FASS

Pevisone (Parallellimporterat)

Orifarm

Kräm 1 mg/g + 10 mg/g

Inga avvikelser.

Antimykotikum med brett spektrum + medelstark (Grupp II) glukokortikoid

Visa information om det parallellimporterade läkemedlet

Aktiva substanser:
Ekonazol
Triamcinolonacetonid

ATC-kod:
D01AC20

Läkemedel från Orifarm omfattas av Läkemedelsförsäkringen.

Miljöpåverkan

Miljöinformationen för ekonazol är framtagen av företaget Janssen för Pevaryl, Pevaryl®, Pevisone®

Miljörisk: Användning av ekonazol har bedömts medföra låg risk för miljöpåverkan.
Nedbrytning: Det kan inte uteslutas att ekonazol är persistent, då data saknas.
Bioackumulering: Det kan inte uteslutas att ekonazol kan bioackumuleras, då data saknas.

Detaljerad miljöinformation

1. PREDICTED ENVIRONMENTAL CONCENTRATION (PEC):
The Predicted Environmental Concentration is calculated using the following formula:

PEC (µg/L) = $A \times 10^9 \times (100 - R) / 365 \times P \times V \times D \times 100$

Where:

A (kg/year)	=	301.6933 kg (total sold amount API in the most recent sales data for Sweden (2017) was distributed by IQVIA / LIF in 2018)
R (%)	=	removal rate (due to loss by adsorption to sludge particles, by volatilization, hydrolysis or biodegradation)
	=	0% (worst-case scenario: no removal)
P	=	number of inhabitants in Sweden (9 x 10^6)
V (L/day)	=	volume of waste water per capita and day
	=	200 (ECHA default) [1]
D	=	factor for dilution of waste water by surface water flow
	=	10 (ECHA default) [1]
PEC (µg/L)	=	0.0459 µg/L

2. PREDICTED NO EFFECT CONCENTRATION (PNEC):

2.1. Ecotoxicological studies

2.1.1 Algae

Growth inhibition test with the green algae *Pseudokirchneriella subcapitata* (OECD 201) [2]:

E_rC_{50} 72 h = 0.17 mg/L

$NOEC_r$ 72 h = 0.034 mg/L

2.1.2 Crustacean

Acute Toxicity to water fleas *Daphnia magna* (OECD 202) [3]:

EC_{50} 48 h = 0.26 mg/L

NOEC 48h < 0.053 mg/L (immobilization)

2.1.3 Fish

Acute Toxicity to Zebra fish (*Brachydanio rerio*) (OECD 203) [4]:

LC_{50} 96 h = 0.23 mg/L

NOEC 96h = 0.16 mg/L (Mortality)

2.2. Calculation of Predicted No Effect Concentration (PNEC)

PNEC (µg/l) = lowest EC_{50}/1000, where 1000 is the assessment factor used.

The EC_{50} for the green alga *Pseudokirchneriella subcapitata* has been used, as this was the most sensitive of the three species tested (algae, water flea and fish). No NOEC values were used to derive the PNEC as they were statistically calculated and not experimentally derived.

PNEC = 0.17 mg/L / 1000 = 0.17 µg/L ≈ 0.2 µg/L

2.3. Environmental risk classification (PEC/PNEC ratio)

PEC/PNEC = 0.0459 µg/L / 0.2 µg/L = 0.2296, i.e. 0.1 < PEC/PNEC ≤ 1

Conclusion for environmental risk:

Use of econazole and econazole nitrate has been considered to result in low environmental risk.

3. DEGRADATION

No data available.
The potential for persistence of econazole and econazole nitrate cannot be excluded, due to lack of data.

4. BIOACCUMULATION

No data available.
The potential for persistence of econazole and econazole nitrate cannot be excluded, due to lack of data.

5. REFERENCES

1. 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
2. Kirkwood A.; Econazole nitrate - 27-hour toxicity test with freshwater green alga *Pseudokirchneriella subcapitata;* Smithers Viscient Study No. 13751.6175; Janssen Study No. RMD1125; January 18, 2011.
3. Sayers L.E.; Econazole nitrate – Acute toxicity to water fleas (*Daphnia magna*) under static conditions; Smithers Viscient Study No. 13751.6176; Janssen Study No. RMD1126; January 7, 2011.
4. Sayers L.E.; Econazole nitrate – Acute toxicity to zebra fish (*Brachydanio rerio*) under static-renewal conditions; Smithers Viscient Study No. 13751.6177; Janssen Study No. RMD1127; April 19, 2011.

