Common Implementation Strategy for the Water Framework Directive

Environmental Quality Standards (EQS)

Substance Data Sheet

Priority Substance No. 13

Diuron

CAS-No. 330-54-1

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* [13]*. 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: 13	Diuron
CAS-Number:	330-54-1
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 all surface waters covered by the WFD	0.2 µg/l	The suggested overall QS refers to the protection of the pelagic communities in both freshwater and saltwater; see section 8.1
MAC-QS	1.8 µg/l	see section 8.1

2.2 Specific quality standards

Protection Objective #	Quality Standard	Comment:
Pelagic community (freshwater & saltwater)	0.2 µg/l	see section 8.1
Benthic community (freshwater & marine sediment)	derivation of QS not required	trigger value not met; see section 8.2
Predators (secondary poisoning)	derivation of QS not required	trigger value not met; see section 8.3
Food uptake by man	426 µg/kg fishery products (wet wt) corresponding concentration in water: 213µg/l	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:
Carc. Cat. 3; R40 - Xn; R22-48/22 - N; R50-53	[12]

4 Physical and chemical properties

Property	Value:	Reference:
Vapour pressure	1.1 x 10^{-6} Pa (25 °C)	[5]
Henry's law constant		
Solubility in water	42 mg/L (25 °C) 35 mg/L (20 °C)	[5]
Dissociation constant		

5 Environmental fate and partitioning

Property	Value:	Ref.
Hydrolytic stability (DT_{50})	Negligible at normal temperatures and in the neutral pH range.	[5]
Photostability (DT_{50}) (aqueous, sunlight, state pH)		
Readily biodegradable (yes/no)	De-methylisation in soil	[5]
Degradation in Water/sediment -DT_{50} water - DT_{50} whole system	 90 d 200 d (Sediment) 48 d (river Erft) * 232 d (Hönning Weiher) *	 [5] [5] [10] [10][
Mineralization		
Bound residue		
Distribution in water / sediment systems (active substance)		
Residues relevant to the aquatic environment		
Partition co-efficient (log P_{OW}) Koc Kd (Partition coefficient water- [suspended]sediment)	2.8 2.82 2.84 2.75 302-309 L/kg log Koc 2.55 (average experimental; ≈Koc 355) < 14 L/kg	[1], [8] [5] [5] [10] [5] [7] [5]
BCF (fish) Pimephales promelas	 2 (24 d)	 [5], [10]

* At present a scientific discussion is ongoing on how such multi-compartment systems should be evaluated since the degradation rates obtained may be such systems may be "system specific" (e.g. highly dependable of the relative size of the individual compartments) and not easy to extrapolate to environmental conditions. [10]

6 Effect data

All data and information provided in this section are based on the proposal for a Diuron quality standard by Denmark [11].

Denmark is Rapporteur Member State for the review of Diuron as a plant protection product under Directive 91/414/EEC, and as such has agreed to provide data for the setting of the Environmental Quality Standard (QS) in relation to the Water Framework Directive.

The risk assessment of Diuron is finished and a draft assessment report (DAR) [10] has been submitted to the European Food Safety Authority (EFSA) on 15 September 2003. As RMS Denmark proposes non-inclusion of Diuron unless it is demonstrated that use of Diuron in orchards will not affect non-target arthropods, birds and mammals to an unacceptable level. If such information is provided by the notifier, the conclusion may change to include Diuron in Annex 1. Furthermore, the conclusions in the DAR may change during the process of commenting by other Member States.

It was agreed at the meeting of the Expert Group on Quality Standards (12-16 May 2003, Brussels) that for plant protection products the toxicity data used for the derivation of the quality standards should be the same as those used in the risk assessment according to Directive 91/414/EEC. The assessment of Diuron is mainly based on dossier data submitted by the notifier. However, the data have been supplemented with an effect study and a BCF study from the Diuron data sheet compiled by the Fraunhofer Institute (draft of 200902). It has been examined if the toxicity studies presented in the data sheet from FHI indicated higher toxicity of Diuron than data presented in the dossier. This lead to the inclusion of one additional algae study in the DAR from the Fraunhofer data sheet.

