Common Implementation Strategy for the Water Framework Directive

Environmental Quality Standards (EQS)

Substance Data Sheet

Priority Substance No. 10

1,2-Dichloroethane

CAS-No. 107-06-2

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[14]. 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: 10	1,2-Dichloroethane
CAS-Number:	107-06-2
Classification WFD Priority List *:	PS

* 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 all types of surface waters covered by the WFD	10 µg/l, as already set by Council Directive 86/280/EEC	Human health is the most critical objective of protection. Therefore, the suggested QS may be subject to reduction if an assessment of drinking water production by "simple means" technology reveals that the removal efficiency is not sufficient to guarantee compliance with the drinking water standard of 3 µg/l in case the drinking water is produced from surface water containing 10 µg/l 1,2-dichloroethane. The proposed QS is covered by Article 4(9) of the Water Framework Directive. This Article stipulates that it must be ensured that new provisions guarantee at least the level of protection as the existing Community legislation. see sections 8.4, 8.5 & 8.6
MAC-QS (ECO)	1180 µg/l (rounded: **1.2 mg/l**)	see section 8.1

2.2 Specific quality standards

Protection Objective #	Quality Standard	Comment:
Pelagic community (freshwater & saltwater)	1060 µg/l	see section 8.1
Benthic community (sediment)	derivation of QS not required	trigger for derivation of QS not met see section 8.2
Predators (secondary poisoning)	derivation of QS not required	trigger for derivation of QS not met; see section 8.3
Food uptake by man	carcinogen, derivation of QS normally required but QS for drinking water abstraction will presumably cover this exposure route as well	appropriate data to derive QS not available see section 8.4
Abstraction of water intended for human consumption (AWIHC)	calculation of a DW abstraction QS required based on DW limit value of 3 µg/l	Expert assessment on treatment removal efficiency in DW processing required; see section 8.5
Water intended for human consumption (WIHC)	3 µg/l	Drinking water standard set by 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
F; R11 - Carc. Cat. 2; R45 - Xn; R22 - Xi; R36/37/38	[13]

4 Physical and chemical properties

Property	Value	Reference
Molecular weight	98.96	[8]
Vapour pressure	8700 Pa (at 20°C) 8.53 kPa	[8] [1]
Henry's law constant	1.1 10^2 Pa. m^3 / mol	[8]
Solubility in water	8.5-9.0 g/l 8.6 - 8.8 g/L (20 – 25°C)	[8] [5]

5 Environmental fate and partitioning

Property	Value	Ref:	Comments
Hydrolysis Photolysis	Weeks - > 20 years	[5]	
Biodegradation	Not ready biodegradable	[1]	
Partition coefficients Octanol – Water Koc (organic carbon-water)	 1.45 (measured) 1.48 1.79 (calculated) 19-152 11- 220 l/kg	 [8] [7], [6] [5] [8] [5]	
Bioaccumulation Bioconcentration Factor (BCF) Fish Lepomis macrochirus	 <10 2	 [8] [8], [5]	

6 Effect data (aquatic environment)

Table 6.1: Overview on toxicity data of most sensitive species from different sources (master reference).

