12	CAS No.: 119-61-9	Substance: Benzophenone

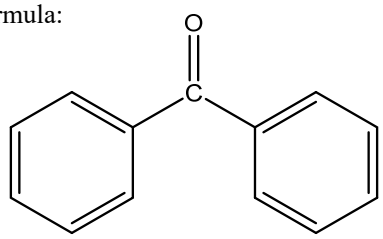
Chemical Substances Control Law Reference No.: 3-1258、4-125

PRTR Law Cabinet Order No.: 1-403

Molecular Formula: $C_{13}H_{10}O$

Molecular Weight: 182.22

Structural Formula:



1.General information

The aqueous solubility of this substance is 75 mg/1,000 g (20°C), the partition coefficient (1-octanol/water) (log K_{ow}) is 3.18, and the vapor pressure is 0.02360 mmHg (=3.146Pa) (55.9°C). The biodegradability (aerobic degradation) is characterized by a BOD degradation rate of 0%, and bioaccumulation is thought to be nonexistent or low. In addition, this substance does not possess any hydrolyzable groups and therefore is not expected to undergo hydrolysis.

This substance is classified as a Class 1 Designated Chemical Substance under the PRTR Law. The main use of this substance is as a raw material for pharmaceuticals and pesticides. The production and import quantity in fiscal 2016 was less than 1,000 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 2016 under the PRTR Law was 0.022 t; all releases were reported. In addition, approximately 0.44 t was transferred to waste. The chemical industry reported large releases to the atmosphere and public water bodies. A multi-media 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 soil in particular, the predicted proportion distributed to water bodies was 63.5% and to bottom sediment was 25.4%. Where the largest quantities were estimated to have been released to the atmosphere, the predicted proportion distributed to soil was 74.7% and to the atmosphere was 22.0%.

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. Furthermore, predicted maximum expected concentration of exposure to humans via inhalation of around 0.0031 μg/m^3 for the ambient atmosphere and around 0.098 μg/m^3 for indoor air have been obtained in the past. The mean annual value for the atmospheric concentration in fiscal 2016 was calculated by use of a plume-puff model on the basis of releases to the atmosphere reported according to the PRTR Law; this model predicts a maximum level of 0.0021 μg/m^3.

Data for potable water, ground water, food and soil to assess oral exposure could not be obtained. Thereupon, assuming intake solely from public freshwater bodies, a maximum expected concentration of exposure of around less than 0.0015 μg/kg/day is obtained. Furthermore, a reference value of 0.13 μg/kg/day is obtained for maximum expected concentration of exposure based on data measured for public water bodies and past data measured for food and soil. River concentrations were not estimated due to no environmental monitoring stations located downstream of businesses releasing to public water bodies in fiscal 2016.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was reported to be around 0.038 μg/L for public freshwater bodies and around 0.0082 μg/L for seawater. Further, past data for public freshwater bodies and seawater indicated values of around 0.31 μg/L and around 0.02 μg/L, respectively. River concentrations were not estimated due to the lack of environmental monitoring stations located downstream of businesses

releasing to public water bodies in fiscal 2016.

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3. Initial assessment of health risk

This substance is mildly irritating to the skin and causes redness.

