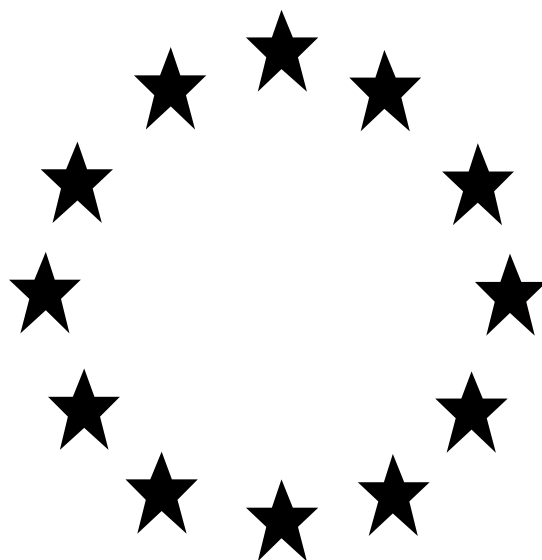




Draft Assessment Report (DAR)

- public version -

**Initial risk assessment provided by the rapporteur Member State
The Netherlands for the existing active substance**

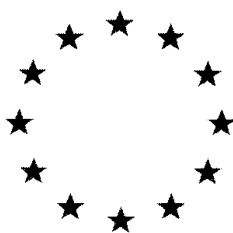
DICHLOBENIL

**of the third stage (part B) of the review programme
referred to in Article 8(2) of Council Directive 91/414/EEC**

Volume 1

January 2008

European Commission



DICHLOBENIL

VOLUME 1

Rapporteur Member State: The Netherlands

April 2007

Draft Assessment Report and Proposed Decision of the Netherlands prepared in the context of the possible inclusion of dichlobenil in Annex I of Council Directive 91/414/EEC

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LEVEL 1

Dichlobenil

STATEMENT OF THE SUBJECT MATTER AND PURPOSE OF THE MONOGRAPH

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1 Statement of subject matter and purpose for which the monograph was prepared**1.1 Purpose for which the monograph was prepared (dossier Document A)**

This monograph on the active substance dichlobenil has been prepared to support the inclusion of the active substance dichlobenil in Annex I of the Directive 91/414/EEC.

1.2 Summary and assessment of information relating to the collective provision of dossiers (Dossier Document B)

Crompton Europe B.V. –now Chemtura Netherlands B.V.- is the sole notifier for dichlobenil. The question of steps taken to collectively present the dossier does not therefore arise.

1.3 Identity of the active substance (Annex IIA 1) (Dossier Documents J, K-II and L-II)**1.3.1 Name and address of applicant(s) for inclusion of the active in Annex I (Annex IIA 1.1)****Applicant (name, address, etc.)**

Address: **Chemtura Netherlands B.V.**

Ankerweg 18

1041 AT Amsterdam

The Netherlands

Contact person:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

1.3.2 Common name and synonyms (Annex IIA 1.3)

Dichlobenil (ISO).

1.3.3 Chemical name (Annex IIA 1.4)

2,6-dichlorobenzonitrile (IUPAC, CA)

1.3.4 Manufacturer's development code number (Annex IIA 1.5)

H-133

1.3.5 CAS, EEC and CIPAC numbers (Annex IIA.1.6)

CAS no. 1194-65-6

ELINCS no. not applicable

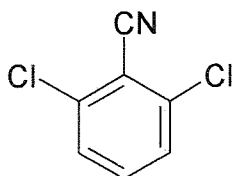
EINECS no. 214-787-5
CIPAC no. 73

1.3.6 Molecular and structural formulae, molecular mass (Annex IIA 1.7)

Molecular formula C₇H₃Cl₂N

Molecular mass 172.0 g/mol

Structural formula



1.3.7 Manufacturer or manufacturers of the active substance (Annex IIA 1.2)

Name Factory: [REDACTED]

Address: [REDACTED]

Contact person: [REDACTED]

1.3.8 Method or methods of manufacture (Annex IIA 1.8)

See Volume 4, Annex C (Confidential Information).

1.3.9 Specification of purity of the active substance (Annex IIA 1.9)

The minimum content of pure Dichlobenil in the technical grade product is 980 g/kg.

1.3.10 Identity of isomers, impurities and additives (Annex IIA 1.10)

See Volume 4, Annex C (Confidential Information).

1.3.11 Analytical profile of batches (Annex IIA 1.11)

See Volume 4, Annex C (Confidential Information).

1.4 Identity of the plant protection products (Annex IIA 3.1; IIIA 1) (Dossier Documents J, K-II, L-II, K-III and L-III)

1.4.1 Current, former and proposed trade names and development code numbers (Annex IIIA 1.3)

Trade names Casoron® G, Ducason® G, Prefix® G, Sprion®, Surfassol® G

Code number H133

1.4.2 Manufacturer or manufacturers of the plant protection product (Annex IIIA 1.2)

Name Factory: [REDACTED]

Address: [REDACTED]
[REDACTED]
[REDACTED]

Contact person: [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Location of plant See Volume 4, Annex C (Confidential Information).

1.4.3 Type of the preparation and code (Annex IIIA 1.5)

Casoron® G is a ready-to-use granular formulation. The GIFAP formulation code is GR.

1.4.4. Function (Annex IIA 3.1; Annex IIIA 1.6)

Non-selective herbicide.

1.4.5 Composition of the preparation (Annex III 1.4)

See Volume 4, Annex C (Confidential Information).

1.5 Use of the plant protection product (Annex IIA 3.2 to 3.4; Annex IIIA 3.1 to 3.7, 3.9 and 12.1) (Dossier Documents C, D and E)

1.5.1 Field of use (Annex IIA 3.3; Annex IIIA 3.1)

Dichlobenil can be used for selective weed control of annual and perennial weeds, including light grass vegetation, vineyards, woody ornamentals, amenity plantings and forests. It can, furthermore, be applied as a total weed killer on industrial sites and other non-crop areas.

Casoron® G is proposed for use as a selective herbicide in grapes and as herbicide for total weed control on non-crop land (e.g. industrial sites, roadsides, railway tracks, along fences).

1.5.2 Effects on harmful organisms (Annex IIA 3.2; Annex IIIA 3.2)

Casoron® G, a non-selective herbicide, is a powerful inhibitor of germinating seedlings and of actively growing meristems. Dichlobenil acts primarily on growing points and root tips. It can inhibit the incorporation of cellulose into cell walls; however the exact mode of action is not yet known. Both mono- and dicotyledous plants are controlled, especially by inhibition of germinating seeds and growth of young seedling plants. Older plants, especially when shallow-rooted, are controlled under favourable conditions and/or with high dosages. The growth of sprouts of perennial weeds is stopped. Established plants tolerate Dichlobenil well.

1.5.3 Summary of intended uses (Annex IIA 3.4; Annex IIIA 3.3 to 3.7, 3.9)

Casoron® G, a 6.75% (w/w) (67.5 g/kg) ready-to-use granular formulation of Dichlobenil, is submitted for authorisation for use in Northern and Southern Europe as a herbicide for selective, pre-emergence weed control in the cultivation of grapes as well as non-crops in Southern and Northern European regions.

The application rate for grapes range from 40 - 80 kg Casoron® G per ha (equal to 2.7 - 5.4 kg Dichlobenil/ha). For non-crops, the application rate can range from 30 - 80 kg Casoron® G/ha (equal to 2.03 - 5.4 kg Dichlobenil/ha).

Casoron® G is either applied with manually operated granule spreaders, with motorised equipment (e.g. knapsack spreader) or with tractor-mounted equipment suitable for granular applications.

For use in vines the general application time will be February-March; for non-crop uses this will be February-May, depending on the climatologically circumstances.

See Table 1.5.3.

1.5.4 Information on authorization in EU Member States (Annex IIIA 12.1)

Information on authorized uses is submitted. The use of Casoron® G is authorised in Austria, Belgium, Czech Republic, Finland, France, Greece, Hungary, Ireland, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, and United Kingdom for various crop and non-crops.

Table 1.5.3 Summary of intended uses (Annex IIA 3.4; Annex IIIA 3.3 - 3.7, 3.9)

Crop and/or situation (a)	Member State or Country	Product name	F G or I	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
					Type (d-f)	Conc of as (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		
Around buildings and on industrial sites*	EU	Casoron G	F	Weeds	GR	67.5 g/kg	Broadcast spreading of granules	Pre-emergence until early post-emergence (February – May)	1	N/A	N/A	N/A	2.03-5.4	N/A	*applied to soil or gravel surface ** current PHI = 60 days in Italy & 200 days in France
Alongside paths and roads and under fence lines and hedges*	EU	Casoron G	F	Weeds	GR	67.5 g/kg	Broadcast spreading of granules	Pre-emergence until early post-emergence (February – May)	1	N/A	N/A	N/A	2.03-5.4	N/A	
Around well established trees and shrubs in parks and recreational areas*	EU	Casoron G	F	Weeds	GR	67.5 g/kg	Broadcast spreading of granules	Pre-emergence until early post-emergence (February – May)	1	N/A	N/A	N/A	2.03-5.4	N/A	
Grape	EU	Casoron G	F	Weeds	GR	67.5 g/kg	Broadcast spreading of granules	Pre-emergence (February – March)	1	N/A	N/A	N/A	2.7-5.4	N/A **	

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- (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)
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
- (f) All abbreviations used must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated
- (i) g/kg or g/l
- (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
- (k) Indicate the minimum and maximum number of application possible under practical conditions of use
- (l) PHI - minimum pre-harvest interval
- (m) Remarks may include: Extent of use/economic importance/restrictions

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LEVEL 2

Dichlobenil

OVERALL CONCLUSIONS

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2 Reasoned statement of the overall conclusions drawn by the Rapporteur Member State

2.1.1 Identity

All points of Section 1, Annex IIA and IIIA have been addressed (see Level 1, points 1.1 – 1.4).

2.1.2 Physical and chemical properties

Active substance

Dichlobenil is a white, needle-shaped, crystalline solid (the purified substance) or a white sticky solid (the technical substance) with a musty odour. Its relative density (D_{4}^{20}) is 1.55. In a melting point apparatus a melting point of 144-145°C was observed. Because the substance sublimes, no boiling point can be determined. The vapour pressure is 0.14 Pa at 25°C and the volatility (Henry's law constant) is 1.317 Pa·m³·mol⁻¹.

Dichlobenil is hardly soluble in water (21 mg/L at pH 7 and 25 °C for the analytical grade material) and its partition coefficient ($\log P_{ow}$) is 2.7 at pH 3 and 22 °C. The surface tension of a 90% saturated solution in water at 20 °C is 68.5 mN/m, indicating that the compound is not surface active.

The solubility in various organic solvents is 53 g/L at 25°C in xylene, 15 g/L at 25°C in ethanol, 3.7 g/L at 25°C in cyclohexane, 86 g/L at 20°C in acetone, 17.2 g/L at 20°C in methanol, 151 g/L at 20°C in dichloromethane and 59.3 g/L at 20°C in ethylacetate.

The substance is not flammable and not self-ignitable. The substance has no explosive properties and no oxidizing properties. No dissociation occurs over pH range 2 – 12.

The results of the investigation of the photochemical degradation at 25°C resulted in DT50 under Xenon light and natural sun light account for 15 and 10 days, respectively.

The quantum yield in water accounts for 1.5E-03 mol/einstein. The estimated half life of the photochemical oxidative degradation accounts for 63 days.

Main metabolite

The main metabolite in various environmental and biological matrices is 2,6-dichlorobenzamide (BAM).

Some physical and chemical properties of BAM were therefore elucidated as well. The spectra for this substance are in agreement with the structure. This substance has a vapour pressure of less than $2 \cdot 10^{-5}$ Pa at 25 °C. Its solubility in water at 20 °C and pH 6 is 1.83 g/L and its partition coefficient ($\log P_{ow}$) at 22 °C and pH 3 is 0.38. For the latter parameter, also 0.51 is reported, but the temperature and pH are not known.

However, both values do not differ significantly. A study on the hydrolysis rate was submitted under IIA7.2.11. Here BAM was hydrolytically stable at 25°C and 50°C for 5 days at pH 4, 7 and 9. No dissociation is expected at relevant pHs (pH range 2 – 12).

Formulation

Casoron® G is a grey-coloured, free-flowing granular product with an aromatic odour and containing 6.75% (w/w) of Dichlobenil. The content of Dichlobenil in the product remained stable during accelerated storage testing (14 days at 54 °C). There was also no apparent change in the percentage of the active ingredient after three years of storage under ambient warehouse conditions in the absence of direct sunlight. The bulk density is approximately 1.10 g/mL, while the tap density is approximately 1.17 g/mL. The nominal size of the granules did not undergo any apparent changes during three years storage under warehouse conditions. The friability (attrition characteristics) did not deteriorate over a 3-years storage interval at ambient warehouse conditions. The formulation is nearly dust-free. The flowability of the granules after 14 days storage at 54 °C under pressure (25 g/cm²) is unaffected. The shelf life time is at least three years under normal warehouse conditions.

The formulation is not flammable and not self-ignitable. The formulation has no explosive properties and no oxidizing properties.

2.1.3 Details of uses

All points of Annex IIA 3.1 - 3.9 and Annex IIIA 3 – 4.6 have been addressed (see Level, 1, point 1.5).

Details of further information

Information supplied addresses methods for handling and storage of the active substance and plant protection product.

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2.1.4 Classification and labelling

Active substance

Physical and chemical properties

No classification and labelling is needed based on the physical and chemical properties of the active substance dichlobenil.

Human health effects

Justified proposals for classification and labelling of the active substance, relating to human health effects, according to Directive 2001/59/EC are listed below.

Hazard symbol	: Xn
Indication of danger	: harmful
Risk phrases	: R40 "Limited evidence of a carcinogenic effect", category 3
Safety phrases	: no obligatory safety phrases for professional use

Justification for the proposal:

R40: Obligatory for substances which cause concern for man owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment. There is some evidence from appropriate animal studies (110 week oral study in rat), but this is insufficient to place the substance in category 2.

Ecotoxicological effects

Classification is based on the following:

- Acute toxicity is the toxicity to fish, crustaceans (*Daphnia*/mysid shrimp), algae or higher aquatic plants.
- 96h-LC₅₀ fish is 7.2 mg a.s./L.
- 48h-EC₅₀ *Daphnia* is 6.2 mg a.s./L; 96h-LC₅₀ *Mysidopsis bahia*: 2.37 mg a.s./L.
- 72h-EC₅₀ algae is > 3.2 mg a.s./L.
- 14d-EC₅₀ *Lemna gibba* is 0.0279 mg a.s./L.
- The log P_{ow} value is 2.70.
- The test substance will not hydrolyse.
- The test substance is not readily biodegradable.
- The solubility in water is ca. 21 mg/L.

Based on this information the hazard classification of the active substance dichlobenil is N, R50/R53.

Formulation

Physical and chemical properties

No classification and labelling is needed based on the physical and chemical properties of Casoron® G.

Human health effects

Justified proposals for classification and labelling of the preparation Casoron® G, relating to human health effects, according to Directive 2001/59/EC are listed below.

Hazard symbol	:	Xn
Indications of danger	:	harmful
Risk phrases	:	R40 "Limited evidence of a carcinogenic effect", category 3
Safety phrases	:	no obligatory safety phrases for professional use

Justification for the proposal

R40: obligatory for formulations which contain substances classified with R40 at concentrations at or above the limit value of 1%. As dichlobenil is classified as carcinogenic and present at more than 1%, R40 is assigned to the preparation.

Ecotoxicological effects

Classification is based on the following:

- No aquatic toxicity studies with the formulation are available.
- The active substance has been assigned R50/53 based on its toxicity to *Lemna gibba* and its biodegradability characteristics.
- 14d-EC₅₀ *Lemna gibba* is 0.0279 mg a.s./L.
- The other components of Casoron G pose no environmental risks.
- Concentration of the active substance in the formulation is 6.75% w/w.
- According to Directive 2006/8/EG a substance with R50/53 and $0.01 \text{ mg/L} < \text{EC}_{50} \leq 0.1 \text{ mg/L}$ leads to R50/53 for a formulation when its concentration in this formulation is $\geq 2.5\% \text{ w/w}$.

Based on this information the hazard classification of the formulation Casoron G is N, R50/R53, S60, S61.

2.2 Methods of analysis

2.2.1 Analytical methods for analysis of the active substance as manufactured

A CIPAC method is available for the determination of granular Dichlobenil technical (CIPAC method Dichlobenil 73), based on the extraction with dichloroethane and determination of Dichlobenil by GC-FID using methyl myristate as internal standard.

An analytical method for the determination of impurities in Dichlobenil technical is submitted as well. Since it is confidential information, the analytical method of the specified impurities is summarised in Volume 4 Annex C.

2.2.2 Analytical methods for formulation analysis

A collaboratively validated CIPAC method for the determination Dichlobenil in a granular formulation (CIPAC method Dichlobenil 73) is available as well.

The described GC-FID method (method no. GRL-GM-1117) is validated for the determination of 2,6-dichlorobenzonitrile in formulated material (Casoron G). This method (GRL-GM-1117) is similar to the method (BAI 41 003) used in the storage stability test.

2.2.3 Analytical methods for residue analysis

Treated plants, plant products, foodstuffs, feeding stuffs

Plant and plant products

Various study reports on the validation of analytical methods for the determination of Dichlobenil and/or 2,6-dichlorobenzamide (BAM) in plant (products) are submitted.

First of all the applicability of different multi-residue methods (MRM) was investigated: FDA method for the determination of 2,6-dichlorobenzamide in apples and hazelnut (Pouwelse and van Loo, 1992), DFG method S 19 for the determination of 2,6-dichlorobenzamide in grape (Specht, 1991a) and DFG method S 19 for the determination of 2,6-dichlorobenzamide in apple (Specht, 1991b).

DFG method S19 is suitable for the determination of 2, 6-dichlorobenzamide (BAM) in grape and apple, an ILV is however not submitted.

Furthermore, one handbook reference (van Rossum et al., 1978) and three study reports on method validation are submitted (van Balkom, 1993; Brereton, 2000; Bacher, 2005) and one method validation was part of a processing study (Maselli, 1998).

The methods supplied cover next to the determination of BAM in apples also the determination of Dichlobenil and its metabolite BAM in grapes, the residue definition in the commodity of the intended use.

All determinations are based on the same principle:

- extraction of the homogenised samples with ethyl acetate (for determination of BAM) or with 20% ethyl acetate in hexane (for determination of Dichlobenil),

- clean-up of the extract with or column chromatography on alumina or in one study (Brereton, 2000) with gel permeation chromatography,
- measurement, applying GC-ECD; in one study (Bacher, 2005) also GC-MS/MS.

The handbook method description (van Rossum et al., 1978) did not contain any validation data. The information submitted in the studies of Maselli (1998), van Balkom (1993) and Brereton (2000) is not in accordance with the guideline to allow the derivation of an LOQ, since all studies have shortcomings regarding their performance and/or documentation.

Only the study of Bacher (2005) does fulfil the requirements of guideline SANCO/825/00. The LOQs of the described GC-ECD and GC-MS/MS method for the determination of both Dichlobenil and BAM in grapes account in all cases for 0.01 mg/kg. An ILV (Wolf, 2006) has also been submitted.

Products of animal origin

The notifier submitted no analytical method for products of animal origin.

Since relevant intake levels (>0.1 mg/kg dry feed) of the metabolite BAM, the component of the residue definition, occur for cattle, additional data on metabolism are requested, possibly followed by the performance of a feed intake study. In case significant residues (≥ 0.01 mg/kg) occur in any edible part of the animal after intake of relevant residue (levels), appropriate validated analytical method(s) have to be submitted as well.

Residues in body fluids and tissues

Since the active substance Dichlobenil and its main metabolite BAM are both not classified as toxic or highly toxic, an analytical method for the residue determination in body fluids and tissues is not required.

Soil, water and air

For soil samples, a validated GC-ECD method is available for the determination of the parent Dichlobenil and its metabolite 2,6-dichlorobenzamide, which comprise together the residue definition in soil at the current intended use. As confirmatory methods GC-MS (for Dichlobenil and BAM) and GC-MS/MS (only for Dichlobenil) were applied. The LOQ of the GC-ECD method accounts for 0.01 mg/kg soil for both, Dichlobenil as well as for BAM.

The residue definition in water comprises also the parent compound Dichlobenil and its metabolite 2,6-dichlorobenzamide (BAM). For surface and groundwater validated analytical GC-MS methods are available for the determination of Dichlobenil and BAM. Furthermore, two ILVs are available for the GC-MS methods in surface water as well as in groundwater for both Dichlobenil and BAM, resulting in all cases in a LOQ of 0.1 µg/L.

Therefore, the validated LOQ for both Dichlobenil and BAM accounts for 0.1 µg/L groundwater and surface water, determined by GC-MS.

For the determination of Dichlobenil in air a method based on HPLC-ECD was submitted. The method specificity was confirmed by GC-MS, extraction efficacy, recovery and breakthrough were determined for ambient and also warm humid air, resulting in both cases in a validated LOQ of 0.8 µg/m³ Dichlobenil.

2.3 Impact on human and animal health

2.3.1 Effects having relevance to human and animal health arising from exposure to the active substance or impurities contained in the active substance or to their transformation products

Toxicokinetics

Absorption

In one rat study with single low dose (ca. 6 mg/kg bw) in which oral and i.v. administration were compared, oral absorption was 89-97% (m-f).

In the rat, oral absorption after repeated exposure is at least approximately 60%, irrespective of dose and sex, based on radiolabel recovered from urine and cage wash. However, as the liver is the critical target organ for dichlobenil toxicity, it is the amount of compound which has passed the liver, that should be considered in risk assessment. After repeated low dose, the amount absorbed from the gut into the liver is more than 80% (see below under "Excretion").

In order to calculate internal doses after dermal exposure a value of 1.4% was used, based on an *in vitro* dermal absorption study with human skin.

Excretion

In rats, radiolabel is primarily excreted via the urine after oral exposure to [¹⁴C]-dichlobenil. Around 60% is excreted in the urine and around 20% in the faeces, irrespective of sex or dose regime, 9 to 10 days after initiation of exposure. Increasing dose or multiple dosing slows down the rate of excretion, without changing the final amount excreted. After repeated dosing, approximately 80% of the last administered dose is excreted within 24 h after low and mid dose (4 and 30 mg/kg bw/d), while for high dose (240 mg/kg bw/d) ca. 65% was excreted within 24 h.

After single oral low dose in rats, a substantial amount of the administered radioactivity is excreted in bile (80% in the first 24 h hours after administration). As the majority of the radiolabel ended up in the urine, enterohepatic cycling takes place with part of the radiolabel ultimately becoming systemically available and excreted via urine. As comparison with a concurrent i.v. experiment indicates that more than ca. 90% of the administered single oral dose becomes systemically available, also part of the faecally excreted radiolabel must have been excreted from systemic circulation. As with other dose regimes (multiple and/or increased) no i.v. and bile cannulation experiments were executed, the quantitative importance of biliary excretion and systemic absorption can not be definitely established for those dose regimes. However, with respect to low repeated dose, absorption from the gut is likely to be higher than 80% as only a low percentage of parent compound is found in faeces (less than 10%) and all metabolites identified are probably liver metabolites: In bile and urine no parent compound was detected at any dose regimen, and in faeces the relative amount of

parent compound increases with increasing and multiple doses (see below "Metabolism"). Therefore, once it enters the liver dichlobenil appears to immediately be metabolised, while no metabolism takes place in faeces. Consequently ca. 90% of the faecal radiolabel (non-parent compound) will have originated from the liver via the bile, representing ca. 20% of the administered dose, which should be added to the radiolabel recovered from urine and the cage wash (respectively, ca. 60 and 4% at repeated low dose) in order to obtain the amount of administered radiolabel which has been absorbed from the gut.

In one study with single oral low dose (significant) differences in excretion between males and females were observed. However, two other studies, among which one with single and multiple low, mid and high doses, did not demonstrate these differences. Therefore this difference is considered to have occurred by coincidence.

Distribution

After single low dose (2.5 mg/kg bw/d) in rats, most radiolabel is recovered from liver, kidney, kidney-fat and brown-fat. In all tissues and organs investigated, concentrations peak between 1 and 3 hours after administration, in liver and kidney even after 1 hour. Therefore, radiolabel appears to be rapidly distributed and excreted. Seven days after administration little radioactivity was retained. No potential for accumulation was observed.

In another study with rats various distributions after various oral dose regimes (single/multiple, low/mid/high) was studied. In all cases less than 0.01% of the last administered dose was recovered from selected tissues and organs (blood, plasma, liver and kidneys), while between 0.2 and 0.4% was encountered in residual carcass, eight days after administration of the last dose.

Metabolism

In rats, ten metabolites were identified in urine and no parent compound. Most metabolites were conjugates such as sulphate, glutathione (and derivatives) and glucuronic acid conjugates. In faeces, three major metabolites (each representing 5% of the administered dose or more) were observed as well as parent compound (Dichlobenil). The proportion of conjugated metabolites decreases with increasing and multiple doses, while the amount of parent compound in faeces increases. No chemical names were provided for the identified metabolites.

Toxicodynamics

The acute toxicity of dichlobenil is low. In the acute oral toxicity studies, liver and kidney histopathological effects were observed. Oral repeated dose studies clearly indicate the liver and kidney as the critical target organ. The hamster is more sensitive for dichlobenil than mice based on the 90-days semi-chronic oral toxicity studies. Therefore, the second carcinogenicity study was performed with the hamster instead of with the mouse.

Acute toxicity

Dichlobenil does not need to be classified on the basis of its acute oral and dermal toxicity in rats.

Dichlobenil is considered not irritating to skin and eyes according to the criteria mentioned in Annex VI of Directive 2001/59/EC. Dichlobenil does not have sensitising properties in a Maximisation test. No adequate data on the acute inhalation toxicology of dichlobenil were provided. However, in view of the particle size (99.9% >100 µm; granule) and the application of the preparation (not in enclosed spaces), no acute inhalation studies are required.

Short-term toxicity

In a 21-day dermal mice study exposure of mice to dichlobenil at doses of 100, 300 and 1000 mg/kg bw/d did not result in toxic effects. Therefore, the NOAEL was set at >1000 mg/kg bw/d.

In a 28-day inhalation rat study respiratory exposure of rats to dichlobenil at concentrations of 2.3, 5.1 and 12 mg/m³ for 5 days/week did not result in toxic effects. Therefore, the NOAEL was set at ≥12 mg/m³.

A 90-day oral toxicity study was performed on mice administered 3.7, 19, 91, 445 mg/kg bw/d. The critical effects were reduced body weight gain, reduced food consumption and liver effects (swollen hepatocytes, increased organ weight), observed at doses of 91 mg/kg bw/d and higher. Based on these effects, the NOAEL is set at 19 mg/kg bw/d.

A 90-day oral toxicity study was performed on hamsters administered 2.3, 12, 73 and 302 mg/kg bw/d for males and 2.6, 13, 81 and 320 mg/kg bw/d for females. The following effects were considered toxicologically relevant: increased liver weight, a decrease of prostate weight, testes weight and uterus weight, a degeneration of testes tubules and a decrease of viable spermatocytes, calculi in the gallbladder, decreased food intake, increased ALAT and increased cholesterol and phospholipids. Therefore, the NOAEL in this study is 2.3 mg/kg bw/d, based on the effects found at the 12 mg/kg bw/d dose level (effects on liver, kidney and male reproductive organs).

Two repeated dose toxicity studies in dogs are submitted. In an oral 52-week and a 2-years study, the dogs were exposed to 1, 6 and 36 mg/kg bw/d and 0.5, 1.3, and 9.1 mg/kg bw/d, respectively.

The 2-year oral toxicity study in dogs showed in the highest dose group elevated alkaline phosphatase (from week 12 and higher), glucose-6-phosphatase and glucose-6-phosphate dehydrogenase activities, increased weight of the liver and thyroid and histopathological liver changes in both sexes. At dietary levels of 1.3 mg/kg bw/d and less, no treatment related effects were noted.

Therefore, the NOAEL is set at 1.3 mg/kg bw/d based on liver effects and increased thyroid weights at the next higher level.

In the two highest dose groups in the 52-week oral toxicity study, reduced body weight gain and elevated alkaline phosphatase activities, increased liver weight and hepatocytic hypertrophy and effects in the clinical chemistry were observed. Other changes at this dose level included vacuolation in the adrenals, considered to represent changes in mineralocorticoid production. Males had slightly lowered red cell parameters and there was some evidence of haemosiderin deposits in the spleen of animals of both sexes.

Females showed decreased ovaries and uterus weights. A dose related increased liver weight in females was observed from the lowest dose group at 1 mg/kg bw/d. In conclusion, the LOAEL is set at 1 mg/kg bw/d.

Genotoxicity

In vitro, dichlobenil tested negative in the point mutation tests with *S. typhimurium* strains TA 98, TA 100, TA 1535, TA 1537 and TA 1538, in a gene mutation test with Chinese hamster ovary cells (CHO), in a chromosome aberration test with Chinese hamster ovary cells (CHO), in an unscheduled DNA synthesis test with human HeLa S3 epithelioid cells and in two transformation assay in BALB/c-3T3 mouse cells. *In vivo*, dichlobenil tested negative in a micronucleus test in mice, with the bone marrow as observed target organ. Based on the available data the substance dichlobenil does not need to be classified according to the classification criteria of Directive 93/21/EC. The test results of an *in vitro* gene mutation test with mouse lymphoma cells (L5178Y) and the chromosome aberration test with human blood lymphocytes were considered unacceptable due to wrong concentration ranges tested. As the *in vitro* chromosome aberration test performed with CHO cells is considered acceptable, the chromosome aberration test performed with human lymphocytes is not considered relevant for the evaluation of the genotoxic potential of the substance.

Long-term toxicity and carcinogenicity

In an oral combined chronic and carcinogenicity study with dichlobenil rats were exposed to 3.2, 26 and 241 mg/kg bw/d. The main effects of dichlobenil in this study were seen on the liver and kidney. Blood biochemistry parameters (urea, cholesterol and electrolytes) were affected primarily in the highest dose group with urea and cholesterol also increased at 26 mg/kg bw/d indicating changes in liver and/or kidney function. Renal pathological effects were already noted at interim sacrifice after 52 weeks.

The pattern of histopathological changes observed in several organs (primarily in males) is most likely directly or indirectly related to this renal pathology. Increases in nephrosis, glomerulosclerosis and renal fibrosis, parathyroid hyperplasia, calcification in the kidney and blood vessels, and atrophy of the bones represent a coherent pathological pattern induced by renal failure.

At the 3.2 mg/kg bw/d level the increase in renal fibrosis is already highly statistical significant while related histopathological effects are all present at borderline importance. Because this histopathological pattern is coherent and well known in the literature and, moreover, is dose-dependently increased, the 3.2 mg/kg bw/d level will be considered to be an effect level. Therefore, the NOAEL in this study cannot be determined, and the LOAEL is set at 3.2 mg/kg bw/d.

At the highest dose, in both males and females an increase in malignant tumour incidence was observed (adenocarcinoma in kidney, carcinoma in liver, leukemia and malignant lymphoma). At the dose of 241 mg/kg bw/d two adenomas were observed in female liver. In this study, the highest dose clearly exceeds the so-called maximal tolerated dose (MTD) considering the high mortality in males. Therefore, the relevance of the increased tumour incidences at the highest dose should be questioned (however taking into account that there seems to be a dose-related increase in liver adenoma). At the dose of 400 mg/kg food two adenomas were observed in female liver. However, no indications of liver cytotoxicity were observed which could constitute a possible indirect mechanism of carcinogenesis, caused by high toxicity. Furthermore, the incidence of the adenomas observed in the rat study in female liver at the dose of 400 mg/kg food is slightly

above the historical control range. Therefore, a direct effect of dichlobenil on the tumor incidence cannot be excluded.

Two oral carcinogenicity studies with hamster were performed.

In the first (80-88-week) and the second (78-91 week) carcinogenicity study in hamsters, the hamsters were exposed to respectively 0.34, 1.7, 9.2, and 46 mg/kg bw/d and 51, 117 and 277 mg/kg bw/d.

In the first study treatment by prolonged oral administration of dichlobenil to hamsters at levels up to 46 mg/kg bw/d revealed no evidence of a carcinogenic potential. Treatment related changes were confined to the high dosage level. In the 46 mg/kg bw/d male group these changes included initial impairment of body weight gain with associated lower food consumption, and lower overall body weight change together with the histopathological finding of a reduction in the adipose tissue in the male decedents. In high dose females liver changes (slightly higher weights, pitted liver and centrilobular hepatocyte enlargement and rarefaction) and cortical hyperplasia of the adrenals were observed. Based on the effects above, the NOAEL is set at the next lower dose level of to 9.2 mg/kg bw/d.

In the second study with hamster in all dose groups decrease of body weight was observed. An increased incidence of benign liver tumours in males receiving 277 mg/kg bw/d was seen. A single malignant tumour was also recorded for males at this treatment level, whilst a single benign liver tumour was recorded amongst males receiving 117 mg/kg bw/d

Non-neoplastic changes were evident in the liver, principally amongst hamsters receiving 117 or 277 mg/kg bw/d consisting of hepatitis in both sexes receiving 277 mg/kg bw/d and also females receiving 117 mg/kg bw/d; pigmented giant cells in males receiving 277 mg/kg bw/d; brown pigments in hepatocytes in both sexes receiving 117 or 277 mg/kg bw/d and minimal centrilobular hepatocyte enlargement in all treatment groups. In addition to hepatotoxicity, evident at all treatment levels, toxicity was also manifest as impaired body weight gain food intake amongst all treated males and for females receiving 277 mg/kg bw/d.

The doses of 51 mg/kg bw/d for males and 277 mg/kg bw/d for females was considered to be the NOAEL with respect to tumorigenicity. Regarding the non-neoplastic effects, no NOAEL could be established. The LOAEL is considered to be 51 mg/kg bw/d.

In this study, mid and highest dose levels exceed the so-called maximal tolerated dose (MTD), e.g. the high increase of relative liver weight. Therefore, the relevance of the tumours observed at doses of 1500 and 3375 mg/kg food should be questioned.

