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This investigation has been performed by order and for the account of Directorate-General for Environmental Protection, Directorate Environmental Safety and Risk Management, within the framework of 'International and National Environmental Quality Standards for Substances in the Netherlands' (INS).

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Rapport in het kort

Milieurisicogrenzen voor EDTA

Dit rapport geeft milieurisicogrenzen voor alle vormen van EDTA in oppervlakte- en grondwater. Milieurisicogrenzen zijn de technisch-wetenschappelijke advieswaarden voor de uiteindelijke milieukwaliteitsnormen in Nederland. De milieurisicogrenzen voor EDTA zijn gebaseerd op de uitkomsten van de EU risicobeoordeling voor EDTA en Na_4EDTA (Bestaande Stoffen Verordening 793/93). De afleiding van de milieurisicogrenzen sluit tevens aan bij de richtlijnen uit de Kaderrichtlijn Water. Gebaseerd op monitoringsgegevens voor Nederland is het mogelijk dat het nieuwe verwaarloosbaar risiconiveau wordt overschreden. De overige milieurisicogrenzen worden naar verwachting niet overschreden.

Trefwoorden: milieukwaliteitsnormen; milieurisicogrenzen; EDTA; maximaal toelaatbaar risiconiveau; ethyleendiamine tetraacetyl zuur

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Summary

Environmental risk limits (ERLs) are derived using ecotoxicological, physico-chemical and human toxicological data. They represent environmental concentrations of a substance offering different levels of protection to man and ecosystems. It should be noted that the ERLs are scientifically derived values. They serve as advisory values for the Dutch Steering Committee for Substances, which is appointed to set the Environmental Quality Standards (EQSs) from these ERLs. ERLs should thus be considered as preliminary values that do not have any official status.

This report contains ERLs for all species of EDTA in water and groundwater. The following ERLs are derived: Negligible Concentration (NC), Maximum Permissible Concentration (MPC), Maximum Acceptable Concentration for ecosystems (MAC_{eco}), and Serious Risk Concentration for ecosystems (SRC_{eco}). The risk limits were solely based on data presented in the Risk Assessment Reports (RAR) for this compound, prepared under the European Existing Substances Regulation (793/93/EEC). No risk limits were derived for the sediment compartment, because of the relatively low sediment-water partition coefficient. Due to the lack of available data, no ERLs for the soil compartment could be derived. Considering the salty character of EDTA derivation of an MPC_{air} is not relevant. The NC protects for human and environmental exposure to several substances at the same time (mixture toxicity).

For the derivation of the MPC and MAC_{eco} for water, the methodology used is in accordance with the Water Framework Directive. This methodology is based on the Technical Guidance Document on risk assessment for new and existing substances and biocides (European Commission (joint Research Centre), 2003). For the NC and the SRC_{eco}, the guidance developed for the project 'International and National Environmental Quality Standards for Substances in the Netherlands' was used (Van Vlaardingen and Verbruggen, 2007). An overview of the derived environmental risk limits is given in Table 1.

Monitoring data indicates that currently the NC_{water} could be exceeded. For the other ERLs there is no indication that they would be exceeded.

Table 1. Derived MPC, NC, MAC_{eco}, and SRC_{eco} values for EDTA.

ERL	**unit**	**value**			
		MPC	NC	MAC_{eco}	SRC_{eco}
water	$mg.L^{-1}$	2.2	2.2×10^{-2}	1.6	33
drinking water [a]	$mg.L^{-1}$	6.9			
marine	$mg.L^{-1}$	n.d.			
sediment	$mg.kg_{dwt}^{-1}$	n.d.			
soil	$mg.kg_{dwt}^{-1}$	n.d.			
groundwater	$mg.L^{-1}$	2.2	2.2×10^{-2}		33
air	$\mu g.m^{-3}$	n.d.			

[a] The exact way of implementation of the $MPC_{dw, water}$ in the Netherlands is at present under discussion. Therefore, the $MPC_{dw, water}$ is presented as a separate value in this report.
n.d. = not derived.

