

Aerius®

MSD

Filmdragerad tablett 5 mg
(ljusblå, rund, märkt SP)

Antihistamin - H1 -antagonist

Aktiv substans:

Desloratadin

ATC-kod:

R06AX27

Läkemedel från MSD omfattas av Läkemedelsförsäkringen.

Läkemedlet distribueras också av företag som inte omfattas av Läkemedelsförsäkringen, se Förpackningar.

MR F_f

Miljöpåverkan

Desloratadin

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

Nedbrytning: Desloratadin är potentiellt persistent.

Bioackumulering: Desloratadin har låg potential att bioackumuleras.

Detaljerad miljöinformation

Detailed background information

Environmental Risk Classification

Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

$$PEC (\mu\text{g/L}) = (A \cdot 10^9 \cdot (100-R)) / (365 \cdot P \cdot V \cdot D \cdot 100) = 1.5 \cdot 10^{-6} \cdot A(100-R)$$

$$PEC = 0.049 \mu\text{g/L}$$

Where:

A = 329 kg (total sold amount API in Sweden year 2016, data from QuintilesIMS).

R = 0 % removal rate (worst case assumption)

P = number of inhabitants in Sweden = $9 \cdot 10^6$

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

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

Predicted No Effect Concentration (PNEC)

Ecotoxicological studies

Crustacean, water flea (*Daphnia magna*):

Acute toxicity

EC₅₀ 48h = 9600 µg/L (endpoint: immobilization; FDA 4.08) (Ref. II)

Chronic toxicity

NOEC 21d = 480 µg/L (endpoint: mean total length; OECD 211) (Ref. III)

Bluegill Sunfish (*Lepomis macrochirus*):

Acute toxicity

LC₅₀ 96h = 9200 µg/L (endpoint: mortality; FDA 4.11) (Ref. IV)

Fathead minnow (*Pimephales promelas*)

Chronic Toxicity

NOEC 21d = 480 µg/L (endpoints: reproduction and growth; OECD 211) (Ref V)

Green Algae (*Pseudokirchneriella subcapitata*):

Acute toxicity

LC₅₀ 72h = 1600 µg/L (endpoint: growth; OECD 201) (Ref. VI)

Chronic Toxicity

NOEC = 360 µg/L (endpoint: growth; OECD 201) (Ref. VI)

PNEC = 36 µg/L (360 µg/L / 10 based on the most sensitive chronic NOEC for the green algae and an assessment factor (AF) of 10)

Environmental Risk Classification (PEC/PNEC ratio)

PEC/PNEC = $0.049/36 = 1.4 \times 10^{-3}$, i.e. $PEC/PNEC \leq 0.1$ which justifies the phrase "Use of desloratadine has been considered to result in insignificant environmental risk."

Degradation

Biotic degradation

Degradability:

The degradability of desloratadine was determined using the carbon dioxide evolution method (FDA 3.11). Flasks of 0.098 mg/mL of desloratadine were incubated aerobically in the dark for a period of 28 days. The day 28 mean cumulative ¹⁴CO₂ evolved from aqueous media dosed with ¹⁴C-desloratadine was 0.0% of the initial ¹⁴C-desloratadine applied and the mean cumulative ¹⁴C-volatile organic products evolved from the

aqueous media dosed with ^{14}C -desloratadine was also 0.0% of the initial ^{14}C -desloratadine applied. Mass balance at the end of the experiment ranged from 93.3 to 100.6%. Based on these results, desloratadine did not degrade under laboratory conditions during this study. Therefore an exact half-life could not be determined and is, therefore, estimated to be greater than 28 days (Ref VII).

Sediment Transformation:

The degradation of desloratadine was determined according to OECD 308B. The DT50 for the total water/sediment system was determined to be 193 to 433 days (Ref VIII).

Abiotic degradation

Hydrolysis:

Desloratadine is hydrolytically stable with greater than 90% of the initial concentrations remaining after 5 days at 50°C. It has a half-life of greater than 1 year at 25°C (FDA 3.09) (Ref. IX)

Justification of chosen degradation phrase:

Desloratadine is not considered degradable, thus the phrase "desloratadine is potentially persistent" is chosen.

Bioaccumulation

Partitioning coefficient:

$\log K_{ow} = 1.24$ at pH 7 (Shake Flask Method; OECD 107) (Ref. X)

Justification of chosen bioaccumulation phrase:

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

References

I.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

II.Springborn Laboratories, Inc, 1993. "SCH 34117 - Acute Toxicity to Daphnids (Daphnia magna) Under Static Conditions," Study No. 1560.0592.6199.110, SLI, Wareham, MA, 21 January 1993.

III.Smithers Viscient, 2012. "Desloratadine - Full Life-Cycle Toxicity Test with Water Fleas, Daphnia magna, Under Static Renewal Conditions, Following OECD Guideline 211," Study No. 359.6487, SV, Wareham, MA, USA, 13 February 2012.

IV.Springborn Laboratories, Inc, 1993. "SCH 34117 - Acute Toxicity to Bluegill Sunfish (Lepomis macrochirus) Under Static Renewal Conditions," Study No. 1560.0592.6198.100, SLI, Wareham, MA, 21 January 1993.

V.Smithers Viscient, 2012. "Desloratadine - Early Life-Stage Toxicity Test with Fathead Minnow, Pimephales promelas, Following OECD Guideline #210," Study No. 359.6488, SV, Wareham, MA, USA, 05 July 2012.

VI.Smithers Viscient, 2012. "Desloratadine - 72-Hour Acute Toxicity Test with Freshwater Green Alga, Pseudokirchneriella subcapitata, Following OECD Guideline 201," Study No. 359.6486, SV, Wareham, MA, USA, 06 January 2012.

VII.Springborn Laboratories, Inc, 1993. "SCH 34117 - Aerobic Biodegradation in Water," Study No. 1560.0592.6200.725, SLI, Wareham, MA, 21 January 1993.

VIII.Smithers Viscient, 2011. "[^{14}C]Desloratadine - Aerobic Transformation in Aquatic Sediment Systems Following OECD Guideline 308B," Study No. 359.6485, SV, Wareham, MA, USA, 01 December 2011.

IX.Springborn Laboratories, Inc, 1993. "SCH 34117 - Determination of Aqueous Hydrolysis Rate Constant and Half-Life," Study No. 1560.0592.6184.715, SLI, Wareham, MA, 21 January 1993.

X.Smithers Viscient, 2012. "Desloratadine - Determining the Partitioning Coefficient (n-Octanol/Water) by the Shake Flask Method Following OECD Guideline 107," Study No. 359.6483, SV, Wareham, MA, USA, 08 March 2012.