In the rat study, the highest dose clearly exceeds the so-called maximal tolerated dose (MTD) considering the high mortality in males. Therefore, the relevance of the increased tumour incidences at the highest dose should be questioned (however taking into account that there seems to be a dose-related increase in liver adenoma). However, in the rat also liver adenomas were observed at a dose level below the MTD. It was concluded that the two adenomas observed in female liver at the dose of 400 mg/kg food (2 adenomas in 47 animals = 4.3%) are slightly above the historical control range of the conducting laboratory (and the breeder).

In the second hamster study (Chambers *et al*, 1992a), the mid and highest dose levels exceed the so-called maximal tolerated dose (MTD), e.g. the high increase of relative liver weight. Therefore, the relevance of the tumours observed at doses of 1500 and 3375 mg/kg food should be questioned.

The background tumour incidence study in hamsters showed no benign or malignant tumours in liver. In fact, the study of Hooks *et al*. (1990) might also be regarded as background tumour incidence study showing no tumours in 600 animals.

In conclusion, the relevance of the observed tumours in rats and hamsters at levels exceeding the MTD, for the assessment of the carcinogenic potential of dichlobenil, should be questioned. However, it seems that dichlobenil has some carcinogenic potential in the rat, not explainable by cytotoxicity in liver as this was not observed. It is proposed to regard dichlobenil as a potential carcinogen according to the criteria mentioned in Annex VI of Directive 2001/59/EC and to classify with R40 (category 3; Limited evidence of a carcinogenic effect). As dichlobenil is not genotoxic, a threshold mechanism of its carcinogenicity is likely.

Reproductive and developmental toxicity

From the 2-generation study in rats with doses of 4, 23 and 133 mg/kg bw/d, the NOAEL for parental toxicity is 4 mg/kg bw/d. Above this NOAEL, a decreased body weight and a decreased food consumption in adults and offspring in both F0 and F1 generations is observed. The NOAEL for developmental toxicity is also 4 mg/kg bw/d. Above this NOAEL, a decreased pup body weight is observed.

Reproductive effects were not observed in this study. The NOAEL for reproductive toxicity is therefore set at 133 mg/kg bw/d.

Two teratogenicity studies in rats and rabbits are performed. The rats and rabbit were exposed to respectively 20, 60, and 180 mg/kg bw/d and 15, 45 and 135 mg/kg bw/d.

The maternal NOAEL of the study in rats is 20 mg/kg bw/d. Above this NOAEL, decreased body weight gain during day 6-16 and decreased food consumption were observed.

All observed external, skeletal and visceral findings are common in this strain of rats and do not indicate embryotoxic or teratogenic effects that could be related to the exposure of dichlobenil. The developmental NOAEL is therefore >180 mg/kg bw/d. In the study in rabbits both the maternal and developmental NOAEL are 45 mg/kg bw/d. Above the maternal NOAEL, decreased weight gain (day 7-19) and food consumption were observed. Above the developmental NOAEL, major abnormalities, such as grossly enlarged fontanelles and other major cranial defects and open eyes, are seen in the foetuses. Since these teratogenic defects only occur at a maternally toxic level, dichlobenil does not have to be labelled for developmental effects.

Delayed neurotoxicity

The chemical structure of dichlobenil does not resemble that of the organophosphates or carbamates, nor do the results of the submitted repeated dose studies suggest a neurotoxic effect of dichlobenil. Therefore, a delayed neurotoxicity study is not deemed necessary.

Further toxicological studies

The notifier submitted a statement with regard to the effect of dichlobenil on the olfactory nasal mucosa of rodents (reported in the literature). The statement is considered acceptable.

The metabolite of dichlobenil tested is 2,6-dichlorobenzamide (BAM). BAM is a soil metabolite of dichlobenil and becomes available as residue in plants. BAM is not formed in rats based on the submitted metabolism studies.

An acute oral toxicity study in rats with BAM showed that it should be classified as Harmful (Xn, R22). The acute oral LD₅₀ was 500 mg/kg in rats. No acute dermal or inhalation toxicity studies with BAM were provided (not necessary since BAM is a soil metabolite).

In vitro, BAM tested negative in two point mutation tests with *S. typhimurium* strains TA 98, TA 100, TA 1535, TA 1537 and TA 102, in a gene mutation test with Chinese hamsters V79 cells, and in an unscheduled DNA synthesis test with rat primary hepatocytes. *In vivo*, BAM tested negative in a micronucleus test in mice, with the bone marrow as observed target organ. Based on these tests, BAM does not possess genotoxic potential.

Two repeated dose toxicity studies with BAM were performed in rats. In a 90-day and 2-years diet study, the rats were exposed to respectively 4, 14, 49 and 172 and 2, 3.5, 6.5, and 18 mg/kg bw/day. The 90-day oral toxicity study in rats showed, in the 49 mg/kg bw/d dose group, reduced body weight (gain), reduced food consumption, hair loss and a reduction in skeletal muscle tone in the female animals, increased relative adrenal weight in males and liver- and kidney effects in both sexes. The NOAEL is set at 14 mg/kg bw/d based on these effects at the next higher dose.

In the 2-year oral toxicity study in rats in the highest dose group liver weight increase, hepatocellular adenoma, hepatocyte vacuolation centrilobular and Eosinophilic/Basophilic hepatocytes were observed. The NOAEL is set at 6.5 mg/kg bw/d.

In the two year rat study, dietary administration of 2,6-dichlorobenzamide resulted in an increase in hepatocellular adenomas in females at the highest dose group. The highest dose level in this study exceeds the MTD. Therefore, the relevance of the increased tumour incidences at the highest dose should be questioned. However, considering that these tumours:

- are increased only at the highest dose,
- in a single species,
- occur also spontaneously in this species and sex,
- are at the border of statistical significance,
- occur under conditions of clear local cytotoxicity (i.e. in the liver), and
- only occur at a dose level that may be considered to clearly exceed the maximum tolerated dose criterion, and that this substance clearly has no genotoxic potential,

application of the criteria mentioned in Annex VI of Directive 67/548/EC allows to conclude that this substance should be classified with R40 (category 3; Limited evidence of a carcinogenic effect). It should be noted that this is not in line with the evaluation of BAM in the DAR for fluopicolide.

The relevant NOAELs and LOAELs derived in the different repeated dose toxicity studies are summarised in the tables 2.3.1.1, 2.3.1.2, and 2.3.1.3.

Table 2.3.1.1 Short-term toxicity studies

Duration	Species	Route	NOAEL	LOAEL	Critical effects	Reference
21 days	mice	dermal	1000	> 1000	-	Allan, 1995
28 days	rats	inhalation	≥12 mg/m ³	-	-	Newton, 2002
90 days	hamster	oral	2.3	12	decreased food intake, increased ALAT, increased cholesterol and phospholipids, increased liver weight, decreased prostate weight	Kemp, 1987a
90 days	mice	oral	19	91	decreased food consumption, decreased glucose, increased testis weight, swollen centrilobular cells of the liver	Kemp, 1987b
52 weeks	dog, Beagle	oral	-	1	increased liver weight	Pickersgil, 1995
two years	dog, Beagle	oral	1.3	9.1	increased ALAT and ALP; increased glucose-6-phosphatase and glucose-6-phosphate dehydrogenase; increased liver and thyroids weight	Til, <i>et al.</i> , 1969, Dijkstra, 1990

Table 2.3.1.2 Long-term toxicity studies

Duration (weeks)	Species	NOAEL (mg/kg bw/d)	LOAEL (mg/kg bw/d)	Critical effects	Reference
110	rat		3.2	Kidney: nephrosis (grade 2+3), glomerulosclerosis, fibrosis; hyperplasia of Parathyroid, telangiectasis of the bone marrow. Esophagus: hyperkeratosis. Stomach: fibrosis; vessels (fibrosis and calcification). Tumors: adenocarcinoma kidney and adenoma and carcinoma liver in the 26 and 241 mg/kg bw/d groups	Inoue and Enomoto (1984) and Inoue and Enomoto (1998)
88 (males) and 80 (females)	hamsters	9.2	46	Liver: slightly higher weights, pitted liver and centrilobular hepatocyte enlargement and rarefaction and cortical hyperplasia of the adrenals	Hooks <i>et al.</i> , 1990
91 (males, and 78	hamsters	-	51	body weight and food consumption decrease, liver weight gain, heart weight	Chambers

Duration (weeks) females)	Species	NOAEL (mg/kg bw/d)	LOAEL (mg/kg bw/d)	Critical effects	Reference
				decrease, penis protrusion, liver effects (among centrilobular hepatocyte enlargement).	et al., 199a
				Tumors: In males benign and malignant tumours were found in liver, at dose levels ≥ 117 mg/kg bw	

Table 2.3.1.3 Reproduction and teratogenicity studies

Type of study	Species		NOAEL (mg/kg bw/d)	LOAEL (mg/kg bw/d)	Critical effects	Reference
<i>Reproduction toxicity</i>						
2-generation toxicity study	rat	parental	4	23	- decreased body weight and food consumption	Leeming, 1989
		developmental	4	23	- decreased pup body weight	Barker, 1992a Barker, 1992b
		reproduction effects	not observed	-		Barker, 1993
<i>Embryo/foetal toxicity and teratogenicity</i>						
teratogenicity study	rat	maternal	20	60	- decreased body weight gain (day 6-16) and food consumption	Koëter, 1984
		developmental	>180	-		
		teratogenicity	no			
teratogenicity study	rabbit	maternal	45	135	- decreased body weight gain (day 7-19) and food consumption	Barker, 1989a
		developmental	45	135	- major abnormalities in the foetuses (grossly enlarged fontanelles, body weight decrease other major cranial defects, open eyes; decreased body weight)	
		teratogenicity	yes at 135			

2.3.2 ADI

The ADI was derived from the results of toxicity studies with experimental animals. The calculation of the ADI is based on the highest dose at which no adverse effect is observed in the most appropriate study in the most sensitive species. Dichlobenil was tested in several subacute, semi-chronic, and chronic toxicity studies in dogs, rats, hamster, and mice, providing the basis for the establishment of the ADI. The dog is the most sensitive species, and as such was used for the derivation of the ADI.

The lowest LOAEL (1 mg/kg/day) was obtained from a 52 weeks study in dogs. The NOAEL from the 2-year dog study is 1.3 mg/kg bw/d. In view of almost equal NOAEL of the 2-years study and the LOAEL from the 52-weeks dog study, only a factor of 2 for extrapolation from a LOAEL to NAEL is used. This NAEL (0.5

mg/kg bw/d) is used as a starting point for the establishment of the ADI. Application of a safety factor for inter- and intraspecies differences of 100 results in an ADI of 0.005 mg/kg bw/d. Based on the two dog studies the NOAEL does not decrease with increased exposure duration. Therefore no correction factor for exposure duration is used. Furthermore, no additional factor is used for carcinogenic effects, caused via a threshold mechanism, as they are observed well above the LOAEL for non-carcinogenic systemic effects.

For the main soil metabolite of dichlobenil, 2,6-dichlorobenzamide (BAM), a separate ADI is proposed. This metabolite has been included in the residue definition, whereas it is not observed as a metabolite in toxicokinetic studies conducted with dichlobenil. The proposed ADI is based on the chronic NOAEL of 6.5 mg/kg bw/d from the 2-year chronic study with rats and safety factor for inter- and intraspecies differences of 100. Furthermore, as tumours were formed, be it via threshold mechanism, at the LOAEL for non-carcinogenic systemic effects, an uncertainty factor of 3 is proposed in view of the serious nature of this effect. Applying these safety factors leads to an ADI for BAM of 0.022 mg/kg bw/d. This results in a factor of 800 between the ADI for BAM and the dose level at which tumours were observed in the 2-year study with BAM.

2.3.3 ARfD (acute reference dose)

For dichlobenil no ARfD is derived. No classification is required based on the acute toxicity studies and there are no indications for acute effects from the repeated dose toxicity studies.

For the main soil metabolite of dichlobenil, 2,6-dichlorobenzamide (BAM), a separate ARfD is proposed. This metabolite has been included in the residue definition, whereas it is not observed as a metabolite in toxicokinetic studies conducted with dichlobenil. Based on the submitted data on BAM, the following considerations were made:

- The acute oral LD50 of BAM was estimated to be 2000 mg/kg bw in male rats and 500 mg/kg bw in females rats.
- In the 90-day toxicity study, a significant reduction in skeletal muscle tone was observed from day 4 – day 92, at dose levels of ≥ 600 ppm (49 mg/kg bw/d).

Based on the above data, it can be concluded that the criteria for not allocating an ARfD are not met, since the LD50 value < 2000 mg/kg bw. Furthermore, an acute toxic effect for BAM was observed in the 90-day study, and it was concluded that allocation of an ARfD is considered justified.

It is proposed to consider the 90-day oral toxicity study with BAM in rats as the most suitable study to derive an ARfD. The NOAEL for skeletal muscle hypotonus is 14 mg/kg bw/d. Application of a safety factor of 100 for inter- and intraspecies differences results in an ARfD for BAM of 0.14 mg/kg bw.

2.3.4 AOEL

Dichlobenil is the active ingredient of Casoron G, at a concentration of 6.75% in granules. Casoron G is used as an herbicide. Dichlobenil is applied by mechanical or manual scattering of granules around buildings, on industrial sites, alongside paths and roads, under fence lines and hedges around well-established trees and shrubs in parks and recreational areas and around grape vines.

The application frequency is for all applications once a year, pre-emergence in spring only. Therefore, the operator exposure will not exceed a period of 3 months, and it is considered semichronic. The lowest NAEL of 0.5 mg/kg bw/d is derived from the 52-week dog toxicity study. The oral absorption is derived from the metabolic studies and is assumed >80%. Application of a safety factor for inter- and intraspecies differences of 100 results in a systemic AOEL of 0.005 mg/kg bw/day. As the derived bioavailability is >80%, no correction for bioavailability will be implemented, and the systemic AOEL will remain 0.005 mg/kg bw/d.

2.3.5 Drinking water limit

According to Council Directive 97/57/EC, exposure to dichlobenil through drinking water should account for not more than 10% of the ADI. If it is assumed that the average daily consumption of water amounts to 2 litre per person of 60 kilogram, a drinking water limit of $((60 \times 0.005) / 10) / 2$ mg/L, i.e. 0.015 mg/L can be established. According to Document 8064/VI/79 of the European Commission, the EU drinking water limit for pesticides of 0.1 µg/l is applicable for dichlobenil.

According to Council Directive 97/57/EC, exposure to 2,6-dichlorobenzamide (BAM) through drinking water should account for not more than 10% of the ADI. If it is assumed that the average daily consumption of water amounts to 2 litre per person of 60 kilogram, a drinking water limit of $((60 \times 0.022) / 10) / 2$ mg/L, i.e. 0.07 mg/L can be established. According to Document 8064/VI/79 of the European Commission, the EU drinking water limit for relevant metabolites of 0.1 µg/l is applicable for 2,6-dichlorobenzamide (BAM).

2.3.6 Impact on human or animal health arising from exposure to the active substance or to impurities contained in it

Internal exposure levels for the operator were estimated with the PHED-model, and a risk assessment was performed, see Table 2.3.6.1..

Table 2.3.6.1 Operator internal exposure and risk assessment

Activity	Route	Estimated internal exposure (mg a.s./day)		AOEL-systemic * (mg a.s./day)	% AOEL	
		without PPE	with PPE		without PPE	with PPE
Mechanical scattering in grapes with a solid broadcast spreader with open cab						
Mix/loading	Respiratory	0.16	0.016	0.35	46	4.6
Mix/loading	Dermal	0.04	<0.01	0.35	11	1.1

Activity	Route	Estimated internal exposure (mg a.s./day)		AOEL- systemic * (mg a.s./day)	% AOEL	
		without PPE	with PPE		without PPE	with PPE
Application	Respiratory	0.11	0.011	0.35	31	3.1
Application	Dermal	0.05	<0.01	0.35	14	1.4
Total		0.36	0.03	0.35	103	10
<i>Mechanical scattering in grapes with a solid broadcast spreader with closed cab</i>						
Mix/loading	Respiratory	0.16	0.016	0.35	46	4.6
Mix/loading	Dermal	0.04	<0.01	0.35	11	1.1
Application	Respiratory	0.02	<0.01	0.35	6	0.6
Application	Dermal	0.003	<0.01	0.35	1	0.1
Total		0.22	0.02	0.35	64	6
<i>Manual scattering alongside paths and roads and under fence lines and hedges, and around buildings and on industrial sites, with 5 kg ready-to-use container</i>						
Mix/loading		n.a.	n.a.	-	n.a.	n.a.
Application		negligible	negligible	-	negligible	negligible
<i>Manual scattering alongside paths and roads and under fence lines and hedges, and around buildings and on industrial sites, with 25 kg 'knap sacked' applicator</i>						
Mix/loading	Respiratory	0.01	<0.01	0.35	3	0.3
Mix/loading	Dermal	<0.01	<0.01		negligible	negligible
Application		negligible	negligible	-	negligible	negligible
Total		0.01	<0.01	0.35	3	0.3
<i>Manual scattering around well established trees and shrubs in parks and recreational areas, with 1 or 5 kg ready-to-use container</i>						
Mix/loading		n.a.	n.a.	-	n.a.	n.a.
Application		negligible	negligible	-	negligible	negligible

* AOEL (mg/d) was calculated using a body weight of 70 kg

n.a. = not applicable

Conclusions

- A safe use was identified for operators without PPE for mechanical application of Casoron G in grapes, using the PHED model. The exposure estimate for operators using a solid broadcast spreader with open cab is 103% of the AOEL and for operators using a solid broadcast spreader with closed cab 64% of the AOEL. It should be taken into account that these are worst-case estimates. Casoron G is a nearly dust-free formulation (see physical/chemical properties) and the dust-fractions of the formulations used in the underlying data-base of PHED are unknown, but are likely to be higher. Furthermore, it should be noted that a spreader with closed cab is used in current practice.

- Safe uses were identified for operators without PPE for manual application of Casoron G alongside paths and roads, under fence lines and hedges, around buildings and on industrial sites, and around well established trees and shrubs in parks and recreational areas.
- No risk assessment was performed for bystanders, as it is assumed that no bystander exposure will occur.
- No risk assessment was performed for workers, as it is assumed that no re-entry exposure will occur.

2.4 Residues

2.4.1 Definition of the residues relevant to MRLs

Plant products

Studies on the uptake and metabolism of Dichlobenil in grapes and apples are submitted and provide sufficient information on the nature and levels of residue after soil application. No detectable levels of the parent compound are found in the fruit grown on the treated soil. The only significant metabolite is 2,6-dichlorobenzamide (BAM). Therefore, the residue definition in plants is 2,6-dichlorobenzamide (BAM) for both monitoring and risk assessment. A conversion factor is not applicable.

It has to be noted that in case the intended use will be modified, this issue has to be reconsidered.

Animal products

No definition of the residue for animal products can be derived, since no data on metabolism, distribution and expression of residues in livestock is available. However, based on the intended use of Dichlobenil in grapes, intake of residues by livestock is possible due to feeding of dry/wet grape pomace to dairy and beef cattle. Since relevant intake levels (>0.1 mg/kg dry feed) of the metabolite BAM were calculated to occur for cattle, data on the metabolism of BAM in ruminants have to be submitted.

Drinking water

Metabolite BAM was found as a pregnant metabolite in surface water and ground water after modelling in FOCUS and FOCUS-PEARL (B.8.5.1 and B.8.5.2, respectively).

2.4.2 Residues relevant to consumer safety

General

Dichlobenil (2,6-dichlorobenzonitrile) is the active substance of Casoron[®] G, submitted for authorisation for use in Northern and Southern Europe. Casoron[®] G, a ready-to-use granular formulation containing 6.75% (w/w) (67.5 g/kg) formulation of Dichlobenil, intended to be used for the cultivation of grapes as pre-emergence herbicide for selective weed control of most germinating seeds and seedlings from both annual and perennial weeds.

Uptake, distribution and metabolism

Uptake, distribution and metabolism of Dichlobenil were investigated after soil application of a slightly exaggerated dose (about 1.2 N) in grapes, the crop of the intended use, as well as in apples. Both belong regarding their metabolism to the same crop group (fruits). The same metabolism pattern was found in the investigated commodities: at harvest the parent compound was not detectable and 2,6-dichlorobenzamide (BAM) was in both cases the major metabolite. The metabolic pathway of Dichlobenil after soil application proceeds via the hydroxylation of the cyanogroup resulting in the formation of the main metabolite 2,6-

dichlorobenzamide (BAM). It is likely that the conversion of Dichlobenil to BAM occurs in the soil followed by the translocation of the metabolite to the fruits.

No information regarding succeeding and rotational crops is submitted, which is due to the intended use of Dichlobenil in vine, a permanent crop, also not required. However, based on the soil degradation data for both parent (DT50 of 39 – 296 days) and the main metabolite BAM (DT50_(extrapolated) of 404 – 2666 days) (see chapter B.8) an accumulation of especially the metabolite in the ground after application in more than one growing season is likely. Supplementary residue trials with repeated yearly applications showed increasing residue levels over time. A PECsoil of 6.88 mg/kg is calculated for metabolite BAM. Therefore, the influence of repeated applications in successive growing seasons on the residue levels in grapes has to be elucidated. This additional information on repeated application in successive growing seasons might influence the view on the MRL setting as performed based on the currently available data of only one growing season per trial site.

Furthermore, it is noted that in case the intended use is changed to other - non-permanent - crops, this issue has to be reconsidered.

Residue trials

In total 12 residue trials were submitted – 6 for Northern Europe, 6 for Southern Europe. All trials were performed in 1999 and 2002 with grapes under field conditions and GLP. All applications were carried out in spring, at the latest at BBCH 15 (5 vine leaves unfolded) but two trials (one Northern and one Southern European trial) the application rates are too high, accounting for more than 25% above the application rate of the critical GAP (>6.75 kg a.s./ha). In all trials the parent compound Dichlobenil and its main metabolite 2,6-dichlorobenzamide (BAM) were determined. Only for BAM levels above the LOQ were found: in Southern Europe the residue levels of 2,6-dichlorobenzamide range from 0.015 mg/kg (at 136 DAT) – 0.173 mg/kg (at 201 DAT) and in Northern Europe the residue levels of 2,6-dichlorobenzamide range from 0.012 mg/kg (at 166 DAT) – 0.152 mg/kg (at 171 DAT).

Since the residue levels obtained in the Northern and Southern trials are in the same range it is justified to combine the trial data from Northern and Southern Europe for the derivation of the MRL. Based on this approach the available trial data are considered sufficient (n = 10) to derive an MRL for the current intended use of Dichlobenil in vine in Northern and Southern Europe.

However it has to be mentioned that the eight residue trials reported by Gillis (2004) are considered provisional, since the reliability of these results is questionable due to the sample extract storage conditions. The plant extracts were stored at -18C over a considerable amount of time. Additional information has therefore to be submitted in order to enable the assessment if these storage conditions influence the residue levels as measured and documented in the report.

Next to the 12 trials summarised above, the notifier did also submit in total 14 studies as additional information but none of the additionally submitted data are considered suitable for the current evaluation. However, it is noted that the results reported in these studies do support the results of the trials used for the derivation of the MRL.

Derivation of the MRL (provisional)

The provisional MRL for grapes as elaborated by the RMS accounts for 0.3 mg/kg 2,6-dichlorobenzamide (BAM), the provisional STMR accounts for 0.085 mg/kg BAM.

MRL and STMR are considered provisional since the influence of repeated applications in successive growing seasons on the residue levels in grapes over the years has to be elucidated and additional information is available in order to enable the assessment if the storage conditions as applied in the study of Gillis (2004) do influence the accuracy of the residue levels measured (in the study of Gillis (2004) the samples for the determination of Dichlobenil were extracted within 252 days after storage at $\leq -18^{\circ}\text{C}$ and analysed within 130 days after storage of the extracts at -18°C ; the samples for the determination of BAM were extracted within 429 days after storage at $\leq -18^{\circ}\text{C}$ and analysed within 84 days after storage of the extracts at -18°C).

No storage stability study as such is submitted, storage stability data are provided in one of the processing studies (Maselli, 1998); these data were obtained without GLP-compliance. Fortified samples were stored at $-20 \pm 5^{\circ}\text{C}$. The following results were obtained:

- grape samples were stable over the whole testing period of 323 days (Dichlobenil) and 345 days (BAM),
- raisin samples were stable over the whole testing period of 273 days (Dichlobenil) and 266 days (BAM),
- grape juice samples were stable over the whole testing period of 322 days (Dichlobenil) and 343 days (BAM).

These storage stability data are accepted to support the storage condition for the processing study and the residue trial study of Brereton (2000). The storage period for the BAM grape samples in the residue study of Gillis (2004) is 443d and can be extrapolated from the storage stability data of Maseli (1998). Therefore, the respective data on the storage stability of dichlobenil BAM in grape extracts for the period of 180d and 84d has still to be submitted, respectively.

Furthermore, depending on the outcome on the requested animal metabolism and/or feed intake studies, data on the storage stability of the relevant residue(s) in the relevant animal matrices have to be submitted. The effect of processing of grapes to juice, raisins, must, wet pomace and (young) wine on the residue levels of Dichlobenil and its major metabolite 2,6-dichlorobenzamide (BAM) was investigated. In none of the processed fractions levels above the LOQ of the parent compound Dichlobenil were found. In all cases only its main metabolite BAM was detected. A concentration of BAM occurred during the production of raisins, resulting in a transfer factor of 2.9. The transfer factors for the production of wet pomace range and juice account for 1.5 and 1.2, respectively. The concentration of BAM in must and wine remain approximately the same, the transfer factors account for 0.9 and 1.1, respectively.

It was shown that BAM is hydrolytically stable for 5d at 50°C at PH4. However, since the effect of processing on the nature of residue during fermentation was not investigated. it can not be assessed if the compounds determined in the two studies do cover all residue components which occur after making wine. Therefore information regarding the influence of the relevant processing processes (preparation of wine from grape juice) on the chemical nature of the residue has still to be submitted. Only based on this information a final conclusion about the appropriateness of the above mentioned processing studies can be drawn.

Residue levels in drinking water

Worst case levels of 0.38 mg/L in ground water can be expected as calculated under the Hamburg scenario

by FOCUS modeling (B.8.5.2). since ground water can be used for drinking water, this level will be used for consumers intake calculations.

Intake calculations (provisional)

Based on the available information intake calculations for livestock and humans were performed. Since the data used for the calculation are provisional, the outcome of the intake calculations has to be considered provisional as well.

Due to the intended use of Dichlobenil in grapes, livestock intake occurs via feeding of dry/wet grape pomace to dairy and beef cattle. Relevant levels ($>LOQ$) of BAM, the main metabolite of Dichlobenil, were found in the residue trials in grapes and due to the results of the processing study, a concentration of these content in fruit pomace is expected. No data on the transfer during processing of dry pomace are available. Since no livestock feeding studies were submitted, it cannot be stated if the plateau levels are reached slowly or within 7 days. Therefore intake calculations were performed using both the provisional MRL and STMR, accounting for 0.3 mg/kg BAM and 0.085 mg/kg BAM, respectively.

In both cases a transfer factor of 1.5 (mean value for the transfer during processing to wet pomace) was applied, resulting in levels of 0.45 mg/kg and 0.13 mg/kg BAM if calculated with the provisional MRL and STMR, respectively. This results in provisional TDMIs, ranging from 0.057 – 0.20 mg/kg diet (dry weight) for dairy cattle and 0.17 – 0.59 mg/kg diet (dry weight) for beef cattle. Since these levels are above the limit value as set in the guideline, the metabolism in ruminants has to be investigated.

Long-term intake calculations for humans were performed based on the provisional MRL. As described above, relevant intake of BAM is considered to occur in livestock, but no information about the consequences regarding the residue levels in animal parts used for human consumption are available. Therefore are all further intake calculations for human provisional. Depending on the additional information (influence on repeated treatment in successive growing seasons on the residue levels in grapes, influence of the storage conditions of the plant extracts in the residue trial study of Gillis (2004) on the residue levels measured, influence of processing on the nature of residue and data on animal metabolism, eventually followed by a feeding study), the calculation of the human intake levels have to be reconsidered.

The provisional human ITMDI for the FAO/WHO EUR diet accounts for 0.3% of the ADI and was determined on the basis of an ADI for BAM of 0.022 mg/kg bw/day or 3.84 mg/person/day (assumed body weight is 60 kg) and the proposed provisional MRL for grape. Taking an additional residue intake through drinking water of 0.38 mg/L into account, the ITMDI account for 58% of the ADI. When assuming that during processing of potable water all BAM will be removed up to the legal value of 0.1 µg/L BAM, the additional intake for consumers by the intake of water is less than 0.1% of the ADI and filling the ADI for 0.3%.

If based on the provisional STMR of 0.085 mg/kg BAM and considering the processing factors 2.9 for raisins and 1.2 for wine, an IEDI (provisional) of 0.3% of the ADI is calculated for the WHO European diet. Taking an additional residue intake through drinking water of 0.38 mg/L into account, the ITMDI account for 58% of the ADI. When assuming that during processing of potable water all BAM will be removed up to the legal value of 0.1 µg/L BAM, the additional intake for consumers by the intake of water is less than 0.1% of the ADI and filling the ADI for 0.3%.

The provisional NTMDI based on the Dutch TMDI model for the general population accounts for 1.2% of the ADI and was determined on the basis of an ADI for BAM of 0.022 mg/kg bw/day or 8.82 mg/person/day (assumed body weight is 63 kg) and the proposed provisional MRL. Taking an additional residue intake through drinking water of 0.38 mg/L into account, the TMDI accounts for 55% of the ADI. When assuming that during processing of potable water all BAM will be removed up to the legal value of 0.1 µg/L BAM, the additional intake for consumers by the intake of water is less than 0.1% of the ADI and filling the ADI for 1.2%.

The provisional NTMDI based on the Dutch TMDI model for children of 1 - 6 years accounts for 1.1% of the ADI and was determined on the basis of an ADI for BAM of 0.022 mg/kg bw/day or 0.38 mg/person/day (assumed body weight is 17.1 kg) and the proposed provisional MRL for grape. Taking an additional residue intake through drinking water into account, the TMDI accounts for 202% of the ADI. When assuming that during processing of potable water all BAM will be removed up to the legal value of 0.1 µg/L BAM, the additional intake for consumers by the intake of water is less than 0.1% of the ADI and filling the ADI for 1.1%.

If based on the provisional STMR of 0.085 mg/kg BAM and the highest processing factor 2.9, provisional NEDIs of 1.0% of the ADI for both the general population and children were calculated for the Dutch model taking into account only the provisional MRL for grape.

Based on the toxicological data available, an acute reference dose for 2,6-dichlorobenzamide (BAM) was set at 0.14 mg/kg bw/d. The national estimates of short-term intakes (NESTI) for the Dutch general population and children (1-6 y) was 3.9 and 7.2% of the ARfD, respectively. The national estimates of short-term intakes (IESTI) for the UK adults and toddlers was 2.8 and 9.7% of the ARfD, respectively.

Conclusion

Based on these calculations (although partly based on provisional data) and the information available, the use of Dichlobenil according to the intended uses for which a provisional MRL is proposed, is not considered to result in an unacceptable risk on adverse health effects due to long-term exposure to residues in food products. An unacceptable risk, however, cannot be excluded for young children due to the consumption of BAM containing drinking water.

2.4.3 Residues relevant to worker safety

See toxicology section.

2.4.4 Proposed EU MRLs and compliance with existing MRLs

The following provisional EU MRL is proposed:

MRL for grapes: 0.3 mg/kg 2,6-dichlorobenzamide (BAM) (provisional).

So far no EU-MRL is derived for this use of Dichlobenil in grapes.

2.4.5 Proposed EU import tolerances and compliance with existing MRLs

Not applicable, since no non-EU applications are proposed in the intended use pattern.

2.4.6 Basis for differences, if any, in conclusions reached having regard to established or proposed CAC MRLs

Not applicable, since no Codex MRLs have been established or proposed yet.

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

2.5 Fate and behaviour in the environment

2.5.1 Definition of the residues relevant to the environment

The residue definition for assessment is as follows:

Soil:	dichlobenil, 2,6-dichlorobenzamide
Surface water:	dichlobenil, 2,6-dichlorobenzamide (entry route through soil); 4-chloro-2(3H)benzoxazolone and 2-chlorobenzoic acid (these metabolites could not be assessed, ecotox data are required)
Groundwater:	dichlobenil, 2,6-dichlorobenzamide
Sediment:	dichlobenil, 2,6-dichlorobenzamide (entry route through soil)
Air:	dichlobenil

The residue definitions for monitoring (i.e. ecotoxicologically relevant metabolites according to SANCO/3268/2001) are as follows:

Soil:	dichlobenil
Surface water:	dichlobenil; 4-chloro-2(3H)benzoxazolone and 2-chlorobenzoic acid (these metabolites could not be assessed, ecotox data are required).
Groundwater:	dichlobenil
Sediment	-
Air:	dichlobenil

2.5.2 Fate and behaviour in soil

2.5.2.1 Degradation

The route of degradation study with one soil was not considered reliable. One reliable aerobic degradation study with three soils is available; it was carried out over a period of 273 days. Dichlobenil degraded under aerobic conditions with calculated DT₅₀ values of 38.9 d, 39.0 d and 43.6 d in clay loam, silt loam and loamy sand soil respectively (see Table 2.5.2.1a). 2,6-dichlorobenzamide (BAM) was identified as the major metabolite; the highest percentage formed was 69.41% a.r. (at the end of the study in the clay loam soil). Simple first order DT₅₀ and DT₉₀ values were calculated by RMS. These values are given in Table 2.5.2.1a.

Table 2.5.2.1a DT₅₀ values and DT₉₀ values for dichlobenil in three soils, calculated by RMS

Soil	clay loam	silt loam	loamy sand
DT ₅₀ (days)	38.9	39	43.6
DT ₉₀ (days)	129	130	145
r ²	0.968	0.975	0.821

A separate aerobic degradation study for 2,6-dichlorobenzamide with two soils showed that this metabolite did not degrade under aerobic conditions in the laboratory. DT₅₀ values were calculated in two ways (assuming simple first-order (SFO) or first-order multi-compartment (FOMC) kinetics). This resulted in DT₅₀ values (extrapolated) of 2666 and 795 days (SFO kinetics) and 3.1×10^{10} and 4.8×10^4 days (FOMC kinetics); see Table 2.5.2.1b. Metabolites were not identified.