6.1 Aquatic Toxicity [11]

The relevant ecotoxicity data as identified in the draft risk assessment monograph [10] are presented in Annex 1 to this data sheet.

Diuron acts by inhibition of photosynthesis, which is evident from the toxicity studies, where the lowest reported effect concentrations (i.e. the highest toxicity values) refer to algae studies (see extract of ecotoxicity data from the draft risk assessment report in Annex 1 to this data sheet). The tests of the impact of Diuron on algae differ in several aspects and often deviate from the recommendations given in OECD-guidelines, or they are conducted according to other guidelines, especially with respect to pH-values, amount of EDTA in media and start population size. Therefore, results cannot directly be compared. However, considered individually they are sufficiently reliable. Further they are thoroughly described and therefore it would be possible to repeat the studies. In accordance with the TGD – which states that growth rate is the scientifically correct endpoint for algae toxicity – the E_rC_{50} is used as an endpoint for toxicity in algae. Three species of algae were tested in 7 studies (see annex 1, table 9.2.6-1), and the E_rC_{50} (72 h) values ranged from 0.019 to 0.037 mg a.s./l and NOECs from 0.00046 to 0.01 mg a.s./l, with *Scenedesmus subspicatus* being the most sensitive species.

The derivation of the QS is based on the same studies, in accordance with the methodological framework for deriving Quality Standards [4]. In the three toxicity tests with *S. subspicatus* the NOEC differs by more than one order of magnitude from 0.0051 to 0.00046 mg a.s./l. This variation can not be explained by the spacing of the exposure concentrations in the studies. It is therefore suggested to calculate the geometric mean of the NOECs and to use the result for derivation of the QS.

Thus, the $NOEC_{geometric\ mean}$ (*S. subspicatus*, Algae) = 0.00196 mg Diuron /l

Diuron is less toxic to fish and crustaceans as compared to algae. The NOEC for *Daphnia magna* in a 21 d survival experiment is reported at 0.096 mg a.s./l, although a later study showed no lethal effects below 1.75 mg a.s./l following 21 days exposure. The lowest NOEC for fish in chronic test is reported at 0.41 mg a.s./l. For sediment dwelling organisms, the amphipod *Hyella azteca* showed the lowest NOEC of 0.06 mg a.s./l (see data in annex 1).

6.2 Summary on Endocrine Disrupting Potential

Diuron is a substance with evidence of ED or evidence of potential ED [2].

7 Effect data (human health)

According to the draft RAR [10] the acceptable daily intake (ADI) of Diuron is 0.007 mg/kg bw/day.

Long-term feeding studies have shown that the critical effects of Diuron are damage to the blood system and effects on the urothelial system. In rats increased neoplasia was seen in urothelium and in mice increased number of mammae carcinomas were seen.

Table 7.1: Overall combined long-term NOAELs and LOAELs

Study	NOAEL mg/kg bw/day males/females	LOAEL mg/kg bw/day males/females
Rat 2-year	1.0/-	10/1.7
Mice 2-year	50.8/77.5	111/203
Dog 2 year	6/6	12/12

The rat is the most sensitive species and therefore the ADI should be derived on the basis of the rat study. Due to effects on the blood system at all dose levels the LOAEL is 1.7 mg/kg bw/day in female rats (the most sensitive sex). An extra safety factor of 2.5 (on top of the standard assessment factor mammal – man) is considered necessary as the calculation is based on a LOAEL. The proposed ADI is:

ADI = 1.7 mg/kg bw/day / 2.5 * 100 = **0.007 mg/kg bw/day.**

8 Calculation of quality standards

The proposals made for the overall annual average water quality standard (AA-QS) as well as for the standards referring to secondary poisoning and protection of humans from adverse effects due to uptake of fishery products are based on the "Proposal for a Diuron Quality Standard" [11] by Denmark, the Reporting Member State for the risk assessment of Diuron in the context of Council Directive 91/414/EEC.

