19	CAS No.: 108-44-1	Substance: *meta*-Toluidine

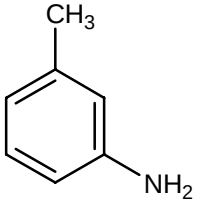
Chemical Substances Control Law Reference No.: 3-186(as toluidine)

PRTR Law Cabinet Order No.:

Molecular Formula: C_7H_9N

Molecular Weight: 107.16

Structural Formula:



1. General information

The aqueous solubility of this substance is 1.50×10^4 mg/L (20°C) and the partition coefficient (1-octanol / water) (log Kow) is 1.53. The vapor pressure is 0.303 mmHg (= 40.4 Pa) (25°C). Degradability (aerobic degradation) in terms of BOD-based degradation percentage is estimated to be 0%. This substance is determined to be no or little bioaccumulative. The hydrolizability of this substance was stable at 25℃, and pH 7 and 9.

This substance is a Type 2 Monitoring Chemical Substance under the Law Concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances. It is used primarily as a synthetic raw material of organic chemicals, mainly an intermediate of polyazo dyes. 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

As this substance is not 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), release and transfer quantities could not be obtained. When predictions of distribution ratios by medium were made using the Mackay-Type Level III Fugacity Model, in the event of equal release to the atmosphere, water and soil, the distribution ratio was highest for soil and water.

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 0.00086 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, dizziness, headache, laboured breathing , shortness of breath and weakness. Contact with the skin may be absorbed and cause the similar symptoms. Contact with the eyes causes redness and pains.

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 the oral exposure, the LOAEL of 30 mg/kg/day (deposition of pigment and extramedullary hematopoiesis in the spleen) was obtained from the medium- and long-term toxicity testing for rats. As this was a LOAEL, it was divided by 10, and because of the short experimental period, the value was further divided by 10, and a value of 0.3

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 130,000 was derived from the 'Non-toxic level' of 0.3 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' was not determined, and the exposure concentrations were not estimated, its health risk could not be identified. The half-life of this substance in the atmosphere was estimated to be 0.32-3.2 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 at present.

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' 0.3 mg/kg/day	Rats	deposition of pigment and extramedullary hematopoiesis in the spleen	Drinking water	– μg/kg/day	MOE	–	×	○
				Groundwater	< 0.00024 μg/kg/day	MOE	> 130,000	○	
Inhalation	'Non toxic level' – mg/m^3	–	–	Ambient air	– $\mu g/m^3$	MOE	–	×	×
				Indoor air	– $\mu g/m^3$	MOE	–	×	×

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4. Initial assessment of ecological risk

With regard to acute toxicity, reliable information of a 48-hour LC_{50} value of 730 μg/L was found for the crustacea *Daphnia magna* (water flea), and a 60-hour inhibitory growth concentration (IGC_{50}) value of 278,000μg/L was found for the other organism *Tetrahymena pyriformis* (*tetrahymena*). Accordingly, an assessment factor of 1,000 was used, a predicted no effect concentration (PNEC) of 0.73 μg/L was obtained based on the acute toxicity values. As no reliable information regarding chronic toxicity could be obtained, as the PNEC for the substance, a value of 0.73 μg/L obtained from the acute toxicity for the crustacea was used.

The PEC/PNEC ratio was less than 0.008 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)	Acute	LC_{50} Mortality	1,000	0.73	Freshwater	< 0.006	< 0.008	○
					Seawater	< 0.006	< 0.008	

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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.