

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E - Food Safety: Production and distribution chain
Unit E.3 - Chemicals, contaminants and pesticides

Diuron

SANCO/2184/2008 rev 3

10 July 2008

Review report for the active substance **diuron**

finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
11 July 2008

in view of the inclusion of diuron in Annex I of Directive 91/414/EEC

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of diuron, made in the context of a new application by the main data submitter after the non-inclusion of this substance.

Diuron is a substance that was covered by the second stage of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

At the outcome of that evaluation, diuron has not been included through Commission Decision 2007/417/EC¹ as, on the basis of the available information, it has not been demonstrated that the risk to operators, groundwater and birds and mammals was acceptable. All information as regards this initial evaluation is recorded in the relevant Commission Review Report (document SANCO/10542/2005 final of 7 September 2007).

In accordance with Article 6(2) of Directive 91/414/EEC, the European Diuron Task Force (DTF) consisting of Dupont de Nemours and Lanxess Distributions GmbH, the main data submitter, by its letter of 26 June 2007, presented a request to Denmark, the original Rapporteur Member State, for a new application aiming at Annex I inclusion of the substance.

Denmark finalised in November 2007 its examination, in the form of an additional report to the original Draft Assessment Report. This Report was sent to the Commission and the European Food Safety Authority on 15 November 2007 and included a recommendation as to include diuron in Annex I for uses in strip application.

The Commission referred the dossier to the **Standing Committee on the Food Chain and Animal Health**, on 3 December 2007, and it was finalised in the meeting of this Committee on 11 July 2008.

¹ OJ No L 156, 16.6.2007, p.32.

The review did not reveal open scientific questions which would have triggered the involvement of the European Food Safety Authority.

The present review report contains the conclusions of the examination and the comments and clarifications submitted during that process. These documents are added to the original background documents A, B and C and are part of it.

2. Purposes of this review report

This review report, including the background documents and appendices hereto, has been developed and finalised in support of Commission Directive **2008/91/EC**² concerning the inclusion of diuron in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing diuron they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 8 of Regulation (EC) No 451/2000, as modified by Regulation (EC) No 1490/2002, Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion from the evaluation is that it may be expected that plant protection products containing diuron will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each diuron containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the main data submitter and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the

² Commission Directive 2008/91/EC (OJ L 262, 1.10.2008, p. 31)

requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

The following reference values have been finalised as part of this re-evaluation:

ADI	0.007 mg/kg bw/day
ARfD	0.016 mg/kg bw/day
AOEL	0.007 mg/kg bw/day

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) for a 60 kg adult is 1.6 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). Additional intake from water is not expected to give rise to intake problems.

Estimates of acute dietary exposure of adults and children revealed that the Acute Reference Dose (ARfD) would not be exceeded (According to the UK model (2005): below 7.8% of the ARfD, for adults, toddlers and infants (apples) and 3.3% of the ARfD for adults (wine grapes).

The review has identified several acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC.

4. Identity

The main identity of diuron is given in Appendix I.

The active substance shall comply with the FAO specification and there seem not to be reasons for deviating from that specification; the FAO specification is given in Appendix I of this report.

The review has established that for the active substance notified by the main data submitter none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in the additional report to the Draft Assessment Report in the diuron List of Endpoints, and at section 3 of this report.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing diuron

On the basis of the proposed and supported uses (as listed in Appendix II), the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

Member States should pay particular attention to:

- the operator safety. Conditions of use should prescribe the application of adequate protective equipment, where appropriate.
- the protection of aquatic organisms and non-target plants.

Conditions of use should include risks mitigation measures, if appropriate.

7. List of studies to be generated

No further studies were identified which were at this stage considered necessary in relation to the inclusion of diuron in Annex I under the current inclusion conditions.

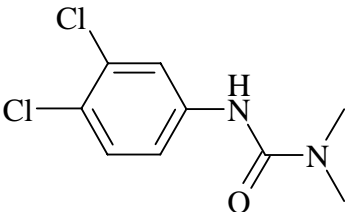
8. Information on studies with claimed data protection

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC and neither does it commit the Commission.

9. Updating of this review report

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Any such adaptation will be finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for diuron in Annex I of the Directive.

APPENDIX I**Identity****DIURON**

Common name (ISO)	Diuron
Chemical name (IUPAC)	3-(3,4-dichlorophenyl)-1,1-dimethylurea
Chemical name (CA)	<i>N'</i> -(3,4-dichlorophenyl)- <i>N,N</i> -dimethylurea
CIPAC No	100
CAS No	330-54-1
EEC No	006-015-00
FAO SPECIFICATION	No. 100/TC/S11 (1980) Minimum purity 930 g/kg declared content 950 g/kg ± 20 g/kg FAO specification: Free amine salts: max 0.4 % of the diuron content calculated as dimethylamine hydrochloride. water: max 1%
Minimum purity	930 g/kg
Molecular formula	C ₉ H ₁₀ Cl ₂ N ₂ O
Molecular mass	233.1 g/mol
Structural formula	

APPENDIX II
List of uses supported by available data

DIURON

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min/max (k)	interval between applications (min)	kg as/hl min/max	water l/ha min/max	kg as/ha min/ max		
Orchards (pome fruit), Vines Professional outdoors	North & South	Karmex 80 WG	F	Mono- and dicotyledonous weeds	WG	800 g/kg	Field (ground directed tractor mounted sprayer, manual knapsack sprayer ground directed with shield)	From 3 years after planting, application in spring, weed stage BBCH 00	1	-	0.167/0.5	100/300	0.5	60*	Application must be directed and limited to ground in strip-band application under the rows avoiding drift by using low pressure and shields. The treated area would be approximately 1 meter across the plants, allowing natural weed emergence and growth between the rows.

Remarks:	*	Uses for which risk assessment could not be concluded due to lack of essential data are marked grey	(h)	Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
	(a)	For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)	(i)	g/kg or g/L
	(b)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(j)	Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	(c)	e.g. biting and suckling insects, soil born insects, foliar fungi, weeds		
	(d)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
	(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989	(l)	PHI - minimum pre-harvest interval
	(f)	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	(m)	Remarks may include: Extent of use/economic importance/restrictions
	(g)	All abbreviations used must be explained		

* 60 days is a minimum. PHI in practice will be longer as application is made at the beginning of the season when fruits are not yet developed.