

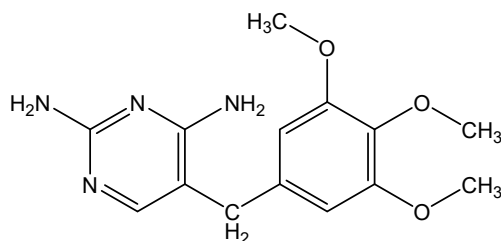
Chemical Substances Control Law Reference No.:

PRTR Law Cabinet Order No.:

Molecular Formula: C<sub>14</sub>H<sub>18</sub>N<sub>4</sub>O<sub>3</sub>

Structural Formula:

Molecular Weight: 290.32



### 1. General information

The aqueous solubility of this substance is 400 mg/1,000 g (25°C), the partition coefficient (1-octanol/water) (log K<sub>ow</sub>) is 0.91, and the vapor pressure is 1.00×10<sup>-6</sup> Pa (calculated value). Data for biodegradability (aerobic degradation) and hydrolyzability could not be obtained.

The main use of this substance is as a synthetic antibiotic for humans and animals. In addition, the production quantity of this substance calculated from production of sulfamethoxazole-trimethoprim mixture for 2019 was 5.9 t.

### 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 0.061 µg/L for public water bodies and generally less than 0.005 µg/L for seawater. Further, a maximum value of around 0.13 µg/L was obtained, albeit for a limited area of public water body. Further, a survey in the vicinity of a pig farm reported values that did not exceed 0.13 µg/L.

### 3. Initial assessment of ecological risk

With regard to acute toxicity, the following reliable data were obtained: a 7-d EC<sub>50</sub> of 27,430 µg/L for growth inhibition in the flowering plant *Lemna minor* (common duckweed), a 48-h EC<sub>50</sub> of 54,800 µg/L for swimming inhibition in the crustacean species *Moina macrocopa*, a 96-h LC<sub>50</sub> exceeding 100,000 µg/L in the fish species *Oryzias latipes* (medaka), a 96-h LC<sub>50</sub> exceeding 100,000 µg/L for African clawed frog *Xenopus laevis* embryos, and a 96-h LC<sub>50</sub> exceeding 100,000 µg/L for the freshwater Cnidarian *Hydra attenuate*. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 270 µg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 7-d NOEC of 6,250 µg/L for growth inhibition in the flowering plant *L. minor*, a 21-d NOEC of 3,120 µg/L for reproductive inhibition in the crustacean species *D. magna*, and a 96-h NOEC of 100,000 µg/L for the freshwater Cnidarian *H. attenuate*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a PNEC of 31 µg/L was obtained.

The value of 31 µg/L obtained from the chronic toxicity to the crustacean species was used as the PNEC for this substance.

The PEC/PNEC ratio is 0.002 for freshwater bodies and less than 0.0002 for seawater. Further work to assess the ecological risk this substance is considered unnecessary at this time

A maximum concentration of around 0.13 µg/L was obtained, albeit for a limited area of public water body. The ratio of this value to PNEC is 0.004. Further, a survey in the vicinity of a pig farm reported values that did not exceed 0.13 µg/L.

Accordingly, based on a comprehensive review of the above findings, there is little need to collect new data regarding this substance.

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)		
Crustacean <i>Daphnia magna</i>	Chronic	NOEC Reproductive inhibition	100	31	Freshwater	0.061	0.002	○
					Seawater	<0.005	<0.0002	

#### 4. Conclusions

	Conclusions	Judgment
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