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Dimethenamid-P

Afleiding van milieukwaliteitsnormen voor oppervlaktewater

Versie 18-08-2025

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Kwaliteitsprocedures en beoordelingskader
De afleiding van de waterkwaliteitsnormen in dit rapport is opgesteld in overeenstemming met de vigerende VSP kwaliteitsprocedures. De afleiding is beoordeeld en goedgekeurd door een aantal (agenda-)leden van de Wetenschappelijke Klankbordgroep normstelling water en lucht.

Contents

1 Introduction

1.1 General

Dimethenamid-P is the herbicidal active S-enantiomer of dimethenamid (1:1). The herbicide is authorised in the EU for the use against annual monocotyledonous and dicotyledonous weeds in maize, sweet corn, soy bean, sunflower and sugar beet (EFSA, 2018). The current quality standards for freshwater in the Netherlands are an Annual Average Environmental Quality Standard (AA-EQS) of 0.13 μg/L and a Maximum Acceptable Concentration (MAC-EQS) of 1.6 μg/L. These values are included in the Environmental Quality Decree (*Besluit kwaliteit leefomgeving; Bkl*) under the Dutch Environment and Planning Act (*Omgevingswet*). Annex IIIa of the Bkl lists the indicators for good ecological quality for substances that are designated as specific pollutants under the Water Framework Directive (WFD).

BASF, one of the applicants of dimethenamid-P as plant protection product (PPP) in the Netherlands, requested an update of the water quality standards and submitted a proposal and underlying data. The Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) commissioned RIVM to evaluate the submitted dossier, check for additional data in the open literature and derive environmental quality standards (EQSs) according to the methodology of the WFD.

> The Dutch Environment and Planning Act entered into force on 1 January 2024. Annex IIIa of the Bkl uses the Dutch terms 'Kalenderjaargemiddelde waarde van de concentratie' and 'Maximaal aanvaardbare waarde van de concentratie'. For the ease of reading, RIVM will use the terminology used in European Technical Guidance for deriving Environmental Quality Standards under the Water Framework Directive (EC, 2018b). AA-EQS and MAC-EQS are literally translated into JG-MKN and MAC-MKN.
>
> The EQS derived in this report are technical advisory values which do not have an official status until approved by Ctgb. It should be noted that current legal values remain in force until revision of the Bkl. See also section 5.

1.2 Current water quality standards for dimethenamid-P

Currently, an AA-EQS of 0.13 μg/L and an MAC-EQS of 1.6 μg/L are used as legal standards in the Netherlands. These values have been derived in 2008 by the RIVM (Scheepmaker, 2008).

Environmental quality standards have also been proposed by other European countries and institutes, and by the applicant BASF. Below an overview is given of existing and proposed values.

Table 1 (Proposed) EQS-values by other institutes in comparison to the current Dutch EQS for dimethenamid-P.

Institute/country	$AA\text{-}EQS_{fw}$ (µg/L)	$AA\text{-}EQS_{sw}$ (µg/L)	$MAC\text{-}EQS_{fw}$ (µg/L)	$MAC\text{-}EQS_{sw}$ (µg/L)
RIVM, NL (2008)	0.13	-	1.6	-
UBA, DE (2025)	0.26	0.026	2.5	0.5
Oekotoxzentrum, CH (2019)	0.26	-	2.5	-
INERIS, FR (2011)	0.2	0.02	1.3	0.13
BASF, applicant (2024)	2.73	-	4.57	-

1.3 Standards considered in this report

Under the WFD, two types of EQSs are derived to cover both long- and short-term effects resulting from exposure (EC, 2018b):

- an Annual Average EQS (AA-EQS) for aquatic ecosystems – a long-term standard, expressed as an annual average concentration which should protect aquatic ecosystems against adverse effects resulting from long-term exposure, and
- a Maximum Acceptable Concentration EQS (MAC-EQS) for aquatic ecosystems – the concentration protecting aquatic ecosystems from effects due to short-term exposure or concentration peaks.

The AA-EQS should not result in risks due to direct toxicity, secondary poisoning and/or risks for human health aspects. The latter two aspects are therefore also addressed in the AA-EQS, when triggered by the characteristics of the compound (i.e., human toxicity and/or potential to bioaccumulate). The MAC-EQS is based on direct ecotoxicity only. In the context of pesticide authorisation, only freshwater EQSs are used. However, since the values may be used for other purposes as well, standards for the marine environment are also derived in this report.

For authorisation of PPP, transient effects may be considered acceptable under certain conditions if the potential for recovery is demonstrated (EFSA, 2013). However, the quality standards in the context of the WFD refer to the absence of any impact on community structure of aquatic ecosystems. Hence, long-term undisturbed function is the protection goal under the WFD. Therefore, recovery in a test situation, after a limited exposure time, is not included in the derivation of the AA- and MAC-EQS (EC, 2018b).

1.4 Methodology

1.4.1 Guidance documents

The methodology is in accordance with the European Technical Guidance for deriving Environmental Quality Standards under the Water Framework Directive (EC, 2018b). This document is further referred to as the WFD-guidance. For those aspects that may not be fully covered by the WFD-guidance, additional information can be found in national guidance documents (RIVM, 2025).

1.4.2 *Data sources*

The applicant submitted a statement with an EQS-proposal for dimethenamid-P ([redacted], 2024). This EQS-derivation was primarily based on data from the Renewal Assessment Report (RAR) that was prepared for dimethenamid-P within the context of the European pesticides Regulation 1107/2009 and associated EFSA conclusion (EC, 2018a). On January 7, 2025 RIVM performed additional searches in SCOPUS (http://www.scopus.com/) using the search string 'dimethenamid-P and aquatic' and the US EPA Ecotox Knowledgebase to check for any additional relevant scientific papers. This resulted in two additional potentially relevant studies.

1.4.3 *Data evaluation and selection*

In general, studies that were accepted in the RAR were not re-evaluated, but checked for adequate reporting of relevant endpoints. Where necessary, however, additional calculations were made, e.g., when statistical re-evaluation of the applicant only considered the EC_{50} but not the EC_{10}. Based on the RAR evaluation, reliability indices (Ri) of 1 to 4 were assigned as follows: Ri1: fully reliable, Ri2: reliable with restrictions, Ri3: not reliable and Ri4: not assignable. The reliability assessment was performed according to Klimisch et al. (1997), considering the criteria of CRED (Moermond et al., 2016). Study-specific details concerning the reliability assessment are listed in the footnotes in Annex 1.

The German UBA and Swiss Oekotoxzentrum also provided Klimisch reliability scores in their EQS-derivations (Marti et al., 2019; UBA, 2025). These were checked and when reliability scores differed from the current evaluation, this was noted. INERIS did not report reliability scores, therefore the report was only briefly scanned for any additional relevant information (INERIS, 2011).

The newly retrieved data from the literature search were also evaluated with respect to the validity (scientific reliability) of the study. A detailed description of the evaluation procedure is given in the WFD-guidance (EC, 2018b). The reliability of these scientific articles within the scope of the EQS derivation are discussed in Annex 1.

In line with the WFD-guidance, preference is given to studies with the active substance over studies with formulated products. However, if for a species the only reliable effect concentrations are from a study with a formulation, this information is used.

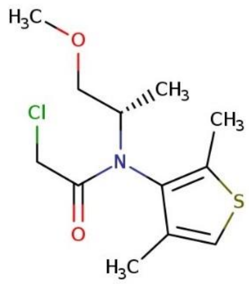
Not all studies summarised in the RAR were included in the current evaluation. Some studies in the RAR were considered not relevant in the scope of the current EQS derivation due to unconventional exposure regimes (e.g., exposure duration too short or too long or pulse exposure) and were therefore not further evaluated.

2 Information on the substance

2.1 Identity

Table 2 shows the identification of the substance.

Table 2. Substance identification.

Substance name	dimethenamid-P
Chemical name (IUPAC)	2-chloro-N-(2,4-dimethylthiophen-3-yl)-N-[(2S)-1-methoxypropan-2-yl]acetamide
CAS number	163515-14-8
EC number	605-329-9
Molecular formula	$C_{12}H_{18}ClNO_2S$
Molar mass	275.80
Structural formula	
SMILES code	CC1=CSC(=C1N([C@@H](C)COC)C(=O)CCl)C
Use class	thiophenes
Mode of action	inhibition of lipid synthesis (herbicidal)

2.2 Physico-chemical properties

Relevant physico-chemical properties are summarised in Table 3.

Table 3. Relevant physico-chemical properties of dimethenamid-P. Data obtained from the list of endpoints (LoE) of the RAR (2018) supplemented with data from EPISuite models.

Parameter	**Unit**	**Value**	**Remark**
Water solubility	mg/L	1499	at 25 °C and pH 6.16
	mg/L	1200	at 25 °C; EPISuite, experimental value
	mg/L	1902	at 25 °C; EPISuite predicted value (WATERNT v1.01)
pK_a			no dissociation between pH 1-11
log K_{ow}		1.89	at 25 °C

		2.15	EPISuite, experimental value
		2.57	EPISuite predicted value (KOWWIN v1.68)
Vapour pressure	Pa	0.00347 (± 1.29)*	at 20 °C
	Pa	0.00251 (± 0.39)*	at 25 °C
	Pa	0.0367	at 25 °C; EPISuite, experimental value
	Pa	0.004	at 25 °C; EPISuite predicted value (MPBPVP v1.43)
Henry's law constant	Pa·m^3/mol	0.00048	at 25 °C
Melting point	°C	<-50	
Boiling point	°C	>280 °C	decomposition observed at a lower temperature

** The lower vapour pressure value is found at the higher test temperature. The two values from the RAR are therefore not as expected.*

2.3 Fate and behaviour

Selected environmental properties of dimethenamid-P are given in Table 4.

Table 4. Selected environmental properties of dimethenamid-P. All data from RAR (2018).

Parameter	**Name/ Unit**	**Value**	**Remark**
Readily biodegradability			*no information available*
Hydrolysis half-life	DT_{50} [d]	-	stable at pH 5, 7, 9; EPA 161-1 guideline
Photolysis half-life	DT_{50} [d]	17.29	direct; 855 W/m^2 for 19 days; EPA 161-2 guideline
Biodegradation in surface water	DT_{50} [d]	-	no biodegradation observed in an OECD TG 309 study
Biodegradation in water/sediment systems	DT_{50} [d]	-	<10% mineralisation observed in an OECD TG 308 study; three metabolites >5% detected.

Bioconcentration factor (BFC) in fish	L/kg	58	EPA 165-4 guideline
K_{oc}	L/kg	167.4	median, n=10 soils, used in the LoE
	L/kg	140.5	EPISuite predicted value (KOCWIN v2.00 – MCI method)
	L/kg	94.7	EPISuite predicted value (KOCWIN v2.00 – Kow method)

2.4 Mode of action

Dimethenamid-P is a chloroacetamide herbicide that interferes with key plant processes such as protein and flavonoid production, as well as affecting isoprenoid biosynthesis. The exact molecular mode of action is still unknown, but it is suggested that the mechanism of action includes disrupting the formation of coenzyme A conjugates and interference with other chemical reactions involving thiol (SH) groups. These disruptions prevent cell division and tissue development in plants, ultimately causing plant death either before or shortly after seedlings emergence (Health Canada, 2009). Cyanobacteria, despite being classified as primary producers, are not considered to be sensitive species. Cyanobacteria are prokaryotes and lack the compartmentalized systems, such as a distinct cell wall and membrane structures found in eukaryotic plants and algae, which likely play a central role in the herbicide's mode of action. Therefore, only plants and algae (eukaryotic primary producers) are regarded as the most sensitive species.

2.5 Bioconcentration and biomagnification

Since log K_{ow} is < 3, the trigger for bioconcentration and biomagnification is not exceeded. A QS based on secondary poisoning of predators ($QS_{fw,\ sec\ pois}$ or $QS_{sw,\ sec\ pois}$) does not have to be derived.

2.6 Human toxicity

Dimethenamid-P does not have a harmonised classification for any of the human toxicological relevant hazard classifications for triggering the fish consumption route (ECHA, 2025). Therefore, a $QS_{water,\ hh\ food}$ does not need to be derived.

3 Derivation of water quality standards

3.1 Ecotoxicity data

This section reports the available acute and chronic laboratory ecotoxicity data for aquatic organisms. Detailed ecotoxicity data are presented in Annex 1 and the final data selection is given below in Table 5 (chronic ecotoxicity data) and Table 6 (acute ecotoxicity data).
All relevant and reliable ecotoxicity data were obtained from the RAR. The two studies retrieved from the open literature were considered not reliable (see Annex 1). Most studies in the RAR were conducted with

either the racemic mixture of dimethenamid or the herbicidal S-enantiomer (dimethenamid-P). However, for several higher plant species, the effects of dimethenamid-P have been investigated using a formulated product (containing 711.4 g/L active substance), of which the composition is confidential and thus not fully known. However, these studies were considered relevant in the current evaluation as no other ecotoxicological information of the active substance for these macrophyte species was available. This decision is in accordance with the WFD-guidance. Moreover, these studies provide valuable ecotoxicological information for the most sensitive taxonomic group (eukaryotic primary producers), including the species *Acorus calamus, Iris pseudacorus, Ludwigia palustris, Mentha aquatica, Sparganium erectum, Veronica beccabunga, Ceratophyllum demersum, Crassula recurva, Elodea densa, Myriophyllum spicatum, Potamogeton crispus* and *Vallisneria spiralis*. With this approach, we deviate from the evaluations performed by the UBA (DE) and Oekotoxzentrum (CH), which consider all studies done with formulated products to be invalid.

During the assessment of the RAR summaries for the plant studies conducted with the formulation, several uncertainties were identified. For instance, it was unclear why no E_rC_{10} values had been reported. To address these uncertainties, the original study reports were requested and subsequently provided by Ctgb, allowing for a more thorough evaluation. The raw data showed a high variability in both the control replicates (up to 46%) as well as the test concentration replicates. As non-standard plant species were tested, performance criteria are not available. Therefore, it is unknown whether the control variability can be considered acceptable or not. Regardless of this uncertainty, E_rC_{10} were derived. However, derivation of reliable E_rC_{10} was not deemed feasible due to the high variability in test results and the absence of a clear dose-response relationship. Also, the reliability of the available NOEC values is questioned. Due to these uncertainties, the plant studies were assigned a reliability score of Ri2 and we decided to both include and exclude the NOEC values in the SSDs, to compare the results and to determine the impact of the studies on the HC_5 outcomes (see section 3.1).

The two studies with the algae *Dictyococcus varians* and *Pandorina morum* that were considered not acceptable in the RAR are not included in this EQS-derivation. The studies were not considered valid in the RAR as the section-by-section specific growth rate in the controls were respectively 43.7 and 46.2%, exceeding the limit of 35% as specified in OECD TG 201. It is acknowledged that both algae are non-standard species and that a higher variation up to 50% may be acceptable in the risk assessment of Plant Protection Products[1], however as the EQS are derived in accordance with the WFD-guidance and as both species did not maintain exponential growth during the exposure period, the data

[1]Working document on Risk Assessment of Plant Protection Products in the Central Zone. Ecotoxicology. Version 3.0, December 2024. https://circabc.europa.eu/rest/download/1b0ffec2-09dc-4943-b929-c8a7b9cd9611?ticket=

for both species are not included. It is, however, noted that the derived EQS are protective for both species (see section 3.1 and 3.2).

Lastly, for some species the geometric mean of multiple study results was calculated and used. This was only done when the test set up and test conditions were similar and the effect concentrations are based on the same endpoint.

Table 5. Chronic ecotoxicity of dimethenamid-P for aquatic organisms. All data originate from the RAR. All values are expressed as the concentration active substance. The critical effect concentration is highlighted in bold.

Taxon/ Species	Duration	Criterion	Value [mg/L]	Remark
Fish				
Oncorhynchus mykiss	90-d	EC_{10}	0.44	
Invertebrates				
Daphnia magna	21-d	EC_{10}	0.94	
Cyanobacteria				
Anabaena flos-aquae	72-h	E_rC_{10}	0.21	
Algae				
Ankistrodesmus bibraianus	72-h	E_rC_{10}	0.00367	
Chlamydomonas reinhardtii	72-h	E_rC_{10}	0.062	
Desmodesmus subspicatus	72-h	E_rC_{10}	0.012	
Monoraphidium griffithii	**72-h**	$\mathbf{E_rC_{10}}$	**0.0021**	recalculated by assessor
Navicula pelliculosa	72-h	E_rC_{10}	0.082	
Neochloris aquatica	72-h	E_rC_{10}	0.0871	
Planktosphaeria botryoides	72-h	E_rC_{10}	0.0517	
Raphidocelis subcapitata	72-h	E_rC_{10}	0.012	geomean (n=2)
Schroederia setigera	72-h	E_rC_{10}	0.0287	
Macrophytes*				
Lemna gibba	9-d	E_rC_{10}	0.0042	
Ceratophyllum demersum	9-d	NOE_rC	<0.00381	
Myriophyllum spicatum	9-d	NOE_rC	0.0087	
Potamogeton crispus	9-d	NOE_rC	0.0295	
Crassula recurva	12-d	NOE_rC	0.039	
Elodea densa	12-d	NOE_rC	0.0316	
Vallisneria spiralis	12-d	NOE_rC	≥0.261	

Taxon/ Species	Duration	Criterion	Value [mg/L]	Remark
Acorus calamus	13-d	NOE_rC	≥1.314	formulated product
Iris pseudacorus	13-d	NOE_rC	0.018	
Ludwigia palustris	13-d	NOE_rC	0.007	
Mentha aquatica	13-d	NOE_rC	0.042	
Sparganium erectum	13-d	NOE_rC	0.041	
Veronica beccabunga	13-d	NOE_rC	0.009	
Glyceria maxima	14-d	E_rC_{10}	0.027	

*The reliability of all NOECs derived from studies with formulated product and macrophytes is ambiguous. SSDs were derived both including and excluding this data.

Table 6. Acute ecotoxicity of dimethenamid-P to aquatic organisms. All data originate from the RAR. The critical effect concentration is highlighted in bold.

Taxon/ Species	Duration	Criterion	Value [mg/L]	Remark
Fish				
Cyprinodon variegatus	96-h	LC_{50}	12	marine species
Lepomis macrochirus	96-h	LC_{50}	8	geometric mean (n=2)
Oncorhynchus mykiss	96-h	LC_{50}	4.05	geometric mean (n=2)
Invertebrates				
Americamysis bahia	96-h	LC_{50}	3.2	marine species
Daphnia magna	48-h	EC_{50}	13.9	geometric mean (n=2)
Cyanobacteria				
Anabaena flos-aquae	72-h	E_rC_{50}	1.478	
Algae				
Ankistrodesmus bibraianus	72-h	E_rC_{50}	0.037	
Chlamydomonas reinhardtii	72-h	E_rC_{50}	0.2245	
Desmodesmus subspicatus	72-h	E_rC_{50}	0.065	
Monoraphidium griffithii	72-h	E_rC_{50}	0.0200	recalculated by assessor
Navicula pelliculosa	72-h	E_rC_{50}	0.287	
Neochloris aquatica	72-h	E_rC_{50}	>1	

Taxon/ Species	Duration	Criterion	Value [mg/L]	Remark
Planktosphaeria botryoides	72-h	E_rC_{50}	0.912	
Raphidocelis subcapitata	72-h	E_rC_{50}	0.044	geometric mean (n=2)
Schroederia setigera	72-h	E_rC_{50}	>0.4055	
Macrophytes*				
Lemna gibba	9-d	E_rC_{50}	0.01829	
Ceratophyllum de mersum	**9-d**	$\mathbf{E_rC_{50}}$	**0.0135**	formulated product
Myriophyllum spicatum	9-d	E_rC_{50}	0.0884	
Potamogeton crispus	9-d	E_rC_{50}	0.191	
Crassula recurva	12-d	E_rC_{50}	0.0795	
Elodea densa	12-d	E_rC_{50}	0.188	
Vallisneria spiralis	12-d	E_rC_{50}	>0.261	
Acorus calamus	13-d	E_rC_{50}	>1.314	
Iris pseudacorus	13-d	E_rC_{50}	0.153	
Ludwigia palustris	13-d	E_rC_{50}	0.033	
Mentha aquatica	13-d	E_rC_{50}	0.206	
Sparganium erectum	13-d	E_rC_{50}	0.369	
Veronica beccabunga	13-d	E_rC_{50}	0.104	
Glyceria maxima	14-d	E_rC_{50}	0.184	

*The reliability of all E_rC_{50}s derived from studies with formulated product and macrophytes is ambiguous. SSDs were derived both including and excluding this data.

3.1 Derivation of the AA-EQS

Two main approaches are possible, the deterministic and probabilistic method. Essentially the deterministic approach takes the lowest credible effect concentration and applies an AF (which, in principle, may be as low as 1 or as high as 10000) to extrapolate to a QS, the AF allowing for the uncertainties in the available data. Probabilistic methods adopt a species sensitivity distribution (SSD) modelling in which all reliable toxicity (usually NOEC) data are ranked and a model is fitted. From this, the HC_x, which is the concentration at which the EC_{10} or NOEC will be greater for a certain proportion of species (typically 95%, HC_5) can be estimated. A smaller AF (1-5) would normally be applied to the HC_5.

3.1.1 Deterministic approach

NOEC/EC_{10}-values are available for 26 species from five taxonomic groups: cyanobacteria, algae, macrophytes, crustaceans and fish. A complete base set is available. Therefore, the $QS_{fw,\ eco}$ is derived from the lowest chronic available effect concentration, the 72-h E_rC_{10} value of 0.0021 mg/L (2.1 µg/L) for *Monoraphidium griffithii* based on growth rate. An assessment factor of 10 may be applied because the substance has a known mode of action and representatives of the presumed most sensitive taxonomic groups (eukaryotic primary producers; algae and higher plants) are included in the dataset. Therefore, based on the deterministic approach, the AA-$QS_{fw,\ eco}$ is 2.1 / 10 = 0.21 µg/L.

The AA-$EQS_{sw,\ eco}$ is derived on the basis of the same dataset. Since there are no chronic data from specific marine taxa, an additional assessment factor of 10 is applied, resulting in a AA-$EQS_{sw,\ eco}$ of 0.021 µg/L.

3.1.2 *Probabilistic approach*

According to the WFD-guidance, statistical extrapolation using Species Sensitivity Distributions (SSD) may be performed when the database contains preferably more than 15, but at least 10 $L(E)C_{50}$-values, from different species covering at least eight taxonomic groups. For substances exerting a specific mode of action, SSDs should be constructed for the entire dataset as well as for only those taxa that are expected to be particularly sensitive.

If a subgroup of species is particularly sensitive and if there are sufficient data for this subgroup (minimum of 10 different species), a species-specific SSD may be constructed. However, this should be underpinned, if possible, by some mechanistic explanation, e.g., high sensitivity of certain species to this particular chemical.

The current chronic dataset contains 26 species. The taxa to be included are indicated below, with the representative species in the current dataset.

- Fish (species frequently tested include salmonids, minnows, bluegill sunfish, channel catfish, etc.); ➔ *Oncorhynchus mykiss*; family: Salmonidae
- A second family in the phylum Chordata (e.g. fish, amphibian, etc.); ➔ no data
- A crustacean (e.g. cladoceran, copepod, ostracod, isopod, amphipod, crayfish, etc.); ➔ *Daphnia magna*
- An insect (e.g. mayfly, dragonfly, damselfly, stonefly, caddisfly, mosquito, midge, etc.); ➔ no data
- A phylum other than Arthropoda or Chordata (e.g. Rotifera, Annelida, Mollusca, etc.); ➔ no data
- An order of insect or any phylum not already represented; ➔ no data
- Algae or Cyanobacteria; ➔ *Raphidocelis subcapitata*
- Higher plants. ➔ *Lemna gibba*

The requirements for the SSD on the entire dataset are not met, as several taxonomic groups are missing. However, as dimethenamid-P is a herbicide with a specific mode of action (see section 2.4) and considering that more than 10 chronic datapoints are available for the most sensitive type of organisms (eukaryotic primary producers: algae and macrophytes), an SSD on the entire dataset can be constructed to examine for a notable ‘break’ in sensitivity. Based on these results it may be decided to construct an SSD using only the eukaryotic primary producers.

Based on the SSD on the complete chronic dataset, a ‘break’ in sensitivity is not clearly visible (see Annex 2). However, it should be noted that the SSD includes data for 23 eukaryotic primary producers and only 1 cyanobacteria, 1 fish and 1 crustacean, which makes it difficult to determine if there is a clear distinction between these two groups. Almost all eukaryotic primary producers are more sensitive than the crustacean and fish, with the exception of two seemingly insensitive algae/higher plants species (*V. spiralis* and *A. calamus*). As a difference in sensitivity between eukaryotic primary producers and other taxonomic groups was observed based on the acute toxicity data (see section 3.2.2), the herbicidal mode of action is known, sufficient data on algae and higher plants are available, but limited data is available to compare the chronic toxicity between different eukaryotic primary producers and other taxonomic groups, a species-specific SSD using only the eukaryotic primary producers was constructed to determine the HC_5.

The chronic dataset includes, however, several censored datapoints (i.e., ‘greater than’ or ‘lower than’ values). Traditionally, such values cannot be used in an SSD. The E_TX 2.3 software mentioned in the WFD-guidance does not allow integrating censored data in fitting an SSD. However, some calculation models currently have integrated statistical methods that allow the use of censored values for fitting an SSD. The R-package E_TX 3.0, which is a follow-up of E_TX 2.3, provides functions for fitting univariate distributions to different types of data, including censored data. E_TX 3.0 handles censored data using Bayesian statistics via numerical Markov Chain Monte Carlo (MCMC) simulation (i.e., not via extrapolation constants as in E_TX 2.3). This method has recently been applied in a derivation of Dutch water quality standards for free cyanide (de Groot-Heijtel et al., 2024). The E_TX 3.0 R-package is available on request[2]. For the chronic dataset with only eukaryotic primary producers, E_TX 3.0 is used for constructing the SSD and deriving the HC_5 values.

As mentioned in section 3.1.1, SSDs were constructed including the data for macrophytes exposed to the formulated product and excluding this data. For the latter E_TX 2.3.1 was used, as the dataset does not contain censored data. The SSD constructed with E_TX 3.0 is presented in Figure 1.The HC_5 value is 1.52 µg/L (90% C.I.: 0.526-3.38 µg/L), which is below the lowest chronic value of 2.1 µg/L for *M. griffithii*. The HC_5 value excluding the plants exposed to formulated product is 1.97 µg/L (90% C.I.: 0.449-4.66 µg/L). The HC_5 values are comparable, and therefore the data with formulated product has limited impact on the HC_5. The lowest HC_5 can be used as a worst-case value for derivation of the $QS_{fw, eco}$.

[2] etx.info@rivm.nl

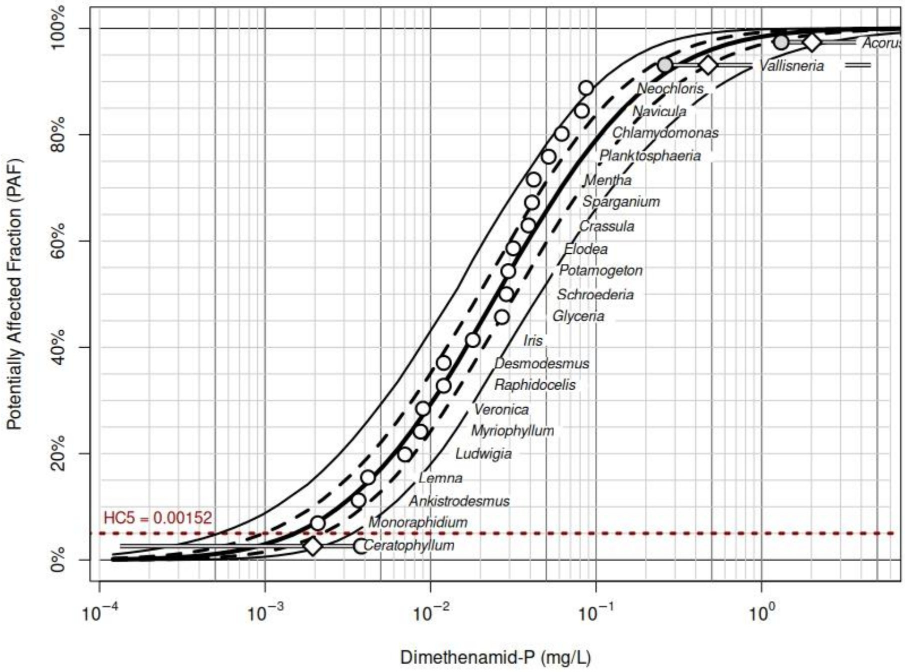


Figure 1 Species Sensitivity Distribution for dimethenamid-P based on chronic toxicity data for eukaryotic primary producers only. The X-axis represents log-transformed NOEC/EC_{10}-values in mg/L, the Y-axis represents the potentially affected fraction of species. White dot = non-censored data point. Grey dot = censored data point. White diamond = median estimate of censored data point.

For derivation of the $QS_{fw,\ eco}$ following the probabilistic approach on the chronic dataset, a default assessment factor of 5 is applied to account for residual uncertainties that are not accounted for by the SSD model. The WFD-guidance lists five topics that are relevant when considering a lower factor. When species-specific SSDs are constructed for sensitive subgroups, some of the uncertainty described in the WFD-guidance still remains, which should be addressed. Nonetheless, when using a HC_5 value derived from a species-specific SSD, lowering the assessment factor is reasonable because uncertainty about the representativeness of the tested species is reduced. In RIVM's *Additional guidance for some aspects of aquatic ERLs* (RIVM, 2025), a default assessment factor of 3 is proposed for species-specific SSDs. The reasoning behind this factor is further elaborated by Brock et al. (2011). The uncertainty topics listed in the WFD-guidance are discussed below.

Overall quality of dataset, presence of true chronic studies
The overall quality of the database and the endpoints covered are deemed to be reliable. For all data points, a reliability evaluation has been conducted either based on previous EQS derivations or directly in the current evaluation. Only studies that are considered reliable for assessment (Klimisch score 1 or 2) were considered. The impact of exclusion of the studies with formulated product was assessed to be limited. The chronic (and acute) dataset covers a wide variety of species

representing the sensitive taxonomic groups (algae and higher plants). It should be noted that there are several censored datapoints. Using *E$_T$X* 3.0, these censored values are also integrated into the SSD.

Mode of action
The mode of action of dimethenamid-P is known (see Section 2.4) and is considered to be species-specific for eukaryotic primary producers due to the herbicidal mechanism. It is unlikely that other types of aquatic species, not represented in the current dataset, will be significantly more sensitive.

Field and mesocosm studies
One microcosm study (de La Broise & Stachowski-Haberkorn, 2012) was retrieved from the literature search, but the test design was not considered reliable after evaluation. (see Annex 1 for a brief evaluation). Therefore, the assessment factor is not influenced based on these grounds.

Statistical uncertainties around HC_5 *calculation*
The current version of *E$_T$X* 3.0 does not include goodness-of-fit statistics for the Bayesian evaluation of censored datasets. However, using the censored data as such in *E$_T$X* 2.3.1 demonstrates that the goodness-of-fit tests for normality are accepted. Moreover, the narrow range of the 90% confidence interval for the calculated HC_5 (0.526-3.38 µg/L) further supports the acceptability of the fit. Consequently, it is concluded that the level of statistical uncertainty around the chronic HC_5 is minimal.

Selection of the AF

Based on the present considerations, some uncertainty concerning the derivation of the HC_5 remains, but given the overall reliability of the dataset which covers a large variety of species representing the sensitive taxonomic groups, an assessment factor of 3 is considered reasonable for the AA-EQS derivation. This is also in line with the default assessment factor for species specific SSD as proposed by RIVM's *Additional guidance for some aspects of aquatic ERLs* (RIVM, 2025). In addition, an AA-$QS_{fw, eco}$ of 0.51 µg/L (1.52/3) almost equals the lower limit value of the 90% confidence interval of the HC_5 (0.53 µg/L).

3.1.3 *Selection of the AA-EQS*
Considering that the probabilistic AA-EQS is based on a broad range of species representing the most sensitive taxonomic groups, covers the most critical chronic effect concentration and is similar to the lower limit of the confidence interval around the HC_5, it is considered sufficiently protective for freshwater ecosystems. Therefore, the probabilistic AA-EQS_{fw} of 0.51 µg/L is selected. As no additional marine taxonomic groups are available in the chronic dataset, an additional assessment factor of 10 is applied for the marine AA-EQS. Therefore, the AA-EQS_{sw} is 0.51/10 = 0.051 µg/L.

3.2 Derivation of the MAC-EQS

3.2.1 *Deterministic approach*

Valid acute ecotoxicity data are available for 29 species from five taxonomic groups: cyanobacteria, algae, macrophyta, crustaceans and Chordata (fish). A complete acute base set is available, comprising of mostly freshwater species and a few marine species (*Cyprinodon variegatus* and *Americamysis bahia*). Due to the low number of marine species compared to the freshwater species available in the dataset, no statistical analysis on the potential difference in sensitivity between freshwater and marine species is performed. For this reason, the effect values for freshwater and marine species were pooled.

For the deterministic approach, the $MAC\text{-}QS_{fw,\ eco}$ is derived from the lowest relevant available acute effect concentration, which is the 9-d E_rC_{50} of 13.5 µg/L for the macrophyte *Ceratophyllum demersum* based on growth rate. An assessment factor of 10 may be applied because the substance has a known mode of action (see Section 2.4) and representatives of the presumed most sensitive taxonomic groups (eukaryotic primary producers; algae and higher plants) are included in the dataset. The $MAC\text{-}QS_{fw,\ eco}$ is 13.5 / 10 = 1.35 µg/L.

Data for additional marine-specific taxonomic groups (e.g. echinoderms, molluscs, annelids) are not available. Therefore, the $MAC\text{-}EQS_{sw,\ eco}$ is derived applying an additional assessment factor of 10 (total AF=100) to the lowest acute effect concentration. This results in a $MAC\text{-}EQS_{sw,\ eco}$ of 0.135 µg/L.

3.2.2 *Probabilistic approach*

For derivation of the $MAC\text{-}QS_{fw,\ eco}$ by statistical extrapolation the same considerations apply as described above for the $AA\text{-}QS_{fw,\ eco}$.

The current acute dataset contains 29 species. The taxa to be included are indicated below, with the representative species in the current dataset.

- Fish (species frequently tested include salmonids, minnows, bluegill sunfish, channel catfish, etc.); ➔ *Oncorhynchus mykiss*; family: Salmonidae
- A second family in the phylum Chordata (e.g. fish, amphibian, etc.); ➔ *Lepomis macrochirus*; family Centrarchidae
- A crustacean (e.g. cladoceran, copepod, ostracod, isopod, amphipod, crayfish, etc.); ➔ *Daphnia magna*
- An insect (e.g. mayfly, dragonfly, damselfly, stonefly, caddisfly, mosquito, midge, etc.); ➔ <u>no data</u>
- A family in a phylum other than Arthropoda or Chordata (e.g. Rotifera, Annelida, Mollusca, etc.); ➔ *Anabeana flos-aquae*
- A family in any order of insect or any phylum not already represented; ➔ <u>no data</u>
- Algae; ➔ *Raphidocelis subcapitata*
- Higher plants. ➔ *Lemna gibba*

The requirements for the SSD on the entire dataset are not met, as several taxonomic groups are missing. However, as for the chronic toxicity data two SSD are constructed; the first based on the complete dataset and the second based on the most sensitive species based on the mode of action (algae and macrophytes).

As a clear difference in sensitivity was observed between the eukaryotic primary producers and the higher trophic levels (see Annex 2), the final acute HC_5 value is derived from the SSD based on only the eukaryotic primary producers (algae and higher plants) and including censored data. E_TX 3.0 was also used for the derivation of the acute SSD. The SSD plot is presented in Figure 2. The HC_5 value is 12.8 µg/L (90% C.I.: 4.92 – 25.7 µg/L), which is close to the lowest E_rC_{50} value for *C. demersum.* Also an SSD was constructed excluding the data with formulated product. Based on this dataset the HC_5 value is 8.53 µg/L (90% C.I.: 1.41 – 26.4 µg/L), which is lower than the HC_5 value based on the complete dataset with eukaryotic primary producers, but also has a larger confidence interval. To be protective, preference is given to the lowest HC_5 for derivation of the $QS_{fw,\ eco}$.

For the selection of assessment factors for species-specific SSDs, the RIVM drafted additional guidance next to the WFD-guidance on EQS derivation (RIVM, 2025), as explained in Section 3.1.2. Where the default assessment factor on the chronic HC_5 may be lowered from 5 to 3, the default assessment factor on the acute HC_5 may be lowered from 10 to 6. Similar to the chronic assessment factor, when sufficient acute effect concentrations are available for the most sensitive subgroup, the remaining uncertainty on potentially sensitive species is sufficiently addressed. In essence, the ratio between the AFs for AA- and MAC-QS is maintained (i.e. a factor of 2). Therefore, the current dataset allows the use of an assessment factor of 6 on the acute HC_5, which results in a MAC-$QS_{fw,\ eco}$ of 1.42 µg/L (rounded to 1.4 µg/L).

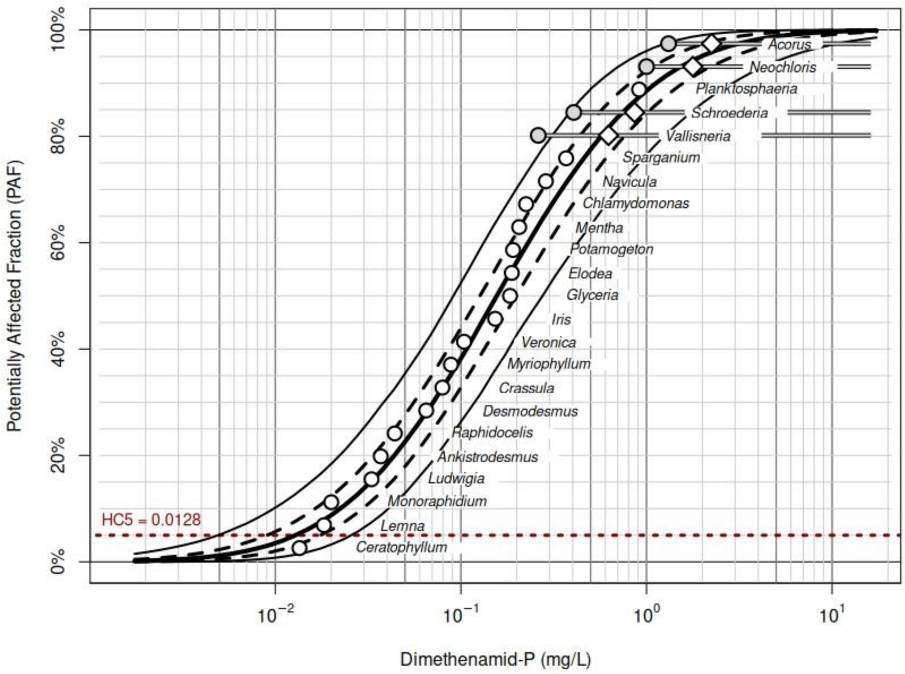


Figure 2. Species Sensitivity Distribution for dimethenamid-P based on acute toxicity data for eukaryotic primary producers only. The X-axis represents log-transformed L(E)C_{50}-values in mg/L, the Y-axis represents the potentially affected fraction of species. White dot = non-censored data point. Grey dot = censored data point. White diamond = median estimate of censored data point.

3.2.3 *Selection of the MAC-EQS*

The probabilistic MAC-$QS_{fw, eco}$ of 1.42 µg/L is slightly higher than the deterministic MAC-$QS_{fw, eco}$ of 1.35 µg/L, but still below the critical acute effect value of 13.5 µg/L. Considering the probabilistic MAC-QS is based on a broad range of species representing the most sensitive taxonomic groups, covers the most critical chronic effect concentration and is close to the lower limit of the confidence interval of the HC_5, it is considered sufficiently protective for freshwater ecosystems. Therefore, the probabilistic MAC-$QS_{fw,eco}$ of 1.4 µg/L is selected as MAC-$EQS_{fw, eco}$. The MAC-$EQS_{sw, eco}$ is derived using the default additional assessment factor of 10 and amounts to 0.14 µg/L.

3.3 Alternative SSDs

E_TX 3.0 was used to construct SSDs using data for eukaryotic primary producers and to include censored data to calculate a HC_5. For comparison, *E_TX* 3.0 was also run using all data. Also *E_TX* 2.3.1 was run by either leaving out censored data (>-values), or including them as if they were the actual results, for all data and for only eukaryotic primary producers. In the end, eight different acute and chronic HC_5 values were derived based on the various subsets of data (see Table 7). Given the remaining uncertainty regarding the plant studies, the lowest HC_5 values

derived using *E_TX* 3.0 were selected for EQS-derivation as a conservative approach (acute HC_5 = 8.53 μg L^{-1}; chronic HC_5 = 1.52 μg L^{-1}).

Table 7 HC_5 outcomes for the different SSD approaches. In bold the values used for QS-derivation.

Software	Trophic levels	Formulation	Censored data	Acute HC_5 (μg/L)	Chronic HC_5 (μg/L)
E_TX 2.3.1	all	incl.	incl.*	11.5 (3.83-25.9)	2.03 (0.724-4.27)
E_TX 2.3.1	all	incl.	excl.	8.45 (2.35-21.1)	2.44 (0.915-4.87)
E_TX 2.3.1	all	excl.	excl.	8.77 (1.08-33.5)	1.74 (0.33-5.01)
E_TX 2.3.1	eukaryotic primary producers	incl.	incl.*	16.0 (6.87-28.8)	2.07 (0.781-4.11)
E_TX 2.3.1	eukaryotic primary producers	excl.	incl.*	11.2 (2.22-28.7)	1.97$ (0.449-4.66)
E_TX 3.0	eukaryotic primary producers	excl.	incl.	**8.53** (1.41-26.4)	calculated with *E_TX* 2.3.1
E_TX 3.0	eukaryotic primary producers	incl.	incl.	12.8 (4.92-25.7)	**1.52** (0.526-3.38)
E_TX 3.0	all	incl.	incl.	15.8 (3.32-25.3)	1.52 (0.499-3.60)

*included as actual values

$ no censored data available

4 Discussion and conclusions

In this report, RIVM conducted a revision of the water quality standards for dimethenamid-P according to the methodology of the European Water Framework Directive. As expected for this herbicide, green algae and macrophytes are most sensitive.

Based on additional ecotoxicological information in the RAR by EFSA and with the support of previous derivations by other institutes, RIVM proposes a new AA-EQS_{fw} of 0.51 µg/L and MAC-EQS_{fw} of 1.4 µg/L in the current evaluation. Both values are based on species-specific SSDs that integrate censored data (probabilistic approach).

Below, on overview is provided to demonstrate how these values compare to proposed values by others as well as the current EQS values for the Netherlands (Table 8). The proposed values in the current study are higher than the values derived by the Swiss Oekotoxzentrum and German UBA, which used a deterministic approach. The difference between the values proposed in this study and those of the applicant are mainly explained by the difference in assessment factors applied (see Table 8). The applicant proposed an AA-EQS of 2.73 µg/L based on an SSD on the chronic dataset for eukaryotic primary producers and an assessment factor of 1. Similarly, the applicant proposed an SSD-based MAC-EQS of 4.57 µg/L after applying an assessment factor of 1. An assessment factor of 1 for the derivation of the MAC-EQS is not appropriate, since this ignores the fact that the MAC-EQS is based on 50%-effect values, while it should protect from any effects. An assessment factor of 1 also implies that all residual uncertainty is covered, which is not the case. In general, an AF of 1 will only be applied when there is evidence that a higher AF will lead to quality standards that are biologically inappropriate, e.g., causing deficiency in the case of some metals.

Table 8 (Proposed) AA-EQS-values by RIVM and other institutes in comparison to the current Dutch EQS for dimethenamid-P

		Freshwater				Saltwater			
Institute/country	Approach to derive EQS	AF	$AA\text{-}EQS_{fw}$ (µg/L)	AF	$MAC\text{-}EQS_{fw}$ (µg/L)	AF	$AA\text{-}EQS_{sw}$ (µg/L)	AF	$MAC\text{-}EQS_{sw}$ (µg/L)
RIVM, NL (2025)	**probabilistic**	**3**	**0.51**	**6**	**1.4**	**30**	**0.051**	**60**	**0.14**
RIVM, NL (2008)	deterministic	10	0.13	10	1.6				
UBA, DE (2025)	deterministic	10	0.26	10	2.5	100	0.026	50	0.5
Oekotoxzentrum, CH (2019)	deterministic	10	0.26	10	2.5				
INERIS, FR (2011)	deterministic	10	0.2	10	1.3	100	0.02	100	0.13
BASF, applicant (2025)	probabilistic	1	2.73	1	4.57				

5 Status of this advice/disclaimer

This advisory report was prepared in the context of an assignment by the Dutch board for the authorisation of plant protection products and biocides (Ctgb). The report was reviewed according to internal quality procedures of RIVM and by members of the Scientific advisory group for standard setting in air and water of the Dutch Ministry of Infrastructure and Water management (*Wetenschappelijke Klankbordgroep normstelling water en lucht*). It is issued to Ctgb, which has a mandate to officially set water quality standards.

It is noted that legal standards for dimethenamid-P are set under the Dutch Environment and Planning Act (Besluit kwaliteit leefomgeving). EQS set by Ctgb will be included in the Bkl upon revision of the legal act.

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[redacted]

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Annex 1. Aquatic ecotoxicity data

Legend to column headings	
A	test water analysed Y(es)/N(o)
Test type	S = static; Sc = static closed; R = renewal; F = flow through; CF = continuous flow; IF = intermittent flow system
Test compound	ag = analytical grade; tg = technical grade; form = formulated product
Purity	refers to purity of active substance or content of active substance in formulation
Test water	am = artificial medium; dtw = dechlorinated tap water; dw = deionised/dechlorinated/distilled water; nw = natural water; rw = reconstituted water; rtw = reconstituted tap water; tw = tap water
T	temperature
Ri	reliability index according to Klimisch et al. (1997)
Ref.	reference
In SSD dataset	Effect concentration used in the SSDs: Y(es)/N(o)

Acute toxicity data

Table A1.1 Acute toxicity data of Dimethenamid-P for freshwater and marine organisms. Selected values for the deterministic approach are given on a grey background (see section 1.4.3 for information on criteria). The effect concentrations used in the SSDs are indicated in the 'In SSD dataset-column.

Species	**Species properties**	**A**	**Test type**	**Test comp.**	**Purity [%]**	**pH**	**T [°C]**	**Exp. time**	**Criterion**	**Test endpoint**	**Value [mg/L]**	**Ri**	**In SSD dataset**	**Ref.**	**Notes**
Oncorhynchus mykiss	juveniles	Y	F	dimethenamid-P	91.1	8.2-8.3	12±1	96 h	LC50	mortality	6.3	1	Y (geomean 4.05 mg/L)	EFSA RAR 2018	
Oncorhynchus mykiss	juveniles	Y	F	racemate	91.4	7.2-7.6	12-13	96 h	LC50	mortality	2.6	2	Y (geomean 4.05 mg/L)	EFSA RAR 2018	1
Cyprinodon variegatus	juveniles, marine species	Y	F	dimethenamid-P	91.1	8.3-8.4	22.1-22.9	96 h	LC50	mortality	12	1	Y	EFSA RAR 2018	

Species	Species properties	A	Test type	Test comp.	Purity [%]	pH	T [°C]	Exp. time	Criterion	Test endpoint	Value [mg/L]	Ri	In SSD dataset	Ref.	Notes
Lepomis macrochirus	juveniles	Y	F	dimethenamid-P	91.1	8.2-8.4	22±1	96 h	LC50	mortality	10	1	Y (geomean 8.0 mg/L)	EFSA RAR 2018	2
Lepomis macrochirus	juveniles	Y	F	racemate	91.4	7.27.6	22±1	96 h	LC50	mortality	6.4	1	Y (geomean 8.0 mg/L)	EFSA RAR 2018	
Daphnia magna	<24h d old	Y	F	racemate	91.1	8.1-8.3	20±1	48 h	EC50	immobility	12	1	Y (geomean 13.9 mg/L)	EFSA RAR 2018	
Daphnia magna	<24h d old	Y	F	racemate	91.4	7.8-8.4	20±1	48 h	EC50	immobility	16	1	Y (geomean 13.9 mg/L)	EFSA RAR 2018	
Americamysis bahia	<24h d old	Y	F	dimethenamid-P	96.3	8.3	24.8-25.0	96 h	LC50	mortality	3.2	1	Y	EFSA RAR 2018	
Raphidocelis subcapitata	initial 1E+04 cells/mL	Y	S	dimethenamid-P	95.9	7.8-8.1	22±1	72 h	EC50	growth rate	0.0663	1	Y (geomean 0.044 mg/L)	EFSA RAR 2018	
Raphidocelis subcapitata	initial 1E+04 cells/mL	N	S	dimethenamid-P	91.1	7.7-10	25	72 h	EC50	growth rate	0.0303	1	Y (geomean 0.044 mg/L)	EFSA RAR 2018	
Anabaena flos-aquae	initial 1E+04 cells/mL	N	S	dimethenamid-P	96.0	7.5-8.2	24±1	72 h	EC50	growth rate	1.478	1	Y	-	3
Anabaena flos-aquae	initial 0.3E+04 cells/mL	Y	S	dimethenamid-P	91.1	7.3-8.9	25	72 h	EC50	growth rate	1.34	3	N	EFSA RAR 2018	4, 5
Desmodesmus subspicatus	initial 1E+04 cells/mL	N	S	dimethenamid-P	96,0	7.7-8.1	22±1	72 h	EC50	growth rate	0.065	1	Y	-	3
Desmodesmus subspicatus	initial 1E+04 cells/mL	Y	S	dimethenamid-P	95.9	7.6-8.1	22±1	72 h	EC50	growth rate	>0.509	1	N	EFSA RAR 2018	
Ankistrodesmus bibraianus	initial 1E+04 cells/mL	Y	S	dimethenamid-P	95.9	7.6-8.1	22±1	72 h	EC50	growth rate	0.037	1	Y	EFSA RAR 2018	
Chlamydomonas reinhardtii	initial 1E+04 cells/mL	N	S	dimethenamid-P	95.9	7.1-8.1	22±1	72 h	EC50	growth rate	0.2245	1	Y	EFSA RAR 2018	
Dictyococcus varians	initial 1E+04 cells/mL	N	S	dimethenamid-P	95.9	7.8-8.1	22±1	72 h	EC50	growth rate	>0.1	3	N	EFSA RAR 2018	5

Species	Species properties	A	Test type	Test comp.	Purity [%]	pH	T [°C]	Exp. time	Criterion	Test endpoint	Value [mg/L]	Ri	In SSD dataset	Ref.	Notes
Monoraphidium griffithii	initial 1E+04 cells/mL	Y	S	dimethenamid-P	95.9	7.8-8.2	22±1	72 h	EC50	growth rate	0.020025	1	Y	EFSA RAR 2018	6
Navicula pelliculosa	initial 1E+04 cells/mL	Y	S	dimethenamid-P	91.1	7.2-8.5	25	72 h	EC50	growth rate	0.287	1	Y	EFSA RAR 2018	
Neochloris aquatica	initial 1E+04 cells/mL	N	S	dimethenamid-P	95.9	7.9-8.1	22±1	72 h	EC50	growth rate	>1.0	1	Y	EFSA RAR 2018	7
Pandorina morum	initial 1E+04 cells/mL	N	S	dimethenamid-P	95.9	7.3-8.1	22±1	72 h	EC50	growth rate	0.924	3	N	EFSA RAR 2018	5
Planktosphaeria botryoides	initial 1E+04 cells/mL	Y	S	dimethenamid-P	95.9	7.4-8.1	22±1	72 h	EC50	growth rate	0.912	1	Y	EFSA RAR 2018	
Schroederia setigera	3E+03 cells/mL initial	Y	S	dimethenamid-P	95.9	7.8-8.1	22±1	72 h	EC50	growth rate	>0.4055	1	Y	EFSA RAR 2018	
Staurastrum punctulatum	initial 1E+04 cells/mL	N	S	dimethenamid-P	95.9	7.8-8.1	22±1	72 h	EC50	growth rate	>1.0	3	N	EFSA RAR 2018	5
Skeletonema costatum	initial 1E+04 cells/mL	Y	S	dimethenamid-P	91.1	8.1-9.0	20±1	72 h	EC50	growth rate	0.309	3	N	EFSA RAR 2018	5
Lemna gibba	7 to 10 days old	Y	S	dimethenamid-P	95.9	7.5-8.8	24.8-24.9	7 d	EC50	growth rate	0.0434	1	N	EFSA RAR 2018	8
Lemna gibba	7 to 10 days old	Y	R	dimethenamid-P	91.1	4.9-6.6	24-25	9 d	EC50	growth rate	0.01829	2	Y	EFSA RAR 2018	9
Glyceria maxima		N	S	dimethenamid-P	95.9	7.6-8.8	20.3-20.7	14 d	EC50	growth rate	0.184	1	Y	EFSA RAR 2018	
Acorus calamus		Y	S	form.	711.4 g/L	7.9-10.1	19.6-25.2	13 d	EC50	growth rate	>1.314	2	Y	EFSA RAR 2018	10
Iris pseudacorus		Y	S	form.	711.4 g/L	7.9-10.1	19.6-25.2	13 d	EC50	growth rate	0.153	2	Y	EFSA RAR 2018	10
Ludwigia palustris		Y	S	form.	711.4 g/L	7.9-10.1	19.6-25.2	13 d	EC50	growth rate	0.033	2	Y	EFSA RAR 2018	10

