

## **1.General information**

The aqueous solubility of this substance is  $9.23 \times 10^5$  mg/L (20°C), the partition coefficient (1-octanol/water) (log K<sub>ow</sub>) is 1.33, and the vapor pressure is 1 mmHg (= 133.3 Pa) (51°C). The biodegradability (aerobic degradation) is characterized by a BOD degradation rate of 7%, and bioaccumulation is thought to be nonexistent or low. Further, the substance does not possess any hydrolyzable groups.

This substance is classified as a Class 1 Designated Chemical Substance under the PRTR Law. The main uses of this substance are as a pharmaceutical raw material, anticorrosion agent, keratolytic agent, paint remover, protein remover, and in vivo fractionator of body protein and fat. The production and import quantity in fiscal 2016 was not disclosed because the number of reporting businesses was not more than two. The production and import quantity in fiscal 2016 was more than 1 t and less than 100 t.

## 2. Exposure assessment

Total release to the environment in fiscal 2016 under the PRTR Law was approximately 0.82 t, of which 0.069 t or 8% of total releases were reported. In addition, 0.06 t was transferred to waste. The shipbuilding and repair industry and ship engine manufacturing industry reported large releases to the atmosphere, while the chemical industry reported large releases to public water bodies. The majority of reported releases were to water bodies. A multi-media model used to predict the proportions distributed to individual media in the environment indicated that in regions where the largest quantities were estimated to have been released to the environment overall or the atmosphere in particular, the predicted proportion distributed to water bodies was 99.0%. Where the largest quantities were estimated to have been released to public water bodies, the predicted proportion distributed to water bodies was 99.1%.

Data for setting the predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, could not be obtained. However, use of measurements of drinking water sourced from surface water, lake water and dam reservoir water for the PEC gives a value of around 20  $\mu$ g/L for freshwater. In addition, past data for public freshwater bodies indicates a maximum value of around 1.6  $\mu$ g/L whereas for seawater the maximum value was around 6.5  $\mu$ g/L. Further, past data, albeit obtained from a survey of a limited area, indicate a maximum value of around 7  $\mu$ g/L for seawater. Further, albeit surveyed for a limited area, values of around 22  $\mu$ g/L for public freshwater bodies and 15  $\mu$ g/L for seawater have been reported. River concentrations were not estimated because all of the 6 kg of releases to public water bodies reported in fiscal 2016 under the PRTR Law were to seawater.

## 3. Initial assessment of ecological risk

With regard to acute toxicity, the following reliable data were obtained: a 72-h EC<sub>50</sub> of 16,200  $\mu$ g/L for growth inhibition in the green alga *Pseudokirchneriella subcapitata*, a 24-h LC<sub>50</sub> of 1,200  $\mu$ g/L for the crustacean *Streptocephalus proboscideus* (fairy shrimp), and a 7-d EC<sub>50</sub> of 864,300  $\mu$ g/L for growth inhibition in the duckweed

Lemna gibba. While no reliable data could be obtained for fish species, it is considered unlikely that toxicity values will be found that are lower than those summarized here. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 12 µg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 3,000 µg/L for growth inhibition in the green algae P. subcapitata and Desmodesmus subspicatus, a 21-d NOEC of 285,000 µg/L for reproductive inhibition in the crustacean Daphnia magna, and a 7-d NOEC of 30,000 µg/L for growth inhibition in the duckweed L. gibba. While no reliable data could be obtained for fish species, it is considered unlikely that toxicity values will be found that are lower than those summarized here. Accordingly, based on these chronic toxicity values and an assessment factor of 10, a PNEC of 300 µg/L is obtained.

The value of 12  $\mu$ g/L obtained from the acute toxicity to the crustacean was used as the PNEC for this substance.

Data to determine the predicted environmental concentration (PEC) of this substance could not be obtained. Accordingly, ecological risk could not be determined. However, albeit past data, maximum concentrations of around 1.6  $\mu$ g/L for public freshwater bodies and around 6.5  $\mu$ g/L for seawater were measured and the ratios of these values to the PNEC are 0.13 and 0.5, respectively. Moreover, concentrations of 22  $\mu$ g/L for public freshwater bodies and 15  $\mu$ g/L for seawater were reported in a past survey that covered a limited area and the ratios of these values to PNEC are 1.8 and 1.3, respectively. Furthermore, using measurements of drinking water sourced from surface water, lake water and dam reservoir water for the PEC gives a value of around 20 µg/L for freshwater and the ratio PEC/PNEC ratio is 1.7; accordingly, efforts to collect data are needed, and environmental concentration data needs to be augmented taking into consideration emission sources.

Hazard assessment (basis for PNEC)				Predicted no	Exposure assessment			
Species	Acute/ chronic	Endpoint	Assessment coefficient	effect concentration PNEC (µg/L)	Water body	Predicted environmental concentration PEC (µg/L)	PEC/ PNEC ratio	Assessment result
Crustacean Streptocephalus proboscideus	Acute	LC50 mortality	100	12	Freshwater		—	(▲)
					Seawater		_	

## 4. Conclusions

	Conclusions	Judgment		
Ecological risk	Further efforts to collect data required based on comprehensive review of existing relevant data.			
Risk judgments	$[A] \bigcirc$ : No need for further work $\blacktriangle$ : Requiring information collection			

[Risk judgments]

▲: Requiring information collection

Candidates for further work ×: Impossibility of risk characterization

 $(\blacktriangle)$  : 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