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C.W.M. Bodar

Environmental risk limits for dibutylphthalate (DBP)

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C.W.M. Bodar

Contact:

Dr. C.W.M. Bodar

Expertise Centre for Substances

charles.bodar@rivm.nl

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

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Rapport in het kort

Environmental risk limits for dibutylphthalate

Dit rapport geeft milieurisicogrenzen voor dibutylftalaat in (grond)water, lucht en bodem. Milieurisicogrenzen zijn de technisch-wetenschappelijke advieswaarden voor de uiteindelijke milieukwaliteitsnormen in Nederland. De milieurisicogrenzen voor dibutylftalaat zijn gebaseerd op de uitkomsten van de EU risicobeoordeling voor dibutylftalaat (Bestaande Stoffen Verordening 793/93). De afleiding van de milieurisicogrenzen sluit tevens aan bij de richtlijnen uit de Kaderrichtlijn Water.

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Summary

Environmental risk limits (ERLs) are derived using ecotoxicological, physicochemical, 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 dibutylphthalate in water, groundwater, soil and air. 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, created 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.

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} and for the ERLs for the soil and atmospheric compartment, 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.

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

ERL	unit	value			
		MPC	NC	MAC_{eco}	SRC_{eco}
$MPC_{eco, water}$	$\mu g.l^{-1}$	10			
$MPC_{dw, water, prov}$	$\mu g.l^{-1}$	35			
$MPC_{sp, water}$	$\mu g.l^{-1}$	n.d.			
$MPC_{hh, food, water}$	$\mu g.l^{-1}$	340			
water ^a	$\mu g.l^{-1}$	10	0.1	35	430
drinking water ^{a, c}	$\mu g.l^{-1}$	35			
marine, eco	$\mu g.l^{-1}$			3.5 ^c	
sediment		n.d. ^b			
soil ^d	$\mu g.kg_{dw}^{-1}$	130	1.3		160×10^3
groundwater	$\mu g.l^{-1}$	10	0.1		
air	$\mu g.m^{-3}$	0.1			

^a 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} .

^b n.d. = not determined.

^c provisional value.

^d expressed on Dutch standard soil

1 Introduction

1.1 Project framework

In this report environmental risk limits (ERLs) for surface water (freshwater and marine), groundwater, soil and air are derived for dibutylphthalate. 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 (based on (eco)toxicological, fate and physico-chemical data) 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.

2 Methods

2.1 Data collection

The final Risk Assessment Report (RAR) of DBP produced in the framework of Existing Substances Regulation (793/93/EEC) was used as only source of physico-chemical and (eco)toxicity data (European Commission, 2006). Information given in the RARs is checked thoroughly by European Union member states (Technical Committee) and afterwards approved by the Scientific Commission on Health and Environmental Risk (SCHER). Therefore, no additional evaluation of data is performed for the ERL derivation. Only valid data combined in an aggregated data table are presented in the present report. Occasionally, key studies are discussed when relevant for the derivation of a certain ERL.

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 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).

3 Derivation of environmental risk limits for dibutylphthalate

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

3.1.1 Identity

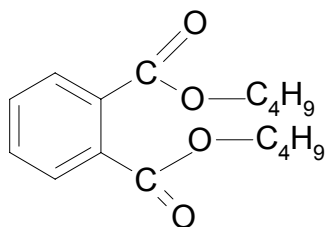


Figure 1. Structural formula of dibutylphthalate.

Table 2. Identification of dibutylphthalate.

Parameter	Name or number
Chemical name	dibutylphthalate
Common/trivial/other name	Di-n-butylphthalat, 1,2-Benzenedicarboxylic acid, dibutyl ester (9CI), Phthalic acid, dibutyl ester (6CI, 8CI), Bis-n-butyl phthalate, Butyl phthalate, DBP, DBP (ester), Di(n-butyl) 1,2-benzenedicarboxylate, Dibutyl o-phthalate, n-Butyl phthalate, Palatinol C, Phthalic acid di-n-butyl ester
CAS number	84-74-2
EC number	201-557-4
Molecular formula	C ₁₆ H ₂₂ O ₄

3.1.2 Physico-chemical properties

Table 3. Physico-chemical properties of dibutylphthalate.

