Common Implementation Strategy for the Water Framework Directive

Environmental Quality Standards (EQS)

Substance Data Sheet

Priority Substance No. 11

Dichloromethane

CAS-No. 75-09-2

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 [11]. 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: 11	Dichloromethane
CAS-Number:	75-09-2
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	Quality Standard "rounded values"	Comment:
AA-QS all types of surface waters covered by the WFD	20 µg/l	**20 µg/l**	see section 8.6
MAC-QS (ECO) *	1.94 mg/l	**2 mg/l**	see section 8.1

* The proposal by the Commission may include a MAC-QS value which is based on the calculation of 12 * AA-EQS. This derivation is based on the minimum annual frequency of monitoring of priority substances in accordance with the Water Framework Directive. The derivation of such a MAC-QS is based on monitoring, compliance and reporting considerations rather than derived from effect data as presented in this EQS datasheet.

2.2 Specific Quality Standards

Protection Objective #	Quality Standard	Comment:
Pelagic community (freshwater & saltwater)	1.65 mg/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	420 µg/kg fishery product corresponding concentration in water: 91 µg/l	see section 8.4
Abstraction of water intended for human consumption (AWIHC)	20 µg/l	No A1 value set in CD 75/440/EEC. Derivation of DW abstraction standard necessary as DW uptake may be the most critical exposure pathway with regard to human health. Suggested standard based on WHO drinking water guideline value of 2 µg/l and 90% removal efficiency in drinking water processing; see section 8.5
Water intended for human consumption (WIHC)	-	No EU 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
Xn; R: 40(Carc. Cat. 3)	ECB 2001

4 Physical and chemical properties

Property	Value	Ref.
Molecular weight	84.9 g	[8]
Vapour pressure	46.5 kPa 475 hPa at 20° C 58.29 x 10^3 Pa (25 °C)	[1] [8] [5]
Henry's law constant	270 Pa.m^3/mol at 20° C	[8]
Solubility in water	13.7 g/l at 20° C 20 x 10^3 mg/L (20 °C) 17 x 10^3 mg/L (10 – 25 °C)	[8] [5] [5]

5 Environmental Fate and Partitioning

Property	Value:	Ref:	Comments:
Hydrolysis Photolysis	hydrolysis is not an important process	[8]	Substance is transferred to the atmosphere by volatilization.Reported half life in water is a few hours
Biodegradation	not ready biodegradable no significant sink in the aquatic environment due to volatility of dichloromethane	[1] [8]	complete biodegradation under anaerobic conditions with sewage seed or activated sludge within 6 h to 7 d reported
Partition coefficients log Kow Koc (l/kg)	 1.25 1.3 1.68 (calculated) 8.8 (sediment) 7.8 (calculated from log Kow) 390 (sewage sludge, aerobic) 157 (sewage sludge, anaerobic)	 [1], [7] [6], [8] [8] [5] [5] [5] [5]	
Bioaccumulation BCF Fish Cyprinus carpio	 6.4 - 40	 [8]	

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	48 h	Mortality	NOEC	68	[7]	Leblanc (1980)	Information based on summary information in UK EQS document Included since it is the lowest acute Daphnia value, but a NOEC and because there is no chronic data
Pimephales promelas	Pisces	32 d	Embryo-larval study, parameter: growth.	NOEC LOEC MATC	82.5 142 108	[5], [6], [7], [8]	Dill et al., 1987	RI 1 in master ref. [8]
Mycrocystis aeruginosa	Cyanobacteria	7 d	Growth	EC0	550	[5]	Bringmann et al. 1978	
Pimephales promelas	Pisces	96 h	Mortality	LC50	193	[7], [8], [6]	Alexander et al (1978)	RI 1
Daphnia magna	Crustacea	24 h	Immobilization	EC50	194	[7]	Lilius et al (1995)	Represents lowest Daphnia value
Daphnia magna	Crustacea	48 h	Mortality	LC50	220	[8]	LeBlanc, 1980 Jaworska & Schultz, 1994 US EPA, 1978	RI 2
Selenastrum capricornutum	Algae	96 h	Growth	EC50	500	[5]	US-EPA 1978	
Selenastrum capricornutum	Algae	96 h	Growth	EC50	>660	[6]	IUCLID (1996)	
Daphnia magna	Crustacea	48 h	Immobilization	EC50	1682	[7]	Kuhn et al (1989)	Based on summary of paper obtained from USEPA ecotox website Represents highest Daphnia value
Lemna minor	Cormophyta	21 d	Growth	EC50	20000	[5]	Merlin et al. 1992	
Saltwater								
Cyprinus variegatus	Pisces	96 h	Mortality	NOEC	130	[7]	Heitmuller et al (1981)	Information based on summary information in UK EQS document Included because there is no chronic fish data and this is a NOEC
Fundulus heteroclitus	Pisces	48 h	Salinity 10‰	LC50	97	[8]	Burton & Fisher, 1990	RI 1
Palaemonetes pugio	Crustacea	48 h	Mortality (Salinity 10‰)	LC50	108.5	[5], [8]	Burton et al. 1990	RI 1