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 LOAEL of 15 mg/kg/day for oral exposure (chronic active inflammation of the liver, hyperplasia of the bile duct, renal tubule and C-cells, etc.), determined from toxicity tests in rats, was divided by a factor of 10 to account for uncertainty in using a LOAEL. The calculated value of 1.5 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 0.0015 μg/kg/day, approximately. The MOE (Margin of Exposure) would exceed 20,000, when calculated from the predicted maximum exposure level and the 'non-toxic level*'of 1.5 mg/kg/day, and subsequently divided by a factor of 10 to account for extrapolation from animals to humans and by another factor of 5 to take into consideration the carcinogenicity. Assuming the substance is absorbed via food and soil, based on past data reported in 2004 and 1998 respectively, in addition to the public freshwater bodies, the exposure level would be less than 0.13 μg/kg/day. The MOE would be 230, when calculated from this exposure level. Therefore, 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. Assuming that 100% of the inhaled substance is absorbed, the 'non-toxic level*' for inhalation exposure, derived from the conversion of the 'non-toxic level*' for oral exposure, would be 5 mg/m^3. The MOE would be 32,000, when calculated from the maximum exposure concentration in ambient air of 0.0031 μg/m^3 approximately (data of 2003), and the converted 'non-toxic level*' for inhalation exposure, and subsequently divided by a factor of 10 to account for extrapolation from animals to humans and by another factor of 5 to take into consideration the carcinogenicity. Alternatively, the maximum concentration (annual mean) in ambient air near the operators releasing large amount of the substance was estimated to be 0.0021 μg/m^3 based on the releases to air reported in FY 2016 under the PRTR Law. When calculated from this concentration, the MOE would be 48,000. When calculated from the maximum exposure concentration in indoor air of 0.098 μg/m^3 approximately (data of 2004), the MOE would be 1,000. Therefore, collection of further information would not be required to assess the health risk of this substance via inhalation in ambient air and in indoor air.

Toxicity				Exposure assessment		Result of risk assessment		Judgment
Exposure Path	Criteria for risk assessment	Animal	Criteria for diagnoses (endpoint)	Exposure medium	Predicted maximum exposure dose and concentration			
Oral	'Non-toxic level*' 1.5 mg/kg/day	Rats	Chronic active inflammation of the liver, hyperplasia of the bile duct, renal tubule and C-cells, etc.	Drinking water	- μg/kg/day	MOE	-	○
				Public freshwater bodies	0.0015 μg/kg/day	MOE	20,000	
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.

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4. Initial assessment of ecological risk

With regard to acute toxicity, the following reliable data were obtained: a 72-h EC_{50} of 3,530 μg/L for growth inhibition in the green alga *Pseudokirchneriella subcapitata*, a 48-h EC_{50} of 6,780 μg/L for swimming inhibition in the crustacean *Daphnia magna*, a 96-h LC_{50} exceeding 10,000 μg/L for the fish species *Oryzias latipes* (medaka), and a 24-h LC_{50} of 56,800 μg/L for the nematode *Caenorhabditis elegans*. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 35 μg/L is obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 1,000 μg/L for growth inhibition in the green alga *P. subcapitata*, a 21-d NOEC of 200 μg/L for reproductive inhibition in the crustacean *D. magna*, a 35–38-d NOEC of 540 μg/L for growth inhibition in the fish species *Pimephales promelas* (fathead minnow), and a 72-h NOEC of less than 1,560 μg/L for growth inhibition in the duckweed *Lemna minor*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 20 μg/L was obtained.

The value of 20 μg/L obtained from the chronic toxicity to the crustacean species was used as the PNEC for this substance.

The PEC/PNEC ratio is 0.002 for freshwater bodies and 0.0004 for seawater. Further, a maximum value of around 0.31 μg/L was reported for freshwater bodies in 2004 and the ratio of this value to the PNEC is 0.02; accordingly, further work is considered unnecessary at this time.

Hazard assessment (basis for PNEC)			Assessment coefficient	Predicted no effect concentration PNEC (μg/L)	Exposure assessment		PEC/ PNEC ratio	Assessment result
Species	Acute/ chronic	Endpoint			Water body	Predicted environmental concentration PEC (μg/L)		
Crustacean *Daphnia magna*	Chronic	NOEC reproductive inhibition	10	20	Freshwater	0.038	0.002	○
					Seawater	0.0082	0.0004	

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need for further work.	○
	Inhalation exposure	No need for further work.	○
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

（▲）: Further efforts to collect data required based on comprehensive review of existing relevant data

（■）: Candidate for further work based on comprehensive review of existing data