Species	Taxonomic Group	Duration	Effect	Endpoint	Value mg/l	Master reference	Reference in master reference	Comments on data reliability in master reference [#]
Freshwater								
Daphnia magna	Crustacea	28 d	Reproduction	NOEC LOEC	10.6 20.7	[7]	Call et al (1983)	This represents the lowest NOEC/LOEC Daphnia value
Daphnia magna	Crustacea	28 d	Reproduction	NOEC	10.6	[5]	Ahmad et al. 1984	
Daphnia magna	Crustacea	28 d	Reproduction	NOEC	11	[6]	Richter et al (1983)	
Daphnia magna	Crustacea	28 d	Reproduction	NOEC	11	[9]	RIVM Rep. No. 679101008	
Daphnia magna	Crustacea	28 d	Reproduction	NOEC LOEC	11 21	[8]	Ahmad et al.,1984 Call et al.,1983	RI 1
Pimephales promelas	Pisces	chronic	embryo-larvae exposure	MATC	20	[7]	EPA (1980)	This appears to relate to a chronic value (for embryo-larvae exposure) determined in the US EPA ambient water quality criteria document from 1980 for chlorinated ethanes (Chronic value = geometric mean of NOEC and LOEC)
Pimephales promelas	Pisces	32 d	Weight	NOEC	29	[6]	Benoit et al (1982)	
Pimephales promelas	Pisces	32 d	Growth	NOEC	29	[9]	RIVM Rep. No. 679101008	
Pimephales promelas	Pisces	32 d	Survival-Hatching	NOEC LOEC	29 59	[8]	Ahmad et al.,1984 Benoit et al.,1982	RI 1
Daphnia magna	Crustacea	28 d	Reproduction	NOEC LOEC	41.6 71.7	[7]	Call et al (1983)	This represents the highest NOEC/LOEC Daphnia value
Microcystis aeruginosa	Cyanobacteria	8 d	Growth	NOEC	53	[9]	RIVM Rep. No. 679101008	
Oncorhynchus kisutch	Pisces	21 d	Hatching	NOEC LOEC	56 150	[8]	Reid et al.,1982	RI 2
Microcystis aeruginosa	Cyanobacteria	8 d	Growth	LOEC	105	[8], [7]	Bringmann,1975 Bringmann & Kuehn, 1976, 1978 a&b	RI 3
Microcystis aeruginosa	Cyanobacteria	7 d	Growth	EC0	105	[5]	Bringmann et al. 1978	
Scenedesmus quadricauda	Algae	8 d	Growth	NOEC	360	[9]	RIVM Rep. No. 679101008	
Pimephales promelas	Pisces	96 h	Mortality	LC50	11.8	[5]	Jarnadan et al. 1984	

Species	Taxonomic Group	Duration	Effect	Endpoint	Value mg/l	Master reference	Reference in master reference	Comments on data reliability in master reference [#]
Micropterus salmoides	Pisces	96 h	Mortality	LC50	66	[8]	Rinehart,1971	RI 2
Lepomis macrochirus	Pisces	96 h	Mortality	LC50	94	[8]	Rinehart,1971	RI 2
Gammarus fasciatus	Crustacea	96 h	Mortality	LC50	100	[5]	Johnson et al. 1980	
Pimephales promelas	Pisces	96 h	Mortality	LC50	116	[8], [7]	Ahmad et al.,1984 Walbridge et al., 1983	[8] : RI 1 [7] : V good study
Daphnia magna	Crustacea	48 h	Immobilisation	EC50	130	[7]	Hermans et al (1984)	Test used nominal concentration and a subsequent test found that concentration dropped by 30% as nominal so EQS suggests value may be lower but this was still used for the EQS - lowest Daphnia value
Daphnia magna	Crustacea	48 h	Survival-Mortality	EC50	155-183	[8]	Ahmad et al.,1984 Call et al.,1983 Richter et al.,1983	RI 1
Scenedesmus subspicatus	Algae	72 h	Growth	EC50	189	[8]	Freitag et al.,1994	RI 2
Saltwater								
Ophryotrocha labronica	Annelida	9 d	Mortality	NOEC	200	[9]	RIVM Rep. No. 679101008	
Ophryotrocha labronica	Annelida	>15 d	Mortality in investigations on hatching	NOEC	<200	[7]	Rosenberg et al (1975)	Based on summary of paper obtained from USEPA ecotox website
Artemia salina	Crustacea	24 h	Survival-Mortality	EC50	36	[8]	Foster & Tullis, 1985	RI 2
Artemia salina	Crustacea	24 h	Survival-Mortality	EC50	94	[8]	Foster & Tullis, 1984	RI 1
Limanda limanda	Pisces	96 h	Mortality	LC50	115	[8], [7]	Pearson & McConnell, 1975	[8]: RI 2
Eliminius modestus	Crustacea	48 h	Larvae	EC50	186	[8]	Pearson & McConnell, 1975	RI 2
Skeletonema costatum	Algae	96 h	Growth	EC50	> 433	[8]	Syracuse,1978b	RI 3

[#] RI = reliability index (by Euro Chlor, based on IUCLID system): 1 (valid without restriction); 2 (valid with restrictions, to be considered with care); 3 (invalid); 4 (not assignable)

Summary on endocrine disrupting potential

A (suspected) potential of 1,2-dichloroethane to exert adverse effects on endocrine regulation is not mentioned in the "Community Strategy for Endocrine Disrupters" [2]. No hints on endocrine disrupting properties of the substance have been found in the information provided to the consultant by Member States or NGOs.

