National Institute
for Public Health
and the Environment

Letter report 601716021/2008
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This investigation has been performed by order and for the account of Directorate-General for Environmental Protection, Directorate for Soil, Water and Rural Area (BWL), within the framework of the project 'Standard setting for other relevant substances within the WFD'.

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Rapport in het kort

Environmental risk limits for pyridaben

Dit rapport geeft milieurisicogrenzen voor het insecticide/acaricide pyridaben 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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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 insecticide/acaricide pyridaben. 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). Pyridaben is part of a series of 25 pesticides that appeared to have a high environmental impact on 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 (direct exposure)
$SRC_{eco, water}$	SRC for freshwater based on ecotoxicological data (direct exposure)
$MPC_{eco, marine}$	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 pyridaben, the evaluation report prepared within the framework of EU Directive 91/414/EC (Draft Assessment Report, DAR) was consulted (EC, 2007). 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 (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 Appendices 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} and the derivation of the $MAC_{eco,\ marine}$ 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 ($MPC_{hh\ food, water}$); the need for 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 (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.

2.3.2 $MAC_{eco, marine}$

The assessment factor for the $MAC_{eco, marine}$ value is based on

- the assessment factor for the $MAC_{eco, water}$ value when acute toxicity data for at least two specific marine taxa are available, or
- using an additional assessment factor of 5 when acute toxicity data for only one specific marine taxon are available (analogous to the derivation of the MPC according to Van Vlaardingen and Verbruggen, 2007), or
- using an additional assessment factor of 10 when no acute toxicity data are available for specific marine taxa.

If freshwater and marine data sets are not combined (which is generally the case for pesticides) the $MAC_{eco, marine}$ is derived on the marine toxicity data using the same additional assessment factors as mentioned above. It has to be noted that this procedure is currently not agreed upon. Therefore, the $MAC_{eco, marine}$ value needs to be re-evaluated once an agreed procedure is available.

3 Derivation of environmental risk limits for pyridaben

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

3.1.1 Identity

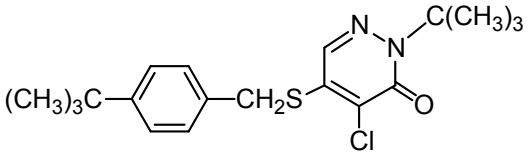

Figure 1. Structural formula of pyridaben.

Table 1. Identification of pyridaben.

Parameter	Name or number	Source
Common/trivial/other name	Pyridaben / Sanmite	
Chemical name	4-chloro-2-(1,1-dimethylethyl)-5-[[[4-(1,1-dimethylethyl)phenyl]methyl]thio]-3(2H)-pyridazinone	EC, 2007
CAS number	96489-71-3	EC, 2007
EC number	405-700-3	EC, 2007
SMILES code	c1cc(C(C)(C)C)ccc1CSC2=C(Cl)C(=O)N(C(C)(C)C)N=C2	
Use class	Insecticide, acaricide	EC, 2007
Mode of action	Inhibitor of mitochondrial electron transport at complex I. Non-systemic. Rapid knockdown and residual acitivity. Active against all developing stages, especially against the larval and nymph stages.	Tomlin, 2002
Authorised in NL	Yes	EC, 2007
Annex 1 listing	No	EC, 2007

3.1.2 Physico-chemical properties

Table 2. Physico-chemical properties of pyridaben.

Parameter	Unit	Value	Remark	Reference
Molecular weight	[g/mol]	364.9		EC, 2007
Water solubility	[mg/L]	0.012		Tomlin, 2002
pK_a	[-]	n.a.		
log K_{OW}	[-]	>6.37	23ºC; shake flask	EC, 2007
log K_{OC}	[-]	4.8		EC, 2007
Vapour pressure	[Pa]	$< 10^{-5}$		EC, 2007
Melting point	[°C]	110		EC, 2007
Boiling point	[°C]		Thermal decomposition starts at 200 ºC	EC, 2007
Henry's law constant	[Pa.m^3/mol]	<0.3		EC, 2007

n.a. = not applicable.

3.1.3 Behaviour in the environment

Table 3. Selected environmental properties of pyridaben.

Parameter	Unit	Value	Remark	Reference
Hydrolysis half-life	DT50 [d]	-	Hydrolytically stable	EC, 2007
Photolysis half-life	DT50 [min]	6.8	Xenon light, 25ºC	EC, 2007
Readily biodegradable		No		EC, 2007
DT50 system	[d]	20.5	Water-sediment	EC, 2007
DT50 water		2.5	system	
Relevant metabolites	PB4, PB7, PB22			EC, 2007

3.1.4 Bioconcentration and biomagnification

An overview of the bioaccumulation data for pyridaben is given in Table 4. Detailed bioaccumulation data for pyridaben are tabulated in Appendix 1.

Table 4. Overview of bioaccumulation data for pyridaben.

Parameter	Unit	Value	Remark	Reference
BCF (fish)	[L/kg]	< 25	A lipid normalised-value of < 48 is also reported.	EC, 2007
BMF	[kg/kg]	1	Default value for BCF < 2000	

3.1.5 Human toxicological threshold limits and carcinogenicity

The following R-phrases were assigned to pyridaben: T; R23/25; N; R50-53 (EC, 2007). Pyridaben is not classified as being a carcinogenic. An ADI of 0.01 mg/kg$_{bw}$/d is proposed in the DAR, based on a number of toxicity studies with NOAEL values of 1 mg/kg$_{bw}$/d (EC, 2007)

3.2 Trigger values

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

Table 5. Pyridaben: collected properties for comparison to MPC triggers.

