

Topimax (Parallellimporterat)

Orifarm AB

Filmdragerad tablett 25 mg

R F

Inga avvikelser.

Visa information om det parallellimporterade läkemedlet

Aktiv substans:

Topiramat

ATC-kod:

N03AX11

Läkemedel från Orifarm AB omfattas av Läkemedelsförsäkringen.

Miljöpåverkan

Miljöinformationen för topiramat är framtagen av företaget Janssen för Topimax, Topimax®

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

Nedbrytning: Det kan inte uteslutas att topiramat är persistent, då data saknas.

Bioackumulering: Topiramat har låg potential att bioackumuleras.

Detaljerad miljöinformation

Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

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

$$\text{PEC} = 0.03967496787 \mu\text{g/L}$$

Where:

A = total actual API sales in Sweden for the most recent year 289.5983057 kg (total sold amount API in the most recent sales data for Sweden (2022) was distributed by IQVIA in 2023)

R = 0

P = number of inhabitants in Sweden = $10 \cdot 10^6$

V (L/day) = volume of wastewater per capita and day = 200 (ECHA default) (Reference VI)

D = factor for dilution of wastewater by surface water flow = 10 (ECHA default) (Reference VI)

Predicted No Effect Concentration (PNEC)

Ecotoxicological studies

Algae (Selenastrum capricornutum) (guideline e.g. OECD 201):

Algal growth inhibition test with the green alga (*Selenastrum capricornutum*) [Reference I]:

$E_b C_{50}$ 72 h (biomass) > 93 mg/L

$NOEC_b$ 72 h = 93 mg/L

$E_r C_{50}$ (growth rate) 72 h > 93 mg/L

$NOEC_r$ 72 h = 93 mg/L

Crustacean (Daphnia magna) (water-flea) (guideline e.g. FDA 4.08):

Acute toxicity

Acute toxicity in the water-flea (*Daphnia magna*) [Reference II]:

EC_{50} 48 h (immobilization) > 1000 mg/L $NOEC$ (immobilization) = 1000 mg/L

Chronic toxicity

No data available

Fish:

Acute toxicity

Acute toxicity in the zebra fish (*Brachydanio rerio*) (guideline e.g. FDA 4.11) [Reference III]:

LC_{50} 96 h (mortality) > 2400 mg/L

$NOEC$ (mortality) < 75 mg/L

Chronic toxicity

No data available

Other ecotoxicity data:

Activated sludge respiration inhibition test (guideline e.g. OECD 209) [Reference IV]:

EC_{50} 3h > 1000 mg/L

$NOEC$ 3h $\geq$ 1000 mg/L

PNEC ($\mu\text{g/l}$) = lowest EC_{50} /1000, where 1000 is the assessment factor used. EC_{50} for the green alga

Pseudokirchneriella subcapitata 93 mg/L has been used for this calculation since it is the most sensitive of the three tested species.

PNEC = 93 mg/L/1000 = 93 $\mu\text{g/L}$

Environmental risk classification (PEC/PNEC ratio)

$PEC/PNEC = 0.03967496787 \mu\text{g/L} / 93 \mu\text{g/L} = 0.000426613$, i.e. $PEC/PNEC \leq 0.1$

Conclusion for environmental risk:

Use of Topiramate has been considered to result in insignificant environmental risk.

Degradation

Biotic degradation

No data on degradation available.

Conclusion for degradation:

The potential for persistence of Topiramate cannot be excluded due to lack of data.

Abiotic degradation

Hydrolysis: -

Photolysis: -

Bioaccumulation

Partition coefficient octanol/water:

The partition coefficient octanol/water was determined using potentiometric titration in octanol/water.
[Reference V] $\log K_{ow} = 0.5$ (pH = 6.0)

Bioconcentration factor (BCF):

No data available

Conclusion for bioaccumulation: As $\log K_{ow} < 4$, Topiramate has low potential for bioaccumulation.

Excretion (metabolism)

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PBT/vPvB assessment

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References

- I. Hoberg J.R.; Topiramate - toxicity to the freshwater green alga *Pseudokirchneriella subcapitata*, Springborn Smithers Study #13674.6116, February 16, 2004.
- II. Collins M.K.; Topiramate - acute toxicity to daphnids (*Daphnia magna*) under static conditions, SLI Study #12653.0392.6104.110, October 12, 1993.
- III. Collins M.K.; Topiramate - acute toxicity to Bluegill sunfish (*Lepomis macrochirus*) under static conditions, SLI Study #12653.0392.6105.100, February 18, 1994.
- IV. Seyfried B.; Toxicity to activated sludge in a respiration inhibition test, RCC Study No. A37991, RMD721, January 18, 2006.
- V. Jacobs A.; Determination of pKa and logP; JPh study PC-CHAR Result 01-141; September 28, 2001.
- VI. ECHA, European Chemicals Agency. 2008 Guidance on information requirements and chemical safety assessment.
http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm

