Common Implementation Strategy for the Water Framework Directive

Environmental Quality Standards (EQS)

Substance Data Sheet

Priority Substance No. 14

Endosulfan
(α-Endosulfan & β-Endosulfan & Endosulfan sulphate)

CAS-No. 115-29-7 (959-98-8)

Final version
Brussels, 15 January 2005

Disclaimer

This data sheet provides background information on the setting of the Environmental Quality Standard in accordance with Article 16 of the Water Framework Directive (2000/60/EC). The information was compiled, evaluated and used as outlined in the Manual [4] and has been discussed in a consultative process with the Expert Advisory Forum on Priority Substances and the Expert Group on Quality Standards. Furthermore, it has been peer-reviewed by the SCTEE [15]. The substance data sheet may, however, not necessarily represent the views of the European Commission.

New upcoming information was considered and included up to the date of finalisation of this data sheet. Information becoming available after finalisation of this document will be evaluated in the review process of priority substances according to Art. 16(4) of the Water Framework Directive. If necessary, the Environmental Quality Standard substance data sheets will then be revised in the light of technical and scientific progress.

1 Identity of substance

Priority Substance No: 14	Endosulfan (α-Endosulfan+ β-Endosulfan + Endosulfan sulphate)
CAS-Number:	115-29-7 (959-98-8)
Classification WFD Priority List*:	PSR

* PS: priority substance; PHS: priority hazardous substance; PSR: priority substance under review according to Decision 2455/2001.

2 Proposed quality standards

2.1 Overall quality standards

Ecosystem	**Quality Standard**	**Comment:**
AA-QS inland surface waters	0.005 µg/l	See sections 8.1 & 8.6
AA-QS all other surface waters covered by the WFD	0.0005 µg/l	See sections 8.1 & 8.6
MAC-QS (ECO) inland surface waters	0.013 µg/l	See sections 8.1 & 8.6
MAC-QS (ECO) all other surface waters covered by the WFD	0.004 µg/l	See sections 8.1 & 8.6

2.2 Specific Quality standards

Protection Objective #	**Quality Standard**	**Comment:**
Pelagic community (freshwater)	0.005 µg/l	See sections 8.1 & 8.6
Pelagic community (transitional, coastal and territorial waters)	0.0005 µg/l	See sections 8.1 & 8.6
Benthic community (freshwater sediment as well as sediment in transitional, coastal and territorial waters)	0.09 µg/l	See section 8.2
Predators (secondary poisoning)	1 mg / kg (prey tissue, wet wt) 0.05 – 0.2 µg/l (corresponding conc. in water)	See section 8.3
Food uptake by man	0.365 mg/kg (fishery products, wet wt); 0.037 – 0.073 µg/l (corresponding conc. in water)	Based on ADI; see section 8.4
Abstraction of water intended for human consumption (AWIHC)	< 1 µg/l	A1-value for Σpesticides in CD 75/440/EEC; see section 8.5
Water intended for human consumption (WIHC)	0.1 µg/l	Drinking water standard set in CD 98/83/EC

\# If justified by substance properties or data available, QS for the different protection objectives are given independently for freshwater environments, transitional waters or coastal and territorial waters

3 Classification

R-Phrases and Labelling	Reference
T+, N, R: 21-26-28-50/53	[1]
T; R24/25 - Xi; R36 - N; R50-53	[14]

4 Physical and chemical properties

Property	Value	Reference
Vapour pressure	α - endosulfan: 1.05×10^{-3} Pa β - endosulfan: 1.38×10^{-4} Pa	[1]
Henry's law constant	α - endosulfan: 1.1 Pa x m^3 x mol^{-1} at 20 °C β - endosulfan: 0.2 Pa x m^3 x mol^{-1} at 20 °C	[1]
Solubility in water	α - endosulfan: 0.41 mg/l β - endosulfan: 0.23 mg/l Thionex (mixture of isomers): 0.63 mg/l No pH dependency observed	[1]
Dissociation constant	According molecular structure Endosulfan cannot dissociate	[1]

5 Environmental fate and partitioning

Property	Value:	Ref.
Hydrolytic stability (DT_{50})	**α - endosulfan** T = 25°C (Aventis) pH 5: > 200 days pH 7: 19 days pH 9: 0.26 days **β - Endosulfan** T = 25°C pH 5: > 200 days pH 7: 10.7 days pH 9: 0.17 days	[1]
Photostability (DT_{50}) (aqueous, sunlight, state pH)	Photolytically stable	[1]
Readily biodegradable (yes/no)	No	[1]
Degradation in Water/sediment -DT_{50} water - DT_{50} whole system	pH 7.3-7.8 15 days; R^2=0.86; n=8 (River main) (α+β endosulfan plus endosulfan sulphate 12 days; R^2=0.85; n=8 (Gravel pit) (α+β endosulfan plus endosulfan sulphate 21 days; R^2=0.82; n=8 (River main) (α+β endosulfan plus endosulfan sulphate 18 days; R^2=0.83; n=8 (Gravel pit) (α+β endosulfan plus endosulfan sulphate	[1]
Mineralization	< 0.1%	[1]
Bound residue	20-23 % at the end of the study (51 DAT)	[1]
Distribution in water / sediment systems (active substance)	10.8% / 37.7 % at 4 DAT	[1]
Distribution in water / sediment systems (metabolites)	0.8 % / 10.6 % at 51 DAT of endosulfan sulfate 28.4% / 4% at 32 DAT of Endosulfan hydrocarboxylic acid 29.6%/43.1% at 4 DAT (α+β endosulfan plus endosulfan sulphate **No information of metabolites in sediment are available**	[1]
Residues relevant to the aquatic environment	Both isomers of the active substance (α endosulfan; β endosulfan), endosulfan sulphate and endosulfan hydrocarboxylic acid	[1]

