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CQC (AA-EQS) and AQC (MAC-EQS) – Proposal by the Ecotox Centre for:

2022

Permethrin

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Executive summary

CQC (AA-EQS):	0.00027 μg/L		
AQC (MAC-EQS):	0.0025 μg/L		

The chronic quality criterion (CQC) and the acute quality criterion (AQC) were derived according to the TGD for EQS of the European Commission (EC 2018a). In order to ensure that the dossiers are internationally comparable, the English terminology of the TGD will be used in the remainder of the dossier. The AQC corresponds to the MAC-EQS ("maximum allowable concentration environmental quality standard") and the CQC corresponds to the AA-EQS ("annual average environmental quality standard"). According to the Swiss Water Protection Ordinance (The Swiss Federal Council 2020), the CQC should not be compared with an annual average value but with the averaged concentration over two weeks.

Zusammenfassung

CQC (AA-EQS):	0.00027 μg/L		
AQC (MAC-EQS):	0.0025 μg/L		

Das chronische Qualitätskriterium (CQK) und das akute Qualitätskriterium (AQK) wurden nach dem TGD for EQS der Europäischen Kommission (EC 2018a) hergeleitet. Damit die Dossiers international vergleichbar sind, wird im Weiteren die englische Terminologie des TGD verwendet. Der AQK entspricht dabei dem MAC-EQS ("maximum allowable concentration environmental quality standard") und der CQK entspricht in der Herleitung dem AA-EQS ("annual average environmental quality standard") soll aber gemäss Schweizer Gewässerschutzverordnung (Der Schweizerische Bundesrat 2020) nicht mit einem Jahresmittelwert sondern mit der gemittelten Konzentration über 2 Wochen verglichen werden.



Résumé

CQC (AA-EQS):	0.00027 μg/L		
AQC (MAC-EQS):	0.0025 μg/L		

Le critère de qualité chronique (CQC) et le critère de qualité aiguë (AQC) ont été dérivés selon le TGD for EQS de la Commission européenne (EC 2018a). Afin que les dossiers soient comparables au niveau international, la terminologie anglaise du TGD est utilisée ci-dessous. La CQA correspond à la MAC-EQS ("maximum allowable concentration environmental quality standard") ou NQE-CMA ("norme de qualité environnementale de la concentration maximale admissible") et la CQC correspond à la AA-EQS ("annual average environmental quality standard") ou NQE-MA ("norme de qualité environnementale de la moyenne annuelle"). Selon l'ordonnance suisse sur la protection des eaux (Le Conseil fédéral suisse 2020), la CQC ne doit cependant pas être comparée à une valeur moyenne annuelle, mais à la concentration moyenne sur deux semaines.

Sommario

CQC (AA-EQS):	0.00027 μg/L		
AQC (MAC-EQS):	0.0025 μg/L		

Il criterio di qualità cronica (CQC) e il criterio di qualità acuta (CQA) sono stati derivati secondo il TGD for TGD della Commissione Europea (EC 2018a). Per garantire che i dossier siano comparabili a livello internazionale, viene utilizzata la terminologia inglese del TGD. Il CQA corrisponde al MAC-EQS ("maximum allowable concentration environmental quality standard") oppure SQA-CMA ("standard di qualità ambientale a concentrazione massima ammissibile") e il CQC corrisponde al AA-EQS ("annual average environmental quality standard") oppure SQA-MA ("standard di qualità ambientale medio annuo"). Secondo l'ordinanza svizzera sulla protezione delle acque (Il Consiglio federale svizzero 2020), tuttavia, il CQC non deve essere confrontato con un valore medio annuo, ma con la concentrazione media su due settimane.



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1 General Information

Selected information on permethrin relevant for the aquatic environment is presented in this chapter. Registration information and risk assessments referred to are:

- Assessment Report Permethrin, Product-Type 8 (Wood Preservative), Rapporteur: Ireland (EC 2014a)
- Assessment Report Permethrin, Product-Type 18 (Wood Preservative), Rapporteur: Ireland (EC 2014b)
- Final BPC Opinion Permethrin, Product-Type 8 (Biocidal Products Committee 2014a)
- Final BPC Opinion Permethrin, Product-Type 18 (Biocidal Products Committee 2014b)
- Canadian Water Quality Guidelines: Permethrin, Scientific Supporting Document (CCME 2006)
- Proposed EQS for Water Framework Directive Annex VIII substances: permethrin (For consultation) (Sorokin *et al.* 2012)
- US EPA Reregistration Eligibility Decision (RED) for Permethrin (Revised December 2009) (US EPA 2009)in connection with issues identified in the reregistration process (US EPA 2011); publication of the decision is expected end of 2020 for public commenting.
- Draft EU EQS Dossier Permethrin (JRC 2021) and corresponding opinion of the SCHEER (SCHEER 2022)

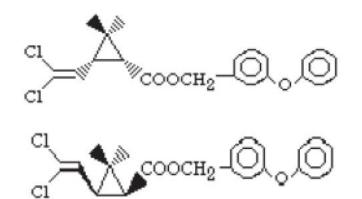
1.1 Identity and physico-chemical properties

Permethrin is a pyrethroid and is composed of four stereoisomers (Figure 1). The technical material contains 5-10 % 1R-cis permethrin, 15-20 % 1S-cis permethrin, 45-55 % 1R-trans, 17-27 % 1S-trans permethrin resulting in a cis : trans ratio of ca. 25 : 75 (EC 2014b). Pyrethroids are organic compounds based on the structure of natural pyrethrins that occur in chrysanthemum flowers.

Pyrethroids occur generally as mixtures of stereoisomeric forms, thus property measurements are available for both, mixtures and specific stereoisomers. Information is usually presented for mixtures (e.g. (CCME 2006, EC 2014b, Laskowski 2002, Sorokin *et al.* 2012) as pyrethroids are usually used as such. This assessment follows this approach.

Figure 1 Stereoisomers of permethrin according to (EC 2014b). a 1S-cis permethrin, b 1R-cis permethrin, c 1S-trans permethrin, d 1R-trans permethrin.

а



b



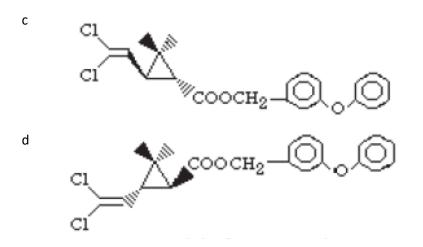


Table 1 summarizes identity and physico-chemical parameters for permethrin as isomeric mixture required for EQS derivation according to the EU TGD for EQS (EC 2018b). In case information on isomers and purity was available, it is included in the description. Where available, experimentally data is identified as (exp.) and estimated data as (est.). When not identified, no indication is available in the cited literature. Test methods are indicated in brackets when available in the cited document.

Characteristics	Values	References
Common name	Permethrin, NRDC 143, FMC 33297, PP557, WL 43479, and LE 79-519	Laskowski (2002)
IUPAC name	3-phenoxybenzyl(1RS)-cis,trans-3-(2,2- dichlorovinyl)-2,2- dimethylcyclopropanecarboxylate or 3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3- (2,2-dichlorovinyl)-2,2- dimethylcyclopropanecarboxylate	EC (2014b), p. 5
Chemical group	Pyrethroid	
Structural formula		EC (2014b), p. 5
Molecular formula	$C_{21}H_{20}CI_2O_3$	EC (2014b), p. 5
CAS	52645-53-1	EC (2014b), p. 5
EC Number	258-067-9	EC (2014b), p. 5

Table 1 Information required for EQS derivation according to the EU TGD for EQS (EC 2018b). In case information on isomers and purity was available, it is included in the description.



		OEChem 2.1.5
SMILES code	CC1(C(C1C(=O)OCC2=CC(=CC=C2)OC3=C	(PubChem release
SIVILLS CODE	C=CC=C3)C=C(CI)CI)C	2019.06.18)
Molecular weight [g/mol]	391.29	EC (2014b), p. 6
		Tagros cited in EC
Melting point [°C]	33 – 35 (99.3%, 25:75 cis:trans), exp.	(2014b), p. 47
		Tagros cited in EC
Boiling point [°C]	305°C (99.3%, 25:75 cis:trans), exp.	(2014b), p. 47
	_	1) Tagros cited in EC
	1) 2.155 x 10 ⁻⁶ at 20°C (99.30%, 25:75	(2014b), p. 47
Vapour pressure [Pa]	cis:trans), exp.	2) Alvarez (1989) cited
	2) 2.15 x 10 ⁻⁸ to 6.90 x 10 ⁻⁹ at 25°C, exp.	in Laskowski (2002)
		1) Bayer/Sumitomo)
		cited in EC (2014b),
Henry's law constant	1) > 4.5 x10 ⁻²	p.47
[Pa·m ³ ·mol ⁻¹]	2) 4.6 x 10 ⁻³	2) Tagros cited in EC
		(2014b), p. 47
		1) Bayer/Sumitomo)
		cited in EC (2014b), p.
		47
	1) <0.00495 at 20°C (≥99.0%, 25:75	2) Tagros cited in EC
	cis:trans), exp. (L383A A6, not reported	(2014b), p. 47
	whether flask or column method)	3) Alvarez (1989) cited
	2) 0.18 at 20°C (99.30%, 25:75 cis:trans),	in Laskowski (2002), p.
	exp. (unknown method)	151
Water solubility [mg·l ⁻¹]	3) 0.175 at 25°C, exp. (generator column	4) Wollerton (1987)
	technique)	cited in Laskowski
	4) 0.0055 at 20°C, exp. (continuous	(2002), p. 151,
	stirring)	preferred value
	5) 0.0052 at 20°C (40:60), exp. (OECD	according to US EPA
	105, OPPTS 830.7840 & EEC A.6)	(2011)
		5) Sowjana/Tagros
		(2010) cited in (FAO
		2019)
Dissociation constant (pK _a)	Molecule is not expected to dissociate	EC (2014b), p. 48
	1) 4.67 +/- 0.01 at 25°C (99.3%, 25:75	-
	cis:trans), exp.	1),2) Tagros cited in
	2) Effect of pH: (93.01%, 25:75 cis:trans),	EC (2014b), p. 48
	exp.	3) Wollerton (1987)
	Water = 4.62 ± 0.05	and Robson (1995)
Octanol-water partition	pH 4.0 buffer = 4.63 ± 0.06	cited in EC (2014b)
coefficient (log K _{ow})	pH 7.0 buffer = 4.58 ± 0.04	applicant data 7536 p.
	pH 9.0 buffer = 4.60 ± 0.04	14
	3) 6.1 (20 °C, 94.5% technical, 25:75	4) US EPA (2007)
	cis:trans), OPPTS 830.7560, exp.	5) geometric mean of
	4) 7.43 (est. EpiSuite)	1-4
	5) 5.14	
Sediment/soil-water partition	1) 4.4 (average, soils, batch equilibrium,	1) Davis (1991) cited
coefficient (log K _{oc}) ^a	see Annex II)	in Laskowski (2002)



	 2) 5.4 (average, four soils, batch equilibrium, see Annex II), exp. 3) 4.12-5.14 (adsorption, Koc: 13165-139092, 5 soils), exp. 4) 4.02-4.94 (Koc 10471-86000), individual values and method unknown 5) 4.39 (Koc 24547, sediment), exp. 6) 4.5 (Koc 32420, est. with EpiSuite based on log K_{ow} 5.14) 7) 5.15 (Koc 141278) 	 2) Hand (2000) cited in Laskowski (2002) 3) Tagros cited in EC (2014b) 4) ChemBank ™ cited in Sorokin <i>et al.</i> (2012) 5) Conrad <i>et al.</i> (1999) 6) US EPA (2007) 7) geometric mean of 1-6
Sediment/Soil adsorption coefficient (K _d [l/kg])	1) 2230 (average, soils), exp.	1) Laskowski (2002)
Aqueous hydrolysis DT₅o	 1) 194 d (trans), 348 d (cis), (pH 9, 25°C), exp. 2) 35 d (cis), 42 d (trans), (pH 9, 25°C), exp. 3) 50 d (pH 9, 25°C) 4) 125-350 d (pH 9), exp. 5) stable at pH 7, exp. 	 Allsup (1976) cited in Laskowski (2002), p. 160 Bayer cited in EC (2014b), p. 56 Chem-Bank[™], (2004) referenced in Sorokin <i>et al.</i> (2012), p. 4 citation 00102043 in US EPA (2011), p. 29 White and Mully (2003) cited in EC (2014b) applicant data 8276, p. 3
Aqueous photolysis DT ₅₀	 1) 103-110 d, exp. 2) 80 d (pH 5), exp. 3) 118 d (extrapolated), 49:51 cis:trans permethrin, latitude 50°N, autumn, 12 h sunlight per day, exp. 4) 33 d (27.1 d cis, 19.6 d trans), pond water, sunlight, exp. 5) 14 d, sea water, exp. 	 Amos and Donelan (1987) cited in Laskowski (2002), p. 160 Amos, R.; Donelan, R. (1987) cited in US EPA (2011), p. 30 Bayer/Sumimoto cited in EC (2014b), p. 56 4), 5) Chem-Bank[™], (2004) referenced in Sorokin <i>et al.</i> (2012), p. 5
Photolysis in soil DT ₅₀	1) 200 d (extrapolated), exp. 2) 104-106 d, exp.	1) Bayer/Sumimoto cited in EC (2014b), p. 65 2) Brown and Leahey cited in Laskowski (2002), p.161



Biodegradation in aqueous environment DT ₅₀ [d]	 60 and 67, trans and cis, exp. (fluvarium channels) 1.8 and 3.1 cis-permethrin, 1.3 and 1.4 trans-permethrin, dissipation, formulated product with 10.1 % w/w permethrin, exp. 2.2 and 2.3 (phenoxyphenyl-label); 1.4 and 2.2 (vinyl-label), dissipation, 25:75 cis:trans permethrin, exp. 	1) Allan et al. (2001) cited in Sorokin <i>et al.</i> (2012) 2), 3) Bayer/Sumimoto cited in EC (2014b), p. 59 3) Tagros cited in EC (2014b), p. 59
Biodegradation in sediment DT ₅₀ [d]	1) 63.7 and 27.3, for 46:54 and 53:47 cis:trans, respectively; 25 °C, aerobic (whole system), exp. 2) 180.2 and 77.2, for 46:54 and 53:47 cis:trans, respectively; 12 °C, aerobic (whole system), exp. 3) 118 and 256 cis-permethrin; 18 and 62 trans-permethrin (field aquatic study – permethrin cis:trans ratio not specified), exp. 4) 179.4 (cis) and 114.5 (trans), anaerobic (whole system), exp. 5) 507.6 (cis) – 323.9 (trans), 12 °C, anaerobic (whole system), exp. 6) 14.3 (phenoxyphenyl-label) and 24.6 (vinyl-label), 20 \pm 2 °C, aerobic, dark (whole system), exp. 7) 27.1 (phenoxyphenyl-label) and 46.1 (vinyl-label), 12 °C, aerobic, dark (whole system), exp. 8) 38.2 (acid label) total pond-water system, exp. 9) 42.9 (alcohol label) total pond-water system, exp. 10) < 2.5	1)-5) Bayer/Sumimoto cited in EC (2014b), p. 57-58 6), 7) Tagros cited in EC (2014b), p. 59 8),9) Robinson, R.; Ryan, J. (1996) cited in US EPA (2011) 10) ChemBank ™ cited in Sorokin <i>et al.</i> (2012)
Biodegradation in soil DT ₅₀ [d]	 ≤28 2) <38, exp. 3) 32-34 (trans), ≥64 (14C cis), exp. 4) 6 - 106, field dissipation, exp. 5) 37, 25 °C, aerobic, n=1 soil, exp. 6) 27.3, 31.4, 47.6 and 49.8, 25 °C, aerobic, n=4 soils, exp. 7) 5.8 - 10.4, aerobic, 20 °C n= 4 soils, 8 results, exp. 	 WHO (1990) cited in Sorokin <i>et al.</i> (2012) Perkow and Ploss (2001) cited in Sorokin <i>et al.</i> (2012) A) ChemBank ™ cited in Sorokin <i>et al.</i> (2012) Bayer/Sumimoto cited in EC (2014b), p. 63 A) Tagros cited in EC (2014b), p. 63

^a Data obtained from HPLC-based, unknown or non-reliable methods are in grey font and were not used for EQS derivation.



1.2 Regulatory context and environmental limits

Table 2 summarizes existing regulation and environmental limits in Switzerland, Europe and elsewhere for permethrin. Existing PNEC/Environment quality standards are listed in Table 3. Please note that the information provided in Table 2 and 3 may have changed since finalization of this dossier.

Table 2 Existing regulation for permethrin in Switzerland and Europe.

Europe		
Regulation (EU) No 528/2012	PT08 (Wood Preservative) approved since 1.5.2016	
concerning the making available on the	PT18 (Insecticides, acaricides and products to control	
market and use of biocidal products	other arthropods) approved since 1.5.2016	
	Acute Tox. 4 H302	
	Acute Tox. 4 H332	
ECHA Classification and Labelling	Skin Sens. 1 H317	
	Aquatic Acute 1 H400	
	Aquatic Chronic 1 H410	
Switzerland		
	PT08 (Wood Preservative) approved since 1.5.2016	
VBP; SR 813.12	PT18 (Insecticides, acaricides and products to control	
	other arthropods) approved since 1.5.2016	

 Table 3 PNEC/quality standards available from authorities and reported in the literature.