Table 2.5.2.1b Extrapolated DT_{50} values for the metabolite 2,6-dichlorobenzamide in two soils, calculated by RMS with a SFO and FOMC model and converted to 20°C using the Arrhenius equation

Soil	Bethany soil		North Dakota soil	
Model	SFO	FOMC	SFO	FOMC
DT_{50} (days)	2666	$3.1 \cdot 10^{10}$	795	$4.8 \cdot 10^4$
r^2	0.761	0.936	0.872	0.996

Anaerobic degradation

An anaerobic degradation study is not available. Due to the intended use it is expected that dichlobenil will not be exposed to anaerobic conditions and therefore anaerobic degradation is not considered as relevant.

Photolysis in soil

A photodegradation study with one agricultural soil, sandy loam, was conducted. No photodegradation of dichlobenil (10.4 mg/kg) was observed upon simulated sunlight irradiation for 30 days and a DT_{50} value could not be derived. A large proportion of dichlobenil volatilised from the soil surface.

Field dissipation tests

Field dissipation studies were conducted in three fields in Germany with CASORON G (commercial granulate). The following dissipation DT_{50} and DT_{90} values for dichlobenil were obtained from the experiments:

- Germany: Goch-Nierswalde (sandy loam - loamy sand, summer application): $DT_{50} = 3.4$ d, $DT_{90} = 11.3$ d
- Eschwege (Meissner-Vockerode) (loam, summer application): $DT_{50} = 6.5$ d; $DT_{90} = 22$ d
- Nottuln (loamy sand, winter application): $DT_{50} = 72$ d, $DT_{90} = 238$ d.

The DT_{50} value to be used for PEC soil calculations is 72 days.

Because volatilisation of dichlobenil as one of the dissipation processes cannot be excluded, these data cannot be used as input for leaching model calculations. 2,6-dichlorobenzamide (BAM) was found as a metabolite. Maximum percentages were: Goch-Nierswalde: 9.6%; Eschwege (Meissner-Vockerode): 3.6%; Nottuln: 7.7%. The metabolite 2,6-dichlorobenzamide (BAM) was found in the 20 – 30 cm soil layer after 1 year. RMS could not calculate DT_{50} values for BAM from this study, because the sum of the BAM concentrations in the different soil layers was still increasing at the end of the experiment.

Field studies with BAM are available in the DAR of fluopicolide (RMS: UK). The notifier refers to these studies for the field degradation of BAM. RMS has evaluated the studies as described in the fluopicolide dossier. In deviation from the fluopicolide dossier, RMS considers that three of the six studies in the fluopicolide dossier are not useful for the derivation of a DT_{50} for modelling purposes for BAM, due to either a demonstrated leaching of BAM to deeper soil layers, or to the lack of sufficient data points to achieve a reliable DT_{50} calculation. Therefore, the $DT_{50\text{field}}$ value for BAM is based on the four remaining studies (all single first order degradation kinetics). The following degradation DT_{50} values for BAM were obtained and can be used in modeling:

- Southern Germany (Rödelsee): DT₅₀ = 315.2 days (standardised DT₅₀ (20 °C, field capacity) = 73.0 days)
- Northern Germany (Huntlosen): DT₅₀ = 257 days (standardised DT₅₀ (20 °C, field capacity) = 141.5 days)
- Southern France (Senas 1999): DT₅₀ = 267 days (standardised DT₅₀ (20 °C, field capacity) = 136.6 days)
- Northern France (Appilly, Picardie): DT₅₀ = 185.7 days (standardised DT₅₀ (20 °C, field capacity) = 173.3 days)
- Arithmetic mean = 256.3 days, Geometric mean (standardised values) = 125.0 days

The worst-case field value to be used for PECsoil calculations is 315.2 days.

The metabolic pathway of dichlobenil in soil is given in the figure below.

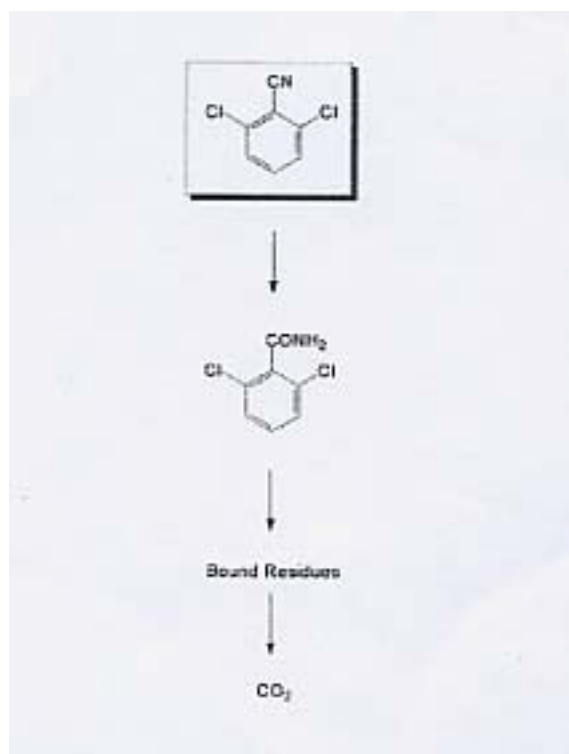


Figure 2.5.2.2 Metabolic pathway of dichlobenil in soil.

2.5.2.2 Adsorption

The adsorption of the parent compound dichlobenil can be classified as a compound with a medium to high mobility in soil, according to its K_{OC} value. In four different types of soils and a hydrosol, the adsorption constants K_d and K_{OC} varied between 0.3 – 10.5 L/kg and 133 – 323 L/kg, respectively, see Table 2.5.2.2a.

Table 2.5.2.2a Adsorption and desorption coefficients of ^{14}C -dichlobenil in five soils

Soil type	% organic carbon	adsorption in L/kg		desorption in L/kg			
		K_d	K_{OC}	K_d phase I	K_d phase II	K_{OC} phase I	K_{OC} phase II
sandy loam	4	10.5	262	12.9	16.4	323	410
silty loam	2.7	7.4	272	10.0	13.1	371	485
Clay	7.2	9.6	133	11.8	15.1	164	210
Sand	0.16	0.3	195	1.2	n.d.	750	-
hydrosoil (silty clay loam)	1.3	4.2	322	6.2	10.0	477	769

The adsorption of the metabolite 2,6-dichlorobenzamide was studied with five soils. The adsorption constants K_d and K_{OC} ranged from 0.208 – 1.890 L/kg and 26 – 51 L/kg, respectively (see Table 2.5.2.3b). 2,6-dichlorobenzamide can be classified as a compound with a high to very mobility in soil.

Table 2.5.2.2b Adsorption and desorption coefficients of [^{14}C]2,6-dichlorobenzamide in five soils

Soil type	% organic matter	adsorption in L/kg		desorption in L/kg	
		K_d	K_{OC}	K_d	K_{OC}
sandy loam RL-51 original data	0.9	0.241	26	4.652	494
without outliers		0.3588	39.9		
sandy loam RL-81	5.7	1.761	31	4.350	76
sand RM-014	1.4	0.529	38	2.577	184
sand RM-019	4.2	1.890	45	4.178	100
sandy clay loam	0.4	0.208	51	6.397	1560

2.5.2.3 Lysimeter studies

Dichlobenil was not mobile in lysimeters with application rates up to 7.1 kg/ha. Dichlobenil remained in the top 30 cm of the soil profile and was not found in the leachate ($< 0.047 \mu\text{g/L}$). Its metabolite 2,6-dichlorobenzamide (BAM) was mobile and was found in deeper soil layers as well as in all samples of leachate up to 2 years after application. The average concentration in the leachate of the 7.1 kg/ha lysimeter over the 2 years experimental period was $80 \mu\text{g/L}$. No other substances were identified in the leachate. Small amounts of very polar unidentified material consisting of several compounds were detected. The average concentrations were probably $< 0.4 \mu\text{g/L}$ (dichlobenil equivalents) per compound.

Dichlobenil was degraded in the lysimeter soil. After 2 years 3-6% of the applied radioactivity was present as dichlobenil in the soil profile. Four to 8% of the applied radioactivity was non-extractable residue. The formation of metabolite BAM (soil+ leachate) was about 8-15% after 2 years.

The unknown radioactive material detected in lysimeter eluates was further analysed. It was found that this material consisted of several compounds. Up to 5 different zones were detected on TLC plates. The pattern of the unknown zones varied with the lysimeter. The concentrations of the several zones found in the leachates of November 20, 1990 (one of the leachates that contained high amounts of unidentified material) are given in Table 2.5.2.3a. In view of the data presented it is not probable that the average concentration of any single compound will exceed an average of $0.4 \mu\text{g/L}$ (dichlobenil equivalents).

Table 2.5.2.3a Concentrations of the several zones of unidentified material found in the leachates of November 20, 1990.

	Concentration (µg/L, dichlobenil equivalents)		
	Lysimeter 1	Lysimeter 2	Lysimeter 3
Zone 1	0.76	not found	not found
Zone 2	0.03	1.93	1.21
Zone 3	0.20	1.64	0.82
Zone 4	0.50	0.33	not found
Zone 5	0.2	not found	not found

In another study, the mobility of ^{14}C -dichlobenil, aged in sandy loam soil for 31 d under aerobic conditions, was investigated. Aged [^{14}C]dichlobenil did not penetrate further than 15 cm in sandy loam. A small amount of the applied radioactivity (3%) appeared in the leachate. 2,6-dichlorobenzamide was the only metabolite found in the columns.

2.5.2.4 Predicted environmental concentrations in soil

Authorisation is requested for the broadcast spreading of granules of dichlobenil involving a single application at a rate of 2.03 – 5.4 kg a.s./ha in spring.

Actual PEC_s and time weighed average (TWA) PEC values were calculated under the following assumptions: it is assumed that the complete dosage of dichlobenil is released into the soil during pre-emergence treatment of vines and non-crop situations. There is no interception by crops. The PEC values were calculated assuming an even distribution to a depth of 5 cm in soil with a bulk density of 1.5 g/cm^3 . PEC values were based on a worst-case DT_{50} (field) value of 72 days.

One metabolite (> 10%), 2,6-dichlorobenzamide (BAM) was detected in soil. The maximum DT_{50} (field) value of 315.2 days was used for the PEC_{soil} calculation. It is assumed that the metabolite is formed at a maximum of 69.41% of the applied dose.

Under the above assumptions, application of dichlobenil will lead to the PEC_s values as given in Table 2.5.2.4a (parent compound, single application) and 2.5.2.4b (metabolite, single application).

Table 2.5.2.4a Actual and TWA PEC_s (mg/kg) of dichlobenil following application on vines and non-crops during pre-emergence in the field, at a maximum rate of 5.4 kg a.s./ha

Day after application	Broadcast spreading of granules in the field (5.4 kg a.s./ha)	
	Actual PEC_s (mg a.s./kg)	TWA PEC_s (mg a.s./kg)
0	7.200	-
1	7.131	7.165
2	7.063	7.131
4	6.928	7.063
7	6.731	6.963
14	6.292	6.736
21	5.882	6.519
28	5.499	6.311
50	4.449	5.715
100	2.749	4.623

Table 2.5.2.4b Actual and TWA PEC_s (mg/kg) of the soil metabolite 2,6-dichlorobenzamide following single application on vines and non-crops during pre-emergence in the field, at a maximum rate of 5.4 kg a.s./ha (this complies with 4.140 kg 2,6-dichlorobenzamide/ha¹)

Day after application	Broadcast spreading of granules in the field (5.4 kg a.s./ha)	
	Actual PEC _s (mg a.s./kg)	TWA PEC _s (mg a.s./kg)
0	5.520	
1	5.508	5.514
2	5.496	5.508
4	5.472	5.496
7	5.436	5.478
14	5.353	5.436
21	5.190	5.353
28	4.945	5.227
50	4.430	4.955
100	5.520	5.514

1 Calculated using: $\text{concentration}_{\text{metabolite}} = \text{application rate} \cdot \frac{\% \text{ formation}}{100\%} \cdot \frac{\text{molar mass}_{\text{metabolite}}}{\text{molar mass}_{\text{parent}}}$.

Since the maximum DT₅₀ of BAM is 315.2 days, the DT₉₀ is clearly larger than one year. Hence, a plateau concentration has to be calculated, according to:

PEC_{acc} = PEC_{soil, ini}/kⁱ, with i the interval between applications (365 days) and k equaling ln2/DT₅₀. This yields a plateau PEC of **6.88** mg/kg soil.

2.5.3 Fate and behaviour in water

2.5.3.1 Hydrolysis

Test results indicate that it is very likely that the parent compound is hydrolytically stable. However, this is only convincingly shown for environments with a pH of 6.8 to 8.3. As this is the environmentally relevant range, the results are considered relevant.

A hydrolysis experiment with the metabolite 2,6-dichlorobenzamide in sterile buffers at a temperature of 50°C at three pH levels showed that the metabolite was hydrolytically stable at pH 4, 7, and 9 for 5 d and at pH 5, 7, and 9 at 25°C for 30 d. Three unidentified degradation products, < 1.2% a.r. were observed.

2.5.3.2 Photolysis

The stability of dichlobenil in aqueous solution, when exposed to xenon light, was determined and compared with the stability under sunlight condition. Dichlobenil was stable in the dark controls. After 15 and 21 days of continuous irradiation, the dichlobenil concentration had decreased to 51.7 and 39.8% of the initial concentration, respectively. The results are summarised in Table 2.5.3.2. The DT₅₀ value of [¹⁴C]-dichlobenil was calculated to be 15.1 d; this corresponds to 10.2 d of natural sunlight.

Table 2.5.3.2 DT₅₀ values for [¹⁴C]-dichlobenil

exposure	DT ₅₀ value (d) at 25 °C
xenon light	15.1
natural sunlight 40° North ¹	10.2

¹ Calculated: 24 h irradiation with the xenon-light source equals 0.675 d of natural sunlight at 40° North latitude.

One of the degradation products found accounted for 14 and 17% of the applied radioactivity after 15 and 21 d, respectively. This compound was identified as 4-chloro-2(3H)benzoxazolone and is a major degradation product.

A photolysis study with 2,6-dichlorobenzamide showed that the metabolite was stable at pH 5 and 25°C for 31 d.

2.5.3.3 Ready Biodegradability

No degradation of dichlobenil was observed in a manometric respiration test. Therefore, dichlobenil is not considered to be readily biodegradable. The metabolite 2,6-dichlorobenzamide (BAM) was degraded for 9.2% after 28 d in a closed bottle test and is therefore considered to be not ready biodegradable as well.

2.5.3.4 Water/sediment studies

An aerobic water/sediment study with two sediment systems was performed. The sediment systems were collected from Goorven (a static pond near Oisterwijk, province Noord-Brabant, NL) and from Engelse Dijk (a static pond near 's-Hertogenbosch, province Noord-Brabant, NL). Dichlobenil degraded slowly with DT₅₀ (system) values of 307 and 66 days. The DT₅₀ and DT₉₀ values based on SFO kinetics for the water phase and the whole systems are summarised in Table 2.5.3.4.

Table 2.5.3.4 DT₅₀ values and DT₉₀ values for [¹⁴C]dichlobenil in water/sediment systems (calculated using a SFO kinetic model).

	Goorven		Engelse Dijk	
	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d)	DT ₉₀ (d)
Water	10.9	36.1	10.1	34
System	307 ¹	1020 ¹	66 ¹	218 ¹

¹ Corrected for volatilised dichlobenil

In the Goorven system, after 100 days, the metabolite 2,6-Dichlorobenzamide (BAM) represented the largest fraction, with a maximum of 4.46%, 1.73% and 6.19% in water, sediment and system, respectively. In the water phase of the Goorven system, a total of 5 radioactive fractions were found in addition to dichlobenil. All other individual metabolites were ≤ 0.61% at any time. In the sediment BAM was the only metabolite detected after 100 days.

In the Engelse Dijk system, after 100 days, 2,6-Dichlorobenzamide (BAM) represented the largest fraction, with a maximum of 5.32, 2.04 and 7.36% in water, sediment and system, respectively. An important unknown metabolite was identified by LC/MS as 2-chlorobenzoic acid and found in the water phase of Engelse Dijk system only, representing 9.13% and 7.91% a.r., at two subsequent sampling times after 59 and 100 days, respectively. All eight other metabolites were individually ≤ 10% a.r. at any time point or ≤ 5% a.r. at two consecutive time points. Also four minor unidentified fractions were detected in the sediment, individually not exceeding 10% a.r. at any time point and not exceeding 5% a.r. at two consecutive time points.

An anaerobic water/sediment study was performed as well. However, this study was not considered acceptable.

The overall fate and the metabolic pathway of dichlobenil in water/sediment systems is given in Figure 2.5.3.4a and b, respectively.

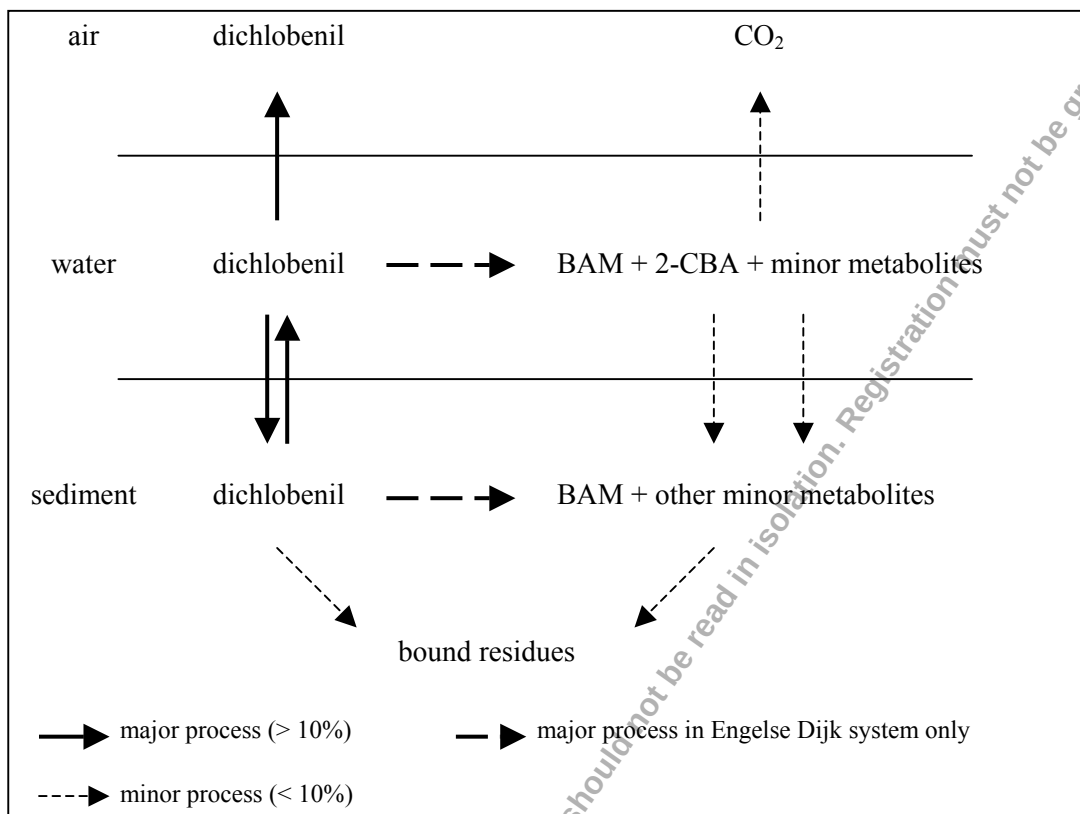


Figure 2.5.3.4a Overall fate of dichlobenil in water/sediment systems.

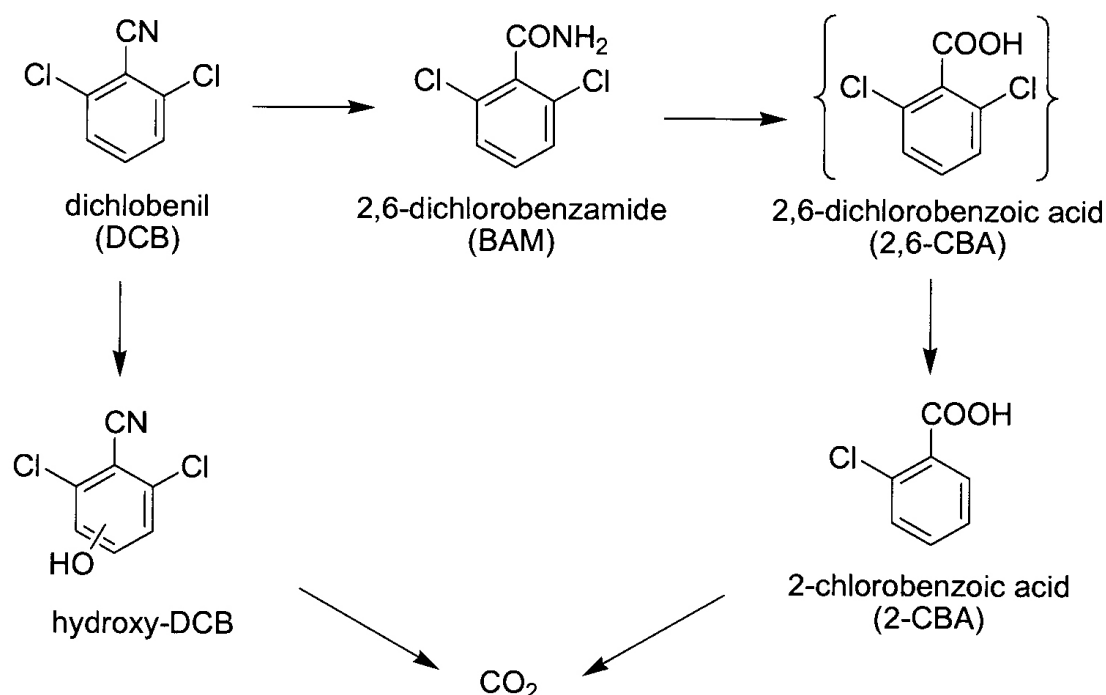


Figure 2.5.3.4b Metabolic pathway of dichlobenil in water/sediment systems.

2.5.3.5 Monitoring of surface water and groundwater

Surface water

There are no data available.

Groundwater

Dichlobenil concentrations in samples taken from 65 relevant wells were below the LOQ of 0.05 µg/L. The Dutch criterion for leaching of pesticides to groundwater (0.1 µg/L) is fulfilled.

2.5.3.6 Predicted environmental concentrations in surface water

Actual and TWA PEC_{SW}: dichlobenil and metabolites

According to the official guidance document of FOCUS Surface Water Scenarios in the context of 91/414/EEC predicted concentrations in surface water need to be calculated for broadcast spreading of granules in the field. Actual and TWA PEC_{SW} estimations for treatment of vines with dichlobenil and the use in non-crop situations were calculated with FOCUS Step 1, Step 2 and Step 3 approach. Only STEP 3 calculations are presented here, as the risk assessment is based on these PEC values. For full presentation of all calculations, refer to Volume 3.

For the scenarios D1, D3, D4, D5, and R1, characterised by non-crop applications, PEC_{SW} values were calculated by using spring oil seed rape as representative for non-crop applications. These are not available in FOCUS surface water scenarios and therefore, a crop with no irrigation and relatively little transpiration

was chosen as a substitute.

The input values for dichlobenil and 2,6-dichlorobenzamide used for the FOCUS Step 3 calculations are shown in the next table.

	dichlobenil	2,6-dichlorobenzamide
Molar mass (g/mol)	172	190
Water solubility (mg/L)	21.2	1830
Saturated vapour pressure (Pa)	0.14	0.00024
Formation from a.s. in soil (%)	-	69.41
Half-life in water (d)	186.5	n.d. (1000)*
Half-life in sediment (d)	1000	n.d.(1000)*
Half-life in soil (d)	40.5	125.0
K _{OM} suspended solids (L/kg)	137.47	24
Freundlich exponent (-)	0.90	0.90
K _{OM} sediment (L/kg)	137.47	24
Freundlich exponent (-)	0.90	0.90

* half-life of 2,6-dichlorobenzamide is not determined, therefore the maximum DT₅₀ value for FOCUS Step 3 is taken as input value (1000 days)

Under the above assumptions, application of dichlobenil leads to actual and TWA PEC_{SW} values of dichlobenil and the metabolite 2,6-dichlorobenzamide as listed in Tables 2.5.3.6a – 2.5.3.6zd. Tables 2.5.3.6a – 2.5.3.6l correspond with applications at vines and Tables 2.5.3.6m-2.5.3.6zd correspond with applications to non-crop (bare soil).

Table 2.5.3.6a Actual and TWA PEC_{SW} (µg/L) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario D6 (Thiva, ditches)

Days after application	Actual and TWA PEC _{SW} of dichlobenil (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	240.486	-
1	123.350	195.714
2	93.901	158.912
4	65.293	120.669
7	50.625	91.760
14	14.213	63.295
21	8.032	46.810
28	6.058	37.234
42	4.098	27.471
50	6.796	23.902
100	0.081	13.362

Table 2.5.3.6b Actual and TWA PEC_{SW} (µg/L) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario D6 (Thiva, ditches)

Days after application	Actual and TWA PEC _{SW} of 2,6-dichlorobenzamide (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	72.034	-
1	51.538	65.298
2	48.706	59.899
4	46.401	54.168
7	47.286	49.501
14	35.042	45.338
21	28.769	41.572
28	25.487	38.264
42	20.543	37.055
50	29.036	36.869
100	0.151	35.813

Table 2.5.3.6c Actual and TWA PEC_{SW} (µg/L) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario R1 (Germany, streams)

Days after application	Actual and TWA PEC _{SW} of dichlobenil (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	16.269	-
1	0.011	7.539
2	0.004	3.775
4	0.001	1.889
7	0.001	1.080
14	0.001	0.649
21	0.000	0.433
28	0.000	0.325
42	0.000	0.231
50	0.000	0.194
100	0.000	0.097

Table 2.5.3.6d Actual and TWA PEC_{SW} (µg/L) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario R1 (Germany, streams)

Days after application	Actual and TWA PEC _{SW} of 2,6-dichlorobenzamide (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	1.160	-
1	0.000	0.537
2	0.000	0.269
4	0.000	0.134
7	0.000	0.077
14	0.000	0.043
21	0.000	0.029
28	0.000	0.022
42	0.000	0.017
50	0.000	0.015
100	0.000	0.007

Table 2.5.3.6e Actual and TWA PEC_{SW} (µg/L) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario R1 (Germany, ponds)

Days after application	Actual and TWA PEC _{SW} of dichlobenil (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	0.098	-
1	0.093	0.095
2	0.089	0.093
4	0.082	0.089
7	0.073	0.084
14	0.078	0.082
21	0.057	0.077
28	0.041	0.070
42	0.029	0.059
50	0.019	0.053
100	0.002	0.030

Table 2.5.3.6f Actual and TWA PEC_{SW} (µg/L) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario R1 (Germany, ponds)

Days after application	Actual and TWA PEC _{SW} of 2,6-dichlorobenzamide (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	0.008	-
1	0.008	0.008
2	0.008	0.008
4	0.008	0.008
7	0.008	0.008
14	0.007	0.008
21	0.007	0.008
28	0.007	0.008
42	0.006	0.007
50	0.006	0.007
100	0.004	0.007

Table 2.5.3.6g Actual and TWA PEC_{SW} (µg/L) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario R2 (Portugal, streams)

Days after application	Actual and TWA PEC _{SW} of dichlobenil (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	10.557	-
1	0.007	5.890
2	0.003	2.950
4	0.001	1.476
7	0.000	0.844
14	0.000	0.422
21	0.000	0.281
28	0.001	0.352
42	0.000	0.235
50	0.000	0.197
100	0.000	0.102

Table 2.5.3.6h Actual and TWA PEC_{SW} (µg/L) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario R2 (Portugal, streams)

Days after application	Actual and TWA PEC _{SW} of 2,6-dichlorobenzamide (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	1.816	-
1	0.001	1.013
2	0.000	0.507
4	0.000	0.253
7	0.000	0.145
14	0.000	0.072
21	0.000	0.048
28	0.000	0.047
42	0.000	0.031
50	0.000	0.026
100	0.000	0.014

Table 2.5.3.6i Actual and TWA PEC_{SW} (µg/L) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario R3 (Italy, streams)

Days after application	Actual and TWA PEC _{SW} of dichlobenil (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	49.280	-
1	0.244	44.173
2	0.071	23.575
4	0.025	11.823
7	0.011	6.765
14	0.003	3.386
21	0.002	2.258
28	0.001	1.694
42	0.001	1.130
50	0.001	0.949
100	0.000	0.475

Table 2.5.3.6j Actual and TWA PEC_{SW} (µg/L) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario R3 (Italy, streams)

Days after application	Actual and TWA PEC _{SW} of 2,6-dichlorobenzamide (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	7.501	-
1	0.018	6.731
2	0.005	3.588
4	0.002	1.796
7	0.001	1.027
14	0.000	0.514
21	0.000	0.343
28	0.000	0.257
42	0.000	0.171
50	0.000	0.144
100	0.000	0.072

Table 2.5.3.6k Actual and TWA PEC_{SW} (µg/L) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario R4 (France, streams)

Days after application	Actual and TWA PEC _{SW} of dichlobenil (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	55.549	-
1	0.056	37.084
2	0.019	18.585
4	0.007	9.301
7	0.003	5.317
14	0.001	2.660
21	0.001	1.773
28	0.008	1.430
42	0.000	0.958
50	0.000	0.805
100	0.000	0.402

Table 2.5.3.6l Actual and TWA PEC_{SW} (µg/L) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario R4 (France, streams)

Days after application	Actual and TWA PEC _{SW} of 2,6-dichlorobenzamide (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	2.932	-
1	0.001	1.957
2	0.000	0.980
4	0.000	0.490
7	0.000	0.280
14	0.000	0.140
21	0.000	0.093
28	0.000	0.077
42	0.000	0.052
50	0.000	0.043
100	0.000	0.022

Spring oil seed rape as example for non-crop application

Table 2.5.3.6m Actual and TWA PEC_{SW} (µg/L) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario R1 (Germany, streams)

Days after application	Actual and TWA PEC _{SW} of dichlobenil (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	36.589	-
1	0.080	19.771
2	0.018	9.907
4	0.053	4.958
7	0.017	3.477
14	0.072	1.936
21	0.001	1.308
28	0.000	0.981
42	0.000	0.673
50	0.000	0.565
100	0.000	0.285

Table 2.5.3.6n Actual and TWA PEC_{SW} (µg/L) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario R1 (Germany, streams)

Days after application	Actual and TWA PEC _{SW} of 2,6-dichlorobenzamide (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	2.590	-
1	0.003	1.401
2	0.001	0.701
4	0.002	0.351
7	0.000	0.228
14	0.006	0.123
21	0.000	0.083
28	0.000	0.063
42	0.000	0.045
50	0.000	0.038
100	0.000	0.019

Table 2.5.3.6o Actual and TWA PEC_{SW} (µg/L) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario R1 (Germany, ponds)

Days after application	Actual and TWA PEC _{SW} of dichlobenil (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	1.592	-
1	1.518	1.554
2	1.456	1.521
4	1.351	1.463
7	1.343	1.409
14	1.252	1.373
21	0.909	1.275
28	0.665	1.153
42	0.406	0.950
50	0.268	0.852
100	0.025	0.477

Table 2.5.3.6p Actual and TWA PEC_{SW} (µg/L) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario R1 (Germany, ponds)

Days after application	Actual and TWA PEC _{SW} of 2,6-dichlorobenzamide (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	0.121	-
1	0.120	0.120
2	0.119	0.120
4	0.117	0.119
7	0.114	0.118
14	0.108	0.115
21	0.102	0.113
28	0.110	0.112
42	0.100	0.111
50	0.094	0.110
100	0.067	0.098

Table 2.5.3.6q Actual and TWA PEC_{SW} (µg/L) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D1 (Lanna, streams)

Days after application	Actual and TWA PEC _{SW} of dichlobenil (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	39.194	-
1	23.965	34.758
2	1.936	34.121
4	0.113	33.713
7	0.043	33.170
14	0.018	30.718
21	25.930	28.266
28	32.993	26.357
42	21.243	23.508
50	18.069	22.208
100	10.873	16.782

Table 2.5.3.6r Actual and TWA PEC_{SW} (µg/L) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D1 (Lanna, streams)

Days after application	Actual and TWA PEC _{SW} of 2,6-dichlorobenzamide (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	138.618	-
1	137.547	138.442
2	135.595	138.009
4	129.460	136.145
7	117.277	131.887
14	113.770	123.539
21	106.168	120.153
28	105.262	118.071
42	101.161	111.611
50	103.073	109.598
100	85.387	105.100

Table 2.5.3.6s Actual and TWA PEC_{SW} (µg/L) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D1 (Lanna, ditch)

Days after application	Actual and TWA PEC _{SW} of dichlobenil (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	53.565	-
1	52.830	53.437
2	52.437	53.135
4	51.985	52.829
7	46.800	51.773
14	37.165	47.432
21	30.850	44.357
28	27.392	41.633
42	23.225	37.221
50	20.543	35.188
100	11.181	26.543

Table 2.5.3.6t Actual and TWA PEC_{SW} (µg/L) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D1 (Lanna, ditch)

Days after application	Actual and TWA PEC _{SW} of 2,6-dichlorobenzamide (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	138.618	-
1	137.547	138.442
2	135.595	138.009
4	129.460	136.145
7	117.277	131.887
14	113.770	123.539
21	106.168	120.153
28	105.262	118.071
42	101.161	111.611
50	103.073	109.598
100	85.387	105.100

Table 2.5.3.6u Actual and TWA PEC_{SW} (µg/L) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D3 (Vredepeel, ditch)

