Conclusion regarding the peer review of the pesticide risk assessment of the active substance

Diuron

finalized: 14 January 2005

SUMMARY

Diuron is one of the 52 substances of the second stage covered by Commission Regulation (EC) No 451/2000[1], as amended by Commission Regulation (EC) No 1490/2002[2]. This Regulation requires the European Food Safety Authority (EFSA) to organise a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within one year a conclusion on the risk assessment to the EU-Commission.

On 19 September 2003, Denmark being the designated rapporteur Member State submitted in accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, the DAR on diuron to the EFSA. The peer review was initiated on 13 October 2003 by dispatching the DAR for consultation of the Member States and the notifier, The European Diuron Taskforce consisting of Bayer and Griffin. However, the task force has in the meantime been changed as DuPont de Nemours (France) S.A. has replaced Griffin (Europe) within the European Diuron Taskforce (DTF) by 5 November 2003. This has been reported to the Commission, the RMS and EFSA on 26 August 2004. The comments received on the DAR were examined by the rapporteur Member State. Remaining issues were evaluated in respective meetings with Member State experts.

A final discussion of the outcome of the consultation of experts took place with representatives from Member States on 14 December 2004 leading to the conclusions as laid down in this report.

The conclusion was reached on the basis of the evaluation of the representative uses as herbicide as proposed by the notifier which comprises spraying to control mono- and dicotyledonous weeds in pome fruit and vine at application rate up to 2 kg diuron per hectare in strip application.
The notifier has applied for an amendment of the GAP after the expert meetings The new intended GAP is pre-emergence application of 1.5 kg a.s./ha in strips. The new intended GAP has not been taken into account by the RMS due to the late submission.

[1] OJ No L 53, 29.02.2000, p. 25
[2] OJ No L 224, 21.08.2002, p. 25

Due to the fact of outstanding data a final comparability of the technical material from the different sources could not be conducted during the evaluation procedure. From an analytical point of view none of the three sources can be regarded as equivalent. Therefore the given minimum purity of 970 g/kg has to be regarded as a provisional value.
No analytical method for monitoring purposes to determine residues of diuron in food of plant origin is available. In addition, the acceptability of the analytical method for the determination of residues in soil and ground water is depending on the residue definitions for monitoring purposes, which can be concluded only after the assessment of outstanding data in the fate and behaviour section.
The necessity for an analytical method for food of animal origin cannot be concluded due to the fact that the risk assessment on food of animal origin cannot be finalised.

The main toxicological effects of diuron are haemolytic anaemia and effects on the urothelial system. It is carcinogenic in rats and mice. The classification is toxic with the risk phrases T; R22, R40, R48/22, R48/23. **Based on the available data the estimated operator exposure (German model, with standard PPE) exceeds the AOEL.** Bystander and worker exposure is assumed to be negligible.

The metabolism of diuron in plants is well understood and yields the metabolites DCPMU (3,4-dichlorophenyl-methylurea) and DCPU (3,4-dichlorophenylurea), which are of toxicological concern. It is noted that these metabolites can derive not only from diuron but also from other herbicides. As long as the investigation of the residue situation according to the critical GAP is not finalised, the risk assessment for consumers cannot be finally concluded, nor can MRLs be proposed.

Soil degradation of diuron yields DCPMU and DCPU as major metabolites. Mineralisation is generally low but occasionally may reach levels up to 32 %. Non-extractable residues build up during the degradation. A photolysis in soil study is necessary to complete the assessment.
Diuron is moderately to highly persistent in soil under aerobic conditions. Degradation of diuron is slower at lower temperatures and under anaerobic conditions. In multiple season field studies, a tendency of soil adaptation is observed with a faster degradation in the later years. The need for further soil degradation studies on metabolites DCPMU and DCPU has been identified during the peer review. Diuron, DCPMU and DCPU have medium to low potential for mobility in soil.
Hydrolysis of diuron shows strong pH dependence being relatively rapid under acidic pH and stable at alkaline pH. Aqueous photolysis could contribute to environmental degradation of diuron. It is proposed to classify this active substance as “non-readily biodegradable” taking into account the results of the water sediment studies. In water sediment systems no metabolites are formed at levels above 10 % AR neither in the water nor in the sediment. Diuron was relatively rapidly adsorbed by the sediment. In the total system, diuron was moderately to highly persistent. Diuron PECsw and PECsed (initial) values used in the risk assessment are based on the spray drift values. The contribution from drainage and run-off was not assessed and should be taken into account by MS when these routes of surface water contamination are envisaged to be relevant. The Notifier is

required to provide the existing surface monitoring data but this data requirement was not considered essential to finalise the EU risk assessment.
The level of uncertainty in the available FOCUSgw modelling is too high to come to a conclusion regarding the risk of ground water contamination and new FOCUS modelling is needed (pending further data on degradation of DCPMU and DCPU). Therefore, the residue definition for groundwater is still open.

A high risk to birds and mammals from the use of diuron was identified. The lowest TER values are 8.8, 5.2 and 0.4 for the acute, short and long term risk to birds, respectively, and 5.1 and 0.7 for the acute and long term risk to small herbivorous mammals, respectively. These values are all below the corresponding Annex VI trigger values of 10 for both the acute and short term risk and 5 for the long term risk. Further data to address this risk is needed and the risk assessment can only be concluded when the outstanding data is evaluated.
Using the lowest algae endpoint, the risk assessment indicates a high risk to aquatic organisms. Even with a buffer zone of 50 m, the calculated TER value (2.5) is below the respective trigger of 10.
Additionally, a high risk to terrestrial plants was identified as the trigger is breached with a buffer zone of 50 m (TER = 3.58, trigger in the guidance document on terrestrial organisms is 5).
Therefore, extensive risk mitigation measures (e.g. buffer zones above 50 m) or further data to address this risk to aquatic and terrestrial plants is considered necessary.
For bees (pending confirmatory data requirement), non-target arthropods, soil micro- and macro-organisms, including earthworms the risk is considered low for the representative uses with regard to diuron and metabolites.

Key words: diuron, peer review, risk assessment, pesticide, herbicide

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BACKGROUND

Commission Regulation (EC) No 451/2000 laying down the detailed rules for the implementation of the second and third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC, as amended by Commission Regulation (EC) No 1490/2002, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Diuron is one of the 52 substances of the second stage covered by the amended Regulation (EC) No 451/2000 designating Denmark as rapporteur Member State.

In accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, Denmark submitted the report of its initial evaluation of the dossier on diuron, hereafter referred to as the draft assessment report, to the EFSA on 19 September 2003. Following an administrative evaluation, the EFSA communicated to the rapporteur Member State some comments regarding the format and/or recommendations for editorial revisions and the rapporteur Member State submitted a revised version of the draft assessment report. In accordance with Article 8(5) of the amended Regulation (EC) No 451/2000 the revised version of the draft assessment report was distributed for consultation on 13 October 2003 to the Member States and the main notifier, The European Diuron Taskforce consisting of Bayer and Griffin as identified by the rapporteur Member State. However, the task force has in the meantime been changed as DuPont de Nemours (France) S.A. has replaced Griffin (Europe) within the European Diuron Taskforce (DTF) by 5 November 2003. This has been reported to the Commission, the RMS and EFSA 26 August 2004.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, representatives of the Member States identified and agreed in an evaluation meeting data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level. A representative of the notifier was attending this meeting.

The discussion of the identified data requirements and/or issues took place in expert meetings organised on behalf of the EFSA by the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL), Germany. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place with representatives from the Member States on 14 December 2004 leading to the conclusions as laid down in this report.

During the peer review of the draft assessment report and the consultation of technical experts no critical issues were identified for consultation of the Scientific Panel on Plant Health, Plant Protection Products and their Residues (PPR).

In accordance with Article 8(7) of the amended Regulation (EC) No 451/2000, this conclusion summarises the results of the peer review on the active substance and the representative formulation evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.

The documentation developed during the peer review was compiled as a **peer review report** comprised of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's draft assessment report:

- the comments received
- the resulting reporting table (rev. 1-2 of 25 March 2004)
- the consultation report

as well as the documents summarising the follow-up of the issues identified as finalised at the end of the commenting period:

- the reports of the scientific expert consultation
- the evaluation table (rev. 2-1 of 14 December 2004)

Given the importance of the draft assessment report including its addendum (compiled version of November 2004) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Diuron is the ISO common name for 3-(3,4-dichlorophenyl)-1,1-dimethylurea (IUPAC).

Diuron, belonging to the class of phenylurea herbicides, can be used as herbicide for the control of mono- and dicotyledonous weeds as well as mosses. Diuron has phytotoxic action by inhibiting photosynthesis and is mainly absorbed by roots and translocated in the apoplast.

The representative formulated product for the evaluation was "Karmex 80 WG", a water dispersible granule (WG), registered under different trade names in Europe.

The representative uses evaluated comprise spraying to control mono- and dicotyledonous weeds in pome fruit and vine at application rate up to 2 kg diuron per hectare in strip application.
The notifier has applied for an amendment of the GAP after the expert meetings. The new intended GAP is pre-emergence application of 1.5 kg a.s./ha in strips. The new intended GAP has not been taken into account by the RMS due to the late submission.

SPECIFIC CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

The minimum purity of diuron as manufactured should not be less than 970 g/kg but has to be regarded as a provisional value due to the fact of outstanding data. This value is higher than the minimum purity given in the FAO specification 100/TC/S11 (1980) of 930 g/kg. The higher value relates to the submitted results of current batch analysis and not to any toxicological concern to increase the minimum purity. However, due to the fact of outstanding data a final comparability of the technical material from the different sources could not be conducted during the evaluation procedure. From an analytical point of view none of the three sources can be regarded as equivalent. The source of Bayer and the source Griffin contain one impurity each, which is not present in the other two sources and in respect to the different content of several impurities in the technical materials. The technical material does not contain relevant impurities, but in the FAO specification the content of free amine salts (calculated as dimethylamine hydrochloride) is limited to a maximum content of 0.4% of the diuron content.

The content of diuron in the representative formulation "Karmex 80 WG" is 800 g/kg (pure).

The assessment of the data package revealed no particular area of concern in respect of the physical and chemical properties of diuron or the respective formulation, but 9 data gaps and open points, respectively, have been identified:

- solubility in aliphatic hydrocarbon and alcohol
- oxidising properties of the technical material
- analytical method for monitoring purposes to determine residues in food of plant origin (incl. independent laboratory validation and a confirmatory method, if appropriate)
- the acceptability of the available analytical method for the determination of residues of diuron in soil and ground water (incl. the need for a confirmatory method for metabolites, if appropriate) depends on the assessment of outstanding data in the fate and behaviour section.
- confirmatory methods to demonstrate the specificity of the analytical methods for the determination of diuron in soil and water.
- analytical method for the determination of residues in blood
- analytical method(s) for the determination of impurities in the technical material (Makhteshim source)
- technical specification (Griffin)
- shelf-life study

Recently submitted data regarding the technical specification of the Bayer CropScience source and the shelf-life study have been evaluated only by the RMS and were not peer reviewed by other MS or discussed in an EPCO expert meeting.

The new technical specification was presented by the RMS in an addendum to Volume 4, Annex C (*amended November 2004*). However, the conclusion of the RMS that the new data fulfils the data gap is confirmed by EFSA.

In case of the shelf-life study, the RMS came to the conclusion that the study addressed the annex point partially, because information in respect to the package stability is missing.

The main data regarding the identity of diuron and its physical and chemical properties are given in appendix 1.

Adequate analytical methods are available for the determination of diuron in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material (Griffin and Bayer CropScience source).
Data submitted to the RMS in April 2004, regarding the purity of the starting material (Makhteshim source) were not peer reviewed by other MS or discussed in an EPCO expert meeting. However, the conclusion of the rapporteur Member State that these data fulfil the data gap is confirmed by EFSA.