Species	Species properties	A	Test type	Test comp.	Purity [%]	pH	T [°C]	Exp. time	Criterion	Test endpoint	Value [mg/L]	Ri	In SSD dataset	Ref.	Notes
Mentha aquatica		Y	S	form.	711.4 g/L	7.9-10.1	19.6-25.2	13 d	EC50	growth rate	0.206	2	Y	EFSA RAR 2018	10
Sparganium erectum		Y	S	form.	711.4 g/L	7.9-10.1	19.6-25.2	13 d	EC50	growth rate	0.369	2	Y	EFSA RAR 2018	10
Veronica beccabunga		Y	S	form.	711.4 g/L	7.9-10.1	19.6-25.2	13 d	EC50	growth rate	0.104	2	Y	EFSA RAR 2018	10
Ceratophyllum demersum		Y	S	form.	711.4 g/L	7.3-11.0	19.8-24.0	9 d	EC50	growth rate	0.0135	2	Y	EFSA RAR 2018	10
Crassula recurva		Y	S	form.	711.4 g/L	7.3-11.0	19.8-24.0	12 d	EC50	growth rate	0.0795	2	Y	EFSA RAR 2018	10
Elodea densa		Y	S	form.	711.4 g/L	7.3-11.0	19.8-24.0	12 d	EC50	growth rate	0.188	2	Y	EFSA RAR 2018	10
Myriophyllum spicatum		Y	S	form.	711.4 g/L	7.3-11.0	19.8-24.0	9 d	EC50	growth rate	0.0884	2	Y	EFSA RAR 2018	10
Potamogeton crispus		Y	S	form.	711.4 g/L	7.3-11.0	19.8-24.0	9 d	EC50	growth rate	0.191	2	Y	EFSA RAR 2018	10
Vallisneria spiralis		Y	S	form.	711.4 g/L	7.3-11.0	19.8-24.0	12 d	EC50	growth rate	>0.261	2	Y	EFSA RAR 2018	10

Notes

1. The RAR reports a test temperature of 22 °C, which is considered too high for the tested species (*O. mykiss*) according to OECD 203. The applicant has pointed out that the test temperature is incorrectly reported and that it should be 12-13 °C. Based on the information provided in the comment and as the study is considered acceptable in the RAR, it is expected that the test temperature reported in the RAR is indeed incorrect.

2. The applicant reports an LC_{50} of 10.4 mg/L. However, the executive summary in the RAR and the list of endpoints report an LC_{50} of 10.0 mg/L. As the applicant did not provide a reason for this inconsistency, the value of 10 mg/L was used in the current evaluation.

3. This study was submitted after publication in the RAR and therefore not included in the RAR document.

4. The applicant reports an ErC_{50} of >0.84 mg/L. However, the executive summary in the RAR and the list of endpoints report an ErC_{50} of 1.34 mg/L. Since the study report was not available, the value could not be checked.

5. Section-by-section specific growth rates for *Dictyococcus varians* and *Pandorina morum* did not meet the OECD 201 validity criteria limits and exponential growth was not maintained. Therefore, these studies were considered not acceptable and scored Ri3. In line with current WFD technical guidance, these data were excluded from EQS derivation. The derived EQS remains protective for these species.

6. The applicant reports an ErC_{50} of 0.0195 mg/L based on mean measured concentrations. However, the executive summary in the RAR and the list of endpoints report a nominal ErC_{50} of 0.025 mg/L. As the measured data are not provided, this value could not be checked. However, the summary does provide a mean recovery of 80.1% of the nominal test concentrations. This recovery was used for the recalculation from nominal into mean measured concentrations, which gives a ErC_{50} of 0.025*0.801=0.0200 mg/L, which corresponds with the value of the applicant. This value is used in the current evaluation.

7. The applicant reports an ErC_{50} of >0.1 mg/L. However, the executive summary in the RAR and the list of endpoints report an ErC_{50} of 1.0 mg/L. Since the study report was not available, the value could not be checked.

8. This effect concentration was not included in the SSD since a more conservative value for this species is available, and since both effect concentrations are based on different endpoints, calculating a geometric mean value is considered inappropriate.

9. The exposure duration in this study was 14 days, and effect concentrations were reported at 3, 6, 9, 12, and 14 days. According to the WFD guidance, effect concentrations at 7 days are preferred for *L. gibba* (in line with OECD Test Guideline 221). In the absence of effect concentrations at 7 days, the first available effect concentrations for longer exposure periods were used. A 6-day effect concentration may underestimate the toxicity. Therefore, the 9-day effect concentrations were used. This approach is in line with the UBA and Oekotoxzentrum derivations.

10. This study was not considered acceptable (Ri3) in the evaluation of UBA and Oekotoxzentrum because the plants were exposed to a formulation containing the active substance. However, as this is the only ecotoxicological information of dimethenamid for this species, it was considered, which is also in line with the WFD-guidance.

Chronic toxicity data

Table A1.2 Chronic toxicity data of Dimethenamid-P for freshwater and marine organisms. Selected values for the deterministic approach are given on a grey background (see section 1.4.3 for information on criteria). The effect concentrations used in the SSDs are indicated in the 'In SSD dataset-column.

Species	**Species properties**	**A**	**Test type**	**Test comp.**	**Purity [%]**	**pH**	**T [°C]**	**Exp. time**	**Criterion**	**Test endpoint**	**Value [mg/L]**	**Ri**	**In SSD dataset**	**Ref.**	**Notes**
Oncorhynchus mykiss		Y	F	racemate	-	-	15±2	21 d	NOEC	mortality	2.19	2	N	EFSA RAR 2018	1,2
Oncorhynchus mykiss		Y	F	racemate	97	8.2-8.3	12±1	90 d	EC10	larval growth (FELS)	0.44	1	Y	EFSA RAR 2018	
Daphnia magna	<24h old	Y	F	racemate	97	7.6-7.9	20±1	21 d	NOEC	reproduction	1.36	1	N	EFSA RAR 2018	3
Daphnia magna	<24h old	Y	S	racemate	92.7	7.5-7.8	19.6-21.1	21 d	EC10	reproduction	0.94	1	Y	EFSA RAR 2018	
Raphidocelis subcapitata	1.0E+04 cells/mL	Y	S	Dimethenamid-P	95.9	7.8-8.1	22±1	72 h	EC10	growth rate	0.00941	1	Y (geomean 0.012 mg/L)	EFSA RAR 2018	
Raphidocelis subcapitata	1.0E+04 cells/mL	Y	S	Dimethenamid-P	91.1	7.7-10	25	72 h	EC10	growth rate	0.0156	1	Y (geomean 0.012 mg/L)	EFSA RAR 2018	
Anabaena flos-aquae	1.0E+04 cells/mL	N	S	Dimethenamid-P	96.0	7.5-8.2	24±1	72 h	EC10	growth rate	0.21	1	Y	EFSA RAR 2018	4
Anabaena flos-aquae	0.3E+04 cells/mL	Y	S	Dimethenamid-P	91.1	7.3-8.9	25	72 h	EC10	growth rate	0.073	3	N	EFSA RAR 2018	5

Species	Species properties	A	Test type	Test comp.	Purity [%]	pH	T [°C]	Exp. time	Criterion	Test endpoint	Value [mg/L]	Ri	In SSD dataset	Ref.	Notes
Desmodesmus subspicatus	1.0E+04 cells/mL	N	S	Dimethenamid-P	96.0	7.7-8.1	22±1	72 h	EC10	growth rate	0.015	1	Y (geomean 0.012 mg/L)	EFSA RAR 2018	4
Desmodesmus subspicatus	1.0E+04 cells/mL	Y	S	Dimethenamid-P	95.9	7.6-8.1	22±1	72 h	EC10	growth rate	0.0093	1	Y (geomean 0.012 mg/L)	EFSA RAR 2018	
Ankistrodesmus bibraianus	1.0E+04 cells/mL	Y	S	Dimethenamid-P	95.9	7.6-8.1	22±1	72 h	EC10	growth rate	0.00367	1	Y	EFSA RAR 2018	
Chlamydomonas reinhardtii	1.0E+04 cells/mL	N	S	Dimethenamid-P	95.9	7.1-8.1	22±1	72 h	EC10	growth rate	0.062	1	Y	EFSA RAR 2018	
Dictyococcus varians	1.0E+04 cells/mL	N	S	Dimethenamid-P	95.9	7.8-8.1	22±1	72 h	EC10	growth rate	0.0049	3	N	EFSA RAR 2018	5
Monoraphidium griffithii	1.0E+04 cells/mL	Y	S	Dimethenamid-P	95.9	7.8-8.2	22±1	72 h	EC10	growth rate	0.0021	1	Y	EFSA RAR 2018	6
Navicula pelliculosa	1.0E+04 cells/mL	Y	S	Dimethenamid-P	91.1	7.2-8.5	25	72 h	EC10	growth rate	0.082	1	Y	EFSA RAR 2018	
Neochloris aquatica	1.0E+04 cells/mL	N	S	Dimethenamid-P	95.9	7.9-8.1	22±1	72 h	EC10	growth rate	0.0871	1	Y	EFSA RAR 2018	
Pandorina morum	1.0E+04 cells/mL	N	S	Dimethenamid-P	95.9	7.3-8.1	22±1	72 h	EC10	growth rate	0.0329	3	N	EFSA RAR 2018	5
Planktosphaeria botryoides	1.0E+04 cells/mL	N	S	Dimethenamid-P	95.9	7.4-8.1	22±1	72 h	EC10	growth rate	0.0517	1	Y	EFSA RAR 2018	
Schroederia setigera	3E+03 cells/mL initial	Y	S	Dimethenamid-P	95.9	7.8-8.1	22±1	72 h	EC10	growth rate	0.0287	1	Y	EFSA RAR 2018	
Staurastrum punctulatum	1.0E+04 cells/mL	N	S	Dimethenamid-P	95.9	7.8-8.1	22±1	72 h	EC10	growth rate	0.0227	3	N	EFSA RAR 2018	5
Skeletonema costatum	1.0E+04 cells/mL	Y	S	Dimethenamid-P	91.1	8.1-9.0	20±1	72 h	EC10	growth rate	0.06	3	N	EFSA RAR 2018	5
Lemna gibba	7 to 10 days old	Y	S	Dimethenamid-P	95.9	7.5-8.8	24.8-24.9	7 d	EC10	growth rate	0.005	1	N	EFSA RAR 2018	7
Lemna gibba	7 to 10 days old	Y	S	Dimethenamid-P	91.1	4.9-6.6	24-25	14 d	EC10	growth rate	0.0042 (9d EC10)	2	Y	EFSA RAR 2018	8

