FASS

Sabrilex®

Sanofi AB

Filmdragerad tablett 500 mg
(vita, ovala, bikonvexa med skåra, märkta SABRILEX på ena sidan, 9×17 mm)

Antiepileptikum

Aktiv substans:
Vigabatrin

ATC-kod:
N03AG04

Läkemedel från Sanofi AB omfattas av Läkemedelsförsäkringen.

Miljöpåverkan

Vigabatrin

Miljörisk: Risk för miljöpåverkan av vigabatrin kan inte uteslutas då ekotoxikologiska data saknas.
Nedbrytning: Det kan inte uteslutas att vigabatrin är persistent, då data saknas.
Bioackumulering: Vigabatrin 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 = 0.022 µg/L

Where:
A =157.2 kg (total sold amount API in Sweden year 2022, 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 (ECHA default) (Ref I)
D = factor of dilution of waste water by surface water flow = 10 (ECHA default) (Ref I)

Predicted No Effect Concentration (PNEC)

No ecotoxicological study results are available.

Environmental Risk Classification (PEC/PNEC ratio)

A PEC/PNEC ratio cannot be calculated due to lack of data, thus justifying the phrase: *"Risk of environmental impact of vigabatrin cannot be excluded, since no ecotoxicity data are available"*.

Degradation

No degradation data is available, hence justifying the degradation phrase:
"The potential for persistence of vigabatrin cannot be excluded, due to lack of data".

Bioaccumulation

Partition coefficient
Log K_{ow} = -2.16 at pH 7
(OECD 107)
(Ref II)
Justification of chosen bioaccumulation phrase:
Since log K_{ow} < 4 at pH 7, vigabatrin has low potential for bioaccumulation.

Excretion (metabolism)

Vigabatrin is not extensively metabolised. No metabolites have been identified in
plasma.

Vigabatrin is eliminated by renal excretion with a half-life of 5-8 hours. About 70 % of one oral single dose was excreted unchanged in the urine for the first 24 hours.

References

I. ECHA, European Chemicals Agency, 2008 Guidance on information requirements and chemical safety assessment. https://echa.europa.eu/guidance-documents/guidance-on-informat

II. Henczi, M., Nagy, J., Weaver, D.F., 1995. Determination of Octanol-water Partition Coefficients by an HPLC method for Anticonvulsant Structure-activity studies. Journal of Pharmacy and Pharmacology. 47, 345-347.
III. SmPC of Sabrilex, retrived from SE MPA website 2021-03-17, find here.