20	CAS No.: 106-49-0	Substance: *para*-Toluidine

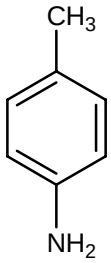
Chemical Substances Control Law Reference No.: 3-186 (as toluidine)

PRTR Law Cabinet Order No.: 1-226

Structural Formula:

Molecular Formula: C_7H_9N

Molecular Weight: 107.16



1. General information

The aqueous solubility of this substance is 7.35 x 10^4mg/L (20°C) and the partition coefficient (1-octanol / water) (log Kow) is 1.39. The vapor pressure is 0.286 mmHg (= 38.1Pa) (25°C, extrapolated value). Degradability (aerobic degradation) in terms of BOD-based (NH_3) degradation percentage is estimated to be 32% (in average). The bioconcentration of this substance is determined not to be high.

This substance is a Type 2 and Type 3 Monitoring Chemical Substance under the Law Concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances 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). It is used primarily as a raw material of organic synthesis, and a special solvent of the production of dyes. The quantities of production (shipment) and import in FY2001 were 1,000 - below 10,000 tons, and the quantities of export and import in FY2004 were 418 tons and 6,051 tons, respectively (total of toluizine and its derivatives, and their salt forms in each value).

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2. Exposure assessment

Total release to the environment in FY2004 under the PRTR Law came to 0.85 tons, all of which was reported. Release to the atmosphere accounted for a large part of the reported release. The source of the reported release was only Chemical Industry.

The distribution into each environment medium predicted by means of a multimedia model was 89.8% for water bodies and 9.3% for bottom in the case of the region where the release quantity to the environment and atmosphere was considered to be the maximum. In the case of the region where the release quantity to the public water bodies was considered to be the maximum, the distribution was 90.7% for water bodies and 8.5% for bottom.

No predicted maximum exposure concentration for inhalation exposure to human beings could be established. However, there was a report that when the data for a limited area (Kawasaki City) was used, it was less than 0.00091 μg/m^3. The predicted maximum oral exposure was estimated to be approximately less than 0.00024 μg/kg/day. Because the bioconcentration of this substance is predicted to be low, exposure from environmental media via the food chain is assumed to be low.

The predicted environmental concentration (PEC) that indicates exposure to aquatic organisms was estimated to be less than 0.006 μg/L for both freshwater and seawater public water bodies.

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3. Initial assessment of health risk

This substance causes irritation of the eyes and skin, and may have effects on blood to produce methemoglobin. Exposure at high concentration may result in disorder of kidney and bladder. The inhalation or ingestion may result in blue lips, nails and skin, confusion, dizziness, headache, laboured breathing, nausea, shortness of breath, unconsciousness, and weakness. Contact

with skin may be absorbed and cause the similar symptoms. Contact with eyes causes redness, pains and severe chemical burn.

There was insufficient information regarding the carcinogenicity of the substance. For this reason, an initial assessment of the substance was conducted based on information of non-carcinogenic effects.

As the 'Non-toxic level' for oral exposure, the LOAEL of 40 mg/kg/day (methemoglobinemia) was obtained from medium- and long-term toxicity testing for rat. As this was a LOAEL, it is divided by 10, and because of the short experimental period, the value was further divided by 10, and a value of 0.4 mg/kg/day was derived as the 'Non-toxic level'. For inhalation exposure, the 'Non-toxic level' could not be estimated.

With regard to oral exposure, in case of intakes of the groundwater, the predicted maximum exposure was approximately less than 0.00024 μg/kg/day. The MOE of exceeding 170,000 was derived from the 'Non-toxic level' of 0.4 mg/kg/day divided by the predicted maximum dose, and divided by 10, because the 'Non-toxic level' was established by means of animal testing. As the exposure to this substance through food intakes is estimated minor, even when the exposures through groundwater and food are combined, it would not greatly affect the MOE values. Accordingly, further action for assessment of its health risk from oral exposure to this substance would not be required at present.

For the inhalation, because its 'Non-toxic level' is not determined, and the exposure concentrations were not estimated, its health risk could not be identified. The total release of this substance to the environment (reported quantity of release) was 0.85 tons, and 62% of it was released to the atmosphere. The half-life of this substance in the atmosphere was estimated to be 0.49-4.9 hrs, and almost all of it is estimated to distribute into the mediums other than the atmosphere. Accordingly, there would be low necessity of collecting information on inhalation exposure to this substance in the ambient air for its health risk assessment.

Information of toxicity				Exposure assessment			Result of risk assessment			Judgment
Exposure path	Criteria for risk assessment	Animal	Criteria for diagnoses (endpoint)	Exposure medium	Predicted maximum exposure quantity and concentration					
Oral	'Non toxic level' 0.4 mg/kg/day	Rats	Methemoglobinemia	Drinking water	–	μg/kg/day	MOE	–	×	○
				Groundwater	< 0.00024	μg/kg/day	MOE	> 170,000	○	
Inhalation	'Non toxic level' – mg/m^3	–	–	Ambient air	–	μg/m^3	MOE	–	×	×
				Indoor air	–	μg/m^3	MOE	–	×	×

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4. Initial assessment of ecological risk

With regard to acute toxicity, reliable information of a 72-hour EC_{50} growth inhibition value of 23,900 μg/L was found for the algae *Pseudokirchneriella subcapitata*, a 48-hour EC_{50} immobilization value of 1,260 μg/L was found for the crustacea *Daphnia magna* (water flea), and a 96-hour LC_{50} value of 118,000 μg/L was found for the fish *Oryzias latipes* (medaka), and a 48-hour EC_{50} form change value of 99,700 μg/L was found for the protozoa *Spirostomum ambiguum*. Accordingly, an assessment factor of 100 was used, a predicted no effect concentration (PNEC) of 13 μg/L was obtained based on the acute toxicity values. With regard to chronic toxicity, reliable information of a 72-hour no observed effect concentration (NOEC) growth inhibition value of 3,120 μg/L was found for the algae *P. subcapitata*, and a 21-day NOEC reproduction value of 11.1 μg/L was found for the crustacea *D. magna*. So an assessment factor of 100 was used, and a PNEC value of 0.11 μg/L was obtained based on the chronic toxicity values. As the PNEC for the substance, a value of 0.11 μg/L obtained from the chronic toxicity for the crustacea was used.

The PEC/PNEC ratio was less than 0.05 for both freshwater bodies and seawater bodies. Accordingly, further work is thought to be unnecessary at this time.

Hazard assessment (basis for PNEC)			Assessment factor	Predicted no effect concentration PNEC (μg/L)	Exposure assessment		PEC/ PNEC ratio	Result of assessment
Species	Acute / chronic	Endpoint			Water body	Predicted environmental concentration PEC (μg/L)		
Crustacea (water flea)	Chronic	NOEC reproduction	100	0.11	Freshwater	< 0.006	< 0.05	○
					Seawater	< 0.006	< 0.05	

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need of further work.	○
	Inhalation exposure	Impossible of risk characterization. However, there is thought to be comparatively little need to collect information, etc.	×
Ecological risk	No need of further work.		○

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

Non-toxic level *

・When a LOAEL is available, it is divided by 10 to obtain a level equivalent to NOAEL.

・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.