

8	CAS No.: 135-19-3	Substance: 2-Naphthol
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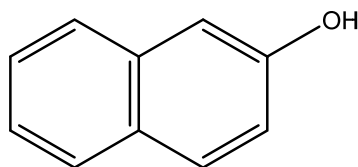
Chemical Substances Control Law Reference No.: 4-355

PRTR Law Cabinet Order No.: 1-393

Structural Formula:

Molecular Formula: C<sub>10</sub>H<sub>8</sub>O

Molecular Weight: 144.17



### 1. General information

The aqueous solubility of this substance is 640 mg/1000 g (20°C), the partition coefficient (1-octanol/water) (log K<sub>ow</sub>) is 2.70, and the vapor pressure is 7.5 mmHg (=1000 Pa) (140.7°C). This substance biodegrades easily (aerobic degradation). Further, the substance does not possess any hydrolyzable groups; therefore, it does not hydrolyze under ambient environmental conditions.

This substance is classified as a Class 1 Designated Chemical Substance under the PRTR Law. The main uses of this substance are as a raw material for pharmaceuticals, bactericides, fungicides, β-oxy-naphthoic acid (an intermediate for dyestuffs and pigments), and iron ore concentrators, and as a plant growth regulator (deregistered pesticide). The production and import quantity in fiscal 2017 was less than 2000 t. The production and import category under the PRTR Law is more than 100 t.

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### 2. Exposure assessment

Total release to the environment in fiscal 2017 under the PRTR Law was approximately 0.73 t, of which approximately 0.37 t or 51% was reported. All reported releases were to public water bodies. In addition, approximately 0.27 t was transferred to waste and 0.53 t to sewage. The chemical industry was the main reporter of releases. The largest releases to the environment including unreported releases were to water bodies. A multimedia model used to predict the proportions distributed to individual media in the environment indicates that in regions where the largest quantities were estimated to have been released to the environment overall or water bodies in particular, the predicted proportion distributed to water was 54.5%, and that to bottom sediment was 45.0%.

The maximum expected concentration of exposure to humans via inhalation could not be determined because ambient atmospheric and indoor air quality data could not be obtained. There were no reported releases to the atmosphere under the PRTR Law; accordingly, atmospheric concentrations are thought to be low.

Data for potable water, ground water, public freshwater bodies, food, and soil to assess oral exposure could not be obtained. In lieu of such data, the maximum expected exposure was calculated to be around 0.0084 μg/kg/day assuming intake solely from public freshwater bodies. However, when releases to public freshwater bodies in fiscal 2017 reported under the PRTR Law were divided by the ordinary water discharge of the national river channel structure database, estimating the concentration in rivers by taking into consideration only dilution gave a maximum value of 13 μg/L. Using this estimated concentration for rivers to calculate oral exposure gives 0.50 μg/kg/day. Further, the maximum estimated concentration for rivers (13 μg/L) and the maximum value for public freshwater bodies (0.21 μg/L) are values for the same location.

Further, data related to food could not be obtained. Therefore, maximum concentrations for fish species (0.0064 μg/g) were used along with the average daily intake (64.4 μg/capita/day) to calculate reference values for exposure by intake from an environmental medium via food to be roughly 0.0082 μg/kg/day, albeit based on past data. Adding this to the oral exposure calculated from freshwater data gives around 0.017 μg/kg/day.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was reported to be around 0.21 μg/L for public freshwater bodies and roughly around less than 0.0023 μg/L for seawater. When releases to public freshwater bodies in fiscal 2017 reported under the PRTR Law were divided by the ordinary water discharge of the

national river channel structure database, estimating the concentration in rivers by taking into consideration only dilution gave a maximum value of 13 µg/L. Further, the maximum estimated concentration for rivers (13 µg/L) and the maximum value for public freshwater bodies (0.21 µg/L) are values for the same location.

### 3. Initial assessment of health risk

This substance is severely irritating to the eyes. Inhalation of this substance causes cough and sore throat. Ingestion causes abdominal pain, nausea, vomiting and diarrhea. Contact with the eyes causes redness, pain and blurred vision.

As sufficient information on the carcinogenicity of the substance was not available, the initial assessment was conducted on the basis of information on its non-carcinogenic effects.

The NOAEL of 40 mg/kg/day for oral exposure (based on squamous hyperplasia in mucosa of the forestomach), determined from toxicity tests in rats, was divided by a factor of 10 to account for extrapolation to chronic exposure. The calculated value of 4.0 mg/kg/day was deemed to be the lowest reliable dose and was identified as the ‘non-toxic level’ of the substance for oral exposure. The ‘non-toxic level’ for inhalation exposure could not be identified.