Parameter	Value	Unit	Method/Source	Derived at section
Log $K_{p,susp\text{-}water}$	3.8	[-]	$K_{OC} \times f_{OC,susp}$ [1]	K_{OC}: 3.1.2
BCF	< 25	[L/kg]		3.1.4
BMF	1	[kg/kg]		3.1.4
Log K_{OW}	> 6.37	[-]		3.1.2
R-phrases	T; R23/25; N; R50-53	[-]		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).

- pyridaben has a log $K_{p,\ susp\text{-}water}$ > 3; derivation of $MPC_{sediment}$ is triggered.
- pyridaben has a log $K_{p,\ susp\text{-}water}$ > 3; expression of the MPC_{water} as $MPC_{susp,\ water}$ is required.
- pyridaben has a BCF < 100 L/kg; assessment of secondary poisoning is not triggered.
- pyridaben has an R25 classification, but a BCF < 100 L/kg. Therefore, an MPC_{water} for human health via food (fish) consumption ($MPC_{water,\ hh\ food}$) does not need to be derived.
- For pyridaben, 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 $MPC_{eco,\ water}$ and $MPC_{eco,\ marine}$

An overview of the selected freshwater toxicity data for pyridaben is given in Table 6. Marine toxicity data are given in Table 7. Detailed toxicity data for pyridaben are tabulated in Appendix 2. Similarly to the DAR (EC, 2007), only data for the technical compound are used for ERL derivation, since the toxicity of the formulation appears to be lower.

Table 6. Pyridaben: 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	> solubility	Algae	>solubility[b]
Crustacea	**0.086**	Crustacea	**0.62[c]**
Pisces	0.28	Pisces	3.0[d]
		Pisces	1.1[e]
		Pisces	2.3

[a] For detailed information see Appendix 2. Bold values are used for ERL derivation.
[b] Preferred endpoint (growth rate) for *Pseudokirchneriella subcapitata*.
[c] Geometric mean of 0.38 and 1.0 µg/L, parameter immobilisation for *Daphnia magna*.
[d] Geometric mean of 2.6 and 3.5 µg/L, parameter mortality for *Lepomis macrochirus*.
[e] Geometric mean of 1.8 and 0.73, parameter mortality for *Oncorhynchus mykiss*.

Table 7. Pyridaben: selected marine toxicity data for ERL derivation.

Chronic [a]		Acute [a]	
Taxonomic group	**NOEC/EC10 (µg/L)**	**Taxonomic group**	**L(E)C50 (µg/L)**
Algae	8	Crustacea	**0.67**
Crustacea	**0.047**	Mollusca	8.3
		Pisces	17

[a] For detailed information see Appendix 2. Bold values are used for ERL derivation.

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). Because there are not many marine toxicity data, it is not possible to determine with high probability that marine organisms are not more sensitive to pyridaben than freshwater organisms. Combined with the non-systemic mode of action, this is enough reason to keep the datasets for freshwater and marine waters separated.

3.3.1.2 Mesocosm and field studies

Evaluation of the key microcosm study is based on the summaries of Rand and Holmes (1995) and Healey (2004) in the DAR (EC, 2007) and on the scientific article of Rand et al. (2000). For a more detailed description see Appendix 3. Outdoor microcosms were exposed to two applications with a 29-day interval. The microcosms contained phytoplankton, periphyton, zooplankton, macroinvertebrates. Bluegill sunfish were introduced as well. The LOEC for short-term effects is based on reduction of the abundance of the insect *Oxyethira* in all treatments after the first monitoring timepoint at 7 days and effects on rotifera (LOEC $\leq$ 0.34 µg/L). The extent of the effects can not be estimated from the presented information, and thus no NOEC can be derived from this study.

3.3.1.3 Derivation of $MPC_{eco, water}$ and $MPC_{eco, marine}$

The base-set for freshwater toxicity data is complete. Chronic NOECs are available for algae (as a 'larger than solubility limit'-value), crustaceans, and fish. The lowest NOEC is 0.086 µg/L for crustacea. Please note that there are no toxicity data for insects. Insects are a sensitive taxon since pyridaben is an insecticide (mode of action is non-systemic, but it is specifically active against all developing stages, especially against the larval and nymph stages (Tomlin, 2002)). This is also shown in the model ecosystem study, where insects and rotifera are shown to be sensitive to the compound. Rotifera are also not present in the single-species toxicity dataset. Thus, despite of the fact that chronic NOECs are available for species from three trophic levels, the assessment factor of 10 may not be protective enough and an assessment factor of 50 is used on the lowest single-species NOEC (0.086 µg/L for crustaceans), which results in an $MPC_{eco, water}$ of $0.086 / 50 = 1.7 \times 10^{-3}$ µg/L.

For the marine environment, the base-set is not complete because acute data for algae are missing. However, the chronic algae study shows that algae are clearly not sensitive to this compound. Further, acute toxicity data for the mollusc *Crassostrea virginica* is available. The endpoint of this study is shell growth, which is generally considered as a sublethal endpoint. This species can be considered as representing a typical marine taxonomic group. Thus with two NOECS for algae and crustacea and subchronic toxicity data for the mollusc, an assessment factor of 50 is used on the lowest NOEC of 0.047 µg/L. The $MPC_{eco, marine}$ is set at $0.047 / 50 = 9.4 \times 10^{-4}$ µg/L.

