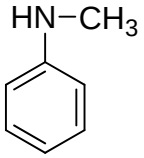
14	CAS No.: 100-61-8	Substance: *N*-Methylaniline

Chemical Substances Control Law Reference No.: 3-106

PRTR Law Cabinet Order No.: 2-90

Molecular Formula: C_7H_9N Structural Formula:

Molecular Weight: 107.15



1. General information

The aqueous solubility of this substance is 5.6×10^3 mg/1,000 g (25°C), the partition coefficient (1-octanol/water) (log K_{ow}) is 1.66, and the vapor pressure is 0.4 mmHg (=50 Pa) (25°C). Biodegradability (aerobic degradation) is not good, and bioaccumulation is thought to be nonexistent or low.

This substance is designated as a Class 2 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). This substance is mainly used as a solvent and rubber additive. It is also used as a raw material for dyes, agricultural chemicals, and pharmaceuticals. The production and import quantity in fiscal 2011 was not disclosed because the number of reporting businesses was not more than two. The production and import category under the PRTR Law is 1 to <100 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 2011 under the PRTR Law was 0.002 t, and all releases were reported. In addition, 0.023 t was transferred to waste materials. The major destination of reported releases was the atmosphere. The only source of 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 soil was 51.4%, and the proportion distributed to the atmosphere was 31.5%.

The maximum expected concentration of exposure to humans via inhalation could not be obtained. However, past general environmental data indicated less than 0.15 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 0.00048 μg/m^3. The maximum expected oral exposure has been estimated in a report to be less than 0.00048 μg/kg/day on the basis of calculations from data for public freshwater bodies. 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 less than 0.012 μg/L for public freshwater bodies and less than around 0.012 μg/L for seawater.

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3. Initial assessment of health risk

This substance may affect blood to produce methemoglobin in it. When inhaled, cyanosis, coughing, dizziness, headache, labored breathing and sore throat may be caused, while abdominal pain may occur when orally ingested, in addition to the symptoms observed by poisoning through its inhalation exposure. When the substance contacts skin, the symptoms observed by poisoning through its inhalation exposure may also occur if it

is absorbed.

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, a LOAEL of 5 mg/kg/day (for decreased hemoglobin levels and spleen congestion) obtained from its mid-term and long-term toxicity tests on rats was divided by a factor of 10 for conservative use of the LOAEL, and further divided by a factor of 10 due to their short test periods. Outcome of 0.05 mg/kg/day was identified to be the reliable lowest dose and its 'non-toxic level*'. As for inhalation exposure to the substance, its 'non-toxic level*' could not be identified.

As for oral exposure to the substance, both its mean exposure level and its predicted maximum exposure level were below about 0.00048 μg/kg/day, when intakes of freshwater from public water bodies were assumed. The MOE (Margin of Exposure) would be over 10,000 when calculated from its 'non-toxic level*' of 0.05 mg/kg/day and its maximum exposure concentration predicted from animal experiments, and divided by a factor of 10 to convert animal data to human data. Therefore, no further action would be required at this moment to assess health risk from oral exposure to the substance.

With regard to inhalation exposure to the substance, its health risk could not be assessed as its 'non-toxic level*' could not be identified nor its exposure concentrations were not known. However, if 100% absorption were assumed, the 'non-toxic level*' for its oral exposure would be converted to the 'non-toxic level*' of 0.17 mg/m^3 for its inhalation exposure. The MOE would be over 110 when calculated from this level and the substance's maximum concentration of about 0.15 $\mu g/m^3$ in the ambient air estimated from its emissions reported in 1990, and divided by a factor of 10 to convert animal data to human data. In addition, its maximum annual mean concentration in the ambient air near the operators discharging the substance in high concentrations was calculated to be 0.00048 $\mu g/m^3$ from its emissions reported in FY 2009 under the PRTR Law. The MOE would be 35,000 when calculated from this for reference. Therefore, collection of further information would not be required to assess health risk from inhalation exposure to the substance 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*' 0.05 mg/kg/day	Rat	Decreased haemoglobin levels and spleen congestion	Drinking water	— μg/kg/day	MOE	—	×	○
				Freshwater	<0.00048 μg/kg/day	MOE	>10,000	○	
Inhalation	'Non-toxic level*' — mg/m^3	—	—	Ambient air	— $\mu g/m^3$	MOE	—	×	(○)
				Indoor air	— $\mu g/m^3$	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 more than 20,400 μg/L for growth inhibition in the green alga *Pseudokirchneriella subcapitata*, a 48-h EC_{50} of 5,580 μg/L for immobilization in the crustacean *Daphnia magna*, and a 48-h LC_{50} of 55,000 μg/L for the fish species *Cyprinus carpio* (common carp). Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 55 μg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h of NOEC of 317 μg/L for growth inhibition in the green alga *P. subcapitata*, and a 21-d NOEC of 290 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 2.9 μg/L was obtained.

The value of 2.9 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 0.004 for both freshwater bodies and seawater. Accordingly, further work 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	2.9	Freshwater	<0.012	<0.004	○	○
					Seawater	<0.012	<0.004		

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need of further work at present.	○
	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.