

2	CAS No.: 15307-86-5 (Diclofenac) 15307-79-6 (Diclofenac sodium (Na salt))	Substance: Diclofenac
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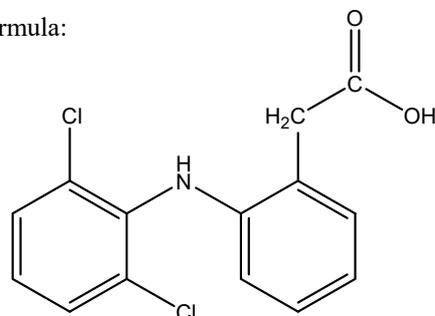
Chemical Substances Control Law Reference No.: 3-3082 (2-(2,6-Dichloroanilino)-phenylacetic acid sodium salt)

PRTR Law Cabinet Order No.:

Molecular Formula: C<sub>14</sub>H<sub>11</sub>Cl<sub>2</sub>NO<sub>2</sub>

Structural Formula:

Molecular Weight: 296.15



### 1. General information

The aqueous solubility of this substance is 7.1 mg/L (25°C) (pH =5.8), the partition coefficient (1-octanol/water) (log K<sub>ow</sub>) is 1.13–4.75 (pH=7.4), and the vapor pressure is 6.14×10<sup>-8</sup> mmHg (=8.19×10<sup>-6</sup> Pa) (25°C, calculated value).

Biodegradability (aerobic degradation) data could not be obtained. Further, the substance does not possess any hydrolyzable groups and as such, it does not hydrolyze under ambient environmental conditions.

Diclofenac sodium's main use is in phenylacetate-based anti-inflammatory analgesics. According to data from fiscal 2016 onwards, the production and import quantity has been increasing.

### 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 reported to be around 0.076 µg/L for public freshwater bodies and roughly 0.0084 µg/L for seawater. Further, albeit obtained from an environmental survey of a limited area, a maximum value of 0.17 µg/L was reported.

### 3. Initial assessment of ecological risk

With regard to acute toxicity, the following reliable data were obtained: a 72-h IC<sub>50</sub> of 5000 µg/L for growth inhibition in the diatom *Skeletonema costatum*, a 96-h LC<sub>50</sub> of 2919 µg/L for the crustacean *Siriella armata*, a 96-h LC<sub>50</sub> of 10,100 µg/L for the fish *Oryzias latipes* (medaka), and a 96-h LC<sub>50</sub> of 3900 µg/L for the dugesiid triclad *Dugesia japonica*. Accordingly, based on these acute toxicity values and an assessment factor of 100, a predicted no effect concentration (PNEC) of 29 µg/L was obtained.

With regard to chronic toxicity, the following reliable data were obtained: a 96-h NOEC of 5900 µg/L for growth inhibition in the green alga *Raphidocelis subcapitata*, a 7-d NOEC of 930 µg/L for reproductive inhibition in the crustacean *Ceriodaphnia dubia* (water flea), and a 34-d NOEC of 11.1 µg/L for growth inhibition in the fish *Danio rerio* (zebrafish). Accordingly, based on these chronic toxicity values and an assessment factor of 10, a PNEC of 1.1 µg/L was obtained.

The value of 1.1 µg/L obtained from the chronic toxicity to the fish species was used as the PNEC for this substance.

The PEC/PNEC ratio is 0.07 for freshwater bodies and 0.008 for seawater; further work to determine ecological risk is

considered unnecessary at this time.

However, past data, albeit obtained from a survey of a limited area, indicate maximum values of around 0.17 µg/L and the ratio to the PNEC is 0.15. Accordingly, based on a comprehensive review of the above findings, efforts to collect data are needed; environmental concentration data need to be augmented taking into consideration major emission sources and trends in production etc.

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)		
Fish <i>Danio rerio</i>	Chronic	NOEC Growth inhibition	10	1.1	Freshwater	0.076	0.07	▲
					Seawater	0.0084	0.008	

#### 4. Conclusion

	Conclusion	Judgment
Ecological risk	Requiring information collection.	▲

[Risk judgments] ○: No need for further work      ▲: Requiring information collection  
 ■: Candidates for further work      ×: Impossibility of risk characterization