No analytical method for monitoring purposes to determine residues of diuron in food of plant origin is available. Due to the new proposed residue definition only an analytical method used for data generation in the residue trials performed in the USA could be used. However, this method does not fulfil the requirements of Directive 96/46/EC or the guidance document SANCO/825/00.
The acceptability of the analytical method for the determination of residues in soil and ground water is depending on the residue definitions for monitoring purposes, which can be concluded only after the assessment of outstanding data in the fate and behaviour section. However, the submitted analytical methods are suitable to determine separately diuron and its metabolites DCPMU, DCPU, 3,4 DCA and mCPDMU down to 0.05 mg/kg (for each analyte) in soil as well as diuron, mCPDMU and 3,4 DCA in water (drinking and surface) down to 0.05 µg/L (for each analyte). Confirmatory methods to demonstrate the specificity of the analytical methods, taken the final residue definition into account, are not available. Concerning the matrix surface water, only a confirmatory method is missing.
A recently submitted method for the determination of residues in blood was neither evaluated in expert meetings nor by the RMS or EFSA.
For air an adequate analytical method is available for the determination of residues of diuron.
The necessity for an analytical method for food of animal origin cannot be concluded due to the fact that the risk assessment on food of animal origin cannot be finalised (see 3.2).

2 Mammalian toxicology

2.1 TOXICOKINETICS (ABSORPTION, DISTRIBUTION, EXCRETION AND METABOLISM)

Diuron is rapidly and nearly totally absorbed via the oral route. The main part is excreted via urine. Diuron is extensively metabolised via N-demethylation and ring hydroxylation. The main metabolite is 3,4-dichlorophenylurea.

2.2 ACUTE TOXICITY

Diuron is of low to moderate acute oral toxicity depending on the vehicle. LD_{50}, oral, rat is 437 mg/kg bw in oil as vehicle. It should be classified **Xn; R22 "Harmful if swallowed**". Diuron is of low acute toxicity by the dermal and inhalatory routes. LD_{50}, dermal, rat >5000 mg/kg bw and LC_{50}, inhalation, rat > 7.1 mg/L (dust exposure). It is not irritating to the skin or eyes and shows no sensitising properties in the submitted acceptable studies.

2.3 SHORT TERM TOXICITY

The primary toxicological effect seen after short-term repeated administration of diuron was changes in the blood system. A number of studies indicate that repeated administration of Diuron causes haemolytic anaemia. Signs of haemolytic anaemia include reduced erythrocyte count, reduced haemoglobin content in blood, reduced haematocrit, spleen enlargement, and increased serum bilirubin. Increased accumulation of iron-containing pigment was found in the liver, kidney and spleen. The accompanying increases in Heinz bodies and reticulocytes, which are not always measured, indicate that the anaemia is compensated. Based on this haemolytic anaemia and the dose levels where it occurs diuron is proposed classified **T; R48/23.**

The relevant oral NOAEL for short-term toxicity is 0.66 mg/kg bw/day in the 6 month rat study.

No NOAEL was established in the dermal study but a LOAEL of 250 mg/kg bw/day in the rat was set based on reduced haemoglobine levels and enlargement of the spleen.

The inhalatory NOAEL was 0.0041 mg/L in the rat based on reduced haemoglobin levels, number of erythrocytes, haematocrit and increased number of Heinz bodies. Thus, the classification of **Xn; R48/22** is proposed**.**

2.4 GENOTOXICITY

A few tests for genotoxicity showed questionable positive results. Especially the UDS test in bladder urothelial cells has been discussed during the Expert meeting (July 2004). The meeting concluded that no further mutagenicity tests were necessary and that the weight of evidence suggests that diuron is of no genotoxic concern.

2.5 LONG TERM TOXICITY

The primary toxicological effects seen in the long-term studies were effects on the blood system and on the urothelial system. The effects on the blood system were haemolytic anaemia as also seen in the short-term toxicity studies. In rats hyperplasia and neoplasia in the urothelium is observed and in mice, hyperplasia in bladder epithelium and mammae carcinomas.

The effects on the bladder can be caused by irritation but there is no clear indication of this in the available documentation. A mechanistic study is ongoing but not yet submitted.

Based on the available documentation diuron is **proposed to be classified as carcinogenic, cat. 3, with R40 "Limited evidence of carcinogenic effect".**

No NOAEL was observed and the LOAEL is set to 1.7 and 1.0 mg/kg bw/day in females and males; respectively.

2.6 REPRODUCTIVE TOXICITY

In a two-generation study in rats no toxicity was experienced to reproduction but the highest dose tested of 1750 ppm was toxic for both adults and pups. Effects seen in adults were decreased body weights, body weight gain and food consumption. The body weights of pups were also decreased. The relevant NOAEL was 250 ppm (i.e.18.2 mg/kg bw/day).

The developmental toxicity studies in rats and rabbits did not show any specific reproduction toxicity of diuron but pregnant dams are more susceptible to the general toxic effects of the test substance. The skeletal alterations and delayed ossifications seen in foetuses in the high dose in the rat study were most likely due to maternal toxicity. In conclusion, diuron has no effect on reproduction or induces developmental toxicity.
The relevant maternal NOAEL was 10 mg/kg bw/day and the NOAEL for development was 50 mg/kg bw/day.

2.7 NEUROTOXICITY

No neurotoxicity studies were submitted. Diuron has no structural relationship to neurotoxic substances. Moreover no evidence of neurotoxic potential is seen in the toxicological studies. No specific studies are required.

2.8 FURTHER STUDIES

Urothelial effects: Bladder hyperplasia was found to begin after 4 weeks of administration to rats of 2500 ppm Diuron in feed for 2, 4, 12 or 26 weeks with and without recovery. The effects were largely reversible.

Immunotoxicity: There was no evidence that Diuron at concentrations up to 2500 ppm could affect the immune system in rats when tested for three weeks.

Tests on metabolites: 3-(4-chlorophenyl)-1,1-dimethyl urea (Monuron), (3,5-dichlorophenyl)-1,1-dimethyl urea and 3-(3-chlorophenyl)-1,1-dimethyl urea were tested in *Salmonella typhimurium* – strains TA100, TA1535, TA97 and TA98 – in Ames test without and with exogenic metabolism activator. No evidence of mutagenic activity was detected for any of the three substances.

2.9 MEDICAL DATA

Chloracne has been seen at a plant in England, but it is stated that this problem has never existed in factories in Germany. Two possible impurities are known to give this effect. Case studies indicate that the metabolism in humans is similar to the metabolism in rats. Diuron showed no phototoxicity in a patch test.

2.10 ACCEPTABLE DAILY INTAKE (ADI), ACCEPTABLE OPERATOR EXPOSURE LEVEL (AOEL) AND ACUTE REFERENCE DOSE (ARFD)

ADI

ADI is based on the long term rat study (Schmidt, 1985). As there is no NOAEL for females in this study the ADI is based on LOAEL for females of 1.7 mg/ kg bw/day. Since the ADI is based on a LOAEL, a safety factor of 250 is used resulting in an ADI of 0.007 mg/kg bw/day.

The ADI is 0.007 mg/kg bw/day.

AOEL

AOEL is based on the NOAEL from the 6 month rat study with a safety factor of 100 resulting in an AOEL of 0.007 mg/kg/day (Schmidt and Karma, 1986). The safety factor of 100 is considered satisfactorily as the NOAEL for carcinogenic effects in rats is 10 mg/kg bw/day. No correction for oral absorption is needed.

The AOEL is 0.007 mg/kg/day.

ARfD

Initially the Rapporteur Member State proposed an ARfD of 0.007 mg/kg bw/day based on the NOAEL of 0.66 mg/kg bw/day in the 6 month rat study (Schmidt and Karma, 1986). This issue was discussed at the Expert meeting (July 2004). The meeting agreed to use the 6 month rat study, however to use the NOAEL of 1.6 mg/kg bw/day which was noted at the time point of 4 weeks in the study. A safety factor of 100 is used.

The ARfD is thus set to 0.016 mg/kg bw/day.

2.11 DERMAL ABSORPTION

The dermal absorption for Karmex 80 WG is 2.7% for mixing/loading and 4.7% for spraying based on an *in vitro* study in rat and human skin. The residues in the skin including the stratum corneum are included.

2.12 EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

Operator

The exposure to operators is calculated with the German model. The calculation is based on the original intended use of 2 kg a.s./ha in strip application. Due to the strip application it is supposed that the work rate per day with tractor mounted equipment is reduced to 1/3 of the normal rate i.e. 6.6 ha/day. But with handheld equipment it is supposed that the work rate is the normal rate of 1 ha per day.

Based on these assumptions the systemic exposure for the operator is 429% and 986% of the AOEL without protective equipment for tractor mounted and handheld equipment respectively. With gloves during mixing/loading and application the exposure is 214% and 557% of the AOEL respectively.

Based on the available data the estimated operator exposure (German model, with standard PPE) exceeds the AOEL.

Bystander

Bystander exposure following the use of Karmex 80 WG is considered to be negligible.

Workers

The intended use is in orchards and wine in spring. Re-entry in these crops at that time of the year is not expected shortly after spraying.

3 Residues

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1 Primary crops

Metabolism studies on orange trees, wheat and maize with diuron radiolabelled in the phenyl-ring have shown a consistent metabolic pathway for these crops. Diuron is metabolised via demethylation to DCPMU (3,4-dichlorophenyl-methylurea), further to DCPU (3,4-dichlorophenylurea), then to highly polar and water soluble components. The same metabolic pattern was seen for lettuce in a confined accumulation study with diuron on rotational crops.

Therefore for plants the residue of concern is defined as diuron including all components containing the 3,4- dichloraniline moiety expressed as 3,4-dichloraniline for risk assessment and monitoring purposes. It is noted that the metabolites DCPMU and DCPU are of toxicological significance, but can derive not only from diuron but also from other herbicides like e.g. linuron, neburon and propanil.

A range of residue trials in pome fruits and grapes conducted with an application rate of 4 kg/as ha and an PHI of 150 days are available and have indicated that the level of residues found in the fruits was always less than LOQ of 0.03 mg/kg for the GC-ELCD method used for analysis in residue trials. All compounds containing 3,4-dichloraniline have been determined. But in these trials field-testing parameters, such as application rate, application time and sampling time were not consistent with the critical GAP. At present there are no residue trials available covering the critical GAP of 2 kg as/ha and a 60 days PHI.

Therefore at least two residue trials according to the critical GAP have to be conducted for pome fruit and grapes in the northern and in the southern region, respectively. In case residues are detected more trials are necessary.

Residues were not found in pome fruits and grapes (<0.03 mg/kg) from presently available residue trials. Thus an investigation of effects of industrial or household processing was not necessary. However, if significant residues would be detected in the outstanding residue trials, an investigation of effects of processing on the nature and magnitude of the residue may become necessary.

3.1.2 Succeeding and rotational crops

A confined accumulation study of diuron on rotational crops revealed that the metabolism in succeeding/rotational crops is comparable to the metabolism in the primary crops. (See point 4.1.1) Normally there is no crop rotation expected in orchards and vineyards. However, if fruit trees/bushes are followed by a succeeding crop, a risk may exist for residues occurring in the succeeding crop.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

At present the only commodity relevant for livestock feeding is apple pomace, which is included in the total diet for beef and dairy cattle. Metabolism or feeding studies in ruminants haven't been presented. However, as long as the investigation of the residue situation according to the critical GAP is not finalised, the risk assessment on food of animal origin cannot be concluded.

