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## Environmental risk limits for fenamiphos

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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 fenamiphos

Dit rapport geeft milieurisicogrenzen voor het nematicide fenamifos 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 are derived for the nematicide fenamiphos. 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). Fenamiphos is part of a series of 25 pesticides that appeared to have a high environmental impact in the evaluation of the policy document on sustainable crop protection (‘Tussenevaluatie van de nota Duurzame Gewasbescherming’; MNP, 2006) or were selected by the Water Boards (‘Unie van Waterschappen’; project ‘Schone Bronnen’; <http://www.schonebronnen.nl/>).

The following ERLs are considered:

- Maximum Permissible Concentration (MPC) – the concentration protecting aquatic ecosystems and humans from effects due to long-term exposure
- Maximum Acceptable Concentration (MAC<sub>eco</sub>) – the concentration protecting aquatic ecosystems from effects due to short-term exposure or concentration peaks.
- Serious Risk Concentration (SRC<sub>eco</sub>) – 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 <sub>eco, water</sub>	MPC for freshwater based on ecotoxicological data (direct exposure)
MPC <sub>sp, water</sub>	MPC for freshwater based on secondary poisoning
MPC <sub>hh food, water</sub>	MPC for fresh and marine water based on human consumption of fishery products
MPC <sub>dw, water</sub>	MPC for surface waters intended for the abstraction of drinking water
MAC <sub>eco, water</sub>	MAC for freshwater based on ecotoxicological data (direct exposure)
SRC <sub>eco, water</sub>	SRC for freshwater based on ecotoxicological data (direct exposure)
MPC <sub>eco, marine</sub>	MPC for marine water based on ecotoxicological data (direct exposure)
MPC <sub>sp, marine</sub>	MPC for marine water based on secondary poisoning
MAC <sub>eco, marine</sub>	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'. The methodology is in accordance with the guidance that is prepared for the Water Framework Directive by 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 Water Framework Directive (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, 2005; 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  $MPC_{\text{water}}$ , an additional comment should be made:

### 2.3.1 Drinking water

The INS-Guidance includes the MPC for surface waters intended for the abstraction of drinking water ( $MPC_{\text{dw, water}}$ ) as one of the MPCs from which the lowest value should be selected as the general  $MPC_{\text{water}}$  (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  $MPC_{\text{dw, water}}$  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  $MPC_{\text{dw, water}}$  is therefore presented as a separate value in this report. The  $MPC_{\text{water}}$  is thus derived considering the individual MPCs based on direct exposure ( $MPC_{\text{eco, water}}$ ), secondary poisoning ( $MPC_{\text{sp, water}}$ ) or human consumption of fishery products ( $MPC_{\text{hh food, water}}$ ); 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  $MPC_{\text{dw, water}}$ . According to the INS-Guidance (see Section 3.1.7), a substance specific removal efficiency related to simple water treatment should be derived in case the  $MPC_{\text{dw, water}}$  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  $\mu\text{g/L}$  for organic pesticides as specified in Directive 98/83/EC.

### 3 Derivation of environmental risk limits for fenamiphos

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

##### 3.1.1 Identity

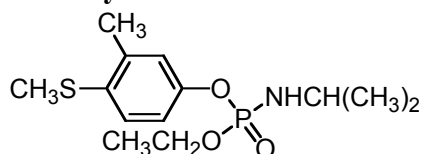


Figure 1. Structural formula of fenamiphos.

Table 1. Identification of fenamiphos.

Parameter	Name or number	Source
Common/trivial/other name	Fenamiphos	EC, 2005
Chemical name	ethyl 4-methylthio-m-tolyl isopropylphosphoramidate	EC, 2005
CAS number	22224-92-6	EC, 2005
EC number	244-848-1	EC, 2005
SMILES code	CCOP(=O)(NC(C)C)Oc1ccc(SC)c(C)c1	EC, 2005
Use class	Nematicide	EC, 2005
Mode of action	Systemic nematicide with contact action. Direct inhibition of cholinesterases.	EC, 2005
Authorised in NL	Yes	
Annex 1 listing	Yes	

##### 3.1.2 Physico-chemical properties

Table 2. Physico-chemical properties of fenamiphos.

