FASS

Brenoxal®

Janssen

Depotkapsel, hård 8 mg + 16 mg

Avregistreringsdatum: 2008-06-30 (Tillhandahålls ej)

Aktiv substans:

Galantamin

ATC-kod:

N06DA04

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

Läs mer om avregistrerade läkemedel

Miljöpåverkan

Galantamin

Miljörisk: Användning av galantamin har bedömts medföra försumbar risk för miljöpåverkan.
Nedbrytning: Galantamin är potentiellt persistent.
Bioackumulering: Det kan inte uteslutas att galantamin kan bioackumuleras, då data saknas.

Detaljerad miljöinformation

1. PREDICTED ENVIRONMENTAL CONCENTRATION (PEC):

The Predicted Environmental Concentration is calculated using the following formula:

$PEC\ (\mu g/L) = A \times 10^9 \times (100 - R) / 365 \times P \times V \times D \times 100$

Where:

A (kg/year)	=	37.23215939kg (total sold amount API in the most recent sales data for Sweden (2016) was distributed by QuintilesIMS in summer 2017))
R (%)	=	

		removal rate (due to loss by adsorption to sludge particles, by volatilization, hydrolysis or biodegradation)
	=	0% (worst-case scenario: no removal)
P	=	number of inhabitants in Sweden (9 x 10^6)
V (L/day)	=	volume of waste water per capita and day
	=	200 (ECHA default) [6]
D	=	factor for dilution of waste water by surface water flow
	=	10 (ECHA default) [6]
PEC (µg/L)	=	0.005666995 µg/L

2. PREDICTED NO EFFECT CONCENTRATION (PNEC):

2.1. Ecotoxicological studies

2.1.1. Algae

Green algae (*Selenastrum capricornutum*) (OECD 201) [1]:

E_bC_{50} 72 h (biomass) > 100 mg/L

$NOEC_b$ (biomass) = 10 mg/L

E_rC_{50} 72 h (growth) > 100 mg/L

$NOEC_r$ (growth) = 32 mg/L

2.1.1. Crustacean

Acute

Acute Toxicity to water-flea (*Daphnia magna*) (OECD 202) [3]:

EC_{50} 48 h (immobilization) = 0.44 mg/L

Chronic

Not available

2.1.1. Fish

Acute

Acute toxicity to zebra fish (*Brachydanio rerio*) (OECD 203) [2]:

LC_{50} 96 h (Mortality) = 32 mg/L

NOEC (Mortality) = 10 mg/L

Chronic

Not available

2.1.1. Other ecotoxicity data

Activated sludge respiration inhibition test (OECD 209) [4]:

EC_{50} 3 h > 1000 mg/L

NOEC = 286 mg/L

2.2. Calculation of Predicted No Effect Concentration (PNEC)

PNEC (µg/L) = lowest EC_{50}/1000, where 1000 is the assessment factor used. EC_{50} for Daphnia magna (0.44 mg/L) has been used for this calculation since it is the most sensitive of the three tested species.

PNEC = 0.44 mg/L/1000 = 0.44 µg/L

2.3. Environmental risk classification (PEC/PNEC ratio)

PEC/PNEC = 0.005666995 µg/L / 0.44 µg/L = 0.012879535 i.e. PEC/PNEC ≤ 0.1

Since PEC/PNEC ≤ 0.1, Galantamine Hydrobromide has been considered to result in insignificant environmental risk.

Conclusion for environmental risk:

Use of Galantamine Hydrobromide has been considered to result in insignificant environmental risk.

3. DEGRADATION

Galantamine Hydrobromide is not readily biodegradable in a biodegradability test according to OECD No. 301 B: “Biodegradation test – CO2 evolution ” [5].

On the basis of the titration results can be concluded that Galantamine Hydrobromide is not readily biodegradable, since the pass level of 60% was not reached after an exposure period of 28 days. Consequently, the medicine is potentially persistent.

Conclusion for degradation:

Galantamine Hydrobromide is potentially persistent

4. BIOACCUMULATION

4.1 Partition coefficient octanol/water

No data available.

4.2 Bioconcentration

No data available.

Conclusion for bioaccumulation:

The potential for bioaccumulation of Galantamine Hydrobromide cannot be excluded, due to lack of data..

5. PBT-ASSESSMENT

	PBT-criteria	Results for Galantamine Hydrobromide
P	DT_{50} freshwater > 40 days or DT_{50} sediment > 120 days	-
B	BCF > 2000	-
T	Chronic NOEC < 0.01 mg/L or CMR or endocrine disrupting	$NOEC_{algae}$ = 10 mg/L $NOEC_{fish}$ = 10 mg/L

The PBT-criteria are not fulfilled. Therefore, Galantamine Hydrobromide is not considered a PBT-substance.

6. REFERENCES

1. Batscher R., Galantamine HBR (R0113675): Toxicity to *Scenedesmus subpicatus* in a 72-Hour Algal Growth Inhibition Test; RCC Study No. A35111; Janssen Study No. RMD706; February 6, 2006.
2. Batscher R., Galantamine HBR (R0113675): Acute Toxicity to Zebra Fish (*Brachydanio rerio*) in a 96-Hour Static Test; RCC Study No. A35133; Janssen Study No. RMD707; February 6, 2006.
3. Woensel M., Van Baelen S., Vos E., The Acute Toxicity of Galantamine HBr (R113675) In The Water-Flea *Daphnia magna*; Janssen Study No. ASKD1/0007. January 19, 1998.
4. Büche C., Galantamine HBR (R0113675): Toxicity to Activated Sludge in a Respiration Inhibition Test; RCC Study No. A35155; Janssen Study No. RMD708; March 2, 2006.
5. Van Baelen S., Vos E., Woensel M., The Biodegradability of Galantamine HBr (R113675) CO_2 Evolution Test; Janssen Study No. BDAS/0074. November 25, 1997.
6. ECHA, European Chemicals Agency. 2008 Guidance on information requirements and chemical safety assessment. http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm