

Clindamycin Orifarm

M R F

Orifarm Generics AB

Kapsel, hård 300 mg

(vita hårda kapslar med märkningen "CLIN 300" på kapselstommen.)

Linkosamider

Aktiv substans:

Klindamycin

ATC-kod:

J01FF01

Läkemedel från Orifarm Generics AB omfattas av Läkemedelsförsäkringen.

Miljöpåverkan

Miljöinformationen för klindamycin är framtagen av företaget GlaxoSmithKline för Duac®

Miljörisk: Risk för miljöpåverkan av klindamycin kan inte uteslutas då ekotoxikologiska data saknas.

Nedbrytning: Det kan inte uteslutas att klindamycin är persistent, då data saknas.

Bioackumulering: Klindamycin har låg potential att bioackumuleras.

Detaljerad miljöinformation

Environmental Risk Classification

Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

$$PEC (\mu\text{g/L}) = (A \cdot 10^9 \cdot (100 - R)) / (365 \cdot P \cdot V \cdot D \cdot 100) = 1.37 \cdot 10^{-6} \cdot A \cdot (100 - R)$$

$$PEC = 0.144 \mu\text{g/L}$$

Where:

A = 1,049.85 kg (total sold amount API in Sweden year 2020, data from IQVIA). Total volume of Clindamycin phosphate = 79.07 = 66.42 clindamycin free base. Total volume of Clindamycin hydrochloride 983.43 = 904.66 clindamycin free base. Total volume of Clindamycin palmitate hydrochloride = 17.63 = 10.83 clindamycin free base. Total Clindamycin = 66.42 + 983.43 + 10.83 = 1,049.85.

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 = $10 \cdot 10^6$

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

Green Algae (Pseudokirchneriella subcapitata):

EC50 (inhibition of growth rate) = 4.1 µg/L (OECD 201) (Reference 3)

EC10 = 0.98 µg/L

Water flea (Daphnia magna):

Acute toxicity

No data

NOEC = 1,000,000 µg/L

Chronic toxicity

No data

Fish:

Acute toxicity

No data

Chronic toxicity

No data

Other ecotoxicity data:

Microorganisms in activated sludge:

No data

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 clindamycin cannot be excluded, since there is not sufficient ecotoxicity data available.

Degradation

Biotic degradation

Ready degradability:

No data

Inherent degradability:

No data

Abiotic degradation

Hydrolysis:

No data

Photolysis:

No data

Justification of chosen degradation phrase:

The phrase "The potential for persistence of Clindamycin is cannot be excluded, due to lack of data" is thus chosen.

Bioaccumulation

Partitioning coefficient:

Log Dow_{calc} at pH 5 = -1.47 (QSAR) (Reference 4)

Log Dow_{calc} at pH 7 = 0.38

Log Dow_{calc} at pH 9 = 1.02

Justification of chosen bioaccumulation phrase:

Since log Kow < 4 at pH 7, the substance has a low potential for bioaccumulation.

Excretion (metabolism)

In an open-label study of 24 patients with moderate-to-severe acne vulgaris, approximately 4 grams of Duac Once Daily 10 mg/g + 30 mg/g Gel was applied once daily for 5 days to the face, upper chest, upper back, and shoulders. Geometric mean maximal plasma clindamycin exposure (C_{max}) on Day 5 was 0.961 ng/mL with an AUC_∞ of 12.9 ng*hr/mL.

In a maximised percutaneous absorption study the mean plasma clindamycin levels during a four-week dosing period for clindamycin 10 mg/g + benzoyl peroxide 50 mg/g gel were negligible (0.043 % of applied dose). (Reference 2).

PBT/vPvB assessment

Clindamycin does not fulfil the criteria for PBT and/or vPvB

All three properties, i.e. 'P', 'B' and 'T' are required in order to classify a compound as PBT (Reference 1). Clindamycin 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. Pharmacokinetic properties: Metabolism and Elimination. Summary of Product Characteristics DUAC once Daily 10mg/g and 30mg/g Gel. Stiefel, March 2018.
3. https://www.amrindustryalliance.org/wp-content/uploads/2018/09/AMR_Industry_Alliance_List-of-Predicted
4. Instant J Chem Log P and LogD. Sep 2012. Chemaxon Inc.

