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Environmental risk limits for lambda-cyhalothrin

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Rapport in het kort

Environmental risk limits for lambda-cyhalothrin

Dit rapport geeft milieurisicogrenzen voor het insecticide lambda-cyhalothrin in water en sediment. Milieurisicogrenzen zijn de technisch-wetenschappelijke advieswaarden voor de uiteindelijke milieukwaliteitsnormen in Nederland. De milieurisicogrenzen zijn afgeleid volgens de methodiek die is voorgeschreven in de Europese Kaderrichtlijn Water. Hierbij is gebruikgemaakt van de beoordeling in het kader van de Europese toelating van gewasbeschermingsmiddelen (Richtlijn 91/414/EEG), aangevuld met gegevens uit de openbare literatuur.

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Contents

1 Introduction

1.1 Background and scope of the report

In this report, environmental risk limits (ERLs) for surface water and sediment are derived for the pyrethroid insecticide lambda-cyhalothrin. The derivation is performed within the framework of the project ‘Standard setting for other relevant substances within the WFD’, which is closely related to the project ‘International and national environmental quality standards for substances in the Netherlands’ (INS). Lambda-cyhalothrin is part of a series of 25 pesticides that appeared to have a high environmental impact in the evaluation of the policy document on sustainable crop protection (‘Tussenevaluatie van de nota Duurzame Gewasbescherming’; MNP, 2006) or were selected by the Water Boards (‘Unie van Waterschappen’; project ‘Schone Bronnen’; http://www.schonebronnen.nl/).

The following ERLs are considered:

- Maximum Permissible Concentration (MPC) – the concentration protecting aquatic ecosystems and humans from effects due to long-term exposure
- Maximum Acceptable Concentration (MAC_{eco}) – the concentration protecting aquatic ecosystems from effects due to short-term exposure or concentration peaks.
- Serious Risk Concentration (SRC_{eco}) – the concentration at which possibly serious ecotoxicological effects are to be expected.

More specific, the following ERLs can be derived depending on the availability of data and characteristics of the compound:

$MPC_{eco, water}$	MPC for freshwater based on ecotoxicological data (direct exposure)
$MPC_{sp, water}$	MPC for freshwater based on secondary poisoning
$MPC_{hh food, water}$	MPC for fresh and marine water based on human consumption of fishery products
$MPC_{dw, water}$	MPC for surface waters intended for the abstraction of drinking water
$MAC_{eco, water}$	MAC for freshwater based on ecotoxicological data
$SRC_{eco, water}$	SRC for freshwater based on ecotoxicological data
$MPC_{eco, marine}$	MPC for marine water based on ecotoxicological data (direct exposure)
$MPC_{sp, marine}$	MPC for marine water based on secondary poisoning
$MAC_{eco, marine}$	MAC for marine water based on ecotoxicological data (direct exposure)

1.2 Status of the results

The results presented in this report have been discussed by the members of the scientific advisory group for the INS-project (WK-INS). It should be noted that the Environmental Risk Limits (ERLs) in this report are scientifically derived values, based on (eco)toxicological, fate and physico-chemical data. They serve as advisory values for the Dutch Steering Committee for Substances, which is appointed to set the Environmental Quality Standards (EQSs). ERLs should thus be considered as proposed values that do not have any official status.

2 Methods

The methodology for the derivation of ERLs is described in detail by Van Vlaardingen and Verbruggen (2007), further referred to as the ‘INS-Guidance’. This guidance is in accordance with the guidance of the Fraunhofer Institute (FHI; Lepper, 2005).

The process of ERL-derivation contains the following steps: data collection, data evaluation and selection, and derivation of the ERLs on the basis of the selected data.

2.1 Data collection

In accordance with the WFD, data of existing evaluations were used as a starting point. For pesticides, the evaluation report prepared within the framework of EU Directive 91/414/EC (Draft Assessment Report, DAR) was consulted (EC, 1996; further referred to as DAR). An on-line literature search was performed on TOXLINE (literature from 1985 to 2001) and Current contents (literature from 1997 to 2007). In addition to this, all potentially relevant references in the RIVM e-tox base and EPA’s ECOTOX database were checked.

2.2 Data evaluation and selection

For substance identification, physico-chemical properties and environmental behaviour, information from the List of Endpoints of the DAR was used. When needed, additional information was included according to the methods as described in Section 2.1 of the INS-Guidance. Information on human toxicological threshold limits and classification was also primarily taken from the DAR.

Ecotoxicity studies (including bird and mammal studies) were screened for relevant endpoints (i.e. those endpoints that have consequences at the population level of the test species). All ecotoxicity and bioaccumulation tests were then thoroughly evaluated with respect to the validity (scientific reliability) of the study. A detailed description of the evaluation procedure is given in the INS-Guidance (see Section 2.2.2 and 2.3.2). In short, the following reliability indices were assigned:

- Ri 1: Reliable without restriction
  ’Studies or data … generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline … or in which all parameters described are closely related/comparable to a guideline method.’
- Ri 2: Reliable with restrictions
  ’Studies or data … (mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable.’
- Ri 3: Not reliable
  ’Studies or data ... in which there are interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure (e.g., unphysiologic pathways of application) or which were carried out or generated according to a method which is not acceptable, the documentation of which is not sufficient for an assessment and which is not convincing for an expert judgment.’

- Ri 4: Not assignable
  'Studies or data … which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.).'

All available studies were summarised in data-tables, that are included as Annexes to this report. These tables contain information on species characteristics, test conditions and endpoints. Explanatory notes are included with respect to the assignment of the reliability indices.

With respect to the DAR, it was chosen not to re-evaluate the underlying studies. In principle, the endpoints that were accepted in the DAR were also accepted for ERL-derivation with Ri 2, except in cases where the reported information was too poor to decide on the reliability or when there was reasonable doubt on the validity of the tests. This applies especially to DARs prepared in the early 1990s, which do not always meet the current standards of evaluation and reporting.

In some cases, the characteristics of a compound (i.e. fast hydrolysis, strong sorption, low water solubility) put special demands on the way toxicity tests are performed. This implies that in some cases endpoints were not considered reliable, although the test was performed and documented according to accepted guidelines. If specific choices were made for assigning reliability indices, these are outlined in Section 3.3 of this report.

Endpoints with Ri 1 or 2 are accepted as valid, but this does not automatically mean that the endpoint is selected for the derivation of ERLs. The validity scores are assigned on the basis of scientific reliability, but valid endpoints may not be relevant for the purpose of ERL-derivation (e.g. due to inappropriate exposure times or test conditions that are not relevant for the Dutch situation). Endpoints from tests with formulated products were not selected if the results (expressed on the basis of the active substance) differed by more than a factor of 3 from the results obtained with the active substance itself.

After data collection and validation, toxicity data were combined into an aggregated data table with one effect value per species according to Section 2.2.6 of the INS-Guidance. When for a species several effect data were available, the geometric mean of multiple values for the same endpoint was calculated where possible. Subsequently, when several endpoints were available for one species, the lowest of these endpoints (per species) is reported in the aggregated data table.

2.3 Derivation of ERLs

For a detailed description of the procedure for derivation of the ERLs, reference is made to the INS-Guidance. With respect to the selection of the final MPC_{water}, some additional comments should be made:

2.3.1 Drinking water

The INS-Guidance includes the MPC for surface waters intended for the abstraction of drinking water ($MPC_{dw,\ water}$) as one of the MPCs from which the lowest value should be selected as the general MPC_{water} (see INS-Guidance, Section 3.1.6 and 3.1.7). According to the proposal for the daughter directive Priority Substances, however, the derivation of the AA-EQS (= MPC) should be based on direct exposure, secondary poisoning, and human exposure due to the consumption of fish. Drinking water was not included in the proposal and is thus not guiding for the general MPC value. The exact way of implementation of the $MPC_{dw,\ water}$ in the Netherlands is at present under discussion within the framework of the "AMvB Kwaliteitseisen en Monitoring Water". No policy decision has been taken yet, and the $MPC_{dw,\ water}$ is therefore presented as a separate value in this report. The MPC_{water}, is thus derived considering the individual MPCs based on direct exposure ($MPC_{eco,\ water}$), secondary poisoning

($MPC_{sp, water}$) or human consumption of fishery products ($MPC_{hh food, water}$); derivation of the latter two is dependent on the characteristics of the compound.

Related to this, is the inclusion of water treatment for the derivation of the $MPC_{dw, water}$. According to the INS-Guidance (see Section 3.1.7), a substance specific removal efficiency related to simple water treatment should be derived in case the $MPC_{dw, water}$ is lower than the other MPCs. For pesticides, there is no agreement as yet on how the removal fraction should be calculated, and water treatment is therefore not taken into account. In case no A1 value is set in Directive 75/440/EEC, the $MPC_{dw, water}$ is set to the general Drinking Water Standard of 0.1 µg/L for organic pesticides as specified in Directive 98/83/EC.

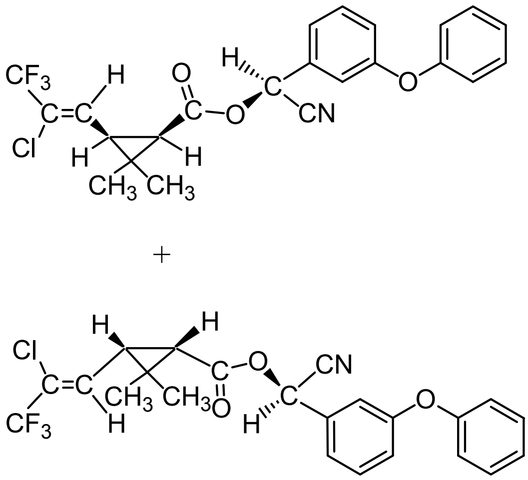
3 Derivation of environmental risk limits for lambda-cyhalothrin

3.1 Substance identification, physico-chemical properties, fate and human toxicology

3.1.1 Identity

Lambda-cyhalothrin is a 1:1 mixture of
(*S*)-α-cyano-3-phenoxybenzyl (*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate
and
(*R*)-α-cyano-3-phenoxybenzyl (*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate

(*S*) (*Z*)-(1*R*)-*cis*-



(*R*) (*Z*)-(1*S*)-*cis*-

Figure 1. Structural formula of lambda-cyhalothrin.

Table 1. Identification of lambda-cyhalothrin.