8.1 Quality standards for water

Freshwater

According to the aquatic toxicity data (see annex 1), algae appear to be the taxonomic group most sensitive to Diuron with a $NOEC_{geometric\ mean}$ (72 h) of 0.00196 mg a.s./l (see section 6.1). In order to sufficiently cover the protection objective of the QS, this NOEC is divided by an assessment factor of 10 in order to derive the long term quality standard for freshwater.

$QS_{freshwater}$ = 2 µg/l / AF (10) = 0.2 µg Diuron /l

Transitional, coastal and territorial waters

All together, toxicity data for 7 different saltwater species covering 4 taxonomic groups (Mollusca, Crustacea, Algae and Pisces) are presented in the draft RAR [10] and in Annex 2 to this data sheet, respectively. Both acute and chronic data are available for algae and crustaceans, whereas only acute data are available for molluscs and fish. A request to the notifier of Diuron did not result in additional data for marine species. However, the existing data do not indicate different sensitivities between freshwater and saltwater species.

As Diuron is a herbicide, with a specific mode of action acting as photosynthesis inhibitor, it is likely that marine taxa are not significantly more sensitive to this plant protection product as freshwater algae species. Therefore, in line with the recommendations for marine risk assessment of the revised TGD [3], it is suggested to set the same quality standard for saltwater as derived for freshwater:

$QS_{saltwater}$ = $QS_{freshwater}$ = 0.2 µg Diuron / l

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

Acute toxicity data are available for algae, higher plants, fish, crustaceans, insects, amphibia, and molluscs (see Annexes 1 & 2). The lowest acute toxicity value validated in the draft RAR [10] is the EC50 of 18.3 µg/l (7 d) obtained with the higher plant *Lemna gibba*. This result is very close to the lowest growth rate based 72 h EC50 of 0.019 mg/l obtained with the freshwater alga species *Scenedesmus subspicatus* (see section 6.1).

It is suggested to derive the MAC-QS on the basis of the lowest EC50 and the guidance given in the TGD on the effects assessment for intermittent releases (section 4.3.6 of the Manual [4]).

Diuron is a herbicide with a specific mode of action (inhibition of photosynthesis) and higher plants/ algae are the most sensitive species. Thus, a reduced assessment factor of 10 is deemed appropriate for the derivation of the quality standard for transient concentration peaks.

MAC-QS = 18 µg/l / AF (10) = 1.8 µg Diuron /l

8.2 Quality standard for sediment

The log Kp_{susp} of diuron is 1.54 (see footnote 1) and therefore the trigger criterion to calculate a sediment quality standard is not met.

8.3 Secondary poisoning of top predators

Diuron is not liable to bioaccumulation (BCF 2, log Kow <3; see section 5 of this data sheet). Thus the trigger criterion to derive a quality standard referring to the protection of top predators from secondary poisoning is not met (see table 1a of the Manual [4]).

8.4 Quality standard referring to food uptake by humans

Diuron is classified as a carcinogen of class 3. Thus a trigger criterion to derive a quality standard referring to the protection of humans from adverse effects on health due to the ingestion of food from aquatic environments is met (see table 1b of the Manual [4]).

According to the draft RAR [10] the acceptable daily intake (ADI) of Diuron is 0.007 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 49 µg Diuron per day.

The average fish consumption of an EU citizen is 115 g d^{-1} [3]. Thus, 115 g edible fish tissue (or fishery products) must not contain more than 49 µg Diuron.

$$\mathbf{QS_{hh.food}} = \frac{49\ \mu g\ \text{diuron}}{115 g\ \text{seafood consumption}} * 1000\ g = \mathbf{426\ \mu g\ Diuron\ /kg\ fishery\ products}$$

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.