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

Pyridaben has a BCF<100 L/kg, thus assessment of secondary poisoning is not triggered.

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

Derivation of $MPC_{water,\ hh\ food}$ for pyridaben is not triggered (Table 5).

3.3.4 $MPC_{dw,\ water}$

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

3.3.5 Selection of the MPC_{water} and MPC_{marine}

In the Fraunhofer document (Lepper, 2005) it is prescribed that the lowest MPC value should be selected as the general MPC. The lowest value of the routes included is the value for direct aquatic toxicity. Therefore, the MPC_{water} is 1.7×10^{-3} µg/L (based on the $MPC_{eco,\ water}$), and the MPC_{marine} is 9.4×10^{-4} µg/L (based on the $MPC_{eco,\ marine}$).

Because the log $K_{p\ susp\text{-}water} \geq 3$ (Table 5), the final MPC_{water} and MPC_{marine} have to be recalculated in an $MPC_{susp,\ water}$ and $MPC_{susp,\ marine}$, which refer to the concentration in suspended matter. The $MPC_{susp,\ water}$ is calculated according to:

$$MPC_{susp,\ water} = MPC_{water,\ total} / (C_{susp,\ Dutch\ standard} \times 10^{-6} + (1/K_{p,susp\text{-}water}))$$

For $MPC_{susp,\ marine}$, the $C_{susp,\ FHI}$ is used instead of $C_{susp,\ Dutch\ standard}$.

For this calculation, $K_{p,susp\text{-}water}$ is calculated using K_{OC} and the $f_{OC,susp\ dutch\ standard}$. This is not the same as the European standard $f_{OC,susp}$ which is used in the table with trigger values. With an $f_{OC,susp\ dutch\ standard}$ of 0.1176 and a log K_{OC} of 4.8, log $K_{p,susp\text{-}water}$ can be calculated to be 3.87.

This results in an $MPC_{susp,\ water}$ of $1.7 \times 10^{-3} / (30 \times 10^{-6} + (1 / 10\text{^}3.87)) = 10.3$ µg/kg, and an $MPC_{susp,\ marine}$ of $9.4 \times 10^{-4} / (3 \times 10^{-6} + (1 / 10\text{^}3.87)) = 5.7$ µg/kg.

3.3.6 MAC_{eco}

3.3.6.1 $MAC_{eco,\ water}$

The BCF is lower than 100 L/kg. However, the most sensitive species (insects, and according to the model ecosystem study also rotifera) are not included in the dataset. Thus, the assessment factor cannot be lowered from 100 to 10. Based on the lowest LC_{50} (0.62 for crustacea), the $MAC_{eco,\ water}$ is set at $0.62 / 100 = 6.2 \times 10^{-3}$ µg/L.

A model ecosystem study was performed with a single exposure of pyridaben (See section 3.3.1.2). Because no dose-effect relationship was reported and it is unclear how much effect was observed, it is not possible to derive a NOEC from this LOEC ($\leq$ 0.34 µg/L). Thus, the $MAC_{eco,\ water}$ is not based on this LOEC, but on the lowest LC_{50} and is 6.2×10^{-3} µg/L.

3.3.6.2 $MAC_{eco,\ marine}$

Three acute marine toxicity values are available, one of which is for a specific marine taxon (mollusca). Thus, an additional assessment factor of 5 is used on the assessment factor of 100 that is used for freshwater MAC derivation. Based on the lowest LC_{50} (0.67 µg/L for crustaceans), the provisional $MAC_{eco,\ marine}$ is set at $0.67 / (5 \times 100) = 1.3 \times 10^{-3}$ µg/L.

3.3.7 SRC_{eco}

Freshwater chronic data are available for crustaceans (*Daphnia*) and fish, the geometric mean of these two NOECs is 0.16 µg/L. The geometric mean of the acute data is 1.49 µg/L and these data are normally distributed (significant at all levels using the Anderson-Darling test for normality). The geometric mean of the acute data (1.49 µg/L) divided by 10 is lower than the geometric mean based on chronic data (0.16 µg/L). Thus, the $SRC_{eco, water}$ is based on the acute data with an assessment factor of 10 and becomes 1.49 / 10 = 0.15 µg/L.

3.4 Toxicity data and derivation of ERLs for sediment

3.4.1 Sediment toxicity data

No valid sediment toxicity data are available for pyridaben.

3.4.2 Derivation of $MPC_{sediment}$

Because there are no sediment toxicity data, the $MPC_{sediment}$ needs to be derived by applying the equilibrium partitioning method on the $MPC_{eco, water}$.

First, the $MPC_{sediment}$ is calculated using TGD default values, and subsequently this $MPC_{sediment}$ is recalculated to Dutch standard sediment.

$$MPC_{\text{sediment, TGD, EqP, ww}} = \frac{K_{\text{P,susp-water}}}{RHO_{\text{susp}}} \times MPC_{\text{eco, water}} \times 1000$$

with $K_{susp\text{-}water}$:

$$K_{\text{susp-water}} = F\text{air}_{\text{susp}} \times K_{\text{air-water}} + F\text{water}_{\text{susp}} + F\text{solid}_{\text{susp}} \times \frac{K\text{p}_{\text{susp}}}{1000} \times RHO\text{solid}$$

$$MPC_{\text{sediment, TGD, EqP, dw}} = \frac{RHO_{\text{susp}}}{F\text{solid}_{\text{susp}} \times RHO\text{solid}} \times MPC_{\text{sediment, TGD, EqP, ww}}$$

$$MPC_{\text{Dutch standard sediment, EqP, dw}} = \frac{Foc_{\text{Dutch standard sediment}}}{Foc_{\text{susp, TGD}}} \times MPC_{\text{sediment, TGD EqP, dw}}$$

For marine sediments, the same calculations can be performed using $MPC_{eco, marine}$.

