

Levaxin[®]**M R F****Orifarm Generics AB**

Tablett 25 mikrog

(vita, runda bikonvexa, 5 mm, märkta 25)

Tyreoideahormoner

Aktiv substans:

Levotyroxin

ATC-kod:

H03AA01

Läkemedel från Orifarm Generics AB omfattas av
Läkemedelsförsäkringen.

Miljöpåverkan

Levotyroxin

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:

$$PEC (\mu\text{g/L}) = (A \cdot 10^9 \cdot (100 - R)) / (365 \cdot P \cdot V \cdot D \cdot 100) = 1.37 \cdot 10^{-6}$$

$$\cdot A \cdot (100 - R)$$

$$PEC = 0.0011 \mu\text{g/L}$$

Where:

A = 7.78 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) = 0 if no data is available.

P = number of inhabitants in Sweden = $1 \cdot 10^7$

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*):
EC₅₀ = 520 mg/L after 72 hours exposure (guideline OECD 201) (Ref.2)

- Crustacean - Fresh water flea (*Daphnia magna*):
 $EC_{50} = 497 \text{ mg/L}$ after 72 hours exposure (guideline OECD 202) (Ref.2)
- Fish - Sheepshed minnow (*Cyprinodon variegatus variegatus*):
 $LC_{50} > 1000 \text{ g/L}$ after 72 hours exposure (modified OECD 203 Fish Acute Toxicity Test) (Ref.2)

$PNEC = 497 \text{ } \mu\text{g/L}$ (justification of chosen assessment factor)
 *$PNEC (\mu\text{g/L}) = \text{lowest } EC_{50} / 1000$ 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)

$$PEC/PNEC = 0.0011 \text{ } \mu\text{g/L} / 497 \mu\text{g/L} = 2.14 \cdot 10^{-6}$$

$PEC/PNEC < 0.1$ 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

References

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/>. Accessed: 21 July 2015