

Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name): Diuron

Chemical Group:

EC Number: 206-354-4

CAS Number: 330-54-1

Submitted by: Finnish Safety and Chemicals Agency (Tukes), Finland

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NOTE

This document has been prepared by the evaluating Member State given in the CoRAP update.

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1 IDENTITY OF THE SUBSTANCE

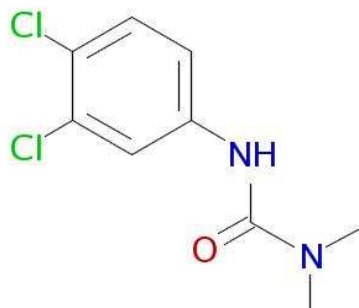
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	Diuron
EC number:	206-354-4
EC name:	Diuron
CAS number (in the EC inventory):	330-54-1
CAS number:	330-54-1
CAS name:	
IUPAC name:	3-(3,4-dichlorophenyl)-1,1-dimethylurea
Index number in Annex VI of the CLP Regulation	006-015-00-9
Molecular formula:	C ₉ H ₁₀ Cl ₂ N ₂ O
Molecular weight or molecular weight range:	233.0945
Synonyms:	

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Index number: 006-015-00-9

Hazard Class and Category Codes	Hazard Statement Codes	Hazard Statements	Pictogram Signal Word Codes	Hazard Statement Codes	Specific Concentration Limits and M Factors
Carc. 2 Acute Tox. 4 * STOT RE 2 * Aquatic Acute 1 Aquatic Chronic 1	H351 H302 H373 ** H400 H410	H351: Suspected of causing cancer. H302: Harmful if swallowed. H373: May cause damage to organs through prolonged or repeated exposure. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects.	GHS08 GHS07 GHS09 Wng	H351 H302 H373 ** H410	M = 10

Classification	Risk Phrase Codes	Risk Phrases	Safety Phrases	Indications of danger	Concentration Limits
Carc. Cat. 3 Xn N	R40 R22, R48/22 R50/53	R40: Limited evidence of a carcinogenic effect. R22: Harmful if swallowed. R48/22: Harmful: danger of serious damage to health by prolonged exposure if swallowed. R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.	S2 S13 S36/37 S46 S60 S61	Xn N	N; R50-53: C ≥ 2,5% N; R51-53: 0,25% ≤ C < 2,5% N; R52-53: 0,025% ≤ C < 0,25%

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None proposed.

2.3 Self classification

Classifications by the lead registrant is consistent with harmonised classifications.

Notifications to the Classification and Labelling Inventory is also mainly consistent with harmonised classifications, but some selv classify with M-factor =100.

3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

3.1 Legal basis for the proposal

- Article 44(1) (refined prioritisation criteria for substance evaluation)
- Article 45(5) (Member State priority)

3.2 Grounds for concern

<input type="checkbox"/> (Suspected) CMR	<input checked="" type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> (Suspected) Sensitiser	<input type="checkbox"/> Consumer use	<input type="checkbox"/> High RCR
<input type="checkbox"/> (Suspected) PBT	<input type="checkbox"/> Exposure of sensitive populations	<input type="checkbox"/> Aggregated tonnage
<input checked="" type="checkbox"/> Suspected endocrine disruptor	<input checked="" type="checkbox"/> Other (provide further details below)	

Identified uses indicate uses in rubber articles and polymer preparations. Only industrial uses are indicated in the dossier. Spin database indicates consumer exposure. Diuron is currently assessed according to the Biocides directive for the following uses: in-can preservatives (PT 6), film preservatives (PT 7) and masonry preservatives (PT 10). Diuron has been accepted as an active ingredient in plant protection product (inclusion in Annex I to Plant Protection Product Directive 91/414/EEC). In Finland, for the time being, there are no plant protection products containing diuron on the market.

Reproductive toxicity tests indicate no effects on fertility or developmental toxicity (for the latter the maximum dose tested was 50 mg/kg bw/day). Substance is classified as Carc Cat 2 according to Regulation EC No 1272/2008.