Parameter	Unit	Value	Remark	Reference
Molecular weight	[g/mol]	303.4		EC, 2005
Water solubility	[g/L]	0.368	20°C MilliQ	EC, 2005
pK <sub>a</sub>	[-]	0.345	20°C buffer pH 7	EC, 2005
log K <sub>OW</sub>	[-]	3.3	20°C	EC, 2005
log K <sub>OC</sub>	[-]	2.47	overall average K <sub>om</sub> is 173 L/kg	EC, 2005
Vapour pressure	[Pa]	1.2 x 10 <sup>-4</sup> 2.3 x 10 <sup>-4</sup>	20°C 25°C	EC, 2005
Melting point	[°C]	43-49		EC, 2005
Boiling point	[°C]	n.a.	thermal decomposition	EC, 2005
Henry's law constant	[Pa.m <sup>3</sup> .mol <sup>-1</sup> ]	9.1 x 10 <sup>-5</sup>	calculation	EC, 2005

n.a. = not applicable.

### 3.1.3 Behaviour in the environment

**Table 3. Selected environmental properties of fenamiphos.**

Parameter	Unit	Value	Remark	Reference
Hydrolysis half-life	DT50 [d]	245	pH 5	EC, 2005
		301	pH 7	
		235	pH 9	
Photolysis half-life	DT50 [h]	3.6	27-28°C	EC, 2005
Readily biodegradable		-		
Water/sediment system	DT50 [d]	9.3	50% bound residues	EC, 2005
		111		
Relevant metabolites	fenamiphos sulfoxide, fenamiphos sulfone			EC, 2005

### 3.1.4 Bioconcentration and biomagnification

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

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

Parameter	Unit	Value	Remark	Reference
BCF (fish)	[L/kg]	127	QSAR estimate with $\log K_{ow}$ 3.3	Veith et al., 1978
BMF	[kg/kg]	1	Default value since $\log K_{ow} < 3.3$	

### 3.1.5 Human toxicological threshold limits and carcinogenicity

The following risk phrases are proposed for fenamiphos in the DAR: R24, 26, 28, 36. Fenamiphos is assigned R24, R28 according to ESIS (<http://ecb.jrc.it/esis/>; date of search 17 March 2008).

Fenamiphos is not classified as being carcinogenic. The ADI of fenamiphos is 0.0008 mg/kg<sub>bw</sub>/day based on a 1-year dog study with a NOAEL of 0.083 mg/kg<sub>bw</sub>/day (brain cholin esterase inhibition) and 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. Fenamiphos: collected properties for comparison to MPC triggers.**

Parameter	Value	Unit	Method/Source	Derived at section
$\log K_{p, \text{susp-water}}$	1.47	[-]	$K_{OC} \times f_{OC, \text{susp}}^1$	$K_{OC}$ : 3.1.2
BCF	110	[L/kg]		DAR; EC, 2005
BMF	1	[kg/kg]		3.1.4
$\log K_{OW}$	3.3	[-]		3.1.2
R-phrases	R24; R26; R28; R36; R50/53	[-]		3.1.5
A1 value	1.0	[µg/L]	Total pesticides	
DW Standard	0.1	[µg/L]	General value for organic pesticides	

<sup>1</sup>  $f_{OC, \text{susp}} = 0.1 \text{ kg}_{OC} / \text{kg}_{\text{solid}}$  (EC, 2003).

