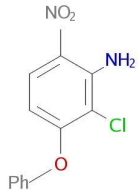
ACLONIFEN

This EQS dossier was prepared by the Sub-Group on Review of the Priority Substances List (under Working Group E of the Common Implementation Strategy for the Water Framework Directive).

The dossier was reviewed by the Scientific Committee on Health and Environmental Risks (SCHER), which commented that the data do not support P (persistence) classification of Aclonifen. The SCHER took a different view from the Sub-Group on how to consider bound residues and on the appropriateness of applying a temperature correction (to 12°C) to laboratory test results. The issue is likely to require further discussion.

1 CHEMICAL IDENTITY

Common name	Aclonifen
Chemical name (IUPAC)	2-chloro-6-nitro-3-phenoxyaniline
Synonym(s)	2-chloro-6-nitro-3-phenoxybenzenamine
Chemical class (when available/relevant)	Diphenylethers
CAS number	74070-46-5
EU number	277-704-1
Molecular formula	$C_{12}H_9ClN_2O_3$
Molecular structure	
Molecular weight (g.mol^{-1})	264.7

2 EXISTING EVALUATIONS AND REGULATORY INFORMATION

Annex III EQS Dir. (2008/105/EC)	Not Included
Existing Substances Reg. (793/93/EC)	Not applicable
Pesticides(91/414/EEC)	Included in Annex I
Biocides (98/8/EC)	Not applicable
PBT substances	Not investigated by ex-EU PBT working group, however, aclonifen should be considered as a candidate PBT. • no decline is observed in sediment in a water/sediment study (see EFSA conclusion List of endpoints*) • BCF > 2000 L/kg (see 4.1) • NOEC < 0.01 mg/L (fish, algae, see 5.1)
POPs (Stockholm convention)	Not investigated.

* http://www.efsa.europa.eu/en/scdocs/doc/149r.pdf

	Aclonifen was discussed under OSPAR and was found to not fulfill the criteria listed for POPs.
Substances of Very High Concern (1907/2006/EC)	No
Other relevant chemical regulation (veterinary products, medicament, ...)	No other relevant information
Endocrine disrupter	Not investigated

3 PROPOSED QUALITY STANDARDS (QS)

3.1 ENVIRONMENTAL QUALITY STANDARD (EQS)

QS_{water_eco} for protection of pelagic organisms is 0.12 µg.l^{-1} for freshwater, respectively 0.012 µg.l^{-1} for marine waters while $QS_{dw, hh}$ for protection of human health *via* consumption of drinking water is 0.1 µg.l^{-1}. According to TGD-EQS (E.C., 2011), $QS_{dw, hh}$ is deemed the "critical QS" for derivation of an Environmental Quality Standard for water bodies which are used for drinking water abstraction while $QS_{water, eco}$ is deemed the "critical QS" for derivation of an Environmental Quality Standard for other water bodies.

Data are available on 3 trophic levels for both acute and chronic ecotoxicity, applying assessment factors of 10 for derivation of QS_{water_eco}, respectively 100 for derivation of MAC-QS. The calculated MAC was lower than the QS_{water_eco} and was set to the value of the QS_{water_eco}. There are no data on marine taxonomic groups that might have reduced the uncertainties associated with extrapolation to the marine ecosystem, i.e. with the greater species diversity in the marine environment and the possibly greater sensitivity of marine species and taxa.

	Value	**Comments**
Proposed AA-EQS for [freshwater] [µg.L^{-1}]	**0.12**	**Critical QS is QS_{water_eco}**
Proposed AA-EQS for [marine water] [µg.L^{-1}]	**0.012**	**See section 7.1**
Proposed MAC-EQS for [freshwater] [µg.L^{-1}]	**0.12**	**See section 7.1**
Proposed MAC-EQS for [marine water] [µg.L^{-1}]	**0.012**	

3.2 SPECIFIC QUALITY STANDARD (QS)

Protection objective[†]	**Unit**	**Value**	**Comments**
Pelagic community (freshwater)	[µg.l^{-1}]	0.12	See section 7.1
Pelagic community (marine water)	[µg.l^{-1}]	0.012	
Benthic community (freshwater)	[µg.kg^{-1} $_{dw}$]	760	e.g. EqP, see section 7.1
Benthic community (marine)	[µg.kg^{-1} $_{dw}$]	76	
Predators (secondary poisoning)	[µg.kg^{-1} $_{biota\ ww}$]	6 667	See section 7.2
	[µg.l^{-1}]	1.1 (freshwaters) 0.5 (marine waters)	
Human health via consumption of fishery products	[µg.kg^{-1} $_{biota\ ww}$]	4 261	See section 7.3
	[µg.l^{-1}]	0.7 (freshwaters) 0.3 (marine waters)	
Human health via consumption of water	[µg.l^{-1}]	0.1	

[†] Please note that as recommended in the Technical Guidance for deriving EQS (E.C., 2011), "EQSs […] are not reported for 'transitional and marine waters', but either for freshwater or marine waters". If justified by substance properties or data available, QS for the different protection objectives are given independently for transitional waters or coastal and territorial waters.

Quality standards for protection of benthic organisms are derived in section 7.1 and reported in the table above for information only as they are not taken into account in the derivation of the EQS (cf. section 7.1 and the TGD-EQS, E.C., 2011).

4 MAJOR USES AND ENVIRONMENTAL EMISSIONS

4.1 USES AND QUANTITIES

"*Aclonifen is a herbicidal active substance belonging to the chemical class of diphenylether for the pre-emergence control of annual grass and broad-leaved weed species in several dicotyledonous crops*" (E.C., 2006). "*Aclonifen is to be used in agriculture and horticulture under field conditions only*" (E.C., 2006).

Summary of representative uses evaluated (aclonifen)*

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hL min - max (l)	water L/ha min - max	kg as/ha min - max (l)		
Sunflower	EU	Bandur	F	monocot and dicot weeds	SC	600 g/L	overall spray	pre-emergence	1	n. a.	0.6 - 1.2	200 - 400	2.4	n. a.	

Extracted from EU-Draft Assessment Report (E.C., 2006), part B.3.3.1.

According to the EU pesticides database (http://ec.europa.eu/sanco_pesticides/public/index.cfm, mars 2010), authorisations are granted at national level in 17 Member states (AT, BE, CY, DE, DK, EE, EL, ES, FI, FR, IE, IT, LT, LU, LV, NL, SE).

