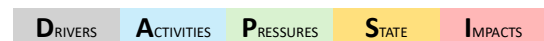


# Chlorhexidine

(CAS numbers: e.g. 55-56-1, EC number: 200-238-7  
/ Entry number in HELCOM list of substances of concern: 9)

General sectors: Personal care product, pharmaceutical, industry and commercial products



## Why a HELCOM concern?

### Main evidence

- P** Approximately **30 - 120 kg of Chlorhexidine** are estimated to enter the Baltic Sea every year via Wastewater Treatment Plants (WWTPs) emissions. Given that the substance is **suspect as very persistent** and is **very toxic**<sup>1</sup>, current inputs are likely significant, in terms of risk they pose for the Baltic Sea and its ecosystem services. The data on WWTP discharges (2010-2019) originates from the study of Undeman et al. (2022)<sup>2</sup>.
- I** Current inputs to the Baltic Sea indicate potential negative impacts at least on pelagic biota.

### Supporting evidence

- A** With sales as pharmaceutical in CPs of  $\geq 7.8 - 8.9$  t/y (2015-2022<sup>3</sup>), the predicted (conservative) river concentration at the proximity of WWTP effluents due to this use, by using the guidelines of Phase I ERA, is about 60 times the threshold value for freshwater.
- I** Chlorhexidine is considered to have a concerning **mode of toxicity**, as for example it disrupts cell membrane<sup>4</sup>.

### Overall assessment

When assessing current levels in the Baltic Sea (no relevant measurement data), current inputs, and the severity of the relevant toxicity mechanism, Chlorhexidine scores **31-99/100** 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** The EU REACH registered volume for Chlorhexidine is 1,000 – 10,000 t/y<sup>5</sup>. REACH-registered uses are only as intermediate in reactions<sup>6</sup>. There are also 90 Classification & Labelling notifications received by ECHA by manufacturers/importers under the EU CLP Regulation<sup>7</sup>. Therefore manufacture/import (accordingly use) in unknown amounts for potential further uses than as intermediate, and of less than a tonne/year per manufacturer/importer, is possible. In fact, Chlorhexidine is indeed authorised in the EU for use in cosmetic products, with the following indicated functions: antistatic, emulsion stabilising, hair conditioning, skin conditioning - emollient, viscosity controlling, antimicrobial, oral care, preservative<sup>8</sup>. Furthermore, Chlorhexidine is also used as pharmaceutical in anti-infectives and antiseptics for local oral treatment or for dermal use (creams and ointments), in amounts as reflected above<sup>9</sup>.

- S ?** *In order to further improve the evaluation of the risk, relevant aspects to consider are a review of the relevant toxicity thresholds (expected relevant matrices) and marine monitoring or modelling for predicted environmental concentrations based on estimated inputs.*

### Relevant policies (existing or planned measures)

- M (on A/P)** • Chlorhexidine is listed in the EU Cosmetics Regulation (EC) 1223/2009 (allowed as a preservative in cosmetic products up to 0,3 %).
- Chlorhexidine is covered by an **Assessment for Regulatory Needs prepared by ECHA** (on a group of guanidylureas, cyanoguanidines and biguanides)<sup>10</sup>. According to this report, there is a potential for endocrine disrupting effects in the environment, whereas the substance has also potentially vPvM and PMT properties.

## References:

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

[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]