- Fenamiphos has a  $\log K_{p, \text{susp-water}} < 3$ ; derivation of  $\text{MPC}_{\text{sediment}}$  is not triggered.
- Fenamiphos has a  $\log K_{p, \text{susp-water}} < 3$ ; expression of the  $\text{MPC}_{\text{water}}$  as  $\text{MPC}_{\text{susp, water}}$  is not required.
- Fenamiphos has a  $\log K_{ow} > 3$ ; assessment of secondary poisoning is triggered.
- Fenamiphos has an R24 and an R28 classification and a  $\log K_{ow} > 3$ . Therefore, an  $\text{MPC}_{\text{water}}$  for human health via food (fish) consumption ( $\text{MPC}_{\text{hh food, water}}$ ) should be derived.

- For fenamiphos, 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<sub>eco, water</sub> and MPC<sub>eco, marine</sub>

An overview of the selected toxicity data for fenamiphos is given in Table 6 for freshwater and in Table 7 for the marine environment. Detailed toxicity data for fenamiphos are tabulated in Appendix 2. There is a large difference in endpoints based on measured or nominal concentrations obtained from otherwise comparable tests with *Cyprinodon variegatus* (see Appendix 2, Table 2.2). This indicates that maintenance of test concentrations is problematic, and therefore only test results based on measured concentrations are accepted. An exception is made for algae, because measurements in algal suspension are not often made. In this case, biomass is selected as the most relevant endpoint, because this is considered more representative for the initial concentration than growth rate.

**Table 6. Fenamiphos: selected aquatic freshwater data for ERL derivation.**

Chronic <sup>a</sup>		Acute <sup>a</sup>	
Taxonomic group	NOEC/EC10 (µg/L)	Taxonomic group	L(E)C50 (µg/L)
Algae	350 <sup>b</sup>	Bacteria	928
Crustacea	<b>0.12<sup>c</sup></b>	Algae	11900 <sup>e</sup>
Pisces	3.8 <sup>d</sup>	Crustacea	5.0
		Crustacea	<b>2.7<sup>f</sup></b>
		Crustacea	20.0
		Crustacea	11.0
		Pisces	9.3

<sup>a</sup>. For detailed information see Appendix 2. Bold values are used for ERL derivation.

<sup>b</sup>. Most relevant endpoint biomass for *Scenedesmus subspicatus*

<sup>c</sup>. Most preferred endpoint for *Daphnia magna*

<sup>d</sup>. Most preferred endpoint for *Onchorhynchus mykiss*

<sup>e</sup>. Most preferred endpoint growth rate for *Scenedesmus subspicatus*

<sup>f</sup>. Geometric mean of 2.2 and 3.3 µg/L, parameter mortality/immobility for *Daphnia carinata*

**Table 7. Fenamiphos: selected aquatic marine data for ERL derivation.**

Chronic <sup>a</sup>		Acute <sup>a</sup>	
Taxonomic group	NOEC/EC10 (µg/L)	Taxonomic group	L(E)C50 (µg/L)
		Bacteria	18822 <sup>b</sup>
		Pisces	17 <sup>c</sup>

<sup>a</sup>. For detailed information see Appendix 2. Bold values are used for ERL derivation.

<sup>b</sup>. Geometric mean of 11200 and 31630 µg/L for *Vibrio fischeri*

<sup>c</sup>. Preferred endpoint, measured concentration and longer exposure time for *Cyprinodon variegatus*

##### 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). The marine dataset is too small (one fish, one crustacean) to meet this requirement, therefore the datasets are kept separated.

### 3.3.1.2 Mesocosm and field studies

In the DAR, a mesocosm study with fish is included. The study is considered unreliable due to the experimental set-up. For further details see Appendix 4.

### 3.3.1.3 Derivation of MPC<sub>eco, water</sub> and MPC<sub>eco, marine</sub>

The base-set for freshwater toxicity data is complete. Chronic NOECs are available for algae, *Daphnia*, and fish. An assessment factor of 10 is applied to the lowest NOEC of 0.12 µg/L for crustacea, which results in an MPC<sub>eco, water</sub> of 0.12/10 µg/L = 0.012 µg/L.

The marine base set is not complete, and the potentially most sensitive group (Crustacea) is not represented. Therefore, marine ERLs cannot be derived.

