

**Enstilar<sup>®</sup>****M R F****LEO Pharma**

Kutant skum 50 mikrogram/g + 0,5 mg/g

(Kutant skum. Efter sprayning bildas ett vitt till benvitt skum.)

Medel vid psoriasis. Övriga medel vid psoriasis för utvärtes bruk, kalcipotriol, kombinationer.

**Aktiva substanser:**

Betametason

Kalcipotriol (vattenfri)

**ATC-kod:**

D05AX52

Läkemedel från LEO Pharma omfattas av Läkemedelsförsäkringen.

## Miljöpåverkan

### Kalcipotriol (vattenfri)

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

Nedbrytning: Kalcipotriol är potentiellt persistent.

Bioackumulering: Kalcipotriol har hög potential att bioackumuleras.

## Detaljerad miljöinformation

### Environmental risk:

The total sale of active ingredient calcipotriol in Sweden 2014 was according to IMS Health (anhydrate + monohydrate) 47.34 kg. This cannot be correct as it is more than 50% of the total production of calcipotriol worldwide. It is likely that there is a factor 100 error and the actual sale of calcipotriol is 0.4734 kg. Anyway we have used the 47.34 kg in our calculations.

$$PEC = 1.5 \times 10^{-6} \times 47.34 \times (100-0) = 0.007 \mu\text{g/L}$$

Experimental ecotoxicity data for algae, daphnia and fish are not available. Because of the lack of data it is not possible to calculate a valid PNEC and a risk of environmental impact cannot be excluded.

### Degradation:

Calcipotriol is not readily biodegradable. It has been tested according to the test guideline OECD 301F and a biodegradation of  $-2 \pm 2\%$  was found after 28 days. (*Winther-Nielsen, OECD 301F, DHI Water & Environment, 2007*) [1]. Calcipotriol is therefore potentially persistent.

### Bioaccumulation:

LogPow, calcipotriol = 4.9 (*Lolansen, B., Calcipotriol (MC 903) Octanol/Water Partition Coefficient, LEO Pharma A/S, 2007*) [2]

As LogPow > 4 the following phrase applies: "Calcipotriol has high potential for bioaccumulation."

### References:

1. Winther-Nielsen, OECD 301F, DHI Water & Environment, 2007

2. Lolansen, B., Calcipotriol (MC 903) Octanol/Water Partition Coefficient, LEO Pharma A/S, 2007