FASS

Dulcolax (Parallellimporterat)

Paranova Läkemedel AB

Suppositorium 10 mg

Avregistreringsdatum: 2018-01-31 (Tillhandahålls ej)

Inga avvikelser.

Kontaktlaxativ

Visa information om det parallellimporterade läkemedlet

Aktiv substans:

Bisakodyl

ATC-kod:

A06AB02

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

Läs mer om avregistrerade läkemedel

Miljöpåverkan

Miljöinformationen för bisakodyl är framtagen av företaget Sanofi AB för Dulcolax®

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

Nedbrytning: Bisakodyl är potentiellt persistent.
Bioackumulering: Bisakodyl har låg potential att bioackumuleras.

Detaljerad miljöinformation

Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

PEC (µg/L) = $(A*10^{9}*(100-R))/(365*P*V*D*100) = 1.52*10^{-4}*A$ = 0.0206 µg/L

Where:
A = 135,75 kg (total sold API in Sweden year 2016, data from QuintilesIMS)
R (%) = 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 = $9*10^{6}$
V = (L/day) = volume of wastewater per capita and day = 200 (ECHA default) (Ref I)
D = factor for dilution of waste = 10 (ECHA default) (Ref I)

Predicted No Effect concentration (PNEC)

Ecotoxicological studies

Green alga (*Scenedesmus subspicatus*) (OECD 201) (Ref II):
No concentrations above the solubility of the test item in the test medium (1.43 mg/L) were tested.
EC_{50} 72 h (growth inhibition) > 1.43 mg/L
NOEC 72 h (growth inhibition) = 1.43 mg/L

Water-flea (*Daphnia magna*) (OECD 202) (Ref III):
No concentrations above the solubility of the test item in the test medium (1.93 mg/L) were tested.
EC_{50} 48 h (immobilization) > 1.93 mg/L
NOEC 48 h (immobilization) = 1.93 mg/L

Zebra fish (*Danio rerio*) (OECD 203) (Ref IV):
No concentrations above the solubility of the test item in the test medium (1.63 mg/L) were tested.
LC_{50} 96 h > 1.63 mg/L
NOEC 96 h (endpoint: mortality and signs of intoxication) = 1.63 mg/L

Conclusion: In the acute effect studies with alga, water-flea and fish, no effects on the test organisms were observed up to the highest test concentrations. In order to be able to calculate a PEC/PNEC ratio, the concentration of 1.43 mg/L and an assessment factor of 1000 are used for calculation of the PNEC.

PNEC = 1.43 mg/L / 1000 = 0.00143 mg/L = 1.43 µg/L

Environmental risk classification (PEC/PNEC ratio)
PEC/PNEC = 0.0206 / 1.43 = 0.014

Justification: PEC/PNEC ≤ 0,1 which justifies the phrase “Use of bisacodyl has been considered to result in insignificant environmental risk”.

Degradation
Bisacodyl is not readily biodegradable:

Tests have shown 11% degradation in 28 days (OECD 301) (Ref V). The percentage biodegradation did not exceed 60 % within a 10 day window. Bisacodyl can therefore be considered to be not readily biodegradable.

Bioaccumulation

The partition coefficient (n-octanol/water) was experimentally determined (OECD 117) (Ref VI):
log D = 2.5

Justification: log D < 4 which justifies the phrase “Bisacodyl has low potential for bioaccumulation”.

Adsorption

After administration in humans, bisacodyl is hydrolyzed to bis-(p-hydroxyphenyl)-pyridyl-2-methane (BHPM) which is the active moiety.

BHMP has no high tendency for adsorption (OECD 121) (Ref VII):
Koc = 88

Excretion (metabolism)

Bisacodyl is a pro-drug. After administration in humans bisacodyl is hydrolyzed to bis-(p-hydroxyphenyl)-pyridyl-2-methane (BHPM) which is the active moiety. BHMP is mainly excreted as monoglucuronide (Ref VIII).

References:

I. ECHA, European Chemicals Agency. 2008 Guidance on information requirements and chemical safety assessment.

Chapter R.10: Characterization of dose [concentration]-response for environment. http://echa.europa.eu/documents/10162/13632/information_requi

II. Boehringer Ingelheim GmbH internal report U02-1644, 2002
III. Boehringer Ingelheim GmbH internal report U02-1645,2002
IV. Boehringer Ingelheim GmbH internal report U03-1253, 2003
V. Boehringer Ingelheim GmbH internal report U02-1606, 2002
VI. Boehringer Ingelheim GmbH internal report U02-1605, 2002
VII. Boehringer Ingelheim GmbH internal report U06-0257, 2006
VIII. Arzneimittelforschung, Nov. 1975, 25(11): 1796-1800