Additional information provided by the associated Stakeholder (Bayer Crop Science):

"By far the dominant use area of Aclonifen in European agriculture is France, both regarding the treated area and the applied amount (Table 1). The uses in France account for approximately 70% of the total uses in Europe (73% of the treated area, 66% of the applied amount). Uses in Italy account for approximately 7% of the treated area in Europe, while each of the other countries account for less than 5%.

country	area treated (ha)	amount applied (kg)
France	921,501	706,529
Italy	92,809	47,159
Spain	64,970	54,098
Germany	50,300	94,182
Belgium	37,662	44,954
Denmark	31,713	23,520
Austria	27,720	66,180
Sweden	18,896	14,172
Finland	7,744	10,560
Netherlands	6,900	7,030
Norway	6,286	4,800

Table 1: Use of Aclonifen in different European countries in 2008, by treated agricultural area and by applied amount of compound (from Bayer CropScience data). The countries are sorted by size of the treated area. Aclonifen is also registered in Cyprus, Estonia, Greece, Ireland, Latvia, Lithuania, Luxembourg, but uses there are minor.

From the database of the French Ministry of Agriculture (http://e-phy.agriculture.gouv.fr/, March 2010), 19 formulations are authorized in France. Authorisations are granted applications such as on aromatic herbs, vegetables, but also maize and vines.

4.2 ESTIMATED ENVIRONMENTAL EMISSIONS

No information available

5 ENVIRONMENTAL BEHAVIOUR

5.1 ENVIRONMENTAL DISTRIBUTION

		Master reference
Water solubility ($mg.l^{-1}$)	1.4 at 20°C Not significantly dependent upon pH (range 5-9)	EFSA, 2008
Volatilisation	**Aclonifen is not likely to volatilize from water phase.**	
Vapour pressure (Pa)	$1.6.10^{-5}$ at 20 °C $3.2.10^{-5}$ at 25 °C (calculated)	EFSA, 2008
Henry's Law constant ($Pa.m^3.mol^{-1}$)	3.03 10^{-3} (calculated)	EFSA, 2008
Adsorption	**The mean K_{OC} of 7 126 and the range 5 318 – 10 612 are used for derivation of quality standards. Aclonifen is likely to adsorb on solid particles.**	
Organic carbon – water partition coefficient (K_{OC})	K_{OC} = 5 318 – 10 612 (mean 7 126) log K_{OC} = 3.7 – 4.0 (mean 3.9)	EFSA, 2008
Sediment – water partition coefficient($K_{sed-water}$)	666 – 1328 (mean 892)	*Calculated from K_{OC}*
Bioaccumulation	**The BCF value of 2 896 on fish is used for derivation of quality standards and BMF_1 = 2; BMF_2 = 2** according to TGD-EQS (E.C., 2011)	
Octanol-water partition coefficient (Log Kow)	4.37	EFSA, 2008
BCF (measured)	2896	EFSA, 2008

5.2 ABIOTIC AND BIOTIC DEGRADATIONS

		Master reference
Hydrolysis	After 31d, at 22°C no hydrolysis was observed at pH values of 5, 7 and 9.	EFSA, 2008
Photolysis	Minimum environmental photolytic half-life of aclonifen ranged from 200 h in June-August to 1400h in December.	E.C., 2006
Biodegradation	Aclonifen was not found to be readily biodegradable, with less than 60% of aclonifen degraded after 28 d.	E.C., 2006 EFSA, 2008

	Water/sediment systems: - dissipation half lives (whole system): DT_{50} = 17.3 d, mineralization: 0.75 – 1.32%), bounds residues: 66-77% - dissipation half lives (sediment) DT_{50} = 92 d in one sediment and no decline in the second sediment.	

Degradation in sediment

In the listing of endpoint contained in the EFSA report (EFSA, 2008), the following conclusions are provided from a laboratory study (Lowden and Early, 2000) in two water/sediment systems.

Degradation in water / sediment

Parent	Distribution: in sediment max of 53.4 % at day 7; in water max of 98.3 % at day 0 No metabolites > 5 % at two subsequent measures in water and sediment									
Water / sediment system	pH water	pH sed.	t. °C	DT_{50} - DT_{90} whole sys.	St. (chi^2)	DT_{50} - DT_{90} water	St.	DT_{50} - DT_{90} sed.	St. (chi^2)	Method of calculation
I Manning-tree	6.7	6.8	20	11.2/ 37.9	- 18.9	3.2/- -	- -	92/- -	-.	SFO (non-linear) SFO
II Ongar	7.5	8.4	20	- 17.3/ 57.7	- 13.4	5.6/-	- -	no decl.*	- -	SFO (non-linear) SFO
DT_{50} Geometric mean/median[1)]						4.2/4.4 [1)]		1000** [1)]		SFO (non-linear)

(* no decline, ** 1000 d worst case assumption, [1)] For PECsw and PECsed calculations separated DT_{50} for water and sediment cannot be used, instead worst case $DT_{50\ whole\ sys.}$ of 17.3 d to be used.)

Mineralisation and non extractable residues					
Water / sediment system	pH water phase	pH sed.	Mineralisation x % after n d (end of the study)	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
I Manning-tree	6.7	6.8	0.75 % after 180 d	77 % after 180 d	77 % after 180 d
II Ongar	7.5	8.4	1.32 % after 180 d	66 % after 180 d	66 % after 180 d

Mineralization is negligible at the end of the 180-d study (0.75 – 1.32%) and bound residues represent their maximum at the end of the study (66-77%). In the Manning-tree sediment a DT_{50} of 92 days was estimated whereas in the Ongar sediment no decrease was observed. However, EFSA (2008) indicated that half lives for the water and sediment phases separately were considered unreliable and not representative of the true degradation. For the purpose of the risk assessment conducted under Directive 91/414/EEC, EFSA stated that the worst-case whole-system half-life could be used (DT_{50} = 17.3 d). At the same time, it is not clear how the reported overall half-life can be so much shorter than the half-life in sediment, if the substance is fully partitioning to sediment.

