FASS

# Corotrop

**Sanofi AB**

Injektionsvätska, lösning 1 mg/ml
(klar, färglös eller svagt gul lösning)

Medel vid hjärtsvikt

**Aktiv substans:**
Milrinon

**ATC-kod:**
C01CE02

Läkemedel från Sanofi AB omfattas av Läkemedelsförsäkringen.

## Miljöpåverkan

### Milrinon

Miljörisk: Risk för miljöpåverkan av milrinon kan inte uteslutas då ekotoxikologiska data saknas.
Nedbrytning: Milrinon är potentiellt persistent.
Bioackumulering: Milrinon har låg potential att bioackumuleras.

**Detaljerad miljöinformation**

**Environmental Risk Classification**
**Predicted Environmental Concentration (PEC)**
PEC is calculated according to the following formula:

PEC (µg/L) = $(A*10^{9}*(100-R))/(365*P*V*D*100) = 1.37*10^{-6}*A*(100-R)$

PEC = $5.48*10^{-6}$ µg/L

Where:
A = 0.04 kg (total sold amount API in Sweden year 2020, data from IQVIA)
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 = $10*10^{6}$
V (L/day) = volume of wastewater per capita and day = 200 ECHA default) (Ref. I)

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

## Predicted No Effect Concentration (PNEC)

### Ecotoxicological studies

No ecotoxicological test results are available.

## Environmental risk classification (PEC/PNEC ratio)

The PEC/PNEC ratio could not be determined since no ecotoxicological test results are available.

According to the European Medicines Agency guideline on environmental risk assessment of medicinal products (EMA/CHMP/SWP/4447/00), use of milrinone is unlikely to represent a risk for the environment, because the predicted environmental concentration (PEC) is below the action limit of 0.01 µg/L.

*Justification of chosen summary phrases for the environmental risk:*
Risk of environmental impact of milrinone cannot be excluded, since no ecotoxicity data are available.

### Degradation

### Biotic degradation

*Ready degradability:*
Milrinone is potentially persistent as indicated by a 2.1 % biodegradation in 28 days. (FDA 3.11)
(Ref. II)

*Chosen degradation phrase:*
Milrinone is potentially persistent.

### Bioaccumulation

*Partitioning coefficient:*
logP = 1.04; 0.33 (predicted (ALOGPS; ChemAxon, respectively)
(Ref. III)

*Justification of chosen bioaccumulation phrase:*
Since logP < 4, milrinone has low potential for bioaccumulation.

### Excretion (metabolism)

Milrinone is mainly excreted in the urine, mainly in unchanged form (83 %) and to a lesser extent as inactive O-glucuronide (12 %). A small amount is excreted via faeces. In healthy subjects, 60 % of the dose was found in the urine within 2 hours supply and within the first 8 hours 90 % were found.
(Ref. IV)

### References


I. ECHA, European Chemicals Agency. 2008 Guidance on information requirements and chemical safety assessment; find here.
II. Internal report, Sterling Winthrop: Milrinone: CO2 Production Test, March 1992. Report number not available.
III. Milrinone at Drug Bank, retrieved 2021-12-13 from Drug Bank.com; find here
IV. SmPC of Corotrop, retrieved 2021-12-13 from SE MPA; find here.