1 Introduction

1.1 Project framework

In this report environmental risk limits (ERLs) for surface water (freshwater and marine) and groundwater are derived for EDTA. The following ERLs are considered:

- Negligible Concentration (NC) – concentration at which effects to ecosystems are expected to be negligible and functional properties of ecosystems must be safeguarded fully. It defines a safety margin which should exclude combination toxicity. The NC is derived by dividing the MPC (see next bullet) by a factor of 100.
- Maximum Permissible Concentration (MPC) – concentration in an environmental compartment at which:
  1. no effect to be rated as negative is to be expected for ecosystems;

  2a no effect to be rated as negative is to be expected for humans (for non-carcinogenic substances);

  2b for humans no more than a probability of 10^{-6} over the whole life (one additional cancer incident in 10^{6} persons taking up the substance concerned for 70 years) can be calculated (for carcinogenic substances) (Lepper, 2005).
- Maximum Acceptable Concentration (MAC_{eco}) – concentration protecting aquatic ecosystems for effects due to short-term exposure or concentration peaks.
- Serious Risk Concentration (SRC_{eco}) – concentration at which serious negative effects in an ecosystem may occur.

It should be noted that ERLs 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) from these ERLs. ERLs should thus be considered as preliminary values that do not have any official status.

1.2 Chemical speciation of EDTA

EDTA is mainly produced and used as acid (H_4EDTA) and as sodium salt (Na_4EDTA). In lower amounts, other salts or metal complexes are produced or used. The environmental exposure from the different uses of all EDTA species is overlapping. Despite the fact that EDTA is likely to occur in the environment in different chemical species, it is analysed as EDTA in environmental samples. For these reasons, one ERL derivation is performed for all species of EDTA.

1.3 Production and use of EDTA

The environmental exposure of EDTA is overlapping with the salt form of the compound (Na_4EDTA). Therefore, data given in the Risk Assessment Reports (RAR) (European Commission, 2004a, European Commission, 2004b) are on production and use of EDTA in general (the salt and the acid form), volumes are given as H_4EDTA equivalents. EDTA is used as complexing agent in many industries but also in household detergents and agriculture. More details can be found in the RARs (European Commission, 2004a, European Commission, 2004b). The European production was 53,900 tonnes.year^{-1} and the use in 1999 was 34,546 tonnes. In 2008, EDTA and Na_4EDTA have been pre-registered under REACH, meaning an expected production volume of at least 1 tonne a year. However, no specific production volumes are given on the ECHA website (echa.europa.eu). Furthermore, it is not known whether the pre-registration will be followed by a definitive registration. No conclusions can be drawn on the current production and import in Europe.

1.4 Previous ERL derivations

In an earlier report (Kalf et al., 2003) the MPC and NC for EDTA in water have also been derived on basis of the final draft of the Risk Assessment Report (RAR) (European Commission, 2004a). However, in that report, the derivation was performed according to a guideline predating the current guideline (Van Vlaardingen and Verbruggen, 2007) and human toxicology had not been taken into account. In the current report human toxicology is taken into account.

2 Methods

2.1 Data collection

The final Risk Assessment Reports (RAR) of EDTA (European Commission, 2004a) and Na_4EDTA (European Commission, 2004b) produced in the framework of Existing Substances Regulation (793/93/EEC) were used as only source of physico-chemical and (eco)toxicity data. Information given in the RARs is checked thoroughly by European Union member states (Technical Committee) and afterwards peer-reviewed by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE, now the Scientific Committee on Health and Environmental Risk - SCHER). In their opinion, the CSTEE agreed with the derivation of the $PNEC_{water}$ but did not accept the $PNEC_{intermittent}$ because the rationale of the procedure was not clear. They also stressed the need for toxicity data on terrestrial organisms. For the RARs of EDTA and Na_4EDTA the CSTEE gave the same opinion. Only valid data combined in an aggregated data table are presented in the current report.
In the aggregated data table only one effect value per species is presented. When for a species several effect data are available, the geometric mean of multiple values for the same endpoint is calculated where possible. Subsequently, when several endpoints are available for one species, the lowest of these endpoints (per species) is reported in the aggregated data table.