Description	Value [µg/L]	Development method	References	
Interim Water Quality	0.004	21-day LOEC of 0.042 μg a.i./L for	CCME (2006)	
Guideline for Freshwater		immobility in nymphs of the	Anderson (1982)	
Aquatic Life		stonefly Pteronarcys dorsata		
		SF (Safety factor) = 10		
PNEC _{freshwater_lt}	0.001	lowest reliable E(L)C50 (Hexagenia	Sorokin <i>et al.</i>	
		<i>bilineata</i> 96-hour LC50 of 0.1 μg/L)	(2012)	
		AF = 100		
PNEC _{freshwater_st}	0.01	96-hour LC50 of 0.1 μg/L for the	Sorokin <i>et al.</i>	
		mayfly Hexagenia bilineata	(2012)	
		AF = 10		
MAC-EQS	0.0025	Geometric mean of the 96h LC50	JRC (2021)	
		of the amphipod Hyalella azteca		
		AF = 10		
AA-EQS	0.00027	Geometric mean of the 21d NOEC	JRC (2021)	
		in the daphnid Daphnia magna		
		AF = 50		

1.3 Use and emissions

In Switzerland and the EU, permethrin was authorised as wood preservative (biocide PT08) and as insecticide (biocide PT18), both until 30/04/2026. It is part of the "active substance Review Programme" (EC 2017) and is not a candidate for substitution. The characterized biocide uses comprise



"Industrial Preventive Uses", "Treated wood in service", "Curative treatment", "Wood in contact with ground" (PT8) and "Spot treatment", "Textile fibre treatment" (PT18) (EC 2014a, 2014b). Thus, wastewater treatment plants, run-off after rain events, aerosols/spray drift can be expected to be major sources of permethrin in the environment (detailed discussion e.g. in Antwi & Reddy (2015)). Permethrin was not re-authorised as pesticide active substance in 2000 in the EU (EC 2000) and is likewise not authorised for use in plant protection products in Switzerland.

1.4 Mode of action

Permethrin is a hydrophobic pyrethroid. Pyrethroids are synthetic insecticides that have been optimized based on the structures of the pyrethrins which are the constituents of the natural insecticide pyrethrum (Soderlund 2010). Pyrethroids exert neurotoxic effects by modifying the kinetics of voltage-sensitive sodium channels.

The interaction of pyrethroids with sodium channels is stringently stereospecific (Soderlund & Bloomquist 1989, Soderlund 2010), with the cis and trans isomers binding competitively to different sites. At the same time, the 1S isomers do not modify channel function but block the effect of the 1R isomers (Ray (1991) cited in Cage et al. (1998)). Pyrethroids in general are more toxic to invertebrates than vertebrates and particularly several orders of magnitude more toxic to insects than to mammals which has been attributed among others to differences rates of detoxification (summarized in Cage et al. (1998)). Temperature specifically influences pyrethroid toxicity in various species. In Chironomus dilutus (aquatic exposure), permethrin was more toxic at 13 °C than at 23 °C, which was attributed to a combination of increased accumulation of parent compound and increased nerve sensitivity (Harwood et al. 2009). In vertebrates including humans, neurotoxicity, immunotoxicity, cardiotoxicity, hepatotoxicity, reproductive, genotoxic, and haematotoxic effects, digestive system toxicity, and cytotoxicity have been reported as a consequence of the mode of action, as summarized in Wang et al. (2016). Potentially due to the mode of action of permethrin, plants and algae seem to be less sensitive with effect concentrations being several orders of magnitude higher. Likewise, effects on microbial communities (Muturi et al. 2017) were observed at a concentration 6 orders of magnitude higher than acute effect concentrations in invertebrates. The same observation was made in microbial inhibition studies (EC 2018b).

With respect to endocrine effects¹, the EQS Dossier by the Environment Agency for England and Wales concludes that "results of these studies are often contradictory and no weight-of-evidence conclusions can currently be drawn on the possible endocrine-disrupting effects" (Sorokin *et al.* 2012). The EU Assessment Report states that "Permethrin does not appear to have an endocrine [e]ffect in fish." (EC 2014b) as the most sensitive endpoint was survival rather than reproduction; and the final BPC opinion states that "permethrin is not considered to have endocrine disrupting properties" (Biocidal Products Committee 2014b). Based on effect concentrations presented in section 4 of this dossier, reproductive

¹ In a fact sheet on endocrine disruptors Bundesamt für Gesundheit (2019) Endokrine Disruptoren. Bundesamt für Gesundheit BAG, B.f.U.B., Bundesamt für Lebensmittelsicherheit und Veterinärwesen BLV, Bundesamt für Landwirtschaft BLW, Staatssekretariat für Wirtschaft SECO, Swissmedic, Suva (ed)., the authors, a group of experts of Swiss BAG, BAFU, BLV, BLW, SECO, Swissmedic and Suva, refer to the WHO definition Damstra, T., Barlow, S., Bergman, A., Kavlock, R. and Van Der Kraak, G. (2002) Global Assessment of the State-of-the-Science of Endocrine Disruptors. adapted from EC/Weybridge UK (1996) European workshop on the impact of endocrine disruptors on human health and wildlife. .: "An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations." According to the ED criteria as defined in Commission Regulation (EU) 2018/605 of 19 April 2018 EC (2018c) Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties and referred to in ECHA/EFSA/JRC, Andersson, N., Arena, M., Auteri, D., Barmaz, S., Grignard, E., Kienzler, A., Lepper, P., Lostia, A.M., Munn, S., Parra Morte, J.M., Pellizzato, F., Tarazona, J., Terron, A. and Van der Linden, S. (2018) Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009, European Chemical Agency (ECHA) and European Food Safety Authority (EFSA) with the technical support of the Joint Research Centre (JRC). EFSA Journal 16(6), e05311., "a substance shall be considered as having ED properties if it meets all of the following criteria: a. it shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population* that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences; b. it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system; c. the adverse effect is a consequence of the endocrine mode of action.



endpoints in fish are less sensitive than survival, while they are more sensitive than survival in some invertebrates (crustaceans *Daphnia magna* and *Ceriodaphnia dubia* and echinoderm *Paracentrotus lividus*). We could not identify studies that added to a clear line of evidence in the sense of the above definitions¹ to support an "endocrine mode of action".

2 Environmental fate

2.1 Stability and degradation products

Abiotic degradation

Laskowski (2002) reported DT_{50} of 194-250 d (pH 9, 25°C) for aqueous hydrolysis, whereas the EU assessment report cited DT_{50} of 35-42 d (pH 9, 25°C) and hydrolytical stability at pH 3.0/4.0 to 7.6/7 at 25/50°C, respectively. According to information referenced in Sorokin *et al.* (2012), permethrin is stable at pH 5 and 7, and shows a DT_{50} of 50 d at pH 9, 25 °C.

Photodegradation

While the EU assessment report EC (2014b) cites a report of permethrin being relatively stable when exposed to photolysing conditions in soil (200 d, with low accuracy as beyond duration of the study), the EU EQS Dossier cites two other sources indicated photolysis in water (Sorokin *et al.* 2012). According to reports referenced in Laskowski (2002) reported DT_{50} in water of 103-110 d and of 104-106 d in soil are similar. In the EU assessment report it was concluded that significant photolysis of permethrin will not occur under environmentally relevant pH and temperature conditions (12°C) (EC 2014b).

Biodegradation

According to the EU Assessment Report, permethrin is not readily biodegradable based on two studies; OECD 301B (CO2 evolution method)/US EPA OPPTS 835.3110 and OECD 301 F (oxygen consumption) (EC 2014b). A publication cited in the EU EQS Dossier reporting ready biodegradability of permethrin could not be verified (Zabel et al. 1988 cited in Sorokin *et al.* (2012)). Biodegradation (25:75 cis:trans permethrin) was found to be above 20% in a valid test (OECD302 C, BOD test), indicating inherent primary biodegradability, but not inherent ultimate biodegradability (biodegradation not above 70%). No clear evidence for degradation was observed in a sewage sludge study (40:60 cis:trans permethrin). It was deemed likely that permethrin adsorbed to the sewage sludge (~80% AR). The dosing rate in this study was above water solubility of permethrin.

Based on available data, permethrin shows quick dissipation from water to sediment or soil with low mobility in both compartments (EC 2014b, Laskowski 2002, Sorokin *et al.* 2012). Consequently, biodegradation for the water phase in water-sediment or water-soil systems can hardly be calculated. As listed in Table 1, degradation in water-sediment systems is slow and is influenced by the conformation of the isomer (cis, trans), aerobic/anaerobic conditions and light/dark conditions. The trans isomer is degraded substantially more quickly than the cis isomer. Biodegradation in seawater was reported to be substantially quicker than in freshwater (ChemBank ™ cited in Sorokin *et al.* (2012)). The proposed degradation scheme in aerobic water-sediment systems to 3-phenoxybenzyl alcohol (PB alcohol) and 3-(2,2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane)carboxylate (DCVA), followed by transformation of PB alcohol to 3-phenoxybenzoic acid (PBA), with carbon dioxide and bound residues as terminal products. Maximum observed levels of DCVA, PBA and PB alcohol in the water compartment were 62.6 % AR, 28.8 % AR and 38.2 % AR, respectively (EC 2014b).



The US EPA Reregistration Review information lists m-PBA (m-phenoxybenzoic acid, CAS # 3739-38-6), m-phenoxybenzyl alcohol (CAS # 13826-35-2), cis-DCVA (cis-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylic acid, CAS # 59042-49-8), and trans-DCVA (trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylic acid, CAS # 59042-50-1) as "major breakdown products" (US EPA 2011).

2.2 Bioavailability

Bioavailability is a complex process which depends on many factors including the sorption capacity of the dissolved organic carbon (DOC) in the water-phase and of the sediment in the water-sediment system (e.g. OC content), the hydrophobicity of the compound, and the physiology, feeding behaviour and activity of the organism considered (Warren *et al.* 2003).

Lu *et al.* (2019) have recently reviewed available literature on passive sampling techniques to obtain the freely dissolved concentration (C_{free}) as analogue for bioavailability of among others permethrin in the aquatic environment, citing logK_{pw} of 4.17 obtained with 381 µm polyurethane film (Liao et al. (2017) cited in Lu *et al.* (2019)) and 5.59 ± 0.04 obtained with 10 µm polydimethylsiloxane (You et al. (2007) cited in Lu *et al.* (2019)).

As stated in the EU TGD for EQS, total and dissolved concentrations of very hydrophobic substances with K_p values above 10000 L/kg or K_{oc} values for linear partitioning into amorphous organic matter above 100000 L/kg, may differ. Thus, for compounds with log Kp<4 (or, if this value is not available, log Kow <6), the EQS_{water, total} is equivalent to the EQS_{water,dissolved} (EC 2018b). For highly hydrophobic compounds the final derived EQS (which is an EQS_{water, dissolved}) should be corrected using the default concentration of suspended matter (CSPM) and the partition coefficient to suspended matter ($K_{p,susp}$) (EC 2018b).

As stated above, based on available data, permethrin shows quick dissipation from water to sediment or soil with low mobility in both compartments (EC 2014b, Laskowski 2002, Sorokin *et al.* 2012). In particular, *cis*- and *trans*-permethrin dissipated rapidly from water and remained primarily in the upper 0-5 cm sediment fraction (EC (2014b), p. 58). Measured Koc for permethrin range from 13165-55000 (geometric mean: 141278, including one estimated value, see Appendix II) depending on the soil/sediment tested. Data from Davis (1991) cited in EC 2014b and in Laskowski (2002) was not used due to co-solvent artefacts as discussed in Laskowski (2002). Further, measured logKow range from 4.6 - 6.1 resulting in a geometric mean of 5.14 (including one estimated value of 7.43, Table 1. While the geometric mean of logKow is below the trigger value of 6, the geometric mean of Koc is above the trigger of 100000 L/kg. In connection with the known quick dissipation from water, correction of the final EQS water,dissolved is considered indicated (see section 9).

2.3 Bioaccumulation and biomagnification

In the following, the term "bioconcentration factor (BCF)" is used for values obtained in water-only exposure studies or exposure studies with uncontaminated food, whereas "bioaccumulation factor (BAF)" is used to refer to values from studies including a (potentially) contaminated food source.

The highest BCF was reported in the eastern oyster (*Crassostrea virginica*) exposed to permethrin in unfiltered sea water (Schimmel *et al.* 1983) (Table 4). BCF in fish were all in a similar range between 290 and 651 (580 ± 81). Freshwater insects showed BCF of a magnitude lower. The highest BAF of 3300 was reported in fathead minnow at an exposure concentration of 0.66 μ g/L (Spehar *et al.* (1983) cited in EC (2014b), p. 37).



In pyrethroid-resistant *H. azteca*, the maximum body burden attained was 89.2 µg/g lipid at 843 ng/L water concentration. Non-resistant animals accumulated up to 9.1 µg/g lipid when surviving 86 ng/L water concentration (Muggelberg *et al.* 2017). With a lipid content of $8.1\pm 2.6\%$ and $5.9\pm 0.4\%$ for non-resistant and resistant populations, respectively, these values correspond to BAF of 8.6 and 6.2, respectively, with respect to whole body weight, or 106 in both cases with respect to lipid weight. Importantly, 86 – 88 % (non-resistant vs. resistant animals) permethrin was biotransformed in 72 h at the lowest exposure concentration (24 ng/L). The extent of biotransformation declined as the exposure concentration increased. At the three highest exposure concentrations (≥210 ng/L) more than 40% of the total permethrin remained. In fish, reported depuration half-lives were between 2 and ~5 d (Table 4).

As reported BCF or BAF are \geq 100 (and a Log K_{ow} \geq 3), assessment of secondary poisoning is necessary according to the requirements of the EU TGD for EQS (EC 2018b).

Species	BCF [L/kg]	Tissue	Exposure	Further information	Reference
Bluegill sunfish (Lepomis macrochirus)	570 ± 81 (acid label) 500 ± 20 (alcohol label)	Whole body	28 d flow-through, ¹⁴ C permethrin	Depuration time 4.7 \pm 0.34 d (acid label) 4.6 \pm 0.86 d (alcohol label) Reliability 1	Burgess (1989) cited in EC (2014b) 7539_ApplicantB_Data_010, p. 74 and Laskowski (2002)
Sheepshead minnow (Cyprinodon variegatus)	290-620	whole body	1.25 -10 μg/L, 28 d, starting after hatching	Maximum bioconcentration at 2.5 μg/L, maximum residue of 5.7 mg/kg at 10 μg/L	Hansen et al. (1983) cited in WHO (1990)
Crassostrea virginica	1900	whole body	1 μg/L (nominal) and 28 d flow- through	Unfiltered sea water, 65 animals per group	Schimmel <i>et al.</i> (1983)
Various aquatic insects	4-24				Chem-Bank™ (2004) cited in Sorokin <i>et al.</i> (2012) ¹
Chironomus tentans	25±24 - 69±23 (trans-permethrin) 8±16 – 166 ±49 (cis-permethrin)s	Whole body	5 and 50 μg/L Static water exposure, 48 h, ¹⁴ C permethrin cyclopropyl-label	fourth instar larvae, animals were kept in nylon-screened glass containers above three different sediments, "rapid" depuration Reliability 2-3	Muir <i>et al.</i> (1985) cited in EC (2014b) 7539_ApplicantB_Data_010, p. 82
Species	BAF [L/kg]	Tissue	Exposure	Further information	Reference
Common carp (Cyprinus carpio)	330–750	whole body	flow-through system at 25°C, ¹⁴ C-permethrin isomer: phenoxyphenyl- labelled [1R,trans], [1R,cis], [1S,trans],	equilibrium on days 7-9, Depuration: half-lives of 2.0- 2.8 d	Ohshima et al. (1988) cited in WHO (1990)

Table 4 BCF and BAF values reported for fenpropimorph



			or [1S,cis] isomers)		
Fathead minnow (Pimephales promelas	1700 (at 0.11 μg/L) 3100 (at 0.18 μg/L) 3100 (at 0.33 μg/L) 3300 (at 0.66 μg/L) 2800 (average)	Whole body	92 % permethrin 0.11-1.4 μg/L measured concentrations, 30 d flow-through	Start of exposure directly after hatching	Spehar <i>et al.</i> (1983) cited in EC (2014b), p. 37
Helisoma trivolvis	700 (at 0.03 μg/L) 800 (at 0.04 μg/L) 600 (at 0.12 μg/L) 800 (at 0.22 μg/L) 1000 (at 0.33 μg/L) 800 (average)	Whole body	92 % permethrin 0.03-0.33 μg/L, measured concentrations		Spehar <i>et al.</i> (1983) cited in EC (2014b), p. 37
Hyalella azteca	6.2	whole body fat	24, 46 and 86 ng/ L, > 95% ¹⁴ C permethrin, 72 h, 4 replicates per treatment, 30-40 animals per replicate, 23 °C, 16:8 h light:dark photoperiod, no information on feeding during exposure	Maximum 9.1 μg/g lipid when surviving 86 ng/L, steady-state concentration reached at 33 h	Muggelberg <i>et al.</i> (2017)
Laccophilus minutus	38 – 1692	whole body	0.004, 0.04 and 0.25 μg/L permethrin, 15 individuals per treatment, 48 h, 16:8 h light: dark photoperiod, 21 ± 1°C, no information on feeding during exposure	measured water concentrations: 0.0013 ± 0.00006 , 0.023 ± 0.001 and $0.18 \pm 0.003 \mu g/L$, measured tissue concentration: 2.2 ± 0.3 , 5.13 ± 0.7 and 6.8 ± 0.43 ng/g dry weight (dw)	Touaylia <i>et al</i> . (2019)
Stonefly (Pteronarcys dorsata)	43-570 average 183±171		0.029-0.21 mg/L, 28 d, flow-through		Anderson (1982) cited in WHO (1990)

¹Information cannot be verified.

Biomagnification

In a biomagnification study, Muggelberg *et al.* (2017) fed *Pimephales promelas* with permethrin exposed *H. azteca* with an average tissue concentration of 96.5 μ g/g lipid for 4 d. The average total permethrin concentration in fish tissue was 0.22 μ g/g lipid. Due to the short feeding period, this may not reflect steady state levels in the fish. The percentage of total tissue permethrin (as parent compound) was 32%, thus lower than in *H. azteca* used as food source (47%), suggesting further biotransformation of permethrin within the fish.