Parameter	Name or number	Source
Common name	Lambda-cyhalothrin	EC, 1996
Chemical name	1:1 mixture of (*S*)-α-cyano-3-phenoxybenzyl (*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (*R*)-α-cyano-3-phenoxybenzyl (*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate	EC, 1996
CAS number	91465-08-6	EC, 1996
EC number	Not allocated	EC, 1996
SMILES code	Cl\C(=C/[C@H]3[C@@H](C(=O)OC(C#N)c2cccc(Oc1ccccc1)c2)C3(C)C)C(F)(F)F	EC, 1996
Use class	Insecticide	EC, 1996
Mode of action	Pyrethroid: interaction with pre-synaptic sodium channels.	Tomlin, 2002
Authorised in NL	Yes	Ctgb website
Annex 1 listing	Yes	Ctgb website

3.1.2 Physico-chemical properties

Table 2. Physico-chemical properties of lambda-cyhalothrin.

Parameter	Unit	Value	Remark	Reference
Molecular weight	[g/mol]	449.9		EC, 1996
Water solubility	[mg/L]	0.004 0.005 0.004	20°C, pH 5 20°C, pH 6.5 20°C, pH 9.2	EC, 1996
pK_a	[-]	>9	No dissociation at environmentally relevant pH values	Tomlin, 2002
log K_{OW}	[-]	7	20°C	EC, 1996
log K_{OC}	[-]	5.20	Mean of 4.58, 4.68, 5.30 and 5.54	EC, 1996
Vapour pressure	[Pa]	$2x10^{-7}$	20°C, extrapolated	EC, 1996
Melting point	[°C]	49.2		EC, 1996
Boiling point	[°C]	-	No measurable boiling point (decomposes)	EC, 1996
Henry's law constant	[Pa.m^3/mol]	0.02	20°C	EC, 1996

n.a. = not applicable.

3.1.3 Behaviour in the environment

Table 3. Selected environmental properties of lambda-cyhalothrin.

Parameter	Unit	Value	Remark	Reference
Hydrolysis half-life	DT50 [d]	Stable at environmentally relevant pH values	No significant hydrolysis at pH 5.2 and 6.9. At pH 9.0, 43-45% of substance stays intact for 7 days.	EC, 1996
Photolysis half-life	DT50 [d]	13 days 4.1 hours	Water Air	EC, 1996
Readily biodegradable		Not tested		EC, 1996
Relevant metabolites		(Z)-3-(2-chloro-3,3,3-trifluoro-propenyl) 2, 2-dimethylcyclopropane-carboxylic acid; 3-phenoxybenzoic acid	> 10%	EC, 1996

3.1.4 Bioconcentration and biomagnification

An overview of the bioaccumulation data for lambda-cyhalothrin is given in Table 4.

Table 4. Overview of bioaccumulation data for lambda-cyhalothrin.

Parameter	Unit	Value	Remark	Reference
BCF (fish)	[L/kg]	1600-2240	Formulation: Karate, geomean 1893 L/kg	EC, 1996
BMF_1	[kg/kg]	10	Default value	Van Vlaardingen and Verbruggen, 2007
BMF_2	[kg/kg]	10	Default value	Van Vlaardingen and Verbruggen, 2007

3.1.5 Human toxicological threshold limits and carcinogenicity

The following human toxicological R phrases are assigned: R21, R25, R26. The R26 risk phrase is based on an acute inhalatory toxicity study in rats with a LC_{50} of 0.06 mg/L (EC, 2003).

3.2 Trigger values

This section reports on the trigger values for ERLwater derivation (as demanded in WFD framework).

Table 5. Lambda-cyhalothrin: collected properties for comparison to MPC triggers.

Parameter	Value	Unit	Method/Source	Derived at section
Log $K_{p,susp\text{-}water}$	4.20	[-]	$K_{OC} \times f_{OC,susp}$[1]	K_{OC}: 3.1.2
BCF	2240	[L/kg]		3.1.4
BMF_1	10	[kg/kg]		3.1.4
BMF_2	10	[kg/kg]		3.1.4
Log K_{OW}	7	[-]		3.1.2
R-phrases	R21, 25, 26, 50/53	[-]		3.1.5
A1 value	1.0	[µg/L]	Total pesticides	
DW Standard	0.1	[µg/L]	General value for organic pesticides	

1 $f_{OC,susp}$ = 0.1 kg_{OC}/kg_{solid} (EC, 2003).

- Lambda-cyhalothrin has a log $K_{p,\ susp\text{-}water}$ > 3; derivation of $MPC_{sediment}$ is triggered.
- Lambda-cyhalothrin has a log $K_{p,\ susp\text{-}water}$ > 3; expression of the MPC_{water} as $MPC_{susp,\ water}$ is required.
- Lambda-cyhalothrin has a BCF > 100 L/kg; assessment of secondary poisoning is triggered.
- Lambda-cyhalothrin triggers the route for human health via food (fish) consumption (BCF ≥ 100 in combination with risk phrase R21 and R25): $MPC_{hh\ food,\ water}$ should be derived.
- For lambda-cyhalothrin, no specific A1 value or Drinking Water Standard is available from Council Directives 75/440, EEC and 98/83/EC, respectively. Therefore, the general Drinking Water Standard for organic pesticides applies.

3.3 Toxicity data and derivation of ERLs for water

3.3.1 $MPC_{eco,water}$

An overview of the selected freshwater toxicity data for lambda-cyhalothrin is given in Table 6. Selected data for chronic marine toxicity is given in Table 7. Detailed toxicity data for lambda-cyhalothrin are tabulated in Appendix 1.

Table 6. Lambda-cyhalothrin: selected freshwater toxicity data for ERL derivation.

Chronic[a]		**Acute**[a]	
Taxonomic group	**NOEC/EC10 (µg/L)**	**Taxonomic group**	**L(E)C50 (µg/L)**
Algae		Algae	
Pseudokirchneriella subcapitata	> solubility	*Pseudokirchneriella subcapitata*	> solubility
Crustacea		Crustacea	
Daphnia magna	**0.002**[b]	*Asellus aquaticus*	0.0248[c]
		Cyclops sp.	0.3
		Daphnia galeata	0.117
		Daphnia magna	0.39
		Gammarus pulex	0.0242[d]
		Hyalella azteca	**0.0023**
		Ostracoda	3.3
		Proasellus coxalis	0.0177[e]
		Simocephalus vetulus	0.957
		Insecta	
		Caenis horaria	0.0136
		Chaoborus obscupires	0.0028
		Cloeon dipterum	0.0248[f]
		Corixa sp.	0.03
		Erythromma viridulum	0.493
		Ischnura elegans	0.13
		Macropelopia sp.	0.0643
		Notonecta glauca	0.0148
		Sialis lutaria	0.028
		Arachnida	
		Hydrocarina	0.047
		Pisces	
		Cyprinus carpio	0.50
		Danio rerio	1.23[g]
		Gasterosteus aculeatus	0.49
		Ictalurus punctatus	0.16
		Lepomis macrochirus	0.21
		Leucistus idus	0.08
		Onchorhynchus mykiss	0.24
		Oryzias latipes	1.60
		Pimephales promelas	0.70

[a] For detailed information see Appendix 1. Bold values are used for ERL derivation.
[b] Most relevant exposure duration (21 days), parameter reproduction for *Daphnia magna.*
[c] Most sensitive end point (immobilisation) and most relevant test duration for *Asellus aquaticus.*
[d] Most relevant exposure duration for *Gammarus pulex*.
[e] Most sensitive end point (immobilisation) and most relevant test duration for *Proasellus coxalis.*
[f] Most sensitive end point (immobilisation) and most relevant test duration for *Cloeon dipterum.*
[g] Geometric mean of 0.78 and 1.94 µg/L, parameter mortality for *Danio rerio*.

Table 7. Lambda-cyhalothrin: selected marine toxicity data for ERL derivation.

Chronic[a]		**Acute**[a]	
Taxonomic group	**NOEC/EC10 (μg/L)**	**Taxonomic group**	**L(E)C50 (μg/L)**
Pisces			
Cyprinodon variegatus	0.25		

[a] For detailed information see Appendix 1.

3.3.1.1 Treatment of fresh- and saltwater toxicity data

ERLs for freshwater and marine waters should be derived separately. For pesticides, data can only be combined if it is possible to determine with high probability that marine organisms are not more sensitive than freshwater organisms (Lepper, 2005). Since the dataset of lambda-cyhalothrin only contains one marine value for fish, combining the datasets for freshwater- and other surface waters is not possible.

3.3.1.2 Mesocosm and field studies

Various mesocosm and field studies were performed with lambda-cyhalothrin; a short summary of the results of these studies is given below. An extensive evaluation of the studies is included in Appendix 2.

- In the studies of Farmer et al. (1995) and Kedwards et al. (1999) a 7 day NOEC value for macroinvertebrates of <0.002 μg/L was found. The studies were attributed a validity of 1.
- The studies of Heckmann and Friberg (2005) and Heckmann et al. (2005) showed NOEC values between <0.305 and 0.42 μg/L for *Gammarus* densities, depending on the time post-exposure. Further, a 14 day NOEC of 0.35 μg/L for oligochaeta and *Elmis aenea* densities and a NOEC for *Gammarus pulex* mortality of 0.05 μg/L were found. These studies were attributed a validity of 1.
- The study of Lauridsen and Friberg (2005) showed a NOEC for drift of *Gammarus* of <0.01 μg/L and was attributed a validity of 2.
- The studies of Leistra et al. (2003), Roessink et al. (2005) and van Wijngaarden et al. (2006) showed 7 day NOEC values for macroinvertebrates and *Chaoborus obscuripes* of <0.01μg/L and were attributed a validity of 1.
- The studies of Hill et al. (1988 and 1994) were attributed a validity of 3.

Since all mesocosm studies use single exposure, the results of these studies are used for the derivation of the $MAC_{eco, water}$. The studies which are considered valid have NOEC values ranging from < 0.02 to 0.42 μg/L.

When lambda-cyhalothrin is monitored, it should be taken into account that the physico-chemical properties of lambda-cyhalothrin (low water solubility, high log Kow) will result in strong sorption to sediment and suspended matter and a non-homogenous distribution of the substance in the aqueous phase. This causes difficulties for the determination of the lambda-cyhalothrin concentration in the water phase in a field (or cosm) situation (e.g. the concentration of lambda-cyhalothrin in a sample taken 4 cm below the water surface can differ significantly from the concentration in a sample taken at a depth of 80 cm). Therefore, the most conservative NOEC value (< 0.002 μg/L) derived from the cosm studies is used in the derivation of the MAC.

