FASS

Ventoline®

GlaxoSmithKline

Lösning för nebulisator 2 mg/ml

(Endosbehållare.)

Bronkdilaterande medel vid astma och KOL att ges via nebulisator

Aktiv substans:

Salbutamol

ATC-kod:

R03AC02

Läkemedel från GlaxoSmithKline omfattas av Läkemedelsförsäkringen.

Miljöpåverkan

Salbutamol

Miljörisk: Risk för miljöpåverkan av salbutamol kan inte uteslutas då det inte finns tillräckliga ekotoxikologiska data.
Nedbrytning: Salbutamol är potentiellt persistent.
Bioackumulering: Salbutamol har låg potential att bioackumuleras.

Detaljerad miljöinformation

Environmental Risk Classification
Predicted Environmental Concentration (PEC)
PEC is calculated according to the following formula:

PEC (µg/L) = $(A*10^{9}*(100-R))/(365*P*V*D*100) = 1.5*10^{-6}*A(100-R)$
PEC = 0.0085 µg/L

Where:
A = 56.57 kg (total sold amount API in Sweden year 2017, data from IQVIA).
R = 0% removal rate (conservatively, it has been assumed there is no loss by adsorption to sludge particles, by volatilization, hydrolysis or biodegradation).
P = number of inhabitants in Sweden = $9 *10^{6}$

V (L/day) = volume of wastewater per capita and day = 200 (ECHA default) (Reference 1)
D = factor for dilution of waste water by surface water flow = 10 (ECHA default) (Reference 1)

Predicted No Effect Concentration (PNEC)

Ecotoxicological studies

Algae
No data

Water flea (Daphnia magna):
Acute toxicity
EC50 48 h (immobility) = 240,000 µg/L (OECD 202) (Reference 6)

Water flea (Ceriodaphnia dubia):
Chronic toxicity
NOEC 8 days (reproduction) = 100,000 µg/L (USEPA 1002) (Reference 9)

Fish:
Acute toxicity
No data
Chronic toxicity
No data

Microorganisms in activated sludge:
EC50 3 h (inhibition) = 830,000 µg/L (OECD 209) (Reference 5)

PNEC cannot be calculated because data is not available for all three (algae, crustacean and fish) of the toxicity endpoints.

Environmental risk classification (PEC/PNEC ratio)

Risk of environmental impact of salbutamol cannot be excluded, since there is not sufficient ecotoxicity data available.

Degradation

Biotic degradation

Ready degradability:
1% degradation in 28 days (TAD 3.11) (Reference 7)

Inherent degradability:
No Data

Soil Degradation
1.3 to 38.7% degradation in 64d (TAD 3.12) (Reference 8)

Abiotic degradation

Hydrolysis:

DT50 > 1 year (OECD 111) (Reference 4)

Photolysis:

No data

Justification of chosen degradation phrase:

Salbutamol is not readily degradable or inherently degradable. The phrase “Salbutamol is potentially persistent in the environment” is thus chosen.

Bioaccumulation

Partitioning coefficient:
Log Dow = -2.80 at pH 7 (TAD 3.04). (Reference 3)

Log Dow at pH5 = -1.50
Log Dow at pH7 = -2.80
Log Dow at pH9 = -2.80

Justification of chosen bioaccumulation phrase:
Since log Dow < 4 at pH 7, the substance has low potential for bioaccumulation.

Excretion (metabolism

The primary route of elimination of hydrofluoroalkane-propelled albuterol (HFA) parent or primary metabolite compound is through the kidney. After an IV dose of racemic albuterol, between 24% to 46% of the R enantiomer is excreted unchanged in the urine (Reference 2)

PBT/vPvB assessment

Salbuatmol does not fulfil the criteria for PBT and/or vBvP.
All three properties, i.e. ‘P’, ‘B’ and ‘T’ are required in order to classify a compound as PBT (Reference 1).
Salbutamol does not fulfil the criteria for PBT and/or vBvP based on log Dow < 4.

Please, also see Safety data sheets on http://www.msds-gsk.com/ExtMSDSlist.asp.

References

1. ECHA, European Chemicals Agency. 2008 Guidance on information requirements and chemical safety assessment.
2. Product Information: VENTOLIN(R) HFA inhalation aerosol, albuterol sulfate HFA inhalation aerosol. GlaxoSmithKline, Research Triangle Park, NC, 2008. Prod Info PROAIR HFA(R) inhalation aerosol, 2008
3. Colwyn TC. AH3365F: Determination of Physico-Chemical Properties. Report No. 94/GLX139/0366. Pharmaco Life Science Research Laboratories, November 1994.
4. Colwyn TC. AH3365F: Determination of Hydrolysis as a Function of pH. Report No. 94/GLX140/0202. Pharmaco Life Science Research Laboratories, November 1994.
5. Jenkins WR. AH3365F: Activated Sludge – Respiration Inhibition Test. Report No. 93/GLX141/1050. Pharmaco Life Science Research Laboratories, January 1995.
6. Jenkins CA. AH3365F: Acute Toxicity to Daphnia magna. Report No. 93/GLX142/0028. Pharmaco Life Science Research Laboratories, December 1994.
7. Jenkins WR. AH3365F: Biotic Degradation with Acclimatised Composite Inoculum- Modified Sturm Test. Report No. 93/GLX143/1128. Pharmaco Life Science Research Laboratories, January 1995.

8. O’Connor J. AH3365F: Aerobic Biodegradation in Soil. Report No. 95/GLX145/0118. Pharmaco Life Science Research Laboratories, February 1995.
9. Wetton PM. Salbutamol: Daphnid, Ceriodaphnia dubia Survival and Reproduction Test. Report No. 1127/0952. Safepharm Laboratories Limited, March 2006.