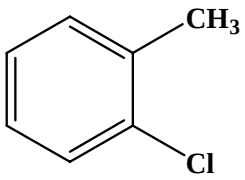
5	CAS No.: 95-49-8	Substance: *o*- chlorotoluene

Chemical Substances Control Law Reference No.: 3-39 (as chlorotoluene)

PRTR Law Cabinet Order No.: 1-89

Molecular Formula: C_7H_7Cl Structural Formula:

Molecular Weight: 126.58



1. General information

The aqueous solubility of this substance is 374 mg/L (25°C), and the partition coefficient (1-octonal / water) (log Kow) is 3.42. The vapor pressure is 3.43 mmHg (= 457 Pa) (25°C). The biodegradability of the substance is 0% by BOD degradation rate, and the accumulation factor is thought to be zero or very low. The substance is thought to not be hydrolyzable in the environment.

This substance 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). Its primary usage and release sources are as a synthetic raw material (dyes, agricultural chemicals and pharmaceuticals). Production and import quantities under the PRTR Law came to 100 tons.

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2. Exposure assessment

Total release to the environment in FY2003 under the PRTR Law came to 13 tons, all of which was reported. All of the reported quantity came from Chemical Industry.

Release to the atmosphere accounted for a large part of the release to the environment. The distribution into each environmental medium as determined by means of a multimedia model was 75.4% for atmosphere and 21.7% for water bodies.

The predicted maximum exposure concentration for inhalation exposure to human beings was estimated at less than 0.01 μg/m^3. The predicted maximum oral exposure was assessed at less than 0.012 μg/kg/day. Moreover, this substance has high aqueous solubility and is judged to have little or no bioaccumulation, so exposure from environmental media through the intake of food is thought to be low.

The predicted environmental concentration (PEC) that indicates exposure to aquatic organisms was estimated to be less than 0.3 μg/L for both freshwater and seawater public water bodies.

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3. Initial assessment of health risk

Even brief exposure to this substance may result in irritation of the eyes, skin and respiratory tract. If inhaled, it may cause coughing, shortness of breath and dizziness. If it comes in contact with the skin and the eyes, it may cause redness and pain. Repeated exposure to the substance in liquid may cause defatting of the skin.

There is insufficient information regarding the carcinogenicity of the substance, and it is not possible to make a judgment as to whether it causes cancer in human beings. For this reason, an initial assessment of the substance was conducted based on information of non-carcinogenic effects.

As the 'Non-toxic level' was observed, used to estimate the margin of exposure (MOE), a no observed adverse effect level (NOAEL) value of 20 mg/kg/day (prevention of weight increase), obtained from rat medium- and long-term toxicity testings, was obtained for oral exposure. As the test period was short, the value was divided by 10 to establish a value of 2 mg/kg/day. For inhalation exposure, a lowest observed adverse effect level (LOAEL) value of 1,000 mg/m^3 (fetal brachymelia and brachydactylia), obtained from rat reproductive and developmental toxicity

testings, was corrected to match the exposure circumstances, resulting in a value of to 250 mg/m^3. As this was a LOAEL value, it was further divided by 10 to establish a value of 25 mg/m^3.

With regard to oral exposure, the predicted maximum exposure when postulating intake of freshwater from public water bodies was estimated at less than 0.012 μg/kg/day. As the 'Non-toxic level' of 2 mg/kg/day and the predicted maximum exposure were established by means of animal testing, the value was divided by 10 to derive an MOE that exceeded 17,000. Moreover, exposure originating in the environment due to the intake of food was estimated to be minor, and it is thought that adding this exposure would not greatly affect the MOE. Accordingly, assessment of the health risk from oral exposure to this substance is thought to be unnecessary at this time.

With regard to inhalation exposure, the predicted maximum exposure concentration in ambient air was estimated at less than 0.01 μg/m^3. The MOE derived in the same manner from the 'Non-toxic level' of 25 mg/m^3 and the predicted maximum exposure concentration exceeded 250,000. Accordingly, there is thought to be no need at this time for assessment of the health risk with regard to inhalation exposure to the substance in the ambient air.

Knowledge of toxicity				Exposure assessment			Result of risk assessment			Judgment
Exposure path	Guidelines for risk assessment	Animal	Impact assessment guideline (endpoint)	Exposure medium	Predicted maximum exposure quantity and concentration					
Oral	No observed adverse effect level 2 mg/kg/day	Rat	Prevention of weight increase	Drinking water	–	μg/kg/day	MOE	–	×	○
				Fresh water	< 0.012	μg/kg/day	MOE	> 17,000	○	
Inhalation	No observed adverse effect level 25 mg/m^3	Rat	Fetal brachymelia and brachydactylia	Ambient air	< 0.01	μg/m^3	MOE	> 250,000	○	○
				Indoor air	–	μg/m^3	MOE	–	×	×

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4. Initial assessment of ecological risk

With regard to acute toxicity, reliable information of a 72-hour EC_{50} growth inhibition value of 7,840 μg/L was found for the algae *Pseudokirchneriella subcapitata*, a 48-hour EC_{50} immobilization value of 700 μg/L was found for the crustacea *Daphnia magna* (water flea), and a 96-hour LC_{50} value of 7,670 μg/L was found for the fish *Oryzias latipes* (medaka). Accordingly, an assessment factor of 100 was used, and a predicted no effect concentration (PNEC) exceeding 7 μg/L was obtained based on the acute toxicity values. With regard to chronic toxicity, reliable information of a 72-hour no observed effect concentration (NOEC) growth inhibition value of 2,610 μg/L was found for the algae *P. subcapitata* and a 21-day NOEC reproduction value of 140 μg/L was found for the crustacea *D. magna*. Accordingly, an assessment factor of 100 was used, and a PNEC value of 1.4 μg/L was obtained based on the chronic toxicity values. As the PNEC for the substance, a value of 1.4 μg/L obtained from the chronic toxicity for the crustacean was used.

The PEC/PNEC ratio was less than 0.2 for both freshwater bodies and seawater bodies. Accordingly, ecological risk cannot be determined at this time. It is necessary to determine trends in production and release quantities and study the need for a determination of environmental concentrations.

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)		
Crustacea	Chronic	NOEC reproduction	100	1.4	Freshwater	< 0.3	< 0.2	×
					Seawater	< 0.3	< 0.2	

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	Assessment is thought to be unnecessary at this time.	○
	Inhalation exposure	Assessment with regard to the ambient air is thought to be unnecessary at this time.	○
Ecological risk	Impossible of risk characterization. It is necessary to determine trends in production and release quantities and study the need for a determination of environmental concentrations.		×

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