### 3.3.2 MPC<sub>sp, water</sub> and MPC<sub>sp, marine</sub>

Fenamiphos has a log K<sub>ow</sub> > 3, the assessment of secondary poisoning is triggered.

The lowest MPC<sub>oral</sub> is 0.014 mg/kg diet for the quail (see Table 8), based on a short-term toxicity study. For quails, however, there is also a long-term NOEC available, which according to the INS-Guidance prevails over the short-term study. Then the lowest MPC<sub>oral</sub> is 0.033 for hen.

**Table 8. Fenamiphos: selected bird and mammal data for ERL derivation**

Species <sup>a</sup>	Exp. Time	Criterion	NOAEC <sub>diet</sub> [mg/kg <sub>diet</sub> ]	AF <sub>oral</sub>	MPC <sub>oral</sub> [mg/kg <sub>diet</sub> ]
mice	20 months	NOAEC	10	30	0.333
rat	2 generations	NOAEC	2.5	30	0.083
rat	2 generations	NOAEC	10	30	0.333
rat	2 generations	NOAEC	40	30	1.333
hen	30 days	NOAEC	10	300	<b>0.033</b>
quail	5 days	LC50	78	3000	0.026
quail	5 days	LC50	43	3000	0.014
quail	25 weeks	NOEC	2.2	30	0.073
duck	5 days	LC50	359	3000	0.120
duck	19 weeks	NOEC	8.9	30	0.297

<sup>a</sup> For detailed information see Appendix 4. Bold values are used for ERL derivation.

The MPC<sub>sp, water</sub> is calculated using the BCF of 128 L/kg and a BMF of 1 (Table 4) and becomes 0.033 / (128 × 1) = 3.0 × 10<sup>-4</sup> mg/L = 0.3 µg/L.

The MPC<sub>oral, min</sub> as derived above is used as a representative for the marine environment also. To account for the longer food chains in the marine environment, an additional biomagnification step is introduced (BMF<sub>2</sub>). This factor is the same as given in Table 4. The MPC<sub>sp, marine</sub> is calculated as MPC<sub>oral</sub> / (BCF × BMF<sub>1</sub> × BMF<sub>2</sub>) = 0.033 / (128 × 1 × 1) = 0.3 µg/L.

### 3.3.3 MPC<sub>hh food, water</sub>

Derivation of MPC<sub>hh food, water</sub> for fenamiphos is triggered (Table 5). MPC<sub>hh food</sub> is calculated from the ADI (0.0008 mg/kg<sub>bw</sub>/d), a body weight of 70 kg and a daily fish consumption of 115 g, as MPC<sub>hh food</sub> = 0.1 × 0.0008 × 70/0.115 = 0.049 mg/kg. Subsequently the MPC<sub>hh food, water</sub> is calculated according to MPC<sub>hh food, water</sub> = 0.049/(BCF<sub>fish</sub> × BMF<sub>1</sub>) = 3.8 × 10<sup>-4</sup> mg/L = 0.38 µg/L.

### 3.3.4 MPC<sub>dw, water</sub>

The MPC<sub>dw, water</sub> is set equal to the Drinking Water Standard of 0.1 µg/L.

### 3.3.5 Selection of the MPC<sub>water</sub> and MPC<sub>marine</sub>

The lowest MPC value of the routes included (see Section 2.3.1) should be selected as the general MPC. The lowest value is derived for direct toxicity (MPC<sub>eco, water</sub>).

The MPC<sub>water</sub> is 0.012 µg/L.

Not enough data are available to derive an MPC<sub>marine</sub>.

### 3.3.6 MAC<sub>eco</sub>

#### 3.3.6.1 MAC<sub>eco, water</sub>

The MAC value is calculated by taking the lowest LC<sub>50</sub> and divide this by an assessment factor. The lowest LC<sub>50</sub> is 2.7 µg/L. Fenamiphos has a potential to bioaccumulate, the mode of action is known (cholin esterase inhibition) and the potentially most sensitive species group is present in the dataset. Therefore an assessment factor of 100 is applied. The MAC<sub>eco, water</sub> is  $2.7/100 = 0.027$  µg/L.

