FASS

Targocid®

Sanofi AB

Pulver till injektions-/infusionsvätska, lösning 400 mg
(Porös, benvit, homogen massa. Klar, gulaktig till mörkt gul lösning.)

Antibakteriella glykopeptider

Aktiv substans:
Teikoplanin

ATC-kod:
J01XA02

Läkemedel från Sanofi AB omfattas av Läkemedelsförsäkringen.

Miljöpåverkan

Teikoplanin

Miljörisk: Användning av teikoplanin har bedömts medföra försumbar risk för miljöpåverkan.
Nedbrytning: Teikoplanin är potentiellt persistent.
Bioackumulering: Teikoplanin 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 = $9.39 * 10^{-5}$ µg/L

Where:
A = 0.68544 kg (total sold amount API in Sweden year 2020, data from IQVIA)
R = 0% removal rate (due to loss by adsorption to sludge particles, by volatilization, hydrolysis or biodegradation)
P = number of inhabitants in Sweden = $10*10^{6}$

V (L/day) = volume of wastewater per capita and day = 200 (Ref I)
D = factor of dilution of waste water by surface water flow = 10 (Ref I)

Predicted No Effect Concentration (PNEC)
Ecotoxicological studies

Algae (Anabaena flos-aquae):
EC_{50} 72 h (growth rate): 236 µg/L
EC_{10} 72 h (growth rate): 12.9 µg/L
Protocol: OECD 201
(Ref II)

Crustacean (Daphnia magna):
EC_{50} 48 h (immobilization): > 100 000 µg/L
Protocol: OECD 202
(Ref III)

Fish (Danio Rerio):
LC_{50} 96 h (lethality): > 100 000 µg/L
Protocol: OECD 236
(Ref IV)

Other ecotoxicity data:

Lowest EC_{50}/1000:

Algae (Anabaena flos-aquae):
EC_{50} 72 h (growth rate): 236 µg/L

PNEC : 236 µg/L/1000 = 0.236 µg/L

Environmental Risk Classification (PEC/PNEC ratio)

PEC/PNEC: 0.00040

1 < PEC/PNEC ≤ 0.1: Use of teicoplanin has been considered to result in insignificant environmental risk.

Degradation
Test showed 0% degradation in 28 days. Therefore, teicoplanin is considered to be potentially persistent.
(Ref V)

Bioaccumulation
Partitioning coefficient:
Teicoplanin has low potential for bioaccumulation, as indicated by a calculated log K_{ow} of 0.8
(method/model: XLogP3-AA)
(Ref VI)

Excretion (metabolism)

In 16 days, more than 80% of administered teicoplanin are excreted in urine as parent compound (Ref VII). Two metabolites (metabolites 1 and 2; 2 to 3% of total teicoplanin) have been isolated and their structures were found to be new teicoplanin-like molecules, bearing 8-hydroxydecanoic and 9-hydroxydecanoic acyl moieties, respectively.
(Ref VIII)

References

I. ECHA, European Chemicals Agency, 2008 Guidance on information requirements and chemical safety assessment. https://echa.europa.eu/sv/guidance-documents/guidance-on-information-requirements-and-chemical-safe
II. Sanofi Internal report: Teicoplanin: Toxicity to Anabaena flos-aquae in an Algal Growth Inhibition Test, Study No 127621218, April 2018
III. Sanofi internal report: : Teicoplanin : Acute toxicity to Daphnia magna in a static 48-hour Immobilisation Test, Study No 127621220, March 2018
IV. Sanofi internal report: Teicoplanin : Acute toxicity to Zebrafish (Danio rerio) Embryos in a 96-hour Static Test, Study No 127621238, March 2018
V. Sanofi internal report: Teicoplanin Sodium Salt: ready biodegradability in a manometric respirometry test, Study No 135541163, October 2018
VI. Pubchem, Targocid, 61036-62-2, NCBI. Available: http://pubchem.ncbi.nlm.nih.gov/summary/summary.cgi?cid=16131925, Accessed Feb 01, 2017
VII. Vidal, 2013, Vidal Product monography – Targocid 100 mg lyoph sol
VIII. DrugBank http://www.drugbank.ca/drugs/DB06149