Property	Value:	Ref.
Partition co-efficient (log P_{OW})	log P_{ow} = 4.7 No pH dependence is observed	[1]
Koc	 OM= 1.06-4,53%¸pH= 5.4-5.9 α Endosulfan: 7969-21347 β Endosulfan: 8612-13906 Endosulfan sulphate: 5667-11445 Endosulfan diol: 724-1216	[5] [7] [7] [7]
BCF (fish)	2500 – 11000 (Clearance time CT50: 1.74-4.04 d) **BCF of 5000** and clearance time CT50 of 2 days suggested by RMS (SP) for risk assessment	[1]
BCF (fish)	500	[8]
Carassius auratus	1250	[10]
Mugil cephalus	2755	[10]
Brachydanio rerio	2006 - 2650	[9]
Hyphessobrycon bifasciatus	9908 – 11583	[9]
Mytilus edulis	22.5	[10]
Mytilus edulis	10 - 600	[7]

6 Effect data (aquatic environment)

Endosulfan acts via the GABA receptor system (opening the chloride transport, increasing glutamate level). It penetrates into the insect via the tracheas, by ingestion, and has some contact activity. The lethal effect (on the insect) may be seen only after several hours (12-24), there is no „knock down effect“, first symptom is mainly tremor. [1]

Spain, the Rapporteur for the assessment of endosulfan in the context of Council Directive 91/414/EEC, reports that the notifier has presented a large number of studies on the toxicity of endosulfan to aquatic organisms. Most submitted data correspond to published studies collected from the public literature. According to the rapporteur, the validity of these studies was carefully checked but obviously the information on the testing conditions, quality assurance, etc., provided in a scientific paper, is lower than that included in the report of a GLP study. Nevertheless the rapporteur, following the principles already accepted for the risk assessment of other existing plant protection products, considers that the information collected in published scientific papers of enough quality is clearly relevant when setting the ecotoxicological profile and potential risk of this active substance.

6.1 Effects on fish

The studies suggest that endosulfan is highly toxic to fish. The rapporteur concludes that the **acute toxicity of endosulfan to fish** is in the range of 0.1-10 μg/l, with an average value of about 1μg/l (see table A1-1 in Annex 1). Due to the large amount of data available, a sensitivity distribution curve can be established. This distribution has been set up using all the data except those obtained in static tests and those data for species showing large differences between studies. The resulting HC5 is 0.13 μg/l[1] (see figure 1).

[1] No further information on the details of the SSD were provided by the rapporteur. Therefore, a SSD was set up by FHI, applying the data selection rules of the rapporteur and the SSD model of Aldenberg & Jaworska included in the software ETX-2000 [13]. It is not clear why all static fish tests were discarded by the Rapporteur whereas static tests performed with invertebrates are accepted. The static fish tests very often yield LC50s in the same range than obtained with the accepted “dynamic” or “semi static” tests.

Only few test results on the **long-term toxicity of endosulfan on fish** are available. The Rapporteur concluded that the use of simplified chronic tests for endosulfan is inappropriate and the effects on reproduction must be addressed in life-cycle studies. The available worst case NOEC of 0.05 µg/l corresponds to growth.

Table 6.1: Chronic toxicity of endosulfan to fish

Test organism	**Study type**	**Test duration**		**LC_{50} µg/l**	**NOEC µg/l**	**Doc. No.:**	**Author**
Cyprinodon variegatus	early life stage test	28	d	n.r.	0.40	A47514	Hansen & Cripe (1991)
Oncorhynchus mykiss	juvenile growth test	21	d	0.28	0.05	A46835	Knacker et al. (1991)
Pimephales promelas	life cycle test	app. 1	y	0.86	0.2	A27951	Maceck et al. (1976)

n.r. not reported

Higher-tier studies were submitted by the notifier and a pond study is considered essential. The rapporteur concludes that the pond study confirms a high risk of endosulfan for fish species if the molecule is able to reach aquatic ecosystems even at concentrations lower than 1µg/l (fish kills were observed at concentrations of 0.4 and 1 µg/l). No effects on water column invertebrates were observed. No conclusions on the effects on sediment dwelling organisms can be drawn on the basis of this study.

From the available information, the conclusion can be drawn that endosulfan has a high potential for bioaccumulation in fish tissues but that its clearance is rapid. The values suggested by the rapporteur are a BCF in fish of 5000 and a half life of 2 days.

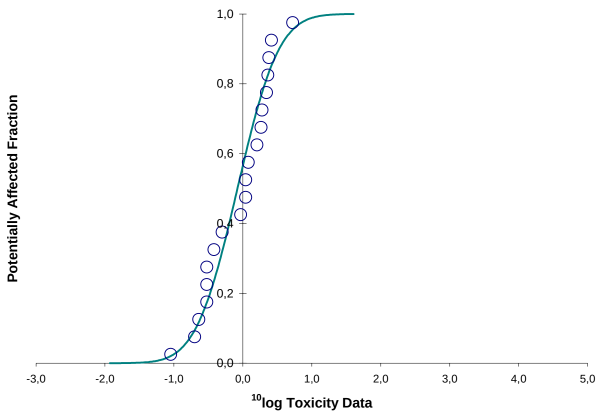

Figure 1: Sensitivity distribution for fish species. Acute LC50 values. The 5%-cut-off value is 0.13 µg/l (0.062 lower and 0.23 upper estimate). Input data (n=20) are listed in table A1-1. The assumption of normal distribution of the data is accepted by the Anderson-Darling test.

6.2 Effects on aquatic invertebrates

Data referring to the acute toxicity of technical endosulfan to aquatic invertebrates are summarised in table A1-2 in Annex 1.

