1	CAS No. 69-53-4 (Ampicillin) 69-52-3 (Ampicillin sodium)	Substance: Ampicillin

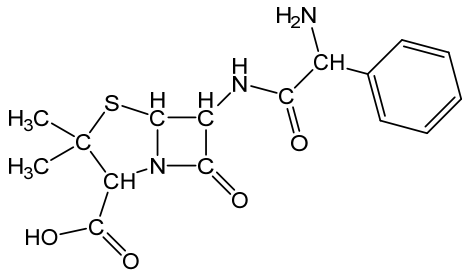
Chemical Substances Control Law Reference No.:

PRTR Law Cabinet Order No.:

Molecular Formula: $C_{16}H_{19}N_3O_4S$

Molecular Weight: 349.40

Structural formula:



1.General information

The aqueous solubility of this substance is 1.01×10^4 mg/L (21°C), the partition coefficient (1-octanol/water) (log Kow) is -2.68 (pH=7.2, buffered solution), and the vapor pressure is 3.79×10^{-11} Pa (25°C) (estimated value). Biodegradability data could not be obtained. Furthermore for hydrolysis, degradability screening tests indicated a residual rate of 17% after 7 days in the dark (preparation concentration: 0.30 ng/mL, pH = 7).

The main uses of this substance are in pharmaceuticals (synthetic penicillin) and veterinary drugs (antibiotic preparations). Furthermore, the calculated import volume based on the quantity of imported formulated products containing ampicillin sodium and sulbactam sodium was 30.6 t in FY 2022. Additionally, the sales volumes as veterinary drugs in FY2022 were 32.9 t for ampicillin and 2.7 t for ampicillin sodium.

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 around 0.0014 μg/L for public freshwater bodies, and generally 0.00049 μg/L for seawater.

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3. Initial assessment of ecological risk

With regard to acute toxicity, the following reliable data were obtained: a 72-h EC_{50} of 162,000 μg/L for growth inhibition in the Trebouxiophyceaen alga *Chlorella sorokiniana*, a 48-h EC_{50} exceeding 1,000,000 μg/L for swimming inhibition in the crustaceans *Daphnia magna* and *Moina macrocopa*, a 96-h LC_{50} exceeding 1,000,000 μg/L for the fish *Oryzias latipes* (medaka), and a 72-h EC_{50} of 29,300 μg/L for embryonic development abnormalities in the black sea urchin *Arbacia lixula*. Accordingly, based on the acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 1600 μg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 96-h NOEC of less than 50 μg/L for growth inhibition in the diatom *Phaeodactylum tricornutum*. Accordingly, based on this chronic toxicity value and an assessment factor of 100, a predicted no effect concentration (PNEC) of less than 0.5 μg/L was obtained.

The value of less than 0.5 μg/L obtained from the chronic toxicity to the diatom species was used as the PNEC for this substance.

The PEC/PNEC ratio exceeds 0.003 for freshwater bodies and exceeds 0.001 for seawater. Accordingly, ecological risk cannot be assessed.

Although the presence of algal species (cyanobacteria and diatoms) that exhibit high toxicity to this substance is a concern, reliable toxicity information regarding algae and similar organisms is insufficient. Accordingly, based on a comprehensive review of the above findings, further efforts to collect and carefully examine data are considered necessary. Toxicity data for this substance needs to be augmented particularly for cyanobacteria and diatom species exhibiting high sensitivity. Further, given that this substance is a veterinary drug widely used for aquaculture purposes in marine areas, understanding of concentrations in the marine environment should be augmented.

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)		
Trebouxiophyceaen alga	Chronic	NOEC Growth inhibition	100	<0.5	Freshwater	0.0014	>0.003	▲
					Seawater	0.00049	>0.001	

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4. Conclusions

	Conclusions	Judgment
Ecological risk	Requiring information collection.	▲

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