6	CAS No.: 95-48-7	Substance: *o*-Cresol

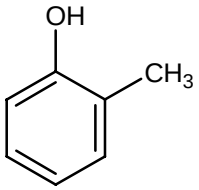
Chemical Substances Control Law Reference No.: 3-499 (As cresol) and 4-57(poly(1 - 3)alkyl(C=1 - 3)poly(1 - 3)hydroxyl-poly(1 - 5)phenyl)

PRTR Law Cabinet Order No.: 1-67 (as cresol)

Molecular Formula: C_7H_8O

Molecular Weight: 108.14

Structural Formula:



1. General information

The aqueous solubility of this substance is 2.60×10^4 mg/L (25°C) and the partition coefficient (1-octanol / water) (log Kow) is 1.95. The vapor pressure is 0.287 mmHg (= 38.3Pa) (25°C, extrapolated value). Degradability (aerobic degradation) in terms of BOD-based degradation percentage is estimated to be 61.1% (Standard Dilution Method), and 60.8% (Sea Water Dilution Method). This substance does not have hydrolyzable groups in the environment.

Cresol 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). It is used primarily as raw materials of synthetic resin, paint and agricultural chemical, an antiseptic and sterilizer. The quantities of production (shipment) and import of this substance in FY2001 were 1,000 - below 10,000 tons, and the quantities of export and import in FY2004 were 31,573 tons and 2,883 tons, respectively (the total of cresol and its salt forms in both cases).

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2. Exposure assessment

Total release of Cresol to the environment in FY2004 under the PRTR Law came to approximately 130 tons. Of this quantity, the amount reported came to 110 tons (81% of the total). Release to the atmosphere accounted for a large part of the reported release. Nonferrous metals accounted for high levels of release to the atmosphere. Chemical Industry reported high levels of release to the public water bodies. When estimated releases outside notification are included, release to the atmosphere accounted for the greatest quantity of release to the environment.

The distribution into each environment medium predicted by means of a multimedia model was 42.3% for soil, 29.1% for water bodies and 28.2% for the atmosphere in the case of the region where the estimated release quantity to the environment and atmosphere was considered to be the maximum. In the case of the region where the estimated release quantity to the public water bodies was considered to be the maximum, the distribution was 99.4% for water bodies.

No predicted maximum exposure concentration for inhalation exposure to human beings could be established. However, there was a report that when the data for a limited area (Kawasaki City) was used, the concentration was approximately less than 0.023 μg/m^3. The predicted maximum oral exposure was estimated to be less than 0.0012 μg/kg/day. Because the 1-octanol/water partition coefficient (log Kow) is 1.95-1.98, and the bioconcentration is also predicted to be low, 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 0.21 μg/L for freshwater and less than 0.03 μg/L for seawater public water bodies.

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3. Initial assessment of health risk

Exposure to this substance may cause corrosivity to the eyes, skin and respiratory tract, and has corrosivity even on ingestion. Inhalation of its vapor or aerosol may cause pulmonary edema. Inhalation of the substance may cause burning sensation, sore

throat, coughing, headache, nausea, vomiting, laboured breathing and shortness of breath. By ingestion, it may cause nausea, vomiting, abdominal pains, burning sensation and shock/collapse. Contact to the skin or eyes may cause redness, pain and burn. It has effect on CNS, cardiovascular system, lung, kidney and liver, and exposure at high levels may result in lowering of consciousness and death.

There was insufficient information regarding the carcinogenicity of the substance. For this reason, an initial assessment of the substance was conducted based on information of non-carcinogenic effects.

As the 'Non-toxic level' for oral exposure, the NOAEL of 30 mg/kg/day (effects on CNS) was obtained from the medium- and long-term toxicity testing for rats. The NOAEL was adjusted to 21 mg/kg/day taking into account the exposure situations. The value was divided by 10, because of the experimental period being short, and a value of 2.1 mg/kg/day was derived as the 'Non-toxic level'. For inhalation exposure, the 'Non-toxic level' could not be estimated.

With regard to oral exposure, in case of groundwater intake, the predicted maximum exposure was approximately less than 0.0012 μg/kg/day . The MOE of exceeding 180,000 was derived from the 'Non-toxic level' of 2.1 mg/kg/day divided by the predicted maximum dose, and divided by 10, because the 'Non-toxic level' was established by means of animal testing. As the exposure to this substance through food intakes is estimated minor, even when the exposures through groundwater and food are combined, it would not greatly affect the MOE values. Accordingly, further action for assessment of its health risk from oral exposure to this substance would not be required at present.

For the inhalation, because its 'Non-toxic level' was not determined, and the exposure concentrations have not been estimated, its health risk can not be identified. Of the total amount of cresol released to the environment, 67% was released to the atmosphere, and some reports indicate that this substance evaporates from water bodies to the atmosphere. Accordingly, it would be required to collect information on inhalation exposure to this substance in the ambient air for its health risk assessment.

Information of toxicity				Exposure assessment			Result of risk assessment			Judgment
Exposure path	Criteria for risk assessment	Animal	Criteria for diagnoses (endpoint)	Exposure medium	Predicted maximum exposure quantity concentration					
Oral	'Non toxic level' 2.1 mg/kg/day	Rats	Effect on CNS	Drinking water	–	μg/kg/day	MOE	–	×	○
				Groundwater	< 0.0012	μg/kg/day	MOE	> 180,000	○	
Inhalation	'Non toxic level' – mg/m^3	–	–	Ambient air	–	$\mu g/m^3$	MOE	–	×	×
				Indoor air	–	$\mu g/m^3$	MOE	–	×	×

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4. Initial assessment of ecological risk

With regard to acute toxicity, reliable information of a 48-hour LC_{50} value exceeding 94,000 μg/L was found for the crustacea *Daphnia pulicaria* (*daphnia*), a 96-hour LC_{50} value of 8,400 μg/L was found for the fish *Oncorhynchus mykiss* (rainbow trout), and a 60-hour inhibitory growth concentration (IGC_{50}) value of 203,390μg/L was found for the other organism *Tetrahymena pyriformis* (*tetrahymena*). Accordingly, an assessment factor of 1,000 was used, a predicted no effect concentration (PNEC) of 8.4 μg/L was obtained based on the acute toxicity values. As no information regarding chronic toxicity could be obtained, as the PNEC for the substance, a value of 8.4 μg/L was used.

The PEC/PNEC ratio was 0.03 for freshwater bodies and less than 0.004 for 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)		
Fish (rainbow trout)	Acute	LC_{50} Mortality	1,000	8.4	Freshwater	0.21	0.03	○
					Seawater	< 0.03	< 0.004	

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need of further work.	○
	Inhalation exposure	Impossible of risk characterization. There is thought to be need to collect information, etc.	×
Ecological risk	No need of further work.		○

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

Non-toxic level *

・When a LOAEL is available, it is divided by 10 to obtain a level equivalent to NOAEL.

・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.