

**Impugan<sup>®</sup>****M R F<sub>f</sub>****Teva**

Tablett 40 mg

(vita till gulaktiga, plana med delskåra 8 mm märkta CJJ)

Loop-diuretikum (kortverkande, snabbverkande),  
antihypertonikum

**Aktiv substans:**

Furosemid

**ATC-kod:**

C03CA01

Företaget omfattas av Läkemedelsförsäkringen

## Miljöpåverkan

**Miljöinformationen för furosemid är framtagen av företaget Takeda Pharma för Furix Retard, Furix<sup>®</sup>, Furosemid Nycomed**

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

Nedbrytning: Furosemid är potentiellt persistent.

Bioackumulering: Furosemid har låg potential att bioackumuleras.

# Detaljerad miljöinformation

## Environmental Risk Classification

### ***Predicted Environmental Concentration (PEC)***

PEC is calculated according to the following formula:

$$PEC (\mu\text{g/L}) = (A \cdot 10^9 \cdot (100 - R)) / (365 \cdot P \cdot V \cdot D \cdot 100) = 1,5 \cdot 10^{-6}$$

$$\cdot A(100 - R)$$

$$PEC = 0,78 \mu\text{g/L}$$

Where:

A = 5224,62 kg (total sold amount API in Sweden year 2016, data from QuintilesIMS).

R = 0% removal rate (due to loss by adsorption to sludge particles, by volatilization, hydrolysis or biodegradation) = 0 if no data is available.

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

V (L/day) = volume of wastewater per capita and day = 200 (ECHA default) (Ref.1)

D = factor for dilution of waste water by surface water flow = 10 (ECHA default) (Ref.1)

### ***Predicted No Effect Concentration (PNEC)***

*Ecotoxicological studies:*

Algae (*Pseudokirchneriella subcapitata*):

EC<sub>50</sub> 72 h = 142 mg/L (guideline OECD 201) (Ref.2)

Crustacean - Fresh water flea (*Daphnia magna*):

$EC_{50}$  48 h = 239 mg/L (guideline OECD 202) (Ref.2)

Fish - Sheepshed minnow (*Cyprinodon variegatus variegatus*):

$LC_{50}$  96 h = 497 mg/L (guideline OECD 203) (Ref.2)

PNEC = 142  $\mu$ g/L (justification of chosen assessment factor)

PNEC ( $\mu$ g/l) = lowest  $EC_{50}$ /1000 where 1000 is the assessment factor used.  $EC_{50}$  for *Pseudokirchneriella subcapitata* has been used as for this calculation since it is the most sensitive of the three tested species.

### ***Environmental risk classification (PEC/PNEC ratio)***

$PEC/PNEC = 0,78 \mu\text{g/L} / 142 \mu\text{g/L} = 5,5 \times 10^{-3}$

$PEC/PNEC < 0,1$  which justifies the phrase "Användning av läkemedlet har bedömts medföra försumbar risk för miljöpåverkan."

### **Degradation**

Test results from "closed bottle test" (OECD guideline 301D) shows that the biological degradation is 0% in 28 days (Ref. 2). There is no information regarding the metabolites.

Furosemide is potentially persistent.

### **Bioaccumulation**

Partitioning coefficient:

$\log K_{ow} \leq 0$  at pH 7, test method used to determine  $\log K_{ow}$  is a HPLC with  $C_{18}$  analytical column. (Ref.2)

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

## Referens

1. ECHA, European Chemicals Agency. 2008 Guidance on information requirements and chemical safety assessment. [http://guidance.echa.europa.eu/docs/guidance\\_document/information\\_](http://guidance.echa.europa.eu/docs/guidance_document/information_)
2. Nycomed AB, "Test Results for the Test Substance Furosemide", Report No. R 196-05, date 2005-06-14.