Bayer CropScience provided during the review process a position paper on Persistency (Nicolaus and Schäfer, 2010a) in which additional results from Muttzall (1992) were reported: this study, "*investigated aclonifen in two test systems from The Netherlands (Kromme Rijn, TNO ditch). The overall mean recoveries were 97% and 95% for TNO and Kromme Rijn, respectively. Soon after application, aclonifen residues in the sediment reached 42.5% and 40.5% of the applied radioactivity for TNO and Kromme Rijn, respectively, and dropped to less than 4% until the end of the study after 13 weeks. Mineralization was low (< 0.9%). The majority of the residues became unextractable over time, approaching 85-86% in both systems. Extractable metabolites in the sediment compartment accounted for <1% to 7% of total radioactivity, three of which were also detected as minor metabolites in the water phase*." Using kinetic evaluation model KIM 1.0 resulted in sediment half-lives of 22 and 25 days for TNO and Kromme Rijn, respectively, and 11 and 14 days in the total water/sediment system for the TNO ditch and Kromme Rijn system, respectively.

Neither of the study reports on sediment degradation was available in full to the rapporteur and they were therefore not assessed in detail. According to the BCS position paper referred to above (Nicolaus and Schäfer, 2010a), the additional results from Muttzall confirm EFSA's conclusions regarding the Lowden and Early (2000) study.

Degradation in soils

After the 4th meeting of the Sub-Group on Review, the stakeholder provided a position paper on soil degradation (Nicolaus and Schäfer, 2010b) and the following reports on laboratory and field studies of degradation and dissipation:

- Comparative degradation in sterile and non-sterile soil (Schannè, 1994)
- Anaerobic soil metabolism, "flooded soil" (Schlueter, 1983)
- Laboratory aerobic degradation in soil (Anonymous, 1982, England, 1988)
- Field dissipation studies (Stratmann, 1994, Hoenzelaers and Schulz, 1994, Duncan and Dora, 2003)

The results of the laboratory soil degradation studies (Schanné, 1994; Schlueter, 1983; Anonymous, 1982; England et al, 1988) were summarized as follows in Nicolaus and Schäfer (2010b). The DT_{50} reported here differ from those included in the study reports. They were recalculated by the applicant from the original studies using a single first order kinetic, as recommended by EFSA and according to FOCUS Kinetics (FOCUS, 2006). They correspond to the values agreed by EFSA (EFSA (2008):

Single First Order DT_{50} values of aclonifen under laboratory conditions, without and with normalisation to 20°C and pF2 according to Nicolaus and Schäfer (2010b).

Study	Soil	DT_{50} [days]	Temperature [°C]	Soil moisture	DT_{50} at 20°C and pF 2 [days]
Schannè, 1994	Aldhams House	134	20	60% FC	**93.6**
	Shelley Field	73	20	60% FC	**51.0**
	Westleton SL	95	20	60% FC	**66.4**
	Westleton SL	> 118	20	30% FC	*unreliable due to very low soil moisture (ca. 6 vol%)*[1)]
Schlueter, 1983	Standard Soil 2.3	78	22	40% MWHC	**72.6**
	Arable	32.2	22	40% MWHC	**29.5**
Anonymous, 1982	Standard Soil 2.2 (A)	93.1	22	40% MWHC	**83.7**
	Standard Soil 2.2 (B)	76.4	22	40% MWHC	**68.7**
	Standard Soil 2.3	53.2	22	40% MWHC	**41.9**
England et al., 1988	Westleton LS	222.6	10	50% MWHC	**86.5**
	Stocklands CL	217.7	10	50% MWHC	**61.8**
Geometric mean		**94***			**62.3**
Median DT_{50}		**93.1***			**67.6**
90th percentile					**87.2**

FC, field capacity; MWHC, maximum water holding capacity of soil

*) includes DT_{50} of 118 days although found unreliable during peer review

1) Rapporteur comment: At 30% of field capacity, level of extractable radioactivity declined from 104% at day 0 to 85% at day 118. Organic volatiles and carbon dioxide were detected at a maximum of 0.1% and 0.7%, respectively, and non-extractable residues were < 8.5% of the applied radioactivity. The low degradation (less than 20%) observed at the end of the study does not allow extrapolation to a reliable DT_{50}. The DT_{50} is therefore reported as > 118 days, corresponding to the end of the study, but the actual DT_{50} would be much higher.

The four studies were considered as valid according to peer review by EFSA. For the purpose of risk assessment under Directive 91/414/EEC, the degradation kinetics were analysed according to FOCUS Kinetics (FOCUS, 2006) using single first-order (SFO) kinetics with optimisation of all parameters. The geometric mean of the half-lives from the ten tests (excluding Westleton SL 30% FC) is 62.3 days (normalisation to 20°C and pF2).

However, the degradation of aclonifen in the England et al tests was very slow, and although the Westleton SL 30% test from Schanné was excluded from the above calculation of the geometric mean, the unreliability of the DT_{50} appears to arise from difficulty extrapolating beyond the end of the study (see comment). It should be noted that the same soil (silty sand) at 60% FC showed no degradation of aclonifen applied at a ten-fold lower concentration than that used in the two tests reported in the above table.

The degradation of aclonifen in the Standard soil in the study by Schlueter (1983), was slower under aerobic than under anaerobic conditions. The results in anaerobic conditions were considered however not acceptable due to the low recoveries and the uncertainty associated with potential volatile components, which were not analysed (EFSA, 2008).

In the field dissipation study by Stratmann, the Schwichteler soil demonstrated a DT_{50} of 149 days (non-normalised).

Overall, the studies provide evidence of no or very slow to moderate degradation in soils. As in the water-sediment system, significant formation of non-extractable residues (max. 63.7%) was observed and mineralisation was low (< ca. 5%).

Discussion on persistence

DT_{50} for sediment as presented in the EFSA 2008 report and in Nicolaus and Schäfer (2010a), normalised for Plant Protection Product assessment, are below the trigger value for persistency, with the exception of the Ongar sediment for which no decline of Aclonifen was observed. With regard to soils, the trigger value of 120 days is exceeded under the experimental/field conditions in at least four study tests, i.e. at least one of the Schanne et al tests, the two England et al tests, and the Stratmann test.

Dependence on temperature

Assessment of whether the trigger value for persistency is reached is complicated by the dependence of DT_{50} on temperature. The original Technical Guidance Document to which the Water Framework Directive refers and in which PBT criteria were originally defined, and the REACH guidance (chapter R.7B) indicate that simulation tests are to be performed at an environmentally relevant temperature. In particular, the original EU TGD defines in "*Table 5 Definition of the standard environmental characteristics*" a temperature of 12°C as standard environment (9°C for marine waters). The study by England et al. (1988) was conducted at 10°C, i.e. close to 12°C, and the DT_{50} clearly exceeds the trigger value for persistency. Persistency was also shown in the field study by Stratmann which was apparently conducted at ambient temperatures lower than 20°C.