3.3. CONSUMER RISK ASSESSMENT

As long as the investigation of the residue situation according to the critical GAP is not finalised the chronic dietary risk assessment and the short term exposure risk assessment for consumers can not be finally concluded.

3.4. PROPOSED MRLS

As long as the investigation of the residue situation according to the critical GAP is not finalised MRLs cannot be proposed. Diuron is approved in non-EU countries; however no Codex MRLs have been established or proposed yet and need to be considered.

4. Environmental fate and behaviour

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. Route of degradation in soil

Information of ^{14}C phenyl labelled diuron metabolism in soil under aerobic conditions is provided by two separated studies where a total of four soils are used. The soils covered a range of pH values (4.6 – 7.3), clay contents (2.1 % – 19 %) and organic matter contents (0.78 %- 3.7 %). Incubation temperature ranges from 10 ^{o}C (one soil) to 20 ^{o}C (three soils) or 25 ^{o}C (one soil). All laboratory studies were performed in dark.

In aerobic conditions, degradation of diuron starts by the demethylation of the nitrogen atom in the urea moiety, yielding the metabolites DCPMU (N'-(3,4-dichlorophenyl)-N'-methylurea, maximum 33 % AR after 100d at the end of the study) and DCPU ((3,4-dichlorophenyl)-urea, maximum 25 % AR after 64 d). No other metabolites were found at levels above 10 % AR (DCA, 3,4-dicholoraniline, maximum 2% AR after 100d at the end of the study). Mineralisation was extremely low in two soils where no quantifiable CO_2 was collected at the end of the studies (100 d). A maximum of a 31.8 % AR of CO_2 formed after 101 d in one of the soils (de Vries 1996). In all the experiments non-

extractable residue reaches a maximum at the end of the study (maximum: 14 % AR - 44 % AR at 20 °C). Nature of non-extractable residue was not investigated and distribution was only investigated in one of the soils where 20 % of the non extractable residue was found in the humic fraction and 7 % in the fulvic fraction.

Under anaerobic conditions the degradation is considerably slower and only the first metabolite DCPMU attains levels of 10 % AR.

No study on photolysis in soil is available. This information was deemed necessary to complete the assessment in the Evaluation Meeting (March 2004). Experts meeting (EPCO 7, June 2004) confirmed the need for this study. EFSA notes that for the representative uses the product is not soil incorporated and that the potential formation of photolysis metabolites needs to be assessed for these uses. Notifier informed during the Evaluation meeting that a photolysis study could be available within one year (March, 2005).

4.1.2. Persistence of the active substance and their metabolites, degradation or reaction products

Additional to the metabolism studies, degradation of diuron is investigated in another soil (pH 5.9, clay content 1.9 %, OC 0.62 %, t = 20 °C) to determine degradation rate of diuron and its metabolite DCPMU.

The studies available indicate that diuron is moderately (DT_{50} = 20 d, 51 d) to highly (DT_{50} = 112 d, 119 d) persistent in soil under aerobic conditions under environmental relevant conditions (t = 20 – 25 °C, MHC = 70 %). However, differences in half-lives may not be attributed to any particular soil characteristic such pH or organic matter content and the mean DT_{50} = 75 d (20 °C, MHC = 70 % field capacity) was used in FOCUSgw modelling. The longest laboratory aerobic soil half-life was observed in one metabolism study (DT_{50} = 372 d). Since there is no soil photolysis study available it is not possible to know to which extend photolysis may contribute to the environmental dissipation of diuron. Degradation of diuron is slower at lower temperatures (DT_{50} = 143 d at 10 °C vs DT_{50} = 51 d at 20 °C in the same soil and conditions) and under anaerobic conditions (DT_{50} = 1000 d).

Three (two published and one unpublished) field studies are available in which a total of nine field sites are studied. Half-life in these studies ranged from 14 d to 231 d. The quality of the field studies is doubtful due to the lack of analytical information and that specific guidelines were not followed. The unpublished field studies show quite variable results among the six sites. From one of the published field studies, with consecutive applications during four years, a tendency of soil adaptation is observed with a faster degradation in the later years. This is attributed to specialisation of the soil microflora. Experts meeting (EPCO 7, June 2004) discussed the worst case DT_{50} more appropriate for PEC soil calculations. It was concluded that: PEC based on laboratory data and DT_{50} = 119 d was maintained as calculated by the RMS in the Addendum (May 2004) and considered representative of worst case for pre-adapted soils. A longer DT_{50} = 231 days is available from field studies. This DT_{50} may need to be considered by MS for non pre-adapted soil uses and is also reported in the endpoints list. Therefore, two different values are reported in the list of end points, one for single application and one for pre-adapted soils.

There is only one DT_{50} value for DCPMU (DT_{50} = 35 d), obtained from the degradation observed in one laboratory study with the parent. Reliability of this single value is doubtful since there are only two data points after the maximum and the maximum for this metabolite is reached at the end or one time point before study termination in the rest of the soils studied. No degradation data was available for the metabolite DCPU. The Evaluation meeting (March 2004) already identified the need for more soil degradation data for the metabolite DCPMU. The Notifier informed that these data could be available in one year (March 2005). The Experts meeting agreed that data on degradation of metabolite DCPU in soil was also necessary to complete the risk assessment on soil and potential ground water contamination.
Ecotoxicological risk assessment is based on initial soil concentrations calculated by RMS from the maximum formation rates of the metabolites in an Addendum (May 2004).

4.1.3. Mobility in soil of the active substance and their metabolites, degradation or reaction products

Batch adsorption / desorption studies in five soils are available for diuron and metabolites DCPMU and DCPU. Sorption distribution coefficients were recalculated by the RMS in an Addendum (May 2004). The data indicate that diuron (Koc = 468 – 1666 mL / g, mean Koc = 920 mL / g), DCPMU (Koc = 651 – 1358 mL / g, mean Koc = 812 mL / g) and DCPU (Koc = 527 – 861 mL / g, mean Koc = 698 mL / g) have medium to low potential for mobility in soil. No pH dependence is observed for adsorption of any of the three compounds.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. Surface water and sediment

In sterile buffer solutions at 25 ^{o}C, hydrolysis of diuron shows strong pH dependence. Half life is < 1 d at pH 4 and 5 but diuron is considered stable at pH 7 and 9. Aqueous photolysis could contribute to environmental degradation of diuron (DT_{50} = 43 d of 12 h irradiation).
No readily biodegradability test is available in the dossier of diuron. The need for such study was discussed in the experts meeting (EPCO 7, June 2004). In this meeting it was agreed that, if no additional information is made available, it would be proposed to classify this active substance as "non-readily biodegradable" taking into account the results of the water sediment study.
A study with two water sediment systems is available. The study was performed in natural water / sediment systems with slightly alkaline and slightly acidic waters and sediments (pH (water) = 6.5 and 7.5; pH(sediment) = 5.9-6.3 and 7-7.4). No metabolite reached levels above 10 % AR neither in the water nor in the sediment. In the total system only m-CPDMU (N'-(3-chlorophenyl)-N-N'-dimethylurea, maximum 15.2 % after 55 d) exceeded 10 % AR. Mineralisation is quite variable with levels of CO_2 from 2 % to 30 %. The proportion of bound residues in sediment was 17.5 % AR and 45.9 % after 120 d (end of the study). Diuron was relatively rapidly adsorbed by the sediment (maximum 73.5 % after 28 d) with dissipation half-lives in the water phase of 4 and 9 days. In the total system, diuron was moderately to highly persistent (DT_{50} = 48 – 232 d).

Diuron PECsw and PECsed (initial) values to be used in the risk assessment of the representative uses were calculated by the RMS in an Addendum (May 2004) and discussed by the experts meeting (EPCO 7, June 2004). The spray drift values for downward application have been used for the calculations, because the substance is applied to the weeds. Also initial PECsw for the metabolite m-CPDMU is provided in this addendum. The contribution from drainage and run-off was not assessed and should be taken into account by MS when these routes of surface water contamination are envisaged to be relevant.

The Evaluation meeting pointed out the availability of monitoring surface water data for at least two MS. The need for requiring these data was discussed in the experts meeting (EPCO 7, June 2004). After the meeting the RMS checked and found that no monitoring data for surface water data had been provided in the dossier. The Notifier is required to provide the existing surface monitoring data relevant for the representative uses. This data requirement was not considered essential to finalise the EU risk assessment.

4.2.2. Potential for ground water contamination of the active substance their metabolites, degradation or reaction products

FOCUS PELMO calculations presented by the notifier in the dossier and summarised in the DAR where discussed in an experts meeting (June 2004). The meeting agreed on the assessment of the RMS with regard to acceptability of the use of worst case input values (Koc, DT_{50}). As a post meeting note, EFSA underlines that for the metabolite DCPU Koc employed in the FOCUS calculation (Koc = 727 mL / g) is neither a worst case (Koc = 527 mL / g) nor a mean value (Koc = 698 mL / g).

However some concerns were raised on these calculations. Only one DT_{50} value for one metabolite is available (DCPMU). For DCPU a DT_{50} = 360 d is assumed in the calculations but, since there is no degradation data available, it may not be guaranteed that this estimation is protective enough. As a basis for decisions on the potential relevance of the metabolites (DCPMU and DCPU), reliable predictive values for their concentrations in the leachate and thus reliable DT_{50} values for these metabolites are needed.

The nominal application rate is 2 kg/ha. However, it is argued by the notifier that in practice only 1/3 of the area is treated (strip application), which will lead to an actual application rate of 0.6 kg/ha. Results from lysimeter studies at application rates of 2 and 4 kg / ha show ground water contamination risk for metabolites DCPMU and for a.s. DCPMU and DCPU respectively. However, when the results of the lysimeters are linearly extrapolated to an application rate of 0.6 kg/ha leaching would be < 0.1 µg / L for all three substances.

The general applicability of this approach was discussed among the experts. It was questioned if this application practice can be described unambiguously enough on the labels, to avoid misunderstandings. Acceptability of reducing the actual doses by assuming strip application also raised some scientific concerns among the experts. Detailed information is missing on the properties of aquifers and agricultural practice as well as for the differences between North and South Europe. These questions would need more thoroughly discussions in a specialised scientific group before a reduction in the application rate due to strip application can be used in the risk assessment.

Due to the lack of data for the degradation of metabolites and the use of the reduced application rate in the FOCUS calculations, the level of uncertainty is too high to come to a conclusion regarding the risk of ground water contamination (above the trigger 0.1 µg/L) for the representative uses.
The residue definition for groundwater is still open, pending further data on the two metabolites (DCPMU and DCPU).

4.3. FATE AND BEHAVIOUR IN AIR

Concentrations of diuron in the air compartment are expected to be negligible, due to low volatility.

5 Ecotoxicology

5.1. RISK TO TERRESTRIAL VERTEBRATES

The risk to birds and mammals is calculated according to the Guidance Document on Birds and Mammals (SANCO/4145/2000). The risk was calculated for an insectivorous bird and a small herbivorous mammal as foreseen in the above mentioned guidance document for a use in pome fruit and vines. The risk was also calculated for a large herbivorous bird which is not foreseen in the above mentioned guidance document but given the representative use the RMS considered this necessary which was agreed by the EPCO 8 Expert meeting of June 2004. Also the risk for an insectivorous mammal is presented in the DAR. Secondary poisoning is not considered relevant for this compound, since the potential for bioaccumulation is expected to be low (log Pow < 3).