Days after application	Actual and TWA PEC _{SW} of dichlobenil (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	0.001	-
1	0.001	0.001
2	0.001	0.001
4	0.001	0.001
7	0.001	0.001
14	0.001	0.001
21	0.001	0.001
28	0.001	0.001
42	0.001	0.001
50	0.001	0.001
100	n.c.	0.001

n.c. = not calculable

Table 2.5.3.6v Actual and TWA PEC_{SW} (µg/L) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D3 (Vredepeel, ditch)

Days after application	Actual and TWA PEC _{SW} of 2,6-dichlorobenzamide (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	89.744	-
1	89.624	89.671
2	89.656	89.669
4	89.665	89.660
7	89.616	89.645
14	89.377	89.605
21	88.915	89.538
28	88.737	89.485
42	88.391	89.409
50	88.274	89.367
100	85.205	89.035

Table 2.5.3.6w Actual and TWA PEC_{SW} (µg/L) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D4 (Skousbo, stream)

Days after application	Actual and TWA PEC _{SW} of dichlobenil (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	6.051	-
1	4.432	5.290
2	5.591	5.067
4	4.268	4.921
7	3.599	4.746
14	2.379	4.063
21	1.270	3.415
28	0.657	2.863
42	0.300	2.075
50	0.811	1.823
100	0.082	1.049

Table 2.5.3.6x Actual and TWA PEC_{SW} (µg/L) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D4 (Skousbo, stream)

Days after application	Actual and TWA PEC _{SW} of 2,6-dichlorobenzamide (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	93.717	-
1	90.683	92.234
2	91.905	91.582
4	86.462	91.190
7	83.019	90.732
14	75.299	89.240
21	63.976	87.451
28	64.607	84.598
42	79.140	77.678
50	65.925	77.688
100	38.912	66.761

Table 2.5.3.6y Actual and TWA PEC_{SW} (µg/L) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D4 (Skousbo, pond)

Days after application	Actual and TWA PEC _{SW} of dichlobenil (µg/L)	
	Actual PEC _{SW}	TWA PEC _{SW}
0	185.381	-
1	185.346	185.378
2	185.242	185.369
4	184.850	185.333
7	183.856	185.225
14	180.769	184.712
21	177.261	183.883
28	173.525	182.830
42	165.917	180.300
50	161.661	178.699
100	n.c.	171.136

n.c. = not calculable

Table 2.5.3.6z Actual and TWA PEC_{SW} ($\mu\text{g/L}$) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D4 (Skousbo, pond)

Days after application	Actual and TWA PEC_{SW} of 2,6-dichlorobenzamide ($\mu\text{g/L}$)	
	Actual PEC_{SW}	TWA PEC_{SW}
0	185.381	-
1	185.346	185.378
2	185.242	185.369
4	184.850	185.333
7	183.856	185.225
14	180.769	184.712
21	177.261	183.883
28	173.525	182.830
42	165.917	180.300
50	161.661	178.699
100	n.c.	171.136

n.c. = not calculable

Table 2.5.3.6za Actual and TWA PEC_{SW} ($\mu\text{g/L}$) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D5 (France, streams)

Days after application	Actual and TWA PEC_{SW} of dichlobenil ($\mu\text{g/L}$)	
	Actual PEC_{SW}	TWA PEC_{SW}
0	1.180	-
1	0.661	0.880
2	0.771	0.871
4	0.841	0.834
7	0.888	0.814
14	0.373	0.759
21	0.264	0.735
28	0.221	0.724
42	0.259	0.710
50	0.230	0.695
100	n.c.	0.636

n.c. = not calculable

Table 2.5.3.6zb Actual and TWA PEC_{SW} ($\mu\text{g/L}$) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D5 (France, streams)

Days after application	Actual and TWA PEC_{SW} of 2,6-dichlorobenzamide ($\mu\text{g/L}$)	
	Actual PEC_{SW}	TWA PEC_{SW}
0	47.618	-
1	46.961	45.759
2	44.363	45.580
4	39.841	45.026
7	34.979	43.851
14	30.714	41.478
21	27.957	39.014
28	25.869	37.318
42	33.678	36.485
50	34.467	35.869
100	n.c.	34.110

n.c. = not calculable

Table 2.5.3.6zc Actual and TWA PEC_{SW} ($\mu\text{g/L}$) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D5 (France, ponds)

Days after application	Actual and TWA PEC_{SW} of dichlobenil ($\mu\text{g/L}$)	
	Actual PEC_{SW}	TWA PEC_{SW}
0	1.237	-
1	1.230	1.236
2	1.216	1.234
4	1.178	1.226
7	1.116	1.209
14	0.978	1.157
21	0.845	1.101
28	0.733	1.094
42	0.611	1.058
50	0.545	1.029
100	n.c.	0.847

n.c. = not calculable

Table 2.5.3.6zd Actual and TWA PEC_{SW} ($\mu\text{g/L}$) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D5 (France, ponds)

Days after application	Actual and TWA PEC_{SW} of 2,6-dichlorobenzamide ($\mu\text{g/L}$)	
	Actual PEC_{SW}	TWA PEC_{SW}
0	114.400	-
1	114.379	114.398
2	114.326	114.392
4	114.118	114.368
7	113.652	114.295
14	112.134	114.007
21	110.267	113.747
28	n.c.	113.362
42	n.c.	112.316
50	n.c.	111.700
100	n.c.	102.139

n.c. = not calculable

Total maximum PEC_{SW} for 2,6-dichlorobenzamide in each scenario

The *in situ* formation of BAM in the water-sediment is small compared to the amount of BAM entering the system via the soil (drainage/runoff), as the maximum percentage of *in situ* formed BAM is 5.32 % and 2.04 in water and sediment (both at day 100/end of study), respectively.

The FOCUS surface water report¹ (page 134) provides the following guidance on the need to model metabolites formed in a water-sediment study: the maximum formation mass should be compared to the monthly averaged hydraulic residence time of the FOCUS surface water bodies (τ). The monthly averaged residence time is approximately 0.1, 5 and 150 d for a stream, ditch and pond, respectively. It is then considered that if the time needed for maximum formation is larger than the residence time, the formation of metabolites in the FOCUS surface water body is negligible, (nearly all substance has flowed out before a considerable metabolite mass has been formed).

As the formation percentage at day 100 still can be considered minor, and the maximum residence time of 150 days (pond) is in the same order of magnitude, it is considered unnecessary to take the *in situ* formation

¹ FOCUS (2001). "FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC". Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp.

of BAM into account. Moreover, the amount of soil derived BAM is more than ten times higher than the *in situ* formed amount. Therefore RMS considers that additional PEC calculations for the *in situ* formation of BAM can be considered superfluous.

Actual PEC_{SW} for the major metabolites 2-chlorobenzoic acid and 4-chloro-2(3H)benzoxazolone formed by degradation of dichlobenil in surface water

These metabolites can be formed by transformation of dichlobenil in the surface water. For the metabolites 2-chlorobenzoic acid and 4-chloro-2(3H)benzoxazolone (*photolysis metabolite*) only the maximum percentage of formation is known and no other parameters. The PEC_{SW} of these metabolites are calculated on basis of the maximum PEC_{SW} of the parent and the corresponding percentage of formation: 9.13% and 17% respectively.

For metabolite 2,6-dichlorobenzamide a maximum formation of 5.32% is used to calculate a PEC_{SW}. The total PEC_{SW} of 2,6-dichlorobenzamide consists of the contribution of the formation from dichlobenil in the surface water and the metabolite formed by degradation of dichlobenil in the soil and subsequently entering the surface water. Comparison of the PEC_{SW} values of 2,6-dichlorobenzamide in Table 2.5.3.7zk with those of the preceding tables of this section reveals that for the majority of the scenarios the contribution of the emission route via soil is much higher.

Table 2.5.3.6ze Actual PEC_{SW} (µg/L) of the metabolites 2-chlorobenzoic acid and 4-chloro-2(3H)benzoxazolone following application at maximum dose (5400 g a.s./ha) of dichlobenil to vines and spring oil seed rape in the field according to FOCUS step 3

Crop	Scenario	Maximum PEC _{SW} (µg/L)	
		2-chlorobenzoic acid	4-chloro-(3H)benzoxazolone
Vines	D6 ditch	21.917	40.809
	R1 stream	1.475	2.747
	R1 pond	0.009	0.016
	R2 stream	0.957	1.782
	R3 stream	4.479	8.339
	R4 stream	5.051	9.405
Non-crop (oil seed rape)	D1 stream	3.568	6.644
	D1 ditch	4.775	8.891
	D3 ditch	0.000	0.000
	D4 stream	0.552	1.028
	D4 pond	0.292	0.543
	D5 stream	0.108	0.201
	D5 pond	0.092	0.172
	R1 stream	3.338	6.216
	R1 pond	0.144	0.268

2.5.3.7 Predicted environmental concentrations in groundwater

Annual applications were simulated for a period of 20 years with a six-year "warm-up period", using FOCUS PEARL version 3.3.3. Simulations were performed for vines and non-crop (fallow soil) situations in the North and South of Europe.

The maximum dose of 5.4 kg a.s./ha was not corrected for the interception by the crop (0% for treatment with granules) and the fraction of the dose on soil was assumed to be 1 (100%). Application was set to a yearly dosage. Since the application date was not specified, the date of application was chosen to be 25th May for both North Europe and South Europe. The average lab DT_{50} value (40.5 days), average K_{OM} value (137.5 L/kg) and a default $1/n$ value (0.9) were used for modelling. Sorption was assumed to be pH-independent. One metabolite > 10%, 2,6-dichlorobenzamide, was detected in soil. It is assumed that the metabolite is formed at a maximum of 69.41% of the applied dose. An average DT_{50} (field) value of 125.0 days was determined for the metabolite 2,6-dichlorobenzamide assuming SFO kinetics. The average K_{OC} value for this metabolite amounts to 41 L/kg corresponding with an average K_{OM} value of 24 L/kg. Physico-chemical parameters of dichlobenil and BAM are shown in Table B.8.5.2a. Physico-chemical parameters are shown in Table 2.5.3.8a.

Table 2.5.3.7a Physico-chemical parameters of dichlobenil and BAM used for modelling

Substance	Parameter	Value	Unit
Dichlobenil	molecular mass	172	g/mol
	vapour pressure	0.135	Pa (25°C)
	water solubility	21.2	mg/L (pH 7, 25°C)
2,6-dichlorobenzamide (BAM)	molecular mass	190	g/mol
	vapour pressure	2 E-05	Pa (25°C)
	water solubility	1830	mg/L (pH 7, 25°C)

All other substance parameters in PEARL were set at the default values recommended by the FOCUS working group. The results of the modelling are shown in Table 2.5.3.7b and c.

Table 2.5.3.7b FOCUS-PEARL estimations of concentrations in groundwater (80th percentile, µg/L) of dichlobenil and the metabolite 2,6-dichlorobenzamide after single application to vines

FOCUS scenario	80th percentile concentration in groundwater (µg/L) of dichlobenil	80th percentile concentration in groundwater (µg/L) of 2,6-dichlorobenzamide
Location	Single application (May)	Single application (May)
Chateaudun	0.288	340.961
Hamburg	0.191	380.348
Kremsmünster	0.107	302.933
Piacenza	2.693	290.500
Porto	< 0.001	84.149
Sevilla	0.180	278.559
Thiva	0.3174	262.178

Table 2.5.3.7c FOCUS-PEARL estimations of concentrations in groundwater (80th percentile, µg/L) of dichlobenil and the metabolite 2,6-dichlorobenzamide after single application on bare soil

FOCUS scenario	80th percentile concentration in groundwater (µg/L) of dichlobenil	80th percentile concentration in groundwater (µg/L) of 2,6-dichlorobenzamide
Location	Single application (May)	Single application (May)
Chateaudun	< 0.001	284.050
Hamburg	0.061	364.929
Jokioinen	< 0.0012	324.477
Kremsmünster	0.033	293.002
Okehampton	0.0742	287.690
Piacenza	0.327	284.115
Porto	< 0.001	80.079
Sevilla	< 0.001	180.728
Thiva	< 0.001	284.050

For crop type vines estimated 80th percentile dichlobenil concentrations in groundwater were < 0.1 µg/L for the scenario Porto, but ≥ 0.1 µg/L for the scenarios Chateaudun, Hamburg, Kremsmünster, Piacenza, Sevilla and Thiva. For the metabolite 2,6-dichlorobenzamide concentrations ≥ 0.1 µg/L were found in all relevant scenarios.

In case of application on bare soil (non-crop) dichlobenil concentrations in groundwater were < 0.1 µg/L for 8 of the 9 scenarios. For scenario Piacenza ≥ 0.1 µg/L for dichlobenil was found. For the metabolite 2,6-dichlorobenzamide concentrations ≥ 0.1 µg/L were found in all 9 scenarios.

It can be concluded that a safe use with regard to the leaching potential has been demonstrated for dichlobenil in some scenarios. A potential for leaching is demonstrated for 2,6-dichlorobenzamide in all scenarios.

See for the assessment of non-relevance Volume 1, appendix 4.

2.5.3.8 Predicted environmental concentrations in sediment (PEC_{SED})

Water/sediment studies were conducted in two water/sediment systems. The average DT₅₀ for the whole water/sediment system was 186.5 days and 10.5 days for water (dissipation half-life). As no DegT₅₀ was derived for the water phase, the average system value was used for the PEC values in surface water. For sediment a DT₅₀ value of 1000 d was used for the PEC_{SED} calculations. Dichlobenil is found to be hydrolytically stable.

The PEC_{SED} values are calculated by use of the FOCUS Step 1, Step 2 and Step 3 approach (FOCUS, 2001). The values for degradation in water (186.5 days, mean system value) and sediment (1000 days, default) were used for modelling. The PEC_{SED} values are listed in the Tables 8.5.1 and 8.5.2.a-d. No major metabolites (> 10%, > 5% at two consecutive time points, or increasing towards the end of the study) were detected in sediment. Although the *in situ* formation of 2,6-dichlorobenzamide (BAM) in sediment is negligible, input via soil is considered relevant. Therefore, PEC_{SED} values are also determined for BAM. Only STEP 3 calculations are presented here. For full presentation of all calculations, refer to Volume 3.

The results of the Step 3 calculations are listed in the Tables 2.5.3.8a-zd. Tables 2.5.3.a – 2.5.3.8l correspond with applications at vines and Tables 2.5.3.8m – 2.5.3.8zd correspond with applications to non-crop (bare soil).

Table 2.5.3.8a Actual and TWA PEC_{SED} ($\mu\text{g/kg}$) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario D6 (Thiva, ditches)

Days after application	Actual and TWA PEC_{SED} of dichlobenil ($\mu\text{g/kg}$)	
	Actual PEC_{SED}	TWA PEC_{SED}
0	97.806	-
1	96.380	97.381
2	96.359	96.644
4	88.465	95.783
7	87.882	92.898
14	70.796	87.726
21	61.026	81.243
28	54.911	75.809
42	47.784	67.923
50	47.416	64.598
100	30.698	51.928

Table 2.5.3.98b Actual and TWA PEC_{SED} ($\mu\text{g/kg}$) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario D6 (Thiva, ditches)

Days after application	Actual and TWA PEC_{SED} of 2,6-dichlorobenzamide ($\mu\text{g/kg}$)	
	Actual PEC_{SED}	TWA PEC_{SED}
0	68.868	-
1	68.835	68.864
2	68.801	68.855
4	68.838	68.833
7	67.982	68.818
14	61.011	68.459
21	52.693	68.010
28	n.c.	67.296
42	n.c.	65.912
50	n.c.	65.132
100	n.c.	58.610

n.c. Not calculable.

Table 2.5.3.8c Actual and TWA PEC_{SED} ($\mu\text{g/kg}$) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario R1 (Germany, streams)

Days after application	Actual and TWA PEC_{SED} of dichlobenil ($\mu\text{g/kg}$)	
	Actual PEC_{SED}	TWA PEC_{SED}
0	3.908	-
1	1.794	2.901
2	1.306	2.291
4	0.950	1.728
7	0.732	1.354
14	0.729	1.095
21	0.561	0.944
28	0.480	0.838
42	0.441	0.727
50	0.394	0.678
100	0.267	0.499

Table 2.5.3.8d Actual and TWA PEC_{SED} ($\mu\text{g/kg}$) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario R1 (Germany, streams)

Days after application	Actual and TWA PEC_{SED} of 2,6-dichlorobenzamide ($\mu\text{g/kg}$)	
	Actual PEC_{SED}	TWA PEC_{SED}
0	0.160	-
1	0.060	0.108
2	0.044	0.083
4	0.033	0.062
7	0.026	0.048
14	0.023	0.037
21	0.018	0.032
28	0.015	0.028
42	0.018	0.026
50	0.015	0.024
100	0.010	0.018

Table 2.5.3.8e Actual and TWA PEC_{SED} ($\mu\text{g/kg}$) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario R1 (Germany, ponds)

Days after application	Actual and TWA PEC_{SED} of dichlobenil ($\mu\text{g/kg}$)	
	Actual PEC_{SED}	TWA PEC_{SED}
0	0.190	-
1	0.190	0.190
2	0.190	0.190
4	0.189	0.190
7	0.186	0.189
14	0.189	0.188
21	0.182	0.188
28	0.171	0.188
42	0.149	0.183
50	0.138	0.180
100	0.096	0.154

Table 2.5.3.8f Actual and TWA PEC_{SED} (µg/kg) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario R1 (Germany, ponds)

Days after application	Actual and TWA PEC _{SED} of 2,6-dichlorobenzamide (µg/kg)	
	Actual PEC _{SED}	TWA PEC _{SED}
0.017	-	0.017
0.017	0.017	0.017
0.017	0.017	0.017
0.017	0.017	0.017
0.017	0.017	0.017
0.017	0.017	0.017
0.017	0.017	0.017
0.017	0.017	0.017
0.017	0.017	0.017
0.016	0.017	0.016
0.015	0.017	0.015

Table 2.5.3.8g Actual and TWA PEC_{SED} (µg/kg) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario R2 (Portugal, streams)

Days after application	Actual and TWA PEC _{SED} of dichlobenil (µg/kg)	
	Actual PEC _{SED}	TWA PEC _{SED}
0	2.980	-
1	1.40	2.252
2	1.026	1.796
4	0.749	1.362
7	0.579	1.070
14	0.421	0.817
21	0.350	0.714
28	0.893	0.681
42	0.506	0.668
50	0.443	0.638
100	0.316	0.499

Table 2.5.3.8h Actual and TWA PEC_{SED} (µg/kg) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario R2 (Portugal, streams)

Days after application	Actual and TWA PEC _{SED} of 2,6-dichlorobenzamide (µg/kg)	
	Actual PEC _{SED}	TWA PEC _{SED}
0	0.279	-
1	0.107	0.195
2	0.081	0.151
4	0.060	0.112
7	0.047	0.088
14	0.034	0.064
21	0.028	0.053
28	0.045	0.050
42	0.029	0.045
50	0.026	0.042
100	0.021	0.032

Table 2.5.3.8i Actual and TWA PEC_{SED} (µg/kg) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario R3 (Italy, streams)

Days after application	Actual and TWA PEC _{SED} of dichlobenil (µg/kg)	
	Actual PEC _{SED}	TWA PEC _{SED}
0	17.127	-
1	9.509	14.932
2	7.161	12.453
4	5.313	9.672
7	4.138	7.667
14	3.035	5.652
21	2.524	4.708
28	2.208	4.130
42	1.818	3.426
50	1.668	3.159
100	1.173	2.275

Table 2.5.3.8j Actual and TWA PEC_{SED} (µg/kg) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario R3 (Italy, streams)

Days after application	Actual and TWA PEC _{SED} of 2,6-dichlorobenzamide (µg/kg)	
	Actual PEC _{SED}	TWA PEC _{SED}
0	1.328	-
1	0.677	1.141
2	0.515	0.936
4	0.386	0.718
7	0.301	0.566
14	0.219	0.415
21	0.181	0.344
28	0.158	0.301
42	0.129	0.249
50	0.118	0.229
100	0.076	0.162

Table 2.5.3.8k Actual and TWA PEC_{SED} (µg/kg) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario R4 (France, streams)

Days after application	Actual and TWA PEC _{SED} of dichlobenil (µg/kg)	
	Actual PEC _{SED}	TWA PEC _{SED}
0	16.238	-
1	7.737	12.797
2	5.776	10.272
4	4.258	7.817
7	3.304	6.146
14	2.418	4.507
21	2.012	3.749
28	2.533	3.317
42	1.647	2.862
50	1.492	2.656
100	1.031	1.942

Table 2.5.3.8l Actual and TWA PEC_{SED} ($\mu\text{g/kg}$) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to vines in the field according to FOCUS step 3, scenario R4 (France, streams)

Days after application	Actual and TWA PEC_{SED} of 2,6-dichlorobenzamide ($\mu\text{g/kg}$)	
	Actual PEC_{SED}	TWA PEC_{SED}
0	0.473	-
1	0.200	0.357
2	0.151	0.280
4	0.112	0.211
7	0.088	0.165
14	0.064	0.120
21	0.053	0.100
28	0.071	0.088
42	0.045	0.077
50	0.040	0.071
100	0.026	0.052

Spring oil seed rape as example for non-crop application (bare soil)

Table 2.5.3.8m Actual and TWA PEC_{SED} ($\mu\text{g/kg}$) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario R1 (Germany, streams)

Days after application	Actual and TWA PEC_{SED} of dichlobenil ($\mu\text{g/kg}$)	
	Actual PEC_{SED}	TWA PEC_{SED}
0	9.142	-
1	4.373	7.181
2	3.225	5.708
4	2.586	4.322
7	2.810	3.666
14	2.230	3.096
21	1.625	2.692
28	1.387	2.397
42	1.186	2.045
50	1.070	1.899
100	0.743	1.393

Table 2.5.3.8n Actual and TWA PEC_{SED} ($\mu\text{g/kg}$) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario R1 (Germany, streams)

Days after application	Actual and TWA PEC_{SED} of 2,6-dichlorobenzamide ($\mu\text{g/kg}$)	
	Actual PEC_{SED}	TWA PEC_{SED}
0	0.357	-
1	0.151	0.266
2	0.112	0.206
4	0.089	0.154
7	0.084	0.126
14	0.071	0.101
21	0.050	0.087
28	0.043	0.077
42	0.041	0.067
50	0.036	0.062
100	0.024	0.046

Table 2.5.3.8o Actual and TWA PEC_{SED} ($\mu\text{g/kg}$) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario R1 (Germany, ponds)

Days after application	Actual and TWA PEC_{SED} of dichlobenil ($\mu\text{g/kg}$)	
	Actual PEC_{SED}	TWA PEC_{SED}
0	2.706	-
1	2.705	2.706
2	2.701	2.706
4	2.687	2.704
7	2.653	2.700
14	2.606	2.683
21	2.483	2.665
28	2.323	2.640
42	2.018	2.562
50	1.871	2.504
100	1.316	2.128

Table 2.5.3.8p Actual and TWA PEC_{SED} ($\mu\text{g/kg}$) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario R1 (Germany, ponds)

Days after application	Actual and TWA PEC_{SED} of 2,6-dichlorobenzamide ($\mu\text{g/kg}$)	
	Actual PEC_{SED}	TWA PEC_{SED}
0	0.215	-
1	0.215	0.215
2	0.215	0.215
4	0.214	0.215
7	0.214	0.215
14	0.213	0.215
21	0.211	0.215
28	0.209	0.214
42	0.205	0.214
50	0.202	0.214
100	0.179	0.210

Table 2.5.3.8q Actual and TWA PEC_{SED} ($\mu\text{g/kg}$) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D1 (Lanna, streams)

Days after application	Actual and TWA PEC_{SED} of dichlobenil ($\mu\text{g/kg}$)	
	Actual PEC_{SED}	TWA PEC_{SED}
0	87.808	-
1	n.c.	87.728
2	n.c.	87.697
4	n.c.	87.671
7	n.c.	87.614
14	n.c.	87.252
21	n.c.	86.939
28	n.c.	86.668
42	n.c.	85.812
50	n.c.	85.138

n.c. Not calculable.

Table 2.5.3.8r Actual and TWA PEC_{SED} (µg/kg) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D1 (Lanna, streams)

Days after application	Actual and TWA PEC _{SED} of 2,6-dichlorobenzamide (µg/kg)	
	Actual PEC _{SED}	TWA PEC _{SED}
0	361.788	-
1	n.c.	361.236
2	n.c.	360.811
4	n.c.	360.131
7	n.c.	359.121
14	n.c.	357.118
21	n.c.	354.802
28	n.c.	352.145
42	n.c.	346.417
50	n.c.	342.983
100	n.c.	326.636

n.c. Not calculable.

Table 2.5.3.8s Actual and TWA PEC_{SED} (µg/kg) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D1 (Lanna, ditch)

Days after application	Actual and TWA PEC _{SED} of dichlobenil (µg/kg)	
	Actual PEC _{SED}	TWA PEC _{SED}
0	137.564	-
1	n.c.	137.474
2	n.c.	137.470
4	n.c.	137.466
7	n.c.	137.419
14	n.c.	136.859
21	n.c.	136.429
28	n.c.	136.092
42	n.c.	134.923
50	n.c.	134.000
100	n.c.	131.806

Table 2.5.3.8t Actual and TWA PEC_{SED} (µg/kg) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D1 (Lanna, ditch)

Days after application	Actual and TWA PEC _{SED} of 2,6-dichlorobenzamide (µg/kg)	
	Actual PEC _{SED}	TWA PEC _{SED}
0	212.779	-
1	n.c.	212.629
2	n.c.	212.513
4	n.c.	212.300
7	n.c.	211.998
14	n.c.	211.780
21	n.c.	211.252
28	n.c.	210.458
42	n.c.	208.944
50	n.c.	208.180
100	n.c.	202.644

n.c. Not calculable.

Table 2.5.3.8u Actual and TWA PEC_{SED} (µg/kg) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D3 (Vredepeel, ditch)

Days after application	Actual and TWA PEC _{SED} of dichlobenil (µg/kg)	
	Actual PEC _{SED}	TWA PEC _{SED}
0	0.009	-
1	n.c.	0.009
2	n.c.	0.009
4	n.c.	0.009
7	n.c.	0.009
14	n.c.	0.009
21	n.c.	0.009
28	n.c.	0.009
42	n.c.	0.009
50	n.c.	0.009
100	n.c.	0.008

n.c. Not calculable.

Table 2.5.3.8v Actual and TWA PEC_{SED} (µg/kg) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D3 (Vredepeel, ditch)

Days after application	Actual and TWA PEC _{SED} of 2,6-dichlorobenzamide (µg/kg)	
	Actual PEC _{SED}	TWA PEC _{SED}
0	632.135	-
1	n.c.	632.000
2	n.c.	631.865
4	n.c.	631.596
7	n.c.	631.196
14	n.c.	630.289
21	n.c.	629.474
28	n.c.	628.803
42	n.c.	627.153
50	n.c.	625.641
100	n.c.	612.128

n.c. Not calculable.

Table 2.5.3.8w Actual and TWA PEC_{SED} (µg/kg) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D4 (Skousbo, stream)

Days after application	Actual and TWA PEC _{SED} of dichlobenil (µg/kg)	
	Actual PEC _{SED}	TWA PEC _{SED}
0	7.065	-
1	7.011	7.060
2	6.941	7.052
4	6.767	7.042
7	6.533	7.036
14	5.826	6.939
21	5.219	6.778
28	4.810	6.566
42	4.987	6.099
50	4.634	5.921
100	3.399	5.107

Table 2.5.3.8x Actual and TWA PEC_{SED} (µg/kg) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D4 (Skousbo, stream)

Days after application	Actual and TWA PEC _{SED} of 2,6-dichlorobenzamide (µg/kg)	
	Actual PEC _{SED}	TWA PEC _{SED}
0	133.650	-
1	133.618	133.648
2	133.524	133.644
4	133.157	133.628
7	132.050	133.552
14	129.629	133.123
21	127.043	132.410
28	124.226	131.595
42	119.034	129.704
50	116.393	128.520
100	n.c.	123.693

n.c. Not calculable.

Table 2.5.3.8y Actual and TWA PEC_{SED} (µg/kg) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D4 (Skousbo, pond)

Days after application	Actual and TWA PEC _{SED} of dichlobenil (µg/kg)	
	Actual PEC _{SED}	TWA PEC _{SED}
0	11.270	-
1	11.270	11.270
2	11.267	11.270
4	11.256	11.269
7	11.229	11.266
14	11.125	11.255
21	10.981	11.235
28	10.809	11.208
42	10.419	11.138
50	10.182	11.094
100	n.c.	10.697

Table 2.5.3.8z Actual and TWA PEC_{SED} (µg/kg) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D4 (Skousbo, pond)

Days after application	Actual and TWA PEC _{SED} of 2,6-dichlorobenzamide (µg/kg)	
	Actual PEC _{SED}	TWA PEC _{SED}
0	349.769	-
1	349.764	349.768
2	349.751	349.767
4	349.698	349.763
7	349.594	349.751
14	n.c.	349.699
21	n.c.	349.634
28	n.c.	349.449
42	n.c.	348.702
50	n.c.	347.973
100	n.c.	333.413

n.c. Not calculable.

Table 2.5.3.8za Actual and TWA PEC_{SED} ($\mu\text{g/kg}$) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D5 (France, streams)

Days after application	Actual and TWA PEC_{SED} of dichlobenil ($\mu\text{g/kg}$)	
	Actual PEC_{SED}	TWA PEC_{SED}
0	3.109	-
1	3.109	3.109
2	3.107	3.109
4	3.101	3.108
7	3.092	3.106
14	3.103	3.100
21	3.079	3.100
28	2.921	3.097
42	2.428	3.086
50	2.265	3.076
100	1.723	2.931

Table 2.5.3.8zb Actual and TWA PEC_{SED} ($\mu\text{g/kg}$) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D5 (France, streams)

Days after application	Actual and TWA PEC_{SED} of 2,6-dichlorobenzamide ($\mu\text{g/kg}$)	
	Actual PEC_{SED}	TWA PEC_{SED}
0	177.851	-
1	177.726	177.801
2	177.750	177.781
4	177.681	177.761
7	177.202	177.729
14	n.c.	177.517
21	n.c.	177.207
28	n.c.	176.517
42	n.c.	173.072
50	n.c.	170.059
100	n.c.	153.633

n.c. Not calculable.

Table 2.5.3.8zc Actual and TWA PEC_{SED} ($\mu\text{g/kg}$) of dichlobenil following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D5 (France, ponds)

Days after application	Actual and TWA PEC_{SED} of dichlobenil ($\mu\text{g/kg}$)	
	Actual PEC_{SED}	TWA PEC_{SED}
0	4.321	-
1	4.321	4.321
2	4.319	4.321
4	4.312	4.320
7	4.302	4.319
14	4.258	4.315
21	4.193	4.311
28	4.113	4.306
42	n.c.	4.289
50	n.c.	4.276
100	n.c.	3.707

n.c. Not calculable.

Table 2.5.3.8zd Actual and TWA PEC_{SED} (µg/kg) of the soil metabolite 2,6-dichlorobenzamide following early application at maximum dose (5400 g a.s./ha) of dichlobenil to spring oil seed rape in the field according to FOCUS step 3, scenario D5 (France, ponds)

Days after application	Actual and TWA PEC _{SED} of 2,6-dichlorobenzamide (µg/kg)	
	Actual PEC _{SED}	TWA PEC _{SED}
0	248.863	-
1	248.829	248.861
2	248.740	248.853
4	248.418	248.823
7	247.601	248.745
14	n.c.	248.406
21	n.c.	247.844
28	n.c.	246.829
42	n.c.	242.265
50	n.c.	239.296
100	n.c.	199.208

n.c. Not calculable.

2.5.4 Fate and behaviour in air

The photolytic degradation of dichlobenil in air was determined experimentally by exposing the compound to xenon light. There was no photodegradation of [¹⁴C]-dichlobenil in the dark controls. After 10 d of continuous irradiation, only 10.3% of the initially added amount of test substance was recovered. The calculated half-life of [¹⁴C]-dichlobenil in air is 2.8 d, which equals 1.4 d of natural sunlight at 50° North latitude. One major metabolite was 2,6-dichlorobenzamide (BAM), which accounted for ca. 15% of the initial amount of radioactivity after 10 d of irradiation. At least five minor metabolites were formed, each comprising for ca. 1 – 4% of the initially applied radioactivity.

The gas-phase oxidation rate and half-life of dichlobenil was also predicted using the estimation methods applied by the AOPWIN program, which are based on the structure-activity relation methods of Atkinson. A theoretical calculation of the photo-oxidation of dichlobenil in the atmosphere, based on a hydroxyl concentration of 1.56×10^6 molecules per cubic cm, resulted in a DT₅₀ of 62.78 days, assuming 12 hour light per day. The overall rate constant is 0.1704×10^{-12} cm³/molecule/sec.

A POP is defined as a chemical, which is extremely stable or persistent in the environment; will bioaccumulate in organisms or the food chain; is toxic to humans or animals and has potential to be transported in the environment over long distances far from the place of release. Dichlobenil is toxic and does have a half-life in air far in excess of the 2 days defined in POPs screening criteria. Hence, dichlobenil has to be checked against the POP criteria.

Dichlobenil could be regarded as persistent in air and thus has a potential for long-range transport. In soil and water, it degrades at a moderate rate (mean DT₅₀ soil 40.5 days, mean DT₅₀ water-sediment system 186.5 days). Bioaccumulation will be low to moderate. The log K_{ow} is 2.70 L/kg. In studies with bluegill sunfish (see Vol. 3 B.9), the BCF ranged between 18 (fish fillet) and 110 L/kg (viscera).

Therefore, dichlobenil does not appear to meet all the criteria for classification as a POP. Therefore, global regulatory agreements, such as the United Nations Economic Convention for Europe Convention on Long-

Range Transboundary Air Pollution: 1998 Aarhus Protocol on Persistent Organic Pollutants (POPs) and the Stockholm Convention on Persistent Organic Pollutants do not apply to dichlobenil.