As the BCF_{fish} of diuron is 2, biomagnification is not considered for the calculation of the concentration in water corresponding to the $QS_{hh.food}$, which is calculated as follows:

$$\mathbf{QS_{hh.food.water}} = \frac{QS_{hh.food}\ (426\ [\mu g/kg])}{BCF\ \ (2\ [kg/l])} = \mathbf{213\ \mu g\ Diuron\ /l}$$

Protection of the pelagic community requires a lower quality standard than the protection of humans from adverse effects due to the ingestion of fishery products. It is therefore not necessary to set a specific quality standard for the latter protection objective.

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) derived for the protection of the freshwater community (1.8 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 diuron 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 (0.1 µg/l) / fraction not removable by simple treatment

8.6 Overall quality standard

The QS calculated for the protection of the pelagic communities in both freshwater and saltwater is suggested as overall annual average quality standard (AA-QS, 0.2 µg/l). The MAC-QS is calculated to be 1.8 µg/l. 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.

It should be noted that according to the final draft risk assessment of 3-4 dichloraniline (3,4-DCA) (date: 08.05. 2003), 3,4-dichloraniline is the main stable metabolite of diuron. However, the QS of diuron would not have changed if this metabolite were considered in the quality standard setting since the toxicity of 3,4-DCA is lower than the toxicity of diuron [11].

9 References

[1] 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)

[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 Diuron

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

[7] Crommentuijn, T, et al.; 1997: Maximum Permissible Concentrations and Negligible Concentrations for Pesticides. National Institute of Public Heath and the Environment, Bilthoven. RIVM report no. 601 501 002

[8] 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", Diuron - Fiche de Donnees). Agences de l'Eau, Janvier 1999. ISSN 1161-0425

[9] European Union Risk Assessment: Draft Report 3,4-dichloroaniline (CAS-No. 95-76-1, EINECS-No. 202-448-4). Rapporteur-MS Germany. Status : 14 May 2001 (file: R048_0105_env_hh-3-4-DClaniline.doc)

[10] Draft assessment report Diuron. RMS: Denmark. Submitted to EFSA 15. September 2003 (file: annex B8.doc and annexB9.doc)

[11] Personal communication: Proposal for a Diuron Quality Standard. Ecotox Data for setting EQS. Diuron CAS-No 330-54-1, EINECS-No 206-354-4. File No M: 211/17-0001, Letter by DK-EPA (Alf Aagaard,) to DG-ENV, submitted by e-mail 15.10.2003

[12] 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.

[13] 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

ANNEX 1 - Aquatic toxicity data from the draft RAR [10]

B. 9.2.12 Summary effects on aquatic organisms

Acute effects on fish

Three out of five studies produced reliable results concerning the acute toxicity of diuron or its metabolite mCPDMU. The two studies incapable of producing reliable results were of too poor quality to be included here. The two studies applying diuron techn. showed LC_{50} values of 6.7 and 14.7 mg diuron/L respectively, and the respective NOEC values were 3.6 and 1.0 mg diuron/L. The acute toxicity of the metabolite was less severe than of diuron itself. The formulation Karmex DF, had an LC_{50} of 190 mg/L and consequently it is much less toxic to rainbow trout than diuron technical, i.e. approximately 25 times less toxic.

Table 9.2-1: Summary of acute toxicity of diuron to fish

Reference	Test substance	Species	Study type	LC_{50} mg/L	LOEC mg/L	NOEC mg/L
Annex IIA section 6, pt 8.2.1/01	HR-16, 035 99% active ingredient	Sheepshead minnow	Acute tox. (96 hr)	6.7	6.0 (48 hr)	3.6
Annex IIA section 6, pt 8.2.1/2	Diuron techn. 98.2% purity	Rainbow trout	Acute tox. (96 hr)	14.7	2.15	1.0
Annex IIA section 6, pt 8.2.1/03	mCPDMU 99.5% purity	Rainbow trout	Acute tox. (96 hr)	28.7	15.9	10
Annex IIIA section 6, pt 10.2.1/01	Diuron as (KARMEX® DF) (80%as)	Rainbow trout	Acute tox. (96 hr)	190 (96 hr) nominal conc.	26 (72 hr) nominal conc.	16 nominal conc.
Annex IIIA section 6, pt 10.2.1/02	Diuron as (KARMEX® DF) (80%as)	Bluegill sunfish	Acute tox. (96 hr)	Not. det.	23 (24 hr) nominal conc.	Not. det.