### 3.3.7 SRC<sub>eco, water</sub>

Chronic toxicity values are available for algae, *Daphnia* and fish. The SRC<sub>eco, water</sub> is derived as the geometric mean of all these values, the SRC<sub>eco, water</sub> = 5.4 µg/L.

## 3.4 Toxicity data and derivation of ERLs for sediment

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



## 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 fenamiphos in water. No risk limits were derived for the marine compartment because data were not available, the derivation of ERLs for sediment is not triggered.

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 9. Derived MPC,  $MAC_{eco}$ , and SRC values for fenamiphos.**

ERL	Unit	MPC	$MAC_{eco}$	SRC
Water, old <sup>a</sup>	µg/L	0.0022	-	-
Water, new <sup>b</sup>	µg/L	0.012	0.027	5.4
Drinking water <sup>b</sup>	µg/L	0.1 <sup>c</sup>	-	-
Marine	µg/L	n.d. <sup>d</sup>	n.d. <sup>d</sup>	-

<sup>a</sup> indicative MPC ('ad-hoc MTR'), source: Helpdesk Water

[http://www.helpdeskwater.nl/emissiebeheer/normen\\_voor\\_het/zoeksysteem\\_normen/](http://www.helpdeskwater.nl/emissiebeheer/normen_voor_het/zoeksysteem_normen/)

<sup>b</sup> 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'  $MPC_{water}$ .

<sup>c</sup> provisional value pending the decision on implementation of the  $MPC_{dw, water}$ , (see Section 2.3.1)

<sup>d</sup> n.d. = not derived due to lack of data

## References

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## Appendix 1. Information on bioconcentration

Species	Species properties	Substance purity(%)	Analysed	Test type	Test water	pH	Hardness [mg/L]	Temp. [°C]	Exp. time	Exp. concn. [mg/L]	BCF [L/kg <sub>ww</sub> ]	BCF type	Calculation method	Ri	Reference	Notes
<i>Lepomis macrochirus</i>	8.2g; 6.4cm	90	LSC	F	nw	7.9-8.2	225-275	21	28 +14d	0.00095	110	whole organism	k1/k2	3	EC, 2005	1