7 Effect data (human health)

Following the discussion at the workshop of the Expert Group on Quality Standards (12-16 May, Brussels), the draft SIDS Initial Assessment Report for 1,2-dichloroethane[12] was used as a source of toxicity data. The lowest chronic oral NOEC cited in the SIDS is 25 mg/kg bw d (2 yr study with rats, highest dose administered in the diet). In other studies addressing the occurrence of carcinogenic effects after oral uptake, 1,2-dichloroethane was shown to produce carcinogenic effects at multiple sites in rats and mice of both sexes after oral gavage administration for 78 weeks (up to 195 and 300 mg/kg/d, respectively).

8 Calculation of quality standards

8.1 Quality standards for water

Freshwater

Long-term toxicity data as well as short-term acute data are available across the 3 trophic levels for the "standard" representatives fish, crustaceans and algae. In addition, a test with a marine annelid species has been provided (see table 6.1 of this data sheet).

The lowest apparently reliable long-term toxicity value is the NOEC of 10.6 mg/l for Daphnia magna. The appropriate assessment factor according to the TGD [3] is 10 (long-term toxicity data across at least 3 trophic levels for 3 different taxonomic groups and the lowest acute toxicity datum is obtained with a representative of these groups):

$QS_{freshwater}$ = 10.6 mg/l / AF (10) = 1060 µg 1,2-Dichloroethane /l

The log Kp_{susp} is <3 (see section 5 of this data sheet) and therefore the trigger criterion to calculate a corresponding $QS_{SPM.freshwater}$ referring to the concentration of 1,2-dichloroethane in suspended particulate matter (SPM) is not met.

Transitional, coastal and territorial waters

There are a limited number of acute toxicity tests with saltwater species available, representing 4 different taxonomic groups (fish, crustaceans, annelida, algae). Based on these data there are no obvious differences in sensitivity of freshwater and saltwater species of the same taxonomic groups. It is therefore suggested, in line with both the conclusions drawn in [8] and [1] and the guidance given in the revised TGD in regard to pooling marine and freshwater effects data, to calculate the $QS_{saltwater}$ from the same data set as used for the derivation of the $QS_{freshwater}$. To this end, the TGD assessment factor method as proposed for the marine effects assessment is used (section 4.3.2.2 of the Manual [4]).

In addition to the data on marine and freshwater fish, crustaceans and algae, there is also a NOEC for a marine annelid species. These data confirm that this group is not more sensitive to 1,2-dichloroethane than previously mentioned taxa. Further, it should be considered that as the mode of toxic action of 1,2-dichloroethane is narcosis, it appears reasonable to expect no significantly greater sensitivity of other marine taxonomic groups. It is therefore judged to use the same assessment factor to derive the marine quality standard as used for the freshwater quality standard. The resulting saltwater quality standard is equal to the freshwater standard.

$QS_{saltwater}$ = $QS_{freshwater}$ = 1060 µg 1,2-Dichloroethane /l

The log Kp_{susp} is <3[1] and therefore the trigger criterion to calculate a corresponding $QS_{SPM.saltwater}$ referring to the concentration of 1,2-dichloroethane in suspended particulate matter (SPM) of marine waters is not met.

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

It is suggested to derive the MAC-QS on the basis of the lowest acute toxicity test available that, based on the available information, might be considered as valid (see section on freshwater QS above). This is the 96 h LC50 of 11.8 mg/l reported for *Pimephales promelas* (this LC50 is lower than the lowest NOEC reported for this species).

Based on the guidance given in the TGD on the effects assessment for intermittent releases (see section 4.3.6 of the Manual [4]) it is suggested to apply a reduced assessment factor of 10 in order to derive the MAC-QS (1,2-dichloromethane is believed to have a non-specific mode of toxic action).

