FASS

Bisolvon®

Sanofi AB

Oral lösning 0,8 mg/ml
(färglös med smak av körsbär och choklad)

Mukolytika

Aktiv substans:
Bromhexin

ATC-kod:
R05CB02

Läkemedel från Sanofi AB omfattas av Läkemedelsförsäkringen.

Miljöpåverkan

Bromhexin

Miljörisk: Risk för miljöpåverkan av bromhexin kan inte uteslutas då ekotoxikologiska data saknas.
Nedbrytning: Det kan inte uteslutas att bromhexin är persistent, då data saknas.
Bioackumulering: Bromhexin har hög potential att bioackumuleras.

Detaljerad miljöinformation

BROMHEXINE

Environmental Risk Classification
Predicted Environmental Concentration (PEC)
PEC is calculated according to the following formula:
PEC (µg/L) = $(A*10^{9}*(100-R))/(365*P*V*D*100) = 1.5*10^{-6}*A(100-R)$
PEC =0.00015xA
PEC = 0.09589 µg/L

Where:
A = 639.2744 kg (total sold amount API in Sweden year 2018, data from IQVIA).

R = 0% removal rate (due to loss by adsorption to sludge particles, by volatilization, hydrolysis or biodegradation) (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. I)

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

Predicted No Effect Concentration (PNEC)

No data available.

Environmental Risk Classification (PEC/PNEC ratio)

"Risk of environmental impact of Bromhexine can not be excluded since no ecotoxicity data are available".

Degradation

No degradation data is available, hence justifying the degradation phrase:

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

Bioaccumulation

Partitioning coefficient:

Log P = 4.08 at neutral pH (estimated by ALOGPS method) (Ref II)

Justification of chosen bioaccumulation phrase:

Since log P>4 at pH 7, bromhexine has high potential for bioaccumulation.

Excretion (metabolism)

Bromhexine is rapidly absorbed and is almost completely metabolized in the liver to hydroxylated metabolites and dibromanthranilic acid. The metabolites and bromhexine are conjugated, most likely by glucuronidation. The oral bioavailability of bromhexine is only about 20%. Bromhexine is widely distributed to body tissues and is highly bound to plasma proteins. Bromhexine crosses the blood-brain barrier, and small amounts even cross the placenta. About 85 to 90% of the bromhexine dose is excreted in the urine, mainly as metabolites. Bromhexine has a terminal elimination half-life of up to about 12 hours.
(Ref. III and IV)

References

I. European Chemicals Agency. 2008 Guidance on information requirements and chemical safety assessment.
https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessr

II. ChemIDPlus database, assessed as of November 2019.
https://www.drugbank.ca/drugs/DB09019

III. Summary of product characteristics (SPC) for Bisolvon, Sanofi AB, assessed as of November 2019.
https://www.fass.se

IV. MV Lad, V Jain, R Hasumati; A Review of Analytical Methods for Determination Bromhexine Hydrochloride in Pharmaceutical and Biological Samples; PharmaTutor; 2014; 2(11); 35-41.