2 groups of organisms was applied to the chronic toxicity value to obtain 8.5 μg/L. This value is lower than the PNEC value of 89 μg/L for algal species derived from experimental data.

Further, data for water quality in public water bodies for recent years to assess exposure to this substance was unobtainable. From the above, data related to exposure and chronic toxicity towards crustacean species is insufficient and as such, based on a comprehensive review of the above findings, efforts to collect data are considered necessary.

Efforts to understand production and import quantities and trends in environmental releases, and augmentation of data regarding chronic toxicity towards crustacean species for this substance are considered necessary.

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)		
Green algae	Chronic	NOEC Growth inhibition	100	89	Freshwater	—	—	▲
					Seawater	—	—	

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5. Conclusions

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

［Risk judgments］○: No need for further work ▲: Requiring information collection
■: Candidates for further work ×: Impossibility of risk characterization