2.2 Methodology for derivation of environmental risk limits

The methodology for data selection and ERL derivation is described in Van Vlaardingen and Verbruggen (2007) which is in accordance with Lepper (2005). For the derivation of ERLs for air, no specific guidance is available. However, as much as possible the basic principles underpinning the ERL derivation for the other compartments are followed for the atmospheric ERL derivation (if relevant for a chemical).

2.2.1 Drinking water abstraction

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_{water} value. The $MPC_{dw,\ water}$ is therefore presented as a separate value in this report.

The $MPC_{dw,\ water}$ is also used to derive the MPC_{gw}. For the derivation of the $MPC_{dw,\ water}$, a substance specific removal efficiency related to simple water treatment may be needed. Because there is no agreement as yet on how the removal fraction should be calculated, water treatment is not taken into account.

2.2.2 $MAC_{eco,\ marine}$

In this report, a MAC_{eco} is also derived for the marine environment. 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 the $MAC_{eco,\ marine}$ is based 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 formalised. Therefore, the $MAC_{eco,\ marine}$ value needs to be re-evaluated once an agreed procedure is available.

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3 Derivation of environmental risk limits

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

3.1.1 Identity

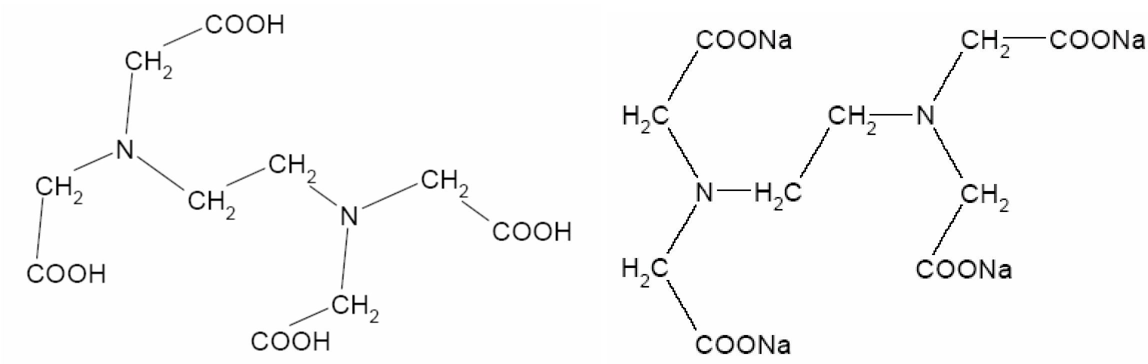

Figure 1. Structural formula of EDTA and Na_4EDTA.

Table 2. Identification of EDTA.

Parameter	Name or number
Chemical name	{[2-(Bis-carboxymethyl-amino)-ethyl]-carboxymethyl-amino} acetic acid
Common/trivial/ other name	Edetic acid; EDTA; H_4EDTA; Ethylenediaminetetraacetic acid; N,N’-1,2-ethanediylbis[N-(carboxymethyl)-gycine]
CAS number	60-00-4
EC number	200-449-4
SMILES code	O=C(O)CN(CCN(CC(=O)O)CC(=O)O)CC(=O)O

Table 3. Identification of Na_4EDTA.

Parameter	Name or number
Chemical name	Tetrasodium {[2-(bis-carboxymethyl-amino)-ethyl]-carboxymethylamino} acetate
Common/trivial/ other name	Ethylenediaminetetraacetic acid tetrasodium salt; Ethylenedinitrilotetraacetic acid tetrasodium salt; Edetic acid tetrasodium salt; Na_4EDTA or EDTA tetrasodium; Edetate sodium or Sodium ededate; N,N’-1,2-Ethanediylbis[N-(carboxymethyl)glycine] tetrasodium salt; Glycine, N,N’-1,2-ethanediylbis[N-(carboxymethyl)-, tetrasodium salt
CAS number	64-02-8
EC number	200-573-9
SMILES code	[Na]OC(=O)CN(CCN(CC(O[Na])=O)CC(O[Na])=O)CC(O[Na])=O

3.1.2 Physico-chemical properties

Table 4. Physico-chemical properties of EDTA.

