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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 imidacloprid

Dit rapport geeft milieurisicogrenzen voor het insecticide imidacloprid in water. 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 (freshwater and marine) are derived for the insecticide imidacloprid. 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). Imidacloprid 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) and/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 pesticides, the evaluation report prepared within the framework of EU Directive 91/414/EC (Draft Assessment Report, DAR) was consulted (EC, 2006; 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).

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

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

3.1.1 Identity

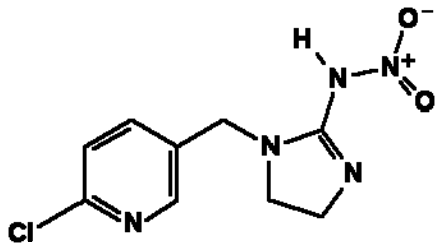

Figure 1. Structural formula of imidacloprid.

Table 1. Identification of imidacloprid.

Parameter	Name or number	Source
Common/trivial/other name	imidacloprid	
Chemical name	1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine	EC, 2006
CAS number	[138261-41-3]	EC, 2006
	[105827-78-9] former number	Tomlin, 2003
EC number	-	
SMILES code	C1CN(C(=N1)N[N+](=O)[O-])CC2=CN=C(C=C2)Cl	
Use class	systemic insecticide	
Mode of action	Binds to postsynaptic nicotinic receptors in the insect central nervous system	Tomlin, 2003
Authorised in NL	Yes	
Annex 1 listing	Yes	

3.1.2 Physico-chemical properties

Table 2. Physico-chemical properties of imidacloprid.

Parameter	Unit	Value	Remark	Reference
Molecular weight	[g/mol]	255.7		EC, 2006
Water solubility	[mg/L]	610	20 ºC	EC, 2006
pK_a	[-]	-		
log K_{OW}	[-]	0.57		EC, 2006
		0.41	KowWin	US EPA, 2007
		-1.56	ClogP	BioByte, 2006
log K_{OC}	[-]	2.36	K_{oc} 212 L/kg (mean of 12 soils)	EC, 2006
Vapour pressure	[Pa]	4×10^{-10}	20 ºC	EC, 2006
		9×10^{-10}	25 ºC (extrapolated; 50 - 70 ºC)	
Melting point	[°C]	144 ºC		EC, 2006
Boiling point	[°C]			
Henry's law constant	[Pa.m^3/mol]	1.7×10^{-10}		EC, 2006

3.1.3 Behaviour in the environment

Table 3. Selected environmental properties of imidacloprid.

Parameter	Unit	Value	Remark	Reference
Hydrolysis half-life	DT50 [d]	appr. 1 year	No degradation at pH 5, slight degradation at pH 9.	EC, 2006
Photolysis half-life	DT50	57 min.	pH 7, 23-24.5 ºC, artificial light, sterile water	EC, 2006
		4.2 h.	environmental, calculated	Liu et al., 2006
		4.7-18 min.	25 ºC, 254 nm	Moza et al., 1998
		1.2 h.	24 ± 1 ºC, ≥ 290 nm, deionised water	Wamhoff & Schneider, 1999
		43 min.	HPLC grade water	Wamhoff & Schneider, 1999
		126 min.	Confidor in tap water	Wamhoff & Schneider, 1999
		144 min.	Confidor + TiO_2 in tap water	Wamhoff & Schneider, 1999
Degradability			not readily biodegradable	EC, 2006
Water/sediment systems	DT50 [d]	129	Stillwell, Kansas, silty clay	EC, 2006
		32	NL, loamy silt	
		142	NL, loamy sand	
Relevant metabolites	photometabolites: NTN33893-desnitro-olefine NTN33893-desnitro NTN33893-urea			EC, 2006

3.1.4 Bioconcentration and biomagnification

There are no experimental data available for imidacloprid.

Table 4. Overview of bioaccumulation data for **imidacloprid**.

Parameter	Unit	Value	Remark	Reference
BCF (fish)	[L/kg]	0.61	calculated with log K_{ow} 0.57	Veith et al., 1979
BMF	[kg/kg]	1	Default value for log K_{ow} < 4.5	

3.1.5 Human toxicological treshold limits and carcinogenicity

Imidacloprid is not classified as being carcinogenic. The following R-phrase related to human toxicology is proposed in the DAR: R22. No data are available in ESIS (http://ecb.jrc.it/esis/; date of search 4 April 2008). An ADI of 0.06 mg/kg_{bw} is proposed in the DAR, based on a 2-year rat study with a NOAEL value of 6 mg/kg_{bw}/d with a safety factor of 100.