1. Determination of rate constants by the Dow BIOFAC program (Non-linear kinetic modelling program)

## Appendix 2. Detailed aquatic toxicity data

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

Species	Species properties	A	Test type	Test compound	Purity [%]	Test water	pH	T [°C]	Hardness CaCO <sub>3</sub> [mg/L]	Exp. time	Criterion	Test endpoint	Value [µg/L]	Ri	Notes	Reference
<b>Bacteria</b>																
<i>Pseudomonas putida</i>		Y	cellsense	fenamiphos					8.5	30 min	EC50	electrical current	928	2		Farre, 2002
<b>Algae</b>																
<i>Scenedesmus subspicatus</i>	1.00E+04 cells/ml	N	S	fenamiphos	92		8-8.4	22		96 h	EC50	biomass growth	380	2	1,2	EC, 2005
<i>Scenedesmus subspicatus</i>	1.00E+04 cells/ml	N	S	fenamiphos	92		8-8.4	22		96 h	EC50	biomass growth	11900	2	1,2	EC, 2005
<b>Crustacea</b>																
<i>Daphnia magna</i>		Y	F	fenamiphos	88.7		8	19-20	160	48 h	EC50	immobility	1.9	3	5,13	EC, 2005
<i>Daphnia magna</i>		N	N	fenamiphos	99.5					24 h	LC100	immobility	10	3	3	EC, 2005
<i>Daphnia magna</i>	<24h	N	N	fenamiphos	>98	am		20		48 h	EC50	immobility	5	3	6,7	Fernandez-Alba et al., 2002
<i>Daphnia carinata</i>	<24h	Y	S	fenamiphos	99	am	6.5	22		48 h	LC50	immobility	2.19	2	6,14	Caceres et al. 2007
<i>Daphnia carinata</i>	<24h	Y	S	fenamiphos	99	nw	7.7	22		48 h	LC50	immobility	3.26	2	6,14	Caceres et al. 2007
<i>Gammarus italicus</i>	adult male	N	S	fenamiphos	97	rw	7.9	8	240	96 h	EC50	immobility	20	3		Pantani et al. 1997
<i>Echinogammarus tibaldii</i>	adult male	N	S	fenamiphos	97	rw	7.9	8	240	96 h	EC50	immobility	11	3		Pantani et al. 1997
<b>Insecta</b>																
<i>Aedes aegypti</i>				fenamiphos	99.5					24 h	LC100		100	3	3	EC, 2005
<b>Pisces</b>																
<i>Lepomis macrochirus</i>	35-75 mm	N	S	fenamiphos			7.2	22		96 h	LC50	mortality	17.7	3	5,10,11	EC, 2005
<i>Lepomis macrochirus</i>	35-75 mm	N	S	Nemacur 15	15		7.2	13		96 h	LC50	mortality	151	3	5,10,11	EC, 2005
<i>Lepomis macrochirus</i>	5.8 cm	Y	S	fenamiphos	96.2		7.2	22		96 h	LC50	mortality	9.3	2	8,9	EC, 2005
<i>Lepomis macrochirus</i>		N	S	fenamiphos	88		7.2	19		96 h	LC50	mortality	9.6	3	5,10,11	EC, 2005
<i>Oncorhynchus mykiss</i>	35-75 mm	N	S	fenamiphos			7.2	22		96 h	LC50	mortality	72.1	3	5,10,11	EC, 2005
<i>Oncorhynchus mykiss</i>	35-75 mm	N	S	Nemacur 15	15		7.2	13		96 h	LC50	mortality	563	3	5,10,11	EC, 2005

- OECD 201
- corrected for purity
- LC50 not determined
- ISO N84
- EPA
- OECD 202
- ISO 6341
- OECD 203, EPA 72-1
- based on mean measured concentrations
- study not accepted in DAR; poorly documented
- no solvent control, solvent concentration not reported
- not clear if corrected for purity
- study not accepted in DAR; exposure concentration not clear due to degradation
- stability confirmed

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

Species	Species properties	A	Test type	Test compound	Purity [%]	Test water	pH	T [°C]	Hardness [mg CaCO <sub>3</sub> /l]	Exp. time	Criterion	Test endpoint	Value [µg/L]	Ri	Notes	Reference
<b>Bacteria</b>																
<i>Vibrio fischeri</i>		N	Biotox assay	fenamiphos	>98	dw	15	20	20	30 min	EC50	bioluminescence	33200	3		Fernandez-Alba et al., 2002
<i>Vibrio fischeri</i>		Y	Biotox assay	fenamiphos	>98	dw	15	20	20	15 min	EC50	bioluminescence	11200	2		Fernandez-Alba et al., 2001
<i>Vibrio fischeri</i>		Y	ToxAlert	fenamiphos				20	20	30 min	EC50	bioluminescence	31630	2		Farre, 2002
<b>Mollusca</b>																
<i>Crassostrea virginica</i>	juvenile	N	F	fenamiphos			11	29		96 h	EC50		>1000	3		Mayer, 1986
<b>Crustacea</b>																
<i>Penaeus duorarum</i>	juvenile	N	F	fenamiphos			11	30		48 h	EC50		150	3		Mayer, 1986
<b>Pisces</b>																
<i>Cyprinodon variegatus</i>	juvenile	Y	F	fenamiphos	88.7	nw	8	22	31-34	96 h	LC50	mortality	17	2	1,2	EC, 2005
<i>Cyprinodon variegatus</i>	juvenile	N	F	fenamiphos			11	30	30	48 h	LC50	mortality	320	3		Mayer, 1986

1. test according to ASTM guidelines

2. based on mean measured concentrations

Table A.2.3. Chronic toxicity of fenamiphos to freshwater organisms.

