17	CAS No.: 122-39-4	Substance: Diphenylamine

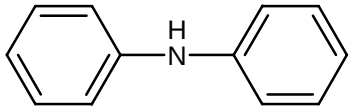
Chemical Substances Control Law Reference No.: 3-133

PRTR Law Cabinet Order No.: 1-159

Structural Formula:

Molecular Formula: $C_{12}H_{11}N$

Molecular Weight: 169.22



1. General information

The aqueous solubility of this substance is 53mg/L (20°C) and the partition coefficient (1-octanol / water) (log Kow) is 3.50. The vapor pressure is 8.05×10^{-4}mmHg (= 0.11Pa) (20°C, extrapolated value). Degradability (aerobic degradation) is insufficient, and the bioconcentration of this substance is thought to be zero or very low. In addition, this substance does not have hydrolyzable groups.

This substance is a 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 organic rubber products, dyes (acidic, sulfonic and seriton dyes), a stabilizer of explorative, stabilizer of chloric solvent, and medicines. The quantities of production (shipment) and import in FY2001 were 1,000 - below 10,000 tons, and the quantity of production in FY2004 was approximately 2,500 tons (an estimated value). The quantities of export and import in FY2004 were 594 tons and 192 tons, respectively (total of diphenylamine 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 0.23 tons, all of which was reported. Release to the atmosphere accounted for a large part of the reported release. Chemical Industry and rubber products accounted for high levels of release to the atmosphere. Chemical Industry reported high levels of release to public water bodies.

The distribution into each environment medium predicted by means of a multimedia model was 80.5% for soil and 14.4% for water bodies 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 82.5% for water bodies and 11.2% for bottom.

No predicted maximum exposure concentration for inhalation exposure to human beings could be established. The predicted maximum oral exposure was estimated to be less than 2.0008 μg/kg/day.

The predicted environmental concentration (PEC) that indicates exposure to aquatic organisms was estimated to be 0.55 μg/L for freshwater and less than 0.02 μg/L for seawater public water bodies.

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3. Initial assessment of health risk

This substance causes irritation of the eyes, skin and respiratory tract, and may have effects on blood to produce methemoglobin. Inhalation and ingestion of this substance may result in coughing, sore throat, blue lips, nails and skin, headache, dizziness, nausea, confusion, convulsion and unconsciousness. Contact to the eyes causes redness. Contact to the skin causes redness, and may cause cyanosis, etc. after absorption.

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 NOAEL of 7.5 mg/kg/day (hematological symptoms) was obtained from

the medium- and long-term toxicity testing for rats. For inhalation exposure, the 'Non-toxic level' could not be estimated.

With regard to oral exposure, in case of intakes of the groundwater and food, the predicted maximum exposure was approximately less than 2.0 μg/kg/day. The MOE of exceeding 380 was derived from the 'Non-toxic level' of 7.5 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. 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 total release of this substance to the environment (reported quantity of release) was 0.23 tons, and almost all of it was released to the atmosphere. The half-life of this substance in the atmosphere was estimated to be 0.33-3.3 hrs, and almost all of it distributed 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' 7.5 mg/kg/day	Rats	Hematological symptoms	Drinking water, food	– μg/kg/day	MOE	–	×	○
				Groundwater ,food	< 2.0 μg/kg/day	MOE	> 380	○	
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 72-hour EC_{50} growth inhibition value of 426 μg/L was found for the algae *Pseudokirchneriella subcapitata*, a 48-hour EC_{50} immobilization value of 1,450 μg/L was found for the crustacea *Daphnia magna* (water flea), and a 96-hour LC_{50} value of 3,790 μg/L was found for the fish *Pimephales promelas* (fathead minnow). Accordingly, an assessment factor of 100 was used, a predicted no effect concentration (PNEC) of 4.3 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 27.3 μg/L was found for the algae *P. subcapitata*, and a 21-day NOEC reproduction value of 125 μg/L was found for the crustacea *D. magna*. So an assessment factor of 100 was used, and a PNEC value of 0.27 μg/L was obtained based on the chronic toxicity values. As the PNEC for the substance, a value of 0.27 μg/L obtained from the chronic toxicity for the algae was used.

The PEC/PNEC ratio was 2 for freshwater bodies and less than 0.07 for seawater bodies. This substance is thought to be a candidate for further work.

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)		
Algae (green algae)	Chronic	NOEC growth inhibition	100	0.27	Freshwater	0.55	2	■
					Seawater	< 0.02	< 0.07	

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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	Candidates for 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.