Long term effects on fish

In a 28 day study of the long term toxicity of diuron to rainbow trout an LC_{50} of 4.01 mg/L and a NOEC of 0.41 mg/L was determined.

Table 9.2-2: Summary of long term effects on fish

Reference	Test substance	Species	Study type	LC_{50} mg/L	LOEC mg/L	NOEC mg/L
Annex IIA section 6, pt 8.2.2.1/01	Diuron Techn. (98.2% purity)	Rainbow trout	Prolonged toxicity 28 days	4.01	0.79	0.41

Reproductive and early life stage effects on fish

Exposure of embryos, larvae and juvenile fish in an early-life-stage fish toxicity test resulted in a lowest observed effect level (LOEL) of 3.6 mg/L active ingredient, a no observed effect level of 1.7 mg/L active ingredient, and a maximum acceptable toxicant concentration of 2.5 mg/L active ingredient. The most sensitive measured effects were the mortality of sheepshead minnows from day 11-day 32 post hatch, and the sublethal effects.

Table 9.2-3: Summary of reproductive and early life stages effects on fish

Reference	Test substance	Species	Study type	LC_{50} mg/L	LOEC mg/L	NOEC mg/L
Annex IIA section 6, pt 8.2.2.2/01	diuron; 96.8% purity	Sheepshead minnow	Early life stage, tox		3.6	1.7

Acute and chronic effects on aquatic invertebrate studies

When testing Daphnia in an acute (48 hr) toxicity test, the LC_{50} was 1.4 mg as/L for Diuron. The metabolite mCPDMU seemed less toxic with an LC_{50} of 67.4 mg as/L. Testing Mysid acute (48 hr) toxicity the LC_{50} was 1.1 mg as/L for Diuron. Testing the shell deposition of Oysters for Diuron toxicity showed a NOEC of 2.4 mg as/L and an EC_{50} of 4.8 mg as/L.

Table 9.2.2-1 Summary of acute effects on aquatic invertebrates

Reference	Substance	Media	Species	EC_{50} mg/L	NOEC mg/L	LOEC mg/L
IIA, section 6, pt 8.2.4/01	Diuron 98% as	Water	*Daphnia magna* (48 hr)	1.4		
IIA, section 6, pt 8.2.4/02	Diuron 99.0% as	Water	*Mysidopsis bahia* (96 hr)	1.1		
IIA, section 6, pt 8.2.4/03	HR-16, 035 99% as	Water	*Crassostrea virginica* (96 hr)	3.2		
IIA, section 6, pt 8.2.4/04	DPX-14740-166 96.8% as	Water	*Crassostrea virginica* (96 hr)	4.8	2.4	
IIA, section 6, pt 8.2.4/05	mCPDMU (metabolite) 99.5% as	Water	*Daphnia magna* (48 hr)	67.4	15.9	
IIIA, section 6, pt 10.2.1/03	DPX-14740-165 (Diuron) 80% (as given)	Water	*Daphnia magna* (48 hr)	12		

For a 21 days exposure of Daphnia to Diuron survival was affected at concentrations above 0.0016 mg as/L, although a later study showed no lethal effects below 1.75 mg as/L following 21 days exposure. Diuron affected reproduction and growth at concentrations above 0.56 and 0.096 mg as/L, respectively. For the 28-day test on Mysid reproduction the number of young was affected above 0.96 mg as/kg.