Diuron is selected for CoRAP to examine the basis of the EC List conclusion for potential evidence of ED and identify if there is significant exposure. Diuron is metabolised to 1-(3,4-dichlorophenyl)-3-methoxyurea and 3,4-dichloroaniline. Diuron is considered to be potentially antiandrogenic because of the great similarity in structure of a) diuron and the antiandrogen linuron (Human health cat. 1, Wildlife cat. 3) and b) the common metabolite, 3,4-dichloroaniline, of diuron and linuron, which was shown to bind to the androgen receptor (Cook et al., 1993). According to EC list 3,4-dichloroaniline is classified in human health ED Cat. 2 and in wildlife ED Cat.1 e.g. based on inhibitory effects on the synthesis and metabolism of androgens in breeding males of sticklebacks (Allner, 1995). Furthermore, basis of the EC list 3,4-dichloroaniline is classified as having high concern for exposure.

In addition, diuron has been identified as one of the most relevant pollutants in European ground waters in terms of frequency of detection and maximum concentrations. It was detected in approximately 30 % of ground water samples taken with a maximum concentration of 279 ng/l (Loos et al. 2010).

In European river waters diuron has been detected in 70 % of samples with a maximum concentration of 864 ng/l and average concentration 41 ng/l (Loos et al 2009). For comparison, the annual average environmental quality standard is 200 ng/l.

3.3 Information on aggregated tonnage and uses

<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input checked="" type="checkbox"/> 100 – 1000 tpa	
<input type="checkbox"/> 1000 – 10,000 tpa	<input type="checkbox"/> 10,000 – 100,000 tpa		
<input type="checkbox"/> 100,000 – 1000,000 tpa	<input type="checkbox"/> > 1000,000 tpa		
<input type="checkbox"/> Confidential			
<i>Please provide further details</i>			
<input checked="" type="checkbox"/> Industrial use	<input type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
Diuron is used in rubber articles and polymer preparations and also in biocidal and plant protection products.			

3.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

<input type="checkbox"/> Compliance check final decision	<input checked="" type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input checked="" type="checkbox"/> Annex VI (CLP)	<input checked="" type="checkbox"/> Plant Protection Products Regulation 91/414/EEC
<input type="checkbox"/> Annex XV (SVHC)	<input checked="" type="checkbox"/> Biocidal Products Directive 98/8/EEC
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
Harmonised classification in Annex VI of the CLP and in Dangerous substances Directive (see section 2.1).	
Ongoing assessment according to Biocidal products directive 98/9/EEC for PT 7 and 10, but prohibited in PT 6 and 21 as off 25.10.2009/21.8.2008 respectively. Included in Annex I of the Plant Protection Products Regulation 91/414/EEC.	

3.5 Information to be requested to clarify the suspected risk

<input checked="" type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Other (provide further details below)	
<p>To examine the basis of the EC List conclusion for potential evidence of ED. The available and the requested information are evaluated on the basis of the criteria for ED chemicals.</p> <p>Clarification on consumer exposure.</p>	

3.6 Potential follow-up and link to risk management

<input type="checkbox"/> Restriction	<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Authorisation	<input checked="" type="checkbox"/> Other (provide further details)
<p>Depending on outcome of 3.5. (e.g., Annex XV dossier for SVHC (article 57f)).</p>			

References

Cook JC, Mullin JS, Frame SR, Biegel LB. Investigation of a mechanism for Leydig cell tumorigenesis by linuron in rats. *Toxicol. Appl. Pharmacol* 1993; 119: 195-204.

Allner, B. (1995). Effekte von endokrin wirksamen Substanzen auf Fische dargestellt am Beispiel der Wirkung von 3,4-Dichloranilin auf den Androgenmetabolismus des Stchlings. - UBA- Texte 65/95, Umweltchemikalien mit endokriner Wirkung, Berlin, 69-76.

Robert Loos, Giovanni Locoro, Sara Comero, Serafino Contini, David Schwesig, Friedrich Werres, Peter Balsaa, Oliver Gans, Stefan Weiss, Ludek Blaha, Monica Bolchi, Bernd Manfred Gawlik. 2010 Pan-European survey on the occurrence of selected polar organic persistent pollutants in ground water. *Water research* 44 (2010) 4115 - 4126.

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