3.2 Trigger values

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

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

Parameter	Value	Unit	Method/Source	Derived at section
Log $K_{p,susp\text{-}water}$	1.326	[-]	$K_{OC} \times f_{OC,susp}$[1]	K_{OC}: 3.1.2
BCF	-	[L/kg]		3.1.4
BMF	-	[kg/kg]		3.1.4
Log K_{OW}	0.57	[-]	mean value	3.1.2
R-phrases	R22, R50/R53	[-]		3.1.5
A1 value	-	[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).

- Imidacloprid has a log $K_{p,\ susp\text{-}water}$ < 3; derivation of $MPC_{sediment}$ is not triggered.
- Imidacloprid has a log $K_{p,susp\text{-}water}$ < 3; expression of the MPC_{water} as $MPC_{susp,\ water}$ is not required.
- Imidacloprid is classified as R22 but has a log K_{ow} < 3; derivation of an MPC_{water} for human health via food (fish) consumption ($MPC_{hh\ food,\ water}$) is not triggered.
- For imidacloprid 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 $MPC_{eco,\ marine}$

Imidacloprid is rapidly degraded under the influence of light (see Table 3). Endpoints from tests that were not performed in the dark were considered not reliable (Ri 3), unless concentrations were measured.

An overview of the selected freshwater toxicity data for imidacloprid is given in Table 6. Marine toxicity data are given in Table 7. Detailed toxicity data for imidacloprid are tabulated in Appendix 2.

Table 6. Imidacloprid: selected freshwater toxicity data for ERL derivation.

Chronic[a]		**Acute**[a]	
Taxonomic group	**NOEC/EC10 (µg/L)**	**Taxonomic group**	**L(E)C50 (µg/L)**
cyanobacteria	24900	cyanobacteria	32800
algae	6690	crustacea	85000[b]
crustacea	1800	crustacea	832[c]
insecta	**0.67**	crustacea	**1**[d]
pisces	1200	crustacea	10[e]
		crustacea	55[f]
		crustacea	3[g]
		insecta	10.5[h]
		insecta	8.10[i]
		pisces	> 83000[j]
		pisces	> 105000[j]

[a] For detailed information see Appendix 1. Bold values are used for ERL derivation.
[b] Most sensitive endpoint for *Daphnia magna*, parameter mortality
[c] Most sensitive endpoint for *Chydorus sphaericus*, parameter immobility
[d] Most sensitive endpoint for *Cypretta seuratti*, parameter immobility
[e] Most sensitive endpoint for *Cypridopsis vidua*, parameter immobility
[f] Most sensitive endpoint for *Hyalella azteca*, parameter immobility
[g] Most sensitive endpoint for *Ilyocypris dentifera*, parameter immobility
[h] Most sensitive endpoint for *Chironomus tentans*, parameter mortality
[i] Geometric mean of 6.75, 8.25 and 9.54 µg/L, parameter mortality for *Simulium vittatum*
[J] Data for fish show that fish are not the most sensitive species. Valid tests did not result in effects > 50% at highest treatment level resulting in LC50 values of > 83 mg/L for *Oncorhynchus mykiss* and > 105 mg/L for *Lepomis macrochirus.*

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

Chronic[a]		**Acute**[a]	
Taxonomic group	**NOEC/EC10 (µg/L)**	**Taxonomic group**	**L(E)C50 (µg/L)**
		crustacea	35.9[b]
		pisces	161000[c]

[a] For detailed information see Appendix 1. Bold values are used for ERL derivation.
[b] Geometric mean of 36, 37.7 en 34.1 µg/L, parameter mortality for *Americamysis bahia*
[c] Most sensitive endpoint for *Ilyocypris dentifera*, parameter immobility

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). For imidacloprid, too few data are available to make a valid comparison, and datasets are kept separated.

3.3.1.2 Mesocosm and field studies

A mesocosm experiment is included in the DAR, a summary is given in Appendix 2. The impact of Imidacloprid SL 200 (17.3% w/w) on freshwater microcosm pond communities was investigated under

outdoor conditions. Experimental ponds were exposed to imidacloprid in two peaks and actual concentrations declined rather rapidly. Therefore, the results of the underlying study are not suitable for $MPC_{eco, water}$ derivation but will be considered for derivation of the $MAC_{eco, water}$. The 0.6 µg/L-treatment is considered as the NOEC, actual initial concentrations at this level were similar to the nominal.

