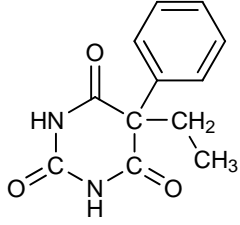


2	CAS No.: 50-06-6	Substance: 2,4,6(1 <i>H</i> ,3 <i>H</i> ,5 <i>H</i> )-Pyrimidinetrione, 5-ethyl-5-phenyl-
<p>Chemical Substances Control Law Reference No.: 9-2248  PRTR Law Cabinet Order No.:</p> <p>Molecular Formula: C<sub>12</sub>H<sub>12</sub>N<sub>2</sub>O<sub>3</sub>      Structural Formula:</p> <p>Molecular Weight: 232.24</p> <div style="text-align: center;">  </div>		
<p><b>1. General information</b></p> <p>The aqueous solubility of this substance is <math>1.2 \times 10^3</math> mg/1,000 g (25°C), the partition coefficient (1-octanol/water) (log <math>K_{ow}</math>) is 1.14 (pH=7.4), and the vapor pressure is <math>1.4 \times 10^{-11}</math> mmHg (25°C, estimated value). Biodegradability (aerobic degradation) is judged to be difficult, and bioaccumulation is thought to be nonexistent or low at low concentrations. Furthermore, data on hydrolyzability could not be obtained.</p> <p>The main use is pharmaceuticals (sleep-inducing/sedatives, barbiturate-based antiepileptic drugs).</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 Law Concerning Reporting, etc. of Releases to the Environment of Specific Chemical Substances and Promoting Improvements in Their Management (PRTR Law), release and transfer quantities could not be obtained. Predictions of proportions distributed to individual media by using a Mackay-type level III fugacity model indicated that if equal quantities were released to the atmosphere, water bodies, and soil, the proportion distributed to soil were greater.</p> <p>The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, was around 0.16 µg/L for public freshwater bodies and generally 0.043 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 72-h EC<sub>50</sub> in excess of 100,000 µg/L for growth inhibition in the green alga <i>Pseudokirchneriella subcapitata</i>, a 48-h EC<sub>50</sub> in excess of 95,800 µg/L for swimming inhibition in the crustacean <i>Daphnia magna</i>, and a 96-h LC<sub>50</sub> in excess of 97,900 µg/L for the fish species <i>Oryzias latipes</i> (medaka). No effects were observed for algae and fish species even at the highest experimental concentrations. In addition, toxicity towards crustaceans was obtained in limit tests. Accordingly, a decision was made not to set a predicted no effect concentration (PNEC) on the basis of acute toxicity values.</p> <p>With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 100,000 µg/L for growth inhibition in the green alga <i>P. subcapitata</i>, and a 21-d NOEC of 31,100 µg/L for reproductive inhibition in the crustacean <i>D. magna</i>. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a PNEC of 310 µg/L was obtained.</p> <p>The value of 310 µg/L obtained from the chronic toxicity to the crustacean was used as the PNEC for this substance.</p>		

The PEC/PNEC ratio was 0.0005 for freshwater bodies and 0.0001 for seawater. Accordingly, further work is considered unnecessary at this time.

Hazard assessment (basis for PNEC)			Assessment factor	Predicted no effect concentration PNEC (µg/L)	Exposure assessment		PEC/PNEC ratio	Judgment based on PEC/PNEC ratio	Assessment result
Species	Acute/ chronic	Endpoint			Water body	Predicted environmental concentration PEC (µg/L)			
Crustacean <i>Daphnia magna</i>	Chronic	NOEC Reproductive inhibition	100	310	Freshwater	0.16	0.0005		
					Seawater	0.043	0.0001		

#### 4. Conclusions

	Conclusions	Judgment
Ecological risk	No need of further work at present.	

[ Risk judgments ]    : No need for further work    ▲: Requiring information collection  
                                  ■: Candidates for further work    ×: Impossibility of risk characterization  
                                  ( ) : Though a risk characterization cannot be determined, there would be little necessity of collecting information.  
                                  ( ) : Further information collection would be required for risk characterization.