

Briviact

M R (F)

UCB Nordic

Filmdragerad tablett 10 mg

(vita till benvita, runda, filmdragerade tabletter med diametern 6,5 mm och "u10" präglad på ena sidan)

Antiepileptika, övriga antiepileptika

Aktiv substans:

Brivaracetam

ATC-kod:

N03AX23

Läkemedel från UCB Nordic omfattas av Läkemedelsförsäkringen.

Miljöpåverkan

Brivaracetam

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

Nedbrytning: Brivaracetam är potentiellt persistent.

Bioackumulering: Brivaracetam har låg potential att bioackumuleras.

Detaljerad miljöinformation

Environmental Risk Classification

Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

$$PEC (\mu\text{g/l}) = (A \cdot 10^9 \cdot (100 - R)) / (365 \cdot P \cdot V \cdot D \cdot 100) = 1.5 \cdot 10^{-6} \cdot A \cdot (100 - R)$$

$$PEC = 1.41 \cdot 10^{-3} \mu\text{g/l}$$

Where:

A = 9.42 kg (total sold amount API in Sweden 2020, data from IQVIA)

R = 0 % removal rate (due to loss by adsorption to sludge particles, by volatilization, hydrolysis or biodegradation)

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

$V \text{ (l/day)} = \text{volume of wastewater per capita and day} = 200 \text{ (Ref II)}$

$D = \text{factor of dilution of waste water by surface water flow} = 10 \text{ (Ref II)}$

Predicted No Effect Concentration (PNEC)

Ecotoxicological studies

Chronic toxicity

Algae (*Pseudokirchneriella subcapitata*):

NOEC 3 days (growth inhibition) = 100 000 µg/l

(Protocol: OECD 201)

(Ref I)

Crustacean (*Daphnia magna*):

NOEC 21 days (reduction in reproduction) = 100 000 µg/l

(Protocol: OECD 211)

(Ref I)

Fish (*Pimephales promelas*):

NOEC 35 days (lethality and developmental effect) = 10 000 µg/l

(Protocol: OECD 210)

(Ref I)

Other ecotoxicity data:

PNEC = 1 000 µg/l

(The PNEC (µg/l) = 10 000/10 using results from the most sensitive chronic toxicity endpoint and an assessment factor of 10 ("long-term results from at least three species representing three trophic levels," [Ref II, Table R.10-4]). The most sensitive species was the fish, *Pimephales promelas* for which the NOEC used was 10 000 µg/l.)

Environmental risk classification (PEC/PNEC ratio)

$PEC/PNEC = 1.41 \cdot 10^{-3} / 1\,000 = 1.41 \cdot 10^{-6}$, i.e. $PEC/PNEC \leq 0.1$. Results show that the use of brivaracetam most likely results in insignificant environmental risk. However, since this is a theoretical value the standard environmental phrase to be used is: "*Use of brivaracetam has been considered to result in insignificant environmental risk*"

Degradation

Biotic degradation

Ready degradability: brivaracetam showed < 60 % degradation over 10 days (protocol: OECD 301B) (Ref I)

Brivaracetam did not pass the ready degradation test and since there is no information available on grade of mineralisation the phrase: "*brivaracetam is potentially persistent.*" should be used.

Bioaccumulation

Partitioning coefficient

$\log P_{ow} = 1.5$ at pH 7 (Protocol: OECD 117) (Ref I)

Justification for chosen bioaccumulation phrase:

Since $\log P_{ow} < 4$ at pH 7, the substance has low potential for bioaccumulation.

Excretion (Metabolism)

Brivaracetam is excreted 5-10 % as parent compound and 3 major metabolites have been identified. The metabolites are pharmacologically inactive. (Ref I)

References

- I. Briviact Assessment report EMA/CHMP/822086/2015.
http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/003851.pdf
- II. ECHA, European Chemicals Agency. Guidance on information requirements and chemical safety assessment, version 3.0 Feb 2016.