

Otrivin Comp

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:

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

$$\text{PEC} = 0.018 \mu\text{g/L}$$

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 = $9 \cdot 10^6$

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 ($\mu\text{g/l}$) = 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 $\mu\text{g/L}$ /1000 = 2.03 $\mu\text{g/l}$

PNEC ($\mu\text{g/L}$) = 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 = $0.018/2.03 = 8.87 \times 10^{-3}$, 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.