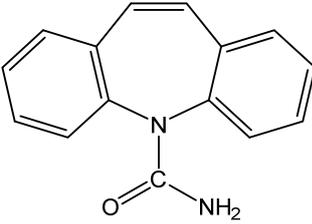


1	CAS No.: 298-46-4	Substance: Carbamazepine
<p>Chemical Substances Control Law Reference No.: 9-630</p> <p>PRTR Law Cabinet Order No.:</p> <p>Molecular Formula: C<sub>15</sub>H<sub>12</sub>N<sub>2</sub>O                      Structural formula:</p> <p>Molecular Weight: 236.27</p> <div style="text-align: center;">  </div>		
<p><b>1. General information</b></p> <p>The aqueous solubility of this substance is 18 mg/L (25°C) (calculated value), the partition coefficient (1-octanol/water) (log K<sub>ow</sub>) is 2.45 (pH=7.4), and the vapor pressure is 1.2×10<sup>-5</sup> Pa (25°C) (calculated value). Biodegradation data could not be obtained. Further, this substance does not possess any hydrolyzable groups.</p> <p>The main use of this substance is as a drug for human use. In addition, the production quantity in 2020 was 43.0 t.</p> <hr/> <p><b>2. Exposure assessment</b></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 around 0.054 µg/L for public freshwater bodies and around 0.0055 µg/L for seawater.</p> <hr/> <p><b>3. Initial assessment of ecological risk</b></p> <p>With regard to acute toxicity, the following reliable data were obtained: a 96-hour EC<sub>50</sub> of 64,000 µg/L for growth inhibition in the green alga <i>Raphidocelis subcapitata</i>, a 48-h EC<sub>50</sub> of &gt;13,800 µg/L for swimming inhibition in the crustacean <i>Daphnia magna</i>, a 96-h LC<sub>50</sub> of 19,900 µg/L in the fish <i>Oncorhynchus mykiss</i> (rainbow trout), and a 96-h LC<sub>50</sub> of 29,400 µg/L in the fresh-water polyp <i>Hydra vulgaris</i>. Accordingly, based on these acute toxicity values and an assessment factor of 100, a PNEC of &gt;130 µg/L was obtained.</p> <p>With regard to chronic toxicity, the following reliable data were obtained: a 96-h NOEC of 6,300 µg/L for growth inhibition in the green alga <i>R. subcapitata</i>, a 7-d NOEC of 25 µg/L for reproductive inhibition in the crustacean <i>Ceriodaphnia dubia</i>, and a 28-d NOEC of 862 µg/L for embryo to post-hatch mortality and growth inhibition in the fish <i>Pimephales promelas</i> (fathead minnow embryo). Accordingly, based on these chronic toxicity values and an assessment factor of 10, a PNEC of 2.5 µg/L was obtained.</p> <p>The value of 2.5 µg/L obtained from the chronic toxicity to the crustacean was used as the PNEC for this substance.</p> <p>The PEC/PNEC ratio is 0.02 for freshwater bodies and 0.002 for seawater. <u>Further work to assess the ecological risk of this substance is considered unnecessary at this time.</u></p> <p>Albeit for a limited area, a river survey covering public water bodies estimated a maximum value of 0.65 µg/L and the ratio of this value and PNEC is 0.3. Accordingly, <u>based on a comprehensive review of the above findings efforts to collect data are considered necessary. Efforts to understand production and import quantities and trends in environmental concentrations are considered necessary.</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)		
Crustacean <i>Ceriodaphnia dubia</i>	Chronic	NOEC Reproductive inhibition	100	2.5	Freshwater	0.054	0.02	▲
					Seawater	0.0055	0.002	

**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