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

The acute base set is not complete. No valid data for algae are available, while for fish valid tests did not result in effects > 50% at concentrations of 83 and 105 mg/L. However, both algae and fish are present in the chronic data set, and as expected from the mode of action, they appear not to be sensitive in comparison with crustacea and insects. It is therefore accepted that the absence of acute data for algae and fish is compensated for by the presence of chronic studies, and the $MPC_{eco, water}$ can be derived by applying an assessment factor of 10 to the lowest NOEC of 0.67 µg/L for *Chironomus tentans*. The $MPC_{eco, water}$ is 0.067 µg/L.

The marine base-set is not complete because data for algae are missing. However, in view of imidacloprid being an insecticide with a specific mode of action, it is not expected that algae are more sensitive than crustacea and the data are treated as if the base set were complete. The $MPC_{eco, marine}$ is therefore derived by putting an assessment factor of 10000 to the LC_{50} of 35.9 µg/L for *Americamysis bahia*. The $MPC_{eco, marine}$ is 3.6×10^{-3} µg/L.

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

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

3.3.3 $MPC_{hh\ food, water}$

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

3.3.4 $MPC_{dw, water}$

An A1 value is not available. The Drinking Water Standard is 0.1 µg/L, the $MPC_{dw, water}$ is 0.1 µg/L.

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

The lowest value of the routes included (see Chapter 2.3) is the $MPC_{eco, water}$. Therefore, the MPC_{water} is 0.067 µg/L.

Therefore, the MPC_{marine} is based on the $MPC_{eco, marine}$ and set to 3.6×10^{-3} µg/L.

3.3.6 MAC_{eco}

3.3.6.1 $MAC_{eco, water}$

The acute base set is not complete, because data on algae are missing. As stated above, algae are not expected to be the most sensitive species, which is confirmed by the chronic data. Imidacloprid has no potential to bioaccumulate, has a known mode of action (systemic insecticide) and the potentially most sensitive group (insects) is included in the data set. Therefore, an assessment factor of 10 is applied to the lowest acute EC_{50} value of 1 µg/L for *Cypretta seuratti*. This results in a $MAC_{eco, water}$ of 0.1 µg/L.

A NOEC of 0.6 µg/L was derived from a mesocosm experiment. Insects (Chironomids and Baetidae) appeared to be most sensitive. From a comparison of mesocosm studies with the insecticides chlorpyrifos and lambda-cyhalothrin, it can be concluded that an assessment factor of 3 may be

necessary to cover variation at the level of the NOEAEC[1] in case one reliable study is available (De Jong et al., 2008, based on Brock et al., 2006).
Lepper (2005) argues that the scope of protection of an environmental quality standard under the WFD is broader than that of the "acceptable concentration" under Directive 91/414. It should be considered that the quality standard must be protective for all types of surface waters and communities that are addressed by the respective standard. Mesocosm studies performed in the context of 91/414 are normally focused on agricultural ditches that can be characterised as eutrophic shallow water bodies. Environmental quality standards under the WFD, however, must assure protection also for water bodies that significantly differ from this paradigm (Lepper, 2005). It is therefore in principle proposed to use an assessment factor of 3 on the NOEC instead of on the NOEAEC.
For derivation of an ERL, it is therefore considered adequate to put the assessment factor of 3 to the NOEC. The $MAC_{eco, water}$ is set to 0.2 µg/L.

3.3.6.2 $MAC_{eco, marine}$

The $MAC_{eco, marine}$ is provisionally derived using the assessment factor for freshwater (10), with an additional factor of 10 because no specific marine taxa (as defined in the TGD: echinoderms, molluscs, coelenterata) are present (see Section 2.3.2). The total assessment factor of 100 is put on the lowest LC_{50} of 35.9 µg/L for *Americamysis bahia* (Crustacea). The provisional $MAC_{eco, marine}$ is 0.36 µg/L.

3.3.7 $SRC_{eco, water}$

NOECs are available for five taxa, including algae, *Daphnia* and fish. The SRC_{eco} is based on the geometric mean of all available NOECs with an assessment factor of 1 and is 752 µg/L.

3.4 Toxicity data and derivation of ERLs for sediment

The log $K_{p, susp-water}$ of imidacloprid is below the trigger value of 3, therefore, ERLs are not derived for sediment.

[1] NOEAEC = No Observed Ecologically Adverse Effect Concentration. Concentration at which effects observed in a study are considered acceptable from a regulatory point of view.

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 imidacloprid in water. No risk limits were derived for the sediment compartment because exposure of sediment is considered negligible.