For compounds with log K_{OW} > 5, such as pyridaben, an additional assessment factor of 10 should be used to account for extra uncertainty due to uptake by ingestion of food.

3.4.2.1 Freshwater sediment

Using log $K_{p,susp}$ = 3.8, $F\text{air}_{susp}$ = 0, $F\text{water}_{susp}$ = 0.9, $F\text{solid}_{susp}$ = 0.1, RHO_{susp} = 1150 kg/m^3, $F\text{solid}_{susp}$ = 0.1, RHO_{solid} = 2500 kg/m^3, $Foc_{\text{Dutch standard sediment}}$ = 0.0588 and $Foc_{susp,TGD}$ = 0.1 and the $MPC_{eco,water}$ of 1.7 × 10^{-3} µg/L, $MPC_{sediment}$ is calculated according to:

$$K_{\text{susp-water}} = 0 + 0.9 + 0.1 \times \frac{10\text{^}3.8}{1000} \times 2500 = 1578$$

$$MPC_{\text{sediment, TGD, EqP, ww}} = \frac{1578}{1150} \times 1.7 \times 10^{-3} \times 1000 = 2.33 \ \mu g/kg_{ww}.$$

$$MPC_{\text{sediment, TGD, EqP, dw}} = \frac{1150}{0.1 \times 2500} \times 2.33 = 10.73 \ \mu g/kg_{dw}$$

$$MPC_{\text{Dutch standard sediment, EqP, dw}} = \frac{0.0588}{0.1} \times 10.73 = 6.3 \ \mu g/kg_{dw}$$

Because pyridaben has a log $K_{OW} > 5$, an additional assessment factor of 10 should be used. Thus, the $MPC_{sediment} = 6.3 / 10 = 0.63$ µg/kg_{dw}.

3.4.2.2 Marine sediment

The $MPC_{marine\ sediment}$ is calculated analogous to the $MPC_{sediment}$ with an MPC_{marine} of 9.4×10^{-4} µg /L and becomes 3.5×10^{-2} µg/kg_{dw}.

3.4.3 Derivation of $SRC_{eco, sediment}$

The $SRC_{eco, sediment}$ is calculated using the $SRC_{eco, water}$ and the partitioning method, analogous to the calculation of the $MPC_{sediment}$. This results in an $SRC_{eco, sediment}$ of 557 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 pyridaben in fresh and marine water and sediment.

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 8. Derived MPC, MAC_{eco}, and SRC values for pyridaben.

ERL	Unit	MPC	MAC_{eco}	SRC
Water, old[a]	µg/L	7.4×10^{-5}	-	-
Water, new[b]	µg/L	1.7×10^{-3}	6.2×10^{-3}	0.15
Water, suspended matter	µg/kg	10.3	-	-
Drinking water[b]	µg/L	0.1[c]	-	-
Sediment	$\mu g/kg_{dw}$	0.63	-	557
Marine	µg/L	9.4×10^{-4}	1.2×10^{-3}[c]	-
Marine, suspended matter	µg/kg	5.7	-	-
Marine sediment	$\mu g/kg_{dw}$	3.5×10^{-2}	-	-

[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 $MPC_{dw, water}$, and the $MAC_{eco, marine}$ (see Section 2.3.1 and 2.3.2)

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Appendix 1. Information on bioconcentration

Table A1.1 Bioconcentration data for pyridaben

Species	Species properties	Substance purity	A	Test type	Test water	T [°C]	pH	Exp. time [d]	Exp. conc. [µg/L]	BCF [L/kg]	BCF type	Method	Ri	Notes	Reference
Oncorhynchus mykiss		tg	LSC	F		11.3-13.1	7.4-8.2	28	0.11	293-398	equi	14C	3	1,2,3	DAR: Jenkins, 1994
Oncorhynchus mykiss		tg	LSC	F		11.3-13.1	7.4-8.2	28	0.11	309-401	k1/k2	14C	3	1,2,3	DAR: Jenkins, 1994
Cyprinus carpio	17.2 g; 8.7 cm; 3.1% lipids		RP-HPLC	F		25		29	1	<25	equi	HPLC	2	4,5	DAR: Ohuchiyama, 1987

Notes:
1 BCF based on total radioactivity, not only for the parent compound. In a supplementary study, no parent pyridaben was identified in any fish sample with a TLC-radiodetection method. Thus, BCF based on total radioactivity can be assumed to be a large overestimation.
2 Nominal concentration was 0.16 µg/L
3 Steady state was reached after 14 or 3 days, depending on which group was 14C labelled.
4 Due to the height of the exposure concentration, toxic effects during the study cannot be excluded, although no abnormal behaviour or appearance was observed
5 No controls

Appendix 2. Detailed aquatic toxicity data

Table A2.1. Acute toxicity of pyridaben to freshwater organisms.