The most sensitive invertebrate organism considered in the Monograph is the pink shrimp with an LC_{50} of 0.04 µg/l. This value was obtained by Schimmel *et al* (1977) in a study with several estuarine species and measured concentrations and clearly showed the highest sensitivity of this shrimp. The toxicity for the standard species the cladoceran species *Daphnia sp*. range from 62 to 740 µg/l. However, the cladoceran species *Moina micrura* with a LC_{50} of 16.2 µg/l is more sensitive than the Daphnia species (Krishnan and Chockalingam, 1989).

The rapporteur proposes the use of an LC_{50} of 0.04 µg/l, as the acute toxicity endpoint for the most sensitive aquatic invertebrate; and a 48 h EC_{50} of 150 µg/l for *Daphnia magna* which – according to the rapporteur -corresponds to the 90th percentile[2] for the toxicity data on this species.

Due to the large differences of the toxicity data among close species the use of sensitivity distribution curves is not considered appropriate in this case.[3] The rapporteur proposes the use of an LC_{50} of 0.04 µg/l, as the acute toxicity endpoint for the most sensitive aquatic invertebrate; and a 48 h. EC_{50} of 150 µg/l for *Daphnia magna.*

The amount on information on the chronic toxicity of endosulfan to aquatic invertebrates is limited and only the risk for Daphnids, a generic species of this group, can be evaluated. The 21 days NOEC for Daphnia magna is 63 µg/l and this value is suggested by the rapporteur for the assessment

6.3 Effects on aquatic plants [12]

The information on algae is limited to a reduced number of species and the most relevant information corresponds to the data on a standard species under standard conditions. Therefore, the 72h NOEC obtained for the green alga *Scenedesmus subspicatus* of 560 µg/l (see table A1-3 in Annex 1) and an LC_{50} reported as higher than this value are used for risk assessment in the endosulfan Monograph.

6.4 Effects on mammals and birds

Table 6.2: Mammal and bird oral toxicity data relevant for the assessment of non compartment specific effects relevant for the food chain (secondary poisoning)

Type of study	Species, test result	Ref.
Long-term toxicity to mammals	Rat, (two generation study) NOEL = 5 mg/kg b.w	[1]
Dietary toxicity to birds	Bobwhite quail = 805 ppm	[1]
Reproductive toxicity to birds	Mallard duck NOEC = 30 ppm	[1]

2 150 µg/l appears to be the geometric mean of the Daphnia magna data, not the 90-percentile.

3 FHI does not see why this should be a reason not to set up a SSD. Using a geometric mean of 148.3 µg/l for Dapnia magna and excluding the data of Oziotelphusa senex because of the differences in the 2 tests available, the 5%-cut-off value of a SSD with the ELC50-data in table A1-2 is 0.45 µg/l (without the "pink shrimp" LC50 of 0.04 µg/l) and 0.1 µg/l with the "pink shrimp" LC50 included. The assumption of normal distribution of the data is accepted by the Anderson-Darling test in both instances.

6.5 Metabolites

Technical endosulfan is a mixture of two isomers (α- and β-endosulfan). The acute 96-h toxicity of these isomers has been studied with fish and daphnia. It seems that α-endosulfan is more toxic than β-endosulfan, but the results are not always congruent. Taking into account that the possible more toxic isomer is the one that shows a faster dissipation in the environment, the use of toxicity and exposure data for the technical product is considered a realistic worst case.

Although the amount of information is scarce, the toxicity of endosulfan-sulphate has been reported as similar to that observed for the technical product while other metabolites, which do not contain the sulphate group appear to be less toxic. However, a proper quantitative assessment on the toxicity of the metabolites is not possible, and it must be concluded that no enough information on the toxicity of the metabolites, including endosulfan sulfate as well as any other relevant metabolite, has been presented, and therefore the was asked to present a proper risk assessment for each relevant metabolite.

The endosulfan metabolites should be classified as highly toxic or toxic according to the EU regulation and must be included in the risk assessment, where relevant.

6.6 Summary on Endocrine Disrupting Potential

Comment	Reference
Endosulfan is a substance with evidence of ED or evidence of potential ED.	[2]
Weight of evidence is that endosulfan is not an endocrine disruptor.	[1]

7 Effect data (human health) [1]

	Value	Study	Safety factor
ADI	0.006 mg/kg bw/day	104-week, rat	100

Table 7.1: Summary human toxicology data [1]

Long term toxicity and carcinogenicity	Lowest relevant NOAEL / NOEL: 0.6 mg/kg bw/day (104-week oral rat study) Target / critical effect: kidney alterations (rats); changes in body and organ weights (mice). No carcinogenic potential.
Genotoxicity	Negative in vitro and in vivo somatic cells. Positive findings in published studies in germ cells. Additional data required.
Reproductive toxicity	Lowest relevant reproductive NOAEL / NOEL: 75 ppm, equivalent to 5 mg/kg bw/day (males) and 6 mg/kg bw/day (females): 2-generation reproduction toxicity study in rats. Reproduction target / critical effect not identified. Lowest relevant developmental NOAEL/NOEL: 2 mg/kg bw/day (teratology study in rats). Developmental target / critical effect: fetotoxicity (isolated skeletal variations) at maternally toxic doses (rats).
Neurotoxicity	NOAEL: 1.5 mg/kg bw (females): rat neurotoxicity st

8 Calculation of quality standards

The derivation of the quality standards is based on monograph data referring to technical grade endosulfan, unless otherwise indicated.

8.1 Quality Standards for Water

Freshwater

A limited set of long-term toxicity data are available for fish, daphnia and algae (lowest NOECs 0.05, 63 and 560 µg/l, respectively; see sections 6.1 – 6.3 and table A1-3 of Annex 1). Further, a pond study is available but cannot be used in this data sheet for the purpose of quality standard setting because relevant information on technical details of the study (i.e., study design, endpoints considered, species affected, monitoring regime and calculation of the exposure concentration, study NOEC etc.) were not provided. However, according to the rapporteur significant fish kills were observed in the study at exposure concentrations down to 0.4 µg/l. This is in the range of NOECs observed in longer-term single-species test with fish (see table 6.1).