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 imidacloprid.

ERL	Unit	MPC	MAC_{eco}	SRC
Water, old[a]	µg/L	0.013	-	-
Water, new[b]	µg/L	0.067	0.2	752
Drinking water[b]	µg/L	0.1[d]	-	-
Marine	µg/L	3.6×10^{-3}	0.36[e]	-

[a] indicative ERL ('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] n.d. = not derived due to lack of data

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

[e] provisional value pending the decision on implementation of the $MAC_{eco, marine}$ (see Section 2.3.2)

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Appendix 1. Detailed aquatic toxicity data

Table A1.1. Acute toxicity of imidacloprid to freshwater organisms.

Species	Species properties	A	Test type	Test compound	Purity [%]	Test water	Hardness $CaCO_3$ [mg/L]	pH	T [°C]	Exp. time	Criterion	Test endpoint	Value [mg/L]	Ri	Notes	Reference
Cyanobacteria																
Anabaena flos-aquae	log phase growth	Y	S	NTN 33893 2F	21.6			7.5	24	96 h	EC50	growth rate	32.8	2	8	Anatra-Cordone and Durkin, 2005
Algae																
Pseudokirchneriella subcapitata		N	S	imidacloprid	98.6					72 h	EC50	biomass	> 100	3	1, 13	DAR, 2005
Pseudokirchneriella subcapitata		N	S	imidacloprid	98.6					72 h	EC50	growth rate	> 100	3	1, 13	DAR, 2005
Scenedesmus subspicatus		N	S	imidacloprid						72 h	EC50	biomass	> 10	3	1, 13	DAR, 2005
Scenedesmus subspicatus		N	S	imidacloprid						72 h	EC50	growth rate	> 10	3	1, 13	DAR, 2005
Scenedesmus subspicatus		N	S	imidacloprid	92.8			8.1-9.2	23	96 h	EC50	growth rate	> 10	3	1, 13	Heimbach, 1986
Crustacea																
Daphnia magna	< 24 h	N	S	imidacloprid	tg	nw			20	48 h	LC50	mortality	17.36	3	1, 2	Song *et al.*, 1997
Daphnia magna	< 24 h	N	S	imidacloprid	tg	nw			27	48 h	LC50	mortality	10.44	3	1, 2, 11	Song *et al.*, 1997
Daphnia magna	< 24 h	Y	S	imidacloprid	95.4					48 h	EC50	immobility	85	2	3	EC, 2006
Daphnia magna	24 h	N	S	imidacloprid	tg	tw		7.5-7.8	22	48 h	LC50	mortality	64.87	3	1, 4	Sanchez-Bayo and Goka, 2006
Daphnia magna	24 h	N	S	imidacloprid	tg	tw		7.5-7.8	22	48 h	EC50	immobility	6.029	3	1, 4	Sanchez-Bayo and Goka, 2006
Chydorus sphaericus	collected from rice fields	N	S	imidacloprid	tg	tw		7.5-7.8	22	48 h	LC50	mortality	132.7	3	1, 4	Sanchez-Bayo and Goka, 2006
Chydorus sphaericus	collected from rice fields	N	S	imidacloprid	tg	tw		7.5-7.8	22	48 h	EC50	immobility	2.209	3	1, 4	Sanchez-Bayo and Goka, 2006
Chydorus sphaericus	collected from rice fields	N	S	imidacloprid	tg	tw		7.5-7.8	22	48 h	EC50	immobility	0.832	2	5, 12	Sanchez-Bayo and Goka, 2006
Cypretta seuratti	collected from rice fields	N	S	imidacloprid	tg	tw		7.5-7.8	22	48 h	LC50	mortality	0.301	3	1, 4	Sanchez-Bayo and Goka, 2006
Cypretta seuratti	collected from rice fields	N	S	imidacloprid	tg	tw		7.5-7.8	22	48 h	EC50	immobility	0.016	3	1, 4	Sanchez-Bayo and Goka, 2006
Cypretta seuratti	collected from rice fields	N	S	imidacloprid	tg	tw		7.5-7.8	22	48 h	EC50	immobility	0.001	2	5, 12	Sanchez-Bayo and Goka, 2006
Cypridopsis vidua	collected from rice fields	N	S	imidacloprid	tg	tw		7.5-7.8	22	48 h	LC50	mortality	0.715	3	1, 4	Sanchez-Bayo and Goka, 2006
Cypridopsis vidua	collected from rice fields	N	S	imidacloprid	tg	tw		7.5-7.8	22	48 h	LC50	mortality	0.273	2	5	Sanchez-Bayo and Goka, 2006
Cypridopsis vidua	collected from rice fields	N	S	imidacloprid	tg	tw		7.5-7.8	22	48 h	EC50	immobility	0.003	3	1, 4	Sanchez-Bayo and Goka, 2006
Cypridopsis vidua	collected from rice fields	N	S	imidacloprid	tg	tw		7.5-7.8	22	48 h	EC50	immobility	0.01	2	5, 12	Sanchez-Bayo and Goka, 2006
Hyalella azteca	2-3 mm juveniles	Y	S	imidacloprid						96 h	LC50	mortality	0.526	2		EC, 2006; Anatra-Cordone and Durkin, 2005
Hyalella azteca	2-3 mm juveniles	Y	S	imidacloprid						96 h	EC50	immobility	0.055	2		addendum DAR, 2007; Anatra-Cordone and Durkin, 2005
Ilyocypris dentifera	collected from rice fields	N	S	imidacloprid	tg	tw		7.5-7.8	22	48 h	LC50	mortality	0.517	3	1, 4	Sanchez-Bayo and Goka, 2006
Ilyocypris dentifera	collected from rice fields	N	S	imidacloprid	tg	tw		7.5-7.8	22	48 h	LC50	mortality	0.214	2	5	Sanchez-Bayo and Goka, 2006
Ilyocypris dentifera	collected from rice fields	N	S	imidacloprid	tg	tw		7.5-7.8	22	48 h	EC50	immobility	0.003	3	1, 4	Sanchez-Bayo and Goka, 2006
Ilyocypris dentifera	collected from rice fields	N	S	imidacloprid	tg	tw		7.5-7.8	22	48 h	EC50	immobility	0.003	2	5, 12	Sanchez-Bayo and Goka, 2006
Insecta																
Aedes aegypti (L.)	first instar, 24 h old	N	S	imidacloprid	tg	am			20	48 h	LC50	mortality	0.045	3	1, 2	Song *et al.*, 1997
Aedes aegypti (L.)	first instar, 24 h old	N	S	imidacloprid	tg	am			27	48 h	LC50	mortality	0.044	3	1, 2	Song *et al.*, 1997
Aedes aegypti	4th instar	N	S	imidacloprid	97.4	dw			25	72 h	LC50	mortality	0.084	3	1	Paul *et al.*, 2006
Aedes aegypti	adults	N	S	imidacloprid	97.4	dw			25	48 h	LC50	mortality	≥ 6.3	3	1, 6	Paul *et al.*, 2006
Aedes albopictus	4th instar, strain MAmAal	N	S	imidacloprid	97.7	tw			25	24 h	LC50	mortality	0.6	3	1	Liu *et al.*, 2004a

