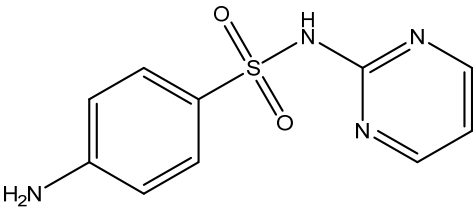


3	CAS No.: 68-35-9	Substance: Sulfadiazine
<p>Chemical Substances Control Law Reference No.:</p> <p>PRTR Law Cabinet Order No.:</p> <p>Molecular Formula: C₁₀H₁₀N₄O₂S Structural Formula:</p> <p>Molecular Weight: 250.28</p> <div style="text-align: center;">  </div>		
<p>1.General information</p> <p>The aqueous solubility of this substance is 77.0 mg/L (25°C), the partition coefficient (1-octanol/water) (log K_{ow}) is – 0.09, and the vapor pressure is 5.26×10⁻⁹ mmHg (=7.02×10⁻⁷ Pa) (25°C) (calculated value).</p> <p>The main uses of this substances are pharmaceuticals (sulfonamides for treating bacterial infections) and veterinary drugs (antibacterial agent). Further, data regarding the production quantity of this substance for human pharmaceuticals could not be obtained. The sales volume (bulk conversion) of this substance as veterinary drugs in fiscal 2018 was 0.047 t.</p> <p>-----</p> <p>2.Exposure assessment</p> <p>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.</p> <p>The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was reported to be around 0.029 µg/L for public freshwater bodies, and generally less than 0.005 µg/L for seawater.</p> <p>-----</p> <p>3.Initial assessment of ecological risk</p> <p>With regard to acute toxicity for sulfadiazine, the following reliable data were obtained: a 96-h EC₅₀ of 110 µg/L for growth inhibition in the diatom <i>Phaeodactylum tricorutum</i>, a 48-h EC₅₀ of 25,000 µg/L for the crustacean <i>Daphnia magna</i>, a 96-h exceeding LC₅₀ 96,000 µg/L for the fish species <i>Oryzias latipes</i> (medaka), and a 96-h EC₅₀ exceeding 50,000 µg/L for swimming inhibition in the dugesiid triclad <i>Dugesia gonocephala</i>. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 1.1 µg/L was obtained.</p> <p>With regard to chronic toxicity for sulfadiazine, the following reliable data was obtained: a 96-h NOEC of 10 µg/L for swimming exhibition in the diatom <i>P. tricorutum</i>. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a PNEC of 0.1 µg/L was obtained.</p> <p>The value of 0.1 µg/L obtained from the chronic toxicity to the diatom was used as the PNEC for this substance.</p> <p>The PEC/PNEC ratio was 0.3 for freshwater bodies and less than 0.05 for seawater. Accordingly, <u>based on a comprehensive review of the above findings, efforts to collect data are needed.</u></p> <p>Environmental concentration data need to be augmented for this substance taking into consideration major emission sources. Further, <u>efforts to collect data regarding chronic toxicity towards crustacean and fish species are needed.</u></p>		

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)		
Diatom	Chronic	NOEC Growth inhibition	100	0.1	Freshwater	0.029	0.3	▲
					Seawater	<0.005	<0.05	

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