

## Artelac

**Bausch och Lomb**

Ögondroppar, lösning  
(klar, färglös)

Tårsubstitut

**Aktiv substans:**

Hypromellos

**ATC-kod:**

S01XA20

Läkemedel från Bausch och Lomb omfattas av Läkemedelsförsäkringen.

## Miljöpåverkan

### Hypromellos

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

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

Bioackumulering: Det kan inte uteslutas att hypromellos kan bioackumuleras, då data saknas.

### Detaljerad miljöinformation

#### Environmental Risk Classification

#### Predicted Environmental Concentration (PEC)

PEC is based on following data:

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

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

A (kg/year) = total sold amount API in Sweden year 2016, data from Quintiles IMS.

R (%) = 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 =  $9 * 10^6$

V (L/day) = volume of wastewater per capita and day = 200 (ECHA default) (Ref.1)

D = factor for dilution of waste water by surface water flow = 10 (ECHA default) (Ref.1)

(Note: The factor  $10^9$  converts the quantity used from kg to  $\mu\text{g}$ ).

A = 0,6491 kg. The total sold amount of hypromellose in Sweden year 2016, data from Quintiles IMS. (Ref.2)

R = 0

PEC =  $1.5 * 10^{-6} * 0,6491 * (100 - 0) = 0,0000974 \mu\text{g/L}$

According to the European Medicines Agency guideline on environmental risk assessment of medicinal products (EMA/CHMP/SWP/4447/00), use of hypromellose is unlikely to represent a risk for the environment, because the predicted environmental concentration (PEC) is below the action limit  $0.01 \mu\text{g/L}$ .

### **Predicted No Effect Concentration (PNEC)**

The risk of environmental impact of hypromellose cannot be excluded, since no ecotoxicity data are available.

### **Degradation**

The potential for persistence of hypromellose cannot be excluded, due to lack of data.

### **Bioaccumulation**

The potential for bioaccumulation of hypromellose cannot be excluded, due to lack of data.

### **References**

1. ECHA, European Chemicals Agency.

October 2012 Version: 2.1 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)

2. Data from Quintiles IMS "Consumption assessment in kg for input to environmental classification - updated 2017".