



to this substance by intake from an environmental medium via food is considered slight, given the low bioaccumulation of the substance expected on the basis of its physicochemical properties.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was reported to be around 65 µg/L for public water bodies. Seawater data capable of withstanding assessment could not be obtained and therefore, a PEC could not be set for seawater. When releases to public freshwater bodies in fiscal 2016 reported according to the PRTR Law were divided by the ordinary water discharge of the national river channel structure database, estimating the concentration in rivers by taking into consideration only dilution gives a maximum value of 2.2 µg/L.

### 3. Initial assessment of health risk

Inhalation of this substance causes cough. Ingestion of the substance causes abdominal pain, nausea and vomiting. Contact with the eyes or skin causes redness and pain with mild irritation.

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

The NOAEL of 27 mg/kg/day for oral exposure (no observed adverse effect dose) determined from human studies was deemed to be the lowest reliable dose and was identified as the ‘non-toxic level\*’ of the substance for oral exposure. The ‘non-toxic level\*’ for inhalation exposure could not be identified.

With regard to oral exposure, assuming the substance is absorbed via public freshwater bodies, the predicted maximum exposure level would be 2.6 µg/kg/day, approximately. The MOE (Margin of Exposure) would be 10,000, when calculated from the predicted maximum exposure level and the ‘non-toxic level\*’ of 27 mg/kg/day. Alternatively, the maximum exposure level, estimated according to the concentration in effluents from the high discharging plants reported in FY 2016 under the PRTR Law, would be 0.088 µg/kg/day. The MOE would be 310,000, when calculated from this level. Since exposure to the substance in environmental media via food is presumed to be limited, including it in the calculation would not change the MOE significantly. Therefore, no further work would be required at present to assess the health risk of this substance via oral exposure.

With regard to inhalation exposure, owing to the lack of identified ‘non-toxic level\*’ and exposure concentrations, the health risk could not be assessed. Assuming that 100% of the inhaled substance is absorbed, the ‘non-toxic level\*’ for inhalation exposure, derived from the conversion of the ‘non-toxic level\*’ for oral exposure, would be 90 mg/m<sup>3</sup>. The maximum concentration (annual mean) in ambient air near the operators releasing large amount of the substance was estimated to be 0.11 µg/m<sup>3</sup> based on the releases to air reported in FY 2016 under the PRTR Law. The MOE would be 820,000, when calculated from this exposure concentration and the converted ‘non-toxic level\*’ for inhalation exposure. Therefore, collection of further information would not be required to assess the health risk of this substance via inhalation in ambient air.

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			
Oral	‘Non-toxic level*’ 27 mg/kg/day	Humans	The dose with no observed adverse effect	Drinking water	- µg/kg/day	MOE	-	○
				Public freshwater bodies	2.6 µg/kg/day	MOE	10,000	
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 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 EC<sub>50</sub> exceeding 100,000 µg/L for growth inhibition in the green alga *Pseudokirchneriella subcapitata*, a 48-h EC<sub>50</sub> exceeding 104,000 µg/L for swimming inhibition in the crustacean *Daphnia magna*, and a 96-h LC<sub>50</sub> exceeding 101,000 µg/L for the fish species *Oryzias latipes* (medaka). A PNEC value could not be set based on these acute toxicity values because they were obtained from limit tests that investigated the presence of effects at a designated concentration.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h of NOEC 100,000 µg/L for growth inhibition in the green alga *P. subcapitata* and a 21-d NOEC of 99,100 µg/L for reproductive inhibition in the crustacean *D. magna*. A PNEC value could not be set based on these chronic toxicity values because they were obtained from limit tests.

The toxicity selected for each organisms was obtained from limit tests that investigated the presence of effects at a designated concentration. For this reason, PNEC values were not set.

Provisionally, based on the lowest of these toxicity values, namely the chronic toxicity towards the crustacean of 99,100 µg/L, and an assessment factor of 100, a PNEC of 990 µg/L is obtained, and the ratio of this value to the PEC is 0.07 for freshwater. A concentration of less than 0.2 µg/L was reported for a single location for seawater and the ratio of this value to the PNEC is less than 0.0002. Further, when releases to public freshwater bodies in fiscal 2016 reported according to the PRTR Law were divided by the ordinary water discharge of the national river channel structure database, estimating the concentration in rivers by taking into consideration only dilution gives a maximum value of 2.2 µg/L and the ratio of this value to the provisional PNEC value is 0.002; accordingly, further work is considered unnecessary at this time.

Hazard assessment (basis for PNEC)			Assessment coefficient	Predicted no effect concentration PNEC (µg/L)	Exposure assessment		PEC/PNEC ratio	Assessment result
Species	Acute/chronic	Endpoint			Water body	Predicted environmental concentration PEC (µg/L)		
—	—	—	—	—	Freshwater	65	—	○
					Seawater	—	—	

#### 5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	No need for further work.	○
	Inhalation exposure	No need for further work.	○
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  
 (▲) : Further efforts to collect data required based on comprehensive review of existing relevant data  
 (■) : Candidate for further work based on comprehensive review of existing data