Normalisation using the Arrhenius equation[‡] from these lower temperatures to higher temperatures should not be done because temperature correction is in the opposite direction from normalisation to environmentally relevant temperatures. Normalisation to 12°C of results from studies performed at the higher temperatures is also not recommended, the outcome will underestimate the DT_{50}. However, if it is done for the studies in the table above and for the sediment studies, the DT50 is found to exceed 120d for 8 of the 10 laboratory degradation studies and for the Manning-tree and Ongar sediments.

Formation and nature of bound residues

Even in studies where the DT_{50} (which REACH defines on the basis of degradation) is less than 120d, concern remains that the formation of bound residues does not in fact represent degradation.

The DT_{50} for soil or sediment presented in the study reports, the EFSA 2008 report, and the BCS position papers (Nicolaus and Schäfer, 2010a, 2010b) referred to above were calculated on the assumption that non-extractable radioactivity was removed from the system. This assumption can translate in a risk assessment to an assumption of low bioavailability and thus low toxicity.

[‡] ($DT_{50}(X\ °C) = DT_{50}(t)\ .\ e^{(0.08.(T-X))}$ where X = 12°C for fresh water, eq. 25 of the TGD). A DT_{50} of 63 days obtained at 20°C corresponds to a DT_{50} of 120 days (P) at 12°C and DT_{50} of 95 days obtained at 20°C corresponds to a DT_{50} of 180 days (vP) at 12°C

The IGE of OSPAR de-selected aclonifen from the OSPAR List of Substances of Possible Concern in 2005. on the grounds that detailed study reports showed that *"aclonifen does not fulfil the P criterion in the aqueous phase, but that radioactivity is highly persistent in the water-sediment system as a whole as unextractable residues in the sediment. The formation of bound residues was shown by an extraction from sterile soil to be the result of binding of metabolites formed by microbial transformation of aclonifen, rather than binding of the parent compound itself. A chironomid toxicity test using a spiked sediment, as has been used in similar cases under the EC Existing Substances Regulation, led to the conclusion that the bound residues did not generate a concern for harm*." This conclusion is consistent with the guidance in a 2005 revised agreement on Cut-Off Values for the Selection Criteria of the OSPAR[§].

However, general concern about the nature of non-extractable residues (NERs) remains. The Pellston PBT/POP workshop (Boethling et al 2009) concluded that "*the state of science is not advanced enough to draw a final conclusion about the nonavailability of NERs* [non extractible residues]." and recommended to distinguish dissipation from degradation. Consistent with such concerns, the biocides and pesticides legislation requires that a substance should not to be included in the positive lists if bound residues exceed 70% of the initial dose after 100 d with a mineralisation rate of less than 5% in 100 d.

In the studies on aclonifen referred to above, significant formation of non-extractable residues was observed in sediments and soils (up to 77-86% in the water-sediment system, and up to 63.7% in soils) and mineralisation was low. If all the NERs are counted as degradation, the DT50s will likely be underestimated.

The stakeholder (Nicolaus and Schäfer 2010b) points to evidence (a study with sterilised soil) that the formation of non-extractable residues is mediated by microorganisms (Schanné, 1994). However, the report does not identify whether the radioactivity associated to bound residues corresponds to the parent product or to metabolites, and not all possible reasons for the results with sterilised soil are investigated.

Conclusion on persistence

Although questions remain about the extent to which the formation of bound residues should count as degradation, the results presented above for at least four soil tests and one sediment test allow the conclusion that, irrespective of the position taken on bound residues, the P criterion is fulfilled. Further, if the other tests referred to had been conducted at the temperature of 12°C advised in Table 5 of the original TGD, many of them too would likely have resulted in DT_{50} values exceeding the trigger value of 120 days.

[§] http://www.ospar.org/documents/DBASE/Publications/p00256_New%20DYNAMEC%20Manual.pdf

6 AQUATIC ENVIRONMENTAL CONCENTRATIONS

6.1 ESTIMATED CONCENTRATIONS

Compartment			Predicted environmental concentration (PEC)	Master reference
Freshwater (µg/l)	Step 1		98.25	E.C., 2006
	Step 2		22.07 – 31.21	
	Step 3	Pond	0.503 – 0.508	
		Stream	8.616 – 12.145	
	Step 4[(1)]	Pond	0.323	
		Stream	1.921 – 2.290	
	-		145	Daginnus *et al.*, 2009[(2)]
Marine waters (coastal and/or transitional)			No data available	
Sediment (µg/kg)	Step 1		5430	E.C., 2006
	Step 2		1160 – 2190	
	Step 3	Pond	2.166 – 4.778	
		Stream	0.268 – 59.681	
	Step 4[(1)]	Pond	1.338 – 1.408	
		Stream	0.06 – 3.258	
Biota (freshwater)			No data available	
Biota (marine)			No data available	
Biota (marine predators)			No data available	

[(1)] Risk assessment concluded to an acceptable risk to aquatic organisms provided that standard measures for risk mitigation are observed, like buffer zones of 10 meters (E.C., 2006). Therefore, PEC values reported here for FOCUS Step 4 correspond to a buffer zone of 10 m.

[(2)] data originated from EU modelling-based prioritisation results.

6.2 MEASURED CONCENTRATIONS

Compartment		Measured environmental concentration (MEC)	Master reference
Freshwater (µg/l)		PEC 1: 0.51 PEC 2: 0.0341	James *et al.*, 2009[(1)]
Marine waters (coastal and/or transitional) (µg/l)		(*0*)	
WWTP effluent (µg/l)		No data available	
Sediment(µg/kg dw)	Sed < 2 mm	PEC 1: - PEC 2: 25	James *et al.*, 2009[(1)]
	Sed 20 µm	(*0*)	
	Sed 63µm	(*0*)	
Biota(µg/kg ww)	Invertebrates	(*0*)	James *et al.*, 2009[(1)]
	Fish	(*0*)	
	Marine predators	No data available	

[(1)] *data originated from EU monitoring data collection*

Stakeholder's comment *(Bayer Crop Science)**:** The aquatic monitoring data come predominantly from France, the main market of Aclonifen in Europe. The data are therefore indicative of the situation in an area of intensive use of Aclonifen. We would also like to point out that the monitoring data refer to the observation period 2000 to 2006. In that period the risk mitigation measures for Aclonifen (buffer zones) that became mandatory with its Annex I listing in 2008 were not yet in place. Since these mitigation measures will significantly reduce losses of Aclonifen to water bodies, it can be expected that measured concentrations of Aclonifen in surface water will further decline in future.*

7 EFFECTS AND QUALITY STANDARDS

"*Aclonifen affects germination of sensitive weeds but does not stop germination. Typical symptoms of susceptible weeds treated with aclonifen are bleaching and chlorosis of young shoot tissue*".