All calculated first tier TER values for birds breach the appropriate Annex VI trigger value and hence the acute, short and long term risk to birds can be considered as high for the representative use in pome fruit and vines. The only exception is the acute risk to insectivorous birds, which can be regarded as low. In the addendum of May 2004 a revised risk assessment to birds from the notifier was presented and evaluated. To refine the acute and short term risk a PT value of 0.3 was proposed based on the strip application. This was discussed in the EPCO 8 Expert meeting and not accepted as no data to support this approach was submitted. As reported in the same addendum the notifier argued that there is no long term risk, as diuron will be applied outside the breeding season. This was also discussed in the EPCO 8 Expert meeting and not accepted as it was agreed that exposure in spring could effect reproduction of birds. Therefore, the EPCO 8 expert meeting agreed on a further data requirement to address the acute, short term and long term risk to insectivorous and herbivorous birds.
None of the calculated first tier TER values for insectivorous mammals breach the appropriate Annex VI trigger values and hence the acute and long term risk to insectivorous mammals can be considered as low for the representative use in pome fruit and vines. However, a high risk was identified for small herbivorous mammals (Annex VI trigger breached). In the addendum of May 2004 a revised risk assessment to mammals from the notifier was presented. For the same reasons as mentioned for the bird risk assessment above, this revised risk assessment was not accepted by the EPCO 8 Expert meeting. Therefore, the EPCO 8 expert meeting agreed on a further data requirement to address the acute and long term risk to herbivorous mammals.

The notifier has provided a new risk assessment for birds and mammals after the EPCO 8 expert meeting based on a revised GAP (pre-emergent application of 1.5 kg as/ha in strips). This assessment has not been evaluated by the RMS.

Based on the data available at the EPCO 8 expert meeting a high risk to birds and mammals from the use of diuron was identified. The lowest TER values are 8.8, 5.2 and 0.4 for the acute, short and long term risk to birds respectively and 5.1 and 0.7 for the acute and long term risk to small herbivorous mammals respectively while the corresponding Annex VI trigger values are 10 for both the acute and short term risk and 5 for the long term risk. Further data to address this risk is needed and the risk assessment can only be concluded when the outstanding data is evaluated.

5.2. RISK TO AQUATIC ORGANISMS

The algae *Scenedesmus subspicatus* was the most sensitive species of all the aquatic species tested with diuron and the lead formulation based on the biomass endpoint. However in the DAR RMS used the growth rate endpoint in accordance with the Technical Guidance Document (TGD - for chemicals and biocides). Also since 3 studies with *S. subspicatus* were available, the geometric mean was used in accordance with the TGD.
However, at the evaluation meeting 11 - 12 March 2004 it was identified that RMS should use both biomass and growth rate of algae as endpoints in the risk assessment. Furthermore, the EPCO 8 Expert meeting (June 2004) stated that use of geometric mean would require further justification for which a data requirement was set.
Using the lowest algae endpoint, the risk assessment indicates a high risk to aquatic organisms. Even with a buffer zone of 50 m, the calculated TER value is below the respective trigger of 10 (EC_{50} = 0.001µg as/L PECsw = 0.4 µg as/L; TER = 2.5).

Studies addressing the long term effects on fish and daphnia are available for diuron. The resulting TER-values indicated a low long term risk for fish (Annex VI trigger not breached). However, a refined risk assessment was required for daphnia (TER = 5.2). The use of a 21 d time weighted average PEC indicates a low long term risk to daphnia (PECtwa = 9 µg as/L; TER = 10.6 at 1m). Alternatively a 5 m bufferzone also provides an acceptable TER without the use of time weighted average PEC values.

Diuron is also very toxic to *Lemna gibba* (ErC50 = 18.3 µg as/L) and a bufferzone of 15 m is required to meet the Annex VI trigger of 10.

As diuron was found to accumulate in the sediment (>10%) and the long term NOEC value for daphnia for diuron did not exceed 0,1 mg/L, a long term study with the sediment dwelling *Hyella azteca* was considered. The initial risk assessment indicated a high risk to *Hyella azteca* (TER = 3.4), and the introduction of a buffer zone of 5 m was necessary to meet the Annex VI trigger level (PECsw = 3.7 µg as/L; TER = 16.3).

The metabolite m-CPDMU was tested in acute studies. The studies show that m-CPDMU is less toxic than the parent for algae, invertebrates and fish. Based on the most sensitive endpoint for algae the risk is considered to be low (TER=174 at 1 m).

As the logPow is below 3, no study on bioconcentration in fish is considered necessary.

5.3. RISK TO BEES

The effects of formulations containing diuron were investigated in two trials, performed by official German testing facilities (according to guideline BBA 23-1). No significant mortality was observed and the resulting HQ values do not breach the appropriate Annex VI trigger value indicating a low risk to bees.

However, neither the a.s. nor the lead formulation has been tested on bees, which was discussed at the EPCO 8 expert meeting. Although the EPCO 8 Expert meeting agreed that the risk should be low (the solubility of the a.s. in water is very high and the influence of coformulants should be low) the need for a confirmatory data requirement to test the effects of the lead formulations on bees was set.

5.4. RISK TO OTHER ARTHROPOD SPECIES

Toxicity to non-target arthropods was low in laboratory studies on the two indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri.* Further testing indicated no adverse effects to the carabid beetles *Poecilus cupreus*, and suppression of feeding rate in the wolf spider *Araneae lycosidae* did not exceed the trigger value of 50% in higher tier tests. However, data for *Aleochara bilineata* from a test on artificial substrate showed considerable effects. In addendum 1 of May 2004 a higher tier test is summarised with natural substrate with a dose that was approximately 2.5 times higher than the intended application rate, maximum 6% effect was observed and thus the Annex VI trigger value of 30% was not exceeded. Hence, the risk for harmful effects on populations of non-target arthropods in the field can be regarded as low for the representative use of diuron.

5.5. RISK TO EARTHWORMS

Studies on the acute toxicity to earthworms from diuron, the formulation diuron WP 80 and the metabolites DCPU and DCPMU are available. The TER-values resulting from the endpoints derived from these studies do not breach the Annex VI trigger values indicating a low acute risk to earthworms for the representative use.

A study on the long term reproductive effects to earthworms from the lead formulation is available. A refined risk assessment based on actual test values (presented in the addendum of November 2004) revealed a TER-value which does not breach the Annex VI triggervalue indicating a low long term risk to earthworms.

Acute TER-values of 703 and 295 for the soil metabolites DCPMU and DCPU respectively indicate a low risk for the representative use. The need for a long term risk assessment for these metabolites is to be decided based on further degradation data which are awaited in the Section on Fate and behaviour (See 4.1.2).

5.6. RISK TO OTHER SOIL NON-TARGET MACRO-ORGANISMS

The need for further data with soil non target macro-organisms was discussed in the EPCO 8 expert meeting. For the representative uses the EPCO 7 Expert meeting agreed on a max. DT_{50} of 45 days for pre-adapted soils and the DT_{90f} is much lower than 365 days. The EPCO 8 Expert meeting therefore agreed that as only one application per year in strips is intended and because earthworms and arthropods are not at risk, no further testing is regarded as necessary for the representative uses.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

The effects of the lead formulation and the soil metabolites DCPMU and DCPU were tested on soil microbial respiration and nitrogen transformation. Deviations of more than 25 % after 28 days were not observed at 2 times the maximum recommended application rate (i.e. the Annex VI trigger value is not breached) and hence the risk to soil non-target micro-organisms is considered to be low for the representative use rate.

5.8. RISK TO OTHER NON-TARGET-ORGANISMS (FLORA AND FAUNA)

In two studies a total of ten plant species (Onion, Corn, Wheat, Sorghum, Sugarbeet, Soybean, Pea, Tomato, Rape, and Cucumber) were investigated for their sensitivity to diuron applied at different life stages. It was observed that plants were most sensitive when diuron was applied after emergence. The first study (by McKelvey and Kuratle 1992) was criticised by the US-EPA for some deviations from the guideline. Therefore a second investigation was carried out and relied up on.

The risk assessment presented in the addendum 1 from May 2004, based on the second study indicates that a buffer zone of 10 m is needed to meet the trigger value for the most sensitive non-target plant species. It is not deemed appropriate to lower the trigger level, since only 5 non-target plant species has been tested in the latest study accepted for the risk assessment. Thus risk mitigation measures for non-target plants would need to be considered at MS-level. The EPCO 8 Expert meeting did not accept to disregard the study (by McKelvey and Kuratle 1992) and requested a risk assessment taking into account the effects observed in this study besides a reasoned case by the notifier on the reason why the study McKelvey and Kuratle 1992 should not be used for the risk assessment process. This assessment was included in the addendum from November 2004, in which the RMS shows that based on the lowest endpoint for tomato a TER value of 3.58 is derived with a buffer zone of 50 m. This indicates a high risk for non-target plants (trigger in the guidance document on terrestrial organisms is 5).

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

For the biological methods for sewage sludge the EC_{50} for respiration was 3080 mg as/L. No adverse effect on carbon mineralisation was observed in sewage studies, when testing the technical compound (diuron purity 97-99%). The risk for biological methods of sewage treatment is considered to be low.

6. Residue definitions

Soil

Definitions for risk assessment: Diuron, DCPMU and DCPU.

Definitions for monitoring: Diuron, **further data needed to reach a conclusion for DCPMU and DCPU**

Water

Ground water

Definitions for risk assessment: **Further data needed to reach a conclusion.**

Definitions for monitoring: **Further data needed to reach a conclusion.**

Surface water

Definitions for risk assessment: Diuron and m-CPDMU

Definitions for monitoring: Diuron

Air

Definitions for risk assessment: Diuron

Definitions for monitoring: Diuron

Food of plant origin

Definitions for risk assessment: Diuron including all components containing 3,4-dichloraniline moiety expressed as 3,4-dichloraniline

Definitions for monitoring: Diuron including all components containing 3,4-dichloraniline moiety expressed as 3,4-dichloraniline

Food of animal origin

Definitions for risk assessment: at present not proposed (pending outstanding residue trial data)

Definitions for monitoring: at present not proposed (pending outstanding residue trial data)

Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Diuron	Moderately to highly persistent ($DT_{50\ lab}$ = 20 -119 d, 20-25 ºC, MWHC = 70 %); ($DT_{50\ field}$ = 14 – 231 d days)	See 5.5, 5.6 and 5.7
DCPMU	**Further data needed to reach a conclusion**	Acute risk to earthworms and risk to soil non-target micro-organisms is considered to be low. Need for long term risk assessment to be decided based on further degradation data.
DCPU	**Further data needed to reach a conclusion**	Acute risk to earthworms and risk to soil non-target micro-organisms is considered to be low. Need for long term risk assessment to be decided based on further degradation data.

Ground water

Compound (name and/or code)	Mobility in soil	> 0.1 µg / L 1m depth FOCUS for the representative uses	Pesticidal activity	Toxicological activity	Ecotoxicological activity
Diuron	Low to medium mobile (Koc = 468-1666 mL/g)	FOCUS modelling: **Further data needed to reach a conclusion.** Yes in lysimeter study (4 kg / ha)	Yes.	Yes	Yes

Compound (name and/or code)	Mobility in soil	> 0.1 µg / L 1m depth FOCUS for the representative uses	Pesticidal activity	Toxicological activity	Ecotoxicological activity
DCPMU	Low to medium mobile (Koc = 651 - 1358 mL/g)	FOCUS modelling: **Further data needed to reach a conclusion.** Yes in lysimeter study (2 and 4 kg /ha)	Further data needed to reach a conclusion.	Further data needed to reach a conclusion.	Further data needed to reach a conclusion.
DCPU	Low to medium mobile (Koc = 527-861 mL/g)	FOCUS modelling: **Further data needed to reach a conclusion.** Yes in lysimeter study (4 kg / ha)	Further data needed to reach a conclusion.	Further data needed to reach a conclusion.	Further data needed to reach a conclusion.