Parameter	Unit	Value	Remark
Molecular weight	[g.mol ⁻¹]	278.34	
Water solubility	[mg.l ⁻¹]	10	at 20°C
log K _{OW}	[-]	4.57	
K _{OC}	[l/kg]	6340	
Vapour pressure	[hPa]	9.7 ± 3.3 x 10 ⁻⁵	at 25°C
Melting point	[°C]	- 69	
Boiling point	[°C]	340	at 1013 hPa
Henry's law constant	[Pa.m ³ .mol ⁻¹]	0.27	

3.1.3 Behaviour in the environment

Table 4. Selected environmental properties of dibutylphthalate.

Parameter	Unit	Value	Remark
hydrolysis half-life	DT ₅₀ [d]	n.a.	RAR: "A test on the hydrolysis potential of DBP indicated that at pH 4.0 and 7.0 DBP was found to be stable, i.e. less than 10% hydrolysis after 5 days. At pH 9.0 and a temperature of 50 °C a half-life time of 65.8 hours was reported. These results are in line with the RIVM-conclusion (RIVM, 1991) that the contribution of hydrolysis to the overall environmental degradation of phthalate esters, including DBP, is expected to be low."
photolysis half-life	DT ₅₀ [h]	n.a.	RAR: "Photo-oxidation by OH radicals contributes to the elimination of DBP from the atmosphere. The <u>experimental</u> degradation rate constant amounts to about 18*10 ⁻¹² cm ³ /mol*sec corresponding to a half-life of 21.4 hours at an average OH concentration of 500,000 molecules/cm ³ . Vapour phase reactions of DBP with photochemically produced hydroxyl radicals were also estimated with a <u>QSAR</u> (Atkinson, 1985). The overall OH rate constant for DBP was estimated to be 8.7*10 ⁻¹² cm ³ /mol*sec. This value corresponds to an atmospheric half-life of about 1.8 days. Howard et al. (1991) estimated the photo-oxidation half-life of DBP in air to range from 7.4 hours to 3.1 days." No data on UV photolysis in either water or air.
degradability	readily biodegradable		RAR: "biodegradation of DBP is much slower in the <u>anaerobic</u> environment, e.g. sediments or deeper soil or groundwater layers".

The RAR gives some general considerations on the environmental distribution of dibutylphthalate: “*The Henry's law constant of 0.27 Pa.m³/mol indicates that DBP will only slowly volatilize from surface waters, i.e. virtually all of the DBP will remain in the water phase at equilibrium. The octanol/water partition coefficient (K_{ow}) of DBP is high and consequently the equilibrium between water and organic carbon in soil or sediment will be very much in favour of the soil or sediment. Soil and sediment thus appear to be important sinks for DBP. Resuspension of DBP from the sediment to the water column may occur. Although DBP is only poorly soluble in water, it may be transported in water following the adsorption of DBP to humic substances. Despite its low volatility, DBP has been reported as particulate and as a vapour in the atmosphere. In the air DBP is transported and removed by both wet and dry deposition.*”

3.1.4 Bioaccumulation and biomagnification

Table 5. Overview of bioaccumulation data for dibutylphthalate.

Parameter	Unit	Value	Remark
BCF (fish)	[l.kg ⁻¹]	1.8	Experimental value used as key study in RAR.
BCF (mussel)	[l.kg ⁻¹]	n.a.	RAR: “ <i>Ray et al. (1983) measured the concentration of DBP in marine sediment, clams and the bristle worm (Neanthes virens) from samples near Portland, Maine U.S. The concentrations in sediment were found to be higher than those in biota, 160 and 100 µg/kg, respectively (BCFs < 1).</i> ” This value refers to a BSAF value rather than an aquatic BCF and can thus not be used for assessing the bioaccumulation potential from the aquatic environment.
BMF	[kg.kg ⁻¹]	1	

3.1.5 Human toxicological threshold limits and carcinogenicity

Classification according to the 28th ATP of Directive 67/548/EEC:

Repr. Cat. 2; R61, Repr. Cat. 3; R62, N; R50,

EFSA (2005) reported a TDI of 10 µg/kg bw/day for dibutylphthalate (www.efsa.europa.eu). No TCA is available.

In the RAR a LOAEL of 52 mg/kg bw/day was derived from an oral two-generation reproductive toxicity study with rats. The inhalatory NOAEC from a 28-day inhalation study with rats amounts to 509 mg/m³.

RAR: “*Based on the data available for dibutylphthalate from a variety of genotoxicity studies and taking into consideration the non-genotoxic properties of other phthalate esters, dibutylphthalate can be considered as a non-genotoxic substance. No adequate long-term toxicity and/or carcinogenicity studies in animals or man are available.*”

3.2 Trigger values

This section reports on the trigger values for MPC_{water} derivation (following WFD methodology).

Table 6. Dibutylphthalate: collected properties for comparison to MPC triggers for water ERL-derivation. n.a. = not available, n.r. = not relevant.

Parameter	Value	Unit	Method/Source
$\log K_{P, \text{susp-water}}$	2.8	[-]	$K_{OC} \times f_{OC, \text{susp}}^1$
BCF	1.8	[l.kg ⁻¹]	
BMF	1	[-]	
$\log K_{OW}$	4.57	[-]	
R-phrases	R61, R62	[-]	
A1 value	n.a.	[$\mu\text{g.l}^{-1}$]	
DW standard	n.a.	[$\mu\text{g.l}^{-1}$]	

¹ $f_{OC, \text{susp}} = 0.1 \text{ kg}_{OC} \cdot \text{kg}_{\text{solid}}^{-1}$ ((European Commission (Joint Research Centre), 2003)).
 $K_{OC} = 6340 \text{ l/kg}$.

- dibutylphthalate has a $\log K_{P, \text{susp-water}} < 3$; derivation of MPC_{sediment} is not triggered.
- dibutylphthalate has a $\log K_{P, \text{susp-water}} < 3$; expression of the MPC_{water} as $MPC_{\text{susp, water}}$ is not required.
- dibutylphthalate is not suspected to bioaccumulate ($BCF < 100$); assessment of secondary poisoning is not triggered.
- dibutylphthalate has an R61/62 classification, Therefore, MPC_{water} for human health via food (fish) consumption ($MPC_{\text{hh food, water}}$) needs to be derived.

3.3 Toxicity data and derivation of ERLs for water

3.3.1 $MPC_{\text{eco, water}}$ and $MPC_{\text{eco, marine}}$

Freshwater acute toxicity data for dibutylphthalate as reported in the RAR are listed in Table 7.

Table 7. Dibutylphthalate: selected acute freshwater data for ERL derivation.

Taxonomic group	L(E)C ₅₀ (mg.l ⁻¹)
Protozoa	
<i>Tetrahymena pyriformis</i>	2.2
Algae	
<i>Scenedesmus subspicatus</i>	1.2
<i>Scenedesmus subspicatus</i>	9.0
Crustacea	
<i>Daphnia magna</i>	3.4
<i>Daphnia magna</i>	5.2

Taxonomic group	L(E)C₅₀ (mg.l⁻¹)
<i>Daphnia magna</i>	17
<i>Daphnia magna</i>	3.4
<i>Gammarus pseudolimnaeus</i>	2.1
Insects	
<i>Chironomus plumosus</i>	0.76
<i>Paratanytarsus parthenogenetica</i>	5.8
Pisces	
<i>Brachydanio rerio</i>	2.2
<i>Pimephales promelas</i>	0.9
<i>Pimephales promelas</i>	2.0
<i>Pimephales promelas</i>	1.3
<i>Pimephales promelas</i>	3.0
<i>Pimephales promelas</i>	1.1
<i>Oncorhynchus mykiss</i>	1.6
<i>Oncorhynchus mykiss</i>	6.5
<i>Ictalurus punctatus</i>	0.46
<i>Ictalurus punctatus</i>	2.9
<i>Lepomis macrochirus</i>	0.9
<i>Lepomis macrochirus</i>	0.7
<i>Lepomis macrochirus</i>	1.2
<i>Lepomis macrochirus</i>	1.2
<i>Perca flavescens</i>	0.35
<i>Leuciscus idus</i>	7.3

In addition to the acute freshwater toxicity data, also marine acute toxicity data were available for dibutylphthalate (Table 8).

Table 8. Dibutylphthalate: selected acute marine data for ERL derivation.

Taxonomic group	L(E)C₅₀ (mg.l⁻¹)
Bacteria	
<i>Vibrio fischeri</i>	10.9
Crustacea	
<i>Nitocra spinipes</i>	1.7
<i>Americamysis bahia</i>	0.8
<i>Artemia salina</i>	8

Freshwater and marine chronic toxicity values from the RAR are reported in, respectively, Table 9 and Table 10.

Table 9. Dibutylphthalate: selected freshwater chronic data for ERL derivation.

