

Rebetol

M

MSD

Kapsel, hård 200 mg

Avregistreringsdatum: 2023-10-18 (Tillhandahålls ej) (vit, ogenomskinlig, märkt Rebetol 200 mg och SP-logo i blått tryck)

Virushämmande medel för systemiskt bruk, virushämmande medel mot HCV-infektioner

Aktiv substans:

Ribavirin

ATC-kod:

J05AP01

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

Läs mer om avregistrerade läkemedel

Miljöpåverkan

Ribavirin

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

Nedbrytning: Det kan inte uteslutas att ribavirin är persistent, då

data saknas.

Bioackumulering: Ribavirin har låg potential att bioackumuleras.

Detaljerad miljöinformation

Environmental Risk Classification

Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

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

$$\text{PEC} = 0.00004 \mu\text{g/L}$$

Where:

A = 0.3 kg (total sold amount API in Sweden year 2021, data from IQVIA) (Ref. I)

R = 0 % removal rate (worst case assumption)

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

V (L/day) = volume of wastewater per capita and day = 200 (ECHA default) (Ref. II)

D = factor for dilution of waste water by surface water flow = 10 (ECHA default) (Ref. II)

Predicted No Effect Concentration (PNEC)

Ecotoxicological studies

Algae (Selenastrum capricornutum) (OECD 201) (Reference III):

NOEC 96 h (growth rate) = 6900 µg/L

Crustacean, water flea (Daphnia magna):

Acute toxicity

EC₅₀ 48 h (mortality) >117000 µg/L (OECD 202) (Ref. IV)

Fish, rainbow trout (Oncorhynchus mykiss):

Acute toxicity

EC₅₀ 96 h (mortality) >119000 µg/L (OECD 203) (Ref. V)

PNEC = 6.9 µg/L (6900 µg/L/ 1000 based on the most sensitive NOEC for the algae and an assessment factor (AF) of 1000)

Environmental risk classification (PEC/PNEC ratio)

PEC/PNEC = 0.00004/6.9 = 5,9E-06, i.e. PEC/PNEC < 0.1 which justifies the phrase "Use of ribavirin has been considered to result in insignificant environmental risk."

Degradation

No degradation studies on ribavirin have been conducted. The potential for persistence of ribavirin cannot be excluded, due to lack of data.

Bioaccumulation

Partitioning coefficient: (OECD 117) (Ref. VI):

Log K_{ow} = 0.971

Justification of chosen bioaccumulation phrase:

Since $\log K_{ow} < 4$, the substance has low potential for bioaccumulation.

References

- I. Data from IQVIA "Consumption assessment in kg for input to environmental classification - updated 2022 (data 2021)".
- II. ECHA, European Chemicals Agency. 2008 Guidance on information requirements and chemical safety assessment.
http://guidance.echa.europa.eu/docs/guidance_document/informa
.
- III. Wildlife International, 2003. Ribavirin (SCH 18908): A 96-Hour Toxicity Test with the Freshwater Algae (*Selenastrum capricornutum*).
- IV. Wildlife International, 2003. Ribavirin (SCH 18908): A 48-Hour Static Acute Toxicity Test with the Cladoceran (*Daphnia magna*).
- V. Wildlife International, 2003. Ribavirin (SCH 18908): A 96-Hour Static Acute Toxicity Test with the Rainbow Trout (*Oncorhynchus mykiss*).
- VI. Wildlife International, 2003. "Determination of n-Octanol/Water Partition Coefficient of Ribavirin (SCH 18908).