

3	CAS No.: 723-46-6	Substance: Sulfamethoxazole
Chemical Substances Control Law Reference No.:		
PRTR Law Cabinet Order No.:		
Molecular Formula: C ₁₀ H ₁₁ N ₃ O ₃ S		Structural Formula:
Molecular Weight: 253.28		

1. General information

The aqueous solubility of this substance is 3942 mg/L (25°C, calculated value), the partition coefficient (1-octanol/water) (log K_{ow}) is 0.89, and the vapor pressure is 1.3×10⁻⁷ mmHg (=1.7×10⁻⁵ Pa) (25°C, calculated value). This substance does not biodegrade easily. Further, hydrolysis does not occur under ambient environmental conditions.

The main use of this substance is as a synthetic antibacterial agent for human and veterinary use. Its use in formulations with trimethoprim (CAS No. 738-70-5) is approved.

2. Exposure assessment

Because this substance is not classified as a Class 1 Designated Chemical Substance under the PRTR Law, release and transfer quantities could not be obtained. Predictions of proportions distributed to individual media by use of a Mackay-type level III fugacity model indicate that if equal quantities were released to the atmosphere, water bodies, and soil, the proportion distributed to soil would be largest.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was reported to be around 0.19 µg/L for public freshwater bodies and roughly around 0.0097 µg/L for seawater.

3. Initial assessment of ecological risk

With regard to acute toxicity, the following reliable data were obtained: a 7-d EC₅₀ of 81 µg/L for growth inhibition in the *Lemna gibba* (duckweed), a 48-h EC₅₀ of 15,510 µg/L for swimming inhibition in the crustacean *Ceriodaphnia dubia* (water flea), a 96-h LC₅₀ of 562,500 for the fish *Oryzias latipes* (medaka), and a 24-h LC₅₀ of 26,270 µg/L for the planktonic rotifer *Brachionus calyciflorus*. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 0.81 µg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 7-d NOEC of 10 µg/L for growth inhibition in the *L. gibba* and a 7-d NOEC of 250 µg/L for reproductive inhibition in the crustacean *C. dubia*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a PNEC of 0.1 µg/L was obtained.

The value of 0.1 µg/L obtained from the chronic toxicity to the *L. gibba* was used as the PNEC for this substance.

The PEC/PNEC ratio is 1.9 for freshwater bodies and 0.097 for seawater; accordingly, this substance is a candidate for detailed assessment of ecological risk, and the overall decision was the same.

Hazard assessment (basis for PNEC)			Assessment coefficient	Predicted no effect concentration PNEC (µg/L)	Exposure assessment		PEC/PNEC ratio	Comprehensive judgment
Species	Acute/chronic	Endpoint			Water body	Predicted environmental concentration PEC (µg/L)		
<i>Lemna gibba</i>	Chronic	NOEC Growth inhibition	100	0.1	Freshwater	0.19	1.9	■
					Seawater	0.0097	0.097	

4. Conclusion

	Conclusion	Judgment
Ecological risk	Candidates for further work.	■

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