Table 9.2.2-2: Summary of chronic effects on aquatic invertebrate studies

Reference	Substance	Media	Species	EC_{50} mg/L	NOEC mg/L	LOEC mg/L (%effect)
IIA, section 6, pt 8.2.5/01	Diuron technical 98%	Water	*Daphnia magna* (21 d) Mortality		≥1.0	
IIA, section 6, pt 8.2.5/02	Diuron technical 98%	Water	*Daphnia magna* (21 d)			
			Mortality		>1.75	
			Growth		0.096	0.17 (22%)
			Reproduction		0.56	0.97 (19%)
IIA, section 6, pt 8.2.5/03	DPX-14740-166 96.8%	Water	*Mysidopsis bahia* (28 d)			
			Mortality		≥3.9	
			Reproduction		0.96	1.9 (57%)

Effects on algae growth

The tests for influence of diuron on alga differ in several aspects and often deviates from recommendation in OECD-guidelines, or they are elaborated after other guidelines, especially concerning pH, amount of EDTA in medium and start population size. Therefore, results cannot directly be compared. However, individually seen they are reliable. Further they are thoroughly described and therefore possible to replicate.

Results of the acute toxicity tests generally indicate a high toxicity of diuron to the tested alga. Examining changes in EbC50 values with increased exposure time (72-120 h), indicating both increasing and decreasing toxicity with increasing exposure time. Transfer of alga to diuron free medium or dilution of the exposure medium leads to alga growth equal to controls. The formulation Karmex DF (80% diuron) was less toxic to *Desmodesmus (Scenedesmus) subspicatus* than diuron technical. However, an additional study included by RMS, showed that the product Diuron WP 80 was at least as toxic as diuron technical. According to notifier, is the toxicity of Diuron WP 80 related to the additives. Since no documentation to verify this has been submitted by notifier, will the effect data for the product Diuron WP 80 be included in the risk assessment.

According to the Guidance Document on Aquatic Ecotoxicity [6] the smaller figure of the endpoints growth rate and biomass should be used in the risk assessment. However, the recently revised TGD states that growth rate is the scientifically correct endpoint for alga toxicity. This is also the official viewpoint of EU in the OECD discussions. In agreement with the latter, growth rate is used as an endpoint in the assessment of the algal studies.

Table 9.2.6-1: Summary of diuron toxicity of alga studies. All concentrations are given in mg as/l. Confidence intervals are given in square brackets, when presented in the studies. – Indicates the length of the study.

Reference	Substance	Species	EbC_{50} mg/L	ErC_{50} mg/L	LOEC mg/L	NOEC mg/L
An IIA sect. 6, pt 8.2.6/01	Diuron techn. 98% purity	*Selenastrum capricornutum*	0.018 (72 hr)	0.022 (120 hr)		0.01
An IIA sect. 6, pt 8.2.6/02	Diuron techn. purity 96.8%	*Selenastrum capricornutum*	0.0023 (72 hr) 0.003 (96 hr) 0.0029 (120 hr) [0.0025-0.0035]			0.0013
An IIA sect. 6, pt 8.2.6/03	Diuron techn. 98.5% purity	*Scenedesmus subspicatus*	0.009 (72 hr) 0.0079 (96 hr)	0.022 (72 hr) 0.022 (96 hr)	0.0056	0.0032
AnIIA sect. 6, pt 8.2.6/04	Diuron techn. 98.7% purity	*Scenedesmus subspicatus*	0.009 (96 hr)*		0.011	
An IIA sect. 6, pt 8.2.6/05	Diuron techn. 98.6% purity	*Anabaena flos-aquae*	0.0232 (72 hr)	0.0309 (72 hr)	0.032	0.01
An IIIA sect. 6, pt 10.2.1/01	Karmex DF (80% diuron)	*Scenedesmus subspicatus*	0.0153 (72 hr) [0.014-0.0168] (as: 0.0124)	0.0372 (72 hr) [0.0324-0.0427] (0.0302)	0.0125 (as: 0.0102)	0.0063 (as: 0.0051)
An IIIA sect. 6, pt. 10.2.1/02**	Diuron WP 80, 80% as	*Scenedesmus subspicatus*	0.001 (72 hr) 0.003 (96 hr)	0.019 (72 hr) 0.024 (96 hr)		0,00046
An IIIA sect. 6, pt 8.2.6/06	mCPDMU, 99.5% purity	*Scenedesmus subspicatus*	0.246 (72 hr)	0.727 (72 hr)	0.29	0.16

* Not in report. Reviewers calculation from graph.