With regard to oral exposure, assuming the substance is absorbed via public freshwater bodies, the predicted maximum exposure level would be 0.0084 µg/kg/day, approximately. The MOE (Margin of Exposure) would be 48,000, when calculated from the predicted maximum exposure level and the ‘non-toxic level’ of 4.0 mg/kg/day, and subsequently divided by a factor of 10 to account for extrapolation from animals to humans. This would lead to the health risk judgment that no further work would be required at present. In addition, the MOE for reference would be 800, when calculated from the estimated maximum exposure level of 0.50 µg/kg/day. This maximum exposure level was estimated according to the concentration in effluents from the high discharging plants reported in FY 2017 under the PRTR Law. Alternatively, the MOE for reference would be 24,000, when calculated from the exposure level of 0.017 µg/kg/day. This exposure level was estimated assuming that the substance is absorbed via fish and public freshwater bodies, in spite of unavailability of data on exposure via food. Therefore, as a comprehensive judgment, no further work would be required at present to assess the health risk of this substance via oral exposure.

With regard to inhalation exposure, owing to the lack of identified ‘non-toxic level’ and exposure concentrations, the health risk could not be assessed. The total release of the substance to the environment was reported to be 0.73 t in FY 2017 under the PRTR Law. However, the release of the substance into the air was reported to be 0 t, and predictions of the multimedia fugacity model indicated that the proportion distributed to air was little. Therefore, as a comprehensive judgment, collection of further information would not be required to assess the health risk of this substance via inhalation in ambient air.

Toxicity				Exposure assessment		MOE		Comprehensive judgment
Exposure Path	Criteria for risk assessment	Animal	Criteria for diagnoses (endpoint)	Exposure medium	Predicted maximum exposure dose and concentration			
Oral	‘Non-toxic Level’ 4.0 mg/kg/day	Rats	Squamous hyperplasia in mucosa of the forestomach	Drinking water	- µg/kg/day	MOE	-	○
				Public Freshwater bodies	0.0084 µg/kg/day	MOE	48,000	
Inhalation	‘Non-toxic level’ - mg/m <sup>3</sup>	-	-	Ambient air	- µg/m <sup>3</sup>	MOE	-	○
				Indoor air	- µg/m <sup>3</sup>	MOE	-	×

Non-toxic level \*

- When a LOAEL is available, it is divided by 10 to obtain a NOAEL-equivalent level.
- 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, the following reliable data were obtained: a 72-h EC<sub>50</sub> of 2080 µg/L for growth inhibition in the green alga *Raphidocelis subcapitata*, a 48-h LC<sub>50</sub> of 850 µg/L for the crustacean *Gammarus minus*, a 96-h LC<sub>50</sub> of

3460 µg/L for the fish *Pimephales promelas* (fathead minnow), and a 24-h LC<sub>50</sub> of 18,700 µg/L for the Japanese brown frog *Rana japonica*. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 8.5 µg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 577 µg/L for growth inhibition in the green alga *Raphidocelis subcapitata* and a 21-d NOEC of 692 µg/L for reproductive inhibition in the crustacean *Daphnia magna*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a PNEC of 5.7 µg/L was obtained.

The value of 5.7 µg/L obtained from the chronic toxicity to the alga was used as the PNEC for this substance.

The PEC/PNEC ratio is less than 0.04 for freshwater bodies and less than 0.0004 for seawater; accordingly, further work is considered unnecessary at this time.

However, when releases to public freshwater bodies in fiscal 2017 reported according to the PRTR Law were divided by the ordinary water discharge of the national river channel structure database, estimating the concentration in rivers by taking into consideration only dilution gives a maximum value of 13 µg/L, and the ratio of this value to the PNEC was 2.3. Further, the maximum estimated concentration for rivers (13 µg/L) and the maximum value for public freshwater bodies (0.21 µg/L) are values for the same location. Accordingly, based on a comprehensive review of the above findings, efforts to collect data are needed, and environmental concentration data needs to be augmented taking into consideration the emission situation.

Hazard assessment (basis for PNEC)			Assessment coefficient	Predicted no effect concentration PNEC (µg/L)	Exposure assessment		PEC/PNEC ratio	Comprehensive judgment
Species	Acute/chronic	Endpoint			Water body	Predicted environmental concentration PEC (µg/L)		
Green algae	Chronic	NOEC Growth inhibition	100	5.7	Freshwater	0.21	0.04	▲
					Seawater	<0.0023	<0.0004	

## 5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need for further work.	○
	Inhalation exposure	No need for further work.	○
Ecological risk	Requiring information collection.		▲

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