It should be further noted that for endosulfan many short-term fish or invertebrate ELC50/100 data are available that are in the range of the NOECs observed for fish or, in the case of invertebrates, are considerably lower than the lowest long-term NOEC available for daphnia (tables A1-1 and A1-2). Hence, the acute to chronic effect ratios for endosulfan appear to be small. In the case of daphnia the lowest 96h EC50 and 21d NOEC cited in the Monograph are nearly identical (62 and 63 µg/l, respectively) and for Rainbow Trout and Fathead Minnow the closest acute to chronic ratios are 6 and 4, respectively.

In line with the proposal of the Rapporteur-MS and the methodological provisions of the Manual [4], it is suggested to derive the quality standard referring to the protection of the pelagic community in freshwater on the basis of the lowest NOEC available in the Monograph (0.05 µg/l, 21d juvenile growth test with Rainbow Trout, *Oncorhynchus mykiss*) and an assessment factor of 10.

$QS_{freshwater}$ = 0.05 µg/l / AF (10) = 0.005 µg/l Endosulfan/l

Transitional, coastal and territorial waters

Toxicity data validated in the monograph suggest that marine species are particularly sensitive towards endosulfan. Acute toxicity data of marine fish and crustaceans are at the lower end of the effect data considered in the monograph, and the “pink shrimp”[4] is the most sensitive species. Its LC50 of 0.04 µg/l is lower than the lowest NOEC considered (0.05 µg/l, rainbow trout) and nearly two orders of magnitude lower than the lowest acute ELC50 for freshwater invertebrates.

Annex 2 contains a table with supplementary marine toxicity data provided by Member States that provides further evidence that marine crustacean species but as well molluscs and fish are particularly sensitive towards endosulfan.

Therefore, and in account of the uncertainty originating from the lack of availability of long-term toxicity data for additional marine taxonomic groups, it is suggested in accordance with the provisions of the TGD for marine risk assessment, to apply an assessment factor of 100 on the

[4] presumably *Pennaeus duoratorum*

lowest NOEC available[5] in order to derive the QS referring to the protection of the pelagic community in marine waters.

$QS_{saltwater}$ = 0.05 µg/l / AF(100) = 0.0005 µg Endosulfan/l

Quality standard accounting for transient concentration peaks (MAC-QS)

In order to derive the MAC-QS, the Rapporteur-MS proposed to use the 5%-cut-off value of 0.13 µg/l from the species sensitivity distribution (SSD) set up with the LC50s of fish (see section 6.1) and to apply an assessment factor of 2 on this value for covering the most sensitive species (i.e., MAC-QS 0.065 µg/l).

With regard to the use of the SSD approach and the acute toxicity data of fish this proposal is appreciated for freshwater environments (fish are the most sensitive species in freshwater) However, the suggested assessment factor is not acceptable. LC50s in the range of 0.1 – 0.3 µg/l have been reported and validated in the monograph for fish species domestic in the EU such as the Common Carp and the Rainbow Trout (marine fish appear to be even a bit more sensitive, see tables 6.1 and A2-1 in annex 2). A factor of less than 1.5 - 5 between the MAC-QS and the LC50 of sensitive fish species is so low that the occurrence of some noticeable fish mortality is highly probable when water concentrations are approaching the MAC-QS level. Therefore it is suggested to apply an assessment factor of 10 on the 5%-cut-off value in order to extrapolate from the acute 50% effect level to the short-term no effect level.

$MAC\text{-}QS_{freshwater}$ = 0.13 µg/l / AF 10 = 0.013 µg Endosulfan/l

In consideration of the apparently higher sensitivity of marine organisms towards endosulfan, it appears necessary to derive a particular MAC-QS for transitional waters. For that purpose, the lowest validated test result of the “pink shrimp” (LC50 0.04 µg/l) is proposed as starting point. As crustaceans appear to be the most sensitive species in saltwater, a reduced assessment factor of 10 in line with the provisions of the TGD for short-term effects assessment is deemed appropriate to extrapolate from the acute 50% mortality level to the short-term no effect level.

$MAC\text{-}QS_{transitional\ waters}$ = 0.04 ug/l / AF 10 = 0.004 µg Endosulfan/l

8.2 Quality standard for sediment

The proposal of the Rapporteur for a sediment quality standard is based on a new sediment study and is:

$QS_{sediment}$ = 0.09 µg/l

The Rapporteur was repeatedly asked to provide further information on the study details and the reasoning behind the derivation of the $QS_{sediment}$. However, to date no such information was given and therefore no conclusion on the appropriateness of the proposed value can be drawn.

[5] i.e., an additional assessment factor of 10 on the $QS_{freshwater}$

8.3 Secondary poisoning of top predators

Endosulfan is classified as very toxic if swallowed and has a BCF > 100. Thus the trigger criteria to derive a quality standard referring to the protection of top predators from secondary poisoning are met (see table 1a of the Manual [4]).

For endosulfan long-term studies for birds (reproductive toxicity to mallard ducks, NOEC 30 mg/kg food) and mammals (long-term toxicity to rats, NOAEL 5 mg/kg bw d) are available.

According to section 4.3.2.5 of the Manual [4] a $NOAEL_{oral}$ may be converted to a $NOEC_{food}$ by multiplication with a conversion factor (CONV) accounting for the ratio between body weight and food uptake. For rats >6 weeks a CONV of 20 is recommended in the TGD.

$NOEC_{food.rat}$ = $NOAEL_{rat}$ (5 mg/kg bw.d) * CONV 20 (kg bw/ kg food.d) = 100 mg endosulfan / kg food

As the $NOEC_{food}$ calculated for rats is higher than the respective NOEC for mallard ducks the NOEC for the ducks is used to derive the quality standard.

