FASS

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:

PEC (µg/L) = $(A*10^{9}*(100-R))/(365*P*V*D*100) = 1.37*10^{-6}*A(100-R)$

PEC (µg/L) = 1,37 x 10^{-6} x 37 011,7914 x 100= 5,07 µg/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 = $10*10^{6}$

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

Bioaccumulation

Partitioning coefficient (Ref. III)
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_requirements_en.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/episuitedl.htm