3.3.1.3 Derivation of $MPC_{eco, water}$

Acute toxicity data are available for crustaceans, insects, arachnids and fish. Algae were tested, but no valid endpoint could be determined since effects, if present, were only observed at concentrations that

were well above water solubility (> 300 µg/L). It is considered justified to treat the data as if the base set is complete and the use of chronic toxicity data can therefore be allowed.
A chronic NOEC for *Daphnia magna* is available (0.002 µg/L), in addition, chronic tests with *Pseudokirchneriella subcapitata* show that no effects occur below the water solubility.
Based on the availability of two chronic values, an assessment factor of 50 could be used. However, the most sensitive species, *Hyallella azteca*, shows an EC_{50} value of 0.0023 µg/L). Assuming a acute to chronic ratio of 10, the NOEC for this species might potentially be lower than the lowest NOEC value (*Daphnia magna*, 0.002 µg/L). In addition, the data show that *D. magna* is over a factor of 100 less sensitive than *H. azteca* and *Chaoborus obscupires* in acute tests. Therefore, an assessment factor of 50 is considered to be insufficient for the protection of the most sensitive species, resulting in the use of an assessment factor of 100. This results in a $MPC_{eco,water}$ of 0.002 /100 = 0.00002 µg/L.

Because the base-set for marine water is incomplete; no $MPC_{eco, marine}$ can be derived.

3.3.2 $MPC_{sp, water}$ and $MPC_{sp, marine}$

Since the BCF of lambda-cyhalothrin is ≥ 100 L/kg (BCF fish is 1660-2240, Ctgb), secondary poisoning should be assessed. The lowest MPC_{oral} is 0.33 mg/kg_{food} for rats (Table 8). Subsequently, the $MPC_{sp,water}$ can be calculated using a BCF of 2240 and a BMF of 10 (section 3.1.4) and becomes 0.33/(2240 x 10) = 0.015 µg/L

Table 8. Lambda-cyhalothrin: bird and mammal toxicity data.

Species	Exposure time	Criterion	Effect concentration (mg/kg_{diet})	Assessment factor	MPCoral (mg/kg_{food})
Mouse	2 years	NOAEL	20	30	0.67
Rat	90 days	NOEL	50	90	0.56
Rat	90 days	NOAEL	50	90	0.56
Rat	**2 years**	**NOAEL**	**10**	**30**	**0.33**
Rat	Three generations	NOEL	30	30	1
Dog	1 year	NOEL	0.5	30	0.67

Because toxicity data for marine predators are generally not available, the $MPC_{oral, min}$ as derived above is used as a representative for the marine environment also. To account for the longer food chains in the marine environment, an additional biomagnification step is introduced (BMF_2). This factor is the same as given in Table 4. The $MPC_{sp, marine}$ is 0.33 / (2240 × 10 × 10) = 0.0015 µg/L.

3.3.3 $MPC_{hh\ food,\ water}$

Since lambda-cyhalothrin has a BCF > 100 L/kg and the R-phrases R21 and R25, derivation of $MPC_{hh\ food,\ water}$ for lambda-cyhalothrin is triggered (Table 5). The $MPC_{hh\ food,\ water}$ is calculated according to Section 3.1.5 of Vlaardingen en Verbruggen (2007), using the ADI (0.005 mg/kg.bw), a body weight of 70 kg and a daily fish consumption of 115 g. The $MPC_{hh\ food}$ = 0.005 x 0.1 x 70/0.115 = 0.304 mg/kg. The $MPC_{hh\ food,\ water}$ = $MPC_{hh\ food}$ / (BCF x BMF_1) = 0.304 / (2240 x 10) = 0.014 x 10-3 mg/L = 0.014 µg/L.

The $MPC_{hh\ food,\ water}$ is 0.014 µg/L for both the freshwater and marine environment.

3.3.4 $MPC_{dw,\ water}$

The Drinking Water Standard is 0.1 µg/L. Thus the $MPC_{dw,\ water}$ value is also 0.1 µg/L.

3.3.5 Selection of the MPC_{water}

The lowest value of the routes included (see Chapter 2.3.1) is the $MPC_{eco, water}$. Therefore, the MPC_{water} is 0.00002 µg/L.

3.3.5.1 $MPC_{susp, water}$

Because the $K_{p, susp\text{-}water} \geq 3$, the MPC_{water} should be recalculated to $MPC_{susp, water}$ using the following formula:

$MPC_{susp, water} = MPC_{water, total} / (C_{susp, Dutch\ standard} \times 10^{-6} + (1/ K_{p, susp\text{-}water,Dutch\ standard}))$, with $MPC_{water, total}$ being the above derived MPC_{water} in mg/L and $C_{susp, Dutch\ standard}$ is 30 mg/L.

For this calculation, $K_{p,susp\text{-}water,Dutch\ standard}$ is calculated as K_{OC} x $f_{OC,susp,Dutch\ standard}$. This is not the same as the European standard $f_{OC,susp}$ which is used in the table with trigger values. With a log K_{OC} of 5.2 (K_{oc} 158489 L/kg) an $f_{OC,susp,Dutch\ standard}$ of 0.1176, the $K_{p,susp\text{-}water,Dutch\ standard}$ is calculated to be 18645 L.

The $MPC_{susp, water}$ is $0.00002 \times 10^{-3} / (30 \times 10^{-6} + (1 / 18645)) = 2.4 \times 10^{-4}$ mg/kg_{dw}. = 0.24 µg/kg_{dw}.

3.3.6 $MAC_{eco, water}$

Since the BCF of lambda-cyhalothrin is > 100 L/kg, the mode of action is known and the most sensitive species (insects) are included in the dataset, the $MAC_{eco, water}$ is derived using an assessment factor of 100 on the lowest LC_{50} value of 0.0023 µg/L for *Hyalella azteca*. The $MAC_{eco,water}$ derived using this assessment factor is 0.0023/100 = 0.000023 µg/L.

For comparison, the $MAC_{eco, water}$ is also derived applying Species Sensitivity Distribution (SSD) to the chronic data. This is allowed when at least 10 values (preferably 15) are available for different species covering at least eight taxonomic groups. The taxonomic groups to be covered and their representatives in the present dataset are as follows:

- Fish: represented by *Ictalurus punctatus* (familiy Ictaluridae)
- A second family in the phylum Chordata: represented by *Oncorhynchus mykiss* (family Salmonidae)
- Crustacea: represented by *Gammarus pulex* and *Daphnia magna*
- Insects: represented by *Chironomus riparius*
- A family in another phylum than Arthropoda or Chordata: -
- A family in any order of insect or any phylum no already represented: represented by *Hydrocarina*
- Algae: represented by *Scenedesmus subspicatus*
- Macrophyta: -

The present dataset neither includes macrophytes nor a phylum "other than arthropoda or chordata". However, lambda-cyhalothrin was shown not to have a direct effect on macrophytes (mesocosm studies of Roessink et al., 2005 and Van Wijngaarden et al., 2006, Appendix 3) and molluscs (LOEC value of > 8.9 µg/L for *Bithynia tentaculata*, Appendix 1) in concentrations below its water solubility. Additionally, a large amount of data is available for the potentially most sensitive taxonomic groups. Therefore, a SSD may be performed (Figure 1).

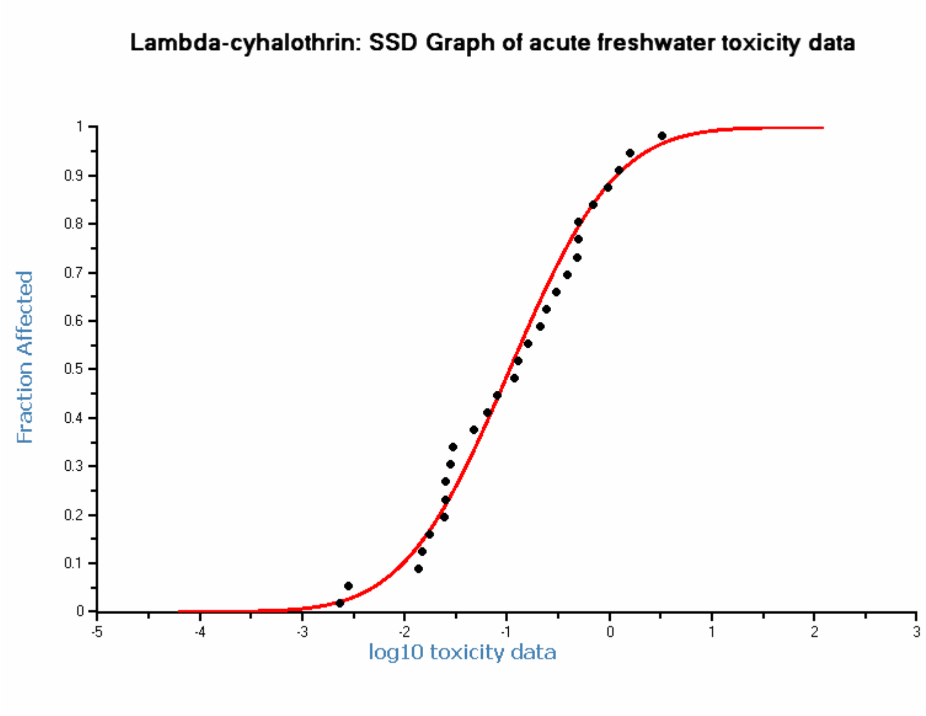


Figure 1. SSD curve based on acute freshwater toxicity data of lambda-cyhalothrin.

The SSD was performed on the complete acute freshwater toxicity dataset of lambda-cyhalothrin (Table 6) and showed a HC_5 value of 0.0047 µg/L, with a 90% confidence interval of 0.0016 - 0.0104 µg/L. The distribution of toxicity data is normal and meets all statistic significance standards tested (Anderson-Darling test, Kolmogorov-Smirnov test, Cramer van Mises test). This HC_5 value exceeds the $L(E)C_{50}$ values for *Hyalella azteca* (0.0023 µg/L) and *Chaoborus obspicurus* (0.0028 µg/L).

When the $MAC_{eco, water}$ is based on a SSD curve, usually a default assessment factor of 10 is applied in order to extrapolate from the short-term $L(E)C_{50}$ level to the short-term no-effect level. For the HC_5 value of 0.0047 µg/L, this would result in a $MAC_{eco, water}$ of 0.00047 µg/L.

For lambda-cyhalothrin however, acute EC_{10} values are available for 11 species of arthropoda (Schroer et al., 2004; Table 9). Since EC_{10} values can be considered to represent the no-effect level, an additional SSD was performed on these data in order to validate the assessment factor used on the HC_5 of the acute EC_{50}-values.

Table 9. Lambda-cyhalothrin: Acute EC_{10} data.