Species	Species properties	A	Test type	Test compound	Purity [%]	Test water	Hardness $CaCO_3$ [mg/L]	pH	T [°C]	Exp. time	Criterion	Test endpoint	Value [mg/L]	Ri	Notes	Reference
Aedes albopictus	4th instar, strain HAmAal	N	S	imidacloprid	97.7	tw			25	24 h	LC50	mortality	0.3	3	1	Liu *et al.*, 2004a
Aedes albopictus	4th instar, strain VBFmAal	N	S	imidacloprid	97.7	tw			25	24 h	LC50	mortality	0.8	3	1	Liu *et al.*, 2004a
Aedes albopictus	4th instar, strain SFmAal	N	S	imidacloprid	97.7	tw			25	24 h	LC50	mortality	0.6	3	1	Liu *et al.*, 2004a
Aedes albopictus	4th instar, strain Ikaken	N	S	imidacloprid	97.7	tw			25	24 h	LC50	mortality	0.5	3	1	Liu *et al.*, 2004a
Chironomus riparius	1st instar larvae	N	S	imidacloprid	99.9					24 h	LC50	mortality	0.0552	3	1, 7	EC, 2006
Chironomus tentans	2nd instar	Y	R	imidacloprid	95.0%					96 h	LC50	mortality	0.0105	2		Anatra-Cordone and Durkin, 2005
Culex quinquefasciatus	4th instar, VBFmCq	N	S	imidacloprid	97.7%	tw			25	24 h	LC50	mortality	0.3	3	1	Liu *et al.*, 2004b
Culex quinquefasciatus	4th instar, HAmCq	N	S	imidacloprid	97.7%	tw			25	24 h	LC50	mortality	0.2	3	1	Liu *et al.*, 2004b
Culex quinquefasciatus	4th instar, MAmCq	N	S	imidacloprid	97.7%	tw			25	24 h	LC50	mortality	0.4	3	1	Liu *et al.*, 2004b
Culex quinquefasciatus	4th instar, S-Lab	N	S	imidacloprid	97.7%	tw			25	24 h	LC50	mortality	0.04	3	1	Liu *et al.*, 2004b
Simulium vittatum	5th instar	Y	S	imidacloprid	≥ 98%	rw		7.3-7.7	20	48 h	LC50	mortality	0.00675	1	4, 9, 14	Overmyer *et al.*, 2005
Simulium vittatum	5th instar	Y	S	imidacloprid	≥ 98%	rw		7.3-7.7	20	48 h	LC50	mortality	0.00825	1	4, 9, 14	Overmyer *et al.*, 2005
Simulium vittatum	5th instar	Y	S	imidacloprid	≥ 98%	rw		7.3-7.7	20	48 h	LC50	mortality	0.00954	1	4, 9, 14	Overmyer *et al.*, 2005
Amphibia																
Rana limnocharis	1 month old	N	R	imidacloprid	> 95%	dw			20	96 h	LC50	mortality	82	3	1	Feng *et al.*, 2004
Rana N. Hallowell	1.5 months old	N	R	imidacloprid	> 95%	dw			20	96 h	LC50	mortality	129	3	1	Feng *et al.*, 2004
Pisces																
Oncorhynchus mykiss	5.3 cm, 1.3 g	N	S	imidacloprid	95.3					96 h	LC50	mortality	211	3	1, 10	EC, 2006
Oncorhynchus mykiss	4.4 cm, 1.07 g	Y	S	imidacloprid	95.0					96 h	LC50	mortality	> 83	2		EC, 2006
L. idus melanotus		N	S	imidacloprid	95.3					96 h	LC50	mortality	237	3	1	EC, 2006
Lepomis macrochirus	27 mm, 0.46 g	Y	S	imidacloprid	97.4 %					96 h	LC50	mortality	> 105	2		Anatra-Cordone and Durkin, 2005