MAC-QS = 11.8 mg/l / AF (10) = 1180 µg 1,2-Dichloroethane /l

8.2 Quality standard for sediment

The log Kp_{susp} is <3 and therefore the trigger criterion to derive a $QS_{sediment}$ is not met (see table 1a in [4]). However, it might be worth noting that "In the late eighties, 1,2-dichloroethane was detected in sediments in the North Sea (Southampton estuary) and in Baltic Sea from 0.07 up to 10 µg/kg"[8].

8.3 Secondary poisoning of top predators

1,2-dichloroethane is not subject to bioaccumulation and, therefore, the derivation of a quality standard addressing secondary poisoning is not required (trigger criteria not met, see table 1a in [4]).

[1] Kp_{susp} is the partition coefficient solid-water in suspended matter = Koc * foc (with foc 0.1; see TGD section 2.3.5.3 [3]).

8.4 Quality standard referring to food uptake by humans

1,2-dichloroethane is classified as carcinogen of category 2 (R45) and therefore the derivation of a quality standard addressing the protection of human health from adverse effects due to the uptake of food originating from aquatic environments is normally required (trigger criteria met, see table 8.1 in [4]). However, as the substance is not subject to bioaccumulation the oral uptake route might be less important than drinking water ingestion.

Considering the cancer-risk based drinking water standard of 3 µg 1,2-dichloroethane/l (see section 8.5), it appears not appropriate to use the lowest oral NOAEL reported in the draft SIDS [12] (25 mg/kg bw d in a 2 yr rat study) as starting point to derive such a standard, although carcinogenic effects after oral exposure were only observed after gavage of 1,2-dichloroethane at higher concentrations. This NOAEL would result in a $QS_{hh.food}$ of 15.2 mg/kg fishery product - following the provisions for the calculation of this standard as given in the Manual (section 4.3.2.6) [4]. Given the fact that the substance is not subject to bioaccumulation, the water concentration corresponding to the $QS_{hh.food}$ would by far be higher than all other specific quality standards derived in this data sheet.

Thus, the protection of human health from adverse effects due to the ingestion of fishery products may be guaranteed by imposing a quality standard that would allow for the production of drinking water by simple treatment techniques (see 8.5).

8.5 Quality standard for drinking water abstraction

No "A1-value" has been set for drinking water abstraction in Council Directive 75/440/EEC. The limit value for 1,2-dichloroethane in drinking water is 3 µg/l (Council Directive 98/83/EC). The drinking water limit value is in line with the WHO guide value[2] for drinking water of 3 µg/l corresponding to an additional whole life cancer risk of 10^{-6} [11].

The DWS is a limit value never to be exceeded at the tap. The MAC-QS (ECO) derived for the protection of the freshwater community (1180 µg/l) may therefore not suffice to allow for compliance with the DWS if only simple purification techniques (category A1 of CD 75/440/EEC, i.e. filtration and disinfection) are used for the abstraction of drinking water from surface water bodies according to Art. 7 of the WFD.

An assessment by experts in drinking water technology with regard to the question which fraction of the amount of 1,2-dichloroethane present in raw water can be removed by usual simple treatment procedures might be helpful. If the respective fraction were known, this figure could be used together with the drinking water standard to set the maximum acceptable concentration in surface water bodies designated for the **a**bstraction of **w**ater **i**ntended for **h**uman **c**onsumption (AWIHC).

MAC-QS (AWIHC) = DWS (3 µg/l) / fraction not removable by simple treatment

[2] For carcinogenic substances the "guide" value is calculated as the concentration in drinking water corresponding to an additional risk of cancer over the whole life of 10^{-5} (one additional cancer in 100 000 persons drinking during 70 years the water containing the substance at a concentration equal to the guide value). To decrease the risk by a factor of 10 the guide value should be divided by 10. [11]

8.6 Overall quality standard

As 1,2-dichloroethane is a carcinogen, the decisive issue for quality standard setting is human health. A limit value of 3 µg/l has been set for drinking water in CD98/83/EC. A standard referring to fishery product uptake could not be calculated in this paper, however, given the fact that the substance is not subject to bioaccumulation, this uptake route might be less important compared to drinking water ingestion.

