

Opatanol

M R F_f**Novartis**

Ögondroppar, lösning 1 mg/ml
(klar, färglös lösning)

Antiallergiskt medel för lokal behandling av allergisk konjunktivit

Aktiv substans:

Olopatadin

ATC-kod:

S01GX09

Läkemedel från Novartis omfattas av Läkemedelsförsäkringen.
Läkemedlet distribueras också av företag som inte omfattas av
Läkemedelsförsäkringen, se Förpackningar.

Miljöpåverkan

Olopatadin

Miljörisk: Risk för miljöpåverkan av olopatadin kan inte uteslutas då ekotoxikologiska data saknas.

Nedbrytning: Det kan inte uteslutas att olopatadin är persistent, då data saknas.

Bioackumulering: Olopatadin har låg potential att bioackumuleras.

Detaljerad miljöinformation

Environmental Risk Classification

Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

$$\text{PEC } (\mu\text{g/L}) = (A \cdot 10^9 \cdot (100 - R)) / (365 \cdot P \cdot V \cdot D \cdot 100) = 1.37 \cdot 10^{-6} \cdot A \cdot (100 - R) = 1.37 \cdot 10^{-6} \cdot 0.74 \cdot 100 = 0.0001 \mu\text{g/L} = 0.1 \text{ ng/L}$$

Where:

A = 0.7423 kg olopatadin (total sold amount API in Sweden year 2021, data from IQVIA).

R = 0 % removal rate (due to loss by adsorption to sludge particles, by volatilization, hydrolysis or biodegradation) = 0, if no data is available.

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

V (L/day) = volume of wastewater per capita and day = 200 (ECHA default) (ECHA 2008)

D = factor for dilution of waste water by surface water flow = 10 (ECHA default) (ECHA 2008)

Predicted No Effect Concentration (PNEC)

Ecotoxicological studies

Algae: no data available

Crustacean (Daphnia magna): no data available

Fish: no data available

Other ecotoxicity data: No data available

PNEC derivation:

No PNEC can be calculated since there is no environmental toxicity data available

Environmental risk classification (PEC/PNEC ratio)

Calculation of a risk ratio is not possible, due to the lack of environmental toxicity data. Therefore, the following phrase is used: "Risk of environmental impact of olopatadine cannot be excluded, since no ecotoxicity data are available."

Degradation

Biotic degradation

Ready degradability: no data available

Justification of chosen degradation phrase:

As no data on biological degradation is available the following phrase is used: 'The potential for persistence of olopatadine cannot be excluded, due to lack of data.'

Bioaccumulation

Partitioning coefficient:

$\log K_{ow} = 0.342$ (method unknown) (Alcon Technical Report No. 090:38560:1093)

Justification of chosen bioaccumulation phrase:

As the $\log K_{ow}$ remains below the trigger level for a bioaccumulative substance ($\log K_{ow} < 4.0$), the following statement is used for olopatadine: 'Olopatadine has low potential for bioaccumulation.'

Excretion (metabolism)

Following topical application of olopatadine hydrochloride to the eyes, the plasma elimination half-life of the drug is about 3 hours. Olopatadine is not extensively metabolized. Following oral administration, unchanged olopatadine accounts for 77% of peak plasma total radioactivity, while metabolites (e.g., olopatadine N-oxide, N-desmethyl olopatadine) account for less than 6%. The

plasma elimination half-life of olopatadine following oral administration is 8–12 hours.

Olopatadine is eliminated principally by renal excretion; about 60–70% of a systemically absorbed dose of olopatadine is excreted in the urine (86% as unchanged olopatadine), and about 17% is excreted in feces. (AHFS Drug Information, 2017)

PBT/vPvB assessment

Based on screening information, olopatadine cannot be considered a potential PBT substance as the octanol-water partition coefficient remains significantly below the trigger level for a bioaccumulative substance.

References

- ECHA 2008, European Chemicals Agency. 2008 Guidance on information requirements and chemical safety assessment.
http://guidance.echa.europa.eu/docs/guidance_document/informa
- Alcon Technical Report No. 090:38560:1093
- AHFS Drug Information 2017. Medicines Complete.
Pharmaceutical Press.
<https://www.medicinescomplete.com/mc/ahfs/current/a399006.htm>