Taxonomic group	NOEC (mg.l⁻¹)
Bacteria	
<i>Pseudomonas putida</i>	>10
Algae	
<i>Selenastrum capricornutum</i>	2.8
<i>Selenastrum capricornutum</i>	0.8
Crustacea	
<i>Daphnia magna</i>	1
<i>Daphnia magna</i>	0.56
<i>Gammarus pulex</i>	0.10
Pisces	
<i>Oncorhynchus mykiss</i>	0.1

Table 10. Dibutylphthalate: selected marine chronic data for ERL derivation.

Taxonomic group	NOEC (mg.l⁻¹)
Algae	
<i>Skeletonema costatum</i>	0.6
<i>Dunaliella parva</i>	0.2
<i>Thalassiosira pseudomona</i>	2.0

Treatment of fresh- and saltwater toxicity data

No marine PNEC was derived in the RAR. In the current report freshwater and marine data were pooled for the ERL derivations (similar sensitivity).

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

The RAR concludes the following on the PNEC_{aquatic} derivation: “The PNEC for the aquatic compartment is derived from the 99 day NOEC of 100 µg/l for *Oncorhynchus mykiss*. This key study is supported by the *Gammarus pulex* study in which a similar value was found based on a decrease in locomoter activity. An assessment factor of 10 will be used for the extrapolation. This factor is used because long term NOECs for three trophic levels are available. PNEC_{aquatic} = 10 µg/l.”

The MPC_{water, eco} is equal to the PNEC_{aquatic}, thus 10 µg.l⁻¹.

Data on micro-organism were not taken into account in the RAR when deriving the PNEC water for dibutylphthalate. They were only used for deriving a separate PNEC for the sewage treatment plant. (Note: if data on micro-organisms would have been used, a similar PNEC would have been derived).

In the RAR no effect assessment for the marine environment is carried out. When following the TGD and using the pooled dataset for freshwater and marine organisms an assessment factor of 100 should be applied to the lowest NOEC value of 100 µg/l. -> MPC_{marine, eco} = 1 µg.l⁻¹.

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

Dibutylphthalate has a BCF < 100. Thus, assessment of secondary poisoning is not triggered (Table 6).

3.3.3 MPC_{hh food, water}

Derivation of MPC_{hh food, water} for dibutylphthalate is triggered (Table 6). A TL_{hh} of 10 µg/kg bw/day is available. From this an MPC_{hh food} can be derived: $(0.1 * TL_{hh} / 70) / 0.115 = (0.1 * 10 / 70) / 0.115 = 0.07 / 0.115 = 0.61$. The MPC_{hh food, water} then becomes $0.61 / (BCF * BMF) = 0.61 / (1.8 * 1) = 0.34 \text{ mg.l}^{-1}$.

3.3.4 MPC_{dw, water}

No A1 value and DW standard are available. The TDI (TL_{hh}) for dibutylphthalate amounts to 10 µg/kg bw/day is used. The MPC_{dw, water, provisional} = $(0.1 * TL_{hh} * BW) / \text{uptake} = (0.1 * 10 * 70) / 2 = 35 \text{ µg.l}^{-1}$.
(Note: calculation from MPC_{dw, water, provisional} towards MPC_{dw, water} still to be addressed. This awaiting a realistic estimate of purification fraction for DBP).

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

In the Fraunhofer document (Lepper, 2005) it is prescribed that the lowest MPC value should be selected as the general MPC. In the proposal for the daughter directive Priority Substances, a standard based on drinking water was not included. Provisionally, in the Netherlands the MPC_{dw, water} will always be noted 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} (thus excluding the MPC_{dw, water}) the lowest one is taken forward as the 'overall' MPC_{water}. Subsequently, the NC_{water} is always based on this overall MPC_{water} value (1/100th). This irrespective if this value is lower than the MPC_{dw, water} or not. The MPC_{dw, water, provisional} = 35 µg.l⁻¹.

The MPC_{water} is the MPC_{water, eco} (lowest value of the other values) of 10 µg.l⁻¹.

The only marine MPC of 1 µg.l⁻¹ is set as MPC_{marine}. MPC_{marine} = 1 µg.l⁻¹.