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

2.6 Effects on non-target species

2.6.1 Effects on terrestrial vertebrates

2.6.1.1 Birds

Mallard duck and northern bobwhite quail were tested with the active substance for oral and dietary acute toxicity. The same two species were also tested in a reproduction test. The metabolite 2,6-dichlorobenzamide was tested in an acute dietary test. The summarised results are given in Table 2.6.1.1a.

Table 2.6.1.1a Summary of acute toxicity of the active substance dichlobenil and the metabolite 2,6-dichlorobenzamide

<i>dichlobenil</i>					
Purity	Species	Endpoint	Toxicity value	Test Guideline	Reference
<i>Acute oral toxicity</i>					
99.4%	Mallard duck (<i>Anas platyrhynchos</i>)	LD ₅₀ males females NOEL males females	> 50 mg test substance/kg bw > 50 mg test substance/kg bw 50 mg test substance/kg bw 50 mg test substance/kg bw	EPA FIFRA section 71-1	IIA, 8.1.1/01
98.8%	Northern bobwhite quail (<i>Colinus virginianus</i>)	LD ₅₀ males females NOEL males females	698 mg test substance/kg bw 727 mg test substance/kg bw < 400 mg test substance/kg bw < 400 mg test substance/kg bw	EPA FIFRA section 71-1	IIA, 8.1.1/02
<i>Acute dietary toxicity</i>					
99.4%	Mallard duck (<i>Anas platyrhynchos</i>)	LC ₅₀ LD ₅₀ NOEC NOEL	> 5200 mg a.s./kg diet > 470 mg a.s./kg bw/day 1300 mg a.s./kg diet 280 mg a.s./kg bw/day	EPA FIFRA section 71-2	IIA, 8.1.2/01
99.4%	Northern bobwhite quail (<i>Colinus virginianus</i>)	5d-LC ₅₀ 5d-LD ₅₀ 5d-NOEC 5d-NOEL	Approx. 5200 mg a.s./kg diet Approx. 598 mg a.s./kg bw/day 1300 mg a.s./kg diet 241 mg a.s./kg bw/day	EPA FIFRA section 71-2	IIA, 8.1.2/02
<i>Reproduction study</i>					
98.5%	Northern bobwhite quail (<i>Colinus virginianus</i>)	22wk- NOEC 22wk- NOEL males females	150 mg test substance/kg diet 15.7 mg test substance/kg bw/day 14.1 mg test substance/kg bw/day	EPA FIFRA section 71-4; OECD 206	IIA 8.1.3/01
98.5%	Mallard duck (<i>Anas platyrhynchos</i>)	21wk- NOEC 21wk- NOEL males females	300 mg test substance/kg diet 35.5 mg test substance/kg bw/day 36.7 mg test substance/kg bw/day	EPA FIFRA section 71-4; OECD 206	IIA 8.1.3/02
<i>2,6-dichlorobenzamide</i>					
<i>Acute dietary toxicity</i>					
98%	Northern bobwhite quail (<i>Colinus virginianus</i>)	8d-LC ₅₀ ¹ 8d-NOEC 8d-NOEL	3867 mg metabolite/kg bw/day 1780 mg metabolite/kg diet 876 mg metabolite/kg bw/day	EPA FIFRA; section 71-2 OPPTS 850.2200 OECD 205	IIA 8.1.2/03

¹ Due to food avoidance, the conversion of LC₅₀ (in mg/kg diet) to LD₅₀ (in mg a.s./kg bw/day) was unreliable

Risk assessment

Procedures for risk assessment for birds must be in agreement with the recommendations in the Guidance Document on Risk Assessment for Birds and Mammals, under Council Directive 91/414/EEC (Draft Working Document SANCO/4145/2000). The guidance in the EPPO environmental risk assessment scheme for plant protection products, chapter 11: terrestrial vertebrates (EPPO Bulletin 33, 211-238) is followed. The toxicity values used for the risk assessment for birds are summarised in Table 2.6.1.1b.

Table 2.6.1.1b Toxicity values used for the risk assessment for birds

Study type	Species	Endpoint	Toxicity value
<i>dichlobenil</i>			
acute oral toxicity test	mallard duck (<i>Anas platyrhynchos</i>)	LD ₅₀	> 50 mg/kg bw
	northern bobwhite quail (<i>Colinus virginianus</i>)	LD ₅₀	698 mg/kg bw
acute dietary toxicity test	mallard duck (<i>Anas platyrhynchos</i>)	LD ₅₀	> 470 mg/kg bw/d
reproduction study	northern bobwhite quail (<i>Colinus virginianus</i>)	NOEL	14.1 mg/kg bw/d
<i>2,6-dichlorobenzamide (BAM)</i>			
acute dietary toxicity test	northern bobwhite quail (<i>Colinus virginianus</i>)	NOEL ²	876 mg/kg bw/d

² The LD₅₀ could not be accurately calculated because of food avoidance. According to SANCO/4145, the NOEL may then be used as a starting point for the risk assessment.

Routes of exposure

For broadcast spreading of granules, the routes of exposure to birds are considered to be:

- Ingestion of granules by birds seeking grit (acute, short- and long-term);
- ingestion of granules by animals seeking seeds as food;
- ingestion of residues in other food items such as earthworms and fish;
- ingestion of granules with soil, unintentionally ingested with food/water;
- ingestion of residues in drinking water.

It is not usual to assess all these routes in detail. This depends on the risk of achieving a lethal dose by consumption of only one or a few granules, and the resemblance of granules with grit, plant seeds and the bioaccumulation potential of the active ingredient.

The colour of the Casoron granules is grey and the odour is aromatic. The particle size of Casoron granules is 0.5 – 1.0 mm for > 60% and 1.0 – 1.25 mm for < 25%. This means that the granules can be considered as small (< 3.5 mm) and should be taken into account for the risk assessment of small granivorous bird species seeking grit. However the aromatic odour and the taste may prevent the birds for further consumption after one granule has been consumed. Sufficient information on the avoidance of birds with regard to consumption of Casoron granules is not available and therefore acute, short and long term consumption of Casoron granules can not be ruled out at forehand. In case the Casoron granules appear to

be not attractive as grit and not be searched for intentionally it is still possible that unintentional consumption of granules together with soil particles and food items occurs. In addition the granules may also resemble plant seeds because some plant seed types may have a comparable size and colour. Therefore the exposure route ingestion of granules by birds seeking seeds as food is also considered below. Residues of the active ingredient and the metabolite BAM are found in surface water (see Section 8.5.1) and may pose a potential threat for birds using surface water for drinking water.

For the exposure routes ingestion of one granule and ingestion of residues in drinking water, only the acute risk is assessed. For the other exposure routes acute, short term and long term risk is considered. The risk methodology in the EPPO environmental risk assessment scheme for plant protection products, Chapter 11: terrestrial vertebrates (EPPO Bulletin 33, 211-238) applies a realistic worst case (rwc) scenario as a first step in each of the three exposure routes and time scales. In case the threshold value for the risk of this rwc is exceeded, a most likely case (mlc) scenario is elaborated as a second step. In the current risk assessment for Casoron G /dichlobenil only the realistic worst case scenario is elaborated. Toxicity-to-exposure (TER) values are calculated and compared with the trigger values according to the Uniform principles (Annex VI 91/414/EEC). It should be noted that the short term, medium term and long term exposure in EPPO Bulletin 33, 211-238) complies with the acute, short-term and long-term risk assessment, respectively, of Sanco/4145 working document.

Acute risk assessment (standard exposure scenario) (short term in EPPO-scheme)

One granule risk assessment

The one granule criterion is applied as a precautionary warning system for potential high-risk applications for birds and mammals. The following assumptions are made in the calculation of the risk of consumption of one granule. The particle size of Casoron granules is 0.5 – 1.0 mm (> 60%) and 1.0 – 1.25 mm (< 25%). The number of particles per gram product amounts 2500 – 3000. This means that one granule weighs between 0.33 and 0.40 mg. The active ingredient content of the product is to 6.75%, which results in a content of 0.027 mg dichlobenil per granule. The LD₅₀ values that are available for two bird species are 698 and > 50 mg a.s./kg bw for northern bobwhite quail (males) and mallard duck, respectively. The LD₅₀ > 50 mg dichlobenil/kg body weight is selected for acute risk assessment as a worst case approach.

Because the LD₅₀ is expressed as mg a.s./kg bw, the one-granule-dose (OGD) is adjusted to a body weight of 1 kg by using a short-cut value : $OGD = \text{short-cut value} \times G_{\text{loading}}$. G_{loading} is the amount of the active substance in one granule (0.027 mg). The short-cut value represents the number of granules consumed per kg body weight and amounts to 40 for small birds ingesting small granules (<3.5 mm). This results in an OGD of 1.08 mg/kg body weight.

Table 2.6.1.1c Acute Toxicity Exposure Ratios for exposure of granivorous birds with a body weight of 25 g to granules with dichlobenil applied at vines and non-crops at 5.4 kg a.s./ha. One granule risk assessment.

Exposure route	LD ₅₀ (mg/kg bw)	a.s. in one granule (G _{loading}) (mg)	OGD (mg/kg bw)	TER
One granule	> 50	0.027	1.08	> 46

The TER value listed in Table 2.6.1.1c is far above 1. It can be concluded that this application can be considered as posing no high risk for birds as a result of the consumption of one granule.

Intentional ingestion of granules as grit

The acute risk assessment was based on the ingestion of granules by birds, using the realistic worst case daily granule dose (DGD) for a representative typical species, using the formula: $DGD = DGI * (G_{\text{surface}} / SP_{\text{surface}} + G_{\text{surface}}) * G_{\text{loading}}$ [mg/kg body weight/day].

DGI is daily grit intake amounting for small birds with a body weight of 25 gram (based on EPPO).

G_{surface} is the number of granules at the soil surface (granules/m², based on application rate and content of a.s. in 1 granule);

SP_{surface} is the number of soil particles at the soil surface that are in the same size class as granules (based on EPPO);

G_{loading} is the amount of the active substance in one granule.

In the calculation for dichlobenil the following data is used: DGI = 651, G_{surface} = 20000; SP_{surface} = 15200;

G_{loading} = 0.027.

The granules are not incorporated in the soil.

The short-cut values used in these calculations are taken from the EPPO -scheme. The values for the calculated exposure and TER are presented in Table 2.6.1.1d.

Accidental ingestion of granules as grit

The daily dry soil dose (DDSD) for a 25-g bird is calculated with the formula DDSD = short-cut value * application rate in kg a.s./ha. Short-cut values are published in the EPPO-scheme. The values for the calculated exposure and TER are presented in Table 2.6.1.1d.

Table 2.6.1.1d Acute Toxicity Exposure Ratios for exposure of granivorous birds with a body weight of 25 g to granules with dichlobenil applied at vines and non-crops in applications at 5.4 kg a.s./ha.

Exposure route	LD ₅₀ (mg/kg bw)	Daily dose (mg/kg BW)	TER
Grit, intentional consumption	> 50	10.0	> 5
Grit, accidental consumption	> 50	2.55	> 20

From the acute TER values in Table 2.6.1.1d it is concluded that dichlobenil can be classified as low risk for acute exposure for accidental grit consumption (TER above the trigger value of 10) and as high risk for acute exposure for intentional grit consumption.

It should be noticed that the toxicological endpoint used in the risk assessment is worst-case because the LD₅₀ is from a study in which no mortality occurred. The 'real' LD₅₀ for the Mallard duck is unknown, due to vomiting at all test doses except for the lowest.

Therefore, the acute TER for the scenario intentional grit consumption is also calculated using the LD₅₀ from the study with Bobwhite quail in which mortality was observed (LD₅₀ 698 mg/kg bw). This should not be seen as a refinement but as an additional information to the TER that was calculated for the Mallard duck. This results in a TER of $698/10 = 70$. This TER is above the trigger value of 10, thus based on the endpoint for Bobwhite quail the risk is acceptable for this scenario.

Taking into account the fact that:

- the TER value is a '>'-value, based on the LD₅₀ for the Mallard duck from a study in which no mortality occurred, while the study with Bobwhite quail showed an LD₅₀ far above 50 mg/kg bw;
- the TER for the one-granule criterion was far above 1 (>46);
- the vomiting of the Mallard duck took place within 10 minutes after exposure, thus before a lethal dose could be reached, indicating the possibility that this could also take place in the field when birds are exposed to Casoron G;

the acute risk to birds as a result from exposure to dichlobenil is considered acceptable.

Ingestion of granules by animals seeking seeds as food

According to the notifier this scenario is irrelevant, because Casoron G consists of anorganic granules and Sanco\4145 only states that granules based on an organic carrier with nutritional value may be mistaken for seeds.

RMS agrees that the notifier's remark is in accordance with Sanco\4145, but RMS also used the EPPO-scheme, which states that it is recommended to try and assess whether it is possible that the granules can be mistaken for weed seeds. RMS has consulted several experts of the RIVM² by showing them a digital photograph of the granules, which was provided by the notifier. The expert opinion was that the granules were not likely to be mistaken for seeds, not because of the anorganic base, but because of their size and shape. The granules have a grit-like shape of different sizes and according to the experts do not resemble natural seeds.

Based on this expert opinion, in combination with the one-granule risk assessment that showed a TER far above 1 (>46), RMS concludes that the scenario of ingestion of granules by animals seeking seeds as food needs no further assessment and the risk of this route can be considered as low.

Consumption of surface water as drinking water (acute risk assessment, standard exposure scenario)

The acute risk assessment for drinking water was based on a small bird with body weight 15 g, and with daily water intake (DWI) and the daily dose of active substance (ETE) calculated according to Sanco\4145/2000. The selected acute oral LD₅₀ is > 50 mg a.s./kg bw. The estimated theoretical exposure

² National Institute for Public Health and the Environment in the Netherlands

(ETE) for the acute time scale was calculated as $PEC_{SW} \text{ actual} \cdot dwi/bw$. The actual PEC_{SW} is the maximum actual PEC_{SW} value, taken from Section 2.5.3.7. Residue values in water, ETE and TERa values are presented in Table 2.6.1.1e.

Table 2.6.1.1e Acute Toxicity Exposure Ratios for exposure of birds to dichlobenil, due to consumption of contaminated drinking water.

Application	dose (kg a.s./ha)	Bird type	body weight (g)	Route	DWI (mL/d)	LD ₅₀ (mg/kg bw)	PEC _{SURFACEWATER} (µg/L)	ETE (mg/kg bw/d)	TERa
Vines	5.4	small bird	15	water	3.5	> 50	240	0.056	> 893
Non crop	5.4	small bird	15	water	3.5	> 50	53.57	0.012	> 4100

The TERa values in Table 2.6.1.1e for granivorous birds exposed to dichlobenil via drinking (surface) water are above the Annex VI 91/414 EEC trigger of 10. Hence, the acute risk to birds in the field is considered to be acceptable.

Short-term risk assessment (medium term in EPPO scheme)

For the short term risk assessment, the exposure estimation as based on the EPPO scheme is in principle the same as for the acute scenario, except for some of the short cut values, which are published in the EPPO scheme.. The LD₅₀ value of > 470 mg a.s./kg bw/d obtained for mallard duck is used for risk assessment. The values for the calculated exposure and TER are presented in Table 2.6.1.1f.

Table 2.6.1.1f. Short term Exposure Toxicity Ratios for exposure of granivorous birds with a body weight of 25 g to granules with dichlobenil applied at vines and non-crops in applications at 5.4 kg a.s./ha.

Exposure route	LD ₅₀ (mg/kg body weight/day)	Daily dose (mg/kg bw/d)	TER
Grit, intentional consumption	> 470	10.0	47
Grit, accidental consumption	> 470	0.51	922

From the TER values in Table 2.6.1.1f it can be concluded that dichlobenil can be classified as low risk for short term exposure for intentional and accidental grit consumption, because the TER values are above the Annex VI 91/414 trigger value of 10.

Long-term risk assessment

According to the EPPO guideline for birds (2003), long-term risk assessment for granules is often superfluous because granules disintegrate or are covered by soil, or the concentration of active substance in the granule falls by degradation. However, RMS is of the opinion that it cannot be excluded that long term effects (on reproduction) may result from short-term exposure. This is also stated in Sanco/4145 (par. 3.5).

Therefore, a long term risk assessment is performed below, using the same method as for the acute and short-term assessment.

Data from two bird reproduction studies are available, namely with Northern bobwhite quail with a 22wk-NOEL of 14.1 mg a.s./kg bw/d and mallard duck with a 21wk-NOEL of 35.5 mg a.s./kg bw/d. The lowest NOEL value is 14.1 and is compared with the exposure. There are no data on degradation of the active ingredient in the granules, therefore a time weighted average (twa) value is not used. The results are listed in table 2.6.1.1g.

Table 2.6.1.1g Long-term Exposure Toxicity Ratios for exposure of granivorous birds with a body weight of 25 g to granules with dichlobenil applied at vines and non-crops in applications at 5.4 kg a.s./ha.

Exposure route	NOEL (mg/kg bw/day)	Daily dose (mg/kg BW)	TER
Grit, intentional consumption	14.1	10.0	1.4
Grit, accidental consumption	14.1	0.51	27.5

The TER value for dichlobenil is above the Annex VI 91/414 EEC trigger value of 5 for long-term exposure for accidental grit consumption and the risk is therefore acceptable. However, the TER value is below the trigger value of 5 for long-term exposure due to intentional grit consumption indicating an unacceptable risk.

The notifier argues that the long term risk assessment is not relevant, since the granules will dissipate rapidly on contact with moisture and fall apart within one day and thus no long term exposure will occur. Further the notifier states that latent effects (effects on reproduction as a result of acute exposure) are unlikely, since from section B.6.1.4 it appears that the active substance is rapidly excreted from rats and hens (approximately 80% or 65% of the last administered dose is excreted within 24 h after respectively low and high doses). In addition, the notifier also refers to a DEFRA-report (Risk to birds and mammals from solid formulations, DEFRA project code PN0922), in which a DGI of 83 is mentioned for the House sparrow. From the DEFRA-report it remains unclear where this value exactly comes from, it is mentioned without any reference.

RMS does not agree with the argument of rapid dissipation of the granules. Apart from the fact that the time period of dissipation of the granules (within 1 day) as stated by the notifier is not validated with data, the intended uses are not necessarily under moist circumstances, especially as they are also in S-EU. Further, exposure over longer time periods is possible because birds can forage on different fields where intact granules can still be present because applications are made at different time points. Also, it should be noted that the excretion of dichlobenil is not extraordinary rapid. The data from B.6.1.4 show that dichlobenil is of average excretion rate, not different from other substances in general. Both these arguments of the notifier do not address the concern of potential long-term effects caused by short-term exposure, because they do not exclude the possibility of short-term exposure in the field.

Finally, the DGI-value of 83 for the House sparrow is also rejected by RMS, since it is unclear where this value comes from or how it was derived. The value of 651 in the EPPO-scheme was derived from a study with the House sparrow (Luttik & De Snoo, 2004)³, in which grit particles in the stomach of 11 House sparrows amounted 64 (size 0.5 to 1 mm) and 155 (size 0.5 to 1.25). Based on the turnover rate from the EPPO scheme (4.2) the daily grit intake amounts 269 or 651. The particle size of Casoron granules is 0.5 – 1.0 mm (> 60%) and 1.0 – 1.25 mm (< 25%). RMS therefore considers the value of 651 for DGI an appropriate value for risk assessment.

Based on the above, the notifier is requested to submit a refined long-term risk assessment for the intended uses of dichlobenil.

Long term risk assessment (bio-accumulation and food chain behaviour)

The long-term risk assessment for secondary poisoning via earthworms is based on a bird weighing 100 g feeding exclusively on earthworms, with a daily food intake (FIR) of 113 g fresh material/day. The BCF for earthworms was calculated as $BCF = (0.84 + 0.01 \cdot \text{Pow}) / (f_{oc} \cdot K_{oc})$, where $K_{oc} = 237 \text{ L/kg}$ and $f_{oc} = 0.02$ (default value). Pow, calculated from $\log \text{Pow} = 2.70$, is 501. The resulting BCF of dichlobenil for earthworms is 1.23 kg earthworm fresh weight per kg soil dry weight. Residue levels in earthworms were calculated from the 21-day TWA PECsoil (6.519 mg/kg dry weight, section B.8.3), as follows: $\text{PEC}_{\text{FEED}} = \text{PEC}_{\text{worm}} = \text{PEC}_{\text{soil}} \cdot \text{BCF}_{\text{worm}}$.

The NOEC used for risk assessment is 14.1 mg/kg bw/day. The PEC_{FEED} is converted to daily dose by using the multiplication factors from SANCO/4145/2000 (1.1 for worms). Residue levels in earthworms and ETE and TERIt values are presented in the table below.

Long-term Toxicity Exposure Ratios for exposure of birds to dichlobenil due to consumption of contaminated earthworms

application	max. dose (kg as/ha)	NOEC (mg/kg bw/d)	Route	PEC_{FEED} (mg/kg wwt)	ETE (mg/kg bw/d)	TERIt
Vines and non-crops	5.4	14.1	Earthworms	8.0	8.8	1.6

The TERIt value for consumption of worms is below the Annex VI 91/414 EEC trigger of 5. Hence, a risk is assumed to be present for the consumption of worms, and a refinement is necessary.

The notifier stated that since the LogPow is < 3, no risk assessment on secondary poisoning is required for dichlobenil. RMS does not agree, since the risk assessment shows that the trigger value is not met and thus the risk needs to be addressed.

Further the notifier submitted a refined risk assessment based on:

³ Luttik, R. and G.R. de Snoo (2004) Characterisation of grit in arable birds to improve pesticide risk assessment. *Ecotoxicology and Environmental Safety* 57: 319-329.

- the use of time-weighted average concentrations in earthworms (based on soil field DT50 values) over a time period comparable to that from the toxicity study in which the endpoint was estimated;
- a proposal to reduce the application rate by 40% to 3.24 kg a.s./ha, because application of the granules is stated not to be applied to the whole area but only to the areas around the vine rows and not to the grass strips (which cover 40% of the area according to the notifier);
- values for earthworm composition of diets for birds representative for vineyards based on two public literature references (not submitted), used for lowering PD to 10%.

RMS agrees that the ETE should not be based on the maximum initial residues, but it is not agreed that the time period from the toxicity study is to be used. Conform the guidance in Sanco/4145 the PECworm was based on the PECsoil twa 21 d, in which degradation is taken into account.

The refinement by reducing the application rate with 40% is not accepted, since the proposed application rate is 5.4 kg a.s./ha. The dose is expressed as an amount of a.s. (granules) per surface area and this ratio does not change with the size of the area that the granules are applied to. If the granules are only applied around the vines, they would still be applied at a dose rate of 5.4 kg a.s./ha (or 0.54 g a.s./m²). If not, RMS considers that the proposed dose should have been lower for vines. Also, this would still not refine the risk for the other intended uses.

The values for earthworm part in the diet of birds representative for vineyards could be acceptable, however RMS did not check the public literature references yet, since they were not submitted by the notifier and there would still be the need for refinement for the other intended uses. In addition, the PD refinement should consist of estimating residue values for all parts of the diet (i.e. sum of PD should be 1), which was not done in the risk assessment of the notifier. Lowering the PD to 0.1 is therefore considered not sufficient for risk refinement. RMS therefore awaits further data, which could be used for refinement of the other intended uses as well.

The notifier is requested to provide a refined risk assessment for earthworm eating birds for the intended uses of dichlobenil. RMS would suggest that data on measured residues in earthworms after exposure to Casoron G according to the appropriate dose rates are submitted for this purpose. Further the notifier is requested, if they still want them to be used, to submit the relevant parts of the public literature references as used in their refined risk assessment*. As one of the references is in French, an English summary should be submitted as well for this reference.

* Reference 1:

Cramp, S et al -1988 – Handbook of the Birds of Europe and the Middle East and North Africa, The birds of the Western Palearctic Volume V Tyrant Flycatchers to Thrushes – Oxford University Press.

Reference 2:

Gérondet, P. – 1998 – Les Passereaux d'Europe – Tome 1: Des coucous aux Merles and

Tome 2: De la Bouscarle aux Bruants 4th edition, updated by M. Cuisin – Delachaux et Niestlé Ed.

Bio-magnification in terrestrial food chains

As the evaluation of the toxicokinetics studies in the toxicology section (absorption, distribution, excretion and metabolism in mammals) concluded that the potential for bio-accumulation is low it can be assumed that there is no biomagnification along the food chain.

Risk of metabolites for birds

There are 3 metabolites that need to be considered for the risk assessment of birds. These are the substances 2,6-dichlorobenzamide, 2-chlorobenzoic acid and 4-chloro-2(3H)benzoxazolone.

2,6-dichlorobenzamide (BAM) is a major metabolite in soil and surface water. Exposure via ingestion of granules is not relevant because this metabolite will probably not be formed within granules. In addition the risk of exposure via contaminated food items such as earthworms can be considered as low, since the logKow of the metabolite is 0.38. The risk of exposure to this metabolite for birds was only determined for the exposure to residues in the surface water by consumption of drinking water. The maximum PEC_{SW} for the metabolite BAM amounts to 72 and 185 µg/L for applications to vines and non crop, respectively (see section 2.5.3.7). The PEC_{SW} values are solely based on the metabolite formed from dichlobenil in the soil and entering the surface water by drainage and run-off because the contribution of in surface water formation to the total PEC_{SW} is not quantitatively important. An acute dietary bird toxicity test with this metabolite was performed. Due to food avoidance of the birds in the acute dietary toxicity test a NOEL value was derived instead of a LC₅₀ value. This NOEL value was used in the risk assessment for the use of surface water as drinking water (see Table 2.6.1.1h).

Table 2.6.1.1h Acute Toxicity Exposure Ratios for exposure of birds to 2,6-dichlorobenzamide (BAM), due to consumption of drinking water.

Application	dose (kg a.s./ha)	Bird type	Approx. body weight (g)	Route	DWI (mL/d)	NOEL (mg/kg bw/d)	PEC _{Surface water} (mg/L)	ETE (mg/kg bw/d)	TER
Vines	5.4	small bird	15	Water	3.5	876	0.072	0.0168	52143
Non crop	5.4	small bird	15	Water	3.5	876	0.185	0.0432	20278

The TER value in Table 2.6.1.1h for granivorous birds exposed to 2,6-dichlorobenzamide (BAM) via drinking (surface) water is above the Annex VI 91/414 EEC trigger of 10. Hence, the acute risk to birds in the field is considered to be acceptable.

Birds may be exposed to 2-chlorobenzoic acid and 4-chloro-2(3H)benzoxazolone via drinking water.

Although PEC_{SW} values are calculated for these metabolites (see Table 2.5.3.7zk), toxicity tests with birds are not available. Therefore the risk can not be calculated for these two metabolites. However, it can be argued that a risk of these two metabolites for birds is unlikely. The PEC_{SW} values for the two metabolites are a factor 10 lower than the PEC_{SW} for BAM (see Table 2.5.3.7zk). In addition the acute toxicity ratios for

BAM do not indicate a risk for birds (Table 2.6.1.1h). The TER values for BAM are a factor 1000 above the trigger value. It can be argued that the toxicity of the two metabolites should be a factor 10000 higher than the toxicity of BAM in order to lead to exceedance of the trigger value for the two metabolites. This is unlikely, also in view of the molecular structure of the substances under consideration.

2.6.1.2 Mammals

Procedures for risk assessment for mammals were in agreement with the recommendations in the Guidance Document on Risk Assessment for Birds and Mammals, under Council Directive 91/414/EEC (Draft Working Document SANCO/4145/2000). The guidance in the EPPO scheme for environmental risk assessment scheme for plant protection products, Chapter 11: terrestrial vertebrates (EPPO Bulletin 33, 211-238) is followed. The toxicity values used for the risk assessment for mammals are summarised in Table 2.6.1.2a.

Table 2.6.1.2a. Toxicity values used for the risk assessment for mammals.

Study type	Species	Endpoint	Toxicity value	Reference
<i>dichlobenil</i>				
acute oral toxicity test	rat	LD ₅₀	> 2000 mg/kg bw	see section 2.3.1
two-generation study	rat	NOAEL	4 mg/kg bw/d	see section 2.3.1
<i>2,6-dichlorobenzamide (BAM)</i>				
acute oral toxicity test	rat	LD ₅₀	500 mg/kg bw	see section 2.3.1
two-generation study	rat	NOAEL	6.5 mg/kg bw/d	see section 2.3.1

For the long-term risk assessment, toxicity values from two-generation studies are used. These values are ecotoxicologically the most relevant as they are based on effects on parental body weight, food consumption and/or development of the offspring. For the metabolite 2,6-dichlorobenzamide (BAM), the two-generation study is the only chronic study available, but for dichlobenil a lower toxicity value was found in the chronic oral toxicity and carcinogenicity study in rat (< 3.2 mg/kg bw/d). As the effects observed in this study are not considered relevant for the ecotoxicological risk assessment of mammals the toxicity value is not used.

Routes of exposure

For broadcast spreading of granules, the routes of exposure to mammals are considered to be:

- ingestion of granules by animals seeking seeds as food;
- ingestion of residues in other food items such as earthworms and plant seedlings;
- ingestion of granules with soil, unintentionally ingested with food/water;
- ingestion of residues in drinking water.
- It is not usual to assess all these routes for mammals. In contrast with some bird species, mammals do not intentionally ingest grit. Accidental ingestion of a granule as part of soil ingestion may occur.

The approach for these risk assessments is highly comparable with the one applied for birds (section 2.6.1.1).

Acute risk assessment

One granule risk assessment

The one granule criterion is applied as a precautionary warning system for potential high-risk applications for birds and mammals. The method for the calculation of the one granule risk is described in section 2.6.1.1. There is one LD₅₀ value available for mammals, namely > 2000 mg a.s./kg bw. This value is used in the risk assessment.

The TER (toxicity-to-exposure ratio) for one granule is listed in Table 2.6.1.2b.

Table 2.6.1.2b. Acute Exposure Toxicity Ratios for exposure of small mammals with a body weight of 25 g to granules with dichlobenil applied at vines and non-crops at 5.4 kg a.s./ha. One granule risk assessment.

Exposure route	LD ₅₀ (mg/kg bw)	Dose in one granule (OGD) (mg)	Exposure (mg/kg bw)	TER
One granule	>2000	0.027	1.08	> 1852

The TER value listed in table 2.6.1.2b is far above 1. It can be concluded that this application can be considered as posing no high risk for mammals as a result of the consumption of one granule.

Accidental ingestion of granules as part of soil ingestion

The exposure to dichlobenil by accidental ingestion of granules as part of soil ingestion is calculated for a realistic worst case with the formula: DDSD=short-cut value * application rate in kg a.s./ha/d. DDSD is the daily dry soil dose. The short-cut value amounts to 0.113 for small mammals. The dosage is 5.4 kg a.s./ha. The resulting DDSD amounts to 0.61 mg/kg body weight /day. The same LD₅₀ value is taken as for the one granule criterion risk assessment (see sub section above). The TER amounts to > 3278 based on the formula: TER = LD₅₀/DDSD. It can be concluded that there is a low risk for acute exposure (see Table 2.6.1.2c).

Table 2.6.1.2c Acute Exposure Toxicity Ratios for exposure of omnivorous mammals with a body weight of 25 g to granules with dichlobenil applied at vines and non-crops in applications at 5.4 kg a.s./ha.

Exposure route	LD ₅₀ (mg/kg bw)	Daily granule dose (mg/kg BW)	TER
Soil ingestion, accidental consumption	> 2000	0.61	> 3278

From the TER value for short-term exposure in Table 2.6.1.2c and the Annex VI 91/414 EEC trigger of 10 it can be concluded that dichlobenil can be classified as low risk for acute exposure for accidental granule consumption as part of soil ingestion.

Ingestion of granules by animals seeking seeds as food

According to the notifier this scenario is irrelevant, because Casoron G consists of anorganic granules and Sanco 4145 only states that granules based on an organic carrier with nutritional value may be mistaken for seeds.

RMS agrees that notifiers remark is in accordance with Sanco\4145, but RMS also used the EPPO-scheme, which states that it is recommended to try and assess whether it is possible that the granules can be mistaken for weed seeds. RMS has consulted several experts of the RIVM⁴ by showing them a digital photograph of the granules, which was provided by the notifier. The expert opinion was that the granules were not likely to be mistaken for seeds, not because of the anorganic base, but because of their size and shape. The granules have a grit-like shape of different sizes and according to the experts do not resemble natural seeds.

Based on this expert opinion, in combination with the one-granule risk assessment that showed a TER far above 1 (>1852), RMS concludes that the scenario of ingestion of granules by animals seeking seeds as food needs no further assessment and the risk of this route can be considered as low.

Consumption of surface water as drinking water (acute risk assessment, standard exposure scenario)

The acute risk assessment for drinking water was based on a small mammal with body weight 25 g, and with daily water intake (DWI) and the daily dose of active substance (ETE) calculated according to Sanco/4145/2000. The selected acute oral LD₅₀ is > 2000 mg a.s./kg bw. The estimated theoretical exposure (ETE) for the acute time scale was calculated as PEC_{SW} actual*dwi/bw. The actual PEC_{SW} is the maximum actual PEC_{SW} value, taken from Section 2.5.3.7. Residue values in water, ETE and TERa values are presented in Table 2.6.1.2d.

Table 2.6.1.2d Acute Toxicity Exposure Ratios for exposure of mammals to dichlobenil, due to consumption of contaminated drinking water.

Application	Dose (kg a.s./ha)	Mammal type	body weight (g)	Route	DWI (mL/d)	LD ₅₀ (mg/kg bw)	PEC _{WATER} (µg/L)	ETE (mg/kg bw/d)	TER
Vines	5.4	small mammal	25	water	3.58	>2000	240	0.0344	> 5.8*10 ⁴
Non crop	5.4	small mammal	25	water	3.58	>2000	53.57	0.0075	> 2.7*10 ⁵

The acute TER values in Table 2.6.1.2d for omnivorous mammals exposed to dichlobenil via drinking (surface) water are above the Annex VI 91/414 EEC trigger of 10. Hence, the acute risk to mammals in the field is considered to be acceptable.

