

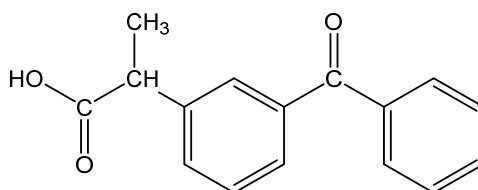
Chemical Substances Control Law Reference No.:

PRTR Law Cabinet Order No.:

Molecular Formula: C₁₆H₁₄O₃

Molecular Weight: 254.28

Structural formula:



1. General information

The aqueous solubility of this substance is 51.0 mg/L (20°C), the partition coefficient (1-octanol/water) (log K_{ow}) is 3.12 (pH=2.0), and the vapor pressure is 2.0x10⁻⁴ Pa (25°C) (calculated value). Biodegradability data could not be obtained. Further, degradability screening tests found a residual ratio of 103% after 7 days (initial concentration: 0.00050 µg/mL, pH: 7) for hydrolyzability.

The main uses of this substance are as analgesics and anti-inflammatory drugs. In addition, the sales value of antipyretic analgesic and anti-inflammatory drugs (other antifebrile analgesic and anti-inflammatory drugs) under the veterinary drug category was JPY1,943,487,000 in 2020.

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 0.050 µg/L for public freshwater bodies, and generally 0.00029 µg/L for seawater. In addition, albeit data for a limited area, a maximum concentration of around 0.068 µg/L for public water bodies was reported.

3. Initial assessment of ecological risk

With regard to acute toxicity, the following reliable data were obtained: a 96-h EC₅₀ of 240 µg/L for growth inhibition in the green alga *Raphidocelis subcapitata*, a 48-h EC₅₀ of 2,300 µg/L for swimming inhibition in the crustacean *Daphnia magna*, and a 96-h LC₅₀ of 632,300 µg/L for the fish *Danio rerio* (zebra fish). Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 2.4 µg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 96-h NOEC of 7.8 µg/L for growth inhibition in the green alga *R. subcapitata* and a 7-d NOEC of 100 µg/L for reproductive inhibition on the crustacean *Ceriodaphnia dubia*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a PNEC of 0.078 µg/L was obtained.

The value of 0.078 µg/L obtained from the chronic toxicity to the green alga was used as the PNEC for this substance.

The PEC/PNEC ratio was 0.6 for freshwater bodies and 0.004 for seawater. Efforts to collect data are considered necessary to determine the ecological risk. Albeit data for a limited area, a maximum concentration of around 0.068 µg/L for public freshwater bodies was reported and the ratio of this value to PNEC was 0.9.

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, and augmentation of data regarding toxicity towards fish species are considered necessary.

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)		
Green algae	Chronic	NOEC Growth inhibition	100	0.078	Freshwater	0.050	0.6	▲
					Seawater	0.00029	0.004	

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