Notes
1 light, actual concentrations not measured; therefore validity 3
2 Inc. solvent controls.
3 OECD guideline 202.
4 16:8 light/dark.
5 Dark conditions, used for MPC derivation.
6 in ng/cm2.
7 method equiv. to OECD 202.
8 study with formulation, results in mg as/L
9 avg of init.+ final conc., DO 92.0.
10 OECD 203.
11 Not selected: T 27 °C.
12 most sensitive endpoint for this species
13 OECD guideline 201.
14 three separate tests

Table A1.2. Acute toxicity of imidacloprid to marine organisms.

Species	Species properties	Analysed	Test type	Test compound	Purity [%]	Test water	pH	T [°C]	Salinity [‰]	Exposure time	Criterion	Test endpoint	Value [mg/L]	Ri	Notes	Reference
Crustacea																
Artemia sp.	4th naupliar stage	N	S	imidacloprid	tg	am	8	27	38	48 h	LC50	mortality	361.23	3	1, 5, 9	Song and Brown, 1998; Song and Brown, 2006
Artemia sp.	4th naupliar stage	N	S	imidacloprid	tg	am	8	27	9.5	48 h	LC50	mortality	> 300	3	1, 6, 9	Song and Brown, 1998
Americamysis bahia	< 24 h old	Y	F	240 S Formulation	22.7	nw	8.2-8.5	19.7-25.0	20	96 h	LC50	mortality	0.036	2	2, 4, 10	Anatra-Cordone and Durkin, 2005
Americamysis bahia	< 24 h old	Y	F	imidacloprid	96.2%					96 h	LC50	mortality	0.0377	2	3, 7, 10	EC, 2006; Anatra-Cordone and Durkin, 2005
Americamysis bahia	< 24 h old	Y	F	imidacloprid	96.2%					96 h	LC50	mortality	0.0341	2	3, 7	EC, 2006; Anatra-Cordone and Durkin, 2005
Insecta																
Aedes taeniorhynchus	1st instar	N	S	imidacloprid	tg	am	8	27	38	48 h	LC50	mortality	0.013	3	1, 5, 8, 9	Song and Brown, 1998; 2006
Aedes taeniorhynchus	1st instar	N	S	imidacloprid	tg	am	8	27	12.7	72 h	LC50	mortality	0.021	3	1, 6, 9	Song and Brown, 1998
Pisces																
Cyprinodon variegatus	29 mm, 0.77 g	Y	S	imidacloprid	96.2					96 h	LC50	mortality	161	2		addendum DAR, 2007; Anatra-Cordone and Durkin, 2005

Notes
1 light, actual concentrations not measured; therefore validity 3
2 mg as/L.
3 additional study, results reported briefly in monograph, no summary.
4 DO was below protocol requirement
5 hyperosmotic conditions
6 isosmotic conditions
7 additional test not formally required for dossier submitted within European Union
8 most relevant duration and lowest toxicity endpoint for the species
9 Including solvent controls.
10 Former name: *Mysidopsis bahia*

Table A1.3. Chronic toxicity of imidacloprid to freshwater organisms.