According to the TGD an assessment factor of 30 is appropriate to derive a $PNEC_{food}$ from a chronic $NOEC_{food}$. The $PNEC_{food}$ is equivalent to the "save" concentration in the prey of predators and thus is the quality standard for biota ($QS_{secpois.biota}$).

Mallard Duck, chronic NOEC: 30 mg/kg food / AF (30) = 1 mg/kg food

$QS_{secpois.biota}$ = 1 mg Endosulfan / kg biota tissue (wet wt)

The highest BCF has been found for fish (500 – 11000, see section 5 of this data sheet). The Rapporteur considers a BCF_{fish} of 5000 as representative for endosulfan and this BCF is therefore used to calculate the concentration in water that corresponds to the $QS_{secpois.biota}$. No information is available on observations regarding biomagnification of endosulfan, however, the Rapporteur considers the biomagnification potential as negligible, due to the rapid clearance of the substance (average CT50 ≈ 2d).

According to the provisions given in the TGD [3] with regard to the assessment of secondary poisoning of top predators, biomagnification factors (BMF) should be taken into account for the calculation of the PEC_{oral} of top predators. Ideally the BMF should be based on measured data but if such data is not available the use of default values is recommended. These default values are defined in the TGD based on the Kow or the BCF of the substance (see section 4.3.2.5 of the Manual [4] for details). For substances with a BCF between 2000 and 5000 the use of a default BMF of 2 is suggested for freshwater environments and for marine environments a BMF of 4 (2*2) in order to take account of the more complex and longer trophic pathways in marine ecosystems.

Because of the uncertainty regarding possible biomagnification of endosulfan, scenario calculations may highlight the potential of this substance for secondary poisoning (table 8.1).

The $QS_{secpois.water}$ is calculated as follows:

$QS_{secpois.water}$ = $QS_{secpois.biota}$ (1000 [µg/kg prey]) / BCF * BMF

Table 8.1: Scenario calculations for "safe" water concentrations with respect to secondary poisoning

Scenario	BCF	default $BMF_{freshwater}$	default BMF_{marine}	$QS_{secpois.freshw}$	$QS_{secpois.saltw}$
1	5,000	2	4	0.1 µg/l	0.05 µg/l
2	5,000	1 (no biomagnifcation)	1 (no biomagnifcation)	0.2 µg/l	0.2 µg/l

From the figures calculated in table 8.1 it can be concluded that protection from secondary poisoning does not require a QS lower than those derived for the pelagic communities in freshwater as well as transitional, coastal and territorial waters.

It should, however, be kept in mind that more persistent but less toxic metabolites of the parent compounds α- and β-endosulfan may accumulate in fish and other aquatic organisms [11]. To assess the risk posed by the metabolites, more information on their bioaccumulation potential and toxicity is required.

8.4 Quality standard referring to food uptake by humans

The acceptable daily intake (ADI) calculated for endosulfan is 0.006 mg/kg bw/day.

In the Manual (section 4.3.2.6) [4] it is suggested that the ADI may not be exhausted for more than 10% by consumption of food originating from aquatic sources. For a person weighing 70 kg this results in an acceptable daily intake of 42 µg endosulfan per day.

The average fish consumption of an EU citizen is 115 g d-1 (TGD [3]). Thus, 115 g edible fish tissue (or seafood) must not contain more than 42 µg endosulfan.

$$\mathbf{QS_{hh.food}} = \frac{\text{42 µg Endosulfan}}{\text{115g fishery product consumption}} * \text{1000 g} = \textbf{365 µg Endosulfan / kg fishery products}$$

In the TGD approach for the assessment of secondary poisoning (see sections 4.3.2.5 & 4.3.2.6 of the manual [4]) it is foreseen to consider bioconcentration and biomagnification as relevant factors affecting body burdens and the PEC, respectively. If no information on BMF values is available, it is proposed in the TGD to use default BMFs for substances with a BCF_{fish} >2000.

The Rapporteur considers a BCF_{fish} of 5000 as representative for endosulfan and this BCF is therefore used to calculate the concentration in water that corresponds to the human health related QS. No information is available on observations regarding biomagnification of endosulfan, however, the Rapporteur considers its biomagnification potential negligible, due to the rapid clearance of the substance (average CT50 $\approx$ 2d). The TGD recommends for substances with a BCF between 2000 and 5000 the use of a default BMF of 2[6].

Because of the uncertainty with respect to a possible biomagnification of endosulfan, scenario calculations may highlight the potential of the substance to exert adverse health effects due to the intake of fishery products (table 8.2).

The concentration in water corresponding to the $QS_{hh.food}$ is calculated as follows:

$$\mathbf{QS_{hh.food.water}} = \frac{QS_{hh.food}\ (365\ [\mu g/kg])}{BCF * BMF}$$

Table 8.2: Scenario calculations for "safe" water concentrations with respect to protection of human health from adverse effects due to ingestion of food from aquatic environments

Scenario	**BCF**	**default BMF_{fish}**	**$QS_{hh.food.water}$**
1	5,000	2	0.037 µg/l
2	5,000	1 (no biomagnifcation)	0.073 µg/l

6 In the secondary poisoning scenario described in section 8.3 a second $BMF_{predator}$ is used for the marine environment. This BMF is not considered for food uptake by humans as fish and not predators higher in the trophic net are ingested.

From the figures calculated in table 8.2 it can be concluded that the quality standard derived for the protection of aquatic life in the water column should also protect human health from adverse effects due to the ingestion of fishery products.

8.5 Quality standard for drinking water abstraction

The imperative A1 value referring to drinking water abstraction by simple treatment is 1 µg/l for the total amount of pesticides (Council Directive 75/440/EEC). The drinking water standard (DWS) set in CD 98/83/EC is 0.1 µg/l for individual pesticides.