Acute	
Taxonomic group	**EC10 (µg/L)**
Crustacea	
Asellus aquaticus	0.0097[b]
Daphnia galeata	0.0440 [a]
Gammarus pulex	0.0131[b]
Proasellus coxalis	0.0130[a]
Simocephalus vetulus	0.334[a]
Insecta	
Caenis horaria	0.0036[b]
Chaoborus obscupires	0.0006[a]
Cloeon dipterum	0.0072[a]
Erythromma viridulum	0.377[a]
Macropelopia sp.	0.125[a]
Notonecta glauca	0.0072[a]

[a] Exposure time 48 hours.
[b] Exposure time 96 hours

The SSD curve on the EC_{10} values showed a HC_5 value of 0.00065 µg/L, with a confidence interval of 0.00008 - 0.0022 µg/L. The distribution of data is normal, though not all statistical significance standards tested are met on all levels of significance.

The EC_{10}-HC_5 value of 0.00065 µg/L is only a factor of 1.39 higher than the EC_{50}-HC_5 value with an assessment factor of 10(0.00047 µg/L). This is a small difference. Furthermore the SSD curve based on the EC_{10}-values does not fully meet the assumptions of a normal distribution. In view of this, an assessment factor of 10 on the EC_{50}-HC_5 is considered valid.

Both the $MAC_{eco,\ water}$ derived using assessment factors (0.000023 µg/L) and the $MAC_{eco,\ water}$ derived using a SSD curve (0.00047 µg/L) are in accordance with the conclusion of the mesocosm studies of Farmer et al. (1995) and Kedwards et al. (1999) which showed a NOEC value of < 0.002 µg/L.

Though the EC_{50}-HC_5 value of the SSD (0.0047 µg/L) only differs by a factor of two from the lowest NOEC (0.0023 µg/L), the assessment factors of 10 and 100 , respectively, cause a factor of 20 difference between the two MAC values. In this case, the lower assessment factor on the EC_{50}-HC_5 value is justified based on the large dataset for the most sensitive taxonomic groups. Therefore, the $MAC_{eco,\ water}$ is 0.00047 µg/L.

3.3.7 $SRC_{eco,\ water}$

For lambda-cyhalothrin one NOEC for *Daphnia magna* (0.002 µg/L) is available. For the derivation of the $SRC_{eco,\ water}$, this value is compared with the geometric mean of the LC_{50} values. This geometric mean is 0.106 µg/L, which is more than 10 times higher than the NOEC. Therefore, an assessment factor of 1 is applied on the NOEC, resulting in a $SRC_{eco,\ water}$ of 0.002 µg/L.

3.4 Toxicity data and derivation of ERLs for sediment

Since the log $K_{p,\ susp\text{-}water}$ of lambda-cyhalothrin is above the trigger value of 3, ERLs for sediment should be derived.

3.4.1 Sediment toxicity data

An overview of the selected freshwater sediment toxicity data for lambda-cyhalothrin is given in Table 10. Detailed toxicity data for lambda-cyhalothrin are tabulated in Appendix 4.

Table 10. Lambda-cyhalothrin: selected freshwater sediment data for ERL derivation.

Chronic[a]		**Acute**[a]	
Taxonomic group	**NOEC/EC10 (μg/kg)**	**Taxonomic group**	**L(E)C50 (μg/kg)**
Crustacea			
Hyalella azteca	**2.3**[b]		
Insecta			
Chironomus riparius	105[c]		

[a] For detailed information see Appendix 4. Bold values are used for ERL-derivation.
[b] most sensitive endpoint (EC_{10}); normalised to Dutch standard sediment
[c] not normalised

3.4.2 Derivation of $MPC_{sediment}$

Two chronic NOECs for sediment organisms are available (Table 10). The endpoint for *Chironomus riparius* cannot be normalised to Dutch standard sediment. However, since the organic matter content in the test should have been > 228 % to result in a normalised NOEC that is lower than 2.3 μg/kg_{dw}, it is considered justified to assume that *Hyalella azteca* is most sensitive. Therefore an assessment factor of 50 can be used. This results in a $MPC_{sediment}$ of 2.3/50 = 0.046 μg/ kg_{dw}.

3.4.3 Derivation of $SRC_{sediment}$

Two chronic NOEC values are available for lambda-cyhalothrin. Therefore, the $SRC_{sediment}$ is based on the geometric mean of these NOECs, the $SRC_{sediment}$ = 15.5 μg/ kg_{dw}.

4 Conclusions

In this report, the risk limits Maximum Permissible Concentration (MPC), Maximum Acceptable Concentration for ecosystems (MAC_{eco}), and Serious Risk Concentration for ecosystems (SRC_{eco}) are derived for lambda-cyhalothrin in water and sediment. Not enough data were available to derive ERLs for the marine compartment.

The ERLs that were obtained are summarised in the table below. The MPC value that was set for this compound until now, is also presented in this table for comparison reasons. It should be noted that this is an indicative MPC ('ad-hoc MTR'), derived using a different methodology and based on limited data.

Table 10. Derived MPC, MAC_{eco}, and SRC values for lambda-cyhalothrin.

ERL	Unit	MPC	MAC_{eco}	SRC
Water, old[a]	µg/L	2.9×10^{-4}		
Water[b]	µg/L	2.0×10^{-5}	4.7×10^{-4}	2.0×10^{-3}
Water, suspended matter	mg/kg_{dw}	0.24		
Drinking water[b]	µg/L	0.1[c]	-	-
Marine	µg/L	n.d.[d]	n.d.[d]	-
Sediment	$µg/kg_{dw}$	0.046	-	15.5

[a] indicative MPC ('ad-hoc MTR'), source: Helpdesk Water http://www.helpdeskwater.nl/emissiebeheer/normen_voor_het/zoeksysteem_normen/

[b] The $MPC_{dw,\ water}$ is reported as a separate value from the other MPC_{water} values ($MPC_{eco,\ water}$, $MPC_{sp,\ water}$ or $MPC_{hh\ food,\ water}$). From these other MPC_{water} values (thus excluding the $MPC_{dw,\ water}$) the lowest one is selected as the 'overall' MPC_{water}.

[c] provisional value pending the decision on implementation of the $MPC_{dw,\ water}$ (see Section 2.3.1)

[d] n.d. = not derived due to lack of data

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Appendix 1. Detailed aquatic toxicity data

Table A1.1. Acute toxicity of lambda-cyhalothrin to freshwater organisms.

Species	Species properties	A	Test type	Test compound	Purity [%]	Test water	pH	T [°C]	Hardness $CaCO_3$ [mg/L]	Exp. time	Criterion	Test endpoint	Value [µg/L]	Ri	Notes	Reference
Algae																
Pseudokirchneriella subcapitata										96h	EC50	growth	> 1000	4		Maund *et al.*, 1998
Pseudokirchneriella subcapitata		Y	S	a.s.	96.5		7.2-8.0	24		96h	EC50	growth rate	> 300	2	23	DAR, Thompson and Williiams, 1985
Pseudokirchneriella subcapitata		Y	S	a.s.	96.5		7.2-8.0	24		96h	EC50	biomass	> 300	2	23	DAR, Thompson and Williiams, 1985
Pseudokirchneriella subcapitata		N	S	product	5.2		6.8-10.4	24		96h	EC50	growth rate	1600	3	23	DAR; Smyth *et al,* 1989
Pseudokirchneriella subcapitata		N	S	product	5.2		6.8-10.4	24		96h	EC50	biomass	1400	3	23	DAR; Smyth *et al,* 1989
Crustacea																
Asellus aquaticus		Y	S	a.s.	≥ 88		7.4-8.8	19,5±1,4	179	48h	LC50	mortality	0.026	2	1,2,3	Maund *et al.*, 1998; Hamer *et al.*, 1998
Asellus aquaticus	(sub) adult 8,8 mm	Y	S	Karate	50 g/L	nw	7.0-7.3	20		48h	EC50	immobilisation	0.0248	2	4	Schroer *et al.*, 2004
Asellus aquaticus	(sub) adult 8,8 mm	Y	S	Karate	50 g/L	nw	7.0-7.3	20		96h	EC50	immobilisation	0.0248	2	4	Schroer *et al.*, 2004
Asellus aquaticus	(sub) adult 8,8 mm	Y	S	Karate	50 g/L	nw	7.0-7.3	20		48h	LC50	mortality	0.14	2	4	Schroer *et al.*, 2004
Asellus aquaticus	(sub) adult 8,8 mm	Y	S	Karate	50 g/L	nw	7.0-7.3	20		96h	LC50	mortality	0.0752	2	4	Schroer *et al.*, 2004
Ceriodaphnia dubia	neonates (≤ 24 h old)	Y	S		13.1	rw		25±1		48h	LC50	mortality	0.30	3	1,5,6,7	Mokry and Hoagland, 1990
Cyclops sp.		Y	S	a.s.	≥ 88		7.4-8.8	19,5±1,4	179	48h	EC50	mortality	0.3	2	1,2,3,12	Maund *et al.*, 1998; Hamer *et al.*, 1998
Daphnia galeata	(sub) adult 0,7 mm	Y	S	Karate	50 g/L	nw	7.3-8.0	20		48h	EC50	immobilisation	0.117	2	4	Schroer *et al.*, 2004
Daphnia galeata	(sub) adult 0,7 mm	Y	S	Karate	50 g/L	nw	7.3-8.0	20		48h	LC50	mortality	0.397	2	4	Schroer *et al.*, 2004
Daphnia magna	4th instar juveniles	Y	S	a.s.	99	am	8.3	20		48h	EC50	immobilisation	0.39	2	8,9	Barata *et al.*, 2006
Daphnia magna	4th instar juveniles	Y	S	a.s.	99	am	8.3	20		24h	EC50	feeding	0.10	3	5,9	Barata *et al.*, 2006
Daphnia magna			S							48h	EC50	immobilisation	0.36	3		DAR; Farelly *et al*, 1984
Daphnia magna	first instars	N	S	product	5.5		7.8-8.4	20±1.0		48 h	EC50	immobilisation	0.09	3	22	DAR, Farelly et al. 1985
Daphnia magna	first instars	N	S	product	12.9		7.8-8.4	20±1.0		48 h	EC50	immobilisation	0.09	3	22	DAR, Farelly et al. 1985
Daphnia magna	neonates (≤ 24 h old)	Y	S		13.1	rw		25±1		48h	LC50	mortality	1.04	3	1,5,6,7	Mokry and Hoagland, 1990
Daphnia sp.										48h	EC50		0.36	4	10	Advisory Committee on Pesticides, 1993
Daphnia sp.				product						48h	EC50		0.09	4	10	Advisory Committee on Pesticides, 1993
Gammarus pulex	(sub) adult 11,6 mm	Y	S	Karate	50 g/L	nw	6.1-7.3	20		48h	EC50	locomotion	0.0236	3	4	Schroer *et al.*, 2004
Gammarus pulex	(sub) adult 11,6 mm	Y	S	Karate	50 g/L	nw	6.1-7.3	20		96h	EC50	locomotion	0.0242	3	4	Schroer *et al.*, 2004
Gammarus pulex	(sub) adult 11,6 mm	Y	S	Karate	50 g/L	nw	6.1-7.3	20		48h	LC50	mortality	0.0314	2	4	Schroer *et al.*, 2004
Gammarus pulex	(sub) adult 11,6 mm	Y	S	Karate	50 g/L	nw	6.1-7.3	20		96h	LC50	mortality	0.0242	2	4	Schroer *et al.*, 2004
Gammarus pulex	neonates									96h	EC50	immobilisation	0.016	4		DAR; List of end points
Gammarus pulex L.		Y	S	a.s.	≥ 88		7.4-8.8	19,5±1,4	179	48h	EC50	mortality	0.014	2	1,2,3	Maund *et al.*, 1998; Hamer *et al.*, 1998
Hyalella azteca		Y	S	a.s.	≥ 88		7.4-8.8	19,5±1,4	179	48h	EC50	mortality	0.0023	2	1,2,3	Maund *et al.*, 1998; Hamer *et al.*, 1998
Hyalella azteca	1-2 weeks old	Y	S	Karate Zeon	22.80	nw			80-100	48h	EC50	immobilisation	0.0038	2	11	Smith and Lizotte 2007
Macrobrachium nippoensis	90 d, 5.0 g, 4.5 cm	N	R	Kung Fu 25EW	>99	rw	7.1	16±2	120-140	96h	LC50	mortality	0.04	3	1,13,14	Wang *et al.*, 2007
Ostracoda		Y	S	a.s.	≥ 88		7.4-8.8	19,5±1,4	179	48h	EC50	mortality	3.3	2	1,2,3	Maund *et al.*, 1998; Hamer *et al.*, 1998
Proasellus coxalis	(sub) adult 4,6 mm	Y	S	Karate	50 g/L	nw	7.1-7.4	20		48h	EC50	immobilisation	0.0177	2	4	Schroer *et al.*, 2004
Proasellus coxalis	(sub) adult 4,6 mm	Y	S	Karate	50 g/L	nw	7.1-7.4	20		96h	EC50	immobilisation	0.0274	2	4	Schroer *et al.*, 2004
Proasellus coxalis	(sub) adult 4,6 mm	Y	S	Karate	50 g/L	nw	7.1-7.4	20		48h	LC50	mortality	0.0788	2	4	Schroer *et al.*, 2004
Proasellus coxalis	(sub) adult 4,6 mm	Y	S	Karate	50 g/L	nw	7.1-7.4	20		96h	LC50	mortality	0.0446	2	4	Schroer *et al.*, 2004
Simocephalus vetulus	(sub) adult 1,7 mm	Y	S	Karate	50 g/L	nw	7.2-8.0	20		48h	EC50	immobilisation	0.957	2	4	Schroer *et al.*, 2004
Simocephalus vetulus	(sub) adult 1,7 mm	Y	S	Karate	50 g/L	nw	7.2-8.0	20		48h	LC50	mortality	1.34	2	4	Schroer *et al.*, 2004
Arachnida																