Species	Species properties	A	Test type	Test compound	Purity	Test water	Hardness $CaCO_3$	pH	T	Exp. time	Criterion	Test endpoint	Value	Ri	Notes	Reference
					[%]		[mg/L]		[°C]				[mg/L]			
Cyanobacteria																
Anabaena flos-aquae	log phase growth	Y	S	NTN 33893 2F	21.6			7.5	24	96 h	growth rate	NOEC	24.9	2	4	Anatra-Cordone and Durkin, 2005
Algae																
Navicula pelliculosa	log phase growth	Y	S	NTN 33893 2F	21.6				24	96 h		NOEC	6.69	2	9	Anatra-Cordone and Durkin, 2005
Pseudokirchneriella subcapitata		N	S	imidacloprid	98.6					72 h	growth rate	NOEC	< 100	3	1, 2, 11	EC, 2006
Pseudokirchneriella subcapitata		N	S	imidacloprid	98.6					72 h	biomass	NOEC	< 100	3	1, 2, 11	EC, 2006
Scenedesmus subspicatus		N	S	imidacloprid						72 h	growth rate	NOEC	10	3	1, 11	EC, 2006
Scenedesmus subspicatus		N	S	imidacloprid						72 h	biomass	NOEC	10	3	1, 11	EC, 2006
Scenedesmus subspicatus		N	S	imidacloprid	92.8			8.1-9.2	23	96 h	growth rate	NOEC	> 10	3	1	Heimbach, 1986
Crustacea																
Daphnia magna	< 24 h	Y	R	imidacloprid	99	am			21 ± 1	21 d	reproduction	LOEC	2.5	2	3	Jemec *et al.*, 2007
Daphnia magna	< 24 h	Y	R	Confidor SL 200	99	am			21 ± 1	21 d	reproduction	LOEC	5	2	4	Jemec *et al.*, 2007
Daphnia magna	< 24 h	Y	S	imidacloprid	95.4					21 d	reproduction	NOEC	1.8	2	5	EC, 2006
Gammarus pulex	different ages	N	S	imidacloprid	tg					28 d		NOEC	0.064	3	1, 6	EC, 2006
Pisces																
Oncorhynchus mykiss	length 5.3 cm, bw 1.3 g	N	F	imidacloprid	95.3					91 d	development	NOEC	9.02	3	1, 8	EC, 2006
Oncorhynchus mykiss	newly fertilized eggs, < 4 h	Y	F	imidacloprid	tg					98 d	growth	NOEC	1.2	2	10	Anatra-Cordone and Durkin, 2005
Insecta																
Chironomus riparius	1st instar larvae	N	S	Confidor SL 200	98.4					28 d	emergence	NOEC	0.01320	3	1, 6, 7	EC, 2006
Chironomus riparius	1st instar larvae	N	S	imidacloprid						28 d	emergence	NOEC	0.00209	3	1, 6, 7	EC, 2006
Chironomus tentans	2nd instar	Y	R	imidacloprid	95.0					10 d	growth	NOEC	0.00067	2		Anatra-Cordone and Durkin, 2005

Notes
1 light, actual concentrations not measured; therefore validity 3
2 former name: Selenastrum capricornutum.
3 expressed as number of neonates per adult.
4 in mg as/L.
5 OECD 202.
6 according to a new proposal for OECD 219.
7 The NOEC from the List of Endpoints was not a NOEC but an EC15-value. Since the EC10 value was also reported in the studies, according to the TGD this value should be used as NOEC, therefore the reported value is the EC10 value reported in the studies.
8 OECD 203, early life stage.
9 study with formulation, results in mg as/L
10 NOEC based on growth (day 36) as most sensitive endpoint
11 OECD 201, limit test.