3 Analytics

As summarized by Li *et al.* (2009), chromatographic techniques have been considered as the best methods to determine pyrethroids in different sample matrices. With respect to environmental concentrations, the challenge for chemical analysis of pyrethroids in general is the strong sorption to



surfaces and the low effect concentrations. As listed in Table 4, The reference analytical method in the EC Assessment Report for permethrin as biocidal active substance is a HPLC-MS/MS method with an LOQ of 0.05 μ g/L (Bayer/Sumitomo cited in EC (2014b)). A method with an LOD of 0.001 μ g/L was published by Delorenzo *et al.* (2014) based on capillary GC/MS.

Table 4 Methods for permethrin analysis in water and corresponding limits of detection (LOD) and limits of quantification (LOQ) (μ g/L). n.a. means not reported.

LOD	LOQ	Analytical method	Reference
n.a.	0.05	Acidified water samples are diluted with acetonitrile, HPLC-MS/MS in positive ionization, no further clean-up	Bayer/Sumitomo cited in EC (2014b)
0.001	n.a.	Capillary GC/MS with electron impact ionization operating in selective ion monitoring mode	Delorenzo <i>et al.</i> (2014)
0.0048	n.a.	GC coupled to a quadrupole MS detector operated in electron capture negative ionization mode (GC-ECNI-MS), methane as the reagent gas, helium as carrier gas, injection in splitless mode	Hasenbein <i>et al.</i> (2015)

4 Effect data

A literature search of the database Scopus was performed on July 21, 2020 for the years 2010-2020 using the search terms permethrin, 52645-53-1 and ecotoxicity, ecotoxicology, or aquatic toxicity, yielding 31, 196 and 308 hits, respectively, with 308 unique hits. These were analysed for relevance resulting in 19 studies on effects in aquatic organisms.

A study by (Sever *et al.* 2020) on *Hyalella azteca* was not retrieved by the literature search but included in the draft EU dossier for Permethrin (JRC 2021) and is thus included in the update of the present dossier. A second study by the same group on *H. azteca* (Heim *et al.* 2018) was previously excluded as one of two reported effect concentrations is identical to the effect concentration in a third paper by the same group on *H. azteca* (Muggelberg *et al.* 2017). An agreement was made with the EU working group on the EQS for Permethrin to include the study but to omit the duplicate effect concentration (Table 5).

Endpoints listed in the EC EQS Dossier for permethrin (Sorokin *et al.* 2012) and in the Assessment Reports on permethrin as biocidal active substance (EC 2014a, 2014b) are included with the previous assessments of reliability having been adopted without additional assessment (face value) except studies lacking analytical data. In case endpoints were not previously assessed, they are listed as R4 in this Dossier.

The database on aquatic toxicity data hosted by the Pyrethroid Working Group (PWG)², a consortium of pyrethroid registrants, as well as publically available databases hosted by national authorities were also considered.

Only reliable and relevant data should be used for EQS derivation (EC 2018b). These data are often referred to as "valid". Different approaches to assessment and classification of (eco)toxicological data have been published. An established method introduced by Klimisch *et al.* (1997) uses four levels of

² <u>www.pyrethroids.com/aquatic-toxicity-database/</u>



validity: (1) reliable, (2) reliable with restrictions, (3) not reliable, (4) not assignable. The CRED approach published by (Moermond *et al.* 2016) is based on a similar classification scheme but additionally takes into account the relevance of test results for the derivation of quality standards. Both methods are recommended in the EU TGD for EQS (EC 2018b). Here, validity in terms of relevance ("C" in Table 5) and reliability ("R" in Table 5) of studies were evaluated according to the CRED-criteria.

Permethrin has high K_{ow} and K_{oc} values and correspondingly very low water solubility (Table 1), with a measured water solubility of ≤ 0.18 mg/L depending on the method of analysis. It has been shown to quickly dissipate from water via sorption e.g. to surfaces. Consequently, endpoints from studies without or with insufficient analytical data have been rated R4 according to the CRED approach, since the actual exposure concentration is uncertain. Analytical data was considered insufficient when permethrin concentrations were not tracked throughout the experiment, at least at the start and the end of exposure. Further, studies on formulations are considered irrelevant due potential effects of unknown co-formulants. When selecting effect concentrations from algae growth inhibition tests in particular, growth rate is preferred over growth, biomass, and cell density according to EC (2018b).

Only effect data considered as relevant and reliable are listed in Table 5. An extended table including all effect data, i.e. also non-relevant/non-reliable effect data, is provided in Annex I, including comments on analytics in case a study being relevant (C1, C2) but with reliability not being assessable (R4). In case the isomeric mixture of permethrin was specifically reported, the information is included in Annex I. Unbounded effect concentrations cannot be used in the calculation of QS, however, they are included in Table 5 and Annex I as valuable information on the sensitivity of a species.



Table 5 Selected effect data collection for permethrin in µg/L, non-relevant and non-reliable data are excluded. Data were evaluated for relevance and reliability according to the CRED criteria (Moermond *et al.* 2016) in case they had not been previously evaluated (face value). The full list of effect data assessed including those assessed as not relevant and not reliable is available in in Annex I. Effect data used for QS derivation are in bold letters. Abbreviations: n. a. = not available.

Group	Species	Endpoint	Duration	Parameter		value (ug/L)	Analytics	Exposure	Purity (%)	Validity	Reference
Acute freshwater effect data											
algae	Pseudokirchnerella subcapitata*	growth rate (cell number)	72h	ErC50	>	1130	m-gm	S	97.3	1	Dorgerloh, M. 2008 cited in BP approval data PT08 (2011) 9013_ApplicantB_Data_009 p. 46 (EC 2014a)
algae	Pseudokirchnerella subcapitata*	growth rate (cell number)	72h	ErC50	>	160	m	S	>96	2	Environment Agency 2008 cited in Sorokin et al. (2012)
algae	Pseudokirchnerella subcapitata*	biomass	72h	EbC50	>	160	m	S	>96	2	Environment Agency 2008 cited in Sorokin et al. (2012)
crustaceans	Daphnia magna	immobilisation	48h	EC50	=	1.27	mm	S	94.5	2	Thompson, R.S., and Williams, T.D. 1978 cited in BP approval data PT08 (2011) 9013_ApplicantB_Data_009 p. 26 (EC 2014a)
crustaceans	Hyalella azteca	mortality	96h	LC50	=	0.0312	mm	S	100	R1/C1	Muggelberg et al. (2017)
crustaceans	Hyalella azteca	mortality	96h	LC50	=	0.0346	mm	S	98		Heim <i>et al.</i> (2018)
crustaceans	Hyalella azteca	mortality	96h	LC50	=	0.02093	mm	S	98.1		Sever <i>et al.</i> (2020)
crustaceans	Hyalella azteca	mortality	96h	LC50	=	0.02037	mm	S	98.1		Sever <i>et al.</i> (2020)
crustaceans	Hyalella azteca	mortality	96h	LC50	=	0.02172	mm	S	98.1		Sever <i>et al.</i> (2020)
						0.0251	1				Geometric mean
				Ch	ronic	and subchro	nic freshwate	effect data			
algae	Pseudokirchnerella subcapitata*	growth rate (cell number)	72h	ErC10	=	2.3	m-gm	S	97.3	1	Dorgerloh, M. 2008 cited in BP approval data PT08 (2011) 9013_ApplicantB_Data_009 p. 46 (EC 2014a)
algae	Pseudokirchnerella subcapitata*	growth rate (cell number)	72h	NOEC	=	160	m	S	>96	2	Environment Agency 2008 cited in Sorokin et al. (2012)
crustaceans	Daphnia magna	mortality	21d	NOEC	=	0.19	mm	т	>98.6	1	Kent, S., Williams, N., Gillings, E., Morris, D.S. 1995 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 112 (EC 2014a)
crustaceans	Daphnia magna	length	21d	NOEC	=	0.039	mm	т	>98.6	1	Kent, S., Williams, N., Gillings, E., Morris, D.S. 1995 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 112 (EC 2014a)
crustaceans	Daphnia magna	weight	21d	NOEC	=	0.34	mm	т	>98.6	1	Kent, S., Williams, N., Gillings, E., Morris, D.S. 1995 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 112 (EC 2014a)

Proposed CQC (AA-EQS) and AQC (MAC-EQS) for Permethrin



Group	Species	Endpoint	Duration	Parameter		value (ug/L)	Analytics	Exposure	Purity (%)	Validity	Reference
crustaceans	Daphnia magna	number of offspring	21d	NOEC	=	0.039	mm	Т	>98.6	1	Kent, S., Williams, N., Gillings, E., Morris, D.S. 1995 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 112 (EC 2014a)
crustaceans	Daphnia magna	number of offspring	21d	NOEC	=	0.0047 0.0135	m-gm	R	93.61	1	Schäfers, C. 2006 cited in BP approval data PT08 (2011) 8767_ApplicantA_Data_012 p. 263 (EC 2014a) Geometric mean
crustaceans	Daphnia magna	growth	21d	NOEC	>	0.06	m-gm	R	93.61	1	Schäfers, C. 2006 cited in BP approval data PT08 (2011) 8767_ApplicantA_Data_012 p. 263 (EC 2014a)
crustaceans	Daphnia magna	time to first breed	21d	NOEC	>	0.06	m-gm	R	93.61	1	Schäfers, C. 2006 cited in BP approval data PT08 (2011) 8767_ApplicantA_Data_012 p. 263 (EC 2014a)
insects	Brachycentrus americanus	mortality	28d	NOEC	>	0.03	m	т	n.r.	2	Anderson, R. 1982 cited in Sorokin et al. (2012)
insects	Pteronarcys dorsata	mortality	28d	NOEC	=	0.029	m	т	n.r.	1	Anderson, R. 1982 cited in Sorokin et al. (2012)
mollusc	Helisoma trivolvis	mortality	28d	NOEC	>=	0.33	mm	т	92	R2/C2	Spehar <i>et al.</i> (1983)
fish	Danio rerio	survival	35d	NOEC	=	0.41	m-gm	Т	93.61	2	Anonymous 2006 cited in BP approval data PT08 (2011) 8027_ApplicantA_Data_011 p. 249 (EC 2014a)
fish	Danio rerio	length	35d	NOEC	>=	0.8	m-gm	Т	93.61	2	Anonymous 2006 cited in BP approval data PT08 (2011) 8027_ApplicantA_Data_011 p. 249 (EC 2014a)
fish	Danio rerio	weight	35d	NOEC	>=	0.8	m-gm	Т	93.61	2	Anonymous 2006 cited in BP approval data PT08 (2011) 8027_ApplicantA_Data_011 p. 249 (EC 2014a)
fish	Pimephales promelas	hatching rate	28d	NOEC	=	1.4	mm	т	92	2	Spehar, R.L., Tanner, D.K., Nordling, B.R. 1983 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 89
fish	Pimephales promelas	morphology	28d	NOEC	=	1.4	mm	т	92	2	Spehar, R.L., Tanner, D.K., Nordling, B.R. 1983 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 89 (EC 2014a)
fish	Pimephales promelas	survival	28d	NOEC	=	0.66	mm	т	92	2	Spehar, R.L., Tanner, D.K., Nordling, B.R. 1983 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 89 (EC 2014a)
fish	Pimephales promelas	growth rate	28d	NOEC	=	0.66	mm	т	92	2	Spehar, R.L., Tanner, D.K., Nordling, B.R. 1983 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 89 (EC 2014a)
				C	hronic	and subchro	onic saltwater	effect data			
fish	Cyprinodon variegatus	mortality	28d	NOEC	=	10	mm	т	93	2	Hansen, D.J., Goodman, L.R., Moore, J.C., Higdon, P.K. 1983 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 98 (EC 2014a)

Legend

Proposed CQC (AA-EQS) and AQC (MAC-EQS) for Permethrin



* formerly Raphidocelis subcapitata/Selenastrum capricornutum

measured concentrations within +/- 80 % of nominal concentrations, results based on nominal

Chemical analytics

- m based on measured concentrations
- m-gm based on mean measured concentrations (geometric mean)
- mm based on mean measured concentrations
- nom-m based on nominal concentrations

Exposure

- S static
- T flow-through



4.1 Graphic representation of effect data

All data listed in Table 5 have been plotted in Figure 2.

Invertebrates are most sensitive to chronic exposure to permethrin compared to algae and fish. A group-based chronic to acute effects ratio is not presented, as available data is not sufficient. Furthermore, the spread of chronic effect data indicates species-specific sensitivity to permethrin.

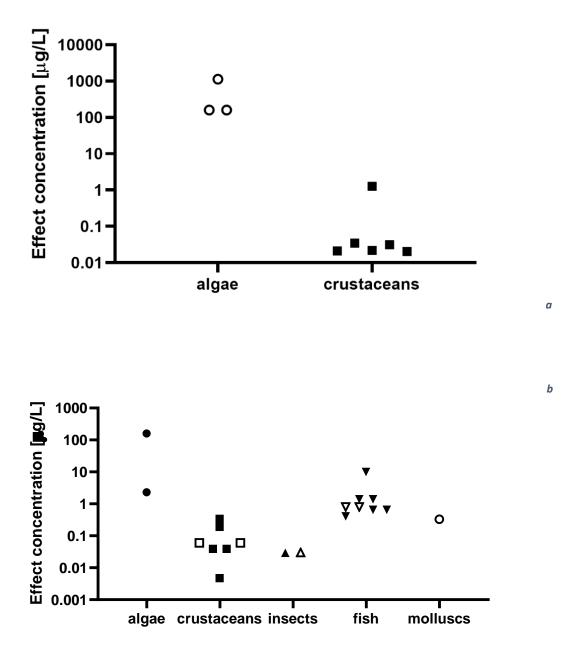


Figure 2 Graphical representation of a) acute and b) chronic effect data from aquatic toxicity tests with permethrin. Open symbols: unbounded data.



4.2 Comparison between marine and freshwater species

As suggested by the EU TGD for EQS (EC 2018b), for statistical comparison of marine and freshwater species, one value per species should be selected, all effect data should be log-transformed, and the two datasets should be compared for significant differences.

Reliable and relevant effect data are only available for freshwater species. Thus, a comparison is not possible.

5 Chronic toxicity

5.1 Derivation of CQC (AA-EQS) using the Assessment Factor (AF) method

The CQC_{AF} (AA-EQS_{AF}) is determined using an assessment factor (AFs) applied to the lowest credible datum from long-term toxicity tests.

The lowest long-term effect datum available for permethrin is 0.0135 µg/L, the geometric mean of the NOEC for number of offspring in *Daphnia magna* derived in two 21 d exposure studies (Schäfers (2006), Kent (1995)).

Schäfers (2006) reported a NOEC of 0.0047 μ g/L (Table 5) in the BP approval data and is listed in the list of endpoints for authorisation of permethrin as biocide (EC 2014a, 2014b). It should be noted that Table A7.4.3.4-7 in the corresponding BP approval data lists 4.3 ng/L as measured concentration. The test was performed according to OECD 211 (1998). Test solutions were measured once per week at test solution renewal for permethrin concentrations. Geometric means of the initial and aged permethrin concentrations were 38-51 % of nominal concentrations at higher concentrations. At a nominal concentration of 3 ng/L, 160 % permethrin were measured at the start, 56 % at the end with a geometric mean of 94 %. Effect concentrations are based on geometric means of measured permethrin concentrations.

An equivalent study by Kent (1995) reported a NOEC of 0.039 μ g/L (Table 5) in the BP approval data. The test was performed according to ASTM "Standard guide for conducting Daphnia magna life cycle toxicity tests" with ¹⁴C labelled permethrin (phenyl label) in a flow-through system. Test concentrations were measured weekly and were between 80 – 93 % of the start solution at the beginning of the experiment and between 87 – 91 % at the end of the experiment. Absolute concentrations were around 50 % of the nominal concentrations throughout the experiment. Effect concentrations are based on mean measured concentrations.



 Table 6 Most sensitive relevant and reliable chronic data summarized from Table 5.

Group	Species	Duration	Effect concentr ation	Value [µg/L]	Reference				
Basic data									
Algae	Pseudokirchnerella subcapitata	72h	ErC10	2.3	Dorgerloh, M. (2008) cited in BP approval data PT08 (2011) 9013_ApplicantB_Data_009 p. 46 for EC (2014a)				
Crustaceans	Daphnia magna	21d	NOEC	0.0135	Geometric mean				
Fish	Danio rerio	35d	NOEC	0.41	Anonymous (2006) cited in BP approval data PT08 (2011) 8027_ApplicantA_Data_011 p. 249 for EC (2014a)				
Additional da	ta								
Insects	Pteronarcys dorsata	28d	NOEC	0.029	Anderson, R. (1982) cited in Sorokin <i>et al.</i> (2012)				

In case of long term tests (NOEC or EC₁₀) being available for three species representing different living and feeding conditions, the EU TGD for EQS recommends the application of an assessment factor of 10 on the lowest credible datum (Table 11 in EC (2018b)). However, the most sensitive species in the acute dataset is *H. azteca*. No relevant and reliable chronic effect data for *H. azteca* are available for comparison. Only one subchronic NOEC (10 d, motility, listed in Annex I) of 0.00498 µg/L was retrieved (Hasenbein *et al.* 2015) and is similar to the 21 d NOEC in *D. magna*, whereas the associated EC50 is 0.03863 µg/L and similar to the 96 h LC50 for mortality of 0.0312 µg/L. At the same time, this LC50 is 40 times lower than the available 48 h EC50 and LC50 in *D. magna* (immobilisation/mortality).