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Diuron (water and sediment phases)	See 5.2
m-CPDMU	The risk to aquatic organisms is considered low (trigger not breached) based on acute toxicity studies with algae, invertebrates and fish.

Air

Compound (name and/or code)	Toxicology
Diuron	No air contamination expected

LIST OF STUDIES TO BE GENERATED,-STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

Identity, physical, chemical properties

- Technical specification (relevant for Griffin source; the study has been submitted to the RMS according to the notifier, but the RMS has not received it yet (18.10.04). This was confirmed verbally at the November evaluation meeting. The study for the Bayer CropScience source has been submitted and was accepted by the RMS; refer to point 1).
- Solubility in aliphatic hydrocarbon and alcohol (the study has been submitted to the RMS according to the notifier, but RMS has not received it yet (18.10.04). this was confirmed verbally at the November evaluation meeting); refer to point 1)
- Oxidising properties of the technical material (submission date proposed by the notifier: the study has been submitted to the RMS according to the notifier, but RMS has not received it yet (18.10.04). This was confirmed verbally at the November evaluation meeting); refer to point 1)
- Shelf life study (the recently submitted study has been evaluated only by the RMS and were not peer reviewed by other MS or discussed in an EPCO expert meeting; refer to point 1)

Methods of analysis

- Analytical method for monitoring purposes for the determination of residues in food of plant origin (incl. independent laboratory validation and confirmatory method, if appropriate) (submission date proposed by the notifier: unknown; data requirement was identified after EPCO 10 meeting; refer to point 1)
- The acceptability of the available analytical method for the determination of residues of diuron in soil and ground water **(**incl. the need for a confirmatory method for metabolites, if appropriate) depends on the assessment of outstanding data in the fate and behaviour section.
- Confirmatory methods to demonstrate the specificity of the analytical methods for the determination of diuron in soil and water.
- Analytical method for the determination of residues in blood (the study has been submitted to the RMS, but was not evaluated; refer to point 1)
- Analytical method(s) for the determination of impurities in the technical material (relevant for Makhteshim source; submission date proposed by the notifier: the study has been submitted to the RMS according to the notifier, but RMS has not received it yet (18.10.04). This was confirmed verbally at the November evaluation meeting; refer to point 1)

Toxicology

- A new mechanistic study in rats proposed by the notifier is ongoing, but has not been submitted (relevant for all the representative uses, but not required to complete risk assessment; submission date proposed by notifier: November 2004).
- A new 90-day study in rats proposed by the notifier is ongoing, but has not been submitted (relevant for all the representative uses, but not required to complete risk assessment; submission date proposed by notifier: November 2004).

Residues

- At least two residue trials with the critical GAP of 2 kg as/ha and a PHI 60 days for pome fruit and grapes in the northern and in the southern region, respectively. If residues are detected more trials are necessary (relevant for all representative uses evaluated; submission date proposed by the notifier: April 2005, refer to point 4.1.1).

Fate and behaviour

- A study on photolysis in soil has not been submitted, which is a formal data requirement (relevant for all the representative uses; submission date proposed by the notifier: March 2005; refer to point 4.1.1).
- Further degradation studies on DCPMU and DCPU in soil are required (relevant for all the representative uses; submission date proposed by the notifier for metabolite DCPMU: March 2005. No date proposed for DCPU; refer to point 4.1.2).
- FOCUS modelling should not use reduction of application rate based on strip application, therefore new FOCUS modelling is needed for diuron and soil metabolites (relevant for all the representative uses, pending further data on degradation, refer to point 4.2.2).
- Provision the existing surface monitoring data relevant for the representative uses (not considered essential to finalise the EU risk assessment; refer to point 4.2.1).

Ecotoxicology

- A new acute and short term as well as chronic risk assessment for herbivorous and insectivorous birds (relevant for all representative uses evaluated; a new assessment has been submitted to the RMS, but this is based on the new GAP and has not been evaluated; refer to point 5.1).
- New acute and long term risk assessment for herbivorous mammals (relevant for all representative uses evaluated; a new assessment has been submitted to the RMS but this is based on the new GAP and has not been evaluated; refer to point 5.1).
- A risk assessment based on the most conservative EC50 for the most sensitive algae species; The confidence limits for the calculated EC50 values of algae should be submitted as well as evidence to support the use of the geometric mean (relevant for all representative uses; a new assessment has been submitted to the RMS but this is based on the new GAP and has not been evaluated; refer to point 5.2).
- Study on the effects of the lead formulation on bees set as confirmatory data requirement by the EPCO expert meeting (relevant for all representative uses; no submission date has been proposed by the notifier; refer to point 5.3).
- A reasoned case on the reason why the study by McKelvey and Kuratle 1992 hasn't been used for the risk assessment process for non-target plants (relevant for all representative uses; a new assessment has been submitted to the RMS but this is based on the new GAP and has not been evaluated; refer to point 5.8).

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as herbicide as proposed by the notifier which comprises spraying to control mono- and dicotyledonous weeds in pome fruit and vine at application rate up to 2 kg diuron per hectare in strip application.

Due to the fact of outstanding data a final comparability of the technical material from the different sources could not be conducted during the evaluation procedure. From an analytical point of view none of the three sources can be regarded as equivalent. Therefore the given minimum purity of 970 g/kg has to be regarded as a provisional value.

No analytical method for monitoring purposes to determine residues of diuron in food of plant origin is available. Due to the new proposed residue definition only an analytical method used for data generation in the residue trials performed in the USA could be used. However, this method does not fulfil the requirements of Directive 96/46/EC or the guidance document SANCO/825/00.
The acceptability of the analytical method for the determination of residues in soil and ground water is depending on the residue definitions for monitoring purposes, which can be concluded only after the assessment of outstanding data in the fate and behaviour section. However, the submitted analytical methods are suitable to determine separately diuron and its metabolites DCPMU, DCPU, 3,4 DCA and mCPDMU down to 0.05 mg/kg (for each analyte) in soil as well as diuron, mCPDMU and 3,4 DCA in water (drinking and surface) down to 0.05 µg/L (for each analyte). Confirmatory methods to demonstrate the specificity of the analytical methods, taken the final residue definition into account, are not available. Concerning the matrix surface water, only a confirmatory method is missing.
A recently submitted method for the determination of residues in blood was neither evaluated in expert meetings nor by the RMS or EFSA.
For air an adequate analytical method is available for the determination of residues of diuron.
The necessity for an analytical method for food of animal origin cannot be concluded due to the fact that the risk assessment on food of animal origin cannot be finalised.

Diuron is rapidly and nearly totally absorbed via the oral route. Diuron is extensively metabolised, the main metabolite is 3,4-dichlorophenylurea. Diuron is of low to moderate acute oral toxicity, LD_{50}, oral, rat is 437 mg/kg bw (**Xn; R22).** Diuron is of low acute toxicity by the dermal and inhalatory routes and is not irritating to the skin or eyes and shows no sensitising properties. The relevant oral NOAEL for short-term toxicity is 0.66 mg/kg bw/day in the 6-month rat study, proposed classification **T; R48/23.** The inhalatory NOAEL was 0.0041 mg/L, the classification **Xn; R48/22** is proposed**.**
A few tests for genotoxicity showed questionable positive results. The Expert meeting concluded that diuron is of no genotoxic concern.

The primary toxicological effects seen in the long-term studies were effects on the blood system and on the urothelial system. The effects on the blood system were haemolytic anaemia as also seen in the short-term toxicity studies. In rats hyperplasia and neoplasia in the urothelium is observed and in mice, hyperplasia in bladder epithelium and mammae carcinomas, diuron is **proposed to be classified as carcinogenic, cat. 3, R40**. No NOAEL was observed and the LOAEL is set to 1.7 and 1.0 mg/kg bw/day in females and males, respectively.

In a two-generation study in rats no toxicity was experienced to reproduction but the highest dose tested of 1750 ppm was toxic for both adults and pups. Effects seen in adults were decreased body weights, body weight gain and food consumption. The body weights of pups were also decreased. The relevant NOAEL was 250 ppm (i.e.18.2 mg/kg bw/day).

Diuron has no effect on reproduction or developmental toxicity and no evidence of neurotoxic potential.

The ADI is based on a LOAEL of 1.7 mg/ kg bw/day in the long term rat study. With the safety factor of 250, since a LOAEL is used, the ADI is 0.007 mg/kg bw/day. The AOEL is based on the NOAEL from the 6 month rat study with a safety factor of 100 resulting in an **AOEL of 0.007 mg/kg/day. The ARfD is 0.016 mg/kg bw/day.** The dermal absorption for Karmex 80 WG is 2.7% for mixing/loading and 4.7% for spraying. Based on these assumptions the systemic exposure for the operator is 429% and 986% of the AOEL without protective equipment for tractor mounted and handheld equipment respectively. With gloves during mixing/loading and application the exposure is 214% and 557% of the AOEL respectively. **Thus, based on the available data, the estimated operator exposure (German model, with standard PPE) exceeds the AOEL**. Bystander and worker exposure is assumed to be negligible.

The metabolism of diuron in plants is well understood. The parent compound usually comprises only a small portion of the total residue. Significant residues include the metabolites DCPMU (3,4-dichlorophenyl-methylurea) and DCPU (3,4-dichlorophenylurea), which are of toxicological concern. It is noted that these metabolites can derive not only from diuron but also from other herbicides. As long as the investigation of the residue situation according to the critical GAP is not finalised, the risk assessment for consumers cannot be finally concluded, nor can MRLs be proposed.

In dark aerobic conditions, soil degradation of diuron yields DCPMU and DCPU as major metabolites. A maximum of a 31.8 % AR of CO_2 formed after 101 d in one experiment but is very low in all other experiments. Non-extractable residue reached a maximum at the end of the essays. No study on photolysis in soil is available. This information was deemed necessary to complete the assessment.

The studies available indicate that diuron is moderately to highly persistent in soil under aerobic environmental relevant conditions. However, differences in half-lives may not be attributed to any particular soil characteristic. Degradation of diuron is slower at lower temperatures and under anaerobic conditions.

Three field studies are available in which a total of nine field sites are studied. A tendency of soil adaptation is observed with a faster degradation in the later years. During the peer review, it was

concluded that: PEC based on laboratory data and DT_{50} = 119 d was considered representative of worst case for pre-adapted soils. A longer DT_{50} = 231 days is available from field studies that may need to be considered by MS for non pre-adapted soil. There is only one DT_{50} value for DCPMU. Reliability of this single value is doubtful. No degradation data was available for the metabolite DCPU. The need for further soil degradation studies on metabolites DCPMU and DCPU has been identified during the peer review.

Diuron, DCPMU and DCPU have medium to low potential for mobility in soil. No pH dependence is observed for adsorption of any of the three compounds.

Hydrolysis of diuron shows strong pH dependence. Half life is < 1 d at pH 4 and 5 but diuron is considered stable at pH 7 and 9. Aqueous photolysis could contribute to environmental degradation of diuron. No readily biodegradability test is available in the dossier of diuron. It is proposed to classify this active substance as "non-readily biodegradable" taking into account the results of the water sediment studies.

A study with two water sediment systems is available. No metabolite reached levels above 10 % AR neither in the water nor in the sediment. Diuron was relatively rapidly adsorbed by the sediment with dissipation half lives in the water phase of 4 and 9 days. In the total system, diuron was moderately to highly persistent.

Diuron PECsw and PECsed (initial) values used in the risk assessment of the representative uses are based on the spray drift values for downward application, because the substance is applied to the weeds. Also initial PECsw for the metabolite m-CPDMU is available. The contribution from drainage and run-off was not assessed and should be taken into account by MS when these routes of surface water contamination are envisaged to be relevant. The Notifier is required to provide the existing surface monitoring data relevant for the representative uses. This data requirement was not considered essential to finalise the EU risk assessment.