Long-term risk assessment (standard exposure scenario)

Long-term risk assessment is based on the same mammals accidentally consuming granules as part of soil ingestion. This is calculated for a realistic worst case with the formula: DDSD=short-cut value * application

⁴ National Institute for Public Health and the Environment in the Netherlands

rate in kg a.s./ha/ * time weighted average (TWA) factor (mg/kg bw/day). DDSD is the daily dry soil dose. The short-cut value amounts to 0.023 for small mammals. Due to the lack of information on degradation of the active substance in the granules a time weighted average (twa) default value is not used. The dosage is 5.4 kg a.s./ha. The resulting DDSD amounts to 0.12 mg/kg body weight /day.

The toxicity value used for risk assessment is taken from section B.6.6.3.1. The lowest relevant NOAEL was 4 mg as/kg bw/d from a 2-generation rat toxicity study, which is taken to be the ecotoxicologically relevant NOAEL in a First-Tier assessment. The values are presented in Table 2.6.1.2e.

Table 2.6.1.2e Long term Exposure Toxicity Ratios for exposure of omnivorous mammals with a body weight of 25 g to granules with dichlobenil applied at vines and non-crops in applications at 5.4 kg a.s./ha.

Exposure route	NOED (mg/kg bw/d)	Exposure via daily dry soil dose (mg/kg bw/d)	TER
Soil ingestion, accidental consumption	4	0.12	32

From the TER value for long term exposure in Table 2.6.1.2e and the Annex VI 91/414 EEC trigger of 5 it is concluded that dichlobenil can be classified as low risk for long-term exposure for accidental granule consumption as part of soil ingestion.

The notifier disagrees with the use of the NOAEL-value of 4 mg/kg bw/d, but instead is of the opinion that the environmentally relevant NOAEL is 27.9 mg/kg bw/d, on the basis that there were no adverse effects of dichlobenil on mating performance, pregnancy rate, offspring survival to weaning or the incidence of macroscopically abnormal offspring at this dietary concentration.

RMS does not agree with the notifier and will remain with the 4 mg/kg bw/d NOAEL, since above this NOAEL a significant decrease in body weight for adults and offspring in the F0, F1 and F2 generations was observed and RMS considers effects on body weight as an ecologically relevant parameter.

Long term risk assessment (bioaccumulation and food chain behaviour)

The long-term risk assessment for secondary poisoning via earthworms is based on a mammal weighing 10 g feeding exclusively on earthworms, with a daily food intake (DFI) of 14 g fresh material/day. PEC calculations were identical to those for exposure of birds to earthworms (see B.9.1.5.1).

The NOEC used for risk assessment is 4 mg/kg bw/day. The PEC_{FEED} is converted to daily dose by using the multiplication factors from SANCO/4145/2000 (1.1 for worms). Residue levels in earthworms and ETE and TER_{It} values are presented in the table below.

Long-term Toxicity Exposure Ratios for exposure of mammals to dichlobenil due to consumption of contaminated earthworms

application	max. dose (kg as/ha)	NOEC (mg/kg bw/d)	Route	PEC _{FEED} (mg/kg wwt)	ETE (mg/kg bw/d)	TER _{It}
Vines and non-crops	5.4	4	Earthworms	8.0	8.8	0.45

The TERIt value for consumption of worms is below the Annex VI 91/414 EEC trigger of 5. Hence, a risk is assumed to be present for the consumption of worms, and a refinement is necessary.

The notifier stated that since the LogPow is < 3 , no risk assessment on secondary poisoning is required for dichlobenil. RMS does not agree, since the risk assessment shows that the trigger value is not met and thus the risk needs to be addressed.

Further the notifier submitted a refined risk assessment based on:

- the use of time-weighted average concentrations in earthworms (based on soil field DT50 values) over a time period comparable to that from the toxicity study in which the endpoint was estimated;
- a proposal to reduce the application rate by 40% to 3.24 kg a.s./ha, because application of the granules is stated not to be applied to the whole area but only to the areas around the vine rows and not to the grass strips (which cover 40% of the area according to the notifier);

RMS agrees that the ETE should not be based on the maximum initial residues, but it is not agreed that the time period from the toxicity study is to be used. Conform the guidance in Sanco/4145 the PECworm was based on the PECsoil twa 21 d, in which degradation is taken into account.

The refinement by reducing the application rate with 40% is not accepted, since the proposed application rate is 5.4 kg a.s./ha. The dose is expressed as an amount of a.s. (granules) per surface area and this ratio does not change with the size of the area that the granules are applied to. If the granules are only applied around the vines, they would still be applied at a dose rate of 5.4 kg a.s./ha (or 0.54 g a.s./m²). If not, RMS considers that the proposed dose should have been lower for vines. Also, this would still not refine the risk for the other intended uses.

Therefore, the notifier is requested to provide a refined risk assessment for earthworm eating mammals for the intended uses of dichlobenil. RMS would suggest that data on measured residues in earthworms after exposure to Casoron G according to the appropriate dose rates are submitted for this purpose.

Biomagnification in terrestrial food chains

From the evaluation of the toxicokinetic studies in the toxicology section (absorption, distribution, excretion and metabolism in mammals) it is concluded that the potential for bio-accumulation is low. It is therefore assumed that there is no bio-magnification along the food chain.

Risk of metabolites for mammals

There are 3 metabolites that need to be considered for the risk assessment of mammals: 2,6-dichlorobenzamide, 2-chlorobenzoic acid and 4-chloro-2(3H)benzoxazalone.

2,6-dichlorobenzamide (BAM) is a major metabolite in soil and surface water. Exposure via ingestion of granules is not relevant in case of the soil metabolite. In addition the risk of exposure via contaminated food items such as earthworms can be considered as low, since the logK_{ow} of the metabolite is 0.38.

The risk of exposure to this metabolite for mammals was therefore only determined for the exposure to residues in the surface water by consumption of drinking water. The total maximum PEC_{SW} for the metabolite BAM amount to 72 and 185 µg/L for applications in vines and non-crop respectively (see section 2.5.3.7). For the acute risk assessment the acute oral LD₅₀ in rat of 500 mg/kg bw was used (see Table 2.6.1.2a). The results are given in Table 2.6.1.2.f.

Table 2.6.1.2f Acute Toxicity Exposure Ratios for exposure of mammals to 2,6-dichlorobenzamide (BAM), due to consumption of drinking water.

Application	dose (kg a.s./ha)	Mammal type	Approx. body weight (g)	Route	DWI (mL/d)	LD ₅₀ (mg/kg bw/d)	PEC _{Surface water} (mg/L)	ETE (mg/kg bw/d)	TERa
Vines	5.4	Omnivorous species	25	Water	3.58	500	0.072	0.0103	48544
Non crop	5.4	Omnivorous species	25	Water	3.58	500	0.185	0.0265	18868

The TER value in Table 2.6.1.2f, for omnivorous mammals exposed to 2,6-dichlorobenzamide (BAM) via drinking (surface) water is above the Annex VI 91/414 EEC trigger of 10. Hence, the acute risk to mammals in the field is considered to be acceptable.

Mammals may be exposed to 2-chlorobenzoic acid and 4-chloro-2(3H)benzoxazolone via drinking water. Although PEC_{SW} values are calculated for these metabolites (see Table 2.5.3.7zk), toxicity tests with mammals are not available. Therefore the risk can not be calculated for these two metabolites. However, it can be argued that a risk of these two metabolites for mammals is unlikely. The PEC_{SW} values for the two metabolites are a factor 10 lower than the PEC_{SW} for BAM (see Table 2.5.3.7zk). In addition, the acute toxicity ratios for BAM do not indicate a risk for mammals (Table 2.6.1.2f). The TER values for BAM are a factor 1000 above the trigger value. It can be argued that the toxicity of the two metabolites should be a factor 10000 higher than the toxicity of BAM in order to lead to exceedance of the trigger value for the two metabolites. This is unlikely, also in view of the the molecular structure of the substances under consideration.

2.6.2 Effects on aquatic species

Summary of acute toxicity data

In the acute risk assessment of dichlobenil for fish, invertebrates and algae the following endpoints were used:

- 96h-LC₅₀ for fish is 7.2 mg a.s./L
- 96h-LC₅₀ for mysid shrimp is 2.37 mg a.s./L
- 72h-EC₅₀ for algae is > 3.2 mg a.s./L

The acute TERs for application of granules dichlobenil on vines and non-crops are shown in Table 2.6.2a. PEC values of the were taken from section 2.5.3.7. The PEC_{SW} from the FOCUS Step 3 calculations were selected for these TER calculations because in FOCUS Step 1 and 2 the TER values for dichlobenil were below the trigger values from Annex VI.

Table 2.6.2a Acute TERs for dichlobenil at different FOCUS step 3 scenarios, following treatment of vines and non-crops

Crop	Scenario	LC/EC ₅₀ (µg a.s./L)			Actual PEC _{SW} (µg a.s./L)	TER		
		Fish	Invertebrates	Algae		Fish	Invertebrates	Algae
Vines	D6 ditch	7200	2370	> 3200	240.47	30	10	>13
	R1 stream	7200	2370	> 3200	16.27	443	146	>197
	R1 pond	7200	2370	> 3200	0.098	73469	24184	>32653
	R2 stream	7200	2370	> 3200	10.557	682	224	>303
	R3 stream	7200	2370	> 3200	49.280	146	48	>65
	R4 stream	7200	2370	> 3200	55.549	130	43	>58
Non-crops	D1 stream	7200	2370	> 3200	39.194	184	60	>82
	D1 ditch	7200	2370	> 3200	53.565	134	44	>60
	D3 ditch	7200	2370	> 3200	0.001	7200000	2370000	>3200000
	D4 stream	7200	2370	> 3200	6.051	1190	392	>529
	D4 pond	7200	2370	> 3200	4.176	1724	568	>766
	D5 stream	7200	2370	> 3200	1.18	6102	2008	>2712
	D5 pond	7200	2370	> 3200	1.237	5821	1916	>2587
	R1 stream	7200	2370	> 3200	36.589	197	65	>87
	R1 pond	7200	2370	> 3200	1.592	4523	1489	>2010

The acute TER for fish is below the Annex VI trigger of 100 for one of the 15 considered scenarios. For invertebrates the TER is below the trigger of 100 for 6 scenarios. For algae the TER values are all above the Annex VI triggers of 10. As a consequence the acute risk from the proposed use is not acceptable for 6 of the 15 scenarios (D6, R3 stream, R4 stream, D1 stream, D1 ditch and R1). Member states for which these scenarios are relevant should use appropriate refinement options or risk mitigating measures.

Long-term risk of the active substance dichlobenil

The proposed broadcast spreading of granules involves a single application. Dichlobenil degrades in water with a DT₅₀ of 10.9 days. According to the Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001), chronic exposure to dichlobenil is therefore possible. In the event of a DT₅₀ < 2 days a long-term/chronic test is not required. Chronic toxicity data for rainbow trout and *Daphnia magna* are

available; the NOEC values are 0.66 and 1.2 mg a.s./L respectively. For the aquatic plant duckweed (*Lemna gibba*) a 14d-EC₅₀ (biomass as area under the growth curve) value of 0.0279 mg a.s./L is available. This value is regarded as a chronic toxicity value and used for the long-term risk assessment.

The chronic TERs for application of granules dichlobenil are shown in Table 2.6.2b. PEC_{SW} values were taken from section 2.5.3.7. The PEC_{SW} from the FOCUS Step 3 calculations were selected for these TER calculations because in FOCUS Step 1 and 2 the TER values for dichlobenil were below the trigger values from Annex VI.

Table 2.6.2b Chronic TERs for dichlobenil at different FOCUS step 3 scenarios, following treatment of vines and non-crops

Crop	Scenario	NOEC/14d-EC ₅₀ (µg a.s./L)			Actual PEC _{SW} (µg a.s./L)	TER		
		NOEC	NOEC	14d-EC ₅₀				
		Fish	<i>Daphnia</i>	Aquatic plants		Fish	<i>Daphnia</i>	Aquatic plants
Vines	D6 ditch	660	1200	27.9	240.47	2.7	5.0	0.1
	R1 stream	660	1200	27.9	16.27	41	74	1.7
	R1 pond	660	1200	27.9	0.098	6735	12245	285
	R2 stream	660	1200	27.9	10.557	63	114	2.6
	R3 stream	660	1200	27.9	49.280	13	24	0.6
	R4 stream	660	1200	27.9	55.549	12	22	0.5
Non-crops	D1 stream	660	1200	27.9	39.194	17	31	0.7
	D1 ditch	660	1200	27.9	53.565	12	22	0.5
	D3 ditch	660	1200	27.9	0.001	660000	1200000	27900
	D4 stream	660	1200	27.9	6.051	109	198	4.6
	D4 pond	660	1200	27.9	4.176	158	287	6.7
	D5 stream	660	1200	27.9	1.18	559	1017	24
	D5 pond	660	1200	27.9	1.237	534	970	23
	R1 stream	660	1200	27.9	36.589	18	33	0.8
	R1 pond	660	1200	27.9	1.592	415	754	18

The long-term TERs for *Daphnia* and fish are above the relevant Annex VI trigger of 10 for all scenarios, except for scenario D6. Therefore, the chronic risk as a result of the proposed use is not acceptable for aquatic crustaceans and fish for scenario D6. For all other scenarios the chronic risk from the proposed use is acceptable as far as these taxonomic groups is concerned. For aquatic plants, long-term TER values are below the trigger value of 10 in the case of 10 of the 15 considered scenarios.

Member states for which these scenarios are relevant should use appropriate refinement options or risk mitigating measures.

A study with sediment-dwelling organisms is not required because the NOEC in the chronic *Daphnia* test was 1.2 mg a.s./L, which is above the trigger of 0.1 mg/L.

Bioaccumulation

The general trigger to require a fish bioconcentration study is $\log P_{ow} > 3$. The $\log P_{ow}$ of dichlobenil is 2.70 which means that a fish bioconcentration study is not required for dichlobenil. However, a bioconcentration study was performed, which revealed that the bioconcentration of dichlobenil in the bluegill sunfish *Lepomis*

macrochirus is low. The BCF varied between 18 (fish fillet) and 110 L/kg (viscera). Depuration was quick; > 96% (fish fillet) and 97% (viscera) after 14 days.

Risk assessment of metabolites

There are 3 metabolites that need to be considered for the risk assessment of aquatic organisms. These are 2,6-dichlorobenzamide (BAM), 2-chlorobenzoic acid and 4-chloro-2(3H)benzoxazolone. PEC_{SW} values are calculated for 2-chlorobenzoic acid and 4-chloro-2(3H)benzoxazolone (see Table B.8.5.1zk) but toxicity tests with aquatic organisms are not available. However, it can be argued that a risk of these two metabolites for aquatic organisms is unlikely. The PEC_{SW} values for these two metabolites are a factor 10 lower than the PEC_{SW} for BAM (see Table B.8.5.1zk). In addition, the acute toxicity ratios for BAM do not indicate a risk for aquatic organisms (see Table B.9.2.7.4 below). Based on this, the risk for the metabolites 2-chlorobenzoic acid and 4-chloro-2(3H)benzoxazolone is considered low.

A risk assessment for aquatic organisms can be carried out for the metabolite 2,6-dichlorobenzamide. This metabolite is formed in the soil at a maximum of 69.41% of the applied dose and can enter the water phase. Also, a small amount can be formed in surface water. Aquatic toxicity tests with 2,6-dichlorobenzamide were carried out with fish, *Daphnia*, algae and aquatic plants. The acute toxicity values are a LC_{50} of 240 mg/L for fish, an EC_{50} of 180 mg/L for *Daphnia* and an EC_{50} of 111 mg/L for algae. One chronic toxicity value is available: a 14d- EC_{50} of 75 mg/L for the aquatic plant *Lemna gibba*.

The acute and chronic TERs for treatment of vines and non-crops with dichlobenil, for the metabolite 2,6-dichlorobenzamide are shown in Table 2.6.2c (acute) and Table 2.6.2d (chronic). PEC_{SW} values for the metabolite were taken from section 2.5.3.7, Table 2.5.3.7zl, containing the maximum PEC_{SW} values resulting from the FOCUS Step 3 calculations for 2,6-dichlorobenzamide. The PEC_{SW} values are only based on the metabolite formed from dichlobenil in the soil and entering the surface water by drainage and run-off because the contribution of in surface water formation to the total PEC_{SW} is not quantitatively important.

Table 2.6.2c Acute TERs for the metabolite 2,6-dichlorobenzamide at different FOCUS step 3 scenarios, following treatment of vines and non-crops

Crop	Scenario	LC/ EC_{50} (μ g metabolite/L)			Actual PEC_{SW} (μ g/L)	TER		
		fish	<i>Daphnia</i>	algae		fish	<i>Daphnia</i>	algae
Vines	D6 ditch	240000	180000	111000	72.034	3332	2499	1541
	R1 stream	240000	180000	111000	1.16	206897	155172	95690
	R1 pond	240000	180000	111000	0.008	30000000	22500000	13875000
	R2 stream	240000	180000	111000	1.816	132159	99119	61123
	R3 stream	240000	180000	111000	7.501	31996	23997	14798
	R4 stream	240000	180000	111000	2.932	81855	61392	37858
Non-crops	D1 stream	240000	180000	111000	137.547	1745	1309	807
	D1 ditch	240000	180000	111000	138.618	1731	1299	801
	D3 ditch	240000	180000	111000	89.744	2674	2006	1237
	D4 stream	240000	180000	111000	93.717	2561	1921	1184
	D4 pond	240000	180000	111000	185.381	1295	971	599
	D5 stream	240000	180000	111000	47.618	5040	3780	2331
	D5 pond	240000	180000	111000	114.400	2098	1573	970
	R1 stream	240000	180000	111000	2.590	92664	69498	42857
	R1 pond	240000	180000	111000	0.121	1983471	1487603	917355

The acute TERs for fish, *Daphnia* and algae are all above the relevant Annex VI triggers (100, 100 and 10 respectively). Therefore, the acute risk for 2,6-dichlorobenzamide from the proposed use is acceptable.

Table 2.6.2d Chronic TERs for the metabolite 2,6-dichlorobenzamide at different FOCUS step 3 scenarios, following treatment of vines and non-crops

Crop	Scenario	LC/EC ₅₀ (µg metabolite/L)			Actual PEC _{SW} (µg metabolite/L)	TER		
		fish	<i>Daphnia</i>	aquatic plants		fish	<i>Daphnia</i>	aquatic plants
Vines	D6 ditch	n.a.	n.a.	75000	72.034	n.a.	n.a.	1041
	R1 stream	n.a.	n.a.	75000	1.16	n.a.	n.a.	64655
	R1 pond	n.a.	n.a.	75000	0.008	n.a.	n.a.	9375000
	R2 stream	n.a.	n.a.	75000	1.816	n.a.	n.a.	41300
	R3 stream	n.a.	n.a.	75000	7.501	n.a.	n.a.	9999
	R4 stream	n.a.	n.a.	75000	2.932	n.a.	n.a.	25580
Non-crops	D1 stream	n.a.	n.a.	75000	137.547	n.a.	n.a.	545
	D1 ditch	n.a.	n.a.	75000	138.618	n.a.	n.a.	541
	D3 ditch	n.a.	n.a.	75000	89.744	n.a.	n.a.	836
	D4 stream	n.a.	n.a.	75000	93.717	n.a.	n.a.	800
	D4 pond	n.a.	n.a.	75000	185.381	n.a.	n.a.	405
	D5 stream	n.a.	n.a.	75000	47.618	n.a.	n.a.	1575
	D5 pond	n.a.	n.a.	75000	114.400	n.a.	n.a.	656
	R1 stream	n.a.	n.a.	75000	2.590	n.a.	n.a.	28958
	R1 pond	n.a.	n.a.	75000	0.121	n.a.	n.a.	619835

n.a. Not available.

The chronic TERs for aquatic plants are all above the relevant Annex VI trigger of 10. Therefore, the chronic risk for 2,6-dichlorobenzamide from the proposed uses is acceptable.

The chronic TERs for fish and *Daphnia* could not be determined. However, it can be expected that algae and aquatic plants are more sensitive than fish and *Daphnia* towards chronic exposure by 2,6-dichlorobenzamide based on the acute toxicity data in Table 2.6.2c. Therefore chronic toxicity tests with fish and *Daphnia* exposed to 2,6-dichlorobenzamide are not necessary. The metabolite may enter the sediment compartment via soil. However, toxicity tests with sediment-dwelling organisms are not required as the acute toxicity of the parent to *Daphnia* is 30 times higher than the toxicity of BAM and exposure via sediment is at the most 2 times higher than via water (28-d time-weighted average PEC values).

2.6.3 Effects on bees and other arthropod species

2.6.3.1 Bees

Active substance

The risk for bees could not be assessed as no toxicity studies for bees exposed to dichlobenil are available. However, the risk of dichlobenil to bees is expected to be low because the formulation is applied in a granular form and dichlobenil is non-systemic. It is therefore unlikely that the bees will come into contact with the a.s., either via contact or ingestion.

BAM

The metabolite 2,6-dichlorobenzamide (BAM) was found in grapes at a MRL of 0.3 mg metabolite/kg grapes (see B.7.12.2). When bees are feeding on grapes, oral exposure to BAM can therefore not be excluded. According to RMS's information bees do feed on grapes. This is the case when ripe grapes are damaged, which is caused by foraging wasps, or sometimes mildew in an early stage of the grapes. If this is the case, bees are attracted to the grapes and can come to forage on the grapes in large numbers.

Following SANCO/10329/2002, the risk to bees is considered negligible when the hazard quotient (HQ) (application rate/oral LD₅₀) is below 50. Considering the maximum application rate of dichlobenil in the field of 5400 g a.s./ha, the oral intake of dichlobenil should be below 5400 / 50 = 108 µg a.s./bee. Assuming the worst-case situation that all the dichlobenil applied to the field is converted into BAM in grapes and that BAM is equally toxic to the parent compound, the acceptable oral intake of BAM would then be < 108 µg BAM/bee. Using the MRL of BAM in grapes (obtained when dichlobenil was applied at the maximum dose), the oral intake of 108 µg BAM/bee is reached at a consumption of 360 g grapes per bee, which is very unlikely to occur. Therefore, RMS considers the risk of BAM to bees low.

2.6.3.2 Arthropods

The summarised results of the tests with non-target arthropods are given in Table 2.6.3.2a.

Table 2.6.3.2a. Summary of effects of the plant protection product Casoron G on non-target arthropod species during laboratory testing

Species	Stage	Test Substance 1	Dose [kg a.s./ha]	Endpoint	Adverse effect 2
Laboratory tests					
<i>Poecilus cupreus</i>	adult	Casoron G	8.1	mortality	3.3%
<i>Pardosa</i> spp.	adult	Casoron G	8.1	mortality	3%
<i>Aleochara bilineata</i>	adult	Casoron G	8.1	consumption parasitism	14% 100%
Extended lab tests					
<i>Aleochara bilineata</i>	adult	Casoron G	8.1	sandy soil mortality parasitism loamy sand soil	47% 88%

Species	Stage	Test Substance 1	Dose [kg a.s./ha]	Endpoint	Adverse effect 2
<i>Aleochara bilineata</i>	adult	Casoron G	4.05	mortality	52%
				parasitism	55%
				mortality	56%
				parasitism	50%
Semi-field tests					
<i>Aleochara bilineata</i>	adult	Casoron G	4.05	parasitism	
				fresh residu	65%
				28-d old residu	25%
				96-d old residu	3%
1 Test substance Casoron G = 67.5 g dichlobenil/kg 2 Adverse effect means: x % effect on mortality = x % increase of mortality compared to control y % effect on a sublethal parameter = y % decrease of sublethal parameter compared to control (sublethal parameters are e.g. reproduction, parasitism, food consumption)					

Risk assessment

For the proposed broadcast spreading of granules of dichlobenil (maximum application rate 5.4 kg a.s./ha), it is assumed that there will be no interception by the crops and no drift. As the proposed use involves a single seasonal treatment, the maximum recommended dose for glass or sand substrate during laboratory tests will be 100% of the field dose for both foliage and soil dwelling insects when applied in the field (SETAC Guidance Document on Regulatory Testing Procedures for Pesticides with Non-target Arthropods, 1994).

Data have been submitted on three soil dwelling species: carabid beetle (*Poecilus cupreus*), wolf spider (*Pardosa sp.*) and rove beetle (*Aleochara bilineata*). Considering the proposed use, these are considered to be sufficient and acceptable test species. It should be noted that the test dose of 8100 g a.s./ha exceeded the maximum dose of 5400 g a.s./ha. However, effects from the tests can not be corrected to a dose of 5400 g a.s./ha.

Effects on *P. cupreus* and *Pardosa sp.* were below the trigger value of 30%.

Effects on reproduction of *A. bilineata* as a result of the active substance dichlobenil, applied at doses of 4050 and 8100 g a.s./ha, did exceed the relevant trigger value of 30% for laboratory studies with inert substrate or the relevant trigger value of 50% for extended laboratory studies. In a semi-field test with *A. bilineata* with fresh and aged residues, no adverse effects on reproduction were found as a result of exposure to 96d-old residues. 28d-old residues showed 25% adverse effect on reproduction but this result was not significant. The results from the semi-field study show the potential for recovery in-field within a year and off-field within an ecologically relevant period, as recommended in ESCORTII.

Based on the above, the risk for non-target arthropods is considered to be acceptable.

2.6.4 Effects on earthworms and other soil macro-organisms

2.6.4.1 Earthworms

For the proposed broadcast spreading of granules of dichlobenil, the initial actual PEC soil has been determined according to the criteria detailed in section 2.5.2.5. An acute toxicity study has been supplied with the active substance dichlobenil (14d-LC₅₀ 270 mg a.s./kg soil (dw)) and with the formulation Casoron G (14d-LC₅₀ of > 67.5 mg a.s./kg soil (dw)). As the log P_{OW} of dichlobenil is > 2, the LC₅₀ was divided by 2 to correct for the difference in organic matter content of the test substrate (10%) and natural soil (5%). The LC₅₀ from the study with the a.s. was used for the risk assessment, since in the study with the formulation no effects were found at the highest test concentration. This LC₅₀ is 135 mg dichlobenil/kg soil (dw) after correction to 5% OM.

Acute risk

The acute TER is presented in Table 2.6.4.1a.

Table 2.6.4.1a Acute risk of dichlobenil to earthworms

Scenario	LC ₅₀ (mg a.s./kg)	PEC _s (mg a.s./kg)	Acute TER	Annex VI trigger 91/414 EEC
Vines and non-crops	135	7.2	19	10

The acute risk to earthworms is acceptable, since the TER is above 10.

Long-term risk

Chronic toxicity data with earthworms are not required for dichlobenil, since the acute trigger value was met and both the (field) DT90 is less than 100 days and the number of applications is less than 3.

Risk assessment of metabolites

An amount of > 10% metabolite BAM in soil was detected and therefore the risk of the metabolite to earthworms should be assessed. Toxicity tests for earthworms were performed with this metabolite. The acute 14d-LC₅₀ mortality was 750 mg metabolite/kg soil dw and the chronic NOEC for reproduction was 250 mg metabolite/kg. The initial actual PEC soil is taken from section 2.5.2.5. The results are given in Tables 2.6.4.1b and c.

Table 2.6.4.1b Acute risk of the metabolite 2,6-dichlorobenzamide to earthworms

Scenario	LC ₅₀ (mg metabolite/kg)	PEC _s (mg metabolite/kg)	Acute TER	Annex VI trigger 91/414 EEC
Vines and non-crops	750	5.52	136	10

The acute risk of the metabolite 2,6-dichlorobenzamide to earthworms is acceptable (TER is above 10).

Table 2.6.4.1c Long-term risk of the metabolite 2,6-dichlorobenzamide to earthworms

Scenario	NOEC (mg metabolite/kg)	PEC _s (mg metabolite/kg)	Chronic TER	Annex VI trigger 91/414 EEC
Vines and non-crops	250	5.52 (PIEC)	45	5

		6.88 (PEC _{plateau})	36	
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The long-term risk of the metabolite 2,6-dichlorobenzamide to earthworms is acceptable (TER is above 5).

2.6.4.2 Other soil macro-organisms

A summary of the chronic toxicity of the formulation Casoron G to the springtail is given in Table 2.6.4.2a

Table 2.6.4.2a Summary of the chronic toxicity of the plant protection product Casoron G to the springtail *Folsomia candida*

% a.s.	Endpoint	Toxicity value (in mg a.s./kg soil dw)	Test Guideline	Reference no.
6.75%	28d-LC ₅₀ 28d-NOEC	> 67.5 ≥ 67.5	ISO 11267	IIA 8.3.2/03

Risk assessment

Collembola reproduction

A chronic toxicity study with a 6.75% formulation is conducted on the springtail *Folsomia candida*, resulting in a 28-d LC₅₀ of > 67.5 mg a.s./kg soil dw and a 28d-NOEC reproduction value of ≥ 67.5 mg a.s./kg soil dw.

The 28d-NOEC value for reproduction was taken as the relevant value for the risk assessment. As the log P_{OW} of dichlobenil is > 2 (2.7), the NOEC was divided by 2 to correct for the difference in organic matter content of the test substrate (10%) and natural soil (5%). The NOEC used for the risk assessment is therefore ≥ 33.8 mg a.s./kg soil (dw).

The PEC soil is taken from section 2.5.2.5. The long-term risk is presented in Table 2.6.4.2b.

Table 2.6.4.2b Long-term risk of dichlobenil to springtails

Scenario	NOEC (mg a.s./kg)	PEC _s (mg a.s./kg)	Chronic TER	Annex VI trigger 91/414 EEC
Potato tubers	≥ 33.8	7.2	≥ 4.7	5

The long-term risk TER dichlobenil to Collembola is ≥ 4.7, which is below the Annex VI trigger value of 5. However, taking into account that no effects were found in the test and the fact that the TER is only slightly below the trigger value, the risk is considered to be acceptable.

Decomposition of organic matter

According to Annex III from Directive 91/414, effects on decomposition of organic matter should be investigated when the DT₉₀field is larger than 1 year. The maximum field DT₅₀ of BAM is estimated to be 315.2 days, the geometric mean of the normalised field DT₅₀ values is 125 days (see section B.8.3). Based on these data, it can be concluded that the field DT₉₀ is larger than one year. Therefore, the notifier is requested to submit data on the effects of soil metabolite BAM on the decomposition of organic matter in soil (e.g. a litterbag study).

2.6.5 Effects on soil micro-organisms

Dichlobenil

In the first study (Dijkstra, 1989), with the formulation casoron G, the influence of dichlobenil on soil microflora was determined in short-time respiration experiments and by monitoring of nitrogen transformations. However, the test was considered unacceptable for the nitrification part and it cannot be determined whether the test substance is really harmless to soil micro-organisms or that the test was not sensitive enough.

Two other recent performed studies with dichlobenil were submitted (Mead, 2006a/b).

The study on N-mineralisation was considered not acceptable, due to the high coefficient of variation in the control samples. Therefore, it cannot be concluded that dichlobenil, when applied at the maximum proposed field rate of 5.4 kg a.s./ha, will not affect soil nitrogen transformation.

The study on C-mineralisation was acceptable and conducted with relevant test concentrations (1-5x highest PIECs). Based on this study it can be concluded that dichlobenil causes no effects >25% on soil respiration when applied at at the maximum proposed field rate of 5.4 kg a.s./ha.

2,6-dichlorobenzamide (BAM)

The influence of the soil metabolite of dichlobenil, 2,6-dichlorobenzamide, was determined in an experiment by monitoring of nitrogen transformation. The test was not considered acceptable. Two other tests with BAM are available, one for soil respiration and one for soil N-mineralisation, which were both acceptable. However, the highest test concentration in these tests was 6 times lower than the PEC_{soil} for BAM at the proposed application rate (0.92 mg/kg vs 5.5 mg/kg). Therefore it cannot be determined whether 2,6-dichlorobenzamide has no adverse effects on soil micro-organisms when applied at label recommended doses.

Conclusion

The notifier is requested to provide new data on the effects on soil microflora for dichlobenil (N-mineralisation) and soil metabolite 2,6-dichlorobenzamide (BAM) (C- and N-mineralisation).

2.6.6 Effects on other non-target organisms (flora and fauna)

Seedling emergence and seedling growth

Adverse effects of dichlobenil on seedling emergence and seedling growth of six terrestrial plant species were observed in the treated seedlings at doses of approximately 13.11 to 3200 g a.s./ha. *Avena sativa* (oats) was the most sensitive species; the overall ER50 and NOER values for fresh weight are 100.31 and 32.77 g a.s./ha.

Phytotoxicity

The phytotoxic potential of dichlobenil for six terrestrial plant species was tested at doses of approximately 0.49 to 72900 g a.s./ha. *Avena sativa* (oats) was the most sensitive species; the overall NOER value for fresh weight is 7.9 g a.s./ha.

Seed germination

The lowest EC₅₀ value for initial growth of seedlings from five terrestrial plant species was 29 mg/L (root growth of *Lycopersicum esculentum*).

Risk assessment

The exposure assessment for terrestrial plants is based on emission via drift. However, dichlobenil enters the terrestrial compartment via drainage and run-off. Therefore, the risk assessment of dichlobenil for terrestrial plants is not relevant.

2.6.7 Effects on biological methods of sewage treatment

Dichlobenil did not cause inhibition of the bacterial respiratory rate at concentrations of 21 mg a.s./L (aqueous solubility), the 3h-EC₅₀ was > 21 mg a.s./L. Due to the intended use, there is no risk of exposure.