Species	Species properties	Test compound	Purity [%]	A	Test type	Test water	pH	T [°C]	Hardness $CaCO_3$ [mg/L]	Exp. Time	Criterion	Test endpoint[b]	Value [µg/L]	Ri	Notes	Reference
Algae																
Pseudokirchneriella subcapitata		formulation	76.8	N	S					72 h	ErC50	growth rate	68000	3	1a,1b,9	DAR, Jenkins 2002c
Pseudokirchneriella subcapitata		formulation	76.8	N	S					72 h	EbC50	Biomass	35000	3	1a,1b,9	DAR, Jenkins 2002c
Crustacea																
Daphnia magna		a.s.								48 h	EC50	immobilisation	0.53	4		EPA, 2000
Daphnia magna	first instars	a.s.	98	Y	S					48 h	EC50	immobilisation	0.38	2	2,3	DAR, Willis & Wilson 1987
Daphnia magna	first instars	a.s.	98	Y	S					48 h	NOEC		0.3	2	3,4	DAR, Willis & Wilson 1987
Daphnia magna	first instars	a.s.	99.7	Y	FT					48 h	EC50	Immobilisation	1.0	2	5,6	DAR, Graves & Swigert 1993
Daphnia magna	first instars	a.s.	99.7	Y	FT					48 h	NOEC		0.22	2	6,7	DAR, Graves & Swigert 1993
Daphnia magna		formulation	76.5	Y	S					48 h	EC50	Immobilisation	0.99	2	8,9,10	DAR, Jenkins 2002b
Daphnia magna		formulation	76.5	Y	S					48 h	NOEC		0.17	2	8,10,11	DAR, Jenkins 2002b
Pisces																
Lepomis macrochirus	juvenile?	formulation	75.8	Y	S					96 h	LC50	Mortality	6.4	3	2,12,13	DAR, Springer et al. 1994
Lepomis macrochirus	juvenile?	formulation		Y	S					96 h	NOEC		< 3.1	3	4,12,13	DAR, Springer et al. 1994
Lepomis macrochirus	juvenile	a.s.	98	Y	R					96 h	LC50	Mortality	2.6	2	5,14,15	DAR, Willis 1988
Lepomis macrochirus	juvenile	a.s.	98	Y	R					96 h	NOEC		1.1	2	7,14,15	DAR, Willis 1988
Lepomis macrochirus	juvenile	a.s.	100	Y	FT					96 h	LC50	Mortality	3.5	2	5,16	DAR, Ward 1994b
Lepomis macrochirus	juvenile	a.s.	100	Y	FT					96 h	NOEC		2.2	2	7,16	DAR, Ward 1994b
Oncorhynchus mykiss	juvenile	a.s.	98	Y	R					96 h	LC50	Mortality	1.8	2	5,15,17	DAR, Willis 1987
Oncorhynchus mykiss	juvenile	a.s.	98	Y	R					96 h	NOEC		1.5	2	7,15,17	DAR, Willis 1987
Oncorhynchus mykiss	juvenile	a.s.	100	Y	FT					96 h	LC50	Mortality	0.73	2	5,16,18	DAR, Ward 1994a
Oncorhynchus mykiss	juvenile	a.s.	100	Y	FT					96 h	NOEC		0.29	2	7,16,18	DAR, Ward 1994a
Oncorhynchus mykiss	juvenile?	formulation	76.8	Y	R					96 h	LC50	Mortality	2.2	2	1a,9,19	DAR, Jenkins 2002a
Oncorhynchus mykiss	juvenile?	formulation	76.8	Y	R					96 h	NOEC		0.57	2	1a,11,19	DAR, Jenkins 2002a
Pimephales promelas		a.s.	99	Y	FT					96 h	LC50	Mortality	2.3	2		Rand & Clark, 2000
Pimephales promelas		a.s.	99	Y	FT					96 h	NOEC		1.6	2		Rand & Clark, 2000

Notes:
b Test endpoints for NOECs not reported in the DAR-summaries, but most probably according to test protocol.
1a Formulation with 76.8% a.s.
1b OECD 201, EEC C3. Far above solubility limits.
2 L(E)C50 based on initial measured concentrations.
3 Study not accepted by RMS for risk assessment due to analytical incompletenesses. However, the test results are useful for ERL derivation as (a) test of 1987 was at that time in accordance with OECD guideline, (b) analytical incompletenesses are considered of minor importance. EPA-540/9-85-005 (1), OECD 202.
4 NOEC based on initial measured concentrations.
5 L(E)C50 based on mean measured concentrations.
6 EPA 72-2 (a).
7 NOEC based on mean measured concentrations.
8 WP formulation with 76.5% a.s..
9 L(E)C50 based on nominal concentrations.
10 EEC C2, OECD 202.
11 NOEC based on nominal concentrations.
12 WP formulation with 75.8% a.s.
13 Study with outdoor microcosms. Approximately 5 cm clay (1.1% organic matter) and 5 cm topsoil (1.3% organic matter) were placed on the bottoms of the tanks and covered with 4 L of hydrosoil. EPA 72-

7(A). This study is not valid for ERL derivation due to the presence of sediment in the exposure systems

14 Study unacceptable for DAR risk evaluation by RMS due to low recoveries after 48 h. However, it is not clear whether this could have been prevented. Therefore, the study is acceptable for ERL derivation.

15 The LC50 clearly falls within the range of other LC50 values for fish. EPA-540/9-85-006, OECD 203.

16 EPA 72-1.

17 Study unacceptable for DAR risk evaluation by RMS due to recoveries of spikes 'at low concentrations' down to 20%. However, it is not clear whether this could have been prevented. Therefore, the study is acceptable for ERL derivation.