** Ekstra studie added by RMS

Effects on sediment-dwelling organisms

For the amphipod *Hyella azteca* survival was affected at concentrations above 0.06 mg as/L and the LC_{50} was calculated to 0.42 mg as/L. For Chironomus larvae emergence was not affected at concentrations below 4.0 mg as/L, although this latter study was not well-grounded. There was no chronic study for aquatic gastropods molluscs.

Reference	Substance	Media	Species	EC_{50} mg/L	NOEC mg/L	LOEC mg/L (%effect)
IIA, section 6, pt 8.2.7/01	Diuron WP 80 79.2% (as given)	Water	*Chironomus riparius* (41 d) Mortality	> 4.0	> 4.0	> 4.0
IIA, section 6, pt 8.2.7/02	Diuron (WP 80) 79.2%	Water	*Hyella azteca* (21 d) Mortality Growth	0.42	0.06 ≥4	0.56 (40%)

Effects on aquatic macrophytes

Only one study including aquatic higher plants *Lemna gibba* was included in the material.

Table 9.2.8-1: Summary of diuron effects on aquatic higher plants *Lemna gibba* (reference: Annex IIA section 6, pt 8.2.8/01)

Test substance	Diuron technical
Test species	*Lemna gibba*
EC_{50} (0-7 days) (µg/L)	18.3
LOEC (µg/L)	10.7 (3.40)*
NOEC (µg/L)	3.40 (not determined)*
Threshold effect concentration, TEC (geometric mean LOEC-NOEC) (µg/L)	6.03 (not determined)*

*The values in the parentheses are presented in addition to those in the report because the statistical calculations in the report are inadequate in the way that they are only based on the set of data that delivers the highest LOEC and NOEC, i.e. average growth rate based on frond area. If either one of the two other measures, i.e. dry weight on day seven or growth rate based on frond counts, are used for the calculation the lowest tested concentration will be LOEC and no NOEC will be observed. The fact that the report choose to base the calculation on the frond area may also give rise to some criticism, because it should be quite obvious to suspect that other response variables could be affected to a higher degree.

ANNEX 2: Overview on Diuron aquatic toxicity data for most sensitive species provided by stakeholders of the Expert Advisory Forum on Priority Substances

