

Urografin[®]

M**Bayer**

Lösning för intravesikal användning 145 mg l/ml

Avregistreringsdatum: 2008-04-30 (Tillhandahålls ej)

Röntgenkontrastmedel

Aktiv substans:

Amidotrizoinsyra

ATC-kod:

V08AA01

För information om det avregistrerade läkemedlet omfattas av Läkemedelsförsäkringen, kontakta Läkemedelsförsäkringen.

Läs mer om avregistrerade läkemedel

Miljöpåverkan

Amidotrizoinsyra

Miljörisk: Risk för miljöpåverkan av amidotrizoinsyra kan inte uteslutas då det inte finns tillräckliga ekotoxikologiska data.

Nedbrytning: Amidotrizoinsyra är potentiellt persistent.

Bioackumulering: Amidotrizoinsyra har låg potential att bioackumuleras.

Detaljerad miljöinformation

Environmental Risk Classification

Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

$$\text{PEC } (\mu\text{g/L}) = (A \cdot 10^9 \cdot (100 - R)) / (365 \cdot P \cdot V \cdot D \cdot 100) = 1.37 \cdot 10^{-6}$$
$$A \cdot (100 - R) = 0.15 \mu\text{g/L}$$

Where:

A = 958.32 kg (meglumine salt) + 145.2 kg (sodium salt) = 1103.52 kg (total sold amount API in Sweden year 2021, data from IQVIA / LIF)

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 = $10 \cdot 10^6$

V (L/day) = volume of wastewater per capita and day = 200 (ECHA default) (Reference I)

D = factor for dilution of wastewater by surface water flow = 10 (ECHA default) (Reference I)

Predicted No Effect Concentration (PNEC)

Ecotoxicological studies

Both studies detailed below were conducted with the amidotrizoate meglumine salt.

Crustacean (waterflea, Daphnia magna):

Acute toxicity

EC₅₀ 48 hours (immobilization) ≥ 100 mg/L. Guideline OECD 202.

(Reference II)

Bacteria (*Pseudomonas putida*)

EC₅₀ 16 hours (growth) > 1000 mg/L. Guideline DIN38412 L8.

(Reference III)

The available ecotoxicological data is insufficient for PNEC derivation.

Environmental risk classification (PEC/PNEC ratio)

Due to limited ecotoxicological data it is not possible to derive the risk quotient (PEC/PNEC).

Justification of chosen environmental risk phrase:

Insufficient data to calculate the PEC/PNEC ratio qualifies for the phrase "Risk of environmental impact of amidotrozoic acid cannot be excluded, since there is not sufficient ecotoxicity data available."

Degradation

Biotic degradation

Ready degradability:

The test compound (meglumin amidotrizoate) was studied for ready biodegradability in a test conducted over 28 days. Total biodegradation reached 19 % at day 3 and was attributed to meglumine, as specific chemical analysis of amidotriazoate did not reveal any biodegradation. Hence, the study reported 0 % biodegradation of amidotrizoic acid in 28 days. Guideline OECD 301E. (Reference IV)

Justification of chosen degradation phrase:

Amidotrozoic acid was assessed to be not readily biodegradable, which qualifies for the phrase "Amidotrozoic acid is potentially persistent."

Bioaccumulation

Partitioning coefficient:

The partitioning coefficient of amidotrizoic acid was reported in the pubchem database as estimated with the US EPA EPI Suite, v4.1. The log D_{ow} was reported with 1.37 (Reference V)

Justification of chosen bioaccumulation phrase:

As the log D_{ow} was < 4 amidotrozoic acid is not considered bioaccumulative which qualifies for the phrase "Amidotrozoic acid has low potential for bioaccumulation."

Excretion (metabolism)

Amidotrizoate meglumine/sodium salt is excreted unmetabolized as the parent compound. (Reference VI).

References

- I. Guidance on information requirements and Chemical Safety Assessment Chapter R.16: Environmental exposure assessment. V3.0, Feb. 2016.
- II. Acute immobilization test of ZK2336/Megl. to *Daphnia magna* (limit test). Schering AG, Experimental Toxicology, Report no. 8944, Study no. TX89378.
- III. Growth inhibition test of meglumin amidotrizoate on the bacterium *Pseudomonas putida*. Schering AG, Experimental Toxicology, Report no. 9193, Study no. TX90151.
- IV. Study on the biodegradability of meglumin amidotrizoate, iohexol and iopromid according to the modified OECD Screening Test. Schering AG, Experimental Toxicology, Report no. 9170, Study no. TX90105.
- V. Pubchem database. LogP estimation of amidotrizoic acid based on US EPA EPI Suite, v4.1.

VI. Bourin M, Jolliet P, Ballereau F. An overview of the clinical pharmacokinetics of x-ray contrast media. Clin Pharmacokinet Mar;32(3):180-93.