The DWS is a limit value never to be exceeded at the tap. The MAC-QS (ECO) suggested for the protection of the freshwater community (0.013 µg/l) covers therefore the standard established by the drinking water directive.

8.6 Overall quality standard

On the basis of the Monograph-data provided by the Rapporteur-MS, overall annual average quality standards for endosulfan of 0.005 µg/l for freshwater and 0.0005 µg/l for transitional, coastal and territorial waters are suggested. The MAC-QS never to be exceeded should be set at 0.013 µg/l in freshwater whereas in transitional waters a concentration limit of 0.004 µg/l should apply.

It should be considered to extent the group (i.e., α- and β-endosulfan) to that the proposed quality standards apply by further metabolites of the parent compounds. At least endosulfan-sulfate, which is similarly toxic than the parent compounds, should be added to the group (i.e., the quality standards in this case would apply to the sum of the α- and β-endosulfan as well as the endosulfan-sulfate concentrations).

The α- and β-isomers of endosulfan are transformed into endosulfan-sulfate and then to other endosulfan-related metabolites (lactone, diol, etc.). All identified metabolites maintain the chlorinated cyclic structure of endosulfan [11]. The toxicity of endosulfan-sulfate has been reported as similar to that observed for the technical product while other metabolites, which do not contain the sulphate group, may be less toxic [12]. The lower acute toxicity of some of these metabolites when compared to the parent isomers is not considered by the Rapporteur-MS as a proof that these metabolites are of no ecological concern. In fact, there is evidence available confirming the persistence and potential for bioaccumulation of metabolites maintaining the chlorinated endosulfan structure in fish and other aquatic organisms. Therefore the Rapporteur-MS concludes that regardless the transformation of α- and β-endosulfan into other endosulfan-metabolites, endosulfan should be considered as fulfilling the P-criteria of the TGD [11]. The rapporteur therefore recommends that monitoring programmes should not only focus on the α- and β-isomers but consider the metabolites as well.

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ANNEX 1: Toxicity data for aquatic species

Table A1-1: Acute toxicity of endosulfan (active substance) to fish. LC50s underlined and given in bold font are used by FHI for setting up the SSD shown in figure 1 of the data sheet.

Test organisms	Study type	Chemical	Test duration	LC_{50} and 95% CI (µg/l)	Study conditions	Doc, Authors	Remarks	Comment by FHI
Fathead minnow	Intermittent flow-bioassay	Endosulfan (99%)	7 days	0.86	Published	Macek et al (1976)		
Fathead minnow	Dynamic	Technical grade	96 h	1	Published	Nebeker et al, 1983 A 27380		
Fathead minnow				**0.93**				Geometric mean of 2 tests
Indian fish species	Flow through	Active ingredient	96 h	**1.2** (1.1-1.3)	Published	Mohanaranga & Murty (1980) A 29255		
Labeo rohita Indian fish species	Flow through	Technical grade (96%)	96 h	**1.1**	Published	Rao et al (1980) A 22299		
Channa punctatus	Flow through	Technical grade (96%)	96 h	4.8	Published	Devi et al (1981) A 22297		
Channa punctatus	Semi-static	Technical grade	96 h	5.78 (4.49-7.44)	Published	Haider & Moses (1986) A36292		
Channa punctatus				**5.27**				Geometric mean of 2 tests
Mystus vittatus	Dynamic	Not specified	96 h	**1.9** (1.8-2.1)	Published	Rao &Murty 1982 A 26105		
M cavasius	Dynamic	Not specified	96 h	**2.2** (2-2.4)	Published	Rao &Murty 1982 A 26105		
Heteropneustes fossilis	Dynamic	Not specified	96 h	**1.1** (0.93-1.30)	Published	Rao &Murty 1982 A 26105		
Rainbow trout	Dynamic	Technical grade	96 h	**0.3**	Published	Nebeker et al, 1983 A 27380		
Saint Peter fish	Semi-static	Not specified	96 h	**2.39** (2.05-2.79)	Published	Herzberg, 1986 A 36295		
Catla Catla	Dynamic	Technical grade (96%)	96 h	**1.84** (1.78-1.91)	Published	Rao (1989) A 43108		
Golden perch	Semi-static	Technical grade (96.2%)	96 h	**0.3**	Published	Sunderam (1992) A 49782		
Bony bream	Semi-static	Technical grade (96.2%)	96 h	**0.2**	Published	Sunderam (1992) A 49782		
Silver perch	Semi-static	Technical grade (96.2%)	96 h	**2.3**	Published	Sunderam (1992) A 49782		
Melanotaenia duboulayi	Flow-through	Technical grade (96.2%)	96 h	**0.5**	Published	Sunderam (1992) A	At 25 º C	