Appendix 2. Description of mesocosm studies

Study 1: Ratte and Memmert, 2003
Microcosm study with natural populations of algae, invertebrates and zooplankton

Reference	Ratte, H.T., Memmert,A. (2003) Biological effects and fate of imidacloprid SL 200 in outdoor micorocosm ponds, RCC Ltd, unpublished report No. 811766. WAT2003-633.
Species; Population; Community	Phytoplankton, periphyton, invertebrates, zooplankton
Test Method	Microcosm
System properties	2.0-2.2 m diameter, 1.0 m deep, 3100-3800 l
Formulation	Imidacloprid SL 200
Exposure regime	0, 0.6, 1.5, 3.8, 9.4 and 23.5 µg/L; 2 applications (May 2 and May 23)
Analysed	Y
Temperature [°C]	Not in summary
pH range	Not in summary
Hardness [mg $CaCO_3$/L]	Not in summary
Exposure time	182 d
Criterion	NOEC
Test endpoint	Population response of benthic invertebrates and zooplankton
Value [µg/L]	< 0.31 (mean actual concentration).
GLP	Y
Guideline	SETAC, 1991, OECD, 2000
Notes	
Ri	2

DESCRIPTION

Test system

Thirteen microcosms of 2.0-2.2 m diameter, 10 cm natural sediment and 1.0 m water, total 3100-3800 l, Aachen, Germany, sediment not specified. Organisms were added with the sediment and phytoplankton and zooplankton were obtained from natural ponds. Ponds were left to establish during 6 months. Application took place on May 2 and 23, 2001, Treatments, 0, 0.6, 1.5, 3.8, 9.4 and 23.5 a.s. µg/L in duplicate, untreated in triplicate. The substance was sprayed on the pond surface.

Analytical sampling

Concentration was measured in the application solutions, and in initial concentrations in pond water samplings, and regularly during the experiment in water and sediment.

Effect sampling

Effect parameters zooplankton, phytoplankton, chlorophyll-a, emerging insects and macrozoobenthos (by artificial substrate and sediment) were regularly monitored.

Statistical analysis

Univariate and multivariate analyses, PRC.

RESULTS

Chemical analysis

The DT_{50} ranged from 5.8 to 13.0 days at all test concentrations after both applications, average DT_{50} 8.2 d. Initial measured concentrations not reported, but it was concluded that nominal concentrations could be used to express initial exposure.

Imidacloprid was found in the sediment, with the highest concentrations one week after second application. Thereafter, the concentration decreased to below LOQ of 7 µg/kg in the highest concentrations after 56-70 d. In the lower treatments, a similar pattern was seen, however the concentrations were close to the LOQ. DT_{50} for imidacloprid in the whole system (determined in the two highest dosages only) is 14.8 d.

Biological observations

Insects (caught by the emergence traps) were the most significantly affected organisms, from 1.5 µg/L upwards. Effects were found on community parameters such as taxa richness, diversity, similarity and

principal response. Chironomidae and Baetidae were the most sensitive taxa. No effects were found at 0.6 µg/L, which can be seen as the NOEC. Indirect effects are found on algae, but only the NOEAEC (defined as recovery within 8 weeks after last application) of 23.5 µg/L is reported. For zooplankton NOEC of 9.4 µg/L is reported for copepods and cladocerans, for macrozoobenthos the NOEC for the most sensitive species (*Chaoborus* spp.) is 9.4 µg/L.

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? Yes, natural populations of algae, zooplankton and macroinvertebrates were present. Macrophytes and fish were not present.
2. Is the description of the experimental set-up adequate and unambiguous? Unclear, not all details are reported in the available summary.
3. Is the exposure regime adequately described? Yes.
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, no details concerning measurement endpoint are given for concentrations and effect data. The data are analysed according to up-to-date methods, however.

These criteria result in an overall assessment of the study reliability. The study is considered to be less reliable (Ri 2) mainly due to the lack of details in the available summary.

The RMS and the notifier appointed the 0.6 µg/L-treatments as the NOEC. The notifier and RMS did not agree on the level of the NOEAEC. Both RMS and notifier agreed on a small TER trigger, because uncertainty of the NOEC is considered to be relatively low. The notifier proposes a factor of two as TER trigger.

Conclusion

For ERL-derivation, the NOEC based on the 0.6 µg/L-treatment with an actual initial concentration similar to the nominal concentration is used. Experimental ponds were exposed to imidacloprid in two peaks and actual concentrations declined rather rapid. Therefore, the results of the underlying study can be used for derivation of the MAC, but the study is not suitable for derivation of the MPC.

rivm

Appendix 3. References used in the appendices

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