Due to the lack of data for the degradation of metabolites and the use of the reduced application rate in the FOCUS calculations, the level of uncertainty is too high to come to a conclusion regarding the risk of ground water contamination for the representative uses. FOCUS modelling should not use reduction of application rate based on strip application, therefore new FOCUS modelling is needed for diuron and soil metabolites (pending further data on degradation).

The residue definition for groundwater is still open, pending further data on the two metabolites (DCPMU and DCPU).

Based on the data available at the EPCO 8 expert meeting a high risk to birds and mammals from the use of diuron was identified. The lowest TER values are 8.8, 5.2 and 0.4 for the acute, short and long term risk to birds, respectively, and 5.1 and 0.7 for the acute and long term risk to small herbivorous mammals, respectively. These values are all below the corresponding Annex VI trigger values of 10 for both the acute and short term risk and 5 for the long term risk. Further data to address this risk is needed and the risk assessment can only be concluded when the outstanding data is evaluated.

Using the lowest algae endpoint, the risk assessment indicates a high risk to aquatic organisms. Even with a buffer zone of 50 m, the calculated TER value (2.5) is below the respective trigger of 10.

Additionally, a high risk to terrestrial plants was identified as the trigger is breached with a buffer zone of 50 m (TER = 3.58, trigger in the guidance document on terrestrial organisms is 5).
Therefore, extensive risk mitigation measures (e.g. buffer zones above 50 m) or further data to address this risk to aquatic and terrestrial plants is considered necessary.
For bees (pending confirmatory data requirement), non-target arthropods, soil micro- and macro-organisms, including earthworms the risk is considered low for the representative uses with regard to diuron and metabolites.

Particular conditions proposed to be taken into account to manage the risk(s) identified

- The contribution from drainage and run-off to surface water contamination was not assessed and should be taken into account by MS when these routes are envisaged to be relevant.
- Appropriate risk mitigation measures are required with regard to the risk to aquatic organisms (in particular algae) and terrestrial plants.

Critical areas of concern

- Based on the available data, the estimated operator exposure (German model, with PPE) exceeds the AOEL
- Due to lack of data, the potential contamination of groundwater cannot be fully assessed
- The risk to aquatic organisms is high, in particular to algae. Using the lowest algae endpoint indicates a high risk to aquatic organisms, even with a buffer zone of 50 m (TER = 2.5).
- A high risk to birds and mammals was identified. The lowest TER values are 8.8, 5.2 and 0.4 for the acute, short and long term risk to birds respectively and 5.1 and 0.7 for the acute and long term risk to small herbivorous mammals respectively which are all below the respective trigger values.
- A high risk to terrestrial plants was identified as the trigger is breached with a buffer zone of 50 m (TER = 3.58).

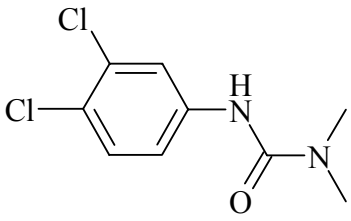
APPENDIX 1 – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

(Abbreviations used in this list are explained in appendix 2)

Appendix 1.1: Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name)	Diuron
Function (*e.g.* fungicide)	Herbicide
Rapporteur Member State	Denmark

Identity (Annex IIA, point 1)

Chemical name (IUPAC)	3-(3,4-dichlorophenyl)-1,1-dimethylurea
Chemical name (CA)	*N*'-(3,4-dichlorophenyl)-*N*,*N*-dimethylurea
CIPAC No	100
CAS No	330-54-1
EEC No (EINECS or ELINCS)	006-015-00
FAO Specification (including year of publication)	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 of the active substance as manufactured (g/kg)	970 g/kg (**provisional**) Bayer: 970 g/kg Griffin: **data required** Makhteshim: 975 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	none
Molecular formula	$C_9H_{10}Cl_2N_2O$
Molecular mass	233.1
Structural formula	

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity)	157.0 ± 0.2 °C (98.8%)
Boiling point (state purity)	Not applicable
Temperature of decomposition	Decomposes starts at app. 300 °C
Appearance (state purity)	Off-white, powder (98.8%)
Relative density (state purity)	1.497 g/ml (relative density not submitted) (98.8%)
Surface tension	72.1 mN/m
Vapour pressure (in Pa, state temperature)	1.15×10^{-6} Pa at 25 °C (99.9%)
Henry's law constant (Pa m^3 mol^{-1})	2×10^{-6} Pa m^3/mole
Solubility in water (g/l or mg/l, state temperature)	35.6 mg/l (35 °C, 99.8%)
Solubility in organic solvents (in g/l or mg/l, state temperature)	methanol: xylene: 1.33 g/l, at 25 °C hexane: acetone: 53.6 g/l, at 25 °C 1,2-dichloroethane: 14.4 g/l, at 25 °C ethylacetate: 21.2 g/l, at 25 °C
Partition co-efficient (log P_{OW}) (state pH and temperature	2.87 at 25°C (distilled water)
Hydrolytic stability (DT_{50}) (state pH and temperature)	pH 4: (25°C) 798 days pH 5: (25°C) 313 days pH 7: (25°C) stable pH 9: (25°C) stable pH 4: (50°C) 25.7 days pH 5: (50°C) 55.6 days pH 7: (50°C) stable pH 9: (50°C) 109 days
Dissociation constant	None
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	max. at 250.2 Tailing absorbency >290nm (959 l / mol · cm)
Photostability (DT_{50}) (aqueous, sunlight, state pH)	Water (distilled): 43 days Air: 2.9-4.5 hours
Quantum yield of direct phototransformation in water at Σ > 290 nm	Φ = 0.0243
Flammability	is not a highly flammable solid
Explosive properties	No risk of explodability

List of representative uses evaluated*

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		
Pome fruit, Vines Professional outdoors	North	Karmex 80 WG	F	Mono- and dicotyledonous weeds	WG	800 g/kg	Field (ground) sprayer, knapsack sprayer	From 3 years after planting, application in spring, weed stage BBCH 05-11	1	-	0.2/0.5	400/1000	2.0		60-90 (generally covered by the period between application and harvest)
Pome fruit, Vines Professional outdoors	South	Karmex 80 WG	F	Mono- and dicotyledonous weeds	WG	800 g/kg	Field (ground) sprayer, knapsack sprayer	From 3 years after planting, application in spring, weed stage BBCH 05-11	1	-	0.2/0.5	400/1000	2.0		60-90 (generally covered by the period between application and harvest

Remarks:				
	*	Uses for which risk assessment could not been 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		
	(f)	Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench	(l)	PHI - minimum pre-harvest interval
	(g)	All abbreviations used must be explained	(m)	Remarks may include: Extent of use/economic importance/restrictions

Appendix 1.2: Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (principle of method)	HPLC-UV
Impurities in technical as (principle of method)	HPLC-UV
Plant protection product (principle of method)	HPLC-UV

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Only method uses for data generation available
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required, due to the fact that the risk assessment on food of animal origin cannot be finalised
Soil (principle of method and LOQ)	Extraction with 150 ml acetone/water (2:1). 50 ml of the raw extract is concentrated to 20 ml by evaporation to the aqueous remainder. The sample is cleaned by liquid-liquid partition on Extrelut®, diuron are extracted with dichloromethane and evaporated to dryness and dissolved in 5 ml acetonitrile/water (2:8). Final determination is performed by high-performance liquid chromatography with photodiode array detection (246nm). LOQ: 0.05 mg/kg for each analyte (diruon, DCPMU, DCPU, 3,4 DCA and mCPDMU)
Water (principle of method and LOQ)	Diuron is extracted from 0.8 l water (drinking and surface water) by solid-phase extraction on Chromabond HR-P. The analytes are eluted with acetonitrile. Glycerol is added as keeper and the acetonitrile is evaporated. The residue is dissolved in 2 ml acetonitrile/water (2:8). Final determination is performed by high-performance liquid chromatography with photodiode array detection (246nm). LOQ: 0.05 µg/L for each analyte (diuron, mCPDMU and 3,4 DCA)

Air (principle of method and LOQ)	Air is sucked through Tenax- or XAD-2 adsorption tubes with a rate of 2 l/min during a period of 6 hours. The adsorbed diuron is extracted with 2.5-5 ml acetonitrile in 20 minutes on a mechanical shaker. For completion of extraction subsequently 2.5-5 ml mixture of acetonitrile/water (1:1) are added and the sample is shaken for 10 minutes. Final the supernatant is determined by high-performance liquid chromatography with UV detection (250nm). LOQ: 0.003 mg/m^3
Body fluids and tissues (principle of method and LOQ)	No data has been provided. Required as the active substance is proposed classified Toxic.

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data	None

Appendix 1.3: Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism in mammals (Annex IIA, point 5.1)

Rate and extent of absorption	> 95% (based on urinary and faecal excretion)
Distribution	Widely distributed (highest residues in blood, organs that produce or contains blood, excretory organs and ovaries)
Potential for accumulation	No evidence
Rate and extent of excretion	Min. 89% excreted within 48 hours, mainly via urine
Metabolism in animals	Extensive via N-demethylation and ring hydroxylation, main metabolite: 3,4-dichlorophenylurea
Toxicologically significant compounds (animals, plants and environment)	Parent and metabolites (animals) Parent and DCPMU, DCPU (plants)

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral	437 mg/kg bw (oil as vehicle) **R22**
Rat LD_{50} dermal	> 5000 mg/kg bw
Rat LC_{50} inhalation	> 7.1 mg/l (dust exposure) > 0.26 mg/l (aerosol exposure)
Skin irritation	Non-irritant
Eye irritation	Non-irritant
Skin sensitization (test method used and result)	Not a skin sensitiser (M & K test)

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Blood system (haemolytic anaemia)
Lowest relevant oral NOAEL / NOEL	0.66 mg/kg bw/day (6 month rat) **R48/22**
Lowest relevant dermal NOAEL / NOEL	No NOAEL established. LOAEL 250 mg/kg bw/day (90-day rat)
Lowest relevant inhalation NOAEL / NOEL	0.0041 mg/l (5x 6 hours/day for 4 or 8 weeks) **R48/23**

Genotoxicity (Annex IIA, point 5.4)	No evidence

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect	Blood system (haemolytic anaemia), bladder
Lowest relevant NOAEL / NOEL	No NOAEL established in females. LOAEL 1.7 mg/kg bw/day (2-year rat females) NOAEL 1.0 mg/kg bw/day (2-year rat males)
Carcinogenicity	Neoplasia in urothelium (rat), mammae carcinoma (mice). **R40**

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect	Decreased body weight in pups in maternal toxic doses, no reproductive effects
Lowest relevant reproductive NOAEL / NOEL	18.2 mg/kg bw/day
Developmental target / critical effect	Decreased foetal weight, skeletal alteration and delayed ossification at maternal toxic doses (rat)
Lowest relevant developmental NOAEL / NOEL	50 mg/kg bw/day (rabbit)

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 5.7) ‡

No studies submitted, no concern from other studies

Other toxicological studies (Annex IIA, point 5.8)

Bladder hyperplasia were found to begin after 4 weeks of administration to rats of 2500 ppm Diuron in feed for 2, 4, 12 or 26 weeks with and without recovery. The effects were largely reversible. No evidence of affection of the immune system after administration of up to 2500 ppm Diuron in feed for 3 weeks in rats. Negative Ames test of 3 metabolites (3-(4-chlorophenyl)-1,1-dimethyl urea, (3,5-dichlorophenyl)-1,1-dimethyl urea and 3-(3-chlorophenyl)-1,1-dimethyl urea).