Species	Species properties	A	Test type	Test comp.	Purity [%]	pH	T [°C]	Exp. time	Criterion	Test endpoint	Value [mg/L]	Ri	In SSD dataset	Ref.	Notes
Glyceria maxima		N	S	Dimethenamid-P	95.9±1	7.6-8.8	20.3-20.7	14 d	EC10	growth rate	0.027	2	Y	EFSA RAR 2018	9
Acorus calamus		Y	S	form.	711.4 g/L	7.9-10.1	19.6-25.2	13 d	NOEC	growth rate	≥1.314	2	Y	EFSA RAR 2018	10
Iris pseudacorus		Y	S	form.	711.4 g/L	7.9-10.1	19.6-25.2	13 d	NOEC	growth rate	0.018	2	Y	EFSA RAR 2018	10
Ludwigia palustris		Y	S	form.	711.4 g/L	7.9-10.1	19.6-25.2	13 d	NOEC	growth rate	0.007	2	Y	EFSA RAR 2018	10
Mentha aquatica		Y	S	form.	711.4 g/L	7.9-10.1	19.6-25.2	13 d	NOEC	growth rate	0.042	2	Y	EFSA RAR 2018	10, 11
Sparganium erectum		Y	S	form.	711.4 g/L	7.9-10.1	19.6-25.2	13 d	NOEC	growth rate	0.041	2	Y	EFSA RAR 2018	10
Veronica beccabunga		Y	S	form.	711.4 g/L	7.9-10.1	19.6-25.2	13 d	NOEC	growth rate	0.009	2	Y	EFSA RAR 2018	10
Ceratophyllum demersum		Y	S	form.	711.4 g/L	7.3-11.0	19.8-24.0	9 d	NOEC	growth rate	<0.00381	2	Y	EFSA RAR 2018	10, 12
Crassula recurva		N	S	form.	711.4 g/L	7.3-11.0	19.8-24.0	12 d	NOEC	growth rate	0.039	2	Y	EFSA RAR 2018	10, 13
Elodea densa		Y	S	form.	711.4 g/L	7.3-11.0	19.8-24.0	12 d	NOEC	growth rate	0.0316	2	Y	EFSA RAR 2018	10
Myriophyllum spicatum		Y	S	form.	711.4 g/L	7.3-11.0	19.8-24.0	9 d	NOEC	growth rate	0.0087	2	Y	EFSA RAR 2018	10, 14
Potamogeton crispus		Y	S	form.	711.4 g/L	7.3-11.0	19.8-24.0	9 d	NOEC	growth rate	0.0295	2	Y	EFSA RAR 2018	10
Vallisneria spiralis		Y	S	form.	711.4 g/L	7.3-11.0	19.8-24.0	12 d	NOEC	growth rate	≥0.261	2	Y	EFSA RAR 2018	10

Notes

1. The applicant reports a NOEC of 0.63 mg/L. However, the effects described were considered very marginal. After re-evaluation, a NOEC of 2.19 mg/L (mean measured concentration) was selected.

2. This effect concentration was not included in the SSD since a more conservative value for this species is available and since both effect concentrations are based on different endpoints, calculating a geometric mean value is considered inappropriate. The study was scored Ri2 because details on the purity of the substance and the pH during exposure are not reported.

3. This effect concentration was not included in the SSD since a more conservative value for this species is available and since these effect concentrations are based on different criteria (EC10 vs NOEC) calculating a geometric mean value is considered inappropriate.

4. This study was submitted after publication in the RAR and therefore not included in the RAR document.

5. The study was considered not acceptable as the OECD TG 201 validity criteria were not met. Therefore, this study was scored Ri3.

6. The applicant reports an E_rC_{10} of 0.002145 mg/L based on mean measured concentrations. However, the executive summary in the RAR and the list of endpoints report a nominal E_rC_{10} of 0.0026 mg/L. As the measured data are not provided, this could not be checked. However, the summary does provide a mean recovery of 80.1% of the nominal test concentrations. This recovery was used for the recalculation from nominal into mean measured concentrations, which gives a ErC_{10} of 0.0026*0.801=0.0021 mg/L, which corresponds with the value of the applicant. This value is used in the current evaluation.

7. This effect concentration was not included in the SSD since a more conservative value for this species is available, and since both effect concentrations are based on different endpoints, calculating a geometric mean value is considered inappropriate.

8. The exposure duration of this study was 14 days and effect concentrations at 3, 6, 9, 12 and 14 days were reported. In accordance with the WFD-guidance, effect concentrations at 7 days are preferred for *L. gibba* (in line with OECD TG 221). The 9-d effect concentration is used in this dataset.

9. It is noted that no E_rC_{10} value is reported in the RAR. However, the applicant reports an EC_{10} of 0.027 mg/L. The information provided in the RAR does allow for derivation of an E_rC_{10}. The data was plotted in GraphPad Prism 10.2.2 and a E_rC_{10} very close to 0.027 mg/L was derived (0.025 mg/L). Therefore, the value of 0.027 was used.

10. This study was not considered acceptable (Ri3) in the evaluation of UBA and Oekotoxzentrum because the plants were exposed to a formulation containing the active substance. However, as this is the only ecotoxicological information of dimethenamid for this species, it was considered, which is also in line with the WFD-guidance.

11. The applicant reports a NOEC of 0.09 mg/L. However, the executive summary in the RAR reports a NOEC 0.042 mg/L, which was considered correct and is used in the current evaluation.

12. The applicant reports a NOEC of 0.00161 mg/L. However, this could not be traced back in the executive summary in the RAR, which reports a NOEC of <0.00381 mg/L. At this measured concentration, 27.1% inhibition of shoot length was observed compared to the control group. Lower nominal test concentrations, which showed no effect, could not be analytically verified (<LOQ). Therefore, the value of <0.00381 mg/L was used for the current evaluation.

13. The applicant reports a NOEC of 0.0405 mg/L. However, the executive summary in the RAR reports a NOEC 0.039 mg/L, which was considered correct and is used in the current evaluation.

14. The applicant reports a NOEC of 0.093 mg/L. However, the executive summary in the RAR reports a NOEC 0.0087 mg/L, which was considered correct and is used in the current evaluation.

Other data

The literature search retrieved two potentially relevant studies. As the results of both studies were considered not relevant/reliable, the results are not given in the tables above and thus also not incorporated into the present derivation. Below the relevance and reliability assessment of these two studies is described briefly.

- Padilla et al. (2012): Dimethenamid was one of the substances tested in a zebrafish developmental screening study by Padilla et al. (2012). This study was considered not reliable for the evaluation. Based on the hatching success and the mortality, an AC50 was calculated. This criterion cannot directly be related to an LC50 and could therefore not be used in the current evaluation. In addition, several important methodological aspects are not reported (e.g. no information on the purity of the test substance, no information on pH or dissolved oxygen, no information on the performance of the controls groups or fertilization rate of the embryo batch(es) used in the study) (Padilla et al., 2012).

- De la Broise & Stachowski-Haberkorn (2012): The phytoplankton community sensitivity to dimethenamid (in formulation) was tested in a marine microcosm study. Researchers tested three specific concentrations of the formulation (1, 10, and 100 µg a.s./L) in 20 small, closed water systems (2-liter glass bottles; without sediment). The actual concentrations in the water were measured after 5 and 12 days to confirm the concentrations. Over time, the concentration in the water steadily decreased, dropping to between 20% and 60% of the initial levels by the 12th day.

Chlorophyll a levels significantly increased at all tested concentrations, resulting in a NOEC below 1 µg a.s./L (nominal). Based on the test design of this study, it was considered not reliable for the current evaluation, as also evaluated in the RAR. Limitations include no measurements of the initial concentrations in the bottles and therefore no estimation of exposure concentrations during the test was possible, no environmental conditions reported during the test and no validated test method was followed (non-GLP) (de La Broise & Stachowski-Haberkorn, 2012).

Annex 2. SSDs on the entire dataset

SSDs on the entire datasets were constructed to examine if a notable ‘break’ in sensitivity is present. For visual inspection, the output of ETX 2.3.1 was used as graphic distinction between taxonomic groups can be made. The daphnids and fish species are indicated as orange and blue squares, respectively. The algae and higher plants are indicated in light green and dark green, respectively.

Acute SSD on the entire dataset

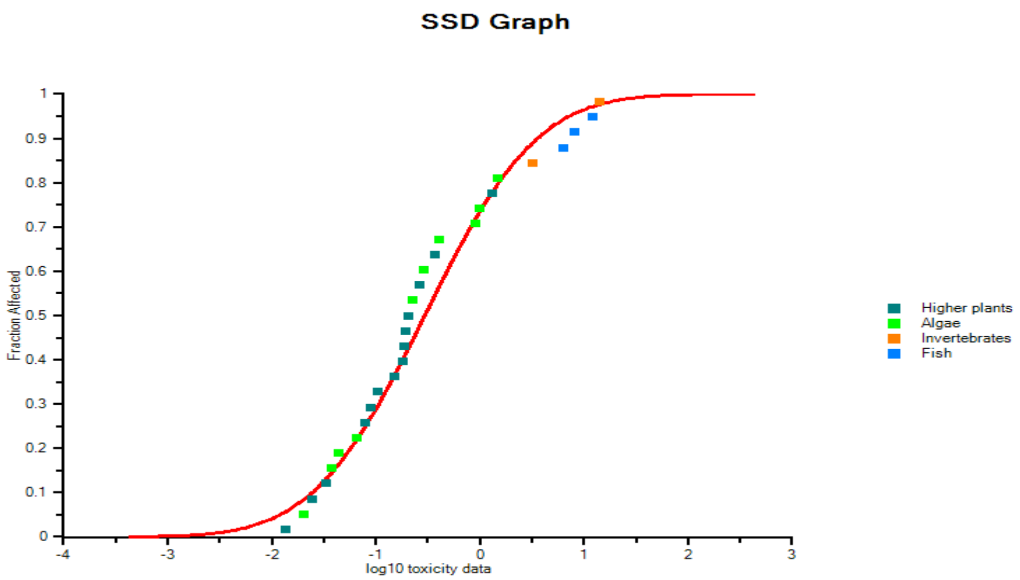

Figure A2.1 Species Sensitivity Distribution for dimethenamid-P based on acute toxicity data for all species, including censored data as actual values in E_TX 2.3.1. The X-axis represents log-transformed $L(E)C_{50}$-values in mg/L, the Y-axis represents the fraction of potentially affected fraction of species.

Chronic SSD on the entire dataset

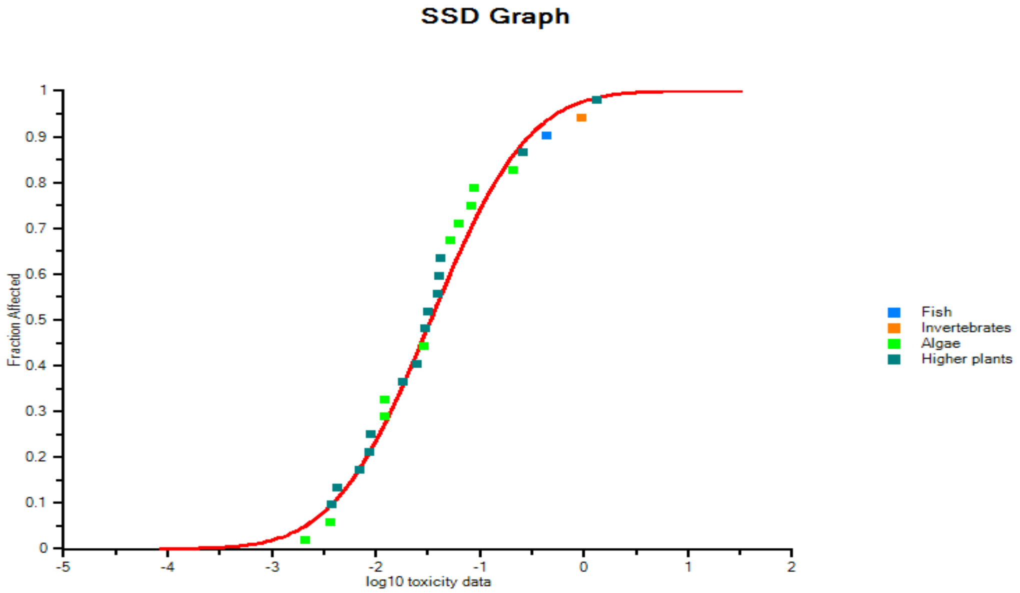

Figure A2.2 Species Sensitivity Distribution for dimethenamid-P based on chronic toxicity data for all species, including censored data as actual values in E_TX 2.3.1. The X-axis represents log-transformed NOEC/EC_{10}-values in mg/L, the Y-axis represents the potentially affected fraction of species.