"*Aclonifen is a member of the diphenylether class of herbicides. In spite of a structural similarity with other diphenylether herbicides, aclonifen does not inhibit protoporphyrinogen oxidase nor chlorophyll biosynthesis: Aclonifen is a bleaching compound of unknown mode of action. It causes an accumulation of phytoene but is not an inhibitor of phytoene destaurase.*" (E.C., 2006)

More detailed information is available in the review report itself (E.C., 2006).

"*Aclonifen presents no metabolite with biological activity*" (E.C., 2006).

All (eco)toxicological data reported below are extracted from EU Draft Assessment Report (E.C., 2006, EFSA, 2008) and are considered reliable (Klimisch codes[**] 1 – 2). Data obtained from mesocosm or in water/sediment system (spiked water) were not retained for the purpose of QS derivation.

7.1 ACUTE AND CHRONIC AQUATIC ECOTOXICITY

ACUTE EFFECTS			**Klimisch reliability codes**	**Master reference**
Algae & aquatic plants ($mg.l^{-1}$)	**Freshwater**	***Desmodesmus subspicatus* / 96h** E_bC_{50} = 0.0067; **E_rC_{50} = 0.0069**	**1**	**E.C., 2006**
		Navicula pelliculosa / 72h E_bC_{50} = 0.47; E_rC_{50} = 1.2	1	
		Lemna gibba / 14d E_bC_{50} = 0.006; E_rC_{50} = 0.012	1	
	Marine	No data available		
Invertebrates ($mg.l^{-1}$)	**Freshwater**	*Daphnia magna* / 48h EC_{50} = 1.2	2	E.C., 2006
	Marine	No data available		
	Sediment	No data available		
Fish ($mg.l^{-1}$)	**Freshwater**	*Oncorhynchus mykiss* / 96h EC_{50} = 0.67	1	E.C., 2006
	Marine	No data available		
	Sediment	No data available		
Other taxonomic groups		No data available		

[**] Klimisch *et al.*, 1997

CHRONIC EFFECTS			Klimisch reliability codes	Master reference
Algae & aquatic plants ($mg.l^{-1}$)	**Freshwater**	*Desmodesmus subspicatus* / 96h NOEC = 0.0025	1	E.C., 2006
		***Lemna gibba* / 14d** **NOEC = 0.0012**	1	E.C., 2006
	Marine	No data available		
Invertebrates ($mg.l^{-1}$)	**Freshwater**	*Daphnia magna* / 21d $NOEC_{repro}$ = 0.016	1	E.C., 2006
	Marine	No data available		
	Sediment	*Chironomus riparius* / 28d $NOEC_{emergence,\ dvp}$ = 32 $mg.kg^{-1}_{dw}$	1	E.C., 2006
Fish ($mg.l^{-1}$)	**Freshwater**	*Pimephales promelas* / 35d-ELS $NOEC_{hatch}$ = 0.005	1	E.C., 2006
	Marine	No data available		
	Sediment	No data available		
Other taxonomic groups		No data available		

Proposed refinement

Bayer Crop Science has proposed a refined approach for the derivation of an aquatic QS based *inter alia* on a study (Wenzel, 2006) which has not been included in the EU review reports, but was evaluated by UK Advisory Committee on Pesticides (ACP, 2008). In the study provided, an SSD approach is used restricted to algae and plants species, on the assumption that for this herbicide, algae and aquatic plants are the most sensitive taxonomic groups. The EC_{50} and EC_{10} or NOEC values are reported in the table below:

Table 1 : EC_{50} and EC_{10} (or NOEC*) values of Aclonifen for 9 algae species and one aquatic plant. The test of *P. subcapitata* was conducted with the formulated product Bandur (Aclonifen content: 600 $g.l^{-1}$); but below, the effect concentrations were re-calculated as $\mu g.l^{-1}$ of Aclonifen.

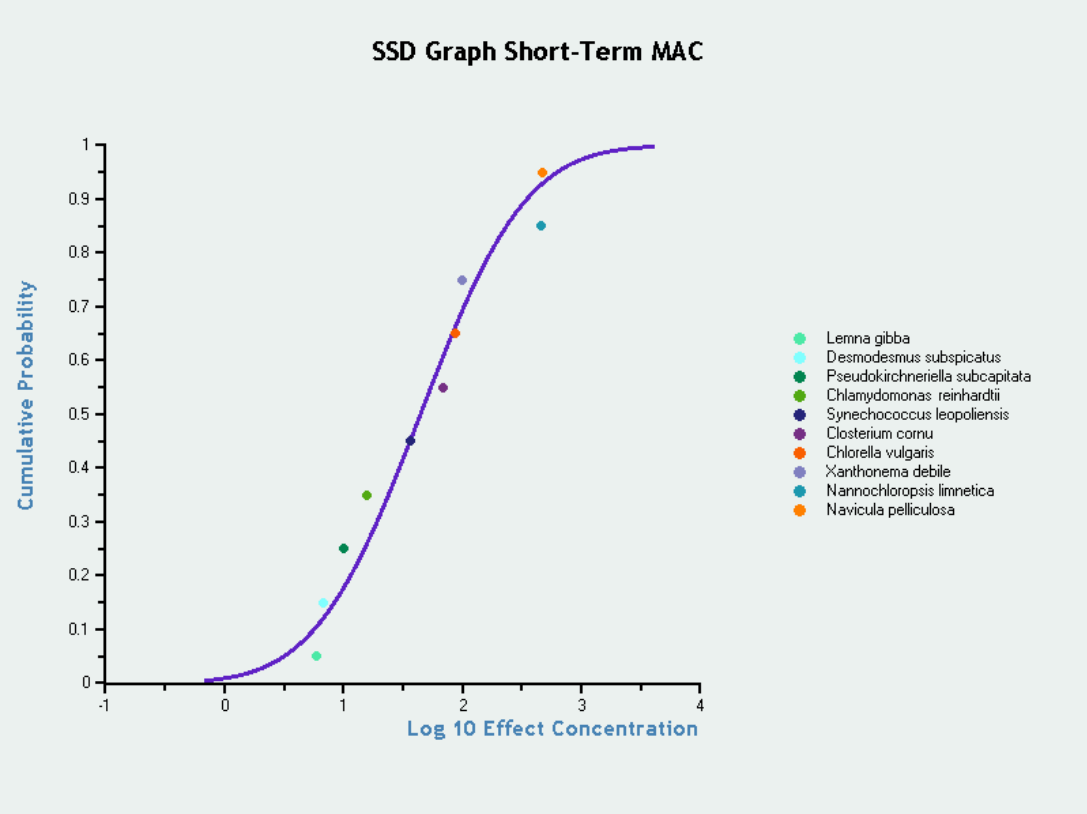
algae species [study]	E_bC_{50} [$\mu g.l^{-1}$]	E_rC_{50} [$\mu g.l^{-1}$]	E_bC_{10} [$\mu g.l^{-1}$]	E_rC_{10} [$\mu g.l^{-1}$]
Desmodesmus subspicatus [1]	6.7	6.9	2.5 *	2.5 *
Navicula pelliculosa [2)	470	1200	68 *	230 *
Pseudokirchneriella subcapitata [3]	10	35	5.1 *	5.1 *
Synechococcus leopoliensis [4]	37.0	74.9	20.1	34.4
Chlamydomonas reinhardtii [4]	15.8	75.3	2.43	5.1
Closterium cornu [4]	68.2	112	19.5	47.8
Xanthonema debile [4]	98.7	319	21.5	108
Chlorella vulgaris [4]	86.8	450	16.2	129
Nannochloropsis limnetica [4]	461	513	303	389
*Lemna gibba [*E.C., 2006*]*	6	12	1.2	

