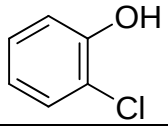
2	CAS No.: 95-57-8	Substance: *o*-Chlorophenol

Chemical Substances Control Law Reference No.: 3-895 (Monochlorophenol)
PRTR Law Cabinet Order No.: 1-120
Molecular Formula: C_6H_5ClO
Molecular Weight: 128.56

Structural Formula:



1. General information

The aqueous solubility of this substance is 2.27×10^4 mg/1,000 g (25°C), the partition coefficient (1-octanol/water) (log K_{ow}) is 2.15, and the vapor pressure is 2.31 mmHg (=308 Pa) (25°C). Biodegradability (aerobic degradation) is characterized by a BOD degradation rate of 0%, and bioaccumulation is judged to be non-existent or low. Furthermore, the substance does not have any hydrolyzable groups.

This substance is designated as 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). The main uses of this substance are as a raw material for other chemicals, dyestuffs, and agricultural chemicals. The production and import category under the PRTR Law is more than 100 t. The production and import quantity as monochlorophenol in fiscal 2011 was less than 1,000 t.

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2. Exposure assessment

Total release to the environment in fiscal 2011 under the PRTR Law was 0.035 t, and all releases were reported. The major destination of reported releases was the atmosphere. In addition, 0.37 t was transferred to waste materials. The only source of reported releases was the chemical industry. 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 the atmosphere in particular, the predicted proportion distributed to soil was 95.0%.

The maximum expected concentration of exposure to humans via inhalation could not be obtained. The mean annual value for atmospheric concentration in fiscal 2011 was calculated by using a plume-puff model on the basis of releases to the atmosphere reported according to the PRTR Law; this model predicted a maximum level of 0.0073 μg/m^3. The maximum expected oral exposure was estimated to be less than around 0.0002 μg/kg/day on the basis of calculations from data for groundwater, and around 0.0028 μg/kg/day on the basis of calculations from data for public freshwater bodies. Around 0.0028 μg/kg/day was adopted as the maximum expected oral exposure. The risk of exposure to this substance by intake from an environmental medium via food is considered slight, based on its low bioaccumulation.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was around 0.071 μg/L for public freshwater bodies and around 0.009 μg/L for seawater.

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3. Initial assessment of health risk

This substance may cause severe irritation to eyes, skin and respiratory tract. Inhalation exposure to its aerosol may cause pulmonary edema. The central nervous system may also be affected. Oral ingestion of the substance may cause abdominal pain, lethargy, weakness and convulsions. When inhaled, coughing, shortness of breath and sore throat may be caused and the symptoms as observed when orally ingested may also occur.

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

With regard to oral exposure to the substance, a NOAEL of 5 mg/kg/day (for decreased number of pups/litter and decreased live births) obtained from its reproductive and developmental toxicity tests on rats was identified

to be the reliable lowest dose as its 'non-toxic level*'. As for inhalation exposure to the substance, its 'non-toxic level could not be identified.

As for oral exposure to the substance, its mean exposure level was below about 0.0002 μg/kg/day and its predicted maximum exposure level was about 0.0028 μg/kg/day, when intakes of freshwater from public water bodies were assumed. The MOE (Margin of Exposure) would be 180,000 when calculated from the substance's 'non-toxic level*' of 5 mg/kg/day and the maximum exposure level predicted from animal experiments and divided by a factor of 10 to convert animal data to human data. As exposure to the substance in the environment through food intakes would be limited, the MOE would not change significantly even when this exposure is included. Therefore, no further action would be required at this moment to assess health risk from oral exposure to the substance.

With regard to inhalation exposure to the substance, its health risk could not be assessed as its 'non-toxic level*' could not be identified nor its exposure concentrations were not known. In addition, if 100% absorption were assumed, its 'non-toxic level* ' for oral exposure would be converted to a 'non-toxic level*' of 17 mg/m^3 for inhalation exposure. The MOE would be 230,000 when calculated for reference from this value and the maximum (annual mean) concentration in the ambient air near an operator discharging the high concentration of 0.0073 μg/m^3 of the substance in their emissions reported in FY 2011 under the PRTR Law, and converted from animal data to human data. Therefore, collection of further information would not be required to assess health risk from inhalation exposure to the substance in the ambient 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*' 5 mg/kg/day	Rat	Decreased number of pups/litter and decreased live births	Drinking water	— μg/kg/day	MOE	—	×	○
				Freshwater	0.0028 μg/kg/day	MOE	180,000	○	
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.

4.Initial assessment of ecological risk

With regard to acute toxicity, the following reliable data were obtained: a 48-h EC_{50} of 8,630 μg/L for growth inhibition in the green alga *Pseudokirchneriella subcapitata*, a 96-h LC_{50} 1,300 μg/L for the crustacean *Americamysis bahia*, a 48-h LC_{50} of 8,100 μg/L for the fish species (bluegill) *Lepomis macrochirus*, and a 60-h IGC_{50} of 67,970 μg/L for reproductive inhibition in the ciliate protozoan *Tetrahymena pyriformis*. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 13 μg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 48-h NOEC of 4,930 μg/L for growth inhibition in the green alga *P. subcapitata*, a 14-d NOEC of 80 μg/L for reproductive inhibition in the crustacean *Daphnia magna*, and a 30-d NOEC of 4,000 μg/L for mortality or post-hatching growth inhibition in the fish species *Pimephales promelas* (fathead minnow). Accordingly, based on these chronic toxicity values and an assessment factor of 10, a PNEC of 8 μg/L was obtained.

The value of 8 μg/L obtained from the chronic toxicity to the crustacean was used as the PNEC for this substance.

The PEC/PNEC ratio was 0.009 for freshwater bodies and 0.001 for seawater; accordingly, further work is considered unnecessary at this time.

Hazard assessment (basis for PNEC)			Assessment factor	Predicted no effect concentration PNEC (μg/L)	Exposure assessment		PEC/PNEC ratio	Judgment based on 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	8	Freshwater	0.071	0.009	○	○
					Seawater	0.009	0.001		

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need of further work at present.	○
	Inhalation exposure	Although risk to human health could not be confirmed, collection of further information would not be required.	(○)
Ecological risk	No need of further work at present.		○

［Risk judgments］ ○: No need for further work ▲: Requiring information collection

■: Candidates for further work ×: Impossibility of risk characterization

（○）: Though a risk characterization cannot be determined, there would be little necessity of collecting information.

（▲）: Further information collection would be required for risk characterization.