As the available subchronic effect concentration in *H. azteca* is one order of magnitude lower than the acute effect concentration in *D. magna*, an assessment factor of 50 in combination with the lowest chronic effect concentration is suggested in accordance with the EU TGD for EQS (EC 2018b). This approach is also deemed justified as *H. azteca* seems to be the most sensitive tested species with respect to acute effects of pyrethroids in general (overview in (Giddings *et al.* 2019)).

$$CQC_{AF} (AA - EQS_{AF}) = \frac{lowest \ EC_{10} \ or \ NOEC}{AF}$$
$$CQC_{AF} (AA - EQS_{AF}) = \frac{0.0135 \left(\frac{\mu g}{L}\right)}{50} = 0.00027 \left(\frac{\mu g}{L}\right)$$

According to the EU TGD for EQS, in case of substantial levels of suspended particulate matter in the test system, the effect concentration is regarded as $c_{test water,total}$ and needs to be corrected for OC concentration to yield $c_{water,dissolved}$.

The critical chronic toxicity studies on *D. magna* were performed according to OECD 211 with 1 L of medium containing 30 mL of a food suspension (*Scenedesmus subspicatus* and LiquizellR) of unknown concentration (Schäfers 2006) and according to ASTM Standard guide to conducting Daphnia magna life cycle toxicity tests, feeding conditions not having been described (Kent et al 1995). The resulting OC concentration in both cases is unknown; however, the OECD 211 guideline states that 0.1 and 0.2 mg *C/Daphnia/*day are necessary to meet the validity criteria. With one animal per 50 mL, this corresponds to 2-4 mg/L OC fed every day. The ASTM Standard (E 1193 – 97, published two years after the study by Kent et al 1995) states, «Sufficient food should be provided to ensure an acceptable level of reproduction. » Estimated OC concentrations cannot be derived based on the information available.



 $c_{water,dissolved} = c_{test water,total} x \frac{1}{1 + K_{oc} x TOC_{test result} x 10^{-6}}$

The resulting $c_{water,dissolved}$ is 3.0 ng/L based on $c_{test water,total}$ of 4.7 ng/L, 4 mg/L OC (food source, maximum) and a K_{oc} of 141278 (geometric mean, see section 2.2).

As details on the ASTM protocol were not available, no OC correction can be performed at present. The suggested EQS is thus not corrected for OC concentration.

5.2 Derivation of CQC (AA-EQS) using the species sensitivity distribution (SSD) method

The minimum data requirements recommended for the application of the SSD approach for EQS water derivation is preferably more than 15, but at least 10 NOEC/EC₁₀, from different species covering at least eight taxonomic groups (EC (2018b), p. 43).

In this case, not enough reliable and relevant data are available for applying the SSD approach.

5.3 Determination of CQC (AA-EQS) according to mesocosm/field data

Wurzel *et al.* (2020) quantified drifting and benthic aquatic macroinvertebrates in Spring Creek (Wyoming, USA) before and during the traditional mosquito control season. Spring Creek is a small (5.6 km long, 1.5 m wide) spring-fed urban stream, flowing within the city of Laramie, Wyoming, USA. Permethrin was applied immediately adjacent to the stream on its entire length as an indiscriminate fog via an ultra-low volume fogger on a tank truck throughout the summer. Two sites were sampled, one typically fogged 5 nights a week and one fogged 2 nights per week during the mosquito season (late May– August). Permethrin concentrations were below the detection limit of $0.25 \mu g/L$ at all times. Immediately after spraying, the density of drifting invertebrates was highest independent of the site. A day after treatment, invertebrate drift decreased to near pre-treatment densities at all sites and dates. Biomass of benthic invertebrates declined throughout the spraying period.

Bendis & Relyea (2016) exposed outdoor mesocosm communities with phytoplankton, periphyton, leopard frog (*Lithobates pipiens*) tadpoles and *Daphnia pulex* to 0.5, 1.0, and 2.0 µg/L permethrin. *D. pulex* were taken from a pesticide-exposed pond and from a remote non-exposed pond. Mesocosms were set up in 75-L garbage cans (58.4 cm x 49.5 cm - Rubbermaid BRUTETM) that were filled with approximately 65-L of well water and covered with a 60% shade-cloth lid. Dry leaf litter, rabbit chow and unglazed ceramic tiles were added. Mesocosms were inoculated with pond water after removing zooplankton and invertebrate predators. Tadpoles were allowed to acclimate for 6 days before the first addition of permethrin/control solutions (0.5, 1, 2 µg/L; ethanol). Permethrin/control solutions were re-applied after three weeks. The actual concentration at 2.0 µg/L nominal concentration was 0.1 ug/L and 0.9 µg/L in two independent applications, respectively. The two lower nominal concentrations (0.5 and 1 µg/L) were below the LOD of 1.02 µg/L, thus permethrin was not quantified. Within 53 d, mesocosms treated with nominal concentrations of 1 and 2 µg/L permethrin showed phytoplankton blooms along with lower *D. pulex* abundance and reduced tadpole survival irrespective of the origin of the *D. pulex* cultures.



The two studies indicate that effects on the community level are to be expected below 0.25 μ g/L (LOD) and 0.1 μ g/L (2 μ g/L nominal concentration), respectively. The actual concentration in the stream studied by Wurzel *et al.* (2020) is unknown, as is the actual concentration in the 1 μ g/L treatments of Bendis & Relyea (2016). Both can thus not be used to assess the CQC (AA-EQS) based on the AF method (section 6.1) and measured concentrations.

6 Acute toxicity

6.1 Derivation of AQC (MAC-EQS) using the Assessment Factor (AF) method

The derivation of AQC_{AF} (MAC-EQS_{AF}) is determined using assessment factors (AFs) applied to the lowest credible datum from short-term toxicity tests.

The lowest short-term effect datum available for permethrin is the geometric mean of 0.0251 μ g/L based on five LC₅₀ for mortality of *Hyalella azteca*. A lower LC₅₀ of 0.02 μ g/L for mortality in *Americamysis bahia* (Schimmel *et al.* 1983) was excluded due to the lack of analytical data (Annex I).

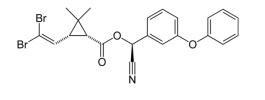
Table 7 Most sensitive relevant and reliable acute data for permethrin summarized from Table 5, estimated values for pyrethroids in fish and crustaceans (logKow 7.427, EpiSuite estimate), and values for permethrin fish rated R4 due to lack of sufficient analytical data (Annex I) in grey.

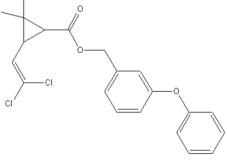
Group	Species	Duration	Effect concentr ation	Value [µg/L]	Reference
Algae	Pseudokirchnerella subcapitata	72h	ErC50	>600	Environment Agency 2008 cited in Sorokin et al. (2012)
Crustaceans	Hyalella azteca	96h	LC50	0.025	rounded geometric mean
Crustaceans	Daphnid	48h	LC50	0.22	Est., EpiSuite v4.11 (ECOSAR v1.11), US EPA (2007)
Fish (freshwater)	Not applicable	96h	LC50	0.354	Est., EpiSuite v4.11 (ECOSAR v1.11), US EPA (2007)
Fish (saltwater)	Not applicable	96h	LC50	0.212	Est., EpiSuite v4.11 (ECOSAR v1.11), US EPA (2007)
Fish	Oncorhynchus clarkii henshawi	96h	LC50	1.6*	Sappington, L.C et al. (2001) cited in Sorokin et al. (2012)
Fish	Menidia menidia	96h	LC50	2.2**	Schimmel <i>et al.</i> (1983)

*only stock concentration measured; ** nominal concentration



The generic assessment factor in case of at least one short-term L(E)C₅₀ from each of three trophic levels of the base set (fish, crustaceans and algae) being available is 100. This factor can be lowered to 10 when acute toxicity data for different species do not have a higher standard deviation than a factor of 3 in both directions or known mode of toxic action and representative species for the most sensitive taxonomic group included in the data set (Table 5 in EC (2018b)). When the base set is not complete, a MAC-QS cannot be derived, however, the base set may be completed with non-testing data e.g. from QSAR modelling (chapter 6.2). Relevant and reliable acute data for fish are not available due to lack of analytical data in most cases (Annex I). Thus, values estimated by ECOSAR/EpiSuite (logKow 7.427, estimated for pyrethroids) have been added to Table 7 along with the lowest acute data for fish from Annex I. The EU TGD for EQS also suggests read-across for structurally similar substances (chapter 6.3). Thus, data from the OZ EQS dossier for the pyrethroid deltamethrin was retrieved. In deltamethrin, the two chloride atoms are replaced by bromine, and it contains a nitrile functional group (Figure 3).





Deltamethrin

Permethrin

Figure 3 Molecular structure of deltamethrin and permethrin

In case of deltamethrin, the base set identified for EQS derivation (Ecotoxcenter 2018) was complete:

- The lowest value for freshwater primary producers was an EC₅₀ of > 0.405 μg/L for Lemna gibba (Banman 2012 zitiert in DRAR 2017, Vol. 3, B.9(AS), S. 197).
- The lowest value for freshwater fish (*Oncorhynchus mykiss*) was an LC_{50} of 0.15 µg/L (Sousa 1990a, DRAR 2017, Vol. 3, B.9(AS), S. 17 (EC 2018a)).
- For crustaceans (*Daphnia magna*), a geometric mean of 0.0429 μg/L was calculated from two EC₅₀ (Ecotoxcenter 2018).

However, the critical datum for deltamethrin EQS derivation (Ecotoxcenter 2018) was the experimental LC_{50} for *Hyalella azteca* of 0.00017 µg/L (Bradley 2013, cited in DRAR 2018, Vol. 3, B.9(AS), S. 84). In summary, algae were the least sensitive towards deltamethrin, followed by fish and crustaceans with *Hyalella azteca* being the most sensitive organism.

In comparison to deltamethrin, the experimental data and data estimated by ECOSAR/EpiSuite for permethrin indicate the same organisms sensitivities with algae being the least and *Hyalella azteca* being the most sensitive organisms.

Against this background, we conclude that it can be assumed that *Hyalella azteca* represents the most sensitive group of organisms and that a MAC-EQS may be derived as estimated acute values from fish and evidence from the pyrethroid deltamethrin compensate for the lack of experimental data for fish.



The suggested assessment factor is 10 based on the requirements listed above.

$$AQC_{AF} (MAC - EQS_{AF}) = \frac{lowest EC_{50} \text{ or } EC_{10}}{AF}$$
$$AQC_{AF} (MAC - EQS_{AF}) = \frac{0.025 \left(\frac{\mu g}{L}\right)}{10} = 0.0025 \left(\frac{\mu g}{L}\right)$$

The critical acute toxicity study on *H. azteca* was performed according to US EPA standards (not further defined) without feeding and sediment Muggelberg *et al.* (2017), thus OC concentrations can be assumed to having been negligible. In this case, "the concentration [of the test substances] is assumed to be fully dissolved" (EC 2018b) and the derived AQC (MAC-EQS) does not need to be corrected for OC concentration in the test system.

The application of an AF of 10 to the lowest credible acute datum results in a MAC-EQS_{AF} = $0.0025 \ \mu g/L$.

6.2 Derivation of AQC (MAC-EQS) using the species sensitivity distribution (SSD) method

The minimum data requirements recommended for the application of the SSD approach for EQS water derivation is preferably more than 15, but at least 10 LC/EC_{50} , from different species covering at least eight taxonomic groups (EC (2018b), p. 56).

In this case, not enough data are available for applying the SSD approach.

6.3 Derivation of MAC-EQS according to mesocosm/field data

No field or mesocosm studies that provide acute effect concentrations of permethrin are available, thus, no AQC (MAC-EQS) based on field data or mesocosm data has been derived.

7 Derivation of a biota standard to protect wildlife from secondary poisoning (QS_{biota, sec pois, fw})

Based on the reported BCF/BAF and logKow values for permethrin, a QS_{biota, sec pois, fw} needs to be derived (see section 2.3).

A relevant food chain for the transfer of permethrin in Swiss surface waters would be

(1) Algae – invertebrate (– fish) – fish/mammal/bird

The EU TGD for EQS states that the "food item that will determine the final value for the quality standard in biota is not only dependent on the energy contents of the food items, but also on the bioaccumulation characteristics of the substance through the food chain." Thus, a "critical food item" needs to be identified based on these properties.



One study on potential biomagnification of permethrin is available (Muggelberg *et al.* 2017). The authors reported lower levels of permethrin in fathead minnow fed with permethrin exposed *H. azteca* over 4 d. In this study, there was no indication of biomagnification, on the contrary, the concentration in fish was lower than in *H. azteca* which could indicate biodilution (EC 2018b).

The authors of the EU EQS Dossier concluded that "due to its rapid metabolism and elimination from the body within a short period of time, the occurrence of biomagnification is considered unlikely" (Sorokin *et al.* 2012). The EU TGD for EQS further states that "For such substances [that are subject to biodilution], the EQS should not be expressed in fish but in invertebrates. Transfer is thus associated with a trophic magnification factor (TMF) of 1 as no experimental TMF are available.

Against this background, the critical food item is selected based on the highest reported energynormalised concentration of permethrin. The highest BAF in aquatic invertebrates was reported for the mollusc *Crassostrea virginica*, with a 28 d steady state BCF of 1900 (see section 2.3).

Table 8 lists mammalian and avian oral toxicity data relevant for the assessment of secondary poisoning. Effect data for wildlife species was not available, thus, the assessment is limited to laboratory test species. Only one study in birds was identified which reported a 28d-NOEL for reproduction in hens (40 mg/kg). The original publication was not available, thus, the statement that the NOEL appeared to be unbounded (WHO (1990) cited in Sorokin *et al.* (2012)) cannot be specified. The avian acute effect concentrations reported in Sorokin *et al.* (2012) are likewise unbounded (LD50 \geq 3,000 mg/kg bw for acute single oral dosage and \geq 5,000 mg/kg diet for dietary exposure, WHO (1990)). Based on these three data points, birds seem to tolerate comparatively high concentrations of permethrin.

For mammals, the lowest NOECs were determined in rat and dog, both at 5 mg/kg bw/day. This corresponds to a NOEC of 100 mg/kg diet in rat, however, information on neither the type of food nor daily energy intake is provided in WHO (1990). Dogs were fed gel capsules containing permethrin and were fed with plain food independently and only on working days.

For the derivation of a QS_{biota, sec pois, fw}, the NOEC of 100 mg/kg diet in rats is selected. The diet concentration is assumed to be based on wet weight. For normalization of permethrin concentration in food to energy content, a standard energy content of 15.1 kJ/g_{dw} and moisture fraction of 8 % are assumed (see Table 8, EC (2018b)).

 $c_{energy normalized} \left[\frac{mg}{kJ} \right] = \frac{c_{diet} \left[\frac{mg}{kgfw} \right]}{energy content_{diet,dwx} (1-moisture fraction_{diet})}$

This results in an energy content normalized concentration of permethrin of 0.0072 mg/kJ.

In order to convert the derived endpoint to the permethrin concentration in the critical food item, the following formula is used:

$$c_{food \; item} \left[\frac{mg}{kg_{ww}} \right] = c_{energy\; nomralized} \left[\frac{mg}{kJ} \right] x \; energy\; content_{food\; item,dw} x \; (1 - moisture\; fraction_{food\; item}) = c_{energy\; nomralized} \left[\frac{mg}{kJ} \right] x \; energy\; content_{food\; item,dw} x \; (1 - moisture\; fraction_{food\; item}) = c_{energy\; nomralized} \left[\frac{mg}{kJ} \right] x \; energy\; content_{food\; item,dw} x \; (1 - moisture\; fraction_{food\; item}) = c_{energy\; nomralized} \left[\frac{mg}{kJ} \right] x \; energy\; content_{food\; item,dw} x \; (1 - moisture\; fraction_{food\; item})$$

According to Table 7 of EU TGD for EQS, standard moisture content and energy content of bivalves are 92 % and 19 kJ/ g_{dw} , respectively.



The resulting permethrin concentration in mussels is 10.94 mg/kg_{ww}. Assuming a BAF of 1900 and a steady state distribution of permethrin between water and organism, the corresponding concentration of permethrin in water is $5.76 \mu g/L$.

According to Table 10 EU TGD for EQS, an assessment factor of 10 should be applied to an effect concentration based on the lowest long-term datum available. The suggested assessment factor is thus 10 in accordance with EU TGD for EQS:

 $QS_{\text{biota,sec pois,fw}} = \frac{10.94 \text{ mg/kg}_{\text{ww}}}{10} \text{ or } QS_{\text{biota,sec pois,fw}} = \frac{5.76 \text{ } \mu\text{g/L}}{10}$

The application of an AF of 10 to the lowest credible chronic datum results in a $QS_{Biota, sec pois, fw} = 1.094$ mg/kg_{ww} or **0.576 µg/L**.