APPENDIX 1 STANDARD TERMS AND ABBREVIATIONS

Part 1 Technical Terms

A	ampere
ACh	acetylcholine
AChE	acetylcholinesterase
ADI	acceptable daily intake
ADP	adenosine diphosphate
AE	acid equivalent
AFID	alkali flame-ionization detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD ₅₀	approximate median lethal dose, 50%
ALT	alanine aminotransferase (SGPT)
AOEL	acceptable operator exposure level
AMD	automatic multiple development
ANOVA	analysis of variance
AP	alkaline phosphatase
approx	approximate
ARC	anticipated residue contribution
ARfD	acute reference dose
as	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BCF	bioconcentration factor
bfa	body fluid assay
BOD	biological oxygen demand
bp	boiling point
BSAF	biota-sediment accumulation factor
BSE	bovine spongiform encephalopathie
BSP	bromosulphophthalein
Bt	Bacillus thuringiensis
Bti	Bacillus thuringiensis israelensis
Btk	Bacillus thuringiensis kurstaki
Btt	Bacillus thuringiensis tenebrionis
BUN	blood urea nitrogen
bw	body weight
c	centi- ($\times 10^{-2}$)
°C	degree Celsius (centigrade)
CA	controlled atmosphere
CAD	computer aided design
CADDY	computer aided dossier and data supply (an electronic dossier interchange and archiving format)
cd	candela
CDA	controlled drop(let) application
cDNA	complementary DNA
CEC	cation exchange capacity
cf	confer, compare to
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CL	confidence limits
cm	centimetre

CNS	central nervous system
COD	chemical oxygen demand
CPK	creatinine phosphatase
cv	coefficient of variation
Cv	ceiling value
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DES	diethylstilboestrol
DFR	dislodgeable foliar residue
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic Acid
dna	designated national authority
DO	dissolved oxygen
DOC	dissolved organic carbon
dpi	days pot inoculation
DRES	dietary risk evaluation system
DT ₅₀	period required for 50 percent dissipation (define method of estimation)
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
DWQG	drinking water quality guidelines
&	decadic molar extinction coefficient
EC ₅₀	median effective concentration
ECD	electron capture detector
ECU	European currency unit
ED ₅₀	median effective dose
EDI	estimated daily intake
ELISA	enzyme linked immunosorbent assay
e-mail	electronic mail
EMDI	estimated maximum daily intake
EPMA	electron probe micro analysis
ERC	environmentally relevant concentration
ERL	extraneous residue limit
F	field
F ₀	parental generation
F ₁	filial generation, first
F ₂	filial generation, second
FIA	fluorescence immuno assay
FID	flame ionization detector
FOB	functional observation battery
fp	freezing point
FPD	flame photometric detector
FPLC	fast protein liquid chromatography
g	gram
G	glasshouse
GAP	good agricultural practice
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionization detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice
GFP	good field practice
GGT	gamma glutamyl transferase
GI	gastro-intestinal
GIT	gastro-intestinal tract

GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice
GM	geometric mean
GMO	genetically modified organism
GMM	genetically modified micro-organism
GPC	gel-permeation chromatography
GPPP	good plant protection practice
GPS	global positioning system
GSH	glutathion
GV	granulosevirus
h	hour(s)
H	Henry's Law constant (calculated as a unitless value) (see also K)
ha	hectare
Hb	haemoglobin
HCG	human chorionic gonadotropin
Hct	haematocrit
HDT	highest dose tested
hL	hectolitre
HEED	high energy electron diffraction
HID	helium ionization detector
HPAEC	high performance anion exchange chromatography
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography - mass spectrometry
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
H _s	Shannon-Weaver index
Ht	haematocrit
I	indoor
I ₅₀	inhibitory dose, 50%
IC ₅₀	median immobilization concentration or median inhibitory concentration
ICM	integrated crop management
ID	ionization detector
IEDI	international estimated daily intake
IGR	insect growth regulator
im	intramuscular
inh	inhalation
ip	intraperitoneal
IPM	integrated pest management
IR	infrared
ISBN	international standard book number
ISSN	international standard serial number
iv	intravenous
IVF	<i>in vitro</i> fertilization
k	kilo
K	Kelvin or Henry's Law constant (in atmospheres per cubic meter per mole) (see also H) ¹
K _{ads}	adsorption constant
K _{des}	apparent desorption coefficient
K _{oc}	organic carbon adsorption coefficient
K _{om}	organic matter adsorption coefficient
kg	kilogram
L	litre
LAN	local area network

LASER	light amplification by stimulated emission of radiation
LBC	loosely bound capacity
LC	liquid chromatography
LC-MS	liquid chromatography- mass spectrometry
LC ₅₀	lethal concentration, median
LCA	life cycle analysis
LC _{Lo}	lethal concentration low
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD ₅₀	lethal dose, median; dosis letalis media
LD _{Lo}	lethal dose low
LDH	lactate dehydrogenase
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
LOQ	limit of quantification (determination)
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LSD	least squared denominator multiple range test
LSS	liquid scintillation spectrometry
LT	lethal threshold
m	metre
M	molar
µm	micrometer (micron)
MC	moisture content
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
MDL	method detection limit
MFO	mixed function oxidase
µg	microgram
mg	milligram
MHC	moisture holding capacity
min	minute(s)
mL	millilitre
MLT	median lethal time
MLD	minimum lethal dose
mm	millimetre
mo	month(s)
mol	Mole(s)
MOS	margin of safety
mp	melting point
MRE	maximum residue expected
MRL	maximum residue level or limit
mRNA	messenger ribonucleic acid
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
n	normal (defining isomeric configuration) or number of observations ¹
NAEL	no adverse effect level
nd	not detected
NEDI	national estimated daily intake
NEL	no effect level
NERL	no effect residue level
ng	nanogram
nm	nanometer

NMR	nuclear magnetic resonance
no	number
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOED	no observed effect dose
NOEL	no observed effect level
NOIS	notice of intent to suspend
NPD	nitrogen-phosphorus detector or detection
NPV	nuclear polyhedrosis virus
NR	not reported
NTE	neurotoxic target esterase
OC	organic carbon content
OCR	optical character recognition
ODP	ozone-depleting potential
ODS	ozone-depleting substances
OM	organic matter content
op	organophosphorous pesticide
Pa	pascal
PAD	pulsed amperometric detection
2-PAM	2-pralidoxime
pc	paper chromatography
PC	personal computer
PCV	haematocrit (packed corpuscular volume)
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
PED	plasma-emissions-detector
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIC	prior informed consent
pic	phage inhibitory capacity
PIXE	proton induced X-ray emission
pKa	negative logarithm (to the base 10) of the dissociation constant)
PNEC	predicted no effect concentration
po	by mouth
P _{OW}	partition coefficient between n-octanol and water
POP	persistent organic pollutants
ppb	parts per billion (10 ⁻⁹)
PPE	personal protective equipment
ppm	parts per million (10 ⁻⁶)
ppp	plant protection product
ppq	parts per quadrillion (10 ⁻²⁴)
ppt	parts per trillion (10 ⁻¹²)
PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit
PT	prothrombin time
PTDI	provisional tolerable daily intake
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r	correlation coefficient

r^2	coefficient of determination
RBC	red blood cell
REI	restricted entry interval
Rf	retardation factor
RfD	reference dose
RH	relative humidity
RL ₅₀	median residual lifetime
RNA	ribonucleic acid
RP	reversed phase
rpm	rotations per minute
rRNA	ribosomal ribonucleic acid
RRT	relative retention time
RSD	relative standard deviation
s	second
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SBLC	shallow bed liquid chromatography
sc	subcutaneous
sce	sister chromatid exchange
SD	standard deviation
se	standard error
SEM	standard error of the mean
SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
SOP	standard operating procedures
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
spp	subspecies
sq	square
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short term exposure limit
STMR	supervised trials median residue
t	tonne (metric ton)
$t_{1/2}$	half-life (define method of estimation)
T ₃	tri-iodothyroxine
T ₄	thyroxine
TADI	temporary acceptable daily intake
TBC	tightly bound capacity
TCD	thermal conductivity detector
TC _{Lo}	toxic concentration, low
TID	thermionic detector, alkali flame detector
TD _{Lo}	toxic dose low
TDR	time domain reflectrometry
TER	toxicity exposure ration
TER _i	toxicity exposure ration for initial exposure
TER _{ST}	toxicity exposure ration following repeated exposure
TER _{LT}	toxicity exposure ration following chronic exposure
tert	tertiary (in a chemical name)
TEP	typical end-use product
TGGE	temperature gradient gel electrophoresis
TIFF	tag image file format

TLC	thin layer chromatography
Tlm	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TOC	total organic carbon
Tremcard	Transport emergency card
tRNA	transfer ribonucleic acid
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor (safety factor)
ULV	ultra low volume
UV	ultraviolet
v/v	volume ratio (volume per volume)
WBC	white blood cell
wk	week
wt	weight
w/v	weight per volume
ww	wet weight
w/w	weight per weight
XRFA	X-ray fluorescence analysis
yr	year
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to

Part 2 Organisations and Publications

ACPA	American Crop Protection Association
ASTM	American Society for Testing and Materials
BA	Biological Abstracts (Philadelphia)
BART	Beneficial Arthropod Registration Testing Group
CA	Chemical Abstracts
CAB	Centre for Agriculture and Biosciences International
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCFAC	Codex Committee on Food Additives and Contaminants
CCGP	Codex Committee on General Principles
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Food
CE	Council of Europe
CIPAC	Collaborative International Pesticides Analytical Council Ltd
COREPER	Comite des Representants Permanents
EC	European Commission
ECB	European Chemical Bureau
ECCA	European Crop Care Association
ECDIN	Environmental Chemicals Data and Information Network of the European Communities
ECDIS	European Environmental Chemicals Data and Information System
ECE	Economic Commission for Europe
ECETOC	European Chemical Industry Ecology and Toxicology Centre
ECLO	Emergency Centre for Locust Operations
ECMWF	European Centre for Medium Range Weather Forecasting
ECPA	European Crop Protection Association
EDEXIM	European Database on Export and Import of Dangerous Chemicals
EHC (number)	Environmental Health Criteria (number)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMIC	Environmental Mutagens Information Centre
EPA	Environmental Protection Agency
EPO	European Patent Office
EPPO	European and Mediterranean Plant Protection Organization
ESCORT	European Standard Characteristics of Beneficials Regulatory Testing
EU	European Union
EUPHIDS	European Pesticide Hazard Information and Decision Support System
EUROPOEM	European Predictive Operator Exposure Model
FAO	Food and Agriculture Organization of the UN
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FRAC	Fungicide Resistance Action Committee
GATT	General Agreement on Tariffs and Trade
GAW	Global Atmosphere Watch
GIFAP	Groupeement International des Associations Nationales de Fabricants de Produits Agrochimiques (now known as GCPF)
GCOS	Global Climate Observing System
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GEDD	Global Environmental Data Directory
GEMS	Global Environmental Monitoring System
GIEWS	Global Information and Early Warning System for Food and Agriculture

GRIN	Germplasm Resources Information Network
HRAC	Herbicide Resistance Action Committee
IARC	International Agency for Research on Cancer
IATS	International Academy of Toxicological Science
IBT	Industrial Bio-Test Laboratories
ICBB	International Commission of Bee Botany
ICBP	International Council for Bird Preservation
ICES	International Council for the Exploration of the Seas
ICPBR	International Commission for Plant-Bee Relationships
ILO	International Labour Organization
IMO	International Maritime Organisation
IOBC	International Organization for Biological Control of Noxious Animals and Plants
IPCS	International Programme on Chemical Safety
IRAC	Insecticide Resistance Action Committee
IRC	International Rice Commission
ISCO	International Soil Conservation Organization
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JECFA	FAO/WHO Joint Expert Committee on Food Additives
JFCMP	Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme
JMP	Joint Meeting on Pesticides (WHO/FAO)
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
NATO	North Atlantic Treaty Organisation
NAFTA	North American Free Trade Agreement
NCI	National Cancer Institute (USA)
NCTR	National Centre for Toxicological Research (USA)
NGO	non-governmental organization
NTP	National Toxicology Programme (USA)
OECD	Organization for Economic Co-operation and Development
OLIS	On-line Information Service of OECD
PAN	Pesticide Action Network
RNN	Re-registration Notification Network
RTECS	Registry of Toxic Effects of Chemical Substances (USA)
SCPH	Standing Committee on Plant Health
SETAC	Society of Environmental Toxicology and Chemistry
SI	Système International d'Unités
SITC	Standard International Trade Classification
TOXLINE	Toxicology Information On-line
UN	United Nations
UNEP	United Nations Environment Programme
WCDP	World Climate Data Programme
WCP	World Climate Programme
WCRP	World Climate Research Programme
WFP	World Food Programme
WHO	World Health Organization
WTO	World Trade Organization
WWF	World Wildlife Fund

Part 3

PREPARATION (FORMULATION) TYPES AND CODES*

Code Description		Definition
AB	Grain bait	Special forms of bait.
AE	Aerosol dispenser	A container-held preparation which is dispersed generally by a propellant as fine droplets/particles upon actuation of a valve.
AL	Other liquids to be applied undiluted	Self defining.
BB	Block baits	Special forms of bait.
BR	Briquette	Solid block designed for controlled release of active ingredient into water.
CB	Bait concentrate	A solid or liquid intended for dilution before use as a bait.
CG	Encapsulated granule	A granule with a protective or release controlling coating.
CS	Capsule suspension	A stable suspension of capsules in a fluid normally intended for dilution with water before use.
DC	Dispersible concentrate	A liquid homogeneous preparation to be applied as a solid dispersion after dilution in water.
DP	Dustable powder	A free-flowing powder suitable for dusting.
DS	Powder for dry seed treatment	A powder for application in the dry state directly to seed.
EC	Emulsifiable concentrate	A liquid, homogenous preparation to be applied as an emulsion after dilution in water.
ED	Electrochargeable liquid	Special liquid preparation for electrostatic (electrodynamic) spraying.
EO	Emulsion, water in oil	A fluid, heterogeneous preparation consisting of a dispersion of fine globules of pesticide in water in a continuous organic liquid phase.
ES	Emulsion for seed treatment	A stable emulsion for application to the seed either directly or after dilution.
EW	Emulsion, oil in water	A fluid, heterogeneous preparation consisting of a dispersion of fine globules of pesticide in an organic liquid in a continuous water phase.
FD	Smoke tin	Special form of smoke generator.
FG	Fine granule	A granule in the particle size range from 300 to 2500 µm.
FK	Smoke candle	A smoke generator in the form of a candle.
FP	Smoke cartridge	Special form of smoke generator.
FR	Smoke rodlet	Special form of smoke generator.

FS	Flowable concentrate for seed treatment	A stable suspension for application to the seed either directly or after dilution.
FT	Smoke tablet	Special form of smoke generator.
FU	Smoke generator	A combustible preparation generally solid, which upon ignition releases the active substances in the form of a smoke.
FW	Smoke pellet	Special form of smoke generator.
GA	Gas	A gas packed in pressure bottle or pressure tank.
GB	Granular bait	Special forms of bait.
GE	Gas generating product	A preparation which generates a gas by chemical reaction.
GG	Macrogranule	A granule in the particle size range from 2000 to 6000 µm.
GP	Flo-dust	Very fine dustable powder for pneumatic application in glass-houses.
GR	Granule	A free-flowing solid preparation of a defined granule size range ready for use.
GS	Grease	Very viscous preparation based on oil or fat.
HN	Hot fogging concentrate	A preparation suitable for application by fogging equipment either directly or after dilution.
KN	Cold fogging concentrate	A preparation suitable for application by cold fogging equipment, either directly or after dilution.
LA	Lacquer	A solvent based film-forming preparation.
LS	Solution for seed treatment	A solution for application to the seed either directly or after dilution.
MG	Microgranule	A granule in the particle size range from 100 to 600 µm.
OF	Oil miscible flowable (=oil active substances in a miscible suspension)	A stable suspension of concentrate fluid intended for dilution in an organic liquid before use.
OL	Oil miscible liquid	A liquid, homogenous preparation to be applied as a homogenous liquid after dilution in an organic liquid.
OP	Oil dispersible powder	A powder preparation to be applied as a suspension after dispersion in an organic liquid.
PA	Paste	A water based film forming preparation.
PB	Plate bait	Special forms of bait.
PC	Gel or paste concentrate	A solid preparation to be applied as a gel or a paste after dilution with water.
PR	Plant rodlet	A small rodlet, usually a few centimetres in length and a few millimetres in diameter containing active substance.
PS	Seed coated with a pesticide	Self defining.
RB	Bait (ready for use)	A preparation designed to attract and be eaten by the target species.

SB	Scrap bait	Special forms of bait.
SC	Suspension concentrate (= flowable concentrate)	A stable suspension of active substance(s) in a fluid intended for dilution with water before use.
SE	Suspo-emulsion	A fluid, heterogeneous preparation consisting of a stable dispersion of active substance(s) in the form of solid particles and of fine globules in a continuous water phase.
SG	Water soluble granules	A preparation consisting of granules to be applied as a true solution of active substance after dissolution in water but may contain insoluble inert ingredients.
SL	Soluble concentrate	A liquid homogenous preparation to be applied as a true solution of the active substance after dilution with water.
SO	Spreading oil	A preparation designed to form a surface layer on application to water.
SP	Water soluble powder	A powder preparation to be applied as a true solution of the active substance after solution in water but which may contain insoluble inert ingredients.
SS	Water soluble powder for seed treatment	A powder to be dissolved in water before application to the seed.
SU	Ultra low volume (ULV) suspension	A suspension ready for use through ULV equipment.
TB	Tablet	Solid preparation in the form of small, flat plates for dissolution in water.
TP	Tracking powder	A rodenticidal contact preparation in powder form.
UL	Ultra low volume (ULV) liquid	A homogenous liquid ready for use through ULV equipment.
VP	Vapour releasing product	A preparation containing one or more volatile ingredients, the vapours of which are released into the air. Evaporation rate normally is controlled by using suitable preparations and/or dispensers.
WG	Water dispersible	A preparation granule consisting of granules to be applied after disintegration and dispersion in water.
WP	Wettable powder	A powder preparation to be applied as a suspension after dispersion in water.
WS	Water dispersible powder for slurry seed treatment	A powder to be dispersed at high concentration in water before application as a slurry to the seed.
XX	Others	

*based upon the catalogue of Pesticide Formulation types and International Coding Systems, developed by GIFAP in co-operation with the German working group on documentation questions. (Arbeitsgruppe EDV Pflanzenschutz Versuchswesen). GIFAP Technical Monograph No 2, 1989.

APPENDIX 2: SPECIFIC TERMS AND ABBREVIATIONS

a	absolute organ weight
AAP	Algal Assay Procedure medium
aerob	aerobic test conditions
a-GT	alpha-glutamyl-transferase
ALAT	alanine aminotransferase
ALP	alkaline phosphatase
amu	atomic mass units
anaer	anaerobic test conditions
AR	applied radioactivity in dermal studies, administered radioactivity in oral studies
ASAT	aspartate aminotransferase
ASTM	American Society for Testing and Materials
B	bacteria
biodeg	biodegradation
Chr. ab.	chromosome aberrations
CMC	carboxymethylcellulose
CoE	Council of Europe
crit.	criterion
d	decreased, but not statistically significantly
dc	statistically significantly decreased
DFI	Daily Food Intake
DMF	dimethylformamide
DO	Dissolved Oxygen
dr	dose-related
DWI	Daily Water Intake
E	total effect of mortality and fecundity/parasitic capacity, used in arthropod toxicity tests
E. coli	<i>Escherichia coli</i>
equal	used when the values given by the notifier are expressed in mg/kg bw/day.
equivalent	used when values given by the notifier are only expressed in mg/kg food, not in mg/kg bw/day, as species-dependent factor is used to translate these data to mg/kg bw/day.
ETE	Estimated Theoretical Exposure
GCP	good clinical practice
GIDH	glutamic-acid dehydrogenase

GOT	glutamic-oxalacetic transaminase
GPT	glutamic-pyruvic transaminase
HDL	high density lipoproteins
HPRT	hypoxanthine- guanine phosphoribosyl transferase
i	increased, but not statistically significantly
ic	statistically significantly increased
MC	moisture content in soil (v/v)
Mc	mammalian cells
MWHC	maximum water holding capacity (soils)
n/a	not applicable
n.d.	not detected
n.r.	not reported
ns	not significant
o.m.	organic matter
PEC	Predicted Environmental Concentration
PEG	polyethylene glycol
pF	moisture tension (soil) in [$\log \text{ cm}_{\text{water column}}$]
PIEC	Predicted Initial Environmental Concentration
pointmut.	pointmutations
r	relative organ weight
r.a.	radioactivity
res.	result
Ri	Reliability Index, referring to the intrinsic reliability of a test with respect to the quality of methodology and the description of the study. 1=reliable (can be used for risk assessment), 2=less reliable (can be used if reliable data are not available), 3=not reliable (can be used if reliable or less reliable data are not available), 4= no original data (reliable (can be used if reliable, less reliable, or unreliable data are not available).
S. typh.	<i>Salmonella typhimurium</i>
SPE	Solid Phase Extraction
Sub.	Substance
T	temperature

TWA	time weighted average
TWAEC	time weighted average environmental concentration
wat/sed	water/sediment system
w/w	weight per weight
-	negative
+	positive
-act.	without activation
+act.	with activation
%v/v	the percentage expressed by volume
%w/w	the percentage expressed by weight

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APPENDIX 3

DICHLOBENIL

LIST OF END-POINTS

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

Chapter 2.1 Identity, Physical and Chemical Properties, Details of Uses, Further Information

Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡

Dichlobenil

Function (e.g. fungicide)

Herbicide

Rapporteur Member State

The Netherlands

Co-rapporteur Member State

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡

2,6-dichlorobenzonitrile

Chemical name (CA) ‡

2,6-dichlorobenzonitrile

CIPAC No ‡

73

CAS No ‡

1194-65-6

EC No (EINECS or ELINCS) ‡

EINECS: 214-787-5

FAO Specification (including year of publication) ‡

Not available

Minimum purity of the active substance as manufactured ‡

980 g/kg

Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured

The impurities in the active substance are provided as confidential information. None of the impurities in technical Dichlobenil are considered to be of (eco)-toxicological significance.

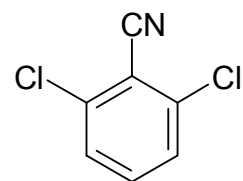
Molecular formula ‡

C₇H₃Cl₂N

Molecular mass ‡

172.0

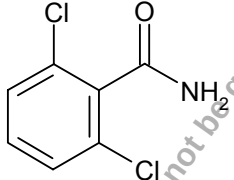
Structural formula ‡



Physical and chemical properties (Annex IIA, point 2) of the parent compound Dichlobenil

Melting point (state purity) ‡	144-145°C (98.8%)
Boiling point (state purity) ‡	Not applicable - dichlobenil sublimed, melted and evaporated (100%)
Temperature of decomposition (state purity)	120°C (100%)
Appearance (state purity) ‡	Purified substance: needle shaped, white crystalline solid with a musty odour (100%). Technical substance: sticky, white solid with a musty odour (99.1%)
Vapour pressure (state temperature, state purity) ‡	1.4×10^{-1} Pa at 25°C (100%)
Henry's law constant ‡	$1.317 \text{ Pa m}^3 \cdot \text{mol}^{-1}$ at 25°C
Solubility in water (state temperature, state purity and pH) ‡	pH 5: 20.5 mg/L at 25°C (99.5%) pH 7: 21.2 mg/L at 25°C (99.5%) pH 9: 21.9 mg/L at 25°C (99.5%)
Solubility in organic solvents ‡ (state temperature, state purity)	cyclohexane: 3.7 g/L at 25°C (99.1%) xylene: 53 g/L at 25°C (99.1%) ethanol: 15 g/L at 25°C (99.1%) dichloromethane: 151 g/L at 20°C (99.1%) acetone: 86 g/L at 20°C (99.1%) methanol: 17.2 g/L at 20°C (99.1%) ethyl acetate: 59.3 g/L at 20°C (99.1%)
Surface tension ‡ (state concentration and temperature, state purity)	68.5 mN/m at 20°C (1.58×10^{-2} g/L solution)(99.3%)
Partition co-efficient ‡ (state temperature, pH and purity)	$\log P_{ow} = 2.7$ at 22 °C (pH 3)(99.8%) (influence of pH was not studied since no dissociation occurs over pH range 2 – 12)
Dissociation constant (state purity) ‡	No dissociation occurs over pH range 2 – 12.
UV/VIS absorption (max.) incl. ϵ ‡ (state purity, pH)	methanol solution: λ_{max} (nm); ϵ ($\text{L} \cdot \text{mol}^{-1} \cdot \text{cm}^{-1}$) 298.9 1985.3 290 1878.8 243 5766.9 236.9 6805.9 211 38528.8 (100%, pH unknown)
Flammability ‡ (state purity)	not highly flammable (99.3%)
Explosive properties ‡ (state purity)	not explosive (99.1%)
Oxidising properties ‡ (state purity)	not oxidizing (99.1%)

Physical and chemical properties (Annex IIA, point 2) of the main metabolite 2,6-dichloro-benzamide (BAM)

Code/Trivial name	Chemical name	Structural formula
BAM (main metabolite, residue definitionplant)	2,6-dichlorobenzamide	
Vapour pressure (state temperature, state purity) ‡	≤2x10 ⁻⁵ Pa at 25°C (99.7%)	
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Spectra confirm structure of 2,6-dichlorobenzamide (absorption coefficients not reported)	
Partition co-efficient ‡ (state temperature, pH and purity)	logPow = 0.38 at 22 °C (pH 3)(not indicated)	
Dissociation constant (state purity) ‡	No dissociation occurs over pH range 2 – 12.	

Classification and proposed labelling (Annex IIA, point 10)

Active substance	RMS/peer review proposal
	No classification and labelling is needed based on the physical and chemical properties of the active substance dichlobenil.

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Summary of representative uses evaluated (dichlobenil)*

Crop and/ or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
					Type (d-f)	Conc of as (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		
(a)			(b)	(c)										(l)	(m)
Around buildings and on industrial sites*	EU	Casoron G	F	Weeds	GR	67.5 g/kg	Broadcast spreading of granules	Pre- emergence until early post- emergence (February – May)	1	N/A	N/A	N/A	2.03-5.4	N/A	*applied to soil or gravel surface ** current PHI = 60 days in Italy & 200 days in France
	EU	Casoron G	F	Weeds	GR	67.5 g/kg	Broadcast spreading of granules	Pre- emergence until early post- emergence (February – May)	1	N/A	N/A	N/A	2.03-5.4	N/A	
	EU	Casoron G	F	Weeds	GR	67.5 g/kg	Broadcast spreading of granules	Pre- emergence until early post- emergence (February – May)	1	N/A	N/A	N/A	2.03-5.4	N/A	
Grape	EU	Casoron G	F	Weeds	GR	67.5 g/kg	Broadcast spreading of granules	Pre- emergence (February – March)	1	N/A	N/A	N/A	2.7-5.4	N/A **	

* For uses where the column "Remarks" is marked in grey further consideration is necessary.
Uses should be crossed out when the notifier no longer supports this use(s).

- (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)
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
- (f) All abbreviations used must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated
- (i) g/kg or g/l
- (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
- (k) Indicate the minimum and maximum number of application possible under practical conditions of use
- (l) PHI - minimum pre-harvest interval
- (m) Remarks may include: Extent of use/economic importance/restrictions

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Chapter 2.2 Methods of Analysis

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

Technical as (analytical technique)	GC-FID (also CIPAC method no. 73)
Impurities in technical as (analytical technique)	No data available, data required
Plant protection product (analytical technique)	GC-FID (also CIPAC method no. 73)

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin	2,6-dichlorobenzamide (BAM)
Food of animal origin	Not derived (requirement depends on outcome of required metabolism study in cattle)
Soil	Dichlobenil and 2,6-dichlorobenzamide (BAM)
Water surface	Dichlobenil and 2,6-dichlorobenzamide (BAM)
drinking/ground	Dichlobenil and 2,6-dichlorobenzamide (BAM)
Air	Dichlobenil

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Two methods available: GC-ECD and GC-MS/MS, LOQ for both methods in grapes: 0.01 mg/kg Dichlobenil and 0.01 mg/kg BAM
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not available (requirement depends on outcome of required metabolism study in cattle)
Soil (analytical technique and LOQ)	Single method: GC-ECD 0.01 mg/kg Dichlobenil and 0.01 mg/kg BAM (specificity confirmed by GC-MS)
Water (analytical technique and LOQ)	Single method: GC-MS 0.1 µg/L Dichlobenil and 0.1 µg/L BAM (surface water and groundwater)
Air (analytical technique and LOQ)	Single method: GC-ECD 0.8 µg/m ³ Dichlobenil (specificity confirmed by GC-MS)
Body fluids and tissues (analytical technique and LOQ)	Not required [Dichlobenil and BAM are both not classified as toxic (T) or very toxic (T ⁺)]

Chapter 2.3 Impact on Human and Animal Health

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

Rate and extent of oral absorption	At least 60% (based on urinary excretion (ca. 58%) and cage wash (ca. 2%) within 24 h. At higher doses the absorption within 24 h was ca. 10-15% lower. After repeated low dose, the amount absorbed from the gut into the liver is more than 80%. As the liver is the critical target organ for dichlobenil toxicity, it is the amount of compound which has passed the liver, that should be considered in risk assessment.
Distribution	Most recovered from liver, kidney, kidney fat and brown fat with concentration peak between 1 and 3 hours.
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Rapid, after repeated dosing, approximately 80% or 65% of the last administered dose is excreted within 24 h after respectively low and high doses.
Metabolism in animals	Extensive, 10 metabolites in urine and no parent compound
Toxicologically relevant compounds (animals and plants)	Dichlobenil (parent compound) and relevant plant metabolite: 2,6-dichlorobenzamide (BAM)
Toxicologically relevant compounds (environment)	Relevant soil metabolite: 2,6-dichlorobenzamide (BAM)

Acute toxicity (Annex IIA, point 5.2)

Rat LD ₅₀ oral	>2000 mg/kg bw	
Rat LD ₅₀ dermal	>2000 mg/kg bw	
Rat LC ₅₀ inhalation	No acceptable data - No study required	
Skin irritation	Non-irritant	
Eye irritation	Non-irritant	
Skin sensitisation	Non-sensitizer (Maximisation test)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Liver (all species)	
Relevant oral NOAEL	52-week dog: 1 mg/kg bw/day (LOAEL) 2-year dog: 1.3 mg/kg bw/day	
Relevant dermal NOAEL	21-day mouse: > 1000 mg/kg bw/day	
Relevant inhalation NOAEL	28-day rat: $\geq 12 \text{ mg/m}^3$	

Genotoxicity (Annex IIA, point 5.4)

No genotoxic potential.	
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Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect

Rat: Kidney, Parathyroid, Stomach Hamster: Liver	
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Relevant NOAEL

110-week rat: 3.2 mg/kg bw/day (LOAEL) 88-week hamster: 9.2 mg/kg bw/day	
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Carcinogenicity

Rat: adenocarcinoma in kidney, and adenoma and carcinoma in liver Hamster: benign and malignant liver tumours. Dichlobenil may pose a carcinogenic risk to humans. Substance has carcinogenic potential in two species, although above MTD, and caused liver adenomas below MTD, not explainable by cytotoxicity in liver. The substance is not proven to be genotoxic and therefore a threshold mechanism of its carcinogenicity is likely.	R40
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Reproductive toxicity (Annex IIA, point 5.6)**Reproduction toxicity**

Reproduction target / critical effect

None. No classification required	
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Relevant parental NOAEL

4 mg/kg bw/day (decreased body weight and food consumption)	
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Relevant reproductive NOAEL

No effects on reproduction	
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Relevant offspring NOAEL

4 mg/kg bw/day (decreased pup body weight)	
--	--

Developmental toxicity

Developmental target / critical effect

Grossly enlarged fontanelles, and other major cranial defects, open eyes; decreased body weight) at maternally toxic dose (rabbit only)	
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Relevant maternal NOAEL

Rat: 20 mg/kg bw/day (decreased body weight and food consumption) Rabbit: 45 mg/kg bw/day (decreased body weight and food consumption)	
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Relevant developmental NOAEL

Rat: > 180 mg/kg bw/day	
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Rabbit: 45 mg/kg bw/day	
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Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity

No data, not required

Repeated neurotoxicity

No data, not required

Delayed neurotoxicity

No data, not required

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies

No data available - not required

Studies performed on metabolites or impurities

acute toxicity, genotoxicity studies and repeated dose studies are performed with the plant and soil metabolite 2,6-dichlorobenzamide (BAM).

Rat LD₅₀ oral: 500 mg/kg bw/day

90-day rat 14 mg/kg bw/day (NOAEL)

2-year rat 6.5 mg/kg bw/day (NOAEL)

The substance is unlikely to be genotoxic

The ADI for BAM is 0.022 mg/kg bw/d, based on the chronic NOAEL of 6.5 mg/kg bw/d from the 2-year chronic study with rats and safety factor of 100 and an additional safety factor of 3 for tumour formation. The ARfD for BAM is 0.14 mg/kg bw based on the 90-day rat study with a safety factor of 100.

Medical data (Annex IIA, point 5.9)

No adverse effects on workers producing dichlobenil as active substance or formulations, and no adverse incidents applying plant protection products were reported.

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI	0.005 mg/kg bw/day	dog, 52-week study	200
AOEL	0.005 mg/kg bw/day	dog, 52-week study	200
ARfD	Not allocated – not necessary		

Dermal absorption (Annex IIIA, point 7.3)

Formulation (e.g. name 50 % EC)

Casoron G (6.75% a.s.), granular formulation
 Dermal absorption is 1.4% (for an area dose of 763 $\mu\text{g}/\text{cm}^2$), based on an *in vitro* dermal absorption study with human skin.

Exposure scenarios (Annex IIIA, point 7.2)

Operator

The estimated exposure for Casoron G based on the PHED-model were below the AOEL with and without PPE.

