



the substance could not be identified on the basis of its non-carcinogenic effects.

Although sufficient information was not available to evaluate the carcinogenic potential of the substance to human, most of the information suggests its possible carcinogenic effects. Therefore, assessment was conducted with assumption that there would be no threshold for its carcinogenicity, although it was still uncertain whether the substance was carcinogenic to human.

As for oral exposure to the substance, with assumption that there would be no threshold for its carcinogenicity, a slope factor of  $3 \text{ (mg/kg/day)}^{-1}$  (for hemangioendothelioma or hemangiosarcoma) obtained from experiments on rats was used. As for inhalation exposure to the substance, its unit risk could not be identified.

As for oral exposure to the substance, its maximum exposure was estimated to be approximately  $0.00032 \text{ }\mu\text{g/kg/day}$  when its intakes through freshwater from public water bodies were assumed. For its carcinogenic potential, the excess cancer incidence rate for the predicted maximum exposure was calculated to be  $9.6 \times 10^{-7}$  with the above slope factor. In addition, when its intakes through fish and freshwater from public water bodies were assumed, its oral exposure would be below  $0.0061 \text{ }\mu\text{g/kg/day}$  (for 60 to 69 years of age) and below  $0.0044 \text{ }\mu\text{g/kg/day}$  (for all age groups). The excess incidence rates for exposures below  $0.0061 \text{ }\mu\text{g/kg/day}$  and below  $0.0044 \text{ }\mu\text{g/kg/day}$  would be below  $1.8 \times 10^{-5}$  and below  $1.3 \times 10^{-5}$ , respectively, with the above slope factor. Therefore, collection of further information would be required to assess health risk from its oral exposure.

With regard to inhalation exposure to the substance, its health risk could not be assessed as neither its 'non-toxic level\*' nor its unit risk could be identified. If 100 % absorption were assumed, the maximum exposure to the substance would be  $0.0021 \text{ }\mu\text{g/kg/day}$ . This ingestion rate would provide an excess incidence rate of  $6.2 \times 10^{-6}$  with the above slope factor. Therefore, collection of further information on inhalation exposure to the substance would be required to assess health risk from its inhalation.

Exposure Path	Toxicity			Exposure assessment		Result of risk assessment			Judgment
	Criteria for risk assessment	Animal	Criteria for diagnoses ( endpoint )	Exposure medium	Predicted maximum exposure dose and concentration	MOE	Excess incidence rate		
Oral	'Non-toxic level*' - mg/kg/day	-	Suppressed body weight increase	Drinking water	- $\mu\text{g/kg/day}$	MOE	-	x	( )
	Slope factor 3 $(\text{mg/kg/day})^{-1}$	Rat	Hemangioendothelioma or hemangiosarcoma	Freshwater	0.00032 $\mu\text{g/kg/day}$	MOE	-	x	
Inhalation	'Non-toxic level*' - $\text{mg/m}^3$	-	-	Ambient air	0.0069 $\mu\text{g/m}^3$	MOE	-	x	( )
	Unit risk - $(\mu\text{g/m}^3)^{-1}$	-	-	Indoor air	- $\mu\text{g/m}^3$	MOE	-	x	

Non-toxic level \*

- When a LOAEL is available, it is divided by 10 to obtain a NOAEL-equivalent level.
- 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, the following reliable data were obtained: a 72-h  $\text{EC}_{50}$  of  $65,900 \text{ }\mu\text{g/L}$  for growth inhibition in the green alga *Pseudokirchneriella subcapitata*, a 48-h  $\text{EC}_{50}$  of  $25,000 \text{ }\mu\text{g/L}$  for swimming inhibition in the crustacean *Daphnia magna*, a 96-h  $\text{LC}_{50}$  of  $440 \text{ }\mu\text{g/L}$  for the fish species *Pimephales promelas* (fathead minnow), and a 96-h  $\text{LC}_{50}$  of  $4,897 \text{ }\mu\text{g/L}$  for the midge *Chironomus riparius* species. Accordingly, based

on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 4.4 µg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 4,800 µg/L for growth inhibition in the green alga *P. subcapitata*, and a 21-d NOEC of 800 µg/L for reproductive inhibition in the crustacean *D. magna*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 8 µg/L was obtained.

The value of 4.4 µg/L obtained from the acute toxicity to the fish species was used as the PNEC for this substance.

The PEC/PNEC ratio was 0.002 for freshwater bodies and seawater. Accordingly, further work is considered unnecessary at this time.

Hazard assessment (basis for PNEC)			Assessment factor	Predicted no effect concentration PNEC (µg/L)	Exposure assessment		PEC/PNEC ratio	Judgment based on PEC/PNEC ratio	Assessment result
Species	Acute/ chronic	Endpoint			Water body	Predicted environmental concentration PEC (µg/L)			
Fish (fathead minnow)	Acute	LC <sub>50</sub> mortality	100	4.4	Freshwater	0.0081	0.002		
					Seawater	0.0067	0.002		

## 5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	Collection of further information would be required.	( )
	Inhalation exposure	Although risk to human health could not be identified, collection of further information would not be required.	( )
Ecological risk	No need of further work at present.		

[ 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.