Table 8 Mammalian and avian oral toxicity data relevant for the assessment of secondary poisoning

Species	Exposure	Duration	Endpoint	Effect concentration	Comment	Reference
Long-term toxicity to	mammals		-	·		
Rattus norvegicus (Long-Evans)	oral	2 y	NOEL LOEL	 5 mg/kg bw/day ≈ 100 mg/kg diet 25 mg/kg bw/day ≈ 500 mg/kg diet 	60 males and 60 females per group, diet dose levels of 0, 20, 100 or 500 mg/kg bw/day assessed for mortality or adverse effects on growth, food consumption or behaviour	Unpublished reports to WHO (1990) cited in Sorokin <i>et al.</i> (2012)
Rattus norvegicus (Wistar)	oral	90 d, 36 d recovery	LO(A)EL NO(A)EL	mg/kg diet 355 mg/kg bw/day 175 mg/kg bw/day	18 male and 18 female weanling rats per group Diet dose levels of 0, 200, 600, 2000 and 4000 mg/kg bw/day 10 male and 10 female animals were sacrificed on day 90, the remainder was offered untreated diet for another 36 days. LOAEL based on hypersensitivity, slight transient leucopoenia, slight but significant increase in liver weight, reduction in bodyweight gain in males	Bayer/Sumitomo cited in 7262_ApplicantB_Data_003 to EC (2014b) Reliability: 2 Acceptable: yes
Rattus norvegicus (Wistar)	oral	104 w	LO(A)EL NO(A)EL	50 mg/kg bw/day 10 mg/kg bw/day	10 animals per group (male and female) Diet dose levels of 0, 10, 50, 250 mg/kg bw/day LO(A)EL based on histopathological evidence of hepatic work hypertrophy	Bayer/Sumitomo cited in 7262_ApplicantB_Data_003 to EC (2014b) Reliability: 2 Acceptable: yes
Rattus norvegicus	oral	104 w	LO(A)EL NO(A)EL	125 mg/kg bw/day 50 mg/kg bw/day	96 animals per group Diet dose levels of 0, 25, 50, 125 mg/kg bw/day LO(A)EL based on tremors and hypersensitivity to noise during the first 2 weeks	Ishmael and Litchfield (1988) cited in 7262_ApplicantB_Data_003 to EC (2014b) Reliability: 2 Acceptable: yes
Mus musculus	oral	98 w	LO(A)EL NO(A)EL	380 mg/kg bw/day 150 mg/kg bw/day	100 animals per group Diet dose levels of 0, 38, 150, 380 mg/kg bw/day LO(A)EL based on decrease body weight gain	Ishmael and Litchfield (1988) cited in 7262_ApplicantB_Data_003 to EC (2014b) Reliability: 2 Acceptable: yes
Canis familiaris (Beagle)	oral	180 d	LO(A)EL NO(A)EL	50 mg/kg bw/day 10 mg/kg bw/day	8 animals per group (male and female) Diet dose levels of 0, 10, 50, 250 mg/kg bw/day LO(A)EL based on bilirubin levels and liver weight according to RMS conclusion.	Bayer/Sumitomo cited in 7262_ApplicantB_Data_003 to EC (2014b) Reliability: 2 Acceptable: yes
Canis familiaris	oral	52 w	LO(A)EL	100 mg/kg bw/day	6 male and 6 female animals per group	



(Beagle)			NO(A)EL	5 mg/kg bw/day	dose levels of 0, 5, 100, 1000 (reduced from 2000 after 2d) mg/kg bw/day, administered as gel capsules LO(A)EL based on liver weight in both sexes, and hepatic cellular swelling.	Sumitomo/Syngenta cited in 7262_ApplicantB_Data_003 to EC (2014b) Reliability: 2 Acceptable: yes
Effects on reproducti	on in mammals	;		·		
Rattus norvegicus (Wistar COBS)	oral	(three- generation study)	NOAEL	180 mg/kg bw/day	20 male and 20 female rats per group diet dose levels of 0, 5, 30 and 180 mg/kg bw/day during growth, mating, gestation, parturition and lactation for three generations, each with two litters. Foetal toxicity and teratogenicity were assessed in the second pregnancy of the F2 generation.	Unpublished report to WHO (1990) cited in Sorokin <i>et al.</i> (2012) and Bayer/Sumitomo cited in 7537_ApplicantB_Data_005 to EC (2014b) Reliability: 2 Acceptable: yes
<i>Oryctolagus cuniculus</i> (New Zealand White)	oral	Day 6-18 post mating, 11 days post exposure period	LO(A)EL NO(A)EL	>400 mg/kg bw/day 400 mg/kg bw/day	diet dose levels (number of animals per group) of 0 (19), 100 (18), 200 (24), 400 (24) mg/kg bw/day LO(A)EL based on maternal and embryotoxic/teratogenic effects	Bayer/Sumitomo cited in 7537_ApplicantB_Data_005 to EC (2014b) Reliability: 2 Acceptable: yes
Effects on reproducti	on of birds					
Hen	oral	28 d	NOAEL	40 mg/kg (apparently unbounded NOEC)	Group size: unknown Diet dose levels: unknown The inclusion of permethrin at up to 40 mg/kg in the diet of laying hens had no adverse effects on the health of parent birds or on egg production quality, hatchability or the viability of the chicks produced.	Unpublished report to WHO (1990) cited in Sorokin <i>et al.</i> (2012)



8 Toxicity of transformation products

Degradation products of permethrin in environmental compartments are PB alcohol, PBA and DCVA, as mentioned in section 2.1. In mammals, the major metabolites were Cl₂CA in free and glucuronide form, the sulphate conjugate of 4'-hydroxy-3-phenoxybenzoic acid (PBA) in free and conjugate form, and hydroxymethyl-Cl₂CA as a glucuronide conjugate (EC 2014b, Sorokin *et al.* 2012). For mammals and birds, the EU EQS Dossier cites WHO information to conclude, "None of the metabolites of permethrin shows a higher acute (oral or intraperitoneal) toxicity than permethrin itself". With respect to aquatic toxicity, the EU Assessment Report summarizes that metabolites (including DCVA, PBA) are far less toxic than permethrin (EC 2014a, 2014b). The EU EQS Dossier did not consider metabolites in the EQS derivation.

In the meantime, one report comparing the effects on development, locomotion, and innate immune response markers of PB alcohol, PBA and permethrin in *Danio rerio* was published (Xu *et al.* 2018). Effects were reported to be in the same range of concentrations, however, effect concentrations were not presented and raw data were not available from the authors at the time of finalization of this assessment.

In the frame of this assessment, reported metabolites are thus not considered relevant for EQS derivation.

9 Proposed CQC (AA-EQS) and AQC (MAC-EQS) to protect aquatic species

The different QS values for each derivation method included in the EU TGD for EQS are summarized in Table 9. According to the EU TGD for EQS, the most reliable extrapolation method for each substance should be used (EC 2018b).

For highly hydrophobic compounds the final derived EQS (which is an EQS_{water, dissolved}) should be corrected using the default concentration of suspended matter (C_{SPM}) and the partition coefficient to suspended matter ($K_{p,susp}$) (EC 2018). As discussed in section 2.2, correction is indicated for permethrin according to the following formula:

 $EQS_{water,total} = EQS_{water,dissolved} \times (1 + K_{p,susp} \times C_{SPM} x 10^{-6})$

The partition coefficient to suspended matter $(K_{p,susp})$ may be estimated as $K_{oc} \times f_{oc}$ (organic carbon content of suspended matter), with the standard f_{oc} being 0.1. 15 mg/L is regarded as standard concentration of suspended particulate matter (C_{SPM}) in the EU but may be adapted to local conditions. Available Koc values are listed in Appendix II. The corresponding geometric mean is 141278. The resulting factor for OC correction is 1.21.

The EQS corrected based on this value are included in Table 9.



Table 9 QS derived according to the methodologies stipulated in the EU TGD for EQS and their corresponding AF compared to current EC EQS. Concentrations expressed as μ g/L if not otherwise indicated. Proposed EQS are in bold letters/numbers.

	Value	AF	Value
			based on
			K _{oc}
CQC _{AF} (AA-EQS _{AF})	0.00027	50	0.00033
AQC _{AF} (MAC-EQS _{AF})	0.0025	10	0.0030
QSBiota, sec pois, fw	0.576	10	0.698

The QS_{Biota, sec pois, fw} derived based on bioaccumulation in the mollusc *Crassostrea virginica* and a dietary NOEC in rats is several orders of magnitude higher than the derived CQC and AQC. It can be safely assumed that both are protective of secondary poisoning of predators.

As concluded above, OC correction for a standard of 15 mg/L SPM of the derived CQC and AQC results in values about 1.21 times higher. Due to the large variability of Koc and OC in surface waters, the non-corrected **CQC (AA-EQS) of 0.00027 \mug/L and an AQC (MAC-EQS) of 0.0025 \mug/L for permethrin including the application of an AF of 50 and 10, respectively, are thus suggested.**

10 Protection of aquatic organisms and uncertainty analysis

Crustacean species have been reported most sensitive to pyrethroid insecticides. Evidence has accumulated that with respect to acute effects, *H. azteca* is the most sensitive tested organism.

The number of reliable effect data is restricted by the lack of quantification of permethrin in many studies. Consequently, acute data relevant for EQS derivation are only available for algae and crustaceans. Modelled effect data for pyrethroids for fish and experimental data for the pyrethroid deltamethrin were used to justify derivation of an AQS. Based on this evidence it was assumed that *Hyalella azteca* represents the most sensitive group. Acute experimental data with measured concentrations of permethrin would improve the robustness of the derived EQS.

The chronic effect dataset likewise contains only two crustacean species without *H. azteca* being among these. An assessment factor of 50 has thus been suggested. A chronic exposure study with *H. azteca* would be helpful to reduce the current uncertainty of the suggested CQC.

Both suggested QC are expected to be protective of secondary poisoning of predators.

Both suggested QC are lower than the LOQ reported for permethrin (Table 4). Lower LOQ are necessary for the implementation of the suggested QC.



Updates compared to the version of 26.05.2021:

- Section 1.2: inclusion of draft EU EQS values
- Section 4: inclusion of the draft EU EQS dossier for Permethrin and the corresponding SCHEER opinion in the list of references, inclusion of effect concentrations from two new references
- Section 4.1: update of Figure 1a
- Section 6.1: update of the list of critical data and the MAC-EQS
- Section 9: update based on section 6.1
- Section 12: inclusion of four references as mentioned in section 4

Correction of 24.09.2023:

- Last sentence of section 9 corrected using the correct values.





12 References

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Annex I

Test item	Acute or Chronic	Group	Species	Endpoint	Duration	Parameter		Value (µg/L)	Analytics	Exposure	Purity (%)	Note	Validity	Reference
as	acute	algae	Desmodesmus subspicatus (Scenedesmus subspicatus)	cell number	72h	ErC50	>	0.022	m	S	n.r.	F	3	Mead, C. 2003 cited in BP approval data PT08 (2011) 8020_ApplicantA_Data_011 p. 223
as	acute	algae	n.r.	n.r.	96h	EC50	=	68	n.r.	n.r.	n.r.	F	4/C4	Perkow W and Ploss H 2001 cited in Sorokin et al. (2012)
as	acute	algae	Pseudokirchnerella subcapitata	biomass	72h	EbC50	=	497	nom	S	94		R4/C1	Satheesh, V.K. 1997 cited in BP approval data PT08 (2011) 9013_ApplicantB_Data_009 p. 54
as	acute	algae	Pseudokirchnerella subcapitata	growth rate	72h	ErC50	=	2348	nom	S	94		R4/C1	Satheesh, V.K. 1997 cited in BP approval data PT08 (2011) 9013_ApplicantB_Data_009 p. 54
as	acute	algae	Pseudokirchnerella subcapitata	biomass	72h	EbC50	>	160	m	S	>96	2	2/C2	Environment Agency 2008 cited in Sorokin et al. (2012)
as	acute	algae	Pseudokirchnerella subcapitata	growth rate	72h	ErC50	>	160	m	S	>96	2	2/C2	Environment Agency 2008 cited in Sorokin et al. (2012)
as	acute	algae	Pseudokirchnerella subcapitata	cell number	72h	ErC50	>	1130	m-gm	S	97.3	F	1	Dorgerloh, M. 2008 cited in BP approval data PT08 (2011) 9013_ApplicantB_Data_009 p. 46
as	acute	crustaceans	Americamysis bahia	mortality	24h	LC50	=	0.9991	nom	S	>=97.7		R4/C1	Delorenzo et al. (2014)
as	acute	crustaceans	Americamysis bahia	mortality	96h	LC50	=	0.1374	nom	S	>=97.7		R4/C1	Delorenzo <i>et al.</i> (2014)
unclear	acute	crustaceans	Asellus aquaticus	n.r.	n.r.	EC50	=	3	n.r.	n.r.	n.r.		R4/C3	Abram, F.S.H.; Evins, C. and Hobson J.A. 1980 cited in Sorokin et al. (2012)
as	acute	crustaceans	Daphnia carinata	immobilisation	24h	EC50	=	75	nom	S	n.r.		R4/C1	Santharam, K.R.; Thayumanavan, B., Krishnaswamy, S. 1976 cited in Indian J. Ecol. 3 (1) 70-73
as	acute	crustaceans	Daphnia carinata	immobilisation	48h	EC50	=	50	nom	S	n.r.		R4/C1	Santharam, K.R.; Thayumanavan, B., Krishnaswamy, S. 1976 cited in Indian J. Ecol. 3 (1) 70-73
as	acute	crustaceans	Daphnia magna	immobilisation	48h	EC50	=	25000	nom	S	99.9		R4/C1	Forbis, A.D., Burgess, D. 1984 cited in BP approval data PT08 (2011) 9013_ApplicantB_Data_009 p. 39



Test item	Acute or Chronic	Group	Species	Endpoint	Duration	Parameter		Value (µg/L)	Analytics	Exposure	Purity (%)	Note	Validity	Reference
as	acute	crustaceans	Daphnia magna	immobilisation	24h	EC50	=	20	nom-m	S	92.5	F	3	Sharma, V.G.S 1998 cited in BP approval data PT08 (2011) 8020_ApplicantA_Data_011 p. 213
as	acute	crustaceans	Daphnia magna	immobilisation	48h	EC50	=	7.2	n.r.	S	95.7		R4/C1	US EPA (1992)
as	acute	crustaceans	Daphnia magna	immobilisation	48h	EC50	=	0.6	n.r.	S	98.7		R4/C3	US EPA (1992)
as	acute	crustaceans	Daphnia magna	immobilisation	48h	EC50	=	0.32	n.r.	S	n.r.		R4/C1	US EPA (1992)
as	acute	crustaceans	Daphnia magna	immobilisation	96h	EC50	=	0.039	n.r.	S	95.7		R4/C1	US EPA (1992)
as	acute	crustaceans	Daphnia magna	immobilisation	48h	EC50	=	1.27	mm	S	94.5	F	2	Thompson, R.S., and Williams, T.D. 1978 cited in BP approval data PT08 (2011) 9013_ApplicantB_Data_009 p. 26
as	acute	crustaceans	Daphnia pulex	mortality	48h	LC50	=	2.75	n.r.	n.r.	n.r.		R4/C1	Sibley, P.K. and Kaushik, N.K. 1991 cited in Sorokin et al. (2012)
as	acute	crustaceans	Daphnia pulex	mortality	48h	LC50	=	7.45	n.r.	n.r.	n.r.		R4/C1	Sibley, P.K. and Kaushik, N.K. 1991 cited in Sorokin et al. (2012)
as	acute	crustaceans	Daphnia pulex	mortality	48h	LC50	=	13.1	n.r.	n.r.	n.r.		R4/C1	Sibley, P.K. and Kaushik, N.K. 1991 cited in Sorokin et al. (2012)
as	acute	crustaceans	Echinogammarus tacapensis	mortality	48h	LC50	=	13.88	nom	S	n.r.		R4/C1	Touaylia <i>et al.</i> (2018)
as	acute	crustaceans	Echinogammarus tacapensis	mortality	72h	LC50	=	8.974	nom	S	n.r.		R4/C1	Touaylia <i>et al.</i> (2018)
as	acute	crustaceans	Echinogammarus tacapensis	mortality	96h	LC50	=	4.259	nom	S	n.r.		R4/C1	Touaylia <i>et al.</i> (2018)
as	acute	crustaceans	Gammarus pulex	mortality	96h	LC50	=	0.34	n.r.	n.r.	n.r.		R4/C4	Maddock, B.G. 1979 cited in Sorokin et al. (2012)
as	acute	crustaceans	Hyalella azteca	survival	1h	EC50	>	2.7	nom-m	S	98		R3/C3	Pedersen <i>et al.</i> (2013)
as	acute	crustaceans	Hyalella azteca	mortality	96h	LC50	=	0.0312	mm	S	100		R1/C1	Muggelberg et al. (2017)
as	acute	crustaceans	Hyalella azteca, pyrethroid-resistant	mortality	96h	LC50	=	1.67	mm	S	100		R1/C3	Muggelberg <i>et al.</i> (2017)
as	acute	crustaceans	Hyalella azteca field caught	mortality	96h	LC50	=	0.045	nom-m	S	98		R2/C4	Heim <i>et al.</i> (2018)
as	acute	crustaceans	Hyalella azteca	mortality	96h	LC50	=	0.0312	nom-m	S	98	7	R2/C1	Heim <i>et al.</i> (2018)
as	acute	crustaceans	Hyalella azteca	mortality	96h	LC50	=	0.0346	nom-m	S	98		R2/C1	Heim <i>et al.</i> (2018)
as	acute	crustaceans	Hyalella azteca, pyrethroid-resistant	mortality	96h	LC50	=	1.144	nom-m	S	98		R2/C3	Heim <i>et al.</i> (2018)