18 Apparently a more reliable study than Willis 1987 due to FT versus SS. However, does that legitimate to skip Willis as was done by RMS?.

19 EEC C-1, OECD 203.

Table A2.2. Acute toxicity of pyridaben to marine organisms.

Species	Species properties	Test compound	Purity [%]	A	Test type	Test water	pH	T [°C]	Salinity [‰]	Exp. Time	Criterion	Test endpoint[b]	Value [µg/L]	Ri	Notes	Reference
Crustacea																
Americamysis bahia	<24-hour old	formulation	75.4	Y	S	Nw	8.1-8.3	24-27		96 h	LC50	mortality	16	3	1	DAR, Cunningham 1996
Americamysis bahia	<24-hour old	formulation	75.4	Y	S	nw	8.1-8.3	24-27		96 h	NOEC		5.9	3	1	DAR, Cunningham 1996
Americamysis bahia		a.s.	99.7	Y	FT					96 h	LC50	Mortality	0.67	2	2	DAR, Morrow 1993
Americamysis bahia		a.s.	99.7	Y	FT					96 h	NOEC		0.15	2	2	DAR, Morrow 1993
Mollusca																
Crassostrea virginica		a.s.	100	Y	FT					96 h	EC50	shell deposition	8.3	2	2	DAR, Ward 1994c
Crassostrea virginica		a.s.	100	Y	FT					96 h	NOEC	shell deposition	0.20	2	2	DAR, Ward 1994c
Pisces																
Cyprinodon variegatus	juvenile	a.s.	99.7	Y	FT					96 h	LC50	Mortality	17	2	2	DAR, Morrow & Ward 1993
Cyprinodon variegatus	juvenile	a.s.	99.7	Y	FT					96 h	NOEC		6.2	2	2	DAR, Morrow & Ward 1993

Notes:
b Test endpoints for NOECs not reported in the DAR-summaries, but most probably according to test protocol.
1 Formulation with 75.4% a.s. Endpoint based on initial measured concentrations. Salinity: 20-23 ‰. EPA 72-2 with modifications. Study performed in outdoor static systems, within 48 or 96 hours of exposure compound was below detection limits, which is not acceptable for ERL derivation.
2 Endpoint based on mean measured concentrations. EPA 72-3.

Table A2.3. Chronic toxicity of pyridaben to freshwater organisms.

Species	Species properties	Test compound	Purity [%]	A	Test type	Test water	pH	T [°C]	Hardness $CaCO_3$ [mg/L]	Exp. Time	Criterion	Test endpoint[b]	Value [µg/L]	Ri	Notes	Reference
Algae																
Navicula pelliculosa		a.s.	99.7	Y	S					120 h	EC6	growth rate	14	2	1	DAR, Hughes & Jackson 1994
Pseudokirchneriella subcapitata		a.s.	99.7	Y	S					72 h	EC1	growth rate	12	2	1	DAR, Hughes & Jackson 1994
Pseudokirchneriella subcapitata		a.s.	98	Y	S					96 h	NOEC	growth rate	1000	3	2	DAR, Jenkins 1988
Pseudokirchneriella subcapitata		formulation	76.8	N	S					72 h	NOEC	growth rate	16000	2	3,4	DAR, Jenkins 2002c
Pseudokirchneriella subcapitata		formulation	76.8	N	S					72 h	NOEC	biomass	16000	2	3,4	DAR, Jenkins 2002c
Cyanophyta																
Anabaena flos-aquae		a.s.	99.7	Y	S					120 h	EC6	growth rate	13	2	1	DAR, Hughes & Jackson 1994
Crustacea																
Daphnia magna	1st instar, ≤ 24 h	a.s.	99.2	Y	R					21 d	NOEC	Immobility/ reproduction	0.043	3	5	DAR, Jenkins et al. 1989
Daphnia magna		a.s.	> 99	Y	FT					21 d	NOEC	reproduction	0.086	2	6	DAR, Drottar & Swigert 1994
Macrophyta																
Lemna gibba		a.s.	99.7	Y	S					14 d	EC3	frond number increase	16	2	7	DAR, Hughes & Jackson 1994
Pisces																
Pimephales promelas	juvenile	a.s.	> 93	Y	FT					301 d	NOEC	fry growth, egg hatchability, survival	0.28	2	8	DAR, Rhodes et al. 1995
Oncorhynchus mykiss	juvenile	a.s.	?	Y	FT					21 d	NOEC	'survival and symptoms'	0.84	3	9	DAR, Jenkins 1989