The quality standard of 10 µg/l as already set in Council Directive 86/280/EEC is suggested as overall annual average quality standard (AA-QS). This QS is to all types of surface waters covered by the WFD. This proposal is based on Article 4(9) of the Water Framework Directive. There it is stipulated that *"Steps must be taken to ensure that the application of the new provisions …. guarantees at least a level of protection as the existing Community legislation."*

If the drinking water standard is exceeded in areas designated for the abstraction of water intended for human consumption in accordance with Art. 7 of the WFD, specific measures need to be taken in order to guarantee compliance with the drinking water standard at the tap.

9 References

[1] De Bruijn, J. et al.: Environmental Risk Limits in The Netherlands. National Institute of Public Health and the Environment (RIVM), Bilthoven. RIVM Report No. 601 640 001, Parts I-III, Appendix C – section on 1,2-dichloroethane & data

[2] COM(2001)262 final: Communication from the Commission to the Council and the European Parliament on the implementation of the Community Strategy for Endocrine Disrupters – a range of substances suspected of interfering with the hormone system of humans and wildlife.

[3] Technical Guidance Document on Risk Assessment in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances and Directive 98/8/EC of the European Parliament and the Council Concerning the placing of biocidal products on the market. Part II. European Commission Joint Research Centre, EUR 20418 EN/2, © European Communities 2003. Available at the internet-site of the European Chemicals Bureau: http://ecb.jrc.it/existing-chemicals/

[4] Manual of the Methodological Framework Used to Derive Environmental Quality Standards for Priority Substances of the Water Framework Directive. Peter Lepper, Fraunhofer-Institute Molecular Biology and Applied Ecology, 15 November 2004. Available at the internet-site of the European Commission: http://europa.eu.int/comm/environment/water/water-dangersub/pri_substances.htm

[5] Frimmel, FH et al., 2001: Ableitung von Qualitätszielen für Kandidatenstoffe der prioritären Liste für die EU-Wasserrahmenrichtlinie. Projektbericht zum Forschungsvorhaben. Substance data sheet for 1,2-Dichlorethan

[6] Les Etudes des Agences de l'Eau Nº 64: Systéme d'Évaluation de la Qualite de l'Eau des Cours d'Eau. SEQ-Eau (version 1) Annexe A – Grilles de seuils par altération avec justifications (Annexe 4: Classes d'Aptitude Pour Divers Micropollutants, Fonction "Potentialites Biologiques de l'Eau", 1,2-Dichloroethane - Fiche de Donnees). Agences de l'Eau, Janvier 1999. ISSN 1161-0425F

[7] UK response to request for information relating to quality standards for the Priority List. Submission of data on toxicity, persistence and bioaccumulation by DETR (e-mail of 23 May 2001 by Natasha Robinson)

[8] de Rooij, C. et al. 1998 : Euro Chlor Risk Assessment for the Marine Environment. OSPARCOM Region: North Sea – 1,2-Dichloroethane. Environmental monitoring and Assessment 52: 425-445

[9] Excel - database provided by RIVM. Personal communication (e-mail Dr. Dick Sijm, 14 February 2002)

[10] Council Directive 86/280/EEC on limit values and quality objectives for discharges of certain dangerous substances included in List I of the Annex to Directive 76/464/EEC. OJ L 181, 04/07/1986, p. 16-27

[11] Information provided by EURO CHLOR. Personal communication (e-mail Prof. André Lecloux, 22 June 2001)

[12] SIDS Initial Assessment Report for 14th SIAM (Paris, France, March 2002). 1,2-dichloroethane, CAS 107-06-2. Sponsor Country Germany.

[13] ESIS: European Chemicals Bureau – ESIS (European Substances Information System), January 2005. http://ecb.jrc.it/existing-chemicals/ ⇒ tick ESIS button, then enter CAS or EINECS number of substance.

[14] Opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) on "The Setting of Environmental Quality Standards for the Priority Substances included in Annex X of Directive 2000/60/EC in Accordance with Article 16 thereof", adopted by the CSTEE during the 43rd plenary meeting of 28 May 2004, European Commission Health & Consumer Protection Directorate General, Brussels. http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out230_en.pdf