

# Diclofenac

(CAS numbers: e.g. 15307-86-5, EC number: 239-348-5  
/ Entry number in HELCOM list of priority substances: 14)

General sectors:  
Pharmaceutical, industrial

**D** RIVERS   **A** CTIVITIES   **P** RESSURES   **S** TATE   **I** MPACTS

## Why a HELCOM priority?

### Main evidence

**S** Concentrations of Diclofenac exceed the applied threshold value in **13** of the 27 examined areas (assessment units) of the Baltic Sea. The threshold is exceeded in both coastal and off-shore areas (2/8 assessed off-shore areas). In these 13 areas, on average **57%** of the assessable samples in **water** (and/or sediment, which is exceeded more rarely) exceed the threshold value. This is based on regular monitoring data gathered by HELCOM Contracting Parties and reported for the period 2016-2021, in the context of the Diclofenac pre-core indicator<sup>1</sup>, as well as scientific articles/reports<sup>2</sup>.

By further considering how much above or below the threshold each concentration is, and how often the substance is detected, Diclofenac scores **7.3/10** (confidence range: **7.3 – 7.3**) in the scale established when assessing the criticality/significance of current levels in the Baltic Sea pose, where 5 indicates concern and 10 extreme risk, and the range reflects the level of reliability and representativeness of concentrations and the thresholds.

The threshold values for Diclofenac, for water and sediment, were acquired respectively from the EC proposed Directive amending WFD and EQSD<sup>3</sup> and the value agreed for the HELCOM indicator for HOLAS 3<sup>1</sup>.

**I** Current levels in the Baltic Sea indicate potential negative impacts on pelagic and sediment dwelling biota.

### Supporting evidence

**P** Approximately **6-9 tonnes of Diclofenac** are estimated to enter the Baltic Sea every year via WWTPs/rivers (WATERBASE<sup>4</sup>; Undemann et al, 2022<sup>5</sup>). Given that the substance is **persistent and very toxic**<sup>6</sup> (according to the EU WFD/EQSD update proposal, it also tends to accumulate in sediment and/or biota<sup>7</sup>), current inputs are considered as likely significant, in terms of risk they pose for the Baltic Sea and its ecosystem services. As mentioned above, levels in Baltic Sea have already exceeded thresholds, due not only to current but also the historical inputs.

**A** With sales in CPs of 48 – 65 t/y (2015-2022<sup>8</sup>), the predicted (conservative) river concentration at the proximity of WWTP effluents by using the guidelines of Phase I ERA is about 50 times the threshold value for freshwater.

### Overall assessment

When assessing current levels in the Baltic Sea, current inputs, and the severity of the relevant toxicity mechanism, Diclofenac scores **61-76/100** in the scale established for assessing the overall risk for impacts/threat for the Baltic Sea, where 50 indicates concern, 100 extreme risk, and the width of the span outlines the uncertainty in the assessment.

## Facts relevant for management considerations

### Causal chain and pathways

**A** It is a NSAID (nonsteroidal anti-inflammatory drug), authorised for human use<sup>9</sup>. It can be applied to the skin, which contributes notably to the total mass of wastewater loadings<sup>10</sup>. It could be suspected that diclofenac, in its topical form, can be present in grey waters currently allowed to be discharged into the Baltic Sea<sup>11</sup>, such as from the water in automatic clothes washers and from bathtubs and showers<sup>13</sup>. Furthermore, topically applied diclofenac may also have a contribution through bathers at coastal locations, where the bathers enter the water without prior removal of the topical pharmaceutical. Beyond its use as pharmaceutical, it is used in the EU in industrial settings as an intermediate in synthesis.

**P** The substance appears to enter the Baltic Sea via WWTP effluents (released either to rivers or to coastal waters).

### Relevant policies (existing or planned measures)

**M (on A/P)** • Listed in the first **EQSD Watch List**. And also as priority substance in the **EU WFD** update proposal. It is a HELCOM pre-core indicator.

• It is one of the 'Category 1' substances (substances that can be very easily treated) in the updated Directive on urban wastewater treatment.

## References:

1. 2. 3. 4. 5. 6. 7. 8. 9. 10. 11.

[Note: Listing of detailed references will be provided in an upcoming update of the fact sheet – for a listing of the most common references among the different substances see the section at the end of the consolidated document which includes all the fact sheets]