Test item	Acute or Chronic	Group	Species	Endpoint	Duration	Parameter		Value (µg/L)	Analytics	Exposure	Purity (%)	Note	Validity	Reference
as	acute	crustaceans	Hyalella azteca, pyrethroid-resistant	mortality	96h	LC50	=	1.668	nom-m	S	98		R2/C3	Heim <i>et al.</i> (2018)
as	acute	crustaceans	Hyalella azteca, pyrethroid-resistant	mortality	96h	LC50	=	3.310	nom-m	S	98		R2/C3	Heim <i>et al.</i> (2018)
as	acute	crustaceans	Hyalella azteca, pyrethroid-resistant	mortality	96h	LC50	=	1.803	nom-m	S	98		R2/C3	Heim <i>et al.</i> (2018)
as	acute	crustaceans	Hyalella azteca	mortality	96h	LC50	=	0.02093	mm	S	98.1		R2/C1	Sever et al. (2020)
as	acute	crustaceans	Hyalella azteca	mortality	96h	LC50	=	0.02037	mm	S	98.1		R2/C1	Sever et al. (2020)
as	acute	crustaceans	Hyalella azteca	mortality	96h	LC50	=	0.02172	mm	S	98.1		R2/C1	Sever et al. (2020)
as	acute	crustaceans	Hyalella azteca, pyrethroid-resistant	mortality	96h	LC50	=	1.399	mm	S	98.1		R2/C3	Sever <i>et al.</i> (2020)
as	acute	crustaceans	Hyalella azteca, pyrethroid-resistant	mortality	96h	LC50	=	1.782	mm	S	98.1		R2/C3	Sever <i>et al.</i> (2020)
as	acute	crustaceans	Hyalella azteca hybrid	mortality	96h	LC50	=	0.01774	mm	S	98.1		R3/C3	Sever <i>et al.</i> (2020)
as	acute	crustaceans	Hyalella azteca hybrid	mortality	96h	LC50	=	0.0265	mm	S	98.1		R3/C3	Sever <i>et al.</i> (2020)
as	acute	crustaceans	Palaemonetes pugio	mortality (larvae)	24h	LC50	=	0.17573	nom	S	>=97.7		R4/C1	DeLorenzo et al. (2012)
as	acute	crustaceans	Palaemonetes pugio	mortality (adult/parent)	24h	LC50	=	0.1127	nom	S	>=97.7		R4/C1	DeLorenzo et al. (2012)
as	acute	crustaceans	Palaemonetes pugio	mortality (larvae)	96h	LC50	=	0.05	nom	S	>=97.7		R4/C1	DeLorenzo et al. (2012)
as	acute	crustaceans	Palaemonetes pugio	mortality (adult/parent)	96h	LC50	=	0.27378	nom	S	>=97.7		R4/C1	DeLorenzo et al. (2012)
as	acute	crustaceans	Procambarus alleni	mortality (juvenile)	96h	LC50	=	0.58	nom	S	>98	3	R4/C1	Halstead <i>et al.</i> (2015)
as	acute	crustaceans	Procambarus blandingii	mortality	96h	LC50	=	210	n.r.	Т	89.1		R4/C1	US EPA (1992)
as	acute	insects	Aedes aegypti	mortality	24h	LC50	=	0.45	nom	S	90.8	4	R4/C1	Parsons & Surgeoner (1991)
as	acute	insects	Aedes albopictus	mortality	24h	LC50	=	0.95	n.r.	n.r.	n.r.		R4/C4	Ali, A., Nayar, J.K. and Xue, R.D. 1995 cited in Sorokin et al. (2012)
as	acute	insects	Aedes atropalpus	mortality	24h	LC50	=	6.168	n.r.	n.r.	n.r.		R4/C4	Cilek, J.E.; Craig, G.B. Jr. and Knapp, F.W. 1995 cited in Sorokir et al. (2012)



Test item	Acute or Chronic	Group	Species	Endpoint	Duration	Parameter		Value (µg/L)	Analytics	Exposure	Purity (%)	Note	Validity	Reference
as	acute	insects	Aedes hendersoni	mortality	24h	LC50	=	3.507	n.r.	n.r.	n.r.		R4/C4	Cilek, J.E.; Craig, G.B. Jr. and Knapp, F.W. 1995 cited in Sorokin et al. (2012)
as	acute	insects	Aedes nigromaculis	mortality (larvae)	24h	LC50	=	0.5	nom	S	n.r.		R4/C1	Mulla <i>et al.</i> (1980)
as	acute	insects	Aedes nigromaculis	mortality (pupae)	24h	LC50	=	0.9	nom	S	n.r.		R4/C1	Mulla <i>et al.</i> (1980)
as	acute	insects	Aedes taeniorhynchus	mortality (larvae)	24h	LC50	=	0.5	nom	S	n.r.		R4/C1	Mulla <i>et al.</i> (1980)
as	acute	insects	Aedes taeniorhynchus	mortality (pupae)	24h	LC50	=	1.4	nom	S	n.r.		R4/C1	Mulla, M.S.; Darwazeh, H.A.; Dhillon, M.S. 1980 cited in Mosquito News 40 (1) 6-12
as	acute	insects	Aedes triseriatus	mortality	24h	LC50	=	4.46	n.r.	n.r.	n.r.		R4/C4	Cilek, J.E.; Craig, G.B. Jr. and Knapp, F.W. 1995 cited in Sorokin et al. (2012)
as	acute	insects	Aedes triseriatus	mortality	24h	LC50	=	6.23	n.r.	n.r.	n.r.		R4/C4	Cilek, J.E.; Craig, G.B. Jr. and Knapp, F.W. 1995 cited in Sorokin et al. (2012)
as	acute	insects	Aedes triseriatus	mortality	24h	LC50	=	6.39	n.r.	n.r.	n.r.		R4/C4	Cilek, J.E.; Craig, G.B. Jr. and Knapp, F.W. 1995 cited in Sorokin et al. (2012)
as	acute	insects	Aedes triseriatus	mortality	24h	LC50	=	7.38	n.r.	n.r.	n.r.		R4/C4	Cilek, J.E.; Craig, G.B. Jr. and Knapp, F.W. 1995 cited in Sorokin et al. (2012)
as	acute	insects	Aedes triseriatus	mortality	24h	LC50	=	7.68	n.r.	n.r.	n.r.		R4/C4	Cilek, J.E.; Craig, G.B. Jr. and Knapp, F.W. 1995 cited in Sorokin et al. (2012)
as	acute	insects	Aedes triseriatus	mortality	24h	LC50	=	8.39	n.r.	n.r.	n.r.		R4/C4	Cilek, J.E.; Craig, G.B. Jr. and Knapp, F.W. 1995 cited in Sorokin et al. (2012)
as	acute	insects	Belostoma flumineum	mortality (adult/parent)	96h	LC50	=	6.852	nom	S	>98	3	R4/C1	Halstead <i>et al.</i> (2015)
as	acute	insects	Chironomus riparius	mortality	96h	LC50	=	2.89	nom	S	94		R4/C1	Conrad, A.U., Flemming, R.J., Crane, M. 1999 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 140
as	acute	insects	Chironomus riparius	mortality	72h	LC50	=	4.62	nom	S	94		R4/C1	Conrad, A.U., Flemming, R.J., Crane, M. 1999 cited in BP approval data PT08 (2011) 7539 ApplicantB Data 010 p. 140

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Test item	Acute or Chronic	Group	Species	Endpoint	Duration	Parameter		Value (µg/L)	Analytics	Exposure	Purity (%)	Note	Validity	Reference
as	acute	insects	Chironomus riparius	mortality	48h	LC50	=	9.27	nom	S	94		R4/C1	Conrad, A.U., Flemming, R.J., Crane, M. 1999 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 140
as	acute	insects	Chironomus riparius	mortality	24h	LC50	=	34.4	nom	S	94		R4/C1	Conrad, A.U., Flemming, R.J., Crane, M. 1999 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 140
as	acute	insects	Chironomus thummi	mortality	24h	LC50	=	16.6	n.r.	n.r.	n.r.		R4/C4	Ibrahim, H.; Kheir, R.; Helmi, S.; Lewis, J. and Crane, M. 1998 cited in Sorokin et al. (2012)
as	acute	insects	Culex incidens	mortality (larvae)	24h	LC50	=	3	nom	S	n.r.		R4/C1	Mulla <i>et al.</i> (1980)
as	acute	insects	Culex incidens	mortality (pupae)	24h	LC50	=	0.7	nom	S	n.r.		R4/C1	Mulla <i>et al.</i> (1980)
as	acute	insects	Culex larsalis	mortality (larvae)	24h	LC50	=	2	nom	S	n.r.		R4/C1	Mulla <i>et al.</i> (1980)
as	acute	insects	Culex larsalis	mortality (pupae)	24h	LC50	=	6	nom	S	n.r.		R4/C1	Mulla <i>et al.</i> (1980)
as	acute	insects	Culex quinquefasciatus	mortality (larvae)	24h	LC50	=	1.4	nom	S	n.r.		R4/C1	Mulla <i>et al.</i> (1980)
as	acute	insects	Culex quinquefasciatus	mortality (pupae)	24h	LC50	=	1	nom	S	n.r.		R4/C1	Mulla <i>et al.</i> (1980)
as	acute	insects	Hexagenia bilineata	mortality	96h	LC50	=	0.1	n.r.	Т	97		R4/C1	US EPA (1992)
as	acute	insects	Hexagenia rigida	mortality	24h/8w	NOEC (8w recovery)	ca.	0.07	m	S	n.r.	3	R4/C3	Friesen <i>et al.</i> (1983)
as	acute	insects	Laccophilus minitus	SOD	48h	n.r.	=	0.18	m	S	n.r.		R4/C3	Touaylia <i>et al.</i> (2019)
as	acute	insects	Laccophilus minitus	catalase	48h	n.r.	=	0.18	m	S	n.r.		R4/C3	Touaylia <i>et al.</i> (2019)
as	acute	insects	Laccophilus minitus	AChE	48h	n.r.	=	0.013	m	S	n.r.		R4/C3	Touaylia <i>et al.</i> (2019)
as	acute	insects	Psorophora columbiae	mortality (larvae)	24h	LC50	=	1.5	nom	S	n.r.		R4/C1	Mulla <i>et al.</i> (1980)
as	acute	insects	Psorophora columbiae	mortality (pupae)	24h	LC50	=	2	nom	S	n.r.		R4/C1	Mulla <i>et al.</i> (1980)
as	acute	fish	Catostomus commersoni	mortality	2h	LC50	=	1	m	S	94.4	F	3	Holdway, D.A. and Dixon, D.G. 1988 cited in Sorokin et al. (2012)