Notes:
1 Limit test with one concentrationl. Endpoint based on initial measured concentrations. Endpoint(s) not mentioned in DAR. As OPP Guideline 122-2 (is OPPTS 850-4400) cannot be retrieved, endpoints are reasonable guess
2 NOEC based on immobilisation. Due to differences between replicates of the same treatment up to 4.8 times the study is considered unreliable and thus not useful for ERL derivation.
3 Formulation with 76.8% a.s.. NOEC based on nominal concentrations. OECD 201, EEC C3.
4 Higher than solubility limts; concentrations not measured
5 NOEC based on mean measured concentrations. RMS considered test as unreliable due to lack of data (specification of measured activity into a.s. and residues). As the rapid photolytic degradation required a specific a.s. analysis, specifically as the study was semi-static, rather than an analysis of equivalents (incl metabolites), the NOEC is unreliable and therefore not useful for ERL derivation. OECD 202. Endpoints not reported in summary in DAR, but most probably according to test protocol.
6 NOEC based on mean measured concentrations. Endpoints not reported in summary in DAR, but most probably according to test protocol.
7 EC3 based on initial measured concentrations. RMS considered study unreliable as only frond numbers and not dry, fresh weight and/or frond area as conform OECD 221 (2002) were determined. However, study is in accordance with guideline those days and not really improper (OPP Guideline 122-2/OPPTS 850-4400). Therefore in principle useful for ERL derivation. A propos, (a) only one test concentration, (b) RMS reported NOEC value erroneously as EC50 value.
8 NOEC based on mean measured concentrations. EPA 72-5.
9 NOEC based on mean measured concentrations. RMS considered test as unreliable due to lack of data (length and weight development, purity, batch number, specification of measured activity into a.s. and residues). As the rapid photolytic degradation required a specific a.s. analysis rather than an analysis of equivalents (incl metabolites), the NOEC is unreliable and therefore not useful for ERL derivation. OECD 204.

Table A2.4. Chronic toxicity of pyridaben to marine organisms.

Species	Species properties	Test compound	Purity [%]	A	Test type	Test water	pH	T [°C]	Salinity [‰]	Exp. Time	Criterion	Test endpoint	Value [µg/L]	Ri	Notes	Reference
Algae																
Skeletonema costatum		a.s.	99.7	Y	S					120 h	NOEC	growth rate	8.0	2	1	DAR, Hughes & Jackson 1994
Crustacea																
Americamysis bahia	<24 h	a.s.	>99	Y	FT					35 d	NOEC	Mortality, reproduction and growth	0.047	2	2	DAR, Holmes & Machado 1994

Notes:
1 NOEC calculated as EC20/2. EC20 = 0.016 ug/L and based on initial measured concentrations. Endpoint(s) not mentioned in DAR. As OPP Guideline 122-2 (is OPPTS 850-4400) cannot be retrieved, endpoints are reasonable guess. Limit test, and thus only one concentration tested.
2 NOEC based on mean measured concentrations. The concentration of the radiolabelled a.s. has only been verified in the stock solution. In view of this verification the measured activity was corrected for the lowest recovery (67% at the top-dose). EPA 72-4 (c).

Appendix 3. Description of mesocosm studies

DAR: Rand and Holmes, 1995; DAR: Healey, 2004; Rand et al., 2000; Rand et al., 2001

Species/Population/ Community	zooplankton, phytoplankton, periphyton, macroinvertebrates, fish			
Test Method	outdoor microcosms			
System properties	6.7 m length * 1.9 m wide * 1.9 m high, oligo-mesotrophic			
Formulation	Pyridaben 75 WP			
Analyzed	Y			
Exposure regime	two applications with 29-d interval; 0.34, 3.4 and 34 µg/L			
Experimental time	until 12 w after first application			
Criterion	NOEC 1 d after 1st treatment	NOEC 7 d after 1st exposure		NOEC 21 d after 1st exposure
Test endpoint	Zooplankton populations (nauplii and Diaptomus); Zooplankton community (PRC)	Macroinvertebrates (Oxyethira)	Macroinvertebrate community (PRC)	Phytoplankton populations (PRC)
Value [µg/L]	0.34	<0.34	≥ 43	3.4
Ri	2	2	2	2
Reference	Rand and Holmes, 1995; Healey, 2004; Rand et al., 2000; Rand et al., 2001			

Evaluation of the underlying microcosm study is performed on the summaries of Rand and Holmes (1995) and Healey (2004) in the DAR and on the scientific article of Rand et al. (2000).

Evaluation of the scientific reliability of the field study

Criteria for a suitable (semi)field study

1. Does the test system represent a realistic freshwater community? Microcosms were supplied with water and sediment from an existing pond, thereby introducing natural assemblages of zooplankton, phytoplankton, periphyton, benthic macroinvertebrates and other microorganisms into the microcosms. No macrophytes were present. Bluegill sunfish were purchased from a commercial supplier and stocked as juveniles in each microcosm (20 fish/cosm, 1.0 g fish/m^3).
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 exposure regime is adequately described. Cosms were treated twice at 0.34, 3.4 and 34 µg/l with a 29-d interval. Control and treatments were replicated 6 times. Half-lives after applications one and two in all three treatments (0.34, 3.4 and 34 µg/l) were ≤ 21.0 h and ≤ 28.5 h, respectively. The half-life of pyridaben in sediment after the second application of 34.0 µg/l was 9.8 d. The study is considered to be useful to derive a MAC value. Residues 0-30 minutes after the first and second treatment were far higher than the nominal values, probably due to an inhomogeneous distribution in the water column. From 12 hours after both applications, the measured concentrations were in fair agreement with the nominal treatment values. The Evaluating Institute considered the use of nominal values to express effect concentrations acceptable.
4. Are the investigated endpoints sensitive and in accordance with the working mechanism of the compound? Yes. In laboratory studies, *Daphnia* and fish were most susceptible to pyridaben, as was also the case in the underlying cosm-experiment. However, macroinvertebrates were monitored only after 7 and 28 days after first and second application (plus 8 weeks after the second treatment). This sampling frequency is considered to be rather low.
5. Is it possible to evaluate the observed effects statistically? No, but the statistics described in the three documents are considered to be sufficient to evaluate the study results adequately.

