



correcting the NOAEL of 37 mg/m<sup>3</sup> (fetal skeleton anomalies), also obtained from rat reproductive and developmental toxicity testings, to match the exposure circumstances.

With regard to oral exposure, the maximum predicted exposure was estimated to be less than 0.036 µg/kg/day when intake through groundwater was postulated. As the 'Non-toxic level' and the maximum predicted exposure were established by animal testing, the MOE was derived by dividing by 10, and the result exceeded 130,000. The food-borne exposure originating in the environment 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 approximately 0.036 µg/m<sup>3</sup>. The MOE derived in the same manner from the 'Non-toxic level' of 9.3 mg/m<sup>3</sup> and the predicted maximum exposure concentration was 2,600. 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 46 mg/kg/day	Rat	Fetal skeletal deformity	Drinking water	— µ g/kg/day	MOE	—	×	○
				Groundwater	< 0.036 µ g/kg/day	MOE	> 130,000	○	
Inhalation	No observed adverse effect level 9.3 mg/m <sup>3</sup>	Rat	Fetal skeletal deformity	Ambient air	0.36 µ g/m <sup>3</sup>	MOE	2,600	○	○
				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 89,500 µg/L was found for the crustacea *Daphnia magna* (water flea), and a 96-hour LC<sub>50</sub> value exceeding 94,700 µg/L was found for the fish *Oryzias latipes* (medaka). Accordingly, an assessment factor of 100 was used, a predicted no effect concentration (PNEC) exceeding 900 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 exceeding 100,000 µg/L was found for the algae *P. subcapitata* and a 21-day NOEC reproduction value exceeding 97,000 µg/L was found for the crustacea *D. magna*, so an assessment factor of 100 was used, and a PNEC value that exceeded 970 µg/L was obtained based on the chronic toxicity values. As the PNEC for the substance, a value exceeding 900 µg/L obtained from the acute toxicity for the crustacea 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)		
Crustacea	Acute	EC <sub>50</sub> immobilization	100	> 900	Freshwater	< 0.9	< 0.001	○
					Seawater	< 0.9	< 0.001	

## 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	No need of further work.		○

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