commercanityasacutefishCyprimus carplomontality98hLC50=15n.r.Tn.r.R4(C1US EPA (1992)asacutefishDanio reniomontality98hEC50>222.6nom-mS99R3(C1Zhang et al. (2017)asacutefishDanio reniomontality98hEC50>252.6nom-mS99R3(C1Zhang et al. (2017)asacutefishDanio reniomatornation96hEC50>252.6nom-mS99R3(C1Zhang et al. (2017)asacutefishDanio reniomatornation96hEC50>63.16nom-mS99R3(C1Zhang et al. (2017)asacutefishDanio reniomatornation96hEC50>63.16nom-mS99R2(C3Zhang et al. (2017)asacutefishDanio reniomatornation96hEC50>63.16nom-mS99R2(C3Zhang et al. (2017)asacutefishGambusia affinismortality98hLC50=12n.r.n.r.n.r.R4(C4Naqvi. S Shafe 1.asacutefishGambusia affinismortality98hLC50=7.2n.r.S91R4(C1US EPA (1922)asacutefishIctalurus punctatusmortality9	Test item	Acute or Chronic	Group	Species	Endpoint	Duration	Parameter		Value (µg/L)	Analytics	Exposure	Purity (%)	Note	Validity	Reference
asacutefishDanio ranomontally (embyo)24hLC50=108nomSn.r.R4IC1Nunes et al. (2019)asacutefishDanio ranomontally98hEC50>252.6nom-mS99R3IC3Zhang et al. (2017)asacutefishDanio ranohatching rate98hEC50>252.6nom-mS99R3IC3Zhang et al. (2017)asacutefishDanio ranomailormation96hEC50>63.15nom-mS99R3IC3Zhang et al. (2017)asacutefishDanio ranomailormation96hEC50>63.15nom-mS99R3IC3Zhang et al. (2017)asacutefishDanio ranomailormation96hEC50>63.15nom-mS99R3IC3Zhang et al. (2017)asacutefishGambusia atlinismortality96hLC50=6.3n.r.n.r.n.r.R4IC4Bottorik et al.asacutefish <i>Gambusia atlinis</i> mortality96hLC50=7.2n.r.S91R4IC1US EPA (1982)asacutefish <i>Lebonis macrochins</i> mortality96hLC50=0.79n.r.Tn.r.R4IC4Bottorik et al.asacutefishLebonis macrochinsmortality96hLC50=<	as	acute	fish		mortality	2h	LC50	=	10	m	S	94.4	F	3	Holdway, D.A. and Dixon, D.G. 1988 cited in Sorokin et al. (2012)
as acute fish Danio rerio mortality 96h EC50 > 252.6 nom-m S 99 R3C1 Zhang et al. (2017) as acute fish Danio rerio hatching rate 96h EC50 > 252.6 nom-m S 99 R3C3 Zhang et al. (2017) as acute fish Danio rerio malformation 96h EC50 > 63.15 nom-m S 99 R3C3 Zhang et al. (2017) as acute fish Gambusis affinis mortality 96h LC50 = 6.3 n.r. n.r. n.r. R4C4 Raghes, R.and Major cleic in Sorokin et al. as acute fish Gambusis affinis mortality 96h LC50 = 7.2 n.r. n.r. R4C4 Naghes, R.and Major cleic in Sorokin et al. as acute fish Iclalurus punctatus mortality 96h LC50 = 7.2 n.r. S	as	acute	fish	Cyprinus carpio	mortality	96h	LC50	=	15	n.r.	Т	n.r.		R4/C1	US EPA (1992)
as acute fish Danio rerio hatching rate 96h EC50 > 252.6 nom-m S 99 R3/C3 Zhang et al. (2017) as acute fish Danio rerio malformation 96h EC50 > 63.15 nom-m S 99 R2/C3 Zhang et al. (2017) as acute fish Gambusia affinis motality 96h LC50 = 6.3 n.r. n.r. n.r. R4/C4 Bottger, A.; Schäer), B.; Schäer), Schä	as	acute	fish	Danio rerio		24h	LC50	=	108	nom	S	n.r.		R4/C1	Nunes <i>et al.</i> (2019)
asacutefishDanio reniomailformation96hEC50>63.15nom-mS99R2C3Zhang et al. (2017)asacutefishGambusia affinismortality96hLC50=6.3n.r.n.r.n.r.n.r.R4/C4Bdager, A: Schäfer, I- Engelice, R: and Maje cited in Sorolin et al.asacutefishGambusia affinismortality96hLC50=12n.r.n.r.n.r.R4/C4Naque, SA, Mart Haw oted in Sorolin et al.asacutefishIctalurus punctatusmortality96hLC50=7.2n.r.S91R4/C1US EPA (1992)asacutefishIctalurus punctatusmortality96hLC50=1.3.3n.r.S94.4R4/C1US EPA (1992)asacutefishLepornis macrochirusmortality96hLC50=0.79n.r.Tn.r.R4/C1US EPA (1992)asacutefishLepornis macrochirusmortality96hLC50=5.1n.r.S94.4R4/C1US EPA (1992)asacutefishLepornis macrochirusmortality96hLC50=5.1n.r.N.r.R4/C1US EPA (1992)asacutefishLepornis macrochirusmortality96hLC50=5.1n.r.S95.7R4/C1US EPA (1992)asacutefish	as	acute	fish	Danio rerio	mortality	96h	EC50	>	252.6	nom-m	S	99		R3/C1	Zhang <i>et al.</i> (2017)
asacutefishGambusia affinismotality96hLC50=6.3n.r.n.r.n.r.R4/C4Bottger, A.; Schäfer, I Engelke, R. and MajeasacutefishGambusia affinismotality96hLC50=12n.r.n.r.n.r.n.r.R4/C4Bottger, A.; Schäfer, I Engelke, R. and MajeasacutefishIctalurus punctatusmotality96hLC50=7.2n.r.S91R4/C1US EPA (1992)asacutefishIctalurus punctatusmotality96hLC50=5.4n.r.S92.4R4/C1US EPA (1992)asacutefishLepomis macrochirusmotality96hLC50=0.79n.r.Tn.r.R4/C1US EPA (1992)asacutefishLepomis macrochirusmotality96hLC50=0.79n.r.Tn.r.R4/C1US EPA (1992)asacutefishLepomis macrochirusmotality96hLC50=0.79n.r.Tn.r.R4/C1US EPA (1992)asacutefishLepomis macrochirusmotality96hLC50=0.79n.r.S9.7R4/C1US EPA (1992)asacutefishLepomis macrochirusmotality96hLC50=2.52n.r.S9.7R4/C1US EPA (1992)asacutefishLepomis ma	as	acute	fish	Danio rerio	hatching rate	96h	EC50	>	252.6	nom-m	S	99		R3/C3	Zhang <i>et al.</i> (2017)
asacutefishGambusia affinismortality96hLC50=12n.r.n.r.n.r.n.r.R4/C4Nagvi, S.M. and Haw cited in Sorokin et al.asacutefishIctalurus punctatusmortality96hLC50=7.2n.r.S91R4/C1US EPA (1992)asacutefishIctalurus punctatusmortality96hLC50=5.4n.r.S92.4R4/C1US EPA (1992)asacutefishLeponis macrochirusmortality96hLC50=0.79n.r.S92.4R4/C1US EPA (1992)asacutefishLeponis macrochirusmortality96hLC50=0.79n.r.Tn.r.R4/C1US EPA (1992)asacutefishLeponis macrochirusmortality96hLC50=0.79n.r.Tn.r.R4/C1US EPA (1992)asacutefishLeponis macrochirusmortality96hLC50=0.79n.r.S95.7R4/C1US EPA (1992)asacutefishLeponis macrochirusmortality96hLC50=2.52n.r.S95.7R4/C1US EPA (1992)asacutefishLeponis macrochirusmortality96hLC50=6.8n.r.S100R4/C1US EPA (1992)asacutefishLeponis macrochirusmortalit	as	acute	fish	Danio rerio	malformation	96h	EC50	>	63.15	nom-m	S	99		R2/C3	Zhang <i>et al.</i> (2017)
acutefishIctalurus punctatusmortality96hLC50=7.2n.r.S91R4/C1US EPA (192)asacutefishIctalurus punctatusmortality96hLC50=5.4n.r.S92.4R4/C1US EPA (192)asacutefishLepomis macrochirusmortality96hLC50=13.3n.r.S94.4R4/C1US EPA (192)asacutefishLepomis macrochirusmortality96hLC50=0.79n.r.Tn.r.R4/C1US EPA (192)asacutefishLepomis macrochirusmortality96hLC50=0.79n.r.Tn.r.R4/C1US EPA (192)asacutefishLepomis macrochirusmortality96hLC50=0.79n.r.Tn.r.R4/C1US EPA (192)asacutefishLepomis macrochirusmortality96hLC50=0.79n.r.S95.7R4/C1US EPA (192)asacutefishLepomis macrochirusmortality96hLC50=6.8n.r.S95.7R4/C1US EPA (192)asacutefishLepomis macrochirusmortality96hLC50=6.1n.r.S100R4/C1US EPA (192)asacutefishLepomis macrochirusmortality96hLC50=13.5	as	acute	fish	Gambusia affinis	mortality	96h	LC50	=	6.3	n.r.	n.r.	n.r.		R4/C4	Böttger, A.; Schäfer, I.; Ewers, U.; Engelke, R. and Majer, J. 1988 cited in Sorokin et al. (2012)
asacutefishletalurus punctatusmortality96hLC50=5.4n.r.S92.4R4/C1US EPA (192)asacutefishLeponis macrochirusmortality96hLC50=13.3n.r.S94.4R4/C1US EPA (192)asacutefishLeponis macrochirusmortality96hLC50=0.79n.r.Tn.r.R4/C1US EPA (192)asacutefishLeponis macrochirusmortality96hLC50=0.79n.r.Tn.r.R4/C1US EPA (192)asacutefishLeponis macrochirusmortality96hLC50=5.1n.r.n.r.R4/C1US EPA (192)asacutefishLeponis macrochirusmortality96hLC50=2.52n.r.S95.7R4/C1US EPA (192)asacutefishLeponis macrochirusmortality96hLC50=6.8n.r.Sn.r.R4/C1US EPA (192)asacutefishLeponis macrochirusmortality96hLC50=6.1n.r.S100R4/C1US EPA (192)asacutefishLeponis macrochirusmortality96hLC50=13.5n.r.S100R4/C1US EPA (192)asacutefishLeponis macrochirusmortality96hLC50=13.5n.r. </td <td>as</td> <td>acute</td> <td>fish</td> <td>Gambusia affinis</td> <td>mortality</td> <td>96h</td> <td>LC50</td> <td>=</td> <td>12</td> <td>n.r.</td> <td>n.r.</td> <td>n.r.</td> <td></td> <td>R4/C4</td> <td>Naqvi, S.M. and Hawkins, R. 1988 cited in Sorokin et al. (2012)</td>	as	acute	fish	Gambusia affinis	mortality	96h	LC50	=	12	n.r.	n.r.	n.r.		R4/C4	Naqvi, S.M. and Hawkins, R. 1988 cited in Sorokin et al. (2012)
asacutefishLepomis macrochirusmortality96hLC50=13.3n.r.S94.4R4/C1US EPA (192)asacutefishLepomis macrochirusmortality96hLC50=0.79n.r.Tn.r.R4/C1US EPA (192)asacutefishLepomis macrochirusmortality96hLC50=0.79n.r.Tn.r.R4/C1US EPA (192)asacutefishLepomis macrochirusmortality96hLC50=5.1n.r.N.r.R4/C1US EPA (192)asacutefishLepomis macrochirusmortality96hLC50=6.8n.r.S95.7R4/C1US EPA (192)asacutefishLepomis macrochirusmortality96hLC50=6.8n.r.S95.7R4/C1US EPA (192)asacutefishLepomis macrochirusmortality96hLC50=6.1n.r.S100R4/C1US EPA (192)asacutefishLepomis macrochirusmortality96hLC50=13.5n.r.S100R4/C1US EPA (192)asacutefishLepomis macrochirusmortality96hLC50=32n.r.Tn.r.R4/C1US EPA (192)asacutefishLepomis macrochirusmortality96hLC50=13.5n.r. <td>as</td> <td>acute</td> <td>fish</td> <td>lctalurus punctatus</td> <td>mortality</td> <td>96h</td> <td>LC50</td> <td>=</td> <td>7.2</td> <td>n.r.</td> <td>S</td> <td>91</td> <td></td> <td>R4/C1</td> <td>US EPA (1992)</td>	as	acute	fish	lctalurus punctatus	mortality	96h	LC50	=	7.2	n.r.	S	91		R4/C1	US EPA (1992)
asacutefishLepomis macrochirusmortality96hLC50=0.79n.r.Tn.r.R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=5.1n.r.n.r.n.r.R4/C4Böttger, A.: Schäfer, IasacutefishLepomis macrochirusmortality96hLC50=2.52n.r.S95.7R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=6.8n.r.S95.7R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=6.8n.r.S100R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=6.1n.r.S100R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=13.5n.r.S91.4R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=32n.r.Tn.r.R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=13.5n.r.S91.4R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50 <td< td=""><td>as</td><td>acute</td><td>fish</td><td>lctalurus punctatus</td><td>mortality</td><td>96h</td><td>LC50</td><td>=</td><td>5.4</td><td>n.r.</td><td>S</td><td>92.4</td><td></td><td>R4/C1</td><td>US EPA (1992)</td></td<>	as	acute	fish	lctalurus punctatus	mortality	96h	LC50	=	5.4	n.r.	S	92.4		R4/C1	US EPA (1992)
asacutefishLepomis macrochirusmortality96hLC50=5.1n.r.n.r.n.r.n.r.R4/C4Böttger, A.; Schäfer, I Engelke, R. and Maje cited in Sorokin et al.asacutefishLepomis macrochirusmortality96hLC50=2.52n.r.S95.7R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=6.8n.r.Sn.r.R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=6.1n.r.S100R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=13.5n.r.S91.4R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=32n.r.Tn.r.R4/C4US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=32n.r.Tn.r.R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=32n.r.Tn.r.R4/C4US EPA (1992)asacutefishDoncorhynchus clarkiimortality96hLC50=32n.r.Tn.r.R4/C1Sappington et al. (200asacutefish<	as	acute	fish	Lepomis macrochirus	mortality	96h	LC50	=	13.3	n.r.	S	94.4		R4/C1	US EPA (1992)
Engelike, R. and Maje cited in Sorokin et al.asacutefishLepomis macrochirusmortality96hLC50=2.52n.r.S95.7R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=6.8n.r.S100R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=6.1n.r.S100R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=6.1n.r.S91.4R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=32n.r.Tn.r.R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=32n.r.Tn.r.R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=32n.r.Tn.r.R4/C1US EPA (1992)asacutefishDoncorhynchus clarkiimortality96hLC50=32n.r.Tn.r.R4/C1US EPA (1992)asacutefishOncorhynchus clarkiimortality96hLC50=1.6nomS95.21R4/C1Sappington et al. (2002)asacute	as	acute	fish	Lepomis macrochirus	mortality	96h	LC50	=	0.79	n.r.	Т	n.r.		R4/C1	US EPA (1992)
asacutefishLepomis macrochirusmortality96hLC50=6.8n.r.Sn.r.R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=6.1n.r.S100R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=13.5n.r.S91.4R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=32n.r.Tn.r.R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=32n.r.Tn.r.R4/C1US EPA (1992)asacutefishDncorhynchus clarkiimortality96hLC50=32n.r.Tn.r.R4/C1US EPA (1992)asacutefishOncorhynchus clarkiimortality96hLC50=1.6nomS95.21R4/C1Sappington et al. (200asacutefishOncorhynchus gilae apachemortality96hLC50>1nomS95.21R4/C1Sappington et al. (200asacutefishOncorhynchus gilae apachemortality96hLC50>1nomS95.21R4/C1Sappington et al. (200asacutefishOncorhynchus gi	as	acute	fish	Lepomis macrochirus	mortality	96h	LC50	=	5.1	n.r.	n.r.	n.r.		R4/C4	Böttger, A.; Schäfer, I.; Ewers, U.; Engelke, R. and Majer, J. 1988 cited in Sorokin et al. (2012)
asacutefishLepomis macrochirusmortality96hLC50=6.1n.r.S100R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=13.5n.r.S91.4R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=32n.r.Tn.r.R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=32n.r.Tn.r.R4/C1US EPA (1992)asacutefishOncorhynchus clarkiimortality96hLC50=32n.r.Tn.r.R4/C1US EPA (1992)asacutefishOncorhynchus clarkiimortality96hLC50=1.6nomS95.21R4/C1Sappington et al. (200asacutefishOncorhynchus clarkiimortality96hLC50>1nomS95.21R4/C1Sappington et al. (200asacutefishOncorhynchus gilae apachemortality96hLC50>1nomS95.21R4/C1Sappington et al. (200asacutefishOncorhynchus gilae apachemortality96hLC50=1.7nomS95.21R4/C1Sappington et al. (200	as	acute	fish	Lepomis macrochirus	mortality	96h	LC50	=	2.52	n.r.	S	95.7		R4/C1	US EPA (1992)
asacutefishLepomis macrochirusmortality96hLC50=13.5n.r.S91.4R4/C1US EPA (1992)asacutefishLepomis macrochirusmortality96hLC50=32n.r.Tn.r.R4/C4US EPA (1992)asacutefishOncorhynchus clarkiimortality96hLC50=1.6nomS95.21R4/C1Sappington et al. (200)asacutefishOncorhynchus clarkiimortality96hLC50>1nomS95.21R4/C1Sappington et al. (200)asacutefishOncorhynchus clarkiimortality96hLC50>1nomS95.21R4/C1Sappington et al. (200)asacutefishOncorhynchus clarkiimortality96hLC50>1nomS95.21R4/C1Sappington et al. (200)asacutefishOncorhynchus gilae apachemortality96hLC50>1nomS95.21R4/C1Sappington et al. (200)asacutefishOncorhynchus gilae apachemortality96hLC50=1.7nomS95.21R4/C1Sappington et al. (200)	as	acute	fish	Lepomis macrochirus	mortality	96h	LC50	=	6.8	n.r.	S	n.r.		R4/C1	US EPA (1992)
asacutefishLepomis macrochirusmortality96hLC50=32n.r.Tn.r.R4/C4US EPA (1992)asacutefishOncorhynchus clarkii henshawimortality96hLC50=1.6nomS95.21R4/C1Sappington et al. (200)asacutefishOncorhynchus clarkii henshawimortality96hLC50>1nomS95.21R4/C1Sappington et al. (200)asacutefishOncorhynchus clarkii stomiasmortality96hLC50>1nomS95.21R4/C1Sappington et al. (200)asacutefishOncorhynchus gilae apachemortality96hLC50=1.7nomS95.21R4/C1Sappington et al. (200)	as	acute	fish	Lepomis macrochirus	mortality	96h	LC50	=	6.1	n.r.	S	100		R4/C1	US EPA (1992)
asacutefishOncorhynchus clarkii henshawimortality96hLC50=1.6nomS95.21R4/C1Sappington et al. (200asacutefishOncorhynchus clarkii stomiasmortality96hLC50>1nomS95.21R4/C1Sappington et al. (200asacutefishOncorhynchus gilae apachemortality96hLC50>1nomS95.21R4/C1Sappington et al. (200	as	acute	fish	Lepomis macrochirus	mortality	96h	LC50	=	13.5	n.r.	S	91.4		R4/C1	US EPA (1992)
Ass acute fish Oncorhynchus clarkii stomias mortality 96h LC50 > 1 nom S 95.2 1 R4/C1 Sappington et al. (200 Sappington et al.	as	acute	fish	Lepomis macrochirus	mortality	96h	LC50	=	32	n.r.	Т	n.r.		R4/C4	US EPA (1992)
stomias as acute fish <i>Oncorhynchus gilae</i> mortality 96h LC50 = 1.7 nom S 95.2 1 R4/C1 Sappington <i>et al.</i> (200 apache	as	acute	fish		mortality	96h	LC50	=	1.6	nom	S	95.2	1	R4/C1	Sappington <i>et al.</i> (2001)
apache	as	acute	fish		mortality	96h	LC50	>	1	nom	S	95.2	1	R4/C1	Sappington <i>et al.</i> (2001)
as acute fish Oncorhynchus kisutch mortality 96h LC50 = 17 n.r. S n.r. R4/C1 US EPA (1992)	as	acute	fish	, ,	mortality	96h	LC50	=	1.7	nom	S	95.2	1	R4/C1	Sappington <i>et al.</i> (2001)
	as	acute	fish	Oncorhynchus kisutch	mortality	96h	LC50	=	17	n.r.	S	n.r.		R4/C1	US EPA (1992)



Test item	Acute or Chronic	Group	Species	Endpoint	Duration	Parameter		Value (µg/L)	Analytics	Exposure	Purity (%)	Note	Validity	Reference
as	acute	fish	Oncorhynchus mykiss	mortality	96h	LC50	=	5.3	n.r.	S	94		R4/C1	US EPA (1992)
as	acute	fish	Oncorhynchus mykiss	mortality	96h	LC50	=	9.8	n.r.	S	100		R4/C1	US EPA (1992)
as	acute	fish	Oncorhynchus mykiss	mortality	96h	LC50	=	2.1	n.r.	Т	n.r.		R4/C1	US EPA (1992)
as	acute	fish	Oncorhynchus mykiss	mortality	6d	LC50	=	0.014	n.r.	n.r.	n.r.	F	4	Abram, F.S.H.; Evins, C. and Hobson, J.A. 1986 cited in Sorokin et al. (2012)
as	acute	fish	Oncorhynchus mykiss	mortality	96h	LC50	=	5.5	n.r.	n.r.	n.r.		R4/C4	Böttger, A.; Schäfer, I.; Ewers, U.; Engelke, R. and Majer, J. 1988 cited in Sorokin et al. (2012)
as	acute	fish	Oncorhynchus mykiss	mortality	96h	LC50	=	3.3	n.r.	n.r.	95.2	1	R4/C1	Sappington et al. (2001)
as	acute	fish	Oncorhynchus mykiss (Salmo gairdneri)	mortality	96h	LC50	>	14700	nom	S	99.9	F	3	Anonymous 1984 cited in BP approval data PT08 (2011) 9013_ApplicantB_Data_009 p. 19
as	acute	fish	Oncorhynchus mykiss (Salmo gairdneri)	NA	96h	LC50	=	5.13	nom	Т	94.5	6	R4/C1	Anonymous 1978 cited in BP approval data PT08 (2011) 9013_ApplicantB_Data_009 p. 10
as	acute	fish	Pimephales promelas	mortality	96h	LC50	=	3	n.r.	S	n.r.		R4/C1	US EPA (1992)
as	acute	fish	Pimephales promelas	mortality	96h	LC50	=	9.4	n.r.	n.r.	95.2	1	R4/C1	Sappington et al. (2001)
as	acute	fish	Pimephales promelas	mortality	96h	LC50	=	16	n.r.	n.r.	n.r.		R4/C4	Geiger, D.L.; Call, D.J. and Brooke, L.T. 1988 cited in Sorokin et al. (2012)
as	acute	fish	Pimephales promelas	mortality	96h	LC50	=	62.6	n.r.	n.r.	n.r.		R4/C4	Böttger, A.; Schäfer, I.; Ewers, U.; Engelke, R. and Majer, J. 1988 cited in Sorokin et al. (2012)
as	acute	fish	Poecilia reticulata or Cyprinus carpio	mortality	96h	LC50	=	0.145	nom-m	R	94.1		R3/C1	Anonymous 1998 cited in BP approval data PT08 (2011) 8020_ApplicantA_Data_011 p. 204
as	acute	fish	Pseudorasbora parva	mortality (adult/parent)	96h	LC50	=	88.252	n.r.	n.r.	96.4		R4/C4	Saylar (2016)
as	acute	fish	Salmo salar	mortality	96h	LC50	=	1.5	n.r.	S	n.r.		R4/C1	US EPA (1992)
as	acute	fish	Salvelinus fontinalis	mortality	96h	LC50	=	3.9	n.r.	S	n.r.		R4/C1	US EPA (1992)
as	acute	amphibians	Rana catesbeiana	mortality	96h	LC50	=	115	n.r.	n.r.	n.r.		R4/C4	Böttger, A.; Schäfer, I.; Ewers, U.; Engelke, R. and Majer, J. 1988 cited in Sorokin et al. (2012)
as	acute	algae	Skeletonema costatum	n.r.	96h	EC50	=	68	nom	S	n.r.		R4/C1	Walsh, G.E. and Alexander, S.V. 1980 cited in Sorokin et al. (2012)
as	acute	molluscs	Crassostrea gigas	immobilisation	48h	EC50	>	1050	n.r.	S	n.r.		R4/C1	US EPA (1992)



