

Metvix®

Galderma Nordic

Kräm 160 mg/g

(gräddfärgad till svagt gul)

M R F

Medel vid tumörsjukdomar

Aktiv substans:

Metylaminolevulinat

ATC-kod:

L01XD03

Läkemedel från Galderma Nordic omfattas av Läkemedelsförsäkringen.

Miljöpåverkan

Metylaminolevulinat

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

Nedbrytning: Det kan inte uteslutas att metylaminolevulinat är persistent, då data saknas.

Bioackumulering: Metylaminolevulinat har låg potential att bioackumuleras.

Detaljerad miljöinformation

Environmental Risk Classification

Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

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

$$\text{PEC} = 4,28 \cdot 10^{-4} \mu\text{g/L}$$

Where:

A = 3,1212 kg (total sold amount API in Sweden year 2022, data from IQVIA)

R = 0 (No data for the removal rate 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 1)

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

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

Environmental risk classification (PEC/PNEC ratio)

Absence of dedicated environmental data justifies the phrase "Risk of environmental impact of methyl aminolevulinat cannot be excluded, since no ecotoxicity data are available".

Degradation

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

No systemic study on the degradation or biodegradation of methyl aminolevulinate hydrochloride has been carried out. In absence of OECD 301-, 302- or 308-studies or abiotic studies, the substance should be regarded as potentially persistent. Methyl aminolevulinate is a methyl ester of 5-aminolevulinic acid (ALA). ALA is abundant in the biosphere and an endogenous compound in all living cells.

Bioaccumulation

Partitioning coefficient:

$\log D_{ow} = -1.93$ at pH 7.4 (OECD 107) (Reference 2).

Justification of chosen bioaccumulation phrase:

Since $\log D_{ow} < 4$ at pH 7.4, the substance has low potential for bioaccumulation.

References

1. ECHA, European Chemicals Agency. 2008 Guidance on information requirements and chemical safety assessment.
2. GALDERMA/VITAS Analytical Services. Determination of Log Dow for MAL HCl in a pH range 4.3 to 8.1. Dahlgren A. et al, 2014. Analytical Report 289 Rev 2.