FASS

Artelac

M F

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:

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

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

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 µg).

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

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

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 µg/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_
2. Data from Quintiles IMS ”Consumption assessment in kg for input to environmental classification - updated 2017”.