FASS

Euthyrox

M

Merck

Tablett 150 mikrog

Avregistreringsdatum: 2017-02-08 (Tillhandahålls ej) (benvit, rund, plan på båda sidor, med skåra och fasad kant, märkt på ovansidan med EM 150)

Tyreoideahormoner

Aktiv substans:

Levotyroxin

ATC-kod:

H03AA01

För information om det avregistrerade läkemedlet omfattas av Läkemedelsförsäkringen, kontakta Läkemedelsförsäkringen.

Läs mer om avregistrerade läkemedel

Miljöpåverkan

Miljöinformationen för levotyroxin är framtagen av företaget Takeda Pharma för Levaxin®, Levotyroxin Nycomed

Miljörisk: Användning av levotyroxin har bedömts medföra försumbar risk för miljöpåverkan.

Nedbrytning: Levotyroxin är potentiellt persistent.
Bioackumulering: Levotyroxin 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) = $(A*10^{9}*(100-R))/(365*P*V*D*100) = 1,5*10^{-6}$ *A(100-R)

PEC = 22,07 x 10^{-4} µg/L

Where:

A = 14,71 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) = 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)

Predicted No Effect Concentration (PNEC)

Ecotoxicological studies:

- Algae (Pseudokirchneriella subcapitata):

EC_{50} = 520 mg/l after 72 hours exposure (guideline OECD 201) (Ref.2)

- Crustacean - Fresh water flea (Daphnia magna):

EC_{50} = 497 mg/l after 72 hours exposure (guideline OECD 202) (Ref.2)

- Fish - Sheepshed minnow (Cyprinodon variegatus variegatus):

LC_{50} > 1000 g/l after 72 hours exposure (modified OECD 203 Fish Acute Toxicity Test) (Ref.2)

PNEC = 497 µg/l (justification of chosen assessment factor)
PNEC (µg/l) = lowest EC_{50}/1000 where 1000 is the assessment factor used. EC_{50} for Daphnia magna has been used as for this calculation since it is the most sensitive of the three tested species.

Environmental risk classification (PEC/PNEC ratio)
PEC/PNEC = 22,07 x 10^{-4} µg/l / 497µg/l = 4,44 x10^{-6}
PEC/PNEC < 0,1 which justifies the phrase ”Användning av läkemedlet har bedömts medföra försumbar risk för miljöpåverkan.”

Degradation

Test results from "closed bottle test" (guideline 301 D) shows that the biological degradation is 0% in 28 days.
Levothyroxine is potentially persistent.

Bioaccumulation

Partitioning coefficient:
Log Pow = 2,4 (Ref.3; computed by XLOGP3-AA method)
Since log Pow < 4, the substance has low potential for bioaccumulation.

Referenser

1. ECHA, European Chemicals Agency. 2008 Guidance on information requirements and chemical safety assessment. http://guidance.echa.europa.eu/docs/guidance_document/informa
2. Report: Test Results for the Test Substance Levothyroxinsodium (Report Nr: R 197–05), Nycomed AB.
3. United States National Library of Medicine, PubChem, Compound, Levothyroxine, http://pubchem.ncbi.nlm.nih.gov/. Accesses: 21 July 2015