

## Otrivin®

Haleon Denmark

Nässpray, lösning 1 mg/ml

(Klar, färglös lösning)

Avsvällande nässpray

### Aktiv substans:

Xylometazolin

### ATC-kod:

R01AA07

Läkemedel från Haleon Denmark omfattas av Läkemedelsförsäkringen.

M EF

## Miljöpåverkan

### Xylometazolin

Miljörisk: Användning av xylometazolin har bedömts medföra försumbar risk för miljöpåverkan.

Nedbrytning: Xylometazolin är potentiellt persistent.

Bioackumulering: Xylometazolin har låg potential att bioackumuleras.

### Detaljerad miljöinformation

#### Environmental Risk Classification

#### Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

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

$$\text{PEC} = 0.013 \mu\text{g/L}$$

Where:

A = 93,77 kg (total sold amount API in Sweden year 2019, derived from data from IQVIA). Reduction of A may be justified based on metabolism data.

R = 0% removal rate (conservatively, it has been assumed there is no loss by adsorption to sludge particles, by volatilization, hydrolysis or biodegradation)

P = number of inhabitants in Sweden =  $10 \cdot 10^6$

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: EC50 = 2.03 mg/L (*Desmodesmus subspicatus*, 72 h (growth rate), (OECD 201) (Reference 2)

Daphnia acute toxicity: EC50 = 5.63 mg/L (*Daphnia magna*, 48h, OECD 202) (Reference 2)

Fish acute toxicity: LC50 = 71 mg/L (Rainbow trout (*Oncorhynchus mykiss*), 96h, OECD203) (Reference 2)

Bacterial Respiration Inhibition: IC20 = 90 mg/L (activated sludge, 0.5h, OECD 209) (Reference 2)

The PNEC is based on the following data:

PNEC (µg/l) = lowest acute EC50 / 1,000, where 1,000 is the assessment factor used.

An EC50 of 2.03 mg/l for green algae has been used for this calculation

PNEC = 2,030 µg/L /1000 = 2.03 µg/l

*PNEC (µg/L) = lowest NOEC/1,000, where 1000 is the assessment factor applied for three short-term EC50s. EC50 for green algae (= 2.03 mg/L) has been used for this calculation since it is the most sensitive of the three tested species.*

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

PEC/PNEC = 0.013/2.03 = 6,40 x 10<sup>-3</sup>, i.e. PEC/PNEC ≤ 0.1 which justifies the phrase "Use of Xylometazoline has been considered to result in insignificant environmental risk."

### **Environmental fate studies:**

#### **Degradation:**

Degradation: < 10% (aerobic, 28d, 20-24°C, OECD 301A) (Reference 2)

This substance is not readily biodegradable.

### **Bioaccumulation**

Partition Coefficient: log Kow 2.84 (OECD107) (Reference 2)

*Justification of chosen bioaccumulation phrase:*

Since log Kow < 4, the substance has low potential for bioaccumulation.

### **PBT/vPvB assessment**

Xylometazoline 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).

Xylometazoline does not fulfil the criteria for PBT and/or vBvP based on log Kow < 4.

### **References**

1. ECHA, European Chemicals Agency. 2008 Guidance on information requirements and chemical safety assessment.
2. Safety Data Sheet. Xylometazoline hydrochloride Version No.23. Fagron UK Ltd, July 2014.