FASS

Zevtera

MRx EF

Unimedic Pharma

Pulver till koncentrat till infusionsvätska, lösning 500 mg
(Vit, gulaktig till lätt brunaktig, kaka till bruten kaka eller pulver.)

Andra cefalosporiner

Aktiv substans:
Ceftobiprol

ATC-kod:
J01DI01

Läkemedel från Unimedic Pharma omfattas av Läkemedelsförsäkringen.

Miljöpåverkan

Ceftobiprol

Miljörisk: Användning av ceftobiprol har bedömts medföra försumbar risk för miljöpåverkan.
Nedbrytning: Det kan inte uteslutas att ceftobiprol är persistent, då data saknas.
Bioackumulering: Ceftobiprol har låg potential att bioackumuleras.

Detaljerad miljöinformation

Predicted Eniviromental 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

A=0,00015 (total amount API of ceftobiprolmedokarilnatrium in Sweden year 2019, data from IQVIA) (Ref.1)
R=removal rate=0% (no data available)
P=number of inhabitants in Sweden=10*10^6
V (L/day)=volume of wastewater per capita and day=200 (ECHA default) (Ref.2)
D= factor for dilution of wastewater by surface water flow=10 (ECHA default) (Ref.2)

Predicted No Effect Concentration (PNEC)

Algae (Anabaena flos-aquae)

The toxicity of Ceftobipro on the growth of the blue-green algal species Anabaena flos-aquae was investigated in a 72-hour static test according to OECD Guideline 201 (Ref. 4).The lowest NOEC value for the blue-green algae was 0.29 µg/l. The primary endpoint was inhibition of growth. The PNEC was calculated to=0,029 µg/l (assessment factor 10). (Ref.3)

Crustacean (Daphnina magna)

Acute toxicity

The acute toxicity of Ceftobipriole to Daphnia magna was determined in a 48-hour static test according to OECD Guideline 202 (Ref. 5).A limited test was performed in accordance with the test guidelines to demonstrate that the test item had no toxic effect on the organisms up to the highest test item concentration that could be applied. In the control and at the loading rate of 100 mg/L (mean measured concentration of 46 mg/L) no immobilized daphnids were determined during the test period of 48 hours. In conclusion, Ceftobiprole (BAL9141-000) had no acute toxic effects on Daphnia magna up to the maximum water solubility of 46 mg/L in test water under the conditions of the test. In conclusion, Ceftobiprole had no acute toxic effects on Daphnia magna up to the maximum water solubility of 46 mg/L in test water under the conditions of the test. In conclusion, Ceftobiprole had no acute toxic effects on Daphnia magna up to the maximum water solubility of 46 mg/L in test water under the conditions of the test. EC_{50} 48h= 46 mg/L.(Ref.2)

Chronic toxicity

Ceftobiprole had no toxic effects on survival and reproduction of Daphnia magna after the exposure period of 21 (OECD guideline 211, Ref 6) days up to the solubility limit of the test item in test water. Thus, the 21-day NOEC of the test item was determined to be at least 37 mg/L.

Fish (Brachydanio rerio)

Acute toxicity

The toxicity of Ceftobiprole to zebra fish (Brachydanio rerio) was investigated in an early-life stage toxicity test according to OECD Guideline 210 (Ref 7). A limit test was performed in accordance with the guidelines to demonstrate that the test item had no toxic effect on the test organisms up to the highest concentration that could be applied.

The 96-hour NOEC of Ceftobiprole was determined to be at least 50 mg/l.(Ref.3)

Chronic toxicity
The chronix toxicity was tested during 35 days according to OECD guideline 210 (Ref 7).

The NOECs for each of the test parameters assessed (egg development and hatching rate, time to hatch/development rate, survival of larvae and juvenile fish, fish length, fish net weight and fish dry weight) were ≥ 5.6 mg/L

Enviromental risk classification (PEC/PNEC Ratio)

PEC/PNEC =0 /0,029 = 0

PEC/PNEC ≤ 0.1 which justifies the phrase "Use of ceftobirpolole has been considered to result in insignificant environmental risk".

Degradation

No data available.

Bioaccumulation

The partition coefficient, log Kow, was calculated to be < -2.2. (Ref.3) in a phase 1 screening, method unknown.
Since log Kow <4, the substance has low potential for bioaccumulation.

References

1. Sales data in kg from IQVIA 2019
2. Committee for Medicinal Product for Human Use (CHMP) Guideline on the Enviromental Risk Assessment of Medicinal Product for Human Use (EMEA/CHMP/SWP/4447/00, June 2006).
3. Environmental Risk Assessment for Ceftobiprole Medocaril Injection Powder for Solution (Infusion) 500 mg, 2013
4. OECD Guideline 201
5. OECD Guideline 202
6. OECD Guideline 211
7. OECD Guideline 210