Parameter	Unit	Value	Remark
Molecular weight	[g.mol^{-1}]	**292.3**	
Water solubility	[mg.L^{-1}]	**400**	At 20 °C
pK_a	[-]	n.r.	
log K_{OW}	[-]	**-5.01**	Calculated in EU-RAR according to Hansch & Leo
		-3.34	Calculated in EU-RAR according to Rekker
log K_{OC}	[-]	n.r.	No sorption to sludge or soil was observed
Vapour pressure	[Pa]	n.d.	Estimated to be very low for partially ionic substances and therefore not determined
Melting point	[°C]	n.a.	Decomposition at > 150 °C
Boiling point	[°C]	n.a.	Decomposition at > 150 °C
Henry's law constant	[Pa.m^3.mol^{-1}]	**1x10^{-20}**	Since no value for the vapour pressure is known, a fictitious low value is used for the EU risk assessment

n.a. = not applicable
n.r. = not reported
n.d. = not determined
bold = value is used in the EU risk assessment

Table 5. Physico-chemical properties of Na_4EDTA.

Parameter	Unit	Value	Remark
Molecular weight	[g.mol^{-1}]	380.2	
Water solubility	[mg.L^{-1}]	5x10^5	at 20 °C
pK_a	[-]		
log K_{OW}	[-]	n.d.	
log K_{OC}	[-]	n.r.	
Vapour pressure	[Pa]	n.d.	
Melting point	[°C]	> 300	
Boiling point	[°C]	n.d.	decomposes at >150ºC
Henry's law constant	[Pa.m^3.mol^{-1}]	1x10^{-20}	A fictitious low Henry's law constant was used for the calculations in the EU-RAR.

n.d. = not determined
n.r. = not reported

3.1.3 Behaviour in the environment

Table 6. Selected environmental properties of EDTA and Na_4EDTA.

Parameter	Unit	Value	Remark	Reference
Hydrolysis half-life	DT50 [d]		hydrolytically stable	EU-RAR
Photolysis half-life	DT50 [d]	20	worst case assumption	EU-RAR
Degradability			not readily biodegradable	EU-RAR
Relevant metabolites		n.r.		EU-RAR

n.r. = not reported

Information on behaviour of EDTA is cited from the EU-RAR for EDTA (European Commission, 2004a). The same information is given in the EU-RAR for Na_4EDTA (European Commission, 2004b).

As results confirm, EDTA is not readily biodegradable, but it can be concluded that EDTA can be biologically degraded if a number of specific conditions are present:
− a relatively high hydraulic and sludge retention time,
− an alkaline pH value of the wastewater,
− a relatively high EDTA concentration,
− EDTA is not complexed with heavy metal ions.
EDTA is resistant to hydrolysis, neither strong acids nor alkalis cause any degradation. Following the investigation of Frank and Rau (1990), a half-life of 20 days for photolysis of Fe(III)EDTA is used as a worst-case in exposure calculations in the RAR. Other EDTA species are considered to be persistent. Further abiotic degradation processes as reaction with OH-radicals or singlet oxygen have (compared to the direct photolysis) very low reaction constants and are of no environmental significance (Kari, 1994; Frank and Rau, 1990). A half-life for aerobic sediment between 200 and 300 days related to mineralisation is assumed. No biodegradation for the anaerobic parts of the sediments is assumed. Because of the ionic properties of EDTA and its metal complexes, it has to be assumed that volatilisation from aqueous solution will not occur. Due to the ionic structure under environmental relevant pH conditions, no adsorption onto the organic fraction of soils or sediments is expected. For the exposure calculations in the EU-RAR, values for Kp_{soil}, Kp_{sed} and Kp_{susp} of 75 $L.kg^{-1}$ are used. This value is based on the distribution between water and sediment of three EDTA-metal complexes.

