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CAS No.: 41859-67-0

Substance: Bezafibrate

Chemical Substances Control Law Reference No.:

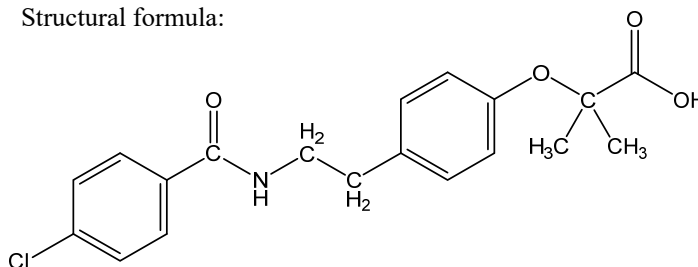
PRTR Law Cabinet Order No.:

Molecular Formula:

 $C_{19}H_{20}ClNO_4$ 

Molecular Weight: 361.82

Structural formula:



### 1. General information

The aqueous solubility of this substance is 34.3 mg/L (37°C), the partition coefficient (1-octanol/water) ( $\log K_{ow}$ ) is 4.3 (calculated value), and the vapor pressure is  $8.2 \times 10^{-9}$  Pa (25°C) (calculated value). Biodegradability data could not be obtained. Further, degradability screening tests found a residual ratio of 101% after 7 days (initial concentration: 0.050  $\mu\text{g/mL}$ , pH: 7) for hydrolyzability.

The main use of this substance is as a drug for human use. Its production quantity in 2020 was 76.7 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 around 0.096  $\mu\text{g/L}$  for public freshwater bodies, and generally 0.015  $\mu\text{g/L}$  for seawater.

### 3. Initial assessment of ecological risk

With regard to acute toxicity, the following reliable data were obtained: a 72-h  $IC_{50}$  exceeding 100,000  $\mu\text{g/L}$  for growth inhibition in the green alga *Raphidocelis subcapitata* and a 24-h  $LC_{50}$  of 39,690  $\mu\text{g/L}$  for the crustacean species *Thamnocephalus platyurus* (beaver-tail fairy shrimp). Accordingly, based on these acute toxicity values and an assessment factor of 1,000, a predicted no effect concentration (PNEC) of 39  $\mu\text{g/L}$  was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 72-h NOEC of 100,000  $\mu\text{g/L}$  for growth inhibition in the green alga *R. subcapitata*, 7-d NOEC of 23  $\mu\text{g/L}$  for reproductive inhibition in the crustacean *Ceriodaphnia dubia*, and a 48-h NOEC of 156  $\mu\text{g/L}$  for reproductive inhibition in the planktonic rotifer *Brachionus calyciflorus*. Accordingly, based on these chronic toxicity values and an assessment factor of 100, a PNEC of 0.23  $\mu\text{g/L}$  was obtained.

The value of 0.23  $\mu\text{g/L}$  obtained from the chronic toxicity to the crustacean species was used as the PNEC for this substance.

The PEC/PNEC ratio was 0.4 for freshwater bodies and 0.07 for seawater. Based on a comprehensive review of the above findings, efforts to collect data are considered necessary. In addition, albeit data for a limited area, maximum concentrations of around 0.26  $\mu\text{g/L}$  for public water bodies and 0.016  $\mu\text{g/L}$  for seawater were reported and the ratios of these values to PNEC are 1.1 and 0.07, respectively. Accordingly, based on a comprehensive review of the above findings, collection of further data is 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)		
Crustacean <i>Ceriodaphnia dubia</i>	Chronic	NOEC Reproductive inhibition	100	0.23	Freshwater	0.096	0.4	▲
					Seawater	0.015	0.07	

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**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