[1] Handley *et al.*, 1990, [2] Hoberg, 1998, [3] Jenkins, 1993, [4] Wenzel, 2006

Proposed refinement for MAC-EQS derivation

Since in all cases the E_bC_{50} was lower than the E_rC_{50}, the assessment was based on the effects on biomass.

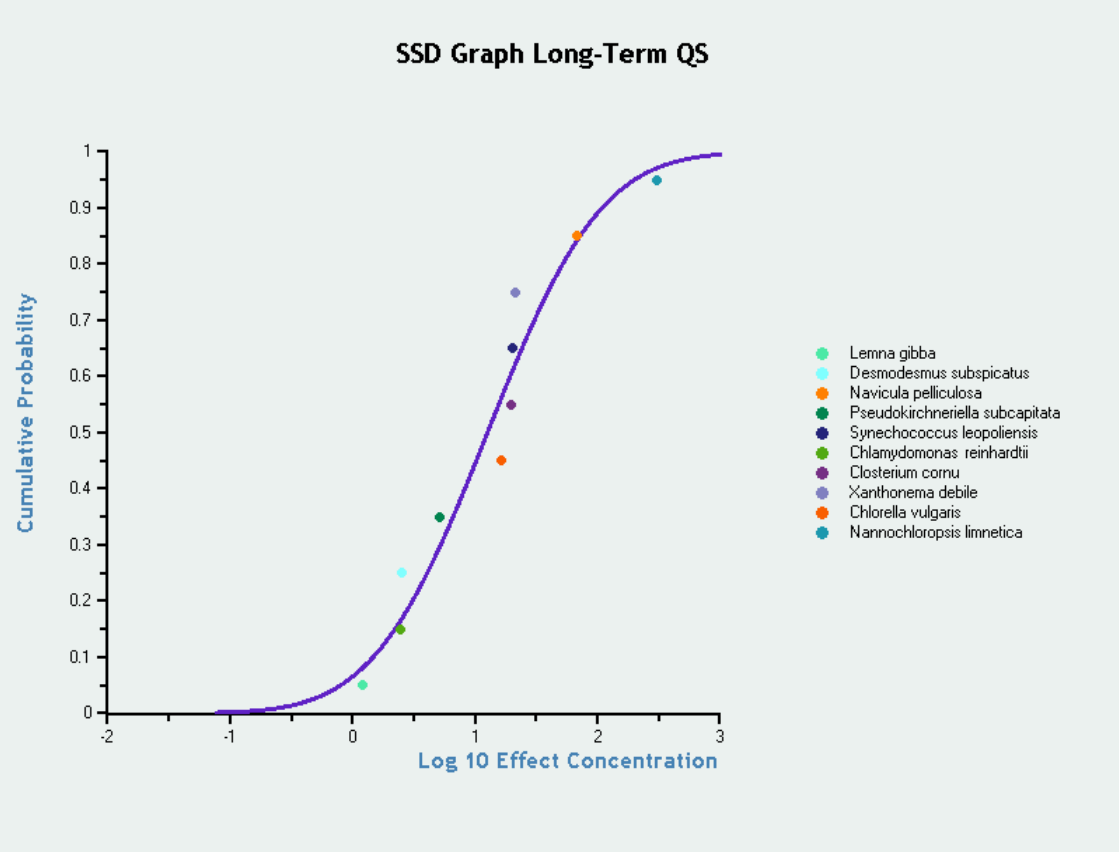
The figure below shows the Species Sensitivity Distribution (SSD) plotted with a 90 % confidence limit based on acute endpoints (EC_{50} values) for primary producers only.



LL HC_5	HC_5 Median	UL HC_5
0.41 µg/L	**2.9 µg/L**	8.7 µg/L

Proposed refinement for $QS_{water, eco}$ derivation

The figure below shows the Species Sensitivity Distribution (SSD) plotted with a 90 % confidence limit based on chronic endpoints (EC_{10} or NOEC values) for algae only.



LL HC_5	HC_5 Median	UL HC_5
0.095 µg/L	**0.73 µg/L**	2.29 µg/L

Tentative derivation of a short term and long term QS_{water}

No data are available on **marine species**. Hence, freshwater data are used with an additional factor of 10 accounting for a higher diversity in marine environment (as is suggested by the TGD-EQS) to establish corresponding marine water QS.

- **Short term QS_{water}**
  - *Assessment factor method:*

Short term values are available on 3 freshwater trophic levels. The lowest value was obtained on the algae *Desmodesmus subspicatus* / 96h: E_bC_{50} = 6.7 µg.l^{-1}; **E_rC_{50} = 6.9 µg.l^{-1}**.

According to the TGD-EQS (E.C., 2011), a default assessment factor of 100 and 1000 applies for freshwater and marine water, respectively.