This result in an overall assessment of the study reliability, due to the presence of fish -> Ri 2.

Evaluation of the results of the study
For Oxyethira, statistically significant reductions were observed at all treatments on day 7 after the first treatment and at the highest treatment after the second treatment. Since the sampling frequency was low, the evaluation of the test results by the RMS is based on significant effects observed on single sampling dates. NOECs for the populations of Hydra, Dero and Oribatei were 3.4 µg/l on day 7 and ≥ 34 µg/l for the macroinvertebrate community as estimated by PRC.
The evaluating institute did not discuss the presence of fish. Mean fish mortality at test termination was 4, 14, 2 and 26% in the control, low, mid and high dose, respectively. Statistical significance of the deviations were not reported. At study end, mean fish length and weight were significantly higher at the high dose compared to the other treatments, probably due to reduced competition for food. Elevated levels of Monostyla, Synchaetidae, Lecanidae and Ilyocryptus were found in the mid and high dose between 28 days after the first dose and 21 to 28 days after the second dosage. The author of the original study report suggested that these increases might be due to reduced predation by fish.

Further discussion
The LOEC is < 0.34 µg/l on basis of nominal concentrations and effects on Oxyethira. Because no dose-effect relationship is reported and it is unclear by how much the Oxyethira were affected, it is not possible to determine a NOEC.

DAR: Singh, 1994

Species Population Community	zooplankton, phytoplankton, periphyton, macroinvertebrates, fish
Test Method	outdoor microcosms
System properties	2.36 m length * 0.87 m wide * 0.53 m high, oligo-mesotrophic
Formulation	Pyridaben 75 WP
Analyzed	Y
Exposure regime	two applications with 20-h interval
Experimental time	56 d
Criterion	NOEC
Test endpoint	fish mortality, length and weight
Value [µg/L]	1.7
Notes	only fish were monitored
Ri	3
Reference	Singh, 1994

Evaluation of the underlying microcosm study is performed on basis of the summaries of Singh (1994) in the DAR.
Evaluation of the scientific reliability of the field study
Criteria for a suitable (semi)field study

1. Does the test system represent a realistic freshwater community? Microcosms were supplied with water and sediment from an existing pond. Primary production was ensured by fertilization with liquid ammoniated polyphosphate fertilizer 1½ month before the first application. Thirty bluegill sunfish with a mean length of 5.6 cm were stocked into each microcosm 17 days prior first application. Only fish were monitored. Acclimatisation period is considered to be rather short to obtain a stable ecosystem.
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? One tank was treated with [benzene-U-14C]-pyridaben, another with [pyridazinone-3,6-14C]-pyridaben and one tank served as control. No replicates. Tanks were treated with a simulated spray drift application on day 0 and a simulated runoff 20 hours later. The first treatment was applied by injecting 400 ml of an aqueous suspension containing 1157 µg of radiolabeled compound and 0.4 mg of inert WP powder (clay, lignosulfonate and silica). The second treatment was applied by pouring 400 mL of an aqueous suspension containing

1389 µg of the radiolabeled compound, 0.5 mg of inert WP powder and 101 g of sieved soil over the water surface. At this time, the control tank was treated with a similar slurry mixture without test substance. The treatment solutions contained 3.75% v/v methanol. Effects at this concentration are considered to be negligible. Radiochemical purity of the test compound was >96% prior to each application. The exposure regime is adequate to derive a MAC-value. However, the compound was only analysed as radioactivity and pyridaben is known to degrade rapidly.

4. Are the investigated endpoints sensitive and in accordance with the working mechanism of the compound? In laboratory studies, *Daphnia* and fish were most susceptible to pyridaben. In the present study, fish were collected for residue analysis on day 4 and 56 after the first application. Zooplankton, macroinvertebrates and phytoplankton were not monitored at all.
5. Is it possible to evaluate the observed effects statistically? One tank was treated with [benzene-U-14C]-pyridaben, another with [pyridazinone-3,6-14C]-pyridaben and one tank served as control. No replicates of the controls. Focus was on bioaccumulation. At the end of the study it was summarized that overall mortality was 10% in the control and 7% in both pyridaben treatments. Fish lengths and weights in the pyridaben treatments were not different from those in the control. However, length and weight were not reported in the DAR-summary.

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

Appendix 4. Detailed sediment toxicity data

Table A4.1. Chronic toxicity of pyridaben to freshwater sediment organisms.

Species	Species properties	Test compound	Purity [%]	A	Test type	Test water	pH	T [°C]	Hardness/ Salinity	Exp. Time	Criterion	Test endpoint	Value [mg/L]	Ri	Notes	Reference
Insecta																
Chironomus riparius	<36 h old, 1st instar	a.s.	>97	Y	S					28d	NOEC	mortality, emergence time, # emerged ♂♀, larval dwt increase	0.0051	3	1	DAR, Albuquerque 2003b

Notes:
1 NOEC based on initial concentrations measured by LSC only, therefore not discriminating between a.s. and residues. In view of photolytic instability, the test result of 0.0051 mg eq/L is not useful for ERL derivation. Guideline Draft OECD 219 recommends a 16 h light period. It should be noted that the RMS has accepted the study for risk assessment (first draft). Draft OECD 219. No result based on sediment concentrations reported.

Appendix 5. References used in the appendices

DAR:
EC. 2007. Pyridaben, Draft Assessment Report. Rapporteur Member State: The Netherlands.
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