3.1.4 Bioconcentration and biomagnification

An overview of the bioaccumulation data for EDTA and Na_4EDTA is given in Table 7.

Table 7. Overview of bioaccumulation data for EDTA and Na_4EDTA.

Parameter	Unit	Value	Remark	Ref.
BCF (fish)	[$L.kg^{-1}$]	1.1-1.8	experimental	EU-RAR
BMF	[$kg.kg^{-1}$]	1	Default value since the BCF is < 2000 $L.kg^{-1}$	

3.1.5 Human toxicological treshold limits and carcinogenicity

EDTA is classified with:
- Xi; R36: Irritant; Irritating to eyes

Na_4EDTA is classified with:
- Xn; R22: Harmful; Harmful if swallowed; Xi; R41: Irritant; Risk of serious damage to eyes

No existing TDIs or TCAs are available. In the risk characterization of the EU-RAR, the lowest NOAEL mentioned is 196 $mg.kg_{bw}^{-1}.day^{-1}$ (reproductive toxicity). Using an assessment factor of 100, as confirmed with RIVM-SIR, leads to a TDI of 1.96 $mg.kg_{bw}^{-1}.day^{-1}$.

3.2 Trigger values

This section reports on the trigger values for ERL_{water} derivation (as demanded in WFD framework).

Table 8. Collected properties of EDTA and Na_4EDTA for comparison to MPC triggers.

Parameter	Value	Unit	Method/Source	Derived at section
Log $K_{p,susp-water}$	1.88	[-]	K_p = 75 $L.kg^{-1}$	3.1.2
BCF	1.1-1.8	[$L.kg^{-1}$]	calculated	
BMF	1	[$kg.kg^{-1}$]		
Log K_{OW}	-5.1	[-]	calculated	3.1.2
R-phrases	R22, R36, R41	[-]		
A1 value	n.a.	[$\mu g.L^{-1}$]		
DW standard	n.a.	[$\mu g.L^{-1}$]		

n.a. = not available

- EDTA and Na_4EDTA have a log $K_{p, susp-water}$ < 3; derivation of $MPC_{sediment}$ is not triggered.
- EDTA and Na_4EDTA have a log $K_{p, susp-water}$ < 3; expression of the MPC_{water} as $MPC_{susp, water}$ is not required.
- EDTA and Na_4EDTA have a BCF > 100 $L.kg^{-1}$ assessment of secondary poisoning is not triggered.
- EDTA and Na_4EDTA are neither classified with an R-sentence that is a trigger nor considered to be bioaccumulative or carcinogenic. Therefore, an MPC_{water} for human health via food (fish) consumption ($MPC_{hh\ food,\ water}$) does not have to be derived.

3.3 Toxicity data and derivation of ERLs for water

An overview of the selected freshwater toxicity data for EDTA is given in Table 9. In the RARs all EDTA species given in the footnotes of Table 9 are considered for derivation of the PNEC for EDTA. Their value is expressed as EDTA, also called H_4EDTA. Marine toxicity data/experimental descriptions are available for *Penaeus stylirostis*, *Crassostrea gigas* and *Arbacia punctulata*. However, no clear endpoints can be derived from these data. Therefore, no marine toxicity data is presented for EDTA and Na_4EDTA.
The toxicity of EDTA depends on a variety of factors:

- hardness of water
- metal speciation (uncomplexed EDTA is never tested, complexation to which metals is not specified in the RARs)
- pH of test medium

It is impossible to combine all these factors into one (geometric mean) value per species. Therefore, in Table 9 only the lowest toxicity data per species are given (except for *Daphnia magna* for which two chronic tests with comparable experimental conditions were available).

Table 9. EDTA and Na_4EDTA: selected freshwater toxicity data for ERL derivation.

Chronic Taxonomic group	NOEC/EC10 ($mg.L^{-1}$)	Acute Taxonomic group	L(E)C50 ($mg.L^{-1}$)
Pisces		**Pisces**	
Danio rerio[1]	> 26.8	*Lepomis macrochirus*[2]	159 (96h)
Crustacea		**Crustacea**	
Daphnia magna[3]	**22** (21d)	*Daphnia magna*[4]	616 (24h)
Algae		**Algae**	
Pseudokirchneriella subcapitata[5]	48.4	*Pseudokirchneriella subcapitata*[6]	> 100
Scenedesmus subspicatus[7]	0.370		

The bold value is used for derivation of the MPC.