Test organisms	Study type	Chemical	Test duration	LC_{50} and 95% CI (µg/l)	Study conditions	Doc, Authors	Remarks	Comment by FHI
						49782		
Zebra fish	Semistatic	Technical grade (97%)	24 h	**1.6**	Published	Jonsson & Toledo (1993) A 51153		
Yellow tetra	Semistatic	Technical grade (97%)	24 h	**2.6**	Published	Jonsson & Toledo (1993) A 51153		
Lagodon rhomboides (pinfish)	Flow-through	Technical endosulfan	96 h	**0.3**	Published	Schimmel et al. (1977) A 22871	Filtered marine water at 23ºC	
Striped bass	Flow-trhough	Technical grade (96%)	96 h	**0.23**	Published	Fujimura et al. 1991 A 47515		
Leiostomus xanthurus (spot)	Flow-through	Technical endosulfan	96 h	**0.09**	Published	Schimmel et al. (1977) A 22871	Filtered marine water at 23ºC	
Mugil cephalus	Flow-through	Technical endosulfan	96 h	**0.38**	Published	Schimmel et al. (1977) A 22871	Filtered marine water at 23ºC	
Tests not used for species sensitivity distribution								
Bluegill fish	Static	Technical (96.6%)	96 h	3.3	Published	Pickering & Henderson, 1966 A14124	Study with hard and soft water	
Guppy fish	Static	Technical (96.6%)	96 h	3.7	Published	Pickering & Henderson, 1966 A14124	Study with hard and soft water	
Rainbow trout	Static	Thiodan ®	96 h	1. 5	Published	Macek et al, 1969 A 23688	At 12º C	
Rainbow trout	Static	Technical (96.4%)	96 h	0.3	Published	Schoettger (1970) A14253	At 10 º C	
White sucker	Static	Technical (96.4%)	96 h	3.0	Published	Schoettger (1970) A14253	At 19 ºC	
Golden orfe	Static	Active substance	96 h	2	No GLP. No publ.	Knauf (1977) A 167322		
Common carp	Static	Active substance	96 h	6.9	No GLP. No publ.	Knauf (1978) A 31512		Discrepancy of data with 2nd carp test
Common carp	Semi-static	Technical grade (96.2%)	96 h	0.1	Published	Sunderam (1992) A 49782		Not used for SSD because of discrepancy of data with 2nd carp test
Mosquito fish	Static	Technical grade	96 h	8	Published	Joshi& rege (1980) A 29254		
Walking catfish	Static	Technical grade (90%)	96 h	14 (14.5-13.4)	Published	Gopal et al (1981) A 23187		
Heteropneustes fossilis	Static	Not specified	96 h	9.7	Published	Singh & Narein,		

Test organisms	Study type	Chemical	Test duration	LC_{50} and 95% CI (µg/l)	Study conditions	Doc, Authors	Remarks	Comment by FHI
						1982 A 23196		
Heteropneustes fossilis	Static	Not specified	96 h	2 (1.8-2)	Published	Singh & Srivastava (1981) A 32901		
Rainbow trout	Static	Active ingredient (95.9%)	96 h	0.93 (0.81-1.08)	No GLP No published	Fischer (1983) A 26006	At 12ºC	
Rainbow trout	Static	Technical grade	96 h	1.6	Published	Nebeker et al, 1983 A 27380		
Fathead minnow	Static	Technical grade	96 h	0.8	Published	Nebeker et al, 1983 A 27380		
Punctius ticto	Static	Technical grade (96.6%)	96 h	160	Published	Singh & Sahai (1984) A 36683		
Harlequin fish	Static	Technical grade (96.6%)	96 h	160	Published	Singh & Sahai (1984) A 36683		Discrepancy of data with 2nd Harelquin fish test
Harlequin fish	Flow-through	Technical grade (96.2%)	96 h	0.2	Published	Sunderam (1992) A 49782	At 25 º C	Not used for SSD because of discrepancy of data with 2nd Harelquin fish test
Freshwater eel	Static	Endosulfan (96%)	96 h	20 (17-23)	Published	Ferrando & Moliner (1989) A 42966	At 29 ºC	
Freshwater eel	static	Technical grade (96%)	96 h	41 (33-50)	Published	Ferrando et al, (1991) A 47633		
Mosquito fish	Static	Technical grade (96.2%)	96 h	2.3	Published	Sunderam (1992) A 49782		
Rainbow trout	Static	Technical grade (96.2%)	96 h	0.7	Published	Sunderam (1992) A 49782		

Table A1-2: Acute toxicity of technical endosulfan to aquatic invertebrates. LC50s underlined and given in bold font are used by FHI for setting up the SSD mentioned in footnote 4 of the data sheet.

Test organisms	Study type	Chemical	Test duration	LC_{50} (µg/l)	Study condition	Authors Doc , Nº	Remarks
Daphnia magna	Static	Technical (96.4%)	48 h	62	Published	Schoettger (1970) A14253	
D.magna	Static	Technical grade	48 h	271	Published	Nebeker et al. 1983	
D.magna	Static	Technical grade	48 h	343	Published	Nebeker et al. 1983	
Daphnia magna	Static	Endosulfan (99%)	48 h	166	Published	Macek et al (1976)	
D.magna	Static	Active ingredient	48h	75	No GLP or published	Knauf 1977b A 16733	
D.magna	Static		48h	**148.3**			Geometric mean of 5 tests
Daphnia magna	Static	No specified	48 h	158-740	Published	Nebeker 1982 A 25040	
D. carinata	Static	Technical grade	48 h	**180**	Published	Santharam et al. 1976 A25919	
Cyclops sirenus	Static	Formulated (35%)	24 h	1000 LC100	Published	Oeser et al. 1971 A 14255	
Brachionus plicatilis	Static	Not specified	24 h	**5600** (5800-5400)	Published	Serrano et al. 1986 A 53745	
Brachionus calyciflorus	Static	endosulfan 96%	24 h	**5150**	Published	Fdez Caslderrey et al. 1992. A 47492	
Enallagma spec.	Static	Technical grade (90%)	96 h	**17.5**	Published	Gopal et al. 1981 A23187	
Gammarus lacustris	Static	Not specified	96 h	**5.8**	Published	Sanders (1969) A 26101	
Gammarus faciatus	Static	Not specified	96 h	**6** (4-8)	Published	Sanders (1972) A 28837	
Gammmarus roeselii	Static	Not specified	24 h	5 (LC100)	Published	Ludemann&Neumann (1960) A 14242	
Caridina weberi	Static	Not specified	96 h	**8.48** (5.1-14.1)	Published	Yadav et al. (1991) A47589	
Hydrachna trilobata	Static	Technical grade	48 h	**2.8** (2.3-3.4)	Published	Nair (1981) A26111	
Ischnura sp.	Static	Technical grade (96.4%)	96 h	**71.8**	Published	Schoettger (1970) A 14253	
Moina micrura	Static	Technical grade (90%)	24 h	**16.2** (17.1-15.3)	Published	Krishnan&Chockalingam (1989) A 43063	
Oziotelphusa senex	Static	Technical grade (99%)	96 h	570-1490	Published	Naidu et al. (1987) A 43105	
Oziotelphusa senex	Static	Technical grade (95%)	96 h	12200-28600	Published	Reddy et al. (1992)	Data at 38º and 12ª respectively
Pteronarcys californica	Static	Not specified	96 h	**2.30** (1.6-3.3)	Published	Sanders &Cope (1968) A 25918	
Pink shrimp				**0.04**			