Species	Species properties	A	Test type	Test compound	Purity [%]	Test water	pH	T [°C]	Hardness $CaCO_3$ [mg/L]	Exp. time	Criterion	Test endpoint	Value [µg/L]	Ri	Notes	Reference
Hydrocarina		Y	S	a.s.	≥ 88		7.4-8.8	19,5±1,4	179	48h	EC50	mortality	0.047	2	1,2,3,12	Maund *et al.*, 1998
Insecta																
Aedes aegypti	late third- and early fourth-instar	N	S	product	tg	tw		27±2		24h	LC50	mortality	0.35	3	15,16,17	Canyon and Hii, 1999
Aedes aegypti	late third- and early fourth-instar	N	S	product	tg	tw		27±2		24h	LC50	mortality	1.00	3	15,16,17	Canyon and Hii, 1999
Caenis horaria	larvae 4,6 mm	Y	S	Karate	50 g/L	nw	6.9-7.5	22		48h	EC50	immobilisation	0.0179	2	4	Schroer *et al.*, 2004
Caenis horaria	larvae 4,6 mm	Y	S	Karate	50 g/L	nw	6.9-7.5	22		96h	EC50	immobilisation	0.0136	2	4	Schroer *et al.*, 2004
Caenis horaria	larvae 4,6 mm	Y	S	Karate	50 g/L	nw	6.9-7.5	22		48h	LC50	mortality	0.257	2	4	Schroer *et al.*, 2004
Caenis horaria	larvae 4,6 mm	Y	S	Karate	50 g/L	nw	6.9-7.5	22		96h	LC50	mortality	0.0346	2	4	Schroer *et al.*, 2004
Chaoborus obscuripes	larvae, instar 3-4	Y	S	Karate	50 g/L	nw	7.1-8.0	20		48h	EC50	immobilisation	0.0028	2	4	Schroer *et al.*, 2004
Chaoborus obscuripes	larvae, instar 3-4	Y	S	Karate	50 g/L	nw	7.1-8.0	20		96h	EC50	immobilisation	0.0028	2	4	Schroer *et al.*, 2004
Chaoborus obscuripes	larvae, instar 3-4	Y	S	Karate	50 g/L	nw	7.1-8.0	20		48h	LC50	mortality	> 0,0274	2	4	Schroer *et al.*, 2004
Chaoborus obscuripes	larvae, instar 3-4	Y	S	Karate	50 g/L	nw	7.1-8.0	20		96h	LC50	mortality	0.0757	2	4	Schroer *et al.*, 2004
Chaoborus sp.	insecta	Y	S	a.s.	≥ 88		7.4-8.8	19,5±1,4	179	48h	EC50	mortality	0.0028	4	1,2,3,12	Maund *et al.*, 1998; Hamer *et al.*, 1998
Cloeon dipterum	nymph, insecta	Y	S	a.s.	≥ 88		7.4-8.8	19,5±1,4	179	48h	EC50	mortality	0.038	2	1,2,3	Maund *et al.*, 1998; Hamer *et al.*, 1998
Cloeon dipterum	larvae 4,1 mm	Y	S	Karate	50 g/L	nw	6.5-7.8	20		48h	EC50	immobilisation	0.0248	2	4	Schroer *et al.*, 2004
Cloeon dipterum	larvae 4,1 mm	Y	S	Karate	50 g/L	nw	6.5-7.8	20		96h	EC50	immobilisation	0.0883	2	4	Schroer *et al.*, 2004
Cloeon dipterum	larvae 4,1 mm	Y	S	Karate	50 g/L	nw	6.5-7.8	20		48h	LC50	mortality	0.122	2	4	Schroer *et al.*, 2004
Cloeon dipterum	larvae 4,1 mm	Y	S	Karate	50 g/L	nw	6.5-7.8	20		96h	LC50	mortality	0.105	2	4	Schroer *et al.*, 2004
Corixa sp.	adult, insecta	Y	S	a.s.	≥ 88		7.4-8.8	19,5±1,4	179	48h	EC50	mortality	0.03	2	1,2,3	Maund *et al.*, 1998; Hamer *et al.*, 1998
Erythromma viridulum	larvae 17,3 mm	Y	S	Karate	50 g/L	nw	7.1-7.7	22		48h	EC50	immobilisation	0.689	2	4	Schroer *et al.*, 2004
Erythromma viridulum	larvae 17,3 mm	Y	S	Karate	50 g/L	nw	7.1-7.7	22		96h	EC50	immobilisation	0.493	2	4	Schroer *et al.*, 2004
Erythromma viridulum	larvae 17,3 mm	Y	S	Karate	50 g/L	nw	7.1-7.7	22		48h	LC50	mortality	1.583	2	4	Schroer *et al.*, 2004
Erythromma viridulum	larvae 17,3 mm	Y	S	Karate	50 g/L	nw	7.1-7.7	22		96h	LC50	mortality	0.493	2	4	Schroer *et al.*, 2004
Ischnura elegans	nymph, insecta	Y	S	a.s.	≥ 88		7.4-8.8	19,5±1,4	179	48h	EC50	mortality	0.13	2	1,2,3	Maund *et al.*, 1998; Hamer *et al.*, 1998
Macropelopia sp.	larvae 7,6 mm	Y	S	Karate	50 g/L	nw	7.4-7.8	20		48h	EC50	immobilisation	0.244	2	4	Schroer *et al.*, 2004
Macropelopia sp.	larvae 7,6 mm	Y	S	Karate	50 g/L	nw	7.4-7.8	20		96h	EC50	immobilisation	0.0643	2	4	Schroer *et al.*, 2004
Macropelopia sp.	larvae 7,6 mm	Y	S	Karate	50 g/L	nw	7.4-7.8	20		48h	LC50	mortality	1.019	2	4	Schroer *et al.*, 2004
Macropelopia sp.	larvae 7,6 mm	Y	S	Karate	50 g/L	nw	7.4-7.8	20		96h	LC50	mortality	0.698	2	4	Schroer *et al.*, 2004
Notonecta glauca	adult 14,4 mm	Y	S	Karate	50 g/L	nw	6.7-7.9	20		48h	EC50	immobilisation	0.0148	2	4	Schroer *et al.*, 2004
Notonecta glauca	adult 14,4 mm	Y	S	Karate	50 g/L	nw	6.7-7.9	20		96h	EC50	immobilisation	0.0164	2	4	Schroer *et al.*, 2004
Notonecta glauca	adult 14,4 mm	Y	S	Karate	50 g/L	nw	6.7-7.9	20		48h	LC50	mortality	0.0226	2	4	Schroer *et al.*, 2004
Notonecta glauca	adult 14,4 mm	Y	S	Karate	50 g/L	nw	6.7-7.9	20		96h	LC50	mortality	0.0164	2	4	Schroer *et al.*, 2004
Sialis lutaria	larvae 17,8 mm	Y	S	Karate	50 g/L	nw	6.6-7.8	20		48h	EC50	immobilisation	0.0515	2	4	Schroer *et al.*, 2004
Sialis lutaria	larvae 17,8 mm	Y	S	Karate	50 g/L	nw	6.6-7.8	20		96h	EC50	immobilisation	0.028	2	4	Schroer *et al.*, 2004
Sialis lutaria	larvae 17,8 mm	Y	S	Karate	50 g/L	nw	6.6-7.8	20		48h	LC50	mortality	> 2,179	2	4	Schroer *et al.*, 2004
Sialis lutaria	larvae 17,8 mm	Y	S	Karate	50 g/L	nw	6.6-7.8	20		96h	LC50	mortality	> 2,179	2	4	Schroer *et al.*, 2004
Sigara striata	adult 7,8 mm	Y	S	Karate	50 g/L	nw	6.8-7.7	20		48h	EC50	immobilisation	0.0182	3	4,24	Schroer *et al.*, 2004
Sigara striata	adult 7,8 mm	Y	S	Karate	50 g/L	nw	6.8-7.7	20		48h	LC50	mortality	0.0492	3	4,24	Schroer *et al.*, 2004
Mollusca																
Bithynia tentaculata	9.7 mm	Y	S	Karate	50 g/L	nw	7.0-7.9	20			LOEC	avoidance	> 8.9	2	4	Schroer *et al.*, 2004
Pisces																
Cyprinus carpio				product						96h	LC50	mortality	9.0	4	10	Advisory Committee on Pesticides, 1993
Cyprinus carpio	juvenile	Y		product	50 g/L		7.4-7.8	22-23	73	96h	LC50	mortality	0.50	2		DAR; Hill 1985
Danio rerio	0,70g; 36mm	Y	F	a.s.	87.7	dtw	7.01-7.43	24,9-25,3	42.3-46.7	96h	LC50	mortality	0.78	1	18,19	Maund *et al.*, 1998; Kent, SJ and Shillabeer, N, 1997