[1]: ELS-test with $CaNa_2EDTA$. NOEC expressed as H_4EDTA.

[2]: Tested at a medium hardness (103 $mg.L^{-1}$ $CaCO_3$) with H_4EDTA.

[3]: Tested with Na_2H_2EDTA. NOEC expressed as H_4EDTA.

[4]: Tested with Na_4EDTA. LC_{50} expressed as H_4EDTA. Value is geometric mean of two tests, 480 and 790 $mg.L^{-1}$

[5]: Tested with Fe(III)EDTA. NOEC expressed as H_4EDTA and based on measured concentrations.

[6]: Tested with Fe(III)EDTA. LC_{50} expressed as H_4EDTA.

[7]: Tested with Na_4EDTA. NOEC expressed as H_4EDTA.

3.3.1 Treatment of fresh- and marine water toxicity data

No clear endpoints for saltwater are available. The behaviour of EDTA in the environment is determined by the presence of different cations. Since the presence of cations in marine waters is completely different than in freshwater, freshwater toxicity data cannot be used for derivation of marine ERLs.

3.3.2 Mesocosm studies

A mesocosm study is described in the EU-RAR, but no clear ecotoxicological endpoint could be derived from the information.

3.3.3 Derivation of MPC_{water} and MPC_{marine}

3.3.3.1 $MPC_{eco, water}$ and $MPC_{eco, marine}$

The effect assessment of EDTA is based on long-term tests, which are available for fish, daphnids and algae. The most sensitive endpoint was found for *Scenedesmus subspicatus* with a NOEC of 0.370 mg $EDTA.L^{-1}$. This value was not used in the RAR because the concentration-effect curve has a bi-phasal shape indicating that the effects are caused by nutrient deficiency. EDTA forms chelates with essential trace elements in the test medium, and these are available only to a smaller extent. The test medium contained a large stoichiometric surplus of Mg and Ca. It was decided that it is unclear whether the effects observed in the algal study are due to the toxicity of EDTA or to the chelating properties of the substance which decrease the availability of essential nutrients. Therefore, it was decided that this NOEC might not represent intrinsic EDTA toxicity and nutrient deprivation is unlikely to occur in the environment. However, the medium used was as recommended in the OECD guidance and these media are supposed to ensure optimal growth. If the EDTA would reduce availability of essential elements in this medium, it might have the same effect in the environment and nutrient deprivation should be seen as a (indirect) toxic effect. Nevertheless, the used OECD TG 201 medium (OECD, 2006) does already contain EDTA to prevent the precipitation of iron. In a footnote to the medium is stated the following: “The molar ratio of EDTA to iron slightly exceeds unity. This prevents iron precipitation and at the same time, chelation of heavy metal ions is minimised”. This indicates that the concentration of EDTA in the medium is properly balanced and additional EDTA would have a detrimental effect on the quality of the medium. This justifies the decision in the EU-RAR that the NOEC of 0.370 mg EDTA.L^{-1} for *Scenedesmus subspicatus* is not used for MPC derivation. Therefore the $PNEC_{aqua}$ of 2.2 mg.L^{-1} as derived in the RAR from the NOEC of 22 mg.L-1 for *Daphnia magna* is taken over as the $MPC_{eco, water}$. Considering the results of the *S. subspicatus* study, it should be noted that this value might not be protective in situations where the availability of nutrients is limited, *ie.* very soft water.

No clear endpoints for saltwater are available in the EU-RAR, therefore no $MPC_{eco, marine}$ can be derived.

3.3.3.2 $MPC_{sp, water}$ and $MPC_{sp, marine}$

EDTA has a BCF < 100 L.kg^{-1}, thus assessment of secondary poisoning is not triggered.