Species	Taxonomic Group	Duration	Effect	Endpoint	Value mg/l	Master reference	Reference in master reference	Comments on data reliability in master reference [#]
Artemia salina	Crustacea	24 h	24 h stage	EC50	122	[8]	Sanchez-Fortun et al., 1997	RI 2
Mysidopsis bahia	Crustacea	96 h	Mortality	LC50	310	[5]	US-EPA 1978	
Skeltonema costatum	Algae	96 h	Physiology	EC50	662	[5]	US-EPA 1978	
Artemia salina	Crustacea	24 h	Mortality	LC50	876	[7]	Heitmuller et al (1981)	

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

Summary on Endocrine Disrupting Potential

A (suspected) potential of dichloromethane 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 dichloromethane have been found in the information provided to the consultant by Member States or NGOs.

7 Effect data (human health)

No oral toxicity data that could be used to assess possible effects on human health due to the ingestion of food originating from aquatic environments has been submitted by Member States or NGOs. However, the World Health Organization has published a drinking water guideline value and a tolerable daily intake (TDI) [9]. These data can be used for deriving the specific human health related quality standards.

General information	Dichloromethane is widely used as a solvent for many purposes, including coffee decaffeination and paint stripping. Exposure from drinking-water is likely to be insignificant compared with that from other sources.
Toxicological Review	Dichloromethane is of low acute toxicity. An inhalation study in mice provided conclusive evidence of carcinogenicity, whereas a drinking-water study provided only suggestive evidence. IARC has placed dichloromethane in Group 2B; however, the balance of evidence suggests that it is not a genotoxic carcinogen and that genotoxic metabolites are not formed in relevant amounts in vivo.
TDI	6 µg/kg of body weight, derived from a NOAEL of 6 mg/kg of body weight per day for hepatotoxic effects in a 2-year drinking-water study in rats, using an uncertainty factor of 1000 (100 for inter- and intraspecies variation and 10 for concern about carcinogenic potential)
Guideline derivation	*allocation to water:* 10% of TD *weight :* 60-kg adult *consumption:* 2 litres/day
Drinking water guideline value	20 µg/litre
Treatment achievability	20 µg/litre should be achievable using air stripping

8 Calculation of Quality Standards

8.1 Quality Standards for Water

Freshwater

Long-term toxicity data (NOEC, EC10) are only available for fish and blue-green algae (canobacteria) but not for invertebrates (see table 6.1 of this data sheet).

The lowest long-term toxicity value is a NOEC value of 82.5 mg/l for Fathead minnow (*Pimephales promelas*) embryo-larval development. Based on the available data and in line with the recommendations of the TGD [3] an assessment factor of 50 on the lowest NOEC is appropriate as long-term tests with species covering 2 trophic levels are available and the species with the highest sensitivity in short-term tests (i.e. $LC50_{fish}$ 97 mg/l) belongs to that levels:

$QS_{freshwater}$ = 82.5 mg/l / AF (50) = 1.65 mg/l Dichloromethane /l

Koc values between up to 390 have been reported for dichloromethane (see section 5 of this data sheet). Hence, the log Kp_{susp}[1] is <1.6 and the trigger criterion to calculate the corresponding concentration to the $QS_{freshwater}$ in SPM is not met (see section 4.2 of the Manual [4]).

Transitional, coastal and territorial waters

Based on the available data (short-term acute toxicity tests with saltwater fish, crustaceans and one algae species) there is no obvious difference in sensitivity of saltwater and freshwater species of the same taxonomic groups. Furthermore, as the mode of toxic action of dichloromethane is narcosis it appears reasonable to expect no significantly greater sensitivity of other marine taxonomic groups. It is therefore suggested to calculate the $QS_{saltwater}$ from the pooled data set of freshwater and saltwater species as outlined in guidance given in the revised TGD (i.e. the same data set as used for the derivation of the $QS_{freshwater}$).

Long-term toxicity data are only available for 2 trophic levels and the QS would therefore normally be derived by applying an assessment factor of 500 to the lowest NOEC resulting in a $Qs_{saltwater}$ of 0.165 mg/l dichloromethane. However, as outlined above, it appears reasonable to expect no significantly greater sensitivity of saltwater species belonging to other taxonomic groups than fish, crustaceans and algae to dichloromethane. Hence, it is suggested to use the same assessment factor as used to derive the freshwater quality standard (50). This results in the same saltwater quality standard as derived for freshwater.

$QS_{saltwater}$ = $Q_{freshwater}$ = 1.65 mg Dichloromethane /l

[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]).

Quality Standard Accounting for Transient Concentration Peaks (MAC-QS)

It is suggested to derive the MAC-QS on the basis of the lowest short-term acute toxicity test available. This is the 48 h LC50 of 97 mg/l reported for the fish *Fundulus heteroclitus*. Based on the guidance given in the TGD on the effects assessment for intermittent releases (section 3.3.2 of part II of [3]) it is suggested to apply a reduced assessment factor of 50 to derive the MAC-QS because the acute to chronic effects ratio of this substance is low (i.e. there is only a small difference between the concentrations that could case acute or chronic effects).

