

Asacol (Parallellimporterat)

Cross Pharma AB

Enterotablett 400 mg

Avregistreringsdatum: 2020-01-31 (Tillhandahålls ej)

Bisterkartan är märkt både OCTASA och Asacol.

Visa information om det parallellimporterade läkemedlet

Aktiv substans:

Mesalazin

ATC-kod:

A07EC02

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

Läs mer om avregistrerade läkemedel

Miljöpåverkan

Miljöinformationen för mesalazin är framtagen av företaget Tillotts Pharma för Asacol, Asacol®

Miljörisk: Risk för miljöpåverkan av mesalazin kan inte uteslutas då ekotoxikologiska data saknas.

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

data saknas.

Bioackumulering: Mesalazin har låg potential att bioackumuleras.

Detaljerad miljöinformation

Mesalazin

Environmental risk: Risk of environmental impact of mesalazin cannot be excluded, since no ecotoxicity data are available.

Degradation: The potential for persistence of mesalazin cannot be excluded, due to lack of data.

Bioaccumulation: Mesalazin has low potential for bioaccumulation.

Detailed background information

Environmental Risk Classification

Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

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

$\text{PEC } (\mu\text{g/L}) = 1,37 \times 10^{-6} \times 37\,011,7914 \times 100 = 5,07 \mu\text{g/L}$. This assumes zero removal.

Where:

A = 37 011,7914 kg total sold amount API of mesalazine in Sweden year 2022, data from IQVIA (Ref. I). Reduction of A may be justified based on metabolism data.

R = X % 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) (Ref. II)

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

Predicted No Effect Concentration (PNEC)

There are no Ecotoxicity data available.

Environmental risk classification (PEC/PNEC ratio)

Justification to chosen risk classification phrase:

The risk of environmental impact of mesalazin cannot be excluded, since no ecotoxicity data are available.

Degradation

Justification to chosen degradation phrase:

The potential for persistence of mesalazin cannot be excluded, due to lack of data

Bioaccumulation

Partitioning coefficient (Ref. III)

$\text{Log } K_{ow} = 0.98$ (est)

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 v1 - updated 2023 (data 2022)".
- II. ECHA, European Chemicals Agency. 2008 Guidance on information requirements and chemical safety assessment.
http://guidance.echa.europa.eu/docs/guidance_document/information.htm
- III. US EPA; Estimation Program Interface (EPI) Suite. Ver.3.12. Nov 30, 2004. Available from, as of Jan 4, 2007:
<http://www.epa.gov/oppt/exposure/pubs/episuite.dll.htm>