FASS

# Otrivin Comp

M EF

**GlaxoSmithKline Consumer Healthcare**

Nässpray, lösning 0,5 mg/ml + 0,6 mg/ml

(Klar, färglös lösning.)

Sympatomimetika, kombinationer exklusive kortikosteroider.

**Aktiva substanser:**

Ipratropium

Xylometazolin

**ATC-kod:**

R01AB06

Läkemedel från GlaxoSmithKline Consumer Healthcare omfattas av Läkemedelsförsäkringen.

## 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:

PEC (µg/L) = $(A*10^{9}*(100-R)/(365*P*V*D*100) = 1.5*10^{-6}*A(100-R)$

PEC = 0.018 µg/L

Where:

A = 121.09 kg (total sold amount API in Sweden year 2016, derived from free base and hydrochloride salt forms, data from Quintiles IMS). 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 = $9 *10^{6}$

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 = 0.018/2.03 = 8.87 x $10^{-3}$, 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.