Species	Taxon. Grp.	Medium *	Duration	Effect	Endpoint	Value	Unit	Master Ref.	Reference in master ref.
Freshwater									
Scenedesmus subspicatus	Algae	fw	96 h	Growth	NOEC	0.46	µg/l	[5]	PSM-Datembank 1991
Scenedesmus subspicatus	Algae	fw			NOEC	0.77	µg/l	[6]	RIVM Report 601501002
Microcystis aeruginosa	Algae	fw	7 d	Growth	EC1	1.1	µg/l	[5]	Bringmann et al. 1975
Lemna major	Cormophyta	fw			NOEC	2.3	µg/l	[6]	RIVM Report 601501002
Lemna perpusilla	Cormophyta	fw			NOEC	2.3	µg/l	[6]	RIVM Report 601501002
Chlorella pyrenoïdosa	Algae	fw			NOEC	4.8	µg/l	[6]	RIVM Report 601501002
Lemna gibba	Cormophyta	fw	7 d	Growth	NOEC	6.03	µg/l	[5]	PSM-Datenbank 1999
Scenedesmus quadricauda	Algae	fw			NOEC	10	µg/l	[6]	RIVM Report 601501002
Pimephales promelas	Pisces	fw	64 d	Reproduction	NOEC	33.4	µg/l	[5]	Call et al. 1987
Daphnia magna	Crustacea	fw	21 d	Reproduction	NOEC	56	µg/l	[5]	PSM-Datembank 1991
Chlorococcum hypnosporum	Algae	fw			NOEC	100	µg/l	[6]	RIVM Report 601501002
Tilapia mosambica	Psices	fw			NOEC	220	µg/l	[6]	RIVM Report 601501002
Oncorhynchus mykiss	Pisces	fw			NOEC	520	µg/l	[6]	RIVM Report 601501002
Xenopus laevis	Amphibia	fw	96 h	Growth	NOEC	7600	µg/l	[5]	Schuytema et al. 1998
Rana catesbeiana	Amphibia	fw	21 d	Growth	NOEC	7600	µg/l	[5]	Schuytema et al. 1998
Lemna paucicostata	Cormophyta	fw	10 d		EC50	11	µg/l	[5]	Boger et al. 1993
Chlorella pyrenoidosa	Algae	fw	96 h	Growth	EC50	24	µg/l	[1]	Shilo (1967)
Chlorella pyrenoidosa	Algae	fw	96 h	Growth	EC50	24	µg/l	[8]	Maule et Wright (1984)
Gammarus fasciatus	Crustacea	fw	96 h	Mortality	LC50	160	µg/l	[1]	Johnson and Finley (1980)
Oncorhynchus clarki	Pisces	fw	96 h	Mortality	LC50	710	µg/l	[5]	Pest. Programs 1995
Salvelinus namaycush	Pisces	fw	96 h	Mortality	LC50	1100	µg/l	[1]	Mayer and Ellersieck (1986)
Pteronarcys californica	Insecta	fw	96 h	Mortality	LC50	1200	µg/l	[1]	Johnson and Finley (1980)
Pteronarcys californica	Insecta	fw	96 h	Mortality	EC50	1200	µg/l	[5]	IRPTC 1989
Daphnia pulex	Crustacea	fw	48 h	Mortality	LC50	1400	µg/l	[1]	Johnson and Finley (1980)
Daphnia pulex	Crustacea	fw	48 h	Mortality	LC50	1400	µg/l	[8]	Crosby et Tucker (1966)
Lepomis macrochirus	Pisces	fw	96 h	Mortality	LC50	2800	µg/l	[1]	Mayer and Ellersieck (1986)
Rana catesbeiana	Amphibia	fw	96 h	Mortality	LC50	3100	µg/l	[5]	IRPTC 1989
Daphnia magna	Crustacea	fw	18 d	Mortality	LC50	>4000	µg/l	[1]	Kersting (1975)
Daphnia magna	Crustacea	fw	24 h	Mortality	LC50	1000 – 4000	µg/l	[1]	Ludermann and Kayser (1966)
Pimephales promelas	Pisces	Fw	168 h	Mortality	LC50	7700	µg/l	[1]	Call et al (1987)
Xenopus laevis	Amphibia	Fw	14 d	Mortality	LC50	8100	µg/l	[5]	Schuytema et al. 1998
Lymnaea sp	Mollusca	Fw	96 h	Mortality	LC50	15000	µg/l	[1]	Christian and Tate (1983)

Species	Taxon. Grp.	Medium *	Duration	Effect	Endpoint	Value	Unit	Master Ref.	Reference in master ref.
Saltwater									
Mercenaria mercenaria	Mollusca	Sw			NOEC	1000	µg/l	[6]	RIVM Report 601501002
Mysidopsis bahia	Crustacea	sw	28 d		LOEC	560	µg/l	[5]	Pest. Programs 1995
Phaeodactylam tricornutum	Algae	sw	10 d	Growth	EC50	10	µg/l	[1]	Mayer (1987)
Phaeodactylam tricornutum	Algae	sw	2 h	Oxygen evolution	EC50	10	µg/l	[1]	Mayer (1987)
Morone saxatilis	Pisces	sw	96 h	Mortality	LC50	500	µg/l	[5]	Hughes 1973
Mysidopsis bahia	Crustacea	Sw	96 h	Mortality	LC50	1100	µg/l	[1]	Upstone (1992) Pers comm.
Crassostrea virginica	Mollusca	sw	96 h	Growth	EC50	1800	µg/l	[5]	Butler 1964
Mugil cephalus	Pisces	sw	48 h	Mortality	LC50	6300	µg/l	[1]	Mayer (1987)

*: fw = freshwater, sw = saltwater