3.3.6 MAC_{eco, water}

The EC₅₀-value of 0.35 mg.l⁻¹ for fish *Perca flavescens* is the lowest reported acute toxicity value in the RAR. The base set is complete and dibutylphthalate has no potential to bioaccumulate. Furthermore the most sensitive species is assumed to be included in the relatively large data set. On top of that, the mode of toxic action of dibutylphthalate is probably polar narcosis. This is supported by the fact that QSAR predictions are in the same range or even lower than the experimental results. Therefore, an assessment factor of 10 is applied. The MAC_{eco} for fresh water is $0.35 / 10 = 35 \text{ µg.l}^{-1}$

MAC_{eco, marine} amounts to $35 / 10 = 3.5 \text{ µg.l}^{-1}$. It has to be noted that this procedure for MAC_{eco, marine} is currently not agreed upon. Therefore, the MAC_{eco, marine} value needs to be re-evaluated once an agreed procedure is available.

3.3.7 NC_{water}

The NC_{water} is set to a factor of 100 below the final MPC_{water}. The NC_{water} becomes $10 / 100 = 0.1 \text{ µg.l}^{-1}$.

3.3.8 SRC_{eco, water}

More than three NOECs are available for dibutylphthalate (see Tables 9 and 10). Therefore the SRC_{eco, water} is based on the geometric mean of these NOEC data without an additional assessment factor (see Table 27 of Van Vlaardingen and Verbruggen, 2007). The SRC_{eco, water} for dibutylphthalate amounts to 430 µg.l⁻¹.

3.4 Toxicity data and derivation of ERLs for sediment

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

3.5 Toxicity data and derivation of ERLs for soil

Only very limited experimental data on the toxicity of dibutylphthalate to soil organisms are reported in the RAR. The only valid study is a 21 days test with plant *Zea mays* in which a NOEC of 200 mg/kg dwt was found.

3.5.1 $MPC_{\text{eco, soil}}$

In the RAR a $PNEC_{\text{terrestrial}}$ of 2 mg.kg_{dwt}⁻¹ is derived. This value is based on the NOEC for *Zea mays* applying a factor of 100. After conversion to Dutch standard soil the value for the $MPC_{\text{eco, soil}}$ becomes $2 * 5.88/2 = 5.9 \text{ mg.kg}_{\text{dwt}}^{-1}$. A more or less similar MPC value is found when applying the equilibrium partitioning method, i.e. 3.7 mg.kg_{dwt}⁻¹. Preference (in line with the RAR) is given to the experimental value: $MPC_{\text{eco, soil}} = 5.9 \text{ mg.kg}_{\text{dwt}}^{-1}$.

3.5.2 $MPC_{\text{human, soil}}$

The $MPC_{\text{human, soil}}$ is based on the 10 µg/kg bw/day (see paragraph 3.2). Specific human intake routes are allowed to contribute 10% of the human toxicological threshold limit. Four different routes contributing to human exposure have been incorporated: consumption of leafy crops, root crops, milk and meat. The critical route for dibutylphthalate was calculated to be consumption of root crops. The $MPC_{\text{soil, human}}$ was determined to be 0.13 mg.kg_{dwt}⁻¹ Dutch standard soil.

3.5.3 Selection of the MPC_{soil}

The lowest MPC_{soil} is the $MPC_{\text{human, soil}}$ of 0.13 mg.kg_{dwt}⁻¹ Dutch standard soil.

3.5.4 NC_{soil}

The NC_{soil} is set a factor 100 lower than the MPC_{soil} . $NC_{\text{soil}} = 1.3 \text{ µg.kg}_{\text{dwt}}^{-1}$ Dutch standard soil.

3.5.5 $SRC_{\text{eco, soil}}$

Based on terrestrial data the $SRC_{\text{eco, soil}}$ becomes 590 mg/kg dwt (assessment factor of 1 on result normalised to Dutch standard soil). The SRC-value can also be based on equilibrium partitioning. From the $SRC_{\text{eco, water}}$ of 430 µg/l an $SRC_{\text{eco, soil}}$ of 160 mg.kg_{dwt}⁻¹ is derived for Dutch standard soil. The lowest value should be taken as $SRC_{\text{eco, soil}}$: 160 mg.kg_{dwt}⁻¹.

3.6 Derivation of ERLs for groundwater

3.6.1.1 $MPC_{\text{eco, gw}}$

Since groundwater-specific ecotoxicological information is absent, the derived ERLs for surface water based on ecotoxicological data are taken as substitute. Thus, $MPC_{\text{eco, gw}} = MPC_{\text{eco, water}} = 10 \text{ µg.l}^{-1}$.