Test item	Acute or Chronic	Group	Species	Endpoint	Duration	Parameter		Value (µg/L)	Analytics	Exposure	Purity (%)	Note	Validity	Reference
as	acute	molluscs	Crassostrea virginica	mortality (larvae)	96h	LC50	>	10000	nom	S	>97		R4/C1	Garcia <i>et al.</i> (2014)
as	acute	molluscs	Crassostrea virginica	mortality (juvenile)	96h	LC50	>	10000	nom	S	>97		R4/C1	Garcia <i>et al.</i> (2014)
as	acute	molluscs	Crassostrea virginica	immobilisation	96h	EC50	>	407	n.r.	Т	95.7		R4/C1	US EPA (1992)
as	acute	molluscs	Crassostrea virginica	immobilisation	96h	EC50	>	536	n.r.	Т	95.7		R4/C1	US EPA (1992)
as	acute	molluscs	Mercenaria mercenaria	mortality (larvae)	96h	LC50	=	7650	nom	S	>97		R4/C1	Garcia <i>et al.</i> (2014)
as	acute	molluscs	Mercenaria mercenaria	mortality (juvenile)	96h	LC50	=	9100	nom	S	>97		R4/C1	Garcia <i>et al.</i> (2014)
as	acute	crustaceans	Americamysis bahia	mortality	96h	LC50	=	0.075	n.r.	S	90.8		R4/C1	US EPA (1992)
as	acute	crustaceans	Americamysis bahia	mortality	96h	LC50	=	0.095	m	S	n.r.	1	R4/C1	Cripe, G.M. 1994 cited in Sorokin et al. (2012)
as	acute	crustaceans	Americamysis bahia	mortality	96h	LC50	=	0.02	nom	Т	93		R4/C1	Schimmel et al. (1983)
as	acute	crustaceans	Crangon septemspinosa	mortality	96h	LC50	=	0.13	n.r.	n.r.	n.r.		R4/C4	McLeese, D.W.; Metcalfe, C.D. and Zitko, V. 1980 cited in Sorok et al. (2012)
as	acute	crustaceans	Penaeus aztecus	mortality	96h	LC50	=	0.34	n.r.	S	89		R4/C1	US EPA (1992)
as	acute	crustaceans	Penaeus duorarum	mortality	96h	LC50	=	0.35	n.r.	n.r.	95.7		R4/C1	US EPA (1992)
as	acute	crustaceans	Penaeus duorarum	mortality	96h	LC50	=	0.17	m	S	n.r.	1	R4/C1	Cripe, G.M. 1994 cited in Soroki et al. (2012)
as	acute	crustaceans	Penaeus duorarum	mortality	96h	LC50	=	0.22	nom	Т	93		R4/C1	Schimmel et al. (1983)
as	acute	crustaceans	Uca pugilator	mortality	96h	LC50	=	2.65	n.r.	S	89		R4/C1	US EPA (1992)
as	acute	crustaceans	Uca pugilator	mortality	96h	LC50	=	2.39	n.r.	S	95.7		R4/C1	US EPA (1992)
as	acute	echinoderms	Paracentrotus lividus	fertilisation rate	30min	IC50	=	0.94	nom	S	94.93	3	R4/C3	Erkmen (2015)
as	acute	echinoderms	Paracentrotus lividus	malformation	72h	IC50	=	0.346	nom	S	94.93	3	R4/C1	Erkmen (2015)
as	acute	fish	Atherinops affinis	mortality	96h	LC50	=	25.3	nom	S	93	1	R4/C1	Hemmer <i>et al.</i> (1992)
as	acute	fish	Cyprinodon bovinus	mortality	96h	LC50	=	21	m	S	95.2	1	R4/C1	Sappington et al. (2001)
as	acute	fish	Cyprinodon variegatus	mortality	96h	LC50	=	7.8	nom	Т	93		R4/C1	Schimmel et al. (1983)
as	acute	fish	Cyprinodon variegatus	mortality	96h	LC50	=	17	m	S	95.2	1	R4/C1	Sappington <i>et al.</i> (2001)
as	acute	fish	Fundulus heteroclitus	mortality (adult/parent)	96h	LC50	=	22.92	nom	S	97	1	R4/C1	Parent <i>et al.</i> (2011)
as	acute	fish	Menidia beryllina	mortality	96h	LC50	=	6.6	n.r.	Т	94.6		R4/C1	US EPA (1992)



Test item	Acute or Chronic	Group	Species	Endpoint	Duration	Parameter		Value (µg/L)	Analytics	Exposure	Purity (%)	Note	Validity	Reference
as	acute	fish	Menidia beryllina	mortality	96h	LC50	=	27.5	nom	S	93	1	R4/C1	Hemmer et al. (1992)
as	acute	fish	Menidia menidia	mortality	96h	LC50	=	2.2	nom	Т	93		R4/C1	Schimmel et al. (1983)
as	acute	fish	Sciaenops ocellatus	mortality (juvenile)	96h	LC50	=	8.53	nom	S	97	1	R4/C1	Parent <i>et al.</i> (2011)
as	chronic	algae	Chlamydomonas reinhardtii	population abundace	72h	EC0	=	4700	nom	S	93	F	3	Gandhi, S.R.; Kulkarni, S.B.; Netrawali, M.S. 1988 cited in Sorokin et al. (2012)
as	chronic	algae	Pseudokirchnerella subcapitata	growth rate	72h	NOEC	=	120	nom	S	94		R4/C1	Satheesh, V.K. 1997 cited in BP approval data PT08 (2011) 9013_ApplicantB_Data_009 p. 54
as	chronic	algae	Pseudokirchnerella subcapitata	growth rate	72h	NOEC	=	160	m	S	>96	2	2/C1	Environment Agency 2008 cited in Sorokin et al. (2012)
as	chronic	algae	Pseudokirchnerella subcapitata	cell number	72h	ErC10	=	2.3	m-gm	S	97.3	F	1	Dorgerloh, M. 2008 cited in BP approval data PT08 (2011) 9013_ApplicantB_Data_009 p. 46
as	chronic	macrophytes	n.r.	mortality	52d	NOEC	>	100	nom	S	94		R4/C1	Conrad, A.U., Flemming, R.J., Crane, M. 1999 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 140
as	chronic	insects	Chironomus riparius	length	52d	NOEC	=	1	nom	S	94		R4/C1	Conrad, A.U., Flemming, R.J., Crane, M. 1999 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 140
as	chronic	insects	Chironomus riparius	emergence	52d	NOEC	=	1	nom	S	94		R4/C1	Conrad, A.U., Flemming, R.J., Crane, M. 1999 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 140
as	chronic	insects	Chironomus riparius	mortality (larvae)	52d	NOEC	=	1	nom	S	94		R4/C1	Conrad, A.U., Flemming, R.J., Crane, M. 1999 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 140
as	chronic	molluscs	Helisoma trivolvis	mortality	28d	NOEC	>	0.33	mm	Т	92		R2/C2	Spehar <i>et al.</i> (1983)
as	chronic	crustaceans	Ceriodaphnia dubia	number of offspring	7d	LOEC	=	0.1	nom-m	S	97	5	R4/C3	Phyu <i>et al.</i> (2013)
as	chronic	crustaceans	Ceriodaphnia dubia	number of offspring	7d	NOEC	=	0.05	nom-m	S	97	5	R4/C1	Phyu <i>et al.</i> (2013)
as	chronic	crustaceans	Ceriodaphnia dubia	number of offspring	7d	NOEC	=	0.05	nom-m	S	97	5	R4/C1	Phyu <i>et al.</i> (2013)
as	chronic	crustaceans	Daphnia magna	growth	21d	NOEC	=	0.039	n.r.	Т	98.6		R4/C1	US EPA (1992)



Test item	Acute or Chronic	Group	Species	Endpoint	Duration	Parameter		Value (µg/L)	Analytics	Exposure	Purity (%)	Note	Validity	Reference
as	chronic	crustaceans	Daphnia magna	hatching rate	21d	NOEC	=	0.039	n.r.	Т	98.6		R4/C1	US EPA (1992)
as	chronic	crustaceans	Daphnia magna	mortality	21d	NOEC	=	0.19	mm	Т	>98.6	F	1	Kent, S., Williams, N., Gillings, E., Morris, D.S. 1995 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 112
as	chronic	crustaceans	Daphnia magna	number hatched	21d	NOEC	=	0.039	mm	Т	>98.6	F	1	Kent, S., Williams, N., Gillings, E., Morris, D.S. 1995 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 112
as	chronic	crustaceans	Daphnia magna	length	21d	NOEC	=	0.039	mm	т	>98.6	F	1	Kent, S., Williams, N., Gillings, E., Morris, D.S. 1995 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 112
as	chronic	crustaceans	Daphnia magna	weight	21d	NOEC	=	0.34	mm	т	>98.6	F	1	Kent, S., Williams, N., Gillings, E., Morris, D.S. 1995 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 112
as	chronic	crustaceans	Daphnia magna	number of offspring	21d	NOEC	=	0.0047	m-gm	R	93.61	F	1	Schäfers, C. 2006 cited in BP approval data PT08 (2011) 9010_ApplicantA_Data_012 p. 263
as	chronic	crustaceans	Daphnia magna	growth	21d	NOEC	>	0.06	m-gm	R	93.61	F	1	Schäfers, C. 2006 cited in BP approval data PT08 (2011) 9010_ApplicantA_Data_012 p. 263
as	chronic	crustaceans	Daphnia magna	time to first breed	21d	NOEC	>	0.06	m-gm	R	93.61	F	1	Schäfers, C. 2006 cited in BP approval data PT08 (2011) 9010_ApplicantA_Data_012 p. 263
as	chronic	crustaceans	Hyalella azteca	survival	10d	NOEC	=	0.0193	m	S	>95.7	3	R4/C3	Hasenbein <i>et al.</i> (2015)
as	chronic	crustaceans	Hyalella azteca	weight	10d	NOEC	<	0.00498	m	S	>95.7	3	R4/C3	Hasenbein <i>et al.</i> (2015)
as	chronic	crustaceans	Procambarus alleni	mortality (juvenile)	10d	LC50	=	0.58	nom	S	>98	3	R4/C3	Halstead <i>et al.</i> (2015)
as	chronic	insects	Belostoma flumineum	mortality (adult/parent)	10d	LC50	=	3.1	nom	S	>98	3	R4/C3	Halstead <i>et al.</i> (2015)
as	chronic	insects	Brachycentrus americanus	immobilisation	28d	NOEC	<	0.03	m	Т	n.r.	F	3	Anderson, R. 1982 cited in Sorokin et al. (2012)
as	chronic	insects	Chironomus dilutus	survival	10d	NOEC	=	0.04498	m	S	>95.7	3	R4/C3	Hasenbein <i>et al.</i> (2015)
as	chronic	insects	Chironomus dilutus	motility	10d	NOEC	=	0.02477	m	S	>95.7	3	R4/C3	Hasenbein <i>et al.</i> (2015)
as	chronic	insects	Chironomus dilutus	weight	10d	NOEC	=	0.01631	m	S	>95.7	3	R4/C3	Hasenbein <i>et al.</i> (2015)



Test item	Acute or Chronic	Group	Species	Endpoint	Duration	Parameter		Value (µg/L)	Analytics	Exposure	Purity (%)	Note	Validity	Reference
as	chronic	insects	Hyalella azteca	motility	10d	NOEC	=	0.00498	m	S	>95.7	3	R4/C3	Hasenbein et al. (2015)
as	chronic	insects	Pteronarcys dorsata	mortality	28d	NOEC	=	0.029	m	Т	n.r.	F	1	Anderson, R. 1982 cited in Sorokin et al. (2012)
as	subchronic	fish	Danio rerio	behaviour	5d	NOEC	>=	10	nom	S	98	4	R4/C2	Awoyemi <i>et al.</i> (2019)
as	subchronic	fish	Danio rerio	multiple endpoints	5d	LOEC	=	0.252	nom	S	98	4	R3/C3	Awoyemi <i>et al.</i> (2019)
as	subchronic	fish	Danio rerio	enzyme(s)	5d	LOEC	=	0.252	nom	S	98	4	R3/C3	Awoyemi <i>et al.</i> (2019)
as	subchronic	fish	Danio rerio	malformation	5d	NOEC	=	1000	nom	S	98	4	R3/C3	Awoyemi <i>et al.</i> (2019)
as	chronic	fish	Danio rerio	survival	35d	NOEC	=	0.41	m-gm	Т	93.61	F	2	Anonymous 2006 cited in BP approval data PT08 (2011) 8020_ApplicantA_Data_011 p. 249
as	chronic	fish	Danio rerio	length	35d	NOEC	>=	0.8	m-gm	т	93.61	F	2	Anonymous 2006 cited in BP approval data PT08 (2011) 8020_ApplicantA_Data_011 p. 24§
as	chronic	fish	Danio rerio	weight	35d	NOEC	>=	0.8	m-gm	т	93.61	F	2	Anonymous 2006 cited in BP approval data PT08 (2011) 8020_ApplicantA_Data_011 p. 249
as	chronic	fish	Danio rerio	malformation	5d	NOEC	=	10	nom	S	98		R4/C2	Awoyemi et al. (2019)
as	chronic	fish	Pimephales promelas	survival	246d	NOEC	=	0.3	n.r.	R	95.7		R4/C1	US EPA (1992)
as	chronic	fish	Pimephales promelas	hatching rate	28d	NOEC	=	1.4	mm	Т	92	F	2	Spehar, R.L., Tanner, D.K., Nordling, B.R. 1983 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 89
as	chronic	fish	Pimephales promelas	morphology	28d	NOEC	=	1.4	mm	Т	92	F	2	Spehar, R.L., Tanner, D.K., Nordling, B.R. 1983 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 89
as	chronic	fish	Pimephales promelas	survival	28d	NOEC	=	0.66	mm	Т	92	F	2	Spehar, R.L., Tanner, D.K., Nordling, B.R. 1983 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 89
as	chronic	fish	Pimephales promelas	growth rate	28d	NOEC	=	0.66	mm	Т	92	F	2	Spehar, R.L., Tanner, D.K., Nordling, B.R. 1983 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 89
as	chronic	molluscs	Crassostrea virginica	mortality (juvenile)	21d	NOEC	=	1250	nom	S	>97		R4/C1	Garcia <i>et al.</i> (2014)



Test item	Acute or Chronic	Group	Species	Endpoint	Duration	Parameter		Value (µg/L)	Analytics	Exposure	Purity (%)	Note	Validity	Reference
as	chronic	molluscs	Mercenaria mercenaria	mortality (juvenile)	21d	NOEC	<	630	nom	S	>97		R4/C1	Garcia <i>et al.</i> (2014)
as	chronic	fish	Cyprinodon variegatus	mortality	28d	NOEC	=	10	mm	Т	93	F	2	Hansen, D.J., Goodman, L.R., Moore, J.C., Higdon, P.K. 1983 cited in BP approval data PT08 (2011) 7539_ApplicantB_Data_010 p. 98
as	NA	algae	Chlorella pyrenoidosa	growth rate	12-14d	EC50	>	100000	nom	S	86.6	F	3	Stratton, G.W. and Corke, C.T. 1982 cited in BP approval data PT08 (2011) 9013_ApplicantB_Data_009 p. 60

Notes

F face value

1 only stock concentration measured

2 measured values were 52 to 83% of nominal concentrations

3 measured values only before start of the exposure

4 only one concentration measured, effect concentrations based on nominal concentrations

5 only three concentrations measured, only at start of exposure

6 sporadic measurements; where measured 40-72 % of nominal concentrations 7 value already reported in (Muggelberg et al. 2017)



Annex II

41700. Sandy Ioam Davis (1991) cited in Laskowski (2002) 18000. Sandy Ioam Davis (1991) cited in Laskowski (2002) 18700. Sandy Ioam Davis (1991) cited in Laskowski (2002) 17300. Clay Ioam Davis (1991) cited in Laskowski (2002) 17300. Clay Ioam Davis (1991) cited in Laskowski (2002) 18400. Clay Ioam Davis (1991) cited in Laskowski (2002) 42200. Sand Davis (1991) cited in Laskowski (2002) 42300. Sandy Ioam Davis (1991) cited in Laskowski (2002) 16600. Silt Ioam Davis (1991) cited in Laskowski (2002) 16600. Sint Ioam Davis (1991) cited in Laskowski (2002) 16600. Sint Ioam Davis (1991) cited in Laskowski (2002) 19600. Sandy Ioam Davis (1991) cited in Laskowski (2002) 19600. Sandy Ioam Davis (1991) cited in Laskowski (2002) 19800. Clay Ioam Davis (1991) cited in Laskowski (2002) 19800. Sandy Ioam Davis (1991) cited in Laskowski (2002) 19800. Clay Ioam Davis (1991) cited in Laskowski (2002) 19800	K _{oc} [L/kg]	Matrix	Reference
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520000	Sandy loam	Hand (2000) cited in Laskowski (2002)
270000	Sandy loam	Hand (2000) cited in Laskowski (2002)
110000	Loamy sand	Hand (2000) cited in Laskowski (2002)
120000	Loamy sand	Hand (2000) cited in Laskowski (2002)
76500	Sand	Davis (1991) cited in Laskowski (2002)
79100	Sand	Davis (1991) cited in Laskowski (2002)
79100	Sand	Davis (1991) cited in Laskowski (2002)
22600	Clay loam	Davis (1991) cited in Laskowski (2002)
21800	Clay loam	Davis (1991) cited in Laskowski (2002)
31600	Sandy loam	Davis (1991) cited in Laskowski (2002)
23100	Sandy loam	Davis (1991) cited in Laskowski (2002)
31700	Sandy loam	Davis (1991) cited in Laskowski (2002)
20700	Silt loam	Davis (1991) cited in Laskowski (2002)
20900	Silt loam	Davis (1991) cited in Laskowski (2002)
21200	Clay loam	Davis (1991) cited in Laskowski (2002)
22900	Sandy loam	Davis (1991) cited in Laskowski (2002)
22500	Sandy loam	Davis (1991) cited in Laskowski (2002)
19900	Silt loam	Davis (1991) cited in Laskowski (2002)
32200	Sandy loam	Davis (1991) cited in Laskowski (2002)
24550	Sediment	Conrad et al. (1999)
139092	Loamy sand, LUFA 2.1	Traub M. (2011) cited in EC (2014b), 7535_ApplicantA_Data_009.pdf p. 152
87432	Loamy sand, LUFA 2.2	Traub M. (2011) cited in EC (2014b), 7535_ApplicantA_Data_009.pdf p. 152
92019	Sandy loam, LUFA 2.3	Traub M. (2011) cited in EC (2014b), 7535_ApplicantA_Data_009.pdf p. 152
13165	Loam, LUFA 2.4	Traub M. (2011) cited in EC (2014b), 7535_ApplicantA_Data_009.pdf p. 152
18309	Clay loam, LUFA 6S	Traub M. (2011) cited in EC (2014b), 7535_ApplicantA_Data_009.pdf p. 152
32420	na	est. with EpiSuite based on log Kow 5.14, US EPA (2007)
141278		Geometric mean