FASS

Risperdal (Parallellimporterat)

Cross Pharma AB

Filmdragerad tablett 4 mg

Avregistreringsdatum: 2009-03-31 (Tillhandahålls ej)

Tabletterna är märkta Ris 4 på ena sidan och Janssen på den andra.

Neuroleptikum

Visa information om det parallellimporterade läkemedlet

Aktiv substans:

Risperidon

ATC-kod:

N05AX08

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

Läs mer om avregistrerade läkemedel

Miljöpåverkan

Miljöinformationen för risperidon är framtagen av företaget Janssen för Belivon, Risperdal, Risperdal Consta, Risperdal®

Miljörisk: Användning av risperidon har bedömts medföra försumbar risk för miljöpåverkan.
Nedbrytning: Risperidon är potentiellt persistent.
Bioackumulering: Risperidon har låg potential att bioackumuleras.

Detaljerad miljöinformation

1. PREDICTED ENVIRONMENTAL CONCENTRATION (PEC):

The Predicted Environmental Concentration is calculated according to the following formula:

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

Where:

A (kg/year)	=	total actual API sales in Sweden for the most recent year 15.2176 kg (Sales from 2015 – IMS Health) [8]
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 (9×10^6)

V (L/day)	=	volume of waste water per capita and day
	=	200 (ECHA default) [7]
D	=	factor for dilution of waste water by surface water flow
	=	10 (ECHA default) [7]
PEC (µg/L)	=	0.0023 µg/L

2. PREDICTED NO EFFECT CONCENTRATION (PNEC)

2.1. Ecotoxicological studies

2.1.1. Algae

Algal growth inhibition test with the green alga (*Selenastrum capricornutum*) (OECD 201) [1]:

EC_{50} 72 h = 26 mg/L (Inhibition of growth)

2.1.2. Crustacean

Acute

The Acute Toxicity of risperidone to the Water-flea (*Daphnia magna*) (FDA 4.08) [2]:

EC_{50} 48 h = 6 mg/L (Immobilization)

Chronic

Not available

2.1.3. Fish

Acute

The Acute Toxicity of risperidone to the Bluegill sunfish (*Lepomis macrochirus*) (FDA 4.00) [3]:
LC_{50} 96 h = 5.8 mg/L (Survival)

Chronic
Not available

2.1.4. Other ecotoxicity data
Toxicity to activated sludge in a respiration inhibition test (OECD 209) [4]:
EC_{50} 3 h > 1000 mg/L (OECD 209)
NOEC = 47 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 the Bluegill sunfish 5.8 mg/L has been used for this calculation since it is the most sensitive of the three tested species.

PNEC = 5.8 mg/L/1000 = 5.8 µg/L

2.3. Environmental risk classification (PEC/PNEC ratio)
PEC/PNEC = 0.0023/5.8 = 0.0004 i.e. PEC/PNEC ≤ 0.1

Conclusion for environmental risk:
The calculated PEC/PNEC ratio is ≤ 1. Hence, risk assessment procedures would indicate that Risperidone would have insignificant long-term risk to the environment. This medicine is potentially persistent and has no significant bioaccumulation potential

3. DEGRADATION

3.1. Biotic degradation

3.1.1. Ready biodegradation

Biodegradability in a CO_2-evolution test (FDA 3.11) [5]:

Based on the measurements of CO2 produced and DOC analysis, the percentage biodegradation calculated for Risperidone was 5%.

Based on the measurements of CO_2 produced and DOC analysis, the percentage biodegradation calculated for the reference substance glucose was > 60%. Consequently, it can be concluded that Risperidone is not readily biodegradable.

Conclusion for degradation:

The medicine is potentially persistent.

4. BIOACCUMULATION

4.1. Partition coefficient octanol/water

Partition coefficient octanol/water (shaking flask method) [6]:
The average apparent partition coefficient (total solute measured, regardless of from) of R064766 in 1-octanol/aqueous solution at 25°C as determined by UV spectrometry is:

- in 1-octanol/buffer pH 5: log P = 0.22
- in 1-octanol/buffer pH 7: log P = 1.67
- in 1-octanol/buffer pH 9: log P = 2.91

Conclusion for bioaccumulation:

As log P_{ow} < 4, risperidone has no significant bioaccumulation potential.

5. REFERENCES

1. Weytjens D.; The effect of risperidone on the growth of the unicellular green alga *Selenastrum capricornutum*, Janssen Pharmaceutica N.V.; Janssen Study No. AASc/0004; May 14, 1993.
2. Weytjens D.; The acute toxicity of risperidone to the water-flea (*Daphnia magna*), Janssen Pharmaceutica N.V.; Janssen Study No. ADK6/0017; February 2, 1993.
3. Weytjens D.; The Acute Toxicity of risperidone to the Bluegill sunfish (*Lepomis macrochirus*), Janssen Pharmaceutica N.V.; Janssen Study No. AFLm/0004; February 2, 1993.
4. Seyfried B.; Toxicity to activated sludge in a respiration inhibition test, RCC Ltd.; RCC Study No. A35087; Janssen Study No. RMD704; April 6, 2006.
5. Weytjens D., Biodegradability in a CO2-evolution test, Janssen Pharmaceutica N.V.; Janssen Study No. BDAS0036; January 11, 1993.
6. Van Dingenen J.; R064766: Partition coefficient; Janssen Pharmaceutica N.V., Report PC-CHAR 92-59 (921209) – R064766; December 09, 1992.
7. ECHA, European Chemicals Agency. 2008 Guidance on information requirements and chemical safety assessment. http://guidance.echa.europa.eu/docs/guidance_document/informa
8. IMS Health - 2015