Medical data (Annex IIA, point 5.9)

Chloracne has been seen at a plant in England, but it is stated that this problem has never existed in factories in Germany. Two possible impurities are known to give this effect. Case studies indicate that the metabolism in humans is similar to the metabolism in rats. Diuron showed no phototoxicity in a patch test.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI	0.007 mg/kg bw/day	LOAEL of 1.7 mg/kg bw/day 2-year study rat	250
AOEL	0.007 mg/kg bw/day	6-month study rat	100
ARfD (acute reference dose)	0.016 mg/kg bw/day	NOAEL of 25 ppm (1.6 mg/kg bw/day) at 4 weeks in 6 month feeding study rat	100

Dermal absorption (Annex IIIA, point 7.3) ‡

The dermal absorption for Karmex 80 WG based on *in vitro* study in human and rat skin is: 2.7% for mixing and loading 4.6% for application

Acceptable exposure scenarios (including method of calculation)

Operator	The estimated exposure (German model) was above the AOEL even with PPE (gloves during mixing/loading and application) Without PPE Tractor monted equipment (6.6 ha/day) 429% of AOEL Handheld equipment (1 ha/day) 986% of AOEL With PPE Tractor monted equipment (6.6 ha/day) 214% of AOEL Handheld equipment (1 ha/day) 557% of AOEL
Workers	Is considered to be negligible
Bystanders	Is considered to be negligible

Classification and proposed labelling (Annex IIA, point 10)

with regard to toxicological data	T; R22, R48/22, R48/23, R40

Appendix 1.4: Residues

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Fruits (orange), leafy crops (spinach), cereals (wheat and maize)
Rotational crops	Root vegetables (turnips), leafy crops (lettuce), cereals (wheat)
Plant residue definition for monitoring	Diuron including all components containing 3,4-dichloraniline moiety expressed as 3,4-dichloraniline
Plant residue definition for risk assessment	Diuron including all components containing 3,4-dichloraniline moiety expressed as 3,4-dichloraniline
Conversion factor (monitoring to risk assessment)	Not relevant

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Hens
Animal residue definition for monitoring	Currently not necessary *
Animal residue definition for risk assessment	Currently not necessary *
Conversion factor (monitoring to risk assessment)	Not relevant
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No

*) To be confirmed after investigation of the residue situation in pome fruit has been finalized

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

In the seldom case of fruit trees/bushes are followed by a succeeding crop, risk may exist for residues in the succeeding crop.

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 introduction)

At least 8 month for citrus fruits, pome fruits and grapes, 3 year for wheat grains and 2 years for maize grain, stover and forage.

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

Intakes by livestock ≥ 0.1 mg/kg diet/day:

Ruminant: no	Poultry: no	Pig: no
Studies are currently not required in any animal *		

*) To be confirmed after investigation of the residue situation in pome fruit has been finalized

Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL	STMR (b)
All crops			LOQ for each of diuron, DCPMU and DCPU should be lowered for the HPLC-MS/MS method so that LOQ for the sum is not higher than 0.05 mg/kg (or 0.1 mg/kg), which is the expected MRL.		
Pome fruits	North and south	1x 3,6 kg as/ha, PHI 138-150 days, < 0.02 (2). 1x 10.8 kg as/ha, PHI 152 days, < 0,015 (1)	Trials required using critical GAP and PHI required for the north and south region	Open	Open
Wine grapes	North and south	1x 3.6 kg as/ha, PHI 161 days, < 0.02 (1) 1x 7.2 kg as/ha, PHI 161 days, < 0.02 (1) 1x 5.4 kg as/ha, PHI 149 days, < 0.02 (1)	Trials required using critical GAP and PHI required for the north and south region	Open	Open

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the critical GAP

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.007 mg/kg bw/day
TMDI (European Diet) (% ADI)	Not calculated, as no MRL could be proposed
NEDI (% ADI)	Not calculated
Factors included in NEDI	Not relevant
ARfD	0.016 mg/kg bw/day
Acute exposure (% ARfD)	Not calculated, as no MRL could be proposed

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/processed crop	Number of studies	Transfer factor	% Transference *
Apples and grapes	1 of each crop	Residues too low for calculation	

* Calculated on the basis of distribution in the different portions, parts or products as determined through balance studies

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

The below mentioned MRLs may be proposed on the condition that the setting of a LOQ of 0.05 mg/kg as sum of components included in the residue definition is possible.

Pome fruits	Open
Grapes	Open

Appendix 1.5: Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days	20 °C: 0.14 – 31.8% (n=4)
Non-extractable residues after 100 days	20 °C: 3.6 – 44% (n=6)
	10 °C: 12% (n=1)
Relevant metabolites - name and/or code, % of applied (range and maximum)	DCPMU: 20 °C: 13.6 – 33% (n=5) 10 °C: 23% (n=1)
	DCPU: 20 °C: 0.5 – 25% (n=6) 10 °C: 2% (n=1)

Route of degradation in soil – Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation	Diuron 9.3 % (60 d)
	Metabolites: (Keyport silt loam, 25 °C, 60 d) DCPMU: 10 %
Soil photolysis	no data – **data required**

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Method of calculation	1st. order kinetics
Laboratory studies (range or median, with n value, with r^2 value)	10 °C: $DT50_{lab}$ = 143 d (n=1) $DT90_{lab}$ = 475 (n=1)
	20 °C: $DT50_{lab}$ = 20 – 119 d (n=5), mean 75.5 $DT50_{lab}$ = 27 d (35% MWHC) $DT90_{lab}$ = 65 – 395 (n=4) $DT50_{lab}$ = 35 d (n=1), metabolite DCPMU **Further data on DCPMU and DCPU required**

	25 °C: $DT50_{lab}$(sterile) = 1920 d (n=1) $DT50_{lab}$(non-sterile) = 372 d (n=1) $DT50_{lab}$(anaerobic) = 1000 d (n= 1)
Field studies (state location, range or median with n value)	$DT50_{field}$: 30-231d (n=7), mean 89 d – non pre-adapted soils $DT50_{field}$: 14-37 d (n=4) - pre-adapted soils $DT90_{field}$ = 99 (n=1) – non pre-adapted soils $DT90_{field}$ = 48–63 (n=3) – pre-adapted soils
Soil accumulation and plateau concentration	Maximum plateau concentration found after 3rd year application: 1.49 mg a.i./kg soil.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_{oc}, K_d (freundlich isoterms)	Adsorption (Diuron): K_{OC}: 468-1666 (n = 3) K_f: 7.9-28 (n = 3) 1/n: 0.85 – 0.93 (n = 3) Desorption (Diuron): Koc: 230 – 769 (n = 3) K_f: 3.9 – 16 (n = 5) Adsorption (DCPMU) Koc: 498 – 1358 (n = 4) K_f: 3.5 – 15.6 (n = 4) 1/n: 0.74 – 0.76 (n = 4) Adsorption (DCPU) Koc: 527 –861 (n = 4) K_f: 4.22 – 12.02 (n = 4) 1/n: 0.76 – 0.80 (n = 4) Adsorption (m-CPDMU) Koc: 139 – 418 (n = 3) K_f: 2.3 – 8 (n = 3) 1/n: 0.69 – 0.78 (n = 3)

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching	no data
Aged residues leaching	no data
Lysimeter/ field leaching studies	Four lysimeters (2 kg and 4 kg a.s/ha, two scenarios in sweden). Test duration 2 years. (annual average concentrations) 2 kg a.s/ha: 0 – 0.09 µg/L (Diuron) 0 – 0.13 µg/l (DCPMU) 0 – 0.04 µg/l (DCPU) 4 kg a.s/ha: 0.19 – 0.36 µg/l (Diuron) 0.12 – 0.27 µg/l (DCPMU) 0.01 – 0.096 µg/l (DCPU)

PEC (soil) (Annex IIIA, point 9.1.3)

Parent

Method of calculation	Worst-case continuous and time weighted average soil concentrations after 1 application on pre-adapted soils. The assumptions are even distribution in the top 5 cm layer, a bulk density of 1.5 g/cm^3 and no interception by plants. DT_{50} = 119 days (worst case for preadopted soils, for non pre-adapted soils a DT_{50} of 231 days would be appropriate).
Application rate	2 kg a.s./ha

$PEC_{(s)}$ (mg/kg)	Single application Actual	SingleApplication Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	2.67	2.67		
Short term 24h 2d 4d	2.65 2.64 2.61	2.66 2.65 2.64		
Long term 7d 28d 50d 100d	2.56 2.27 1.99 1.49	2.61 2.46 2.31 2.02		

Metabolites

Method of calculation	Worst case initial concentrations calculated from the parent PEC and maximum formation of 33% DCMPU and 25% DCPU adjusted for molecular weight (diuron 233, DCPMU 200 and DCPU 186 g/mol)
Application rate	2 kg a.s./ha

$PEC_{(s)}$ (mg/kg)	Single application **DCPMU**	Single application **DCPU**	Multiple application Actual	Multiple application Time weighted average
Initial	0.76	0.53		

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)		pH 4: (25°C) 798 days
		pH 5: (25°C) 313 days
		pH 7 and 9 : (25°C) stable
Photolytic degradation of active substance and relevant metabolites		DT50 = 43 days (distilled water)
Readily biodegradable (yes/no)		no data, not ready degradable based on water/sediment studies
Degradation in water/sediment	- DT_{50} water	River Erft: 8.8 d
	- DT_{90} water	River Erft: 29.3 d
	- DT_{50} water	Hönniger Weiher: 4.2 d
	- DT_{90} water	Hönniger Weiher: 182 d
	- DT_{50} whole system	River Erft: 48 d
	- DT_{90} whole system	River Erft: 159 d
	- DT_{50} whole system	Hönniger Weiher: 232 d
	- DT_{90} whole system	Hönniger Weiher: > 1 year
Mineralization		Supernatant water: 2 – 30 % after 120 days (n=2)
Non-extractable residues		Bound residues in sediment 17.5-45.9 % after 120 days (n=2)
Distribution in water / sediment systems (active substance)		Maximum percentage of parent compound in sediment: 73.5 % at 28 days.
Distribution in water / sediment systems (metabolites)		Maximum percentage of m-CPDMU in water: 6.7 % at 55 days. Maximum percentage of m-CPDMU in sediment: 8.5 % at 55 days.

	Maximum percentage of DCPMU in water: 0.4 % at 120 days. Maximum percentage of DCPMU in sediment: 4.4 % at 91 days.

PEC (surface water) (Annex IIIA, point 9.2.3)

Method of calculation	The worst-case diuron concentrations in surface water are calculated for a model system defined by - a water body with a depth of 0.3 m - maximum application rate of 2 kg a.s./ha - spray drift at 1 m of 2.77 % DT_{50}water = 8.8 days (worst case of two values from two water/sediment systems).
Application rate	2 kg a.s./ha
Main routes of entry	Spray drift

$PEC_{(sw)}$ (µg / l)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	18.5	18.5		
Short term 24h 2d 4d	17.1 15.8 13.5	17.8 17.1 15.8		
Long term 7d 14d 21d 28d 32d 42d	10.6 6.1 3.5 2.0 1.5 0.7	14.2 11.2 9.0 7.5 6.7 5.4		

Metabolite

Method of calculation	Worst case initial concentration at 1 m calculated from the parent PEC and maximum formation of 9% mDCMPU adjusted for molecular weight (diuron 233 and mDCPMU 199 g/mol)
Application rate	2 kg a.s./ha
Main routes of entry	Spray drift

PEC$_{(sw)}$ (µg / l)	Single application Actual mDCPMU	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	1.4			

PEC (sediment) New values – see Addendum 1 to B8 (May 2004) for details.

