

Aerius®

MR Ff

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.

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:

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

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

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 = $9 * 10^6$

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 = 1.4x10⁻³, i.e. PEC/PNEC ≤ 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 $^{14}\text{C}\text{O}_2$ evolved from aqueous media dosed with ^{14}C -desloratadine was 0.0% of the initial ^{14}C -desloratadine applied and the mean cumulative ^{14}C -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:

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

Justification of chosen bioaccumulation phrase:

Since $\text{log } K_{ow} < 4$, 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_
- 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. "[14C]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.