Species	Species properties	A	Test type	Test compound	Purity [%]	Test water	pH	T [°C]	Hardness [mg CaCO3/l]	Exp. time	Criterion	Test endpoint	Value [µg/L]	Ri	Notes	Reference
<b>Algae</b>																
<i>Scenedesmus subspicatus</i>	1.00E+04	N	S	fenamiphos	92		8-8.4	22		96 h	NOEC	biomass growth	350	2	1,2,3	EC, 2005
<i>Scenedesmus subspicatus</i>	1.00E+04	N	S	fenamiphos	92		8-8.4	22		96 h	NOEC	biomass growth	1100	2	1,2,3	EC, 2005
<b>Crustacea</b>																
<i>Daphnia magna</i>	<24h	Y	F	fenamiphos	99.6	nw	7.9-8.4	20	160-180	21 d	NOEC	growth survival	0.1	2	5,7	EC, 2005
<i>Daphnia magna</i>	<24h	Y	F	fenamiphos	99.6	nw	7.9-8.4	20	160-180	21 d	NOEC	growth survival	0.2	2	5,7	EC, 2005
<b>Pisces</b>																
<i>Oncorhynchus mykiss</i>	eggs	Y	S	fenamiphos	89	nw	6.9-7.4	11	26	91 d	NOEC	growth hatch	3.8	2	6,7	EC, 2005
<i>Oncorhynchus mykiss</i>	eggs	Y	S	fenamiphos	89	nw	6.9-7.4	11	26	91 d	NOEC	growth hatch	>15	2	6,7	EC, 2005

1. OECD 201

2. corrected for purity

3. see also acute data

4. ISO N84

5. FIFRA 72-4

6. EPA

7. based on mean measured concentrations.

## Appendix 3. Detailed bird and mammal toxicity data

Species	Species properties (age, sex)	Purity [%]	Application route	Exp. time	Criterion	Test endpoint	NOAEL [mg/kg <sub>bw</sub> .d]	NOAEC Diet [mg/kg <sub>diet</sub> ]	Ri	Notes	Reference
hen			diet	30 d	NOAEL	body weight		10	2	7,10	EC, 2005
quail	10 d, 45 g	96.2	diet	8 d	LC50	mortality		78	2	8,9	EC, 2005
quail	20-25 g	88	diet	5 d	LC50	mortality		43	2	10	EC, 2005
duck	14 days, 291 g	88	diet	5 d	LC50	mortality		359	2	10	EC, 2005
quail	21 weeks	90	diet	25 w	NOEC	hatchling survival		2.2	2	9,10	EC, 2005
duck	19 weeks	90	diet	19 w	NOEC	hatchling survival		8.9	2	9,10	EC, 2005
mice	outbred CD1	90	diet	20 mo	NOAEL	body weight		10	2	1,10	EC, 2005
rat	wistar	88	diet	90 d	NOAEL	body weight		≥ 32	2	10	EC, 2005
rat	wistar, male		diet	2 y	NOAEL	mortality		> 30	3	10,11	EC, 2005
rat	wistar, female		diet	2 y	NOAEL	mortality		> 30	3	10	EC, 2005
rat	male, Fischer 344	89.3	diet	2 y	NOAEL	body weight		> 37	2	2,10	EC, 2005
rat	female, Fischer 344	89.3	diet	2 y	NOAEL	body weight		> 37	2	2,10	EC, 2005
rat	FB 30		diet	2 y	NOAEL	body weight		> 37	2	2,10	EC, 2005
rat	CD Sprague Dawley	88.3-89	diet	3 generations	NOAEL	body weight		2.5	2	3,4,10	EC, 2005
rat	CD Sprague Dawley	88.3-89	diet	2 generations	NOAEL	development		10	2	3,5,10	EC, 2005
rat	CD Sprague Dawley	88.3-89	diet	2 generations	NOAEL	reproduction		≥ 40	2	3,6,10	EC, 2005