3.6.2 MPC_{human, gw}

The MPC_{human, gw} is set equal to the MPC_{dw, water}. Thus, MPC_{human, gw} = MPC_{dw, water} = 35 µg.l⁻¹ (provisional value!)

3.6.3 Selection of MPC_{gw}

The lowest available MPC is the MPC_{eco, gw} of 10 µg.l⁻¹. Thus, the final MPC_{gw} = 10 µg.l⁻¹.

3.6.4 NC_{gw}

The NC_{gw} is set a factor 100 lower than the MPC_{gw}. Thus, NC_{gw} = 10/100 = 0.1 µg.l⁻¹.

3.7 Derivation of ERLs for air

RAR: “In addition to older plant fumigation test with dibutylphthalate (gas phase) a long-term fumigation test was conducted exposing six different plant species to various dibutylphthalate concentrations for a period of 76 days. Mean measured concentrations amounted to 0.14 (control), 0.81, 1.37, 3.07 and 13.67 µg/m³. The plant species chosen for the laboratory experiment were representative of the European flora and included plant species representative for crops, trees and natural vegetation: *Phaseolus vulgaris* (bean), *Brassica campestris* var. *chinensis* (cabbage), *Picea abies* (Norway spruce), *Trifolium repens* (white clover), *Plantago major* (plantain) and *Holcus lanatus* (common velvet grass). Cabbage was ‘automatically’ selected, because this species was found to be the most sensitive one in the earlier dibutylphthalate fumigation tests.” In the RAR a PNEC_{plant-air} of 0.1 µg/m³ was based on this well-performed test. The MPC_{eco, air} therefore amounts to 0.1 µg/m³. The inhalatory NOAEC from a 28-day inhalation study with rats amounts to 509 mg/m³. No TCA is (yet) derived from this value, but the MPC_{human, air} will not be lower than the MPC_{eco, air} of 0.1 µg/m³. The overall MPC_{air} for dibutylphthalate therefore amounts to 0.1 µg/m³.

4 Conclusions

In this report, the environmental risk limits negligible concentration (NC), maximum permissible concentration (MPC), maximum acceptable concentration for aquatic ecosystems (MAC_{eco}), and serious risk concentration for ecosystems (SRC_{eco}) are derived for dibutylphthalate in water, groundwater, soil and air. 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.

Table 11. Derived MPC, NC, MAC_{eco} , and SRC_{eco} values for dibutylphthalate.

ERL	unit	value			
		MPC	NC	MAC_{eco}	SRC_{eco}
$MPC_{eco, water}$	$\mu g.l^{-1}$	10			
$MPC_{dw, water, prov}$	$\mu g.l^{-1}$	35			
$MPC_{sp, water}$	$\mu g.l^{-1}$	n.d. ^b			
$MPC_{hh, food, water}$	$\mu g.l^{-1}$	340			
water ^a	$\mu g.l^{-1}$	10	0.1	35	430
drinking water ^{a, c}	$\mu g.l^{-1}$	35			
marine, eco	$\mu g.l^{-1}$			3.5 ^c	
sediment		n.d. ^b			
soil ^d	$\mu g.kg_{dw}^{-1}$	130	1.3		160×10^3
groundwater	$\mu g.l^{-1}$	10	0.1		
air	$\mu g.m^{-3}$	0.1			

^a 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} .

^b n.d. = not determined.

^c provisional value.

^d expressed on Dutch standard soil

References

EFSA 2005. www.efsa.europa.eu.

European Commission. 2006. Dibutylphthalate. European Union Risk Assessment Report, Luxembourg: Office for Official Publications of the European Communities..

European Commission (Joint Research Centre) 2003. Technical Guidance Documents. European Chemicals Bureau, Institute for Health and Consumer Protection, Ispra, Italy.

Lepper P. 2005. Manual on the Methodological Framework to Derive Environmental Quality Standards for Priority Substances in accordance with Article 16 of the Water Framework Directive (2000/60/EC). Schmallingenberg, Germany: Fraunhofer-Institute Molecular Biology and Applied Biology.

Van Vlaardingen PLA, Verbruggen EMJ. 2007. Guidance for the derivation of environmental risk limits within the framework of 'International and national environmental quality standards for substances in the Netherlands (INS). Bilthoven, the Netherlands: National Institute for Public Health and the Environment. Report no. 601782001/2007.