



vision. Contact of skin with the substance makes it red. It has been reported that LDLo, TDLo and TCLo of the substance for humans are 29 mg/kg, 170 mg/kg (for coma, increased pulse rate, and cyanosis), and 1% (for allergic dermatitis), respectively.

As sufficient information was not available on carcinogenicity of the substance, an initial assessment was conducted on the basis of the information on its non-carcinogenic effects.

As for oral exposure to the substance, a NOAEL of 15 mg/kg/day (for suppressed body weight increase and tremor) obtained from mid- and long-term toxicity tests on rats was divided by 10 due to their rather short test periods. Its outcome of 1.5 mg/kg/day derived was deemed to be the lowest reliable dose without any effect, and this was identified as its 'non-toxic level\*'. As for inhalation exposure to the substance, its 'non-toxic levels\*' could not be identified.

As for its oral exposure, its mean exposure would be about 0.00076 µg/kg/day and its predicted maximum exposure would be around 0.0018 µg/kg/day, respectively, if its intakes through freshwater from public water bodies and through soil were assumed. The MOE would be 83,000 when calculated from the 'non-toxic level\*' of 1.5 mg/kg/day and the predicted maximum exposure, and divided by 10 for conversion of the 'non-toxic level\*' from animal experiments to an equivalent dose for humans. For reference, its concentrations in receiving river water around its major sources were estimated from its releases to public water bodies reported in FY 2009 under the PRTR Law, and it was suggest that its maximum exposure would be 0.17 µg/kg/day and associated MOE would be 880. Since risk of exposure to this substance through food intakes from the environment would be limited, even when this exposure were combined, significant changes in the MOE would not be likely. Therefore, further actions would not be required at the moment to assess health risk from oral exposure to this substance.

As for its inhalation exposure, lack of available information on its 'non-toxic levels\*' and exposure concentrations did not allow its health risk assessment. For information, the half life of the substance in the ambient air would be 2.8 to 28 hours. Its discharge to water bodies would account for 99% of its total release to the environment, and most of the substance would be allocated in media other than the ambient air in the environment. For reference, if 100% absorption were assumed, its 'non-toxic level\*' for oral exposure would be converted to its 'non-toxic level\*' of 5 mg/m<sup>3</sup> for inhalation exposure. The MOE would be 45,000 when calculated from the 'non-toxic level' of 5 mg/m<sup>3</sup> and its maximum annual average concentration of 0.011 µg/m<sup>3</sup> in the ambient air around its major sources of emissions, which is estimated on the basis of releases of the substance into the ambient air reported for FY2009 under Japanese PRTR. Therefore, collection of information would not be required at the moment to assess health risk from inhalation exposure to this substance in the ambient air.

Toxicity				Exposure assessment				Result of risk assessment			Judgment	
Exposure Path	Criteria for risk assessment			Animal	Criteria for diagnoses (endpoint)	Exposure medium	Predicted maximum exposure dose and concentration					
Oral	Non-toxic level *'	1.5	mg/kg/day	Rats	Suppressed body weight increase, tremor	Drinking water	—	µg/kg/day	MOE	—	×	○
						Freshwater	0.0018	µg/kg/day	MOE	83,000	○	
Inhalation	Non-toxic level *'	—	mg/m <sup>3</sup>	—	—	Ambient air	—	µg/m <sup>3</sup>	MOE	—	×	(○)
						Indoor air	—	µg/m <sup>3</sup>	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, the following reliable data were obtained: a 72-h EC<sub>50</sub> of 53 µg/L for growth inhibition in the green algae *Pseudokirchneriella subcapitata*; a 48-h EC<sub>50</sub> of 61 µg/L for immobilization in the crustacean *Daphnia magna*; and a 96-h LC<sub>50</sub> of 97 µg/L for the fish *Oncorhynchus mykiss* (rainbow trout). Also obtained was a 24-h LC<sub>50</sub> of 240 µg/L for the marine rotifer *Brachionus calyciflorus*. Accordingly, based on these acute toxicity values

and an assessment factor of 100, a predicted no effect concentration (PNEC) of 0.53 µg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 1.5 µg/L for growth inhibition in the green algae *P. subcapitata*; and a 21-d NOEC of 2.9 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 0.015 µg/L was obtained. This 0.015 µg/L obtained from the algae chronic toxicity was used as the PNEC for this substance.

The PEC/PNEC ratio was 3 for freshwater bodies and 4 for seawater. For this reason, the substance is considered to be a candidate for detailed assessment.

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)			
Green algae	Chronic	NOEC growth inhibition	100	0.015	Freshwater	0.046	3	■	■
					Seawater	0.058	4		

## 5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need for further work.	○
	Inhalation exposure	Though a risk characterization cannot be determined, there would be little necessity of collecting information.	(○)
Ecological risk	Candidates 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.