1. from an oncogenetic studie
2. OECD 451
3. OECD 416
4. parental toxicity in the F0
5. based on decreased pup body weight
6. no effect on reproduction at the highest dose tested
7. FIFRA 82-5
8. FIFRA 71-2
9. EPA
10. NOAEL is based on test concentration in food
11. accepted as supportive only in DAR, no full report available



## Appendix 4. Description of mesocosm studies

In the DAR, a mesocosm study with fish is included (Kennedy et al., 1991). A NOEC of 3.5 µg as/L was accepted for risk assessment, but the study is considered unreliable due to the experimental set-up. A short summary is given below.

### Methods

Artificial pond systems (30 x 16 m, max. depth 2 m; with a 2:1 slope at all sides), natural colonisation of insects and macro-invertebrates for over one year; circulation 12 weeks before treatment to establish homogeneous systems and to distribute zoo- and phytoplankton. Introduction of bluegill sunfish six weeks before treatment. Spray treatment with NemaCur 35% (35.2% fenamiphos) at 1.0, 3.5 and 12.5 µg as/L, two applications with 7-days interval. Three replicates per treatment, three controls with fish and two additional control ponds without fish to determine effect of fish on the ecosystem functioning. Weekly or bi-weekly chemical and biological sampling.

### Results

Actual concentrations after 1<sup>st</sup> application were between 74 and 124% of nominal, similar results for 2<sup>nd</sup> application, except for one replicate of 3.5 µg as/L nominal which contained 9.2 µg as/L. Half-life of fenamiphos was calculated to be appr. 93 hours, metabolites fenamiphos sulfoxide and fenamiphos sulfone were detected, highest concentrations of fenamiphos sulfoxide were present after 4-6 weeks. No fenamiphos or metabolites in sediment.

Direct effects on fish were observed at 12.5 µg/L. The fish had a severe effect on benthic and pelagic invertebrate community. Zooplankton communities in the littoral zone differed significantly between controls with and without fish until 12 weeks after dosing, which was mainly due to differences in Polyarthra, Anuraeopsis, Notommata and Monostyla. Zooplankton communities in the pelagic zone of the control ponds without fish and the highest dosed ponds differed significantly from the fish controls, mainly due to Diaptomus, Monostyla, Vorticella, Rotifera, Polyarthra and Notommata.

A NOEC of 3.5 µg/L was established, but it was also stated that effects on aquatic taxa were found in the range of 1.0 to 12.5 µg/L, suggesting that the NOEC is < 1.0 µg/L.

### Evaluation of the scientific reliability of the mesocosm study

Criteria for a suitable (semi)field study:

1. Does the test system represent a realistic freshwater community? Yes, fish, zooplankton, phytoplankton and macrophytes were present.
2. Is the description of the experimental set-up adequate and unambiguous? Yes.
3. Is the exposure regime adequately described? Yes, although only recovery percentages are reported, the data indicate that actual concentrations after application were in agreement with nominal.
4. Are the investigated endpoints sensitive and in accordance with the working mechanism of the compound? No. The presence of fish in the mesocosms had a large influence on the invertebrate community. Fenamiphos is expected to have a direct effect on the invertebrate community at levels at or below those where effects on fish occur. However, the presence of fish may have masked direct effects of fenamiphos, i.e. if the effect of fish is dominant, more subtle effects of fenamiphos might not be detected. RMS observed that the PRC-analysis was dominated by the control ponds without fish, and that pesticide application effects might be smothered. Furthermore, no data on algae were provided.
5. Is it possible to evaluate the results statistically? No. Multivariate statistics were applied, but because of the experimental drawbacks listed under point 4 above, the value of the analyses is doubtful.

These criteria result in an overall assessment of the study reliability. The study is considered to be not reliable due to the experimental design (Ri 3).

## **Appendix 6. References used in the appendices**

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