3.3.3.3 $MPC_{hh food, water}$

Derivation of $MPC_{hh food, water}$ for EDTA is not triggered (Table 8).

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

Based on the above, the following MPCs are derived:
MPC_{water}: 2.2 mg.L^{-1}
MPC_{marine}: not derived

3.3.4 Derivation of $MPC_{dw, water}$

No A1 value and DW standard are available for EDTA or Na_4EDTA. With the TDI of 1.96 mg.$kg_{bw}^{-1}day^{-1}$, an $MPC_{dw, water, provisional}$ can be calculated with the following formula: $MPC_{dw, water, provisional} = 0.1.TL_{hh}.BW / uptake_{dw}$ where the TL_{hh} is the TDI, BW is a body weight of 70 kg, and $uptake_{dw}$ is a daily uptake of 2 L. As described in section 2.2 water treatment is currently not taken into account. Therefore, the $MPC_{dw, water} = MPC_{dw, water, provisional}$ and becomes: 0.1 x 1.96 x 70 / 2 = 6.86 mg EDTA.L^{-1}.

3.3.5 Derivation of MAC_{eco}

In the EU-RAR for EDTA, a $PNEC_{intermittent}$ is calculated based on acute data for the freshwater environment. The MAC_{eco} in the context of the WFD is based on the $PNEC_{intermittent}$. The EU-RAR reports a $PNEC_{intermittent}$ of 6.4 mg.L^{-1}, based on the mean EC_{50} of two 24-h Daphnid studies (640 mg.L^{-1}) and an assessment factor of 100.

In both EU-RARs, a $PNEC_{intermittent, marine}$ of 0.64 mg.L^{-1} is reported which is based on the mean value of two 24-h EC_{50} for daphnids and an assessment factor of 1000.

It should be noted that the derivation of the $PNEC_{intermittent}$ in the EU-RAR is not completely performed in line with the INS-guidance. Also, the CSTEE does not accept the figure derived in the RAR. If derivation of the MAC_{eco} would be performed according to the INS-guidance, the acute value of 159 mg.L^{-1} for *Lepomis macrochirus* would be used in the derivation instead of the mean of the two daphnid studies. This would result in a $MAC_{eco, water}$ of 1.6 mg.L^{-1}. Since there are no marine data and the freshwater toxicity data for EDTA cannot be used for the marine environment, a $MAC_{eco, marine}$ could not be derived. Since the $PNECs_{intermittent}$ are not accepted by the CSTEE, the figure derived according to the method in the INS-guidance will set the $MAC_{eco, water}$ and no $MAC_{eco, marine}$ will be derived.

3.3.6 Derivation of NC_{water}

The NC_{water} is derived by using an assessment factor of 100 on the MPC_{water}. This results in an NC_{water} of 22 µg.L^{-1}.

3.3.7 Derivation of $SRC_{eco, aquatic}$

In the EU-RAR, no $SRC_{eco, aquatic}$ is derived. There are NOECs given for algae, daphnids and fish (48.4 mg.L^{-1}, 22 mg.L^{-1} and > 26.8 mg.L^{-1}, respectively). The value of 0.37 mg.L^{-1} which has not been used for derivation of the MPC, is also not used for derivation of the SRC. The NOEC for fish is a > value, which cannot be used to calculate the geometric mean. Therefore, the $SRC_{eco, aquatic}$ is based on the values for daphnid and algae. Using an assessment factor of 1, this results in an $SRC_{eco, aquatic}$ of 33 mg.L^{-1}. Since the freshwater toxicity data of EDTA is not valid for the marine environmental, the $SRC_{eco, aquatic}$ is valid for the freshwater environment only.

3.4 Toxicity data and derivation of ERLs for sediment

The log $K_{p,\ susp\text{-}water}$ of EDTA (1.88) is below the trigger value of 3, therefore, ERLs are not derived for sediment.