MAC-QS = 97 mg/l / AF (50) = 1.94 mg Dichloromethane /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.

8.3 Secondary Poisoning of Top Predators

Dichloromethane has a worst case BCF < 100. Therefore, the trigger criterion to derive a QS referring to secondary poisoning of predators is not required.

8.4 QS referring to food uptake by Humans

Dichloromethane is classified as carcinogen of category 3 (R40) and therefore the derivation of a quality standard addressing the protection of human health from adverse effects due to the uptake of fishery products is required (trigger criteria met, see table 1b in [4]).

The tolerable daily intake (TDI; 6 µg/kg bw/ day) published by the WHO for dichloromethane (see section 7) is used as basis for the derivation of the quality standard referring to the protection of human health against adverse effects due to the ingestion of fishery products.

In section 4.3.2.6 of the Manual [4] it is suggested that the TDI 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 a tolerable daily intake of 420 µg dichloromethane 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 420 µg dichloromethane.

$$\mathbf{QS_{hh.food}} = \frac{\text{420 µg dichloromethane}}{\text{115g seafood consumption}} * 1000\ g = \mathbf{3.65}\ \text{mg dichloromethane / kg fishery products}$$

In the TGD approach for the assessment of secondary poisoning (see section 4.3.2.5 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. However, as the BCF_{fish} of dichloromethane is much lower than the trigger value, biomagnification needs not to be considered. Because not many data / information on bioaccumulation is available, it is suggested to use the highest available BCF (BCF_{fish} 40 l/kg) for the calculation of the water concentration corresponding to the $QS_{hh.food}$.

$$\mathbf{QS_{hh.food.water}} = \frac{QS_{hh.food}\ (3650\ \mu g/kg)}{BCF\ (40\ l/kg)} = \mathbf{91\ \mu g\ dichloromethane\ /\ l}$$

Thus, the quality standard required to protect human health from adverse effects due to ingestion of fishery products is lower than the respective standard required for the protection of the pelagic communities in inland waters or transitional, coastal and territorial waters.

8.5 QS for drinking water abstraction

No "A1- guide value" and not limit value for dichloromethane have been set in the context of Council Directives 75/440/EEC and 98/83/EC, respectively. The calculation of a provisional drinking water standard is not possible[2] as the required toxicity data with relevance to oral uptake of dichloromethane by humans were not provided by the EAF stakeholders.

However, there are two recommendations on the acceptable level of dichloromethane in drinking water available, one from WHO [9] and the other from US EPA [10]. The given concentrations in drinking-water are associated with an excess lifetime cancer risk of 10^{-6} (one additional cancer per 1,000,000 of the population ingesting drinking-water containing the substance at the guideline value for 70 years). The WHO's guideline value is 2 µg/l and the US EPA health advisory value is 5 µg/l.

If the WHO guideline value were considered acceptable, a quality standard for drinking water abstraction from surface water could be calculated on this basis, taking account of the percentage removal of dichloromethane by the use of simple means in drinking water production (see section 4.3.3 of [4]). EuroChlor commented that dichloromethane due to its volatility and low solubility in water can be quite easily removed to 90 – 99 % from surface water in the drinking water preparation process. Based on the figure for removal efficiency and the WHO guideline value for drinking water a specific MAC-QS for areas designated for abstraction of water intended for human consumption (AWHIC) can be calculated. To be on the safe side, a removal efficiency no higher than 90 % in the case of simple treatment is assumed.

$$\mathbf{MAC\text{-}QS\ (AWHIC)} = \frac{WHO\ guideline\ value\ (2\ \mu g/l)}{Fraction\ not\ removable\ by\ simple\ treatment\ (0.1)} = \mathbf{20\ \mu g\ dichloromethane\ /l}$$

8.6 Overall Quality Standard

Protection of human health from adverse effects due to the suspected cancerogenic properties of dichloromethane is the objective that may require the lowest levels in the aquatic environment. For precautionary reasons, the MAC-QS of 20 µg/l suggested for areas designated for the abstraction of water intended for human consumption according to Art. 7 WFD shall outside this area apply as annual average quality standard (AA-QS).

[2] The calculation of a provisional drinking water standard is normally foreseen in this case in order to assess whether drinking water abstraction might require a lower standard as the other objectives of protection (see section 4.3.3 of the Manual [4]).

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 dichloromethane & 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.

[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 Dichlormethan

[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 Agences de l'Eau, Janvier 1999. ISSN 1161-0425F (Annexe 5: Complément au SEQ-Eau: Détermination des seuils de qualité pour de nouveaux micropolluants, Dichloromethane - Fiche de Donnees)

[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] Dichloromethane. Euro Chlor Risk Assessment for the Marine Environment. OSPARCOM Region – North Sea. February 1999

[9] WHO Guidelines for drinking-water quality, 2nd ed. Vol. 2 Health criteria and other supporting information, 1996. Geneva, World Health Organization

[10] US EPA, 2002: Edition of the Drinking Water, Standards and Health Advisories, EPA 822-R-02-038, Office of Water, U.S. Environmental Protection Agency, Washington, DC

[11] 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