Method of calculation	Worst case initial concentration at 1 m calculated from the initial PECsw an maximum distribution to sediment of 73.4% and a sediment depth of 1 cm.
Application rate	2 kg a.s./ha

PEC$_{(sed)}$ mg/kg sed	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.31			

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	A: Lysimeter studies (2 kg and 4 kg a.s./ha, two scenarios in Sweden). Test duration 2 years. 2 kg a.s./ha: 0 – 0.09 µg/L (Diuron) 0 – 0.13 µg/l (DCPMU) 0 – 0.04 µg/l (DCPU) 4 kg a.s./ha: 0.19 – 0.36 µg/l (Diuron) 0.12 – 0.27 µg/l (DCPMU) 0.01 – 0.096 µg/l (DCPU) B: **New FOCUS calculations required.**
Application rate	A: 2 and 4 kg a.s./ha

Maximum concentration	Not relevant
Average annual concentration	A: 2 kg a.s/ha: 0 – 0.09 µg/L (Diuron) 0 – 0.13 µg/l (DCPMU) 0 – 0.04 µg/l (DCPU)

	4 kg a.s/ha: 0.19 – 0.36 µg/l (Diuron) 0.12 – 0.27 µg/l (DCPMU) 0.01– 0.096 µg/l (DCPU)

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air	4.5 h (Atkinson) 2.9 h (Meylan and Howard)
Quantum yield of direct phototransformation	0.0243
Photochemical oxidative degradation in air	No data Latitude: ..... Season: ..... DT_{50} .....
Volatilization	No parent compound evaporated from the different target areas within 24 hours after application. The analyses of these material extracts showed that after this period the majority of the recovered radioactivity was assignable to unchanged parent compound.

PEC (air)

Method of calculation	No data, not required

$PEC_{(a)}$

Maximum concentration	No data, not required

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment	Soil: Diuron, DCPMU ?*, DCPU ?* Surface water: Diuron Ground water: Diuron, DCPMU?*, DCPU ?*

* Further data required

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	no data
Surface water (indicate location and type of study)	no data, data required (not essential for EU risk assessment)
Ground water (indicate location and type of study)	Germany: 185 findings with 89 > 0.1 µg/l Southern Germany: 0.8 % findings Germany, Cologne: 0.05 µg/l , (four findings) Denmark: 0.3 % findings all below 0.1 µg/l
Air (indicate location and type of study)	no data

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data	Proposed: R53 - May cause long-term adverse effects in the aquatic environment

Appendix 1.6: Effects on non-target Species

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Acute toxicity to mammals	Rat LD_{50} = 2000 mg/kg bw
chronic toxicity to mammals	Rat NOAEL = 80 mg/kg bw/day
Acute toxicity to birds	*Colinus virginianus* $LD_{50\ (14\ d)}$ = 1104 mg/kg bw
Dietary toxicity to birds	*Colinus virginianus* $LC_{50\ (5\ d)}$ = 1730 mg as/kg diet (toxic dose: 346 mg/kg bw/day) *Coturnix coturnix* $LC_{50\ (5\ d)}$ > 5000 mg as/kg diet *Phasianus colchicus* $LC_{50\ (5\ d)}$ > 5000 mg as/kg diet
Reproductive toxicity to birds	*Colinus virginianus* NOEC = 300 mg as/kg diet (toxic dose: 24.12 mg/kg bw/day)

Toxicity/exposure ratios for terrestrial vertebrates (birds) (Annex IIIA, points 10.1 and 10.3)

Application rate (kg as/ha)	Crop	Category (*e.g.* insectivorous bird)	Time-scale	TER (tier I)	Annex VI Trigger
		Tier 1*			
2	Short grass	Herbivorous birds	Acute	**8.8**	10
2	Small insects	Insectivorous birds	Acute	10.2	10
2	Short grass	Insectivorous birds	Short-term	**5.2**	10
2	Small insects	Herbivorous birds	Short-term	**5.7**	10
2	Short grass	Herbivorous birds	Long-term	**0.7**	5
2	Small insects	Insectivorous birds	Long-term	**0.4**	5

*) At tier 1 is the risk assessment performed for the standard scenarios suggested for grassland and cereals in the Guidance Document on Risk Assessment for Birds and Mammals.

Toxicity/exposure ratios for terrestrial vertebrates (mammals) (Annex IIIA, points 10.1 and 10.3)

Application rate (kg as/ha)	Crop	Category (*e.g.* insectivorous bird)	Time-scale	TER	Annex VI Trigger
2		**Tier 1***			
2	Short grass	Small herbivorous mammal	Acute	**5.1**	10
2	Large insects	Insectivorous mammal	Acute	113	10
2	Short grass	Small herbivorous mammal	Short-/long-term	**0.7**	5
2	Large insects	Insectivorous mammal	Short-/long-term	12.4	5

*) At tier 1 is the risk assessment performed for the standard scenarios suggested for grassland and cereals in the Guidance Document on Risk Assessment for Birds and Mammals.

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Laboratory tests				
Cyprinodon variegatus	Diuron	96 h	Mortality	LC_{50} = 6.7 mg/L NOEC = 3.6
Oncorhyncus mykiss	Diuron	28 d	Mortality	LC_{50} = 4.01 mg/L NOEC = 0.41 mg/L
Cyprinodon. variegatus (Larvae)	Diuron	32 days	Mortality	LOEC = 3.6 mg/L MATC = 2.5 mg/L NOEC = 1.7 mg/L
Oncorhyncus mykiss	mCPDMU	96 h	Mortality	LC_{50} = 28.7 mg/L NOEC = 10.0 mg/L
Mysidopsis bahia	Diuron	96 h	Mortality	EC_{50} =1.1 mg/L
Daphnia magna	Diuron	21 d	Growth	NOEC=0.096 mg/L
Daphnia magna	mCPDMU	48 h	Immobilisation	EC_{50}=67.4mg/L
Hyella azteca	Diuron WP 80	21 d	Mortality	NOEC=0.06 mg/L
Scenedesmus subspicatus	Diuron WP 80	72 h	Growth inhibition	ErC_{50} = 0.019 mg/L
Scenedesmus subspicatus	Diuron WP 80	72 h	Biomass	EbC_{50} = 0.001 mg/L
Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Laboratory tests				
Anabaena flos-aquae	Diuron	72 h	Biomass	EbC_{50} = 0.023 mg/L
Anabaena flos-aquae	Diuron	72 h	Growth inhibition	ErC_{50} = 0.031 mg/L
Scenedesmus subspicatus	mCPDMU	72 h	Growth inhibition	ErC_{50} = 0.727 mg/L
Scenedesmus subspicatus	mCPDMU	72 h	Biomass	ErC_{50} = 0.246 mg/L
Lemna gibba	Diuron	7 d	Growth inhibition	ErC_{50} = 0.0183 mg/L
Microcosm or mesocosm tests				
not submitted				

Toxicity/exposure ratios for the most sensitive aquatic organisms in early fruit crop scenario (worst case) and early grapewine scenario (best case)(Annex IIIA, point 10.2)

Application rate (kg as/ha)	Crop	*Organism*	Time-scale	Distance(m)	TER	Annex VI Trigger
2	Field crops	*Cyprinodon variegatus*	96 h	1	363	100
2	Field crops	*Oncorhyncus mykiss*	28 d	1	22	10
2	Field crops	*Oncorhyncus mykiss*	28 d	1	55*	10
2	Field crops	*C. variegatus larvae*	32 d	3	92	10
2	Field crops	*C. variegatus larvae*	32 d	3	252*	10
2	Field crops	*Mysidopsis bahia*	96 h	1 5	**60** 290	100
2	Field crops	*Daphnia magna*	21 d	1	**5.2**	10
2	Field crops	*Daphnia magna*	21 d	1	10.6*	10
Application rate (kg as/ha)	Crop	*Organism*	Time-scale	Distance (m)	TER	Annex VI Trigger
2	Field crops	*Scenedesmus subspicatus*	72 h	10 15	**9.8**** 14.3**	10
2	Field crops	*Scenedesmus subspicatus*	72 h	50	**2.5*****	10
2	Field crops	*Lemna gibba*	7 d	10 15	**9.5** 13.7	10
2	Field crops	*Hyella azteca*	21 d	1 5	**3.4** 16.3	10
2 kg mCPDMU/ha	Field crops	*Scenedesmus subspicatus*	72 h	1	514**	10
2 kg mCPDMU/ha	Field crops	*Scenedesmus subspicatus*	72 h	1	174***	10

* PEC_{twa} – see details in Volume 3, Annex B, section B.9.2.13
** Growth rate
*** Biomass

Bioconcentration

Bioconcentration factor (BCF)	not submitted, not required log Pow < 3
Annex VI trigger:for the bioconcentration factor	
Clearance time (CT_{50}) (CT_{90})	

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Acute oral toxicity	> 100 µg as/bee
Acute contact toxicity	> 100 µg as/bee

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Application rate (kg as/ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
2 kg as/ha		Oral	<50	50
2 kg as/ha		Contact	<50	50

Field or semi-field tests
No required

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Species	Test Substance	Dose (g as/ha)	Endpoint	Effect (%)	Annex VI trigger
Typhlodromus pyri Scheuten	Karmex 80 WG	4000	Mortality reproductive capacity	0 5	30%
Aphidius rhopalosiphi	Karmex 80 WG	5000	Mortality no. of mummies	5 35	30%
Aleochara bilineata	Ustinex PA[1]	5400	mortality, feeding rate egg production **hatching rate**	0 0 0 **95**	30%
Peocilus cupreus	Ustinex PA[1]	5600	Mortality feeding rate	0 24 (increase)	30%
Peocilus cupreus	BAY 11310 H	5600	Mortality feeding rate	0 7 (increase)	30%

Species	Test Substance	Dose (g as/ha)	Endpoint	Effect (%)	Annex VI trigger
Araneae lycosidae	BAY 11310 H[2]	4100	Mortality **feeding rate**	0 **33-42**	30%
Aleochara bilineata	Ustinex PA[1]	5400	Mortality Hatching rate	2 6	30%

[1]Ustinex PA (WG 86) containing both Amitrole (29.9% nominal) and Diuron (56.1% nominal).
[2] BAY 11310 HR containing both Diuron (27.0%) and Glyphosate (14.4%).

Field or semi-field tests Not studies submitted

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity – Diuron WP80	LC50 > 798 mg as/kg
Acute toxicity – DCPMU	LC50 = 413 mg/kg
Acute toxicity – DCPU	LC50 = 801 mg/kg
Reproductive toxicity – Karmex WG80	NOEC = 28.8 mg as/kg dw soil; NOECcorr = 14.4 mg as/kg dw soil

Toxicity/exposure ratios for earthworms (Annex IIIA, point 10.6)

Application rate (kg as/ha)	Compound	Time-scale	TER	Annex VI Trigger
2	DCPU	14 d	756	10
2	DCPMU	14 d	272	10
2	Diuron WP80	14 d	>150	10
2	Karmex WG80	56 d	**5.4**	5

Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralization	no effect at the max. application rate (4 kg as./ha)
Carbon mineralization	no effect at the max. application rate (4 kg as./ha)

Classification and proposed labelling (Annex IIA, point 10)

With regard to ecotoxicological data	N, R50/53 – Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
AR	applied radioactivity
ARfD	acute reference dose
a.s.	active substance
bw	body weight
°C	degree Celsius (centigrade)
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GLP	good laboratory practice
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection

LOQ	limit of quantification (determination)
µg	microgram
MHC	moisture holding capacity
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated short term intake
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEL	no observed effect level
OC	organic carbon content
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
pH	pH-value
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
r^2	coefficient of determination
RPE	respiratory protective equipment
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
TWA	time weighted average
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year