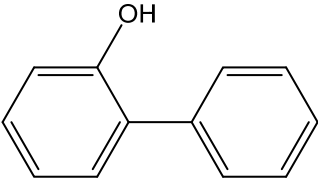


8	CAS No.: 90-43-7	Substance: 2-Phenylphenol
<p>Chemical Substances Control Law Reference No.: 4-19 (Phenylphenol) PRTR Law Cabinet Order No.: 1-346 Molecular Formula: C₁₂H₁₀O Structural Formula: Molecular Weight: 170.21</p> <div style="text-align: right;">  </div>		

1. General information

The aqueous solubility of this substance is 700 mg/1,000 g (25°C), the partition coefficient (1-octanol/water) (log K_{ow}) is 3.09, and the vapor pressure is 5×10⁻⁴ mmHg (=0.07 Pa) (20°C). The biodegradability (aerobic degradation) is characterized by a BOD degradation rate of 66%, and biodegradability is judged to be good. Further, decomposition via hydrolysis was <10% (pH=7, 50°C, 5 d).

This substance is classified as a Class 1 Designated Chemical Substance under the PRTR Law.

The main uses of this substance are as a termite pesticide, bactericide, corrosion inhibitor, and fungicide. It also finds use as a dyestuff carrier for synthetic fibers, and a raw material for synthetic resins, plasticizers, dyestuffs and surfactants. Further, its use is permitted as a food additive to prevent mold in imported citrus fruits. The production and import quantity of phenylphenol in fiscal 2018 was 3,000 t. The production and import category under the PRTR Law is more than 100 t.

2. Exposure assessment

Total release to the environment in fiscal 2018 under the PRTR Law was approximately 1.9 t, of which 0.038 t or 2% of overall releases were reported. All reported releases were to the atmosphere. In addition, approximately 190 t was transferred to waste materials, and 1.7 t was transferred to sewage. The chemical industry was the only reporter of releases.

A multi-media model used to predict the proportions distributed to individual media in the environment indicated that in regions where the largest quantities were estimated to have been released to the environment overall or to public water bodies in particular, the predicted proportion distributed to bottom sediments was 73.5% and that to water was 25.9%. Where the largest quantity was estimated to have been released to the atmosphere, the predicted proportion distributed to soil was 80.6%. Where the largest quantity was estimated to have been released to soil, the predicted proportion distributed to soil was 44.5% and that to bottom sediments was 40.8%.

The maximum expected concentration of exposure to humans via inhalation was not established because neither data measured for the ambient atmosphere nor indoor air could be obtained. However, the mean annual value for atmospheric concentration in fiscal 2018 was calculated by use of a plume-puff model on the basis of releases to the atmosphere reported under the PRTR Law; this model predicts a maximum level of 0.013 µg/m³.

Data for potable water, ground water, food, public freshwater bodies, and soil to assess oral exposure could not be obtained. In addition, because this substance may be added to food as a fungicide, market basket-type survey findings were not used to assess oral exposure via food. Instead, measured data for fish species were used as a reference. Albeit past data, a value of less than 0.00032 µg/kg/day was obtained for maximum oral exposure based on data measured for public water bodies while the average daily intake of fish and shellfish (65.1 g/capita/day) was used to estimate exposure by intake from an environmental medium via food (fish and shellfish) to be 0.0070 µg/kg/day. A reference value of a maximum of less than 0.0073 µg/kg/day for oral exposure was calculated from these values for public freshwater bodies and food (fish and shellfish). Further, no releases to public freshwater bodies were reported in fiscal 2018 under the PRTR Law but transfer to sewage was reported. Accordingly, when releases to public freshwater bodies estimated from reported transfer to sewage 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 34 µg/L, and the oral exposure calculated thereof is 1.4 µg/kg/day.

Data for setting the predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, could not be obtained. Further, past data for public freshwater bodies and seawater indicated values of less than 0.008 µg/L and around less than 0.008 µg/L, respectively. Further, no releases to public freshwater bodies were reported in fiscal 2018 under the PRTR Law but transfer to sewage was reported. Accordingly, when releases to public freshwater bodies estimated from reported transfer to sewage 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 34 µg/L.

3. Initial assessment of health risk

This substance severely irritates the eyes, as well as irritates the skin and respiratory tract. Inhalation of the substance will cause a cough and a sore throat. Contact to the skin will cause redness. Contact to the eyes will cause redness and pain. Ingestion will cause no acute symptoms.

