



mg/m<sup>3</sup> (delay in fetal ossification), obtained from rabbit reproductive and developmental toxicity testings, was established.

As oral exposure could not be determined, the health risk could not be assessed. However, degradability of the substance is good, and exposure via the food chain originating in the environment is estimated to be minor. Accordingly, there is thought to be little need to prioritize the determination of exposure to this substance.

With regard to inhalation exposure, the predicted maximum exposure concentration in ambient air was estimated at approximately 0.033 µg/m<sup>3</sup>. As the 'Non-toxic level' of 2.3 mg/m<sup>3</sup> and the predicted maximum exposure concentration were established by means of animal testing, the value was divided by 10 to derive an MOE of 7,000. 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 1.2 mg/kg/day	Monkey	Decline in fetal survival rate	Drinking water	—	µ g/kg/day	MOE	—	×	×
				Groundwater	—	µ g/kg/day	MOE	—	×	
Inhalation	No observed adverse effect level 2.3 mg/m <sup>3</sup>	Rabbit	Delay in fetal ossification	Ambient air	0.033	µ g/m <sup>3</sup>	MOE	7,000	○	○
				Indoor air	—	µ g/m <sup>3</sup>	MOE	—	×	×

#### 4. Initial assessment of ecological risk

With regard to acute toxicity, reliable information of a 72-hour EC<sub>50</sub> growth inhibition value exceeding 100,000 µg/L was found for the algae *Pseudokirchneriella subcapitata*, a 48-hour EC<sub>50</sub> immobilization value exceeding 84,800 µg/L was found for the crustacea *Daphnia magna* (water flea), and a 96-hour LC<sub>50</sub> value exceeding 88,900 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 850 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 100,000 µg/L was found for the algae *P. subcapitata* and a 21-day NOEC reproduction value exceeding 92,200 µg/L was found for the crustacea *D. magna*. Accordingly, an assessment factor of 100 was used, and a PNEC value exceeding 920 µg/L was obtained based on the chronic toxicity values. As the PNEC for the substance, a value exceeding 850 µg/L obtained from the acute toxicity for the crustacea was used.

At present, the ecological risk cannot be determined, as environmental concentrations sufficient for assessment have not been obtained. Nevertheless, there is thought to be little need to prioritize the determination of environmental concentrations of this substance.

Hazard assessment (basis for PNEC)			Assessment factor	Predicted no effect concentration PNEC (µg/L)	Exposure assessment		PNC/PNC ratio	Result of assessment
Species	Acute / chronic	Endpoint			Water body	Predicted environmental concentration PEC (µg/L)		
Crustacea	Acute	EC <sub>50</sub> immobilization	100	> 850	Freshwater	—	—	×
					Seawater	—	—	

## 5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	Risk cannot be determined. However, there is thought to be little need to prioritize the determination of exposure to this substance.	×
	Inhalation exposure	Assessment with regard to the ambient air is thought to be unnecessary at this time.	○
Ecological risk	Impossible of risk characterization. However, there is thought to be little need to prioritize the determination of environmental concentrations of this substance.		×

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