Annex 3. Comment table Ctgb

Comment table				
Dimethenamid-P – derivation of the JG-MKN and MAC-MKN for surface water (24001671 MTR)				
chapter	**section**	**page**	**comment**	**response RIVM**
3	3.1	10	Table 5: it is assumed that the endpoints from the studies with the formulation are expressed in mg a.s./L. For clearance it is advised to indicate this in the first row of the table in the column 'Value'.	Agreed. A sentence was added to the header of table 5 to indicate that all concentrations are expressed as active substance
3	3.1	10	Table 5: For *Lemna gibba* the 6-day endpoint has been taken as the relevant endpoint. However, this seems a bit best-case, because the standard exposure duration is 7 days. It is preferred to take the geometric mean value of the 6 and 9-days endpoints as a more worst-case approach for the estimation of the toxicity after a 7-day exposure period.	Not agreed. The geometric mean 6d and 9 d EC10 are almost similar, with values of 0.00430 and 0.00419 mg/L. As the original study report is not available, it is not possible to derive a reliable geometric mean value using the 6d and 9d results combined. However, as a worst-case, the 6d EC10 will be replaced by the 9d EC10. Also the 6d EC50 will be replaced by the 9d EC50.
3	3.1	10	Table 5: With regard to the endpoints for macrophytes, nowadays visual phytotoxic effects like necrosis, chlorosis, root development, are taken into account and it is estimated if these effects (estimated 50% effect level) are covered by the default ErC50 based on the lowest measured variable. If the default ErC50 based on the lowest measured variable covers the visual phytotoxic effects this endpoint is appropriate for risk assessment. If this default ErC50 does not cover the visual phytotoxic	Not agreed. For each species a population-relevant endpoint is included in the EQS-derivation. In line with the WFD, endpoints such as growth rate may be included for macrophytes. Visual phytotoxic effects are not considered population-relevant under the WFD, therefore the endpoints included in the EQS-derivation are considered appropriate.

			effects, the default ErC20/ErC10 value based on the lowest measured variable is taken for risk assessment. If the ErC20/ErC10 value is not available or not reliable a standard correction factor of 3 is applied on the ErC50 based on the lowest measured variable. In the Netherlands this approach is already taken into account; in the Central Zone Member States of the EU it is still a draft-agreement, which should be agreed upon in the Central Zone Steering Committee. In Appendix 1 some background information is given on the visual phytotoxic effects. The problem in the case of dimethenamid-P is that the complete studies with macrophytes from the RAR are needed to observe if the visual phytotoxic effects are covered by the default ErC50 based on the lowest measured variable. We don't have these studies at the moment. There are indications from other Lemna studies with dimethenamid-P in combination with quinmerac (quinmerac is not toxic to macrophytes at all), that the visual phytotoxic effects are not covered by the default ErC50.	
3	3.1	12	It is assumed that the visual phytotoxic effects in the tests with macrophytes are covered by the used NOEC and ErC10 values.	Noted.
3	3.2.2	16	There is uncertainty if the visual phytotoxic effects are covered by the default ErC50 values based on the lowest measured variable in the tests with macrophytes. Therefore it is proposed to apply a somewhat higher safety factor on the acute HC5 (e.g. 8 instead of 6).	Not agreed. Current EQS-derivation is in line with the WFD. Therefore, the AF of 6 on the acute HC5 is considered appropriate. See also the response above on the other comment on visual phytotoxic effects.

Annex 4. Comment table BASF

Comment table

Dimethenamid-P – derivation of the JG-MKN and MAC-MKN for surface water (24001671 MTR)

chapter	section	page	comment	response RIVM
1	1.1	4	Dimethenamid-P is the more herbicidal active isomer (the S isomer) of Dimethenamid. The R isomer as an impurity of the enantioenriched Dimethenamid-P. Please adapt accordingly.	Agreed. Text has been amended
1	1.4.2	6	The authors are [redacted]	Agreed. In-text reference has been amended.
3	3.1	10	Table 5, ErC50 data for *Dictyococcus varians* and *Pandorina morum* are missing. Both studies are generally valid. As both species do not represent standard test species, validity criteria do not necessarily apply for non-standard test species. This is covered in Appendix 1 of the Working Document on Risk Assessment of Plant Protection Products in the Central Zone (Version 2.0 August 2023); where the section-by-section specific growth rate criteria is increased from ≥35% for standard test species to <50% for nonstandard species. *Dictyococcus varians* and *Pandorina morum* are below this cut-off value (43.7% and 46%, respectively). They fulfil both other OECD 201 criteria for control increase and average specific growth rate criteria. In addition, for higher tier approaches like SSDs also partially valid studies can be used if the derived endpoints and the observations generally fit into	Not agreed. The EQS has been derived in line with the current technical guidance on deriving EQS under the WFD. For both species the section-by-section specific growth rate is higher than acceptable according to OECD 201, in addition exponential growth is not maintained in both studies. Therefore, the data is not considered valid. It is noted that the (newly) derived EQS are protective for both species.

			the overall response pattern observed for the other species in the same taxa which is clearly the case here.	
3	3.1	10	Table 5, ErC10/NOEC data for *Dictyococcus varians* and *Pandorina morum* are missing. Both studies are generally valid. As both species do not represent standard test species, validity criteria do not necessarily apply for non-standard test species. This is covered in Appendix 1 of the Working Document on Risk Assessment of Plant Protection Products in the Central Zone (Version 2.0 August 2023); where the section-by-section specific growth rate criteria iss increased from ≥35% for standard test species to <50% for nonstandard species. *Dictyococcus varians* and *Pandorina morum* are below this cut-off value (43.7% and 46%, respectively). They fulfil both other OECD 201 criteria for both control increase and average specific growth rate criteria. In addition, for higher tier approaches like SSDs also partially valid studies can be used if the derived endpoints and the observations generally fit into the overall response pattern observed for the other species in the same taxa which is clearly the case here.	Not agreed. See response above
3	3.1	10	Table 5, ErC10/NOEC data for *Glyceria maxima*: The ErC10 value is based on yield (total length). As always growth rate related endpoints should be used, we kindly ask RIVM to use the ErC10 value based on growth rate (wet weight) not on yield. The correct value to be used is 0.027 mg/L	Agreed. As described in the report, no ErC10 value is reported in the RAR. We could not trace back the ErC10 of 0.027 mg/L. We therefore used GraphPad Prism 10.2.2 to derive an ErC10 of 0.025 mg/L using the available data. This value corresponds with the value of the applicant, we replaced our value with the applicant's value.
3	3.1.2	13	The HC5 value should be higher if the data for *Pandorina morum* and *Dictyococcus varians* are considered in the	Not agreed. See response above

			SDD. As both studies are considered reliable by BASF (see argumentations above) we kindly ask RIVM to recalculate the HC5 values based on the ErC10/NOEC values and the ErC50 values including data on these two species.	
3	3.1.2	15	Selection of the AF: As the dataset contains 26 species which is almost 3 x times the minimum required number of species for a taxon specific SDD, the dataset can be considered very comprehensive. In addition, most studies are considered reliable, the knowledge on presumed mode of action of the chemical is given and the level of statistical uncertainty around the chronic HC5 is minimal. Therefore, the AF for the derivation of the AA-QS can be significantly lowered from 5 to 1. Looking at the “Guidance for the derivation of environmental risk limits” (RIVM 2025), 3 out of 5 criteria are met for further lowering of the AF and thus a lowering to an AF to 1 seems to be reasonable and justified.	Not agreed. The choice in AF is in line with the RIVM-guidance. An assessment factor of 1 would assume no uncertainty at all. The guidance does not provide a set to be fulfilled, but should be interpreted as different aspects to take into consideration (as a minimum) when assessing the overall uncertainty for deciding on an AF. All aspects considered, we believe an AF of 3 is appropriate.
3	3.2.2	17	Selection of the AF: As the dataset contains 26 species which is almost 3 x times the minimum required number of species for a taxon specific SDD, the dataset can be considered very comprehensive. In addition, most studies are considered reliable, the knowledge on presumed mode of action of the chemical is given and the level of statistical uncertainty around the chronic HC5 is minimal. Furthermore, for the available acute endpoints, it is clear that the primary producers by far represent the most sensitive groups within the dataset. Therefore, the AF for the derivation of the MAC-QS can be significantly lowered from 10 to 1. Looking at the “Guidance for the derivation of environmental risk limits” (RIVM 2025), 3 out of 5 criteria are met for	Not agreed. See response above.

			further lowering of the AF and thus a lowering to an AF to 1 seems to be reasonable and justified.	
Annex 1	Table 1	24	The trout acute study with the LC50 of 2.6 mg/L, was conducted at acute 12 – 13 °C (see Table 4 of study report), not at 22°C as reported in Table A1.1, and footnote No.1. The test vessels were kept in a water bath to maintain this temperature. This study should be considered as Ri1 for reliability.	Partially agreed. We do not have access to the study report and are therefore not able to verify the test temperature. Based on the information provided in the comment and as the study is considered acceptable in the RAR, it is expected that the test temperature reported in the RAR is incorrect. The LC50 for *O. mykiss* will therefore be considered Ri2. The geomean LC50 for both acute studies with *O. mykiss* will be included in the SSD.
Annex 1	Table 1	25	We kindly ask RVIM to consider *Dictyococcus varians* as valid given further guidance for non-standard algal species for OECD 201 section-by-section validity criteria of 50% to be considered in the Working Document on Risk Assessment of Plant Protection Products in the Central Zone (Version 2.0 August 2023). And to consider a change from Ri3 to Ri2.	Not agreed. See response above
Annex 1	Table 1	26	We kindly ask RVIM to consider *Pandorina morum* as valid given further guidance for non-standard algal species for OECD 201 section-by-section validity criteria of 50% to be considered in the Working Document on Risk Assessment of Plant Protection Products in the Central Zone (Version 2.0 August 2023). And to consider a change from Ri3 to Ri2.	Not agreed. See response above
Annex 1	Table 1	28	Footnote 7 in the footnote is missing from the last column in Table 1.	Noted.