

## Isopto<sup>®</sup>-Atropin

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.

M R EF

## 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](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.