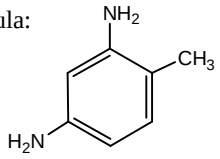
13	CAS No.: 95-80-7	Substance: 2,4-toluenediamine

Chemical Substances Control Law Reference No.: 3-126 (Diaminotoluene)

PRTR Law Cabinet Order No.:1-228

Structural Formula:



Molecular Formula: 95-80-7

Molecular Weight: 122.17

1. General information

The aqueous solubility of this substance is approximately 3.5 x 10^4 mg/L (20°C) and the partition coefficient (1-octanol/water) (log Kow) is 0.14 (pH = 7.4). The vapor pressure is 1.70 x 10^{-4} mmHg (= 0.0227 Pa) (25°C). This substance is determinated to be persistent, also to be non or not highly bioaccumulative. In addition, this substance does not have hydrolyzable groups.

This substance is a Type 2 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). Most of the substance is mainly used as raw materials for toluene diisocyanate. The total of production and imports in FY 2006 was 65,826 tons, and this figure was categorized as falling within the 1000-ton class of production and imports under the PRTR Law.

---

2. Exposure assessment

Total release to the environment in FY2005 under the PRTR Law came to 0.09 tons, all of which was reported. The transfers to sewage and waste were 4.7 tons and approximately 150 tons, respectively. All of the reported quantities were released to the atmosphere.

The distribution into each environment medium predicted by means of a multimedia model was 96.1% for water bodies and 3.9% for the sediment in the case of a region in which the estimated release quantity to the environment and atmosphere was considered to be the maximum.

No predicted maximum exposure concentration for inhalation exposure to human beings could be established. The highest oral predicted exposure was calculated to be approximately 0.0008 μg/kg/day based on groundwater data. The risk of exposure to this substance through food in environmental media is considered to be low.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was estimated to be approximately 0.23 μg/L for freshwater and less than 0.02 μg/L for seawater public water bodies.

---

3. Initial assessment of health risk

The substance irritates the eyes, the skin and respiratory tract. The hot liquid of this substance may cause severe skin burns. The substance may cause effects on the liver and blood, resulting in liver damage and formation of methemoglobin. By inhalation and ingestion, it may cause cough, sore throat, blue lips or finger nails, blue skin, headache, dizziness, nausea, vomiting, confusion, convulsion, and unconsciousness. Additionally, by ingestion, it may cause abdominal pain. Contact with eyes and skin may cause their redness and pain, and , in case of eyes, severe deep burns of eyes.

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.

A lowest-observed-adverse-effect-level (LOAEL) of 3.2 mg/kg/day (depression of body weight gain, chronic renal disease and degeneration of hepatic cells) was obtained for oral exposure from the medium- and long-term toxicity testing for rats. As this was a LOAEL, it was divided by 10, and a value of 0.32 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 groundwater, the predicted maximum exposure was approximately less than 0.0008 μg/kg/day. The margin of exposure (MOE) of exceeding 8,000 was derived from the 'Non-toxic level*' of 0.32 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, and considering the carcinogenesis, further divided by 5. As the exposure to this substance through food intakes was estimated minor, even when the exposure 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.

Concerning inhalation exposure, because its 'Non-toxic level*' was not determined, and the exposure concentrations were not estimated, its health risk could not be identified. The released quantity of this substance to the atmosphere was 0.09 t, and the half- life of this substance in the atmosphere was estimated to be 0.33-3.3 hrs. The vapor pressure of the substance is relatively low. It is estimated to distribute mostly into the media other than the atmosphere. Accordingly, there would be little 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*' 0.32 mg/kg/day	Rats	depression of body weight gain, chronic renal disease and degeneration of hepatic cells	Drinking water	— μg/kg/day	MOE	—	×	○
				Groundwater	< 0.0008 μg/kg/day	MOE	> 8,000	○	
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 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.

---

4. Initial assessment of ecological risk

With regard to acute toxicity, reliable information giving a 72-hour median effective concentration (EC_{50}) growth inhibition value of 18,400 μg/L was found for the algae *Pseudokirchneriella subcapitata*, a 48-hour EC_{50} immobilization value of 15,000 μg/L was found for the crustacea *Daphnia magna* (water flea), and a 96-hour median lethal concentration (LC_{50}) value exceeding 100,000 μg/L was found for the fish *Oryzias latipes* (medaka). Accordingly, an assessment factor of 100 was used, and a predicted no effect concentration (PNEC) of 150 μg/L was obtained based on the acute toxicity values. With regard to chronic toxicity, reliable information giving a 72-hour no observed effect concentration (NOEC) growth inhibition value of 1,000 μg/L was found for the algae *P. subcapitata*, a 21-day NOEC reproduction value of 520 μg/L was found for the crustacea *D. magna*, and a 28-day NOEC growth inhibition value of less than 40,300 μg/L was found for the fish *O. latipes*. Accordingly, an assessment factor of 10 was used, and a PNEC value of 52 μg/L was obtained based on the chronic toxicity values. As the PNEC for the substance, a value of 52 μg/L obtained from the chronic toxicity for the crustacea was used.

The PEC/PNEC ratio was 0.004 for freshwater bodies and less than 0.0004 for 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	10	52	Freshwater	0.23	0.004	○
					Seawater	<0.02	<0.0004	

---

5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need for further work.	○
	Inhalation exposure	Risk cannot be determined. However, there would be little necessity of collecting information.	(○)
Ecological risk	No need for further work.		○

［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.