3.5 Toxicity data and derivation of ERLs for soil

There are only results available from studies in which the decrease of heavy metal toxicity caused by EDTA was investigated. No terrestrial toxicity data for EDTA are available in the EU-RAR. Furthermore, for complex forming agents such as EDTA, the equilibrium partitioning (EP) theory is not suitable because the behaviour of these compounds cannot be described with simple equilibrium partitioning principles. This hampers derivation of $ERLs_{soil}$ from $ERLs_{water}$ using EP. Therefore, no $ERLs_{soil}$ are derived.

3.6 Derivation of ERLs for groundwater

The ERLs for groundwater are based on the ERLs for the surface-water compartment.

3.6.1 Derivation of MPC_{gw}

3.6.1.1 $MPC_{eco, gw}$

The $MPC_{eco, gw}$ is set to the $MPC_{eco, water}$ of 2.2 mg.L^{-1}.

3.6.1.2 $MPC_{human, gw}$

The $MPC_{human, gw}$ is set equal to the $MPC_{dw, water}$ of 6.86 mg.L^{-1}.

3.6.1.3 Selection of the MPC_{gw}

The lowest MPC_{gw} is the $MPC_{eco, gw}$ 2..2 mg.L^{-1}. Thus the MPC_{gw} is 2.2 mg.L^{-1}.

3.6.2 Derivation of NC_{gw}

The NC_{gw} is set a factor 100 lower than the MPC_{gw}. Thus the NC_{gw} is 22 µg.L^{-1}.

3.6.3 Derivation of $SRC_{eco, gw}$

The $SRC_{eco, gw}$ is set to the $SRC_{eco, aquatic}$, which is 33 $mg.L^{-1}$.

3.7 Derivation of ERLs for air

No ecotoxicological data for air are available in the EU-RAR. Considering the salty character of EDTA derivation of an MPC_{air} is not relevant. Therefore, no ERLs for air are derived.

3.8 Comparison of derived ERLs with monitoring data

The RIWA (Dutch Association of River Water companies, www.riwa.org) reports for EDTA for the years 2004, 2005, 2006 and 2007 maximum concentrations of 13 $\mu g.L^{-1}$, 27 $\mu g.L^{-1}$ 10 $\mu g.L^{-1}$and 15 $\mu g.L^{-1}$ respectively. These values are below the MPC, MAC_{eco} and SRC for the water compartments derived in this report. At all sampling locations reported, the annual mean concentrations in these years do exceed the NC_{water} derived in this report in general by more than a factor of 10. The sampling locations were: River Rhine at Lobith, Lek canal at Nieuwegein, Amsterdam-Rhine canal at Nieuwersluis and Lake IJsselmeer at Andijk. This indicates that the NC_{water} could be exceeded at present as well.

4 Conclusions

In this report, the risk limits Negligible Concentration (NC), Maximum Permissible Concentration (MPC), Maximum Acceptable Concentration for ecosystems (MAC_{eco}), and Serious Risk Concentration for ecosystems (SRC_{eco}) are derived for all species of EDTA in water and groundwater. No risk limits were derived for the sediment compartment because exposure of sediment is considered negligible. Also, no risk limits were derived for the soil compartment because of a lack of available data. The ERLs that were obtained are summarised in Table 10. Monitoring data indicates that currently the NC_{water} could be exceeded. For the other ERLs there is no indication that they would be exceeded.

Table 10. Derived MPC, NC, MAC_{eco}, and SRC values for EDTA.

ERL	unit	value			
		MPC	NC	MAC_{eco}	SRC_{eco}
water	$mg.L^{-1}$	2.2	2.2×10^{-2}	1.6	33
drinking water [a]	$mg.L^{-1}$	6.9			
marine	$mg.L^{-1}$	n.d.			
sediment	$mg.kg_{dwt}^{-1}$	n.d.			
soil	$mg.kg_{dwt}^{-1}$	n.d.			
groundwater	$mg.L^{-1}$	2.2	2.2×10^{-2}		33
air	$\mu g.m^{-3}$	n.d.			

[a] The exact way of implementation of the $MPC_{dw, water}$ in the Netherlands is at present under discussion. Therefore, the $MPC_{dw, water}$ is presented as a separate value in this report.

n.d. = not derived.

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