Species	Species properties	A	Test type	Test compound	Purity [%]	Test water	pH	T [°C]	Hardness $CaCO_3$ [mg/L]	Exp. time	Criterion	Test endpoint	Value [µg/L]	Ri	Notes	Reference
Danio rerio	30-45 d old, 0.38 g, 3.5 cm	N	R	Kung Fu 25EW	>99	rw	7.1	25±2	120-140	96h	LC50	mortality	1.94	3	1,13,14,20	Wang *et al*., 2007
Gambusia affinis	25-30 mm	N	S		5	tw					LC50	mortality	2.20	3	21	Mittal *et al*., 1991
Gasterosteus aculeatus L.	0,41g; 34mm	Y	F	a.s.	87.7	dtw	7.03-7.31	12.1-12.4	46.0-47.3	96h	LC50	mortality	0.49	1	18,19	Maund *et al*., 1998; Long, KWJ and Shillabeer, N, 1997
Ictalurus punctatus Raf.	1,57g; 48mm	Y	F	a.s.	87.7	dtw	7.24-7.70	16.8-17.0	43.0-47.7	96h	LC50	mortality	0.16	1	18,19	Maund *et al*., 1998; Long, KWJ and Shillabeer, N, 1997
Lepomis macrochirus										96h	LC50		0.21	4*	10	Advisory Committee on Pesticides, 1993
Lepomis macrochirus	juvenile	Y	FT	a.s.	98		7.4-8.6	22±1	68	96h	LC50	mortality	0.21	2		DAR; Hill 1984
Lepomis macrochirus										96h	LC50	mortality	0.40	4		Maund *et al*., 1998
Leucistus idus	2,15g; 53 mm	Y	F	a.s.	87.7	dtw	7.04-7.39	12,0-12,3	43.3-46.3	96h	LC50	mortality	0.08	1	18,19	Maund *et al*., 1998; Kent, SJ and Shillabeer, N, 1997
Oncorhynchus mykiss										96h	LC50		0.24	4*	10	Advisory Committee on Pesticides, 1993
Oncorhynchus mykiss				product						96h	LC50		16.6	3	10,23	Advisory Committee on Pesticides, 1993
Oncorhynchus mykiss	juvenile	Y	FT	product	50 g/L		7.5-8.0	16	68	96h	LC50	mortality	0.93	4	22	DAR; Hill, 1985
Oncorhynchus mykiss	juvenile	Y	FT	a.s.	98		7.0-7.9	12±1	72.4	96h	LC50	mortality	0.24	2		DAR; Hill, 1984
Oryzias latipes	0,22g; 25mm	Y	F	a.s.	87.7	dtw	7.63-7.83	25.1-25.6	40.0-48.7	96h	LC50	mortality	1.60	2	18,19	Maund *et al*., 1998; Kent, SJ and Shillabeer, N, 1997
Pimephales promelas Raf.	0,37g; 28mm	Y	F	a.s.	87.7	dtw	7.32-7.60	24.4-24.9	39.3-44.6	96h	LC50	mortality	0.70	2	18,19	Maund *et al*., 1998
Poecilia reticulata										96h	LC50	mortality	0.08	4		Maund *et al*., 1998

Notes

1 Test result based on nominal concentrations.
2 0.5 ml acetone per L, did not affect toxicity or oxygen concentration
3 Analysis at test start and termination
4 Analysis 1h after application, value calculated using a log concentration logit effect regression model.
5 Test organisms were fed during the test period.
6 After analysis it was found out the recovery ranged from 6.5 to 72.0 % across all concentrations for five tested pyrethroids; not possible to recalculate the values of LC50 using actual concentrations.
7 Results are reported in active ingredient.
8 According to OECD guidelines
9 Acetone was added to test and control samples in concentration < 0.05 %. No mortality occurred in control and solvent treatments.
10 Purity is not clear; it is also not clear if results are reported in mg/L formulation or mg/L active ingredient.
11 Measured immobilisation, value is geomean (std. 0.0047)
12 Species unclear
13 Water hardness recalculated from the value of 6.8 - 8.0°HG.
14 Solutions were renewed every 24 h.
15 A technical grade product was used but throughout the paper only the name of the a.i. is mentioned
16 Denatured ethanol was added to the control beakers in high concentration (0.4 %); but trials with any control mortalities were repeated.
17 Trials were carried out according to WHO methodology and standards (WHO/VBC/81.807).
18 Vehicle: dimethylformamide, US EPA guideline, GLP, analysis at 0, 48 and 96h, mean measured levels 35-75% of nominal
19 Mean measured values were used
20 3 of 7 used test concentrations above solubility limits.
21 Exposure time unknown; probably < 1 week.
22 Formulation unknown.
23 Value exceeds solubility limit of lambda-cyhalothrin.
24 Mortality in controls >20%

rivm

Table A1.2. Chronic toxicity of lambda-cyhalothrin to freshwater organisms.

Species	Species properties	A	Test type	Test compound	Purity [%]	Test water	pH	T [°C]	Hardness $CaCO_3$ [mg/L]	Exp. time	Criterion	Test endpoint	Value [µg/L]	Ri	Notes	Reference
Algae																
Pseudokirchneriella subcapitata		N	S	Karate	50 g/L		6.8-10.4	24		96h	NOEC	growth rate	460	3	8	DAR; Smyth *et al* 1989
Crustacea																
Dapnia magna	<8h neonate	Y	R	a.s.	98.6	am	8.3	20		12d	EC10	reproduction	0.025	2	1	Barrata *et al*., 2002
Dapnia magna		Y		a.s.	> 96		8.1-8.2	19.5-23	165-175	21d	NOEC	reproduction	0.002	2	2	Maund *et al*., 1998
Insecta																
Aedes aegypti	early 4th instar larvae	N		a.s.	90.99	dw		27±2		14 d	NOEC	larval mortality	0.04	3	3,4,5,6	Shaalan et al., 2005.
Aedes aegypti	early 4th instar larvae	N		a.s.	90.99	dw		27±2		14 d	NOEC	pupal mortality	<0.04	3	3,4,5,6	Shaalan et al., 2005.
Aedes aegypti	early 4th instar larvae	N		a.s.	90.99	dw		27±2		14 d	NOEC	larval development	<0.04	3	3,4,5,6,7	Shaalan et al., 2005.
Aedes aegypti	early 4th instar larvae	N		a.s.	90.99	dw		27±2		14 d	NOEC	pupal development	<0.04	3	3,4,5,6,7	Shaalan et al., 2005.
Aedes aegypti	early 4th instar larvae	N		a.s.	90.99	dw		27±2		14 d	NOEC	total development	<0.04	3	3,4,5,6,7	Shaalan et al., 2005.
Aedes aegypti	early 4th instar larvae	N		a.s.	90.99	dw		27±2		14 d	NOEC	adult mortality	0.04	3	3,4,5,6	Shaalan et al., 2005.
Aedes aegypti	early 4th instar larvae	N		a.s.	90.99	dw		27±2		14 d	NOEC	adult emergence	<0.04	3	3,4,5,6	Shaalan et al., 2005.
Aedes aegypti	early 4th instar larvae	N		a.s.	90.99	dw		27±2		14 d	NOEC	malformations	0.15	3	3,4,5,6	Shaalan et al., 2005.

Notes

1 Value is geomean derived from graph (std. 0,015), shortened OECD test
2 Value based on mean measured concentrations
3 Followed World Health Organization. 1996.
4 Insecticide was diluted in ethanol. Used amount: 10 ml/l. Control with ethanol (10 ml/l =1%).
5 Exposure time - until the emergence of the adults or death of the last larva or pupa. In control: 13.2 days.
6 Not clear if it was static or renewal test, if static → concentration of lambda-cyhalothrin surely decreased over exposure time.
7 Development period decreased with increasing concentrations
8 Concentration expressed in µg a.i./L; concentration exceeds solubility of lambda-cyhalothrin >100x.

Table A1.3. Chronic toxicity of lambda-cyhalothrin to marine organisms.

