10	CAS No.: 86-30-6	Substance: N-nitrosodiphenylamine

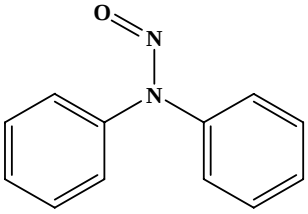
Chemical Substances Control Law Reference No.: 3-431

PRTR Law Cabinet Order No.: 1-238

Molecular Formula: $C_{12}H_{10}N_2O$

Molecular Weight: 198.22

Structural Formula:



1. General information

The aqueous solubility of this substance is 35 mg/L (25°C), and the partition coefficient (1-octanol / water) (log Kow) is 3.13. The vapor pressure is 0.1 mmHg (= 13.3 Pa) (25°C, analogical value). Degradability is 0% by BOD degradation rate, and the accumulation factor is thought to be zero or very low. The substance does not have hydrolyzable groups.

This substance is 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). Its primary uses and release sources are as an antiscorching agent (for rubber chemicals). Production and import quantities under the PRTR Law came to 10 tons.

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2. Exposure assessment

Total release to the environment in FY2003 under the PRTR Law came to 0.72 tons, of which 0.55 tons was reported. Most (0.55 tons) of the reported release was release to public water bodies, and most of the reported release was release by rubber product manufacturers.

When estimated releases outside notification are included, release to water bodies accounted for the greatest quantity of release to the environment. The distribution into each environmental medium predicted by means of a multimedia model was 97.1% for water bodies and 1.7% for bottom sediment.

It was not possible to obtain data to enable a predicted maximum exposure concentration to be established for inhalation exposure to human beings. The predicted maximum oral exposure was estimated to be less than 0.0008 μg/kg/day. As this substance is released primarily to water bodies and its distribution to bottom sediment is predicted to be low, bioaccumulation is judged to be zero or very low, and therefore 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 0.02 μg/L for both freshwater and seawater public water bodies.

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3. Initial assessment of health risk

No information could be obtained with regard to acute symptoms. However, when administered orally to rat, a decrease in food consumption and locomotor activity, exhausing, tremors and collapse were observed, followed by death. In addition, lung congestion, liver discoloration and inflammation of the gastrointestinal tract were observed. On rabbit, there was slight eye irritation, but no skin irritation was observed.

There is insufficient information regarding the carcinogenicity of the substance, and it is not possible to make a judgment as to whether it causes cancer in humans. For this reason, an initial assessment of the substance was conducted based on information of non-carcinogenic effects.

As the ‘Non-toxic level’ was observed, used to estimate the margin of exposure (MOE), a lowest observed adverse effect level (LOAEL) of 50 mg/kg/day (prevention of weight increase; cell degeneration of urinary bladder

transitional epithelium), obtained from rat medium- and long-term toxicity testings, was obtained for oral exposure. As the value was a LOAEL value, it was divided by 10 to establish a value of 5 mg/kg/day. It was not possible to establish a 'Non-toxic level' for inhalation exposure.

With regard to oral exposure, when intake of groundwater was postulated, the maximum predicted exposure was estimated to be less than 0.0008 μg/kg/day. As the 'Non-toxic level' of 5 mg/kg/day and the maximum predicted exposure were established by means of animal testing, the value was divided by 10 to establish an MOE that exceeded 630,000. The exposure originating in the environment through the food chain is estimated to be minor, and it is thought that adding this exposure would not greatly affect the MOE. Accordingly, assessment of the health risk from oral exposure to this substance is thought to be unnecessary at this time.

With regard to inhalation exposure, it was not possible to determine the health risk. However, as more than 99% (0.72 t) of the estimated release of this substance to the environment is release to water bodies, and subsequently it is predicted that almost all of the substance will be distributed in water bodies, there is thought to be little need to gather information, etc. on inhalation exposure in order to evaluate the health risk with regard to exposure to the substance in the ambient air.

Knowledge of toxicity				Exposure assessment			Result of risk assessment			Judgment
Exposure path	Guidelines for risk assessment	Animal	Impact assessment guideline (endpoint)	Exposure medium	Predicted maximum exposure quantity and concentration					
Oral	No observed adverse effect level 5 mg/kg/day	Rat	Prevention of weight increase; cell degeneration of urinary bladder transitional epithelium	Drinking water	–	μg/kg/day	MOE	–	×	○
				Fresh water	< 0.0008	μg/kg/day	MOE	> 630,000	○	
Inhalation	No observed adverse effect level –	–	–	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 3,080 μg/L was found for the algae *Pseudokirchneriella subcapitata*, a 48-hour LC_{50} immobilization value of 7,800 μg/L was found for the crustacea *Daphnia magna* (water flea), and a 96-hour LC_{50} value of 10,200 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 31 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 580 μg/L was found for the algae *P. subcapitata*, and a 21-day NOEC reproduction value of 75 μg/L was found for the crustacea *D. magna*. Accordingly, an assessment factor of 100 was used, and a PNEC value of 0.75 μg/L was obtained based on the chronic toxicity values. As the PNEC for the substance, a value of 0.75 μg/L obtained from the chronic toxicity for the crustacea was used.

The PEC/PNEC ratio was less than 0.03 μg/L for both freshwater 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	Chronic	NOEC reproduction	100	0.75	Freshwater	< 0.02	< 0.03	○
					Seawater	< 0.02	< 0.03	

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	Assessment is thought to be unnecessary at this time.	○
	Inhalation exposure	Risk cannot be determined. However, there is thought to be comparatively little need to collect information, etc.	×
Ecological risk	Assessment is thought to be unnecessary at this time.		○

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