Miljöinformationen för triamcinolonacetonid är framtagen av företaget Janssen för Pevisone®

Miljörisk: Användning av triamcinolon har bedömts medföra försumbar risk för miljöpåverkan.
Nedbrytning: Det kan inte uteslutas att triamcinolon är persistent, då data saknas.
Bioackumulering: Triamcinolon har låg potential att bioackumuleras.

Detaljerad miljöinformation

1. PREDICTED ENVIRONMENTAL CONCENTRATION (PEC):

The Predicted Environmental Concentration is calculated using the following formula:

PEC (µg/L)	=	$A \times 10^9 \times (100 - R) / 365 \times P \times V \times D \times 100$

Where:

A (kg/year)	=	8.302885 kg (total sold amount API in the most recent sales data for Sweden (2016) was distributed by QuintilesIMS in summer 2017)
R (%)	=	

		removal rate (due to loss by adsorption to sludge particles, by volatilization, hydrolysis or biodegradation)
	=	0% (worst-case scenario: no removal)
P	=	number of inhabitants in Sweden (9 x 10^6)
V (L/day)	=	volume of waste water per capita and day
	=	200 (ECHA default) [4]
D	=	factor for dilution of waste water by surface water flow
	=	10 (ECHA default) [4]
PEC (µg/L)	=	0.001263757 µg/L

2. PREDICTED NO EFFECT CONCENTRATION (PNEC)

2.1. Ecotoxicological studies

Growth inhibition test with green algae *Pseudokirchneriella subcapitata* (OECD 201) [1]:

E_bC_{50} 72 h > 10 mg/L

$NOEC_b$ ≥ 10 mg/L

E_rC_{50} 72 h > 10 mg/L

$NOEC_r$ 72 h ≥ 10 mg/L

Acute Toxicity to water fleas *Daphnia magna* (OECD 202) [2]:

EC_{50} 48 h > 10 mg/L (immobilization or lethargy)

NOEC ≥ 10 mg/L (immobilization or lethargy)

Acute Toxicity to Zebra fish (*Brachydanio rerio*) (OECD 203) [3]:

LC_{50} 96 h > 10 mg/L

NOEC ≥ 10 mg/L

2.2. Calculation of Predicted No Effect Concentration (PNEC)

PNEC (µg/l) = lowest EC_{50}/1000, where 1000 is the assessment factor used.

The EC_{50} for all three species (algae, water flea and fish) was > 10 mg/L.

PNEC = 10 mg/L / 1000 = 10 µg/L

2.3. Environmental risk classification (PEC/PNEC ratio)

PEC/PNEC = 0.001263757 µg/L / 10 µg/L = 0.0001263757, i.e. PEC/PNEC ≤ 0.1

Conclusion for Environmental Risk:

Use of the medicine has been considered to result in insignificant environmental risk.

3. DEGRADATION

3.1. Biotic degradation

No data on degradation available.

Conclusion for degradation:

The potential for persistence cannot be excluded due to lack of data.

4. BIOACCUMULATION

4.1. Partition coefficient octanol/water

The partition coefficient octanol/water is log D_{ow} = 1.16 [5]

Conclusion for bioaccumulation:

Triamcinolone has a low potential to bioaccumulate

5. REFERENCES

1. O'Brien E., Growth inhibition test with *Pseudokirchneriella subcapitata*; Smithers Viscient Study No. 1158.001.430; Janssen Study No. RMD1131; January 19, 2011
2. Biester M.A., Acute Toxicity to water fleas *Daphnia magna*; Smithers Viscient; Study No. 1158.001.110; Janssen Study No. RMD1132; January 26, 2011
3. Hasler T., Acute Toxicity to Zebra fish (*Brachydanio rerio*); Smithers Viscient; Study No. 1158.001.106; Janssen Study No. RMD1133; January 19, 2011
4. 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
5. ChemIDPlusAdvanced,RN:71195-58-9, http://chem.sis.nlm.nih.gov/chemidplus/rn/71195-58-9