

Adalat

M

Bayer

KAPSLAR 10 mg

Avregistreringsdatum: 1997-04-30 (Tillhandahålls ej)

Aktiv substans:

Nifedipin

ATC-kod:

C08CA05

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

Läs mer om avregistrerade läkemedel

Miljöpåverkan

Nifedipin

Miljörisk: Risk för miljöpåverkan av nifedipin kan inte uteslutas då det inte finns tillräckliga ekotoxikologiska data.

Nedbrytning: Nifedipin bryts ned långsamt i miljön.

Bioackumulering: Nifedipin har låg potential att bioackumuleras.

Detaljerad miljöinformation

Environmental Risk Classification

Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

$$\text{PEC } (\mu\text{g/L}) = (A \cdot 10^9 \cdot (100 - R)) / (365 \cdot P \cdot V \cdot D \cdot 100) = 1.37 \cdot 10^{-6}$$
$$A \cdot (100 - R) = 0.0017 \mu\text{g/L}$$

Where:

A = 12.73 kg (total sold amount API in Sweden year 2021, data from IQVIA / LIF)

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 = $10 \cdot 10^6$

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

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

Environmental risk classification (PEC/PNEC ratio)

Justification of chosen environmental risk phrase:

Due to a lack of ecotoxicological data the PNEC and the risk quotient could not be determined. This qualifies for the risk phrase "Risk of environmental impact of nifedipine cannot be excluded, since no ecotoxicity data are available".

Degradation

Abiotic degradation

Photolysis:

In an exploratory study, Maafi and Maafi published a study on the assessment of photodegradation of nifedipine. Test item in

ethanolic solution was exposed at 22 °C to continuous monochromatic irradiation at wavelengths between 223 and 390 nm and DAD analysed. Rate constants for degradation were determined in the range of 0.00009 to 0.00489 /s⁻¹ dependent on wave lengths (low to high). The authors concluded that Nifedipin is photolytically degraded at visible wavelengths, with maximum absorbance between 282 and 370 nm. Nitrosophenylpyridine was the main photolytic transformation product. The authors did not report degradation half-lives but based on the rate constant half-lives less than 40 days are expected. (Reference III)

Justification of chosen degradation phrase:

Based on the photolysis data, nifedipine is expected to degrade in the environment, which qualifies for the phrase “Nifedipine is slowly degraded in the environment”.

Bioaccumulation

There is no experimental data on the partition coefficient or bioaccumulation factor of nifedipine and hence the well-established QSAR tool EpiSuite from the US Environmental Protection Agency (EPA) was used to estimate these parameters. Specifically, KOCWIN v2.0 which is a sub-program allowed to calculate the partition coefficient log K_{OW} as 2.19. Furthermore, BCFBAF v3.01 another sub-program was used to estimate the bioaccumulation with a bioconcentration factor (BCF) of 13.14.

Justification of chosen bioaccumulation phrase:

QSAR estimations are sufficiently reliable to conclude, and the results qualify for the risk phrase “Nifedipine has low potential for bioaccumulation”.

References

- I. Guidance on information requirements and Chemical Safety Assessment Chapter R.16: Environmental exposure assessment. V3.0, Feb. 2016.
- II. Maafi W., Maafi M. 2013. Modelling nifedipin photodegradation photostability and actinometric properties. Int J Pharmaceutics 456, 153-164.