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

The NOAEL of 25 mg/kg/day for oral exposure (based on increase in the post-implantation loss), determined from developmental toxicity tests in rabbits, 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.

Regarding the oral exposure, due to the lack of identified exposure levels, the health risk could not be assessed. However, the maximum exposure level was estimated to be less than 0.0073 µg/kg/day, assuming that the substance is absorbed via fish and public freshwater bodies based on past data in 1999, due to the lack of exposure level via food. The MOE (Margin of Exposure) for reference would exceed 340,000, when calculated from the estimated maximum exposure level and the ‘non-toxic level’ of 25 mg/kg/day, and subsequently divided by a factor of 10 to account for extrapolation from animals to the humans. The MOE would still exceed 68,000, when additionally divided by a factor of 5 to take into consideration the carcinogenicity of the sodium salt of this substance. Another estimate of the maximum exposure level was 1.4 µg/kg/day according to the concentration in effluents from the high discharging plants based on the transfers to the sewage system, reported in FY 2018 under the PRTR Law. The MOE would be 1,800, when calculated from this estimate, and would be 360, when additionally divided by a factor of 5 to take into consideration the carcinogenicity of the sodium salt of this substance. Therefore, as a comprehensive judgment, collection of further information would not be required to assess the health risk of this substance via oral exposure.

Regarding the inhalation exposure, due to the lack of identified ‘non-toxic level’ and exposure concentrations, the health risk could not be assessed. However, the MOE for reference would be 640,000, when calculated from the tentative ‘non-toxic level’ for inhalation exposure of 83 mg/m³ and the maximum concentration (annual mean) in ambient air of 0.013 µg/m³ near the operators that are releasing large amount of the substance, based on the releases to air reported in FY 2018 under the PRTR Law and subsequently divided by a factor of 10 to account for extrapolation from animals to the humans, and would be 130,000, when additionally divided by a factor of 5 to take into consideration the carcinogenicity of the sodium salt of this substance. The tentative ‘non-toxic level’ for inhalation exposure was derived from the conversion of the ‘non-toxic level’ for oral exposure, assuming that 100% of the inhaled substance is absorbed. 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’	25	mg/kg/day	Rabbits	Increase in the post-implantation loss	Drinking water	- µg/kg/day	MOE	-	○
						Groundwater	- µg/kg/day	MOE	-	
Inhalation	‘Non-toxic level’	-	mg/m ³	-	-	Ambient air	- µg/m ³	MOE	-	○
						Indoor air	- µg/m ³	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 EC₅₀ of 3,570 µg/L for growth inhibition in the alga *Raphidocelis subcapitata*, a 96-h LC₅₀ of 320 µg/L for the crustacean *Americamysis bahia*, a 96-h LC₅₀ of 2,600 µg/L for the fish species *Oncorhynchus mykiss* (rainbow trout) and a 48-h LC₅₀ of 4,480 µg/L for the great pond snail *Lymnaea stagnalis*. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 3.2 µg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 350 µg/L for growth inhibition in the alga *Chlorella vulgaris* and a 21-d NOEC of 9 µg/L for reproductive inhibition in the crustacean *Daphnia magna*. Accordingly, based on this chronic toxicity value and an assessment factor of 100, a PNEC of 0.09 µg/L was obtained.

The value of 0.09 µg/L obtained from the chronic toxicity to the crustacean was used as the PNEC for this substance.

Data for setting the predicted environmental concentration (PEC) could not be obtained for this substance. Accordingly, an assessment of ecological risk could not be made.

Further, past data for public freshwater bodies and seawater indicated values of less than 0.008 µg/L and around less than 0.008 µg/L, respectively. The ratio of this value to the PNEC is less than 0.09. Further, no releases to public freshwater bodies were reported in fiscal 2018 under the PRTR Law but transfer to sewage was reported. Accordingly, when releases to public freshwater bodies estimated from reported transfer to sewage 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 34 µg/L. The ratio of this value to the PNEC is 378.

Accordingly, based on a comprehensive review of the above findings, efforts to collect data are needed. Environmental concentration data also need to be augmented for this substance taking into consideration major emission sources.

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)		
Crustacean <i>Daphnia magna</i>	Chronic	NOEC Reproductive inhibition	100	0.09	Freshwater	—	—	▲
					Seawater	—	—	

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