Species	Species properties	A	Test type	Test compound	Purity [%]	Test water	pH	T [°C]	Salinity [‰]	Exp. time	Criterion	Test endpoint	Value [µg/L]	Ri	Notes	Reference
Pisces																
Cyprinodon variegatus Lac.	embryo						8.2-8.3	24-26	24-27	28d	NOEC	early life stage	0.25	2		DAR; List of end points; Maund *et al.*, 1998

Appendix 2. Description of mesocosm studies

Farmer et al., 1995 & Kedwards et al., 1999

Species Population Community	Test Method	System properties	Formulation	Analyzed	Exposure regime	Experimental time	Criterion	Test endpoint	Value [µg/l]	Notes	Ri	Reference
Phytoplankton, perifphyton, macrophytes, zooplankton, macroinvertebrates	outdoor mesocosms	Ponds, 25 m^3	not reported	Y	Four applications of 0.17 g as/ha with two weeks intervals	19 w	7-d NOEC	single macroinvertebrate species, macroinvertebrate community on artificial substrates	< 0.002	Water residues were “slightly above” the LOD of 2 ng/l 1 h after application in the single application	1	Farmer et al., 1995 & Kedwards et al., 1999

Evaluation of the scientific reliability of the field study and of the suitability for ERL-derivation

1. Does the test system represent a realistic freshwater community? Yes. Mesocosms were 25 m^3 ponds, containing algae, zooplankton, macroinvertebrates, macrophytes and no fish.
2. Is the description of the experimental set-up adequate and unambiguous? Yes. Two controls and treatments in duplicate.
3. Is the exposure regime adequately described? Is the exposure regime adequate to derive a MAC or an AA value? Lambda-cyhalothrin was applied at 0.17 g as/ha. One hour after application, in the lowest treatment measured water column residues were only slightly above the LOD of 2 ng/l and were below the LOD after 24 hours. Therefore, the application regime is adequate to derive a MAC-value. Residues in the surface hydrosoil increased during the application period, peaking at 7 µg/kg after the third application. Concentration in the hydrosoil were not described enough in detail to base an eventual chronic NOEC for sediment organisms on.
4. Are the investigated endpoints sensitive and in accordance with the working mechanism of the compound? Yes.
5. Is it possible to evaluate the observed effects statistically? No, but statistics were carried out satisfactorily.

This result in an overall assessment of the study reliability -> Ri 1.

Evaluation of the results of the study

Only effects after the first application are evaluated here.

No adverse effects on algal abundance or productivity were detected or on community metabolism. Also, no apparent effect of treatment on phytoplankton community structure were reported. However, in one figure, a significant reduction of phytoplankton gross productivity is appointed in the 0.17 g as/ha treatment, one week after the first application.

No significant effects on macrophyte and zooplankton communities were detected.

One hour after spraying, abnormally behaving Notonectidae and Gyrrinidae were observed. Abundances of *Gammarus* sp. were decreased after the first application. Additionally, significantly fewer chironomids were present in surface substrates. The application had no adverse effects on Turbellaria, Gastropoda and Annelida.

PRC analyses of macroinvertebrate communities did not result in significant deviations of treatment from the control.

The application of 0.17 g as/ha, resulting in an initial concentration of 0.002 µg/l, can be appointed as the LOEC of the present study. Consequently, the actual NOEC is < 0.002 µg/l.

<u>Heckmann and Friberg, 2005 & Heckmann et al., 2005</u>

Species Population Community	Test Method	System properties	Formulation	Analyzed	Exposure regime	Experimental time	Criterion*	Test endpoint	Value [µg/l]	Notes	Ri	Reference
macroinvertebrates	outdoor mesocosms	In-stream cosms, 5.8 m length, 0.15 m width	Karate®	Y	Pulse of 30 seconds	30 sec	0-2 d post exposure NOEC	Total drift and certain macroinvertebrate densities	< 0.05	Acute effect on drift, chronic	1	Heckmann and Friberg, 2005 & Heckmann et al., 2005
						30 sec	2-d post-exposure NOEC	*Gammarus* densities	< 0.35	lower densities compared to the control	1	Heckmann and Friberg, 2005 & Heckmann et al., 2005
						30 sec	7-d post-exposure NOEC	*Gammarus* densities	0.42	lower densities compared to the control	1	Heckmann and Friberg, 2005 & Heckmann et al., 2005
						30 sec	14-d post-exposure NOEC	Oligochaeta and *Elmis aenea* densities	0.35	increase in densities	1	Heckmann and Friberg, 2005 & Heckmann et al., 2005
Gammarus pulex drifting in the in-streams	indoor aquaria	1 l aquaria	Karate®	Y	static	30 sec	24-h post-exposure LC_{50}	mortality *G. pulex*	5.69		1	Heckmann and Friberg, 2005
							NOEC	mortality *G. pulex*	0.05			

Evaluation of the scientific reliability of the field study and of the suitability for ERL-derivation

1. Does the test system represent a realistic freshwater community? Yes. Channels positioned in a natural stream, two weeks of colonization.
2. Is the description of the experimental set-up adequate and unambiguous? Yes.
3. Is the exposure regime adequately described? Is the exposure regime adequate to derive a MAC or an AA value? Lambda-cyhalothrin was applied at a single 30-minutes pulse of 0.05, 0.35, 0.42, 1.97, 4.21 and 16.7 µg/l, four replicates for control and each treatment. The exposure regime is adequate for MAC-derivation.
4. Are the investigated endpoints sensitive and in accordance with the working mechanism of the compound? Yes.
5. Is it possible to evaluate the observed effects statistically? No, but statistics were described and performed sufficiently.

This result in an overall assessment of the study reliability -> Ri 1.

Hill et al., 1988 & Hill et al., 1994

Species Population Community	Test Method	System properties	Formulation	Analyzed	Exposure regime	Experimental time	Criterion*	Test endpoint	Value [µg/l]	Notes	Ri	Reference
Phytoplankton, periphyton, zooplankton, macrophytes, macroinvertebrates, fish	Outdoor macrocosms	Ponds, 15 * 30 m, 450 m^3	Karate™, 13.8% as	Y	twelve sprayings with weekly intervals plus six run-offs with two weeks intervals	Until 22 w after first application = 10 w after last application	7-d NOEC	Crustacea, Tanypodinae	0.001	NOEC is the middle treatment	3	Hill et al., 1988 & Hill et al., 1994
							14-d NOEC	Densities Baetidae and Caenidae	< 0.001	NOEC is the low treatment. Lowest treatment < LOD of 1 ng/l	3	Hill et al., 1988 & Hill et al., 1994

Evaluation of the scientific reliability of the field study and of the suitability for ERL-derivation

1. Does the test system represent a realistic freshwater community? Colonization by water from natural ponds. Additional macroinvertebrates collected from natural ponds, macrophytes were planted. Acclimatisation for approximately half a year. However, twenty-five bluegill sunfish (*Lepomis macrochirus*) were stocked in each mesocosm. At test termination, numbers of young fish ranged from 14,000 fish to 22,000 fish per pond, corresponding to weights of 7 to 14 kg, respectively. Moreover, at test termination numbers varied enormously and were not treated related, i.e. numbers ranged from zero to 12,000 per mesocosm, the latter corresponding to 37 kg. The authors reported signs of overcrowding in controls and treatment cosms. Extreme large numbers of young fish were harvested from all mesocosms. Juvenile fish had condition factors below the optimum value.
2. Is the description of the experimental set-up adequate and unambiguous? No, sampling scheme is unsatisfactorily. Macroinvertebrates were only sampled once each two weeks and not after every application.
3. Is the exposure regime adequately described? Is the exposure regime adequate to derive a MAC or an AA value? Only the two highest application treatments were chemically analysed. Resides in the medium rate pond showed concentrations near the limit of determination. Therefore, actual concentrations in the lowest treatment are believed to be below the LOD of 1 ng/l. The 7-d NOEC of the present study is at the level of the lowest treatment. Thus, the acute NOEC of the present study will be below the LOD of 1 ng/l. The study is adequately for MAC-derivation. It is unclear from the chemically analysis what the chronic exposure regime is, due to the low sampling frequency.
4. Are the investigated endpoints sensitive and in accordance with the working mechanism of the compound? Yes.
5. Is it possible to evaluate the observed effects statistically? No, but the described statistics are considered to be sufficient.

This result in an overall assessment of the study reliability -> Ri 3.

Lauridsen and Friberg, 2005

Species Population Community	Test Method	System properties	Formulation	Analyzed	Exposure regime	Experimental time	Criterion*	Test endpoint	Value [µg/l]	Notes	Ri	Reference
Baetis rhodani, *Leuctra fusca/digitata*, *Gammarus pulex*	outdoor streams	0.1 m wide, 10 m long, flow rate 2.2 $l.min^{-1}$	Karate®, 2.5% EC	Y	60 min pulse	60 min	0 – 3 h NOEC	Drift of Gammarus	< 0.01 µg/l	NOEC was < lowest treatment of 0.001 µg/l. This treatment was dosed below the LOD of 0.01 $µg.l^{-1}$	2	Lauridsen and Nikolai, 2005

Evaluation of the scientific reliability of the field study and of the suitability for ERL-derivation

1. Does the test system represent a realistic freshwater community? No. Artificial streams of 10 m divided in subsections of 2.5 m. The streams were supplied with gravel collected from a stream. Approximately a day before treatment 20 *Baetis*, 20 *Gammarus* and 15 *Leuctra* were placed at the upstream of each subsection. Thus, no effort is done to approximate a natural situation.
2. Is the description of the experimental set-up adequate and unambiguous? Yes.
3. Is the exposure regime adequately described? Is the exposure regime adequate to derive a MAC or an AA value? The channels were dosed to obtain 60-minutes pulses of 0.001, 0.01, 0.1 and 1.0 µg/l. One channel per control and treatment. The channels were divided in four subsections which were considered to be the replicates. Statistically these subsections are not independent (pseudoreplicates). The study is suitable to determine a MAC value.
4. Are the investigated endpoints sensitive and in accordance with the working mechanism of the compound? Yes.
5. Is it possible to evaluate the observed effects statistically? No, but the described statistics are considered to be sufficient.

This result in an overall assessment of the study reliability -> Ri 2. However, the underlying study is not a cosm or field study but a multi-species study.

