

Isopto[®]-Atropin

MR EF

Alcon Nordic

Ögondroppar, lösning 1 %
(Klar, färglös lösning)

Mydriatikum och cykloplegikum

Aktiv substans:

Atropin

ATC-kod:

S01FA01

Läkemedel från Alcon Nordic omfattas *inte* av Läkemedelsförsäkringen.

Miljöpåverkan

Atropin

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

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

Bioackumulering: Atropin har låg potential att bioackumuleras.

Detaljerad miljöinformation

Environmental Risk Classification

Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

$$PEC (\mu\text{g/L}) = (A \cdot 10^9 \cdot (100 - R)) / (365 \cdot P \cdot V \cdot D \cdot 100) = 1.5 \cdot 10^{-6} \cdot A \cdot (100 - R) = 1.5 \cdot 10^{-6} \cdot 0.8241 \text{ kg} \cdot 100$$

$$PEC = 0.000124 \mu\text{g/L}$$

Where:

A = 0.8241 kg (total sold amount API in Sweden year 2015, data from IMS Health).

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 = $9 \cdot 10^6$

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

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 atropine cannot be excluded, due to lack of data.'

Bioaccumulation

Partitioning coefficient:

$\log K_{ow} = 1.83$ (method unknown) (ChemIDplus)

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 atropine: 'Atropine has low potential for bioaccumulation.'

Excretion (metabolism)

Atropine is readily absorbed from mucous membranes, skin and the gastrointestinal tract but not from the stomach. Approximately 80-90% of a dose is excreted in the during 24 hours, 50% of the dose as unchanged drug, <2% as tropic acid and tropine, and ~30% as unknown metabolites. Traces of the dose are eliminated in the faeces. (Clarke's Analysis of Drugs and Poisons, 2017).

PBT/vPvB assessment

Based on screening information, atropine 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/information_requirements_en.htm

-ChemIDplus, U.S. National Library of Medicine, TOXNET. Assessed: 08. June 2017.

-Clarke's Analysis of Drugs and Poisons. Pharmaceutical Press 2017. MedicinesComplete. Royal Pharmaceutical Press.