

## Corsodyl®

MEF

GlaxoSmithKline Consumer Healthcare

Munhålegel 1 %

(Klar, färglös gel med mentolsmak)

Antiseptiskt munvårdsmedel

### Aktiv substans:

Klorhexidin

### ATC-kod:

A01AB03

Läkemedel från GlaxoSmithKline Consumer Healthcare omfattas av Läkemedelsförsäkringen.

## Miljöpåverkan

### Klorhexidin

Miljörisk: Användning av klorhexidin har bedömts medföra medelhög risk för miljöpåverkan.

Nedbrytning: Klorhexidin är potentiellt persistent.

Bioackumulering: Klorhexidin har låg potential att bioackumuleras.

## Detaljerad miljöinformation

## Environmental Risk Classification

### Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

$$\text{PEC } (\mu\text{g/L}) = (A \cdot 10^9 \cdot (100 - R)) / (365 \cdot P \cdot V \cdot D \cdot 100) = 1.5 \cdot 10^{-6}$$

$$\cdot A(100 - 70.20)$$

$$\text{PEC} = 0.17 \mu\text{g/L}$$

Where:

A = 3848.11 kg (total sold amount API in Sweden year 2016, data from QuintilesIMS). Total volume of Chlorhexidine digluconate = 6706.51 = 3775.83 Kg Chlorhexidine free base. Total volume of Paroxetine hydrochloride hemihydrate = 89.45 = 72.28 Kg Chlorhexidine free base. Total Chlorhexidine = 3775.83 + 72.28 = 3848.11 Kg.

R = 70.20% removal rate based on EUSES evaluation of removal to sludge based on a Koc value of 7,944 from REACH registration dossier (Reference 2)

$$P = \text{number of inhabitants in Sweden} = 9 \cdot 10^6$$

V (L/day) = volume of wastewater per capita and day = 200 (ECHA default) (Reference 1)

D = factor for dilution of waste water by surface water flow = 10 (ECHA default) (Reference 1)

### Predicted No Effect Concentration (PNEC)

#### Ecotoxicological studies

*Green Algae (Scenedesmus subspicatus):*

IC50 76h (growth rate) = 46 µg/L (OECD 201) (Reference 2)

NOEC 72h (biomass) = 4.20 µg/L

*Water flea (Daphnia magna):*

Acute toxicity

EC50 48h (immobility) = 49 µg/L (OECD 202) (Reference 2)

*Water flea (Daphnia magna):*

Chronic toxicity

NOEC 21 days (reproduction) = 11.6 µg/L (OECD 211) (Reference 2)

*Zebra Fish (Danio rerio):*

Acute toxicity

LC50 96h = 1,400 µg/L (OECD 203) (Reference 2)

*Other ecotoxicity data:*

*Chironomid (Chironomus riparius):*

NOEC 28 days (emergence) = 2,440 µg/kg (OECD 218) (Reference 2)

*Microorganisms in activated sludge:*

EC50 3 hours (inhibition) = 14,000 µg/L (OECD 209) (Reference 2)

$PNEC = 4.20/50 = 0.084 \mu\text{g/L}$

*PNEC (µg/L) = lowest NOEC/50, where 50 is the assessment factor applied for two long-term NOECs. The chronic NOEC for alga (= 4.20 µg/L) has been used for this calculation since it is the most sensitive of the two tested species.*

## **Environmental risk classification (PEC/PNEC ratio)**

$PEC/PNEC = 0.17/0.084 = 2.02$ , i.e.  $1 < PEC/PNEC \leq 10$ , which justifies the phrase "Use of chlorhexidine has been considered to result in moderate environmental risk."

## **Degradation**

### **Biotic degradation**

*Ready degradability:*

0% degradation in 28 days (OECD 301D) (Reference 2)

### **Abiotic degradation**

*Hydrolysis:*

Half-life (pH 4) > 1 year (OECD 111) (Reference 2)

Half-life (pH 7) > 1 year

Half-life (pH 9) > 1 year

*Photolysis:*

Half-life (Summer) = 8.60 days (OECD Guideline draft - Phototransformation of Chemicals in Water - Direct and Indirect Photolysis - August 2000) (Reference 2)

Half-life (Winter) > 69.10 days

*Justification of chosen degradation phrase:*

Chlorhexidine is not readily biodegradable. The phrase "Chlorhexidine is potentially persistent" is thus chosen.

### **Bioaccumulation**

*Partitioning coefficient:*

$\log P_{ow} = 0.08$  (OECD 107) (Reference 2)

*Justification of chosen bioaccumulation phrase:*

Since  $\log Pow < 4$ , the substance has low potential for bioaccumulation.

### **Excretion (metabolism)**

Not applicable

### **PBT/vPvB assessment**

Chlorhexidine does not fulfil the criteria for PBT and/or vBvP. All three properties, i.e. 'P', 'B' and 'T' are required in order to classify a compound as PBT (Reference 1). Chlorhexidine does not fulfil the criteria for PBT and/or vBvP based on a  $\log Dow < 4$ .

Please, also see Safety data sheets on <http://www.msds-gsk.com/ExtMSDSlist.asp>.

### **References**

1. ECHA, European Chemicals Agency. 2008 Guidance on information requirements and chemical safety assessment.
2. ECHA, European Chemicals Agency. Chlorhexidine - REACH registration dossier 01-2119955049-31-0003, 10 August 2013.