

because the ‘Non-toxic level’* was established by means of animal testing. As the exposure to this substance through food intakes was estimated minor, even when the exposure through freshwater in the public water bodies and food are combined, it would not greatly affect the MOE values. Accordingly, further action would not be required at present for assessment of its health risk from oral exposure to this substance.

Concerning inhalation exposure, because its ‘Non-toxic level’* was not determined, and the exposure concentrations were not estimated, its health risk could not be identified. For reference, assuming that the absorption rate is 100%, the ‘Non-toxic level’* for the oral exposure is converted to the ‘Non-toxic level’* for the inhalation. The resulting value, 67 mg/m³, was comparable to ‘Non-toxic level’* of *o*-chlorotoluene, 25 mg/m³. (see page 124 of Vol. 4). For oral exposure, the ‘Non-toxic level’* of this substance was 20 mg/kg/day, whereas that of *o*- chlorotoluene was 2 mg/kg/day.

Monochlorotoluene is produced and used mostly as intermediate raw materials. It was reported that the ratio of the production volume of *o*- and *p*-chlorotoluene (ortho/para) varies according to reaction temperature and the catalyst at production, ranging from 0.66 to 3.3. Therefore, it is likely that the concentration in the ambient air of this substance(*p*- chlorotoluene) is not different from that of *o*- chlorotoluene greatly.

Because the MOE of *o*-chlorotoluene was estimated to exceed 250,000, it is likely that the MOE of this substance is high enough. Accordingly, there would be little necessity of collecting 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 and concentration	MOE			
Oral	‘ Non-toxic level’* 20 mg/kg/day	Rats	depression of body weight gain, increase in the relative weight of liver and kidneys, etc	Drinking water	- μg/kg/day	MOE	-	×	
				Freshwater	< 0.0004 μg/kg/day	MOE	> 5,000,000		
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 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.

4. Initial assessment of ecological risk

With regard to acute toxicity, reliable information of a 72-hour median effective concentration (EC₅₀) growth inhibition value of 6,110 μg/L was found for the algae *Pseudokirchneriella subcapitata*, a 48-hour EC₅₀ immobilization value of 1,650 μg/L was found for the crustacea *Ceriodaphnia cf. dubia* (water flea), and a 96-hour median lethal concentration (LC₅₀) value of 801 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) of 8 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 2,160 μg/L was found for the algae *P. subcapitata*, a 21-day NOEC reproduction value of 322 μg/L was found for the crustacea *Daphnia magna*, and a 28-day NOEC growth inhibition/mortality value of 1,900 μg/L was found for the fish *Danio rerio* (zebra fish). Accordingly, an assessment factor of 10 was used, and a predicted no effect concentration (PNEC) of 32 μg/L was obtained based on the chronic toxicity values. As the PNEC for the substance, a value of 8 μg/L obtained from the acute toxicity for the fish was used.

The PEC/PNEC ratio was less than 0.001 for both freshwater bodies and 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 (medaka)	Acute	LC ₅₀ mortality	100	8	Freshwater	<0.01	<0.001	○
					Seawater	<0.01		

5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need for further work.	
	Inhalation exposure	Risk cannot be determined. However, there would be little necessity of collecting information.	()
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

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

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