Table A1-3: Most sensitive species of each group (Annex IIA, point 8.2, Annex IIIA, point 10.2) [1]

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Laboratory tests				
Fish	technical	Acute	96h LC50 range	0.0001-0.160
Fish	technical	Acute	96h LC50 95th percentile	0.00013
Fish	Formulation	Acute	96h LC50	0.00024
Invertebrates Invertebrates	Technical Technical	Acute Acute	LC50 range LC50 most sensitive invertebrate	0.00004 – 5.6 0.00004
Invertebrates (Daphnia)	Technical	Acute	48 h EC50 range	0.062-0.740
Invertebrates (Daphnia)	Technical	Acute	48h EC50 Daphnia 90th percentile	0.15
invertebrates	Formulation	Acute	48 h LC50	0.0001
algae	Technical	Chronic	72 h NOEC	0.56
fish	technical	Chronic	28 d NOEC	0.00005
invertebrates	Technical	Chronic	21 d NOEC	0.063
Microcosm or mesocosm tests				
A pond study is considered the essential work, fish mortalities were observed for water concentrations of 0.4 and 1 µg/l and the percentage of species affected is in agreement with the proportion estimated by the sensitivity distribution curve. No effects on water column invertebrates were observed. No conclusions on the effects on sediment dwelling organisms can be achieved.				

ANNEX 2: Supplementary aquatic toxicity data for marine organisms (only some as well included in the Monograph)

Table A2-1: Overview on endosulfan toxicity data of sensitive marine species from different sources (master reference)

Species	Taxonomic Group	Duration	Effect	Endpoint	Value µg/l	Master reference	Reference in master reference
Champia parvula	Chlorophyta			NOEC	80	[6]	RIVM Report No 679101012
Mytilus edulis	Mollusca			NOEC	100	[6]	RIVM Report No 679101012
Cyprinodon variegatus	Pisces	28 d	Growth	NOEC	0.17	[7]	Hansen et al. 1991 [27]
Mysidopsis bahia	Crustacea	38 d	Mortality	MATC *(≈NOEC)*	0.12 *0.08*	[7]	McKenney 1982 [21]
Mysidopsis bahia	Crustacea	28 d	Reproduction	MATC *(≈NOEC)*	0.36 *0.25*	[7]	McKenney 1982 [21]
Mytilus edulis	Mollusca	36 d		LOEC	0.5	[7]	Pest. Programs 1995 [22]
Champia parvula	Algae	14 d	Growth	LOEC	47	[10]	Thursby et al (1985)
Arcatia tonsa	Crustacea	4 d	Mortality	LC50	0.03	[7]	Schimmel 1981 [24]
Penaeus duorarum	Crustacea	3 d	Mortality	LC50	0.04	[7], [10]	Schimmel et al. 1977 [23]
Penaeus duodarum	Crustacea			ELC50	0.04	[6]	RIVM Report No 679101012
Morone saxatilis	Pisces	4 d	Mortality	LC50	0.048	[7]	Korn et al. 1974 [39]
Arcatia tonsa	Crustacea	4 d	Mortality	LC50	0.05	[7]	Schimmel et al. 1977 [23]
Leiostomus xanthurus	Pisces	4 d	Mortality	LC50	0.09	[7], [10]	Schimmel et al. 1977 [23]
Morone saxatilis	Pisces			ELC50	0.1	[6]	RIVM Report No 679101012
Leiostomus xanthurus	Pisces			ELC50	0.26	[6]	RIVM Report No 679101012
Lagodon rhomboides	Pisces			ELC50	0.3	[6]	RIVM Report No 679101012
Penaeus aztecus	Crustacea			ELC50	0.31	[6]	RIVM Report No 679101012
Mugil cephalus	Pisces			ELC50	0.35	[6]	RIVM Report No 679101012
Crassostrea virginia	Mollusca	2 d		EC50	0.45	[7]	Pest. Programs 1995 [22]
Mugil crema	Pisces			ELC50	0.6	[6]	RIVM Report No 679101012
Crangon septemspinosa	Crustacea			ELC50	0.8	[6]	RIVM Report No 679101012
Cymatogaster aggregata	Pisces			ELC50	1.1	[6]	RIVM Report No 679101012
Palaemonetes pugio	Crustacea			ELC50	1.3	[6]	RIVM Report No 679101012
Oncorhynchus kisutch	Pisces			ELC50	2.1	[6]	RIVM Report No 679101012
Lammellidens marginalis	Mollusca	4 d	Mortality	LC50	6	[7]	Mane et al. 1984 [35]
Cancer magister	Crustacea			ELC50	15	[6]	RIVM Report No 679101012

Species	**Taxonomic Group**	**Duration**	**Effect**	**Endpoint**	**Value µg/l**	**Master reference**	**Reference in master reference**
Callinectes sapidus	Crustacea			ELC50	26	[6]	RIVM Report No 679101012
Crassostrea virginica	Mollusca			ELC50	52	[6]	RIVM Report No 679101012
Crassostrea sp.	Mollusca			ELC50	65	[6]	RIVM Report No 679101012
Strongylocentrotus purpuratus	Echinodermata			ELC50	230	[6]	RIVM Report No 679101012