FASS

Allopurinol Orifarm

Orifarm Generics AB

Tablett 100 mg

(Vita, runda med delskåra, 8,0 x 8,0 mm, prägling Nyco)

Medel mot gikt och hyperurikemi

Aktiv substans:

Allopurinol

ATC-kod:

M04AA01

Läkemedel från Orifarm Generics AB omfattas av Läkemedelsförsäkringen.

Miljöpåverkan

Miljöinformationen för allopurinol är framtagen av företaget Aspen Nordic för Zyloric®

Miljörisk: Användning av allopurinol har bedömts medföra medelhög risk för miljöpåverkan.
Nedbrytning: Allopurinol är potentiellt persistent.
Bioackumulering: Allopurinol har låg potential att bioackumuleras.

Detaljerad miljöinformation

Environmental Risk Classification

Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

PEC (µg/L) = $(A*10^{9} *(100-R))/(365*P*V*D*100) = 1.37*10^{-6}$ *A(100-R)

PEC = 0.84 µg/L

Where:
A = 6118.82 kg (total sold amount API in Sweden year 2021, data from IQVIA.)
R = X % removal rate (due to loss by adsorption to sludge particles, by volatilization, hydrolysis or biodegradation) = 0 if no data is available. R=0
P = number of inhabitants in Sweden = $10*10^{6}$
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)

Predicted No Effect Concentration (PNEC)

Ecotoxicological Studies

Aquatic toxicity:
Daphnia: EC_{50} 48h = 130 mg/L (OECD 202) (Ref. 2

Algea:EC_{50} 72h = 450 µg/L (OECD 201) (Ref. 2)

Fish: LC_{50} 96h > 100 mg/L (OECD 203) (Ref. 2)

PNEC (µg/L) = lowest EC_{50} / 1000 where 1000 is the assessment factor used for these data. EC_{50} for green alga (= 450 µg/L) has been used for this calculation since it is the most sensitive of the three tested species.

PNEC = 450 / 1000 = 0.45 µg/L

Environmental risk classification (PEC/PNEC ratio)

PEC/PNEC = 0.84 / 0.45 = 1.86 i.e.
1 < PEC/PNEC ≤ 10 which justifies the phrase "Use of allopurinol has been considered to result in moderate environmental risk".

Degradation

Inherent biodegradation: Test result 2 % degradation in 28 days (Modified Zahn-Wellens - OECD 302B). (Ref. 2)
The medicine is potentially persistent.

Bioaccumulation

Log P_{ow} = 0.32 (Ref. 3)

This material is not likely to sorb to soil or sediment. Measured soil sorption coefficient,
log Koc is < 1.25. (OECD 121).

References

1. [ECHA] European Chemicals Agency. December 2022. Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.16: Environmental exposure assessment (version 3.0)
2. British Pharmacopoeia, Safety Data Sheet according to 1907/2006/EC, Article 31, Allopurinol, Revision 23.04.2020.
3. Kashim N.A.; et al, 2004. Molecular Pharmaceutics, Vol.1 No.1, 85-96.