Despite a defined mode of action of the molecule (aclonifen interferes with plant-specific processes such as photosynthesis and carotenoid biosynthesis), algae or plants data are not clearly lower than the values obtained for other taxons. For example, it can be seen that *O. mykiss* is more sensitive than *N. pelliculosa*. The same applies to the chronic data, where fish and daphnids are equally or more sensitive than the supposedly most sensitive taxa, algae and higher plants. NOECs for fish and daphnids are 5 and 16 $\mu g.l^{-1}$, which is lower than the E_rC_{10} of the majority of algae and macrophyte species. Therefore it is not considered appropriate to lower the assessment factor to 10 for freshwater species or 100 for marine species for this reason.

Industry also underlined that the acute-to-chronic ratio of aclonifen is low (ratio EC_{50} : EC_{10} between 1.5 and 6.9 [for plant and algae]) and that the extrapolation from the ecotoxicological effect concentration used for the MAC-QS to a tolerable short-term exposure concentration in the ecosystem has as such a low uncertainty. As mentioned in the TGD-EQS (Section 3.4.1.2), such narrow ratios justify the use of lower assessment factors. These low ratios are not verified however for fish and invertebrates and the proposal to lower the assessment factor for this reason cannot be retained.

During the review process, industry also proposed to apply "*Since on an acute effect basis the primary producers are clearly the most sensitive, and since the corresponding acute studies are multi-generation studies, an AF of 10 on the lowest acute endpoint is appropriate*." These principles are used under the PPP framework where each taxon is assessed separately. This does not comply however with the TGD on EQS derivation, where the assessment factor is not lower for algae when compared with other taxa.

Nevertheless, applying a factor of 100 and 1000 for freshwater and marine water, respectively, leads to MAC values of:

$MAC_{freshwater}$ = 6.9 / 100 = 0.069 $\mu g.l^{-1}$

$MAC_{marine\ water}$ = 6.9 / 1000 = 0.0069 $\mu g.l^{-1}$

which are lower than the AA-QS obtained with the assessment factor method. It is then proposed to set the MAC values at the same value than the AA-QS

- *Species sensitivity distribution (SSD) method*

The studies submitted for the determination of the SSD were initially submitted to UK and evaluated by UK Advisory Committee on Pesticides (ACP, 2008). The conclusions from UK on the validity of the studies were not reassessed.

For the short-term SSD, E_bC_{50} values were used, following industry's proposal, E_bC_{50} values being lower than E_rC_{50} values. It is noted that E_rC_{50} values would have been recommended according to the TGD-EQS (E.C., 2011), but this worst case can be accepted.

10 data for different species of algae and including higher plants are provided leading to a **median HC_5 of 2.9 $\mu g.l^{-1}$**. An assessment factor of 10 for freshwater and 100 for saltwater would applied to this median HC_5 of 2.9 $\mu g.l^{-1}$ as recommended in the TGD-EQS (E.C., 2011) for the determination of the MAC for fresh- and marine water, respectively.

However, as underlined by NL during the review process, the methodology proposed by industry does not comply with the TGD-EQS (E.C., 2011). SSDs for this specific taxon can only be made if a full SSD is made first. The guidance states the following (section 3.3.1.2):

"For a substance exerting a specific mode of action, SSDs should be constructed using

(a) the entire dataset (i.e. all taxa, so that the relative sensitivities of taxa can be examined) and

(b) only those taxa that are expected to be particularly sensitive (e.g. for a herbicide acting by photosynthetic inhibition, this would be data for higher plants and algae).

In other words, the minimum requirements to perform an SSD should be also be met for a compound with a specific mode of action, in order to be able to demonstrate deviations from the expected distribution. If there is clear evidence of a 'break' in the distribution between the sensitive and other species, or poor model fit, the HC5 should be estimated using only data from the most sensitive group, provided that the minimum number of 10 data points is present. If other evidence is available that indicates there might be a specific sensitive group of species, for example, 'read-across' data from a structurally similar substance, this could also be used."

Therefore refined approach proposed by industry does not meet the requirements set in the guidance. As stated above, despite a defined mode of action (herbicide), algae or plants data are not clearly lower than the values obtained for other taxa, it cannot be concluded beforehand that algae and macrophytes are the most sensitive species groups.

As a conclusion, the use of the assessment factor method is proposed, leading to the MAC values of 6.9/100=0.069 µg.l^{-1}for freshwater and 6.9/1000=0.0069 µg.l^{-1} for marine water.

- **Long term QS_{water}**

  - *Assessment factor method:*

Long term values are available on 3 **freshwater** trophic levels. The lowest value was obtained on the plant *Lemna gibba* / 14d: NOEC = 1.2 µg.l^{-1}.

According to the TGD-EQS (E.C., 2011), a default assessment factor of 10 and 100 applies for freshwater and marine water, respectively.

  - *Species sensitivity distribution (SSD) method*

For the **long-term QS**, EC_{10} and NOEC values are considered. 10 data for different species of algae and including higher plants are provided leading to a **median HC_5 of 0.73 µg.l^{-1}**. The TGD-EQS (E.C., 2011) would recommend an assessment factor of 5 and 50 to be applied to this median HC_5 of 0.73 µg.l^{-1} for the determination of the long term QS for freshwater and marine water, respectively. This would lead to values similar to those calculated using the AF method.

For the same reason as above, and raised by NL during the review process, the approach proposed by industry does not meet the requirements set in the guidance. As stated above, despite a defined mode of action (herbicide), algae or plant data are not clearly lower than the values obtained for other taxa,;it cannot be concluded beforehand that algae and macrophytes are the most sensitive species groups.

In conclusion, the use of the assessment factor method is proposed, leading to the long term QS values of 1.2/10=0.12 µg.l^{-1}for freshwater and 1.2/100=0.012 µg.l^{-1} for marine water.

Tentative derivation of a $QS_{freshwater, sed}$

  - *Assessment factor method*

For the protection of benthic organism, long-term QS, EC_{10} and NOEC values are considered. A spiked sediment test with the benthic organism *Chironomus riparius* exposed over 28 days is available.