Leistra et al., 2003; Roessink et al., 2005; van Wijngaarden et al., 2006

Species Population Community	Test Method	System properties	Formulation	Analyzed	Exposure regime	Experimental time	Criterion*	Test endpoint	Value [µg/l]	Ri	Reference
phytoplankton, periphyton, zooplankton, macroinvertebrates, macrophytes	enclosures in outdoor experimental ditches, started in May	0.5 m^3, mesotrophic, macrophytes dominated	Karate with ZEON Technology™ (100 g/l as capsule suspension)	Y (only in highest treatment of 250 ng/l)	three applications with one-week intervals	6 w	7-d NOEC	Macroinvertebrate community (PRC)	< 0.01	1	Roessink et al., 2005; Leistra et al., 2003; van Wijngaarden et al., 2006
phytoplankton, periphyton, zooplankton, macroinvertebrates	enclosures in outdoor experimental ditches, started in May	0.5 m^3, eutrophic, phytoplankton dominated	Karate with ZEON Technology™ (100 g/l as capsule suspension)	Y (only in highest treatment of 250 ng/l)	three applications with one-week intervals	6 w	7-d NOEC	macroinvertebrates community (PRC), *Chaoborus obscuripes*	< 0.01	1	Roessink et al., 2005 & Leistra et al., 2003
phytoplankton, periphyton, zooplankton, macroinvertebrates, macrophytes	enclosures in outdoor experimental ditches, started in August	0.5 m^3, mesotrophic, macrophytes dominated	Karate with ZEON Technology™ (100 g/l as capsule suspension)	Y (only in highest treatment of 250 ng/l)	three applications with one-week intervals	6 w	7-d NOEC	*Chaoborus obscuripes*	< 0.01	1	van Wijngaarden et al., 2006 & Leistra et al., 2003

[a] one day after application, 24-40% of nominal. After 3 days 1.8-6.5% (according to Leistra et al., 2003)

Evaluation of the scientific reliability of the field study and of the suitability for ERL-derivation

1. Does the test system represent a realistic freshwater community? Experiments in mesotrophic, macrophyte-dominated and in eutrophic, phytoplankton-dominated enclosures of 0.5 m^3 (relatively small). No fish.
2. Is the description of the experimental set-up adequate and unambiguous? Yes. Three times application with one-week interval at 10, 25, 50, 100 and 250 ng/l. Control and treatments in duplicate.
3. Is the exposure regime adequately described? Is the exposure regime adequate to derive a MAC or an AA value? Only the highest treatment was chemically analysed. Lambda-cyhalothrin dissipated quickly from the water column. One hour after application, actual values in the highest treatment were 109% ± 81% of nominal. Therefore, it was considered to be appropriate to use the nominal initial values. One day after application, 24-40% of nominal was found in the water column. After 3 days, only 1.8-6.5% of nominal was recovered from the water column in both the macrophyte-dominated and the phytoplankton-dominated enclosures. None of the lambda-cyhalothrin applied to the water column was recovered from sediment samples (LOD 0.001 µg/g ww). The study setup is suitable to derive a MAC value on basis of nominal concentrations.
4. Are the investigated endpoints sensitive and in accordance with the working mechanism of the compound? Yes.
5. Is it possible to evaluate the observed effects statistically? No. However, extensive statistics were applied to the data and statistical analyses were reported satisfactorily.

This result in an overall assessment of the study reliability -> Ri 1.

Evaluation of the results of the study

Tabel 1 Summary of effects observed in the enclosures treated with lambda-cyahothrin as reported in Roessink et al., 2005 and in Van Wijngaarden et al., 2006. Numbers in the table follow the effect classes as described by Brock et al. (2000). 1 = no effect; 2 = slight effects; 3 = clear short-term effects, full recovery observed (within 4 to 8 weeks); 4 = clear effects, no full recovery observed at the end of the experiment. ↓ = increased endpoint; ↑ = increased endpoint; ↓↑ = decreased and increased endpoint. PRC – principle response curves of either macroinvertebrates or zooplankton.

	treatment levels				
	10 ng/l	**25 ng/l**	**50 ng/l**	**100 ng/l**	**250 ng/l**
Phytoplankton dominated / spring					
macrocrustaceans	-[a]	-[a]	-[a]	-[a]	-[a]
insects	2↓	3↓	3↓	3↓	3↓
other macroinvertebrates	1	1	1	2↑	2↑
PRC macroinvertebrates	2	3	3	3	3
microcrustaceans	2-3↑	4↑	4↑	4↑	4↑↓
rotifers	2↑	3↑	3↑	3↑	3↑
PRC zooplankton	2	2	2	2	2
phytoplankton chlorophyll *a*	1	1	1	1	2↑[b]
macrophyte biomass	-	-	-	-	-
macrophyte dominated / spring					
macrocrustaceans	1	2↓	2↓	4↓	4↓
insects (excl. *Chaoborus*)	1-2↓	3↓	3↓	3↓	3↓
C. obscuripes	2↓	3↓	3↓	3↓	3↓
other macroinvertebrates	1	1	1	1	2↓↑
PRC macroinvertebrates	2	2	3	3	4
microcrustaceans	1	2↓	2↓	2↓	4↓
rotifers	2↑↓	2↑↓	2↓↑	2↓↑	2↓;3↑
PRC zooplankton	1	1	2	2	2
phytoplankton chlorophyll *a*	1	1	1	1	1
macrophyte biomass	1	1	1	1	1
macrophyte dominated / summer					
macrocrustaceans	1	2↓	3↓	4↓	4↓
insects (excl. *Chaoborus*)	1-2↓	1-2↓	4↓	4↓	4↓
C. obscuripes	3↓	3↓	3↓	3↓	4↓
other macroinvertebrates	1	1	1	1	2↑

	treatment levels				
	10 ng/l	**25 ng/l**	**50 ng/l**	**100 ng/l**	**250 ng/l**
PRC macroinvertebrates	1	2	2	4	4
microcrustaceans	1	1	1	2↓	3↓
rotifers	2↑	2↑	2↑	2↑	2↑
PRC zooplankton	1	1	1	1	1
phytoplankton	1	1	1	1	1
chlorophyll *a*					
macrophyte biomass	1	1	1	1	1

[a] low abundance of free-living population.
[b] trend of an increase

Further discussion

For the spring mesotrophic, macrophytes dominated enclosures, the NOEC was appointed to lay below the lowest treatment of 10 ng/l on basis of effects on macroinvertebrate community analysis (PRC-analysis). For the spring eutrophic, phytoplankton dominated enclosures, the NOEC was considered to be the lowest treatment of 10 ng/l on basis of effects on macroinvertebrate community analysis and effects on *Chaoborus obscuripes*. The late summer, macrophytes dominated enclosures showed a NOEC below the 10 ng/l treatment on basis of effects on *Chaoborus obscuripes*.
Lambda-cyhalothrin dissipated quickly from the water column. Actual concentration was only determined in the 250 ng/l treatment. More than 70% of the substance had disappeared after one day (average concentration in the macrophyte dominated ditch 62 ng/l and in the phytoplankton dominated ditch 77.5 ng/l). After 3 days actual concentration had decreased to 16.3 and 8.0 ng/l and after 7 days to 5 and 3 ng/l in the macrophytes and phytoplankton dominated enclosures, respectively. Therefore, it can be expected that concentrations in the 10 ng/l treatment declined to 3 ng/l or less within one day and to concentrations below 0.2 ng/l 3 days after first application. The acute NOECs can be based on nominal values.

Appendix 3. Detailed bird and mammal toxicity data

Species	Species properties	Purity [%]	Application route	Exp time.	Criterion	Test endpoint	Effect Conc. [mg/kg$_{bw}$.d]	Effect Conc. [mg/kg$_{diet}$]	Ri	Notes	Reference
dog	beagle	96.5	oral	1 y	NOEL	clinical effects	0.5		2	2,3	DAR, Stonard 1991
dog	beagle		diet	52w	NOAEL	clinical effects	0.5		4*	4	PMRA 2003
mouse			diet	2y	NOAEL	clinical effects	2	20	2		PMRA 2003
rat	wistar, 21d old, 20/s/d	96.5	diet	90 d	NOEL	body weight, food consumption		50	2	1,3	DAR, Hart 1985
rat	wistar		diet	90d	NOAEL	bw gain, food consumption		50	2		PMRA 2003
rat			diet		NOAEL	neurotoxicity			2		PMRA 2003
rat	wistar		diet	2y	NOAEL	clinical effects	2.5	10	2		PMRA 2003
rat					NOAEL	neurotoxicity	4.6/5.2		2		PMRA 2003
mallard duck	8 day old,	96.5	diet	5d	LC50	mortality		>5300	2	5	DAR, Roberts and Fairley 1985
mallard duck	20 weeks old		diet	20 weeks	NOEC	reproductive parameters		>30	2	6,7	DAR, Beavers et al. 1989

Notes

1 NOEL of 10 ppm based on elevated hepatic amino-N-demethylase activity and liver weight at 50 ppm
2 Neurological effects comprising ataxia, muscle tremors and convulsions were seen in the high dose group, one dog had to be killed in week 46 due to adverse clinical effects consistent with pyrethroid toxicity.
3 No statements concerning GLP, but studies are subjected to Quality Assurance inspections and seem to be of good quality
4 Exposure via capsules
5 EPA 71-2
6 EPA 71-4
7 reproductive parameters recorded: eggs laid, cracked and set, viable embryos, live three-week embryos, hatchlings, body weight of hatchlings, 14-day old survivors, body weight of 14-day old survivors, egg shell thickness

Appendix 4. Detailed sediment toxicity data

Species	Species properties (age, sex)	Sediment type	A	Test compound	Purity [%]	pH	o.m. [%]	Clay [%]	T [°C]	Exp time	Criterion	Test endpoint	Result test sediment [ug.kg_{dw}^{-1}]	Result std. sediment [µg.kg_{dw}^{-1}]	Ri	Notes	Reference
Crustacea																	
Hyalella azteca	6-12 d old	American River, CA	Y				1.87	31.7	23	10 d	LOEC	growth	2.60	14	2	1,2,3	Amweg *et al.*, 2005
Hyalella azteca	6-12 d old	Del Puerto Creek, CA	Y				2.38	43.1	23	10 d	LOEC	growth	2.00	8.4	2	1,2,3	Amweg *et al.*, 2005
Hyalella azteca	6-12 d old	American River, CA	Y				2.38	43.1	23	10 d	NOEC	biomass	1.10	4.6	2	1,2,3,4	Amweg *et al.*, 2005
Hyalella azteca	6-12 d old	American River, CA	Y				2.38	43.1	23	10 d	EC10	biomass	0.54	2.3	2	1,2,3,4,5	Amweg *et al.*, 2005
Hyalella azteca	6-12 d old	Del Puerto Creek, CA	Y				1.87	31.7	23	10 d	NOEC	biomass	1.50	8.0	2	1,2,3,4	Amweg *et al.*, 2005
Insecta																	
Chironomus riparius	larva										EC50		2.4		3	6	Maund *et al.*, 1998
Chironomus riparius	first instar		Y	a.s.						28d	NOEC	emergence	105.00		2	7	Maund *et al* 1998

Notes

1 Pesticide was dissolved in an acetone carrier and spiked into sediment using <200 µl acetone/kg wet sediment (0.02%). Solvent control survival averaged 95 %.

2 Performed using standard U.S. EPA protocols: U.S. Environmental Protection Agency. 2000. Methods for measuring the toxicity and bioaccumulation of sediment-associated contaminants with freshwater invertebrates, 2nd ed. EPA/600/R-99/064. Office of Research and Development, Washington, DC.

3 Test result based on nominal concentrations, measured concentrations were > 80 % of nominal (average 106%).

4 Result recalculated from µg/g o.c.

5 Determined with log-logistic relationship from presented figure

6 Test substance was added to the water.

7 Organic matter content unknown, uncorrected endpoint 105 µg/kg_{dw} is used as supportive information.

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