- The chronic endpoint is 32 mg kg^{-1} at an organic carbon content of 2.1% in the sediment. Normalization to a standard sediment (5% organic carbon) results in a $NOEC_{standard\ sed}$ = 76 mg kg^{-1}.
- Applying an AF of 100 (as is suggested by the TGD-EQS when 1 chronic result is available) with an additional factor of 10 for marine sediment results in
  - $QS_{freshwater,sed}$ **= 760 µg kg^{-1} dw sediment**
  - $QS_{marine\ water,sed}$ **= 76 µg kg^{-1} dw sediment**
- Based on $QS_{freshwater,sed,dw} = RHO_{susp} / (F_{solidsusp} \times RHO_{solid}) \times QS_{sed,wwt}$ ($CONV_{sed}$ = 2.6) the QS for wet weight sediment is
  - $QS_{freshwater,sed}$ **= 293 µg kg^{-1} ww sediment** corresponding to 1.43 – 2.85 µg.l^{-1}
  - $QS_{marine\ water,sed}$ **= 29.3 µg kg^{-1} ww sediment** corresponding to 0.14 – 0.28 µg.l^{-1}

These values are reported in the summarising table hereunder.

However, according to the TGD-EQS (E.C., 2011), sediment quality standards are not to be taken into account in the derivation of the overall standard (e.g. AA-QS_{water}), in particular for substances not likely to adsorb a lot to solid particles (e.g. log K_{OC} < 5). This is the case for Aclonifen, which presents moreover proposed QS_{sed} for which equivalent concentrations in water are anyway less conservative than AA-$QS_{water, eco}$. Therefore, these values are reported herein only for information.

- *Equilibrium partitioning method*

Although the TGD-EQS recommends using this method when the test results are not available, for comparison purpose, the result of the Equilibrium partitioning method is reported (using a Koc of 5318 as a worst case, and the QS_{water} of 0.12 µg.l^{-1} and 0.012 µg.l^{-1}for freshwater and marine water, respectively)

- $QS_{freshwater,sed}$ **= 12 µg kg^{-1} ww sediment** **32 µg kg^{-1} dw sediment**
- $QS_{marine\ water,sed}$ **= 1.2 µg kg^{-1} ww sediment** **3.2 µg kg^{-1} dw sediment**

Keeping in mind all the restrictions that may be associated to the exposure conditions in spiked water test, it may be mentioned here that the EU plant protection product dossier (E.C., 2006) also report a spiked water test with a NOEC of 0.472 mg/L, which is higher than the value used to determined the sediment QS using the EqP method. Applying also here an assessment factor of 100 (as yet considering benthic sensitivity although representing a bias against the use of an AF of 10 for other chronic tests from the pelagic community), the water QS would be 0.472 mg/L / 100 = 4.72 µg/L.

The $QS_{sediment}$ determined using the spiked sediment results are comparable and are preferred due to the lowest uncertainty associated with the test results.

Summary

Tentative QS_{water}	**Relevant study for derivation of QS**	**Assessment factor**	**Tentative QS**
$MAC_{freshwater, eco}$	*The calculated MAC being lower than the* AA-$QS_{freshwater, eco}$*, MAC is set as equal to the* AA-$QS_{freshwater, eco}$	-	0.12 µg.l^{-1}
$MAC_{marine\ water, eco}$		-	0.012 µg.l^{-1}
AA-$QS_{freshwater, eco}$	*Lemna gibba* / 14d	10	0.12 µg.l^{-1}
AA-$QS_{marine\ water, eco}$	NOEC = 0.0012 mg.l^{-1}	100	0.012 µg.l^{-1}
AA-$QS_{freshwater, sed.}$	$NOEC_{emergence, dvp, 2.1\%OC}$ = 32 mg.kg$^{-1}_{dw}$	100	761 µg.kg$^{-1}_{dw}$ 293 µg.kg$^{-1}_{ww}$
AA-$QS_{marine\ water, sed.}$	$NOEC_{emergence, dvp, 5\%OC}$ = 76.19 mg.kg$^{-1}_{dw}$	1000	76 µg.kg$^{-1}_{dw}$ 29 µg.kg$^{-1}_{ww}$

7.2 SECONDARY POISONING

Secondary poisoning of top predators		**Master reference**
Mammalian oral toxicity	Rat Wistar (male and female) / 2 y / Oral route carcinogenicity / 0-20-40-200-1600 ppm / reduced weight (females); liver hypertrophy (males and females) / malignant astrocytoma (females) NOAEL = 7mg.kg$^{-1}_{bw}$.d^{-1} NOEC = 200 mg.kg$^{-1}_{feed\ ww}$ (CF= study specific)	E.C., 2006
Avian oral toxicity	*Coturnix coturnix japonica* / Oral / 6wks / repro $NOEL_{repro}$ ≥ 141 mg.kg$^{-1}_{bw}$.d^{-1} $NOEC_{repro}$ ≥ 1000 mg.kg$^{-1}_{feed\ ww}$	E.C., 2006

Tentative QS_{biota}	**Relevant study for derivation of QS**	**Assessment factor**	**Tentative QS**

Biota	NOEC = 200 $mg.kg^{-1}_{feed\ ww}$	30[(1)]	6 667 $\mu g.kg^{-1}_{biota\ ww}$ corresponding to 1.1 $\mu g.l^{-1}$ (freshwater) 0.5 $\mu g.l^{-1}$ (saltwater)

(1) proposal made for the purpose of this dossier, according to REACH guidance on information requirements and chemical safety assessment (ECHA, 2008)

7.3 HUMAN HEALTH

Human health via consumption of fishery products		Master reference
Mammalian oral toxicity	Rat Wistar (male and female) / 2 y / Oral route carcinogenicity / 0-20-40-200-1600 ppm / reduced weight (females); liver hypertrophy (males and females) / malignant astrocytoma (females) NOAEL = 7 $mg.kg^{-1}_{bw}.d^{-1}$	E.C., 2006
CMR	Aclonifen is not classified for any carcinogenic, mutagenic or reprotoxic properties	E.C., 2008

Tentative $QS_{biota, hh}$	**Relevant study for derivation of $QS_{biota, hh}$**	**AF**	**Threshold level**	**Tentative $QS_{biota, hh}$**
Human health	7 $mg.kg^{-1}_{bw}.d^{-1}$	100*(1)*	0.07*(1)* $mg.kg^{-1}_{bw}.d^{-1}$	4 261 $\mu g.kg^{-1}_{biota\ ww}$ corresponding to 0.74 $\mu g.l^{-1}$ (freshwater) 0.37 $\mu g.l^{-1}$ (saltwater)

(1) This value and the associated assessment factor were determined by E.C., 2006.

Human health via consumption of drinking water		Master reference
Existing drinking water standard(s)	0.1 $\mu g.l^{-1}$ (preferred regulatory standard)	Directive 98/83/EC

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