Mechanical scattering in grapes*broadcast spreader with open cab*

Without PPE: 103%

PPE (default 10%): 10%

broadcast spreader with closed cab

Without PPE: 64%

PPE (default 10%): 6%

Manual scattering alongside paths and roads, under fences and hedges, around buildings and on industrial sides, around trees and shrubs

PHED-model

Without PPE: 3%

PPE (default 10%): 0.3%

Workers

no re-entry exposure will occur

Bystanders

no bystander exposure will occur

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

Substance classified (name)

RMS/peer review proposal

Carcinogen, category 3

Xn "harmful"**R40** "Limited evidence of a carcinogenic effect"

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Chapter 2.4 Residues

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

Plant groups covered	Fruit (grapes, apples), soil application
Rotational crops	No data available, data on residue levels after repeated treatment in successive growing seasons are required for intended use For label extensions, information on uptake of BAM in rotational crops might be necessary
Metabolism in rotational crops similar to metabolism in primary crops?	Not applicable (no rotational crops)
Processed commodities	No data available, data required
Residue pattern in processed commodities similar to residue pattern in raw commodities?	No data available, data required
Plant residue definition for monitoring	2,6-dichlorobenzamide (BAM)
Plant residue definition for risk assessment	2,6-dichlorobenzamide (BAM)
Conversion factor (monitoring to risk assessment)	Not applicable

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

Animals covered	No data available, data required
Time needed to reach a plateau concentration in milk and eggs	No data available, data required
Animal residue definition for monitoring	Not available (requirement depends on outcome of required metabolism study in cattle)
Animal residue definition for risk assessment	Not available (requirement depends on outcome of required metabolism study in cattle)
Conversion factor (monitoring to risk assessment)	Not available (requirement depends on outcome of required metabolism study in cattle)
Metabolism in rat and ruminant similar (yes/no)	Not available (requirement depends on outcome of required metabolism study in cattle)
Fat soluble residue:	No (for Dichlobenil and BAM as main metabolite in plant products. Data on the main residue(s) in livestock are required

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

Due to the properties of both parent (DT50 of 39 – 296 days) and the main metabolite BAM, which is also the main metabolite in grapes (DT50(extrapolated) of 404 – 2666 days, PEC_{soil} = 6.88 mg/kg), an accumulation of especially the metabolite in the ground after application in more than one growing season has to be considered. Respective data are required.

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

Grape samples (commodity with high water content) were stable over the whole testing period of 323 days (Dichlobenil) and 345 days (BAM)
Raisin samples were stable over the whole testing period of 273 days (Dichlobenil) and 266 days (BAM),
Grape juice samples were stable over the whole testing period of 322 days (Dichlobenil) and 343 days (BAM).
Additional storage stability data are required to support trial data (since sample extracts were stored at -18°C for max. 180 days (dichlobenil); storage of sample extracts at -18°C for max. 84 days (BAM).

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (23% dry weight)	yes 0.20 mg/kg (dairy cattle) 0.59 mg/kg (beef cattle) (provisional)	no	no
Potential for accumulation (yes/no):	No data available, data required	No data available – not required	No data available – not required
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No data available, data required	No data available – not required	No data available – not required
	Feeding studies		
Muscle	Not available (requirement depends on outcome of required metabolism study in cattle)	No data available – not required	No data available – not required
Liver			
Kidney			
Fat			
Milk			
Eggs		No data available – not required	

Summary of residues data according to the representative uses on raw agricultural commodities and feedingsuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trial results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
grapes	Northern and Southern European trials combined, field/soil application	1 x 0.012, 1 x 0.015, 1 x 0.045, 1 x 0.049, 1 x 0.080, 1 x 0.090 1 x 0.097, 1 x 0.146, 1 x 0.152, 1 x 0.173 (mg/kg BAM)	MRL derived based on these data is provisional Additional information about the effect of the storage conditions on the reliability of the results are required.	0.3 mg/kg BAM	0.17 mg/kg BAM	0.085 mg/kg BAM

(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 representative use

(c) Highest residue

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

ADI	2,6-dichlorobenzamide (BAM): 0.022 mg/kg
TMDI (% ADI) according to WHO European diet	58% ADI (provisional when drinking water is included, 1.1% when assuming the level of BAM in drinking water is < 0.1 µg/L)
TMDI (% ADI) according to national (to be specified) diets	55% ADI (for adults, based on Dutch TMDI model when drinking water is included, 1.2% when assuming the level of BAM in drinking water is < 0.1 µg/L) 202% ADI (for children of 1-6 years, based on Dutch TMDI model when drinking water is included, 1.2% when assuming the level of BAM in drinking water is < 0.1 µg/L) (provisional)
IEDI (WHO European Diet) (% ADI)	58% ADI (provisional when drinking water is included, 1.1% when assuming the level of BAM in drinking water is < 0.1 µg/L)
NEDI (specify diet) (% ADI)	55% ADI (for adults, based on Dutch TMDI model when drinking water is included, 1.2% when assuming the level of BAM in drinking water is < 0.1 µg/L) 202% ADI (for children of 1-6 years, based on Dutch TMDI model when drinking water is included, 1.2% when assuming the level of BAM in drinking water is < 0.1 µg/L) (provisional)
Factors included in IEDI and NEDI	Processing factors: 2.9 for dried grapes (raisins) and 1.2 for wine
ARfD	2,6-dichlorobenzamide (BAM): 0.14 mg/kg
IENTI (% ARfD)	2.8% ARfD (for adults based on UK model) 9.7% ARfD (for toddlers based on UK model)
NESTI (% ARfD) according to national (to be specified) large portion consumption data	3.9% ARfD (for general population based on NL model) 7.2% ARfD (for children 1-6y based on NL model)
Factors included in IENTI and NESTI	Processing factors: 1.2 for wine

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4) for main metabolite BAM

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor (mean) ^{*)}	Yield factor	
Transfer relevant for 2,6-dichlorobenzamide (BAM)				
juice	1 (2 facilities)	1.2 (1.5, 0.9)	No data available	No data available –

raisins	1	2.9	data required	not required (optional)
must	1 (3 facilities)	0.9 (1.2, 0.8, 0.7)		
wet pomace	1 (3 facilities)	1.5 (0.9, 2.3, 1.4)		
young wine	1 (3 facilities)	1.1 (1.0, 1.2, 1.0)		
wine	1 (3 facilities)	1.2 (0.7, 1.1, 1.7)		

*) Individual results mentioned in brackets

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

Plant products:

Grapes

Animal products:

0.3 mg/kg BAM (provisional)

No data available – derivation of MRL depends on outcome of required metabolism study (possibly followed by feeding study, in cattle).

Chapter 2.5 Fate and Behaviour in the Environment

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

Mineralization after 100 days ‡	0.43 – 1.18% trapped CO ₂ after 112 d, [U- ¹⁴ C]-label (n ⁵ = 3) Sterile conditions: not performed
Non-extractable residues after 100 days ‡	4.66 – 15.2% a.r. after 112 d, [U- ¹⁴ C]-label (n = 3) Sterile conditions: not performed
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	2,6-dichlorobenzamide (BAM): 47.5 – 69.41% a.r. at 273 d (n = 3), [U- ¹⁴ C] label

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

Anaerobic degradation ‡	
Mineralization after 100 days	No data available – not required
Non-extractable residues after 100 days	No data available – not required
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No data available – not required
Soil photolysis ‡	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Photodegradation was not observed

⁵ n corresponds to the number of soils.

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

Laboratory studies ‡

Parent	Aerobic conditions					
Soil type	pH	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	DT ₅₀ (d) 20 °C pF2/10kPa	St. (r ²)	Method of calculation
clay loam	7.6 (KCl)	20°C / not specified	38.9 / 129		0.968	SFO
silt loam	6.1 (KCl)	20°C / not specified	39 / 130		0.975	SFO
loamy sand	5.9 (KCl)	20°C / not specified	43.6 / 145		0.821	SFO
Geometric mean/median				66.5 / 41.3 (DT ₅₀) ¹ 221 / 138 (DT ₉₀) ¹		

1 Geometric mean and median of DT₅₀ and DT₉₀ values normalised for 20°C and determined at 20°C were calculated.

2,6-dichlorobenza- mide (BAM)	Aerobic conditions						
Soil type	pH	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	f. f. k _{dp} /k _f	DT ₅₀ (d) 20 °C pF2/10kPa	St. (r ²)	Method of calculation
sandy loam	4.8	25°C / not specified			2666 (ext)	0.761	SFO
					3.1E+10	0.936	FOMC
sandy loam	7.7	25°C / not specified			795 (ext)	0.872	SFO
					4.8E+04	0.996	FOMC
Geometric mean/median					1730.5 (SFO) / 1.55E+10 (FOMC)		

Field studies ‡

Parent	Aerobic conditions							
Soil type ¹ (indicate if bare or cropped soil was used).	Location (country or USA state).	pH	Depth (cm)	DT ₅₀ (d) actual	DT ₉₀ (d) actual	St. (r ²)	DT ₅₀ (d) Norm.	Method of calculation
sandy loam – loamy sand (bare soil)	Germany	6.3 (KCl)	30	3.4	11.3	0.91		SFO
sandy loam – loamy sand (bare soil)	Germany	5.9 (KCl)	30	could not be determined	could not be determined			SFO
loam (bare soil)	Germany	6.2 (KCl)	30	6.5	22	0.82		SFO
loamy sand (bare soil)	Germany	6.2 (KCl)	30	72	238	0.70		SFO
Geometric mean/median				5.4 / 6.5	39 / 22			

1 German classification; data not sufficient for USDA classification.

In the field study with dichlobenil, the metabolite 2,6-dichlorobenzamide (BAM) was formed. However, RMS could not calculate DT₅₀ values for BAM, because the sum of the BAM concentrations in the different soil layers was still increasing at the end of the experiment. Field data for BAM (as M-1) are available from the DAR of fluopicolide. These studies have been evaluated by the RMS and are considered acceptable.

Field studies ‡

BAM	Aerobic conditions							
Soil type ¹ (indicate if bare or cropped soil was used).	Location (country or USA state).	pH	Depth (cm)	DT ₅₀ (d) actual	DT ₉₀ (d) actual	St. (r ²)	DT ₅₀ (d) Norm.	Method of calculation
Clay (upper layers) (bare soil)	Southern Germany	7.3 (0-30 cm)	20	315.2	n.d.	0.873	73.0	SFO
Loamy sand (upper layers) (bare soil)	Northern Germany	4.9 (0-50 cm)	30	257	n.d.	n.d.	141.5	SFO
Sandy silt loam (bare soil)	Southern France	7.6	20	267	n.d.	0.800	136.6	SFO
Sandy silt loam	Northern France	7.1	20	185.7	n.d.	0.930	173.3	SFO

Field studies ‡

BAM	Aerobic conditions							
Soil type ¹ (indicate if bare or cropped soil was used).	Location (country or USA state).	pH	Depth (cm)	DT ₅₀ (d) actual	DT ₉₀ (d) actual	St. (r ²)	DT ₅₀ (d) Norm.	Method of calculation
Geometric mean/median				256.3 (arithmet ic mean)			131.1 (arithme tic) 125.0 (geome tric)	

pH dependence ‡
(no) (if yes type of dependence)

no

Soil accumulation and plateau concentration ‡

For metabolite 2,6-dichlorobenzamide (BAM) a plateau PEC of **6.88** mg/kg soil was calculated.

Laboratory studies ‡

No data available for anaerobic conditions, not required as exposure of the product to anaerobic conditions is unlikely to occur

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH	K _d (mL/g)	K _{oc} (mL/g)	K _f (mL/g)	K _{foc} (mL/g)	1/n
sandy loam	4	6.6	10.5	262			
silty loam	2.7	7.3	7.4	272			
clay	7.2	7.4	9.6	133			
sand	0.16	7.4	0.3	195			
hydrosoil (silty clay loam)	1.3	6.3	4.2	322			
Arithmetic mean/median			6.4 / 7.4	237 / 262			
pH dependence, Yes or No			no				

2,6-dichlorobenzamide (BAM) ‡							
Soil Type	OC %	Soil pH	K _d (mL/g)	K _{oc} (mL/g)	K _f (mL/g)	K _{foc} (mL/g)	1/n
sandy loam RL-51 original data	0.9	4.8	0.241	26			
without outliers			0.3588	39.9			
sandy loam RL-81	5.7	7.7	1.761	31			
sand RM-014	1.4	6.3	0.529	38			
sand RM-019	4.2	4.9	1.890	45			
sandy clay loam	0.4	6.6	0.208	51			
Arithmetic mean/median ¹			0.949 / 0.529	41.0 / 39.9			
pH dependence (yes or no)			no				

¹ The K_d and K_{OC} determined without outliers were used to calculate the mean and median.

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

Column leaching ‡

No data submitted – not required as reliable adsorption coefficients are available

Aged residues leaching ‡

Aged for (d): 31
 Time period (d): 12
 Elution (mm): 520

Analysis of soil residues post ageing (soil residues pre-leaching): 93.4% active substance, 3.3% Met I, 5.9% bound residue
 95.9% radioactivity retained in top 3 cm

Leachate: 3.0 and 3.1% radioactivity in leachate for two columns
 3.0 and 3.1% active substance
 > 89% radioactivity retained in top 15 cm; 87 – 92% active substance and < 1.8 – 3.7% 2,6-dichlorobenzamide (BAM)

Lysimeter/ field leaching studies ‡

Location: Neustadt am Rübenberge O.T. Borstel (Germany)

Study type: lysimeter (3 lysimeters were used)

Soil properties: loamy sand (0 – 50cm), sand (50 – > 90 cm), pH = 5.5 – 6.9, OC = 0.2 – 1.3%, MWHC = 30.3 – 38.4%

Dates of application : 16 May 1990

Crop/Interception estimated: Not applicable, bare soil

Number of applications: 1 year, 1 application per year

Duration: 2 years (May 1990 until May 1992)

Application rate: 2.39, 3.46, and 7.11 kg a.s./ha/year for the three lysimeters

Average annual rainfall (mm): 856

Average annual leachate volume (mm): 451, 454, and 520 for the three lysimeters

% radioactivity in leachate (maximum/year): 4.57, 8.01, and 6.27% AR (= total of the 2nd yr) for the three lysimeters

Individual annual maximum concentrations: < LOQ active substance (1st and 2nd yr), 22.2, 126, and 175 µg/L (1st yr) and 26.4, 92.4, and 108 µg/L 2,6-dichlorobenzamide (BAM) (2nd yr) for the three lysimeters

Unidentified radioactivity: up to 5 components, 1.63, 4.10, and 4.64 µg/L (1st yr) and 7.89, 2.53, and 1.64 µg/L parent equivalents (2nd yr) for the three lysimeters

Individual annual average concentrations: < LOQ active substance (1st and 2nd yr), 7.47, 54.6, and 94.1 µg/L (1st yr) and 19.3, 49.5, and 69.9 µg/L 2,6-

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dichlorobenzamide (BAM) (2nd yr) for the three lysimeters

Unidentified radioactivity: up to 5 components, 0.53, 1.60, and 1.57 µg/L (1st yr) and 0.52, 0.57, and 0.26 µg/L parent equivalents (2nd yr) for the three lysimeters

Amount of radioactivity in the soils at the end of the study = 28, 22, and 12% AR; 6.2, 6.3, and 3.3% AR as parent, 2.4, 2.1, and 0.8% AR as 2,6-dichlorobenzamide (BAM)

PEC (soil) (Annex IIIA, point 9.1.3)

Parent

Method of calculation

Application data

DT₅₀ (d): 72

Kinetics: SFO

Representative worst case from field studies

Crop: vines and non-crop situations

Depth of soil layer: 5 cm

Soil bulk density: 1.5 g/cm³

% plant interception: Pre-emergence therefore no crop interception

Number of applications: single application in spring

Interval (d): 365

Application rate(s): 5400 g a.s./ha

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PEC _(s) (mg/kg)	Single application	Single application	Multiple application	Multiple application
	Actual	Time weighted average	Actual	Time weighted average
Initial	7.200		Not applicable	

2,6-dichlorobenzamide (BAM)

Method of calculation

Molecular weight relative to the parent: 1.1

DT₅₀ (d): 315.2

Kinetics: SFO

Worst case from field studies

Application data

Application rate assumed: 5400 g a.s./ha (assumed that 2,6-dichlorobenzamide (BAM) is formed at a maximum of 69.41% of the applied dose (76.7% when corrected for molar mass))

PEC _(s) (mg/kg)	Single application	Single application	Multiple application	Multiple application
	Actual	Time weighted average	Actual	Time weighted average
Initial	5.520		Not applicable	

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡

Hydrolytically stable at environmentally relevant pH values of 6.8 to 8.3.

Photolytic degradation of active substance and metabolites above 10 % ‡

DT₅₀: 15.1 daysNatural light, 40°N; DT₅₀ 10.2 days

4-chloro-2(3H)benzoxazolone: 17% AR (21 d)

Quantum yield of direct phototransformation in water at Σ > 290 nm

1.5E-03 mole/Einstein

Readily biodegradable ‡
(yes/no)

No

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Degradation in water / sediment

Parent	Distribution: max in water 97.5 and 98.3% AR after 0 d; max in sediment 55.6 and 47.1% after 15 d for Goorven and Engelse Dijk, respectively									
Water / sediment system	pH water phase	pH sed	t. °C	DT ₅₀ / DT ₉₀ whole sys.	St. (r ²)	DT ₅₀ / DT ₉₀ water	St. (r ²)	DT ₅₀ / DT ₉₀ sed	St. (r ²)	Method of calculation
Goorven	5.44	6.2 (water) 5.2 (KCl)	19.0 – 21.1	307 / 1020	> 0.81	10.9 / 36.1		Not applicable		SFO
Engelse Dijk	7.5	7.5 (water) 7.3 (KCl)	19.0 – 21.1	66 / 218	> 0.81	10.1 / 34				SFO
Geometric mean/median				142 / 187 (DT ₅₀) 472 / 619 (DT ₉₀)		10.5 / 10.5 (DT ₅₀) 35.0 / 35.1 (DT ₉₀)				

The results of the water/sediment study with dichlobenil did not allow the calculation of a DT₅₀ value for the metabolite 2,6-dichlorobenzamide (BAM). For the calculation of PEC_{SW} values, a worst-case value was used (1000 days for FOCUS Step 1, 2 and 3).

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization % after 100 d	Non-extractable residues in sed. % after x d	Non-extractable residues in sed. % after 100 d (end of the study)
Goorven	5.44	6.2 (water) 5.2 (KCl)	0.63%	3.0 (after 100 d)	3.0
Engelse Dijk	7.5	7.5 (water) 7.3 (KCl)	4.5%	7.8 (after 59 and 100 d)	7.8

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

Parent

Parameters used in FOCUSsw step 1 and 2

Version control no. of FOCUS calculator: v 1.1

Molecular weight (g/mol): 172.0

Water solubility (mg/L): 21.2

 K_{OC} (L/kg): 237 DT_{50} soil (d): 40.5 DT_{50} water/sediment system (d): 186.5 DT_{50} water (d): 186.5 DT_{50} sediment (d): 1000

Crop interception (%): 0

Parameters used in FOCUSsw step 3 (if performed)

Version control no.'s of FOCUS software: v 2.2.1

Vapour pressure: 0.14 Pa at 25 °C

 K_{OM} (L/kg): 137.47

1/n: 0.90

Application rate

Crop: vines and non-crops (spring oil seed rape was used as an example for non-crop applications)

Crop interception: none

Number of applications: 1

Interval (d): 365

Application rate(s): 5400 g a.s./ha

Application window: spring

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6 (Thiva), vines	ditch	0 h	240.486		97.806	
		24 h	123.350	195.714	96.380	97.381
		2 d	93.901	158.912	96.359	96.644
		4 d	65.293	120.669	88.465	95.783
		7 d	50.625	91.760	87.882	92.898
		14 d	14.213	63.295	70.796	87.726
		21 d	8.032	46.810	61.026	81.243
		28 d	6.058	37.234	54.911	75.809
		50 d	6.796	23.902	47.416	64.598
		100 d	0.081	13.362	30.698	51.928
R1 (Germany), vines	stream	0 h	16.269		3.908	
		24 h	0.011	7.539	1.794	2.901
		2 d	0.004	3.775	1.306	2.291

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		4 d	0.001	1.889	0.950	1.728
		7 d	0.001	1.080	0.732	1.354
		14 d	0.001	0.649	0.729	1.095
		21d	0.000	0.433	0.561	0.944
		28 d	0.000	0.325	0.480	0.838
		50 d	0.000	0.194	0.394	0.678
		100 d	0.000	0.097	0.267	0.499
R1 (Germany), vines	pond	0 h	0.098		0.190	
		24 h	0.093	0.095	0.190	0.190
		2 d	0.089	0.093	0.190	0.190
		4 d	0.082	0.089	0.189	0.190
		7 d	0.073	0.084	0.186	0.189
		14 d	0.078	0.082	0.189	0.188
		21d	0.057	0.077	0.182	0.188
		28 d	0.041	0.070	0.171	0.188
		50 d	0.019	0.053	0.138	0.180
		100 d	0.002	0.030	0.096	0.154
R2 (Portugal), vines	stream	0 h	10.557		2.980	
		24 h	0.007	5.890	1.40	2.252
		2 d	0.003	2.950	1.026	1.796
		4 d	0.001	1.476	0.749	1.362
		7 d	0.000	0.844	0.579	1.070
		14 d	0.000	0.422	0.421	0.817
		21d	0.000	0.281	0.350	0.714
		28 d	0.001	0.352	0.893	0.681
		50 d	0.000	0.197	0.443	0.638
		100 d	0.000	0.102	0.316	0.499
R3 (Italy), vines	stream	0 h	49.280		17.127	
		24 h	0.244	44.173	9.509	14.932
		2 d	0.071	23.575	7.161	12.453
		4 d	0.025	11.823	5.313	9.672
		7 d	0.011	6.765	4.138	7.667
		14 d	0.003	3.386	3.035	5.652
		21d	0.002	2.258	2.524	4.708

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		28 d	0.001	1.694	2.208	4.130
		50 d	0.001	0.949	1.668	3.159
		100 d	0.000	0.475	1.173	2.275
R4 (France), vines	stream	0 h	55.549		16.238	
		24 h	0.056	37.084	7.737	12.797
		2 d	0.019	18.585	5.776	10.272
		4 d	0.007	9.301	4.258	7.817
		7 d	0.003	5.317	3.304	6.146
		14 d	0.001	2.660	2.418	4.507
		21d	0.001	1.773	2.012	3.749
		28 d	0.008	1.430	2.533	3.317
		50 d	0.000	0.805	1.492	2.656
		100 d	0.000	0.402	1.031	1.942
R1 (Germany), spring oil seed rape	stream	0 h	36.589		9.142	
		24 h	0.080	19.771	4.373	7.181
		2 d	0.018	9.907	3.225	5.708
		4 d	0.053	4.958	2.586	4.322
		7 d	0.017	3.477	2.810	3.666
		14 d	0.072	1.936	2.230	3.096
		21d	0.001	1.308	1.625	2.692
		28 d	0.000	0.981	1.387	2.397
		50 d	0.000	0.565	1.070	1.899
		100 d	0.000	0.285	0.743	1.393
R1 (Germany), spring oil seed rape	pond	0 h	1.592		2.706	-
		24 h	1.518	1.554	2.705	2.706
		2 d	1.456	1.521	2.701	2.706
		4 d	1.351	1.463	2.687	2.704
		7 d	1.343	1.409	2.653	2.700
		14 d	1.252	1.373	2.606	2.683
		21d	0.909	1.275	2.483	2.665
		28 d	0.665	1.153	2.323	2.640
		50 d	0.268	0.852	1.871	2.504
		100 d	0.025	0.477	1.316	2.128
D1 (Lanna),	stream	0 h	39.194		87.808	

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
spring oil seed rape		24 h	23.965	34.758	n.c.	87.728
		2 d	1.936	34.121	n.c.	87.697
		4 d	0.113	33.713	n.c.	87.671
		7 d	0.043	33.170	n.c.	87.614
		14 d	0.018	30.718	n.c.	87.252
		21d	25.930	28.266	n.c.	86.939
		28 d	32.993	26.357	n.c.	86.668
		50 d	18.069	22.208	n.c.	85.138
		100 d	10.873	16.782	n.c.	83.488
D1 (Lanna), spring oil seed rape	ditch	0 h	53.565		137.564	
		24 h	52.830	53.437	n.c.	137.474
		2 d	52.437	53.135	n.c.	137.470
		4 d	51.985	52.829	n.c.	137.466
		7 d	46.800	51.773	n.c.	137.419
		14 d	37.165	47.432	n.c.	136.859
		21d	30.850	44.357	n.c.	136.429
		28 d	27.392	41.633	n.c.	136.092
		50 d	20.543	35.188	n.c.	134.000
		100 d	11.181	26.543	n.c.	131.806
D3 (Vredepeel), spring oil seed rape	ditch	0 h	0.001		0.009	
		24 h	0.001	0.001	n.c.	0.009
		2 d	0.001	0.001	n.c.	0.009
		4 d	0.001	0.001	n.c.	0.009
		7 d	0.001	0.001	n.c.	0.009
		14 d	0.001	0.001	n.c.	0.009
		21d	0.001	0.001	n.c.	0.009
		28 d	0.001	0.001	n.c.	0.009
		50 d	0.001	0.001	n.c.	0.009
		100 d	n.c.	0.001	n.c.	0.008
D4 (Skousbo), spring oil seed rape	stream	0 h	6.051		7.065	
		24 h	4.432	5.290	7.011	7.060
		2 d	5.591	5.067	6.941	7.052
		4 d	4.268	4.921	6.767	7.042
		7 d	3.599	4.746	6.533	7.036

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		14 d	2.379	4.063	5.826	6.939
		21d	1.270	3.415	5.219	6.778
		28 d	0.657	2.863	4.810	6.566
		50 d	0.811	1.823	4.634	5.921
		100 d	0.082	1.049	3.399	5.107
D4 (Skousbo), spring oil seed rape	pond	0 h	4.176		11.270	
		24 h	4.164	4.175	11.270	11.270
		2 d	4.135	4.171	11.267	11.270
		4 d	4.054	4.157	11.256	11.269
		7 d	3.904	4.123	11.229	11.266
		14 d	3.467	4.033	11.125	11.255
		21d	3.059	3.922	10.981	11.235
		28 d	2.693	3.796	10.809	11.208
		50 d	1.977	3.364	10.182	11.094
		100 d	0.881	2.542	n.c.	10.697
D5 (France), spring oil seed rape	stream	0 h	1.180		3.109	
		24 h	0.661	0.880	3.109	3.109
		2 d	0.771	0.871	3.107	3.109
		4 d	0.841	0.834	3.101	3.108
		7 d	0.888	0.814	3.092	3.106
		14 d	0.373	0.759	3.103	3.100
		21d	0.264	0.735	3.079	3.100
		28 d	0.221	0.724	2.921	3.097
		50 d	0.230	0.695	2.265	3.076
		100 d	n.c.	0.636	1.723	2.931
D5 (France), spring oil seed rape	pond	0 h	1.237		4.321	
		24 h	1.230	1.236	4.321	4.321
		2 d	1.216	1.234	4.319	4.321
		4 d	1.178	1.226	4.312	4.320
		7 d	1.116	1.209	4.302	4.319
		14 d	0.978	1.157	4.258	4.315
		21d	0.845	1.101	4.193	4.311
		28 d	0.733	1.094	4.113	4.306
		50 d	0.545	1.029	n.c.	4.276

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		100 d	n.c.	0.847	n.c.	3.707

Metabolite 2,6-dichlorobenzamide (BAM)

Parameters used in FOCUSsw step 1 and 2

Molecular weight: 190 g/mol
 Water solubility (mg/L): 1830
 Soil or water metabolite: soil
 K_{oc}/K_{OM} (L/kg): 41 / 24
 DT₅₀ soil (d): 1731 days (lab, FOCUS SFO)
 DT₅₀ water/sediment system (d): 1E+10 (worst-case value as no DT₅₀ value is available)
 DT₅₀ water (d): 1000 (worst-case value)
 DT₅₀ sediment (d): 1000 (worst-case value)
 Crop interception (%): 0
 Maximum occurrence observed (% molar basis with respect to the parent): 69.41%
 Water: 5.32%
 Sediment: not applicable

Parameters used in FOCUSsw step 3 (if performed)

Vapour pressure: $\leq 2 \cdot 10^{-5}$ Pa at 25 °C
 K_{OM} (L/kg): 23.78
 1/n: 0.90
 DT₅₀ water (d): 1000 (worst-case value as no DT₅₀ value is available; i.e. maximum value that can be entered in model)
 DT₅₀ sediment (d): 1000 (worst-case value)
 Metabolite kinetically generated in simulation (yes/no): not applicable
 Formation fraction in soil (k_{dp}/k_f): not applicable

Application rate

Crop: vines and non-crops (spring oil seed rape was used as an example for non-crop applications)
 Number of applications: 1
 Interval (d): 365
 Application rate(s): 5400 g as/ha (corresponding to 4140 g BAM/ha)
 Depth of water body: 30 cm
 Application window: spring

Main routes of entry

Drainage

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6 (Thiva), vines	ditch	0 h	72.034		68.868	
		24 h	51.538	65.298	68.835	68.864
		2 d	48.706	59.899	68.801	68.855
		4 d	46.401	54.168	68.838	68.833
		7 d	47.286	49.501	67.982	68.818
		14 d	35.042	45.338	61.011	68.459
		21d	28.769	41.572	52.693	68.010
		28 d	25.487	38.264	n.c.	67.296
		50 d	29.036	36.869	n.c.	65.132
		100 d	0.151	35.813	n.c.	58.610
R1 (Germany), vines	stream	0 h	1.160		0.160	
		24 h	0.000	0.537	0.060	0.108
		2 d	0.000	0.269	0.044	0.083
		4 d	0.000	0.134	0.033	0.062
		7 d	0.000	0.077	0.026	0.048
		14 d	0.000	0.043	0.023	0.037
		21d	0.000	0.029	0.018	0.032
		28 d	0.000	0.022	0.015	0.028
		50 d	0.000	0.015	0.015	0.024
		100 d	0.000	0.007	0.010	0.018
R1 (Germany), vines	pond	0 h	0.008	-	0.017	
		24 h	0.008	0.008	0.017	0.017
		2 d	0.008	0.008	0.017	0.017
		4 d	0.008	0.008	0.017	0.017
		7 d	0.008	0.008	0.017	0.017
		14 d	0.007	0.008	0.017	0.017
		21d	0.007	0.008	0.017	0.017
		28 d	0.007	0.008	0.017	0.017
		50 d	0.006	0.007	0.016	0.017
		100 d	0.004	0.007	0.015	0.017
R2 (Portugal), vines	stream	0 h	1.816	-	0.279	
		24 h	0.001	1.013	0.107	0.195
		2 d	0.000	0.507	0.081	0.151

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		4 d	0.000	0.253	0.060	0.112
		7 d	0.000	0.145	0.047	0.088
		14 d	0.000	0.072	0.034	0.064
		21d	0.000	0.048	0.028	0.053
		28 d	0.000	0.047	0.045	0.050
		50 d	0.000	0.026	0.026	0.042
		100 d	0.000	0.014	0.021	0.032
R3 (Italy), vines	stream	0 h	7.501		1.328	
		24 h	0.018	6.731	0.677	1.141
		2 d	0.005	3.588	0.515	0.936
		4 d	0.002	1.796	0.386	0.718
		7 d	0.001	1.027	0.301	0.566
		14 d	0.000	0.514	0.219	0.415
		21d	0.000	0.343	0.181	0.344
		28 d	0.000	0.257	0.158	0.301
		50 d	0.000	0.144	0.118	0.229
		100 d	0.000	0.072	0.076	0.162
R4 (France), vines	stream	0 h	2.932		0.473	
		24 h	0.001	1.957	0.200	0.357
		2 d	0.000	0.980	0.151	0.280
		4 d	0.000	0.490	0.112	0.211
		7 d	0.000	0.280	0.088	0.165
		14 d	0.000	0.140	0.064	0.120
		21d	0.000	0.093	0.053	0.100
		28 d	0.000	0.077	0.071	0.088
		50 d	0.000	0.043	0.040	0.071
		100 d	0.000	0.022	0.026	0.052
R1 (Germany), spring oil seed rape	stream	0 h	2.590		0.357	-
		24 h	0.003	1.401	0.151	0.266
		2 d	0.001	0.701	0.112	0.206
		4 d	0.002	0.351	0.089	0.154
		7 d	0.000	0.228	0.084	0.126
		14 d	0.006	0.123	0.071	0.101
		21d	0.000	0.083	0.050	0.087

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		28 d	0.000	0.063	0.043	0.077
		50 d	0.000	0.038	0.036	0.062
		100 d	0.000	0.019	0.024	0.046
R1 (Germany), spring oil seed rape	pond	0 h	0.121		0.215	
		24 h	0.120	0.120	0.215	0.215
		2 d	0.119	0.120	0.215	0.215
		4 d	0.117	0.119	0.214	0.215
		7 d	0.114	0.118	0.214	0.215
		14 d	0.108	0.115	0.213	0.215
		21 d	0.102	0.113	0.211	0.215
		28 d	0.110	0.112	0.209	0.214
		50 d	0.094	0.110	0.202	0.214
		100 d	0.067	0.098	0.179	0.210
D1 (Lanna), spring oil seed rape	stream	0 h	138.618		212.779	
		24 h	137.547	138.442	n.c.	212.629
		2 d	135.595	138.009	n.c.	212.513
		4 d	129.460	136.145	n.c.	212.300
		7 d	117.277	131.887	n.c.	211.998
		14 d	113.770	123.539	n.c.	211.780
		21 d	106.168	120.153	n.c.	211.252
		28 d	105.262	118.071	n.c.	210.458
		50 d	103.073	109.598	n.c.	208.180
		100 d	85.387	105.100	n.c.	202.644
D1 (Lanna), spring oil seed rape	ditch	0 h	138.618		212.779	
		24 h	137.547	138.442	n.c.	212.629
		2 d	135.595	138.009	n.c.	212.513
		4 d	129.460	136.145	n.c.	212.300
		7 d	117.277	131.887	n.c.	211.998
		14 d	113.770	123.539	n.c.	211.780
		21 d	106.168	120.153	n.c.	211.252
		28 d	105.262	118.071	n.c.	210.458
		50 d	103.073	109.598	n.c.	208.180
		100 d	85.387	105.100	n.c.	202.644
D3	ditch	0 h	89.744		219.226	

FOCUS STEP 3 Scenario (Vredepeel), spring oil seed rape	Water body	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		24 h	89.624	89.671	n.c.	219.199
		2 d	89.656	89.669	n.c.	219.172
		4 d	89.665	89.660	n.c.	219.118
		7 d	89.616	89.645	n.c.	219.037
		14 d	89.377	89.605	n.c.	218.849
		21d	88.915	89.538	n.c.	218.668
		28 d	88.737	89.485	n.c.	218.497
		50 d	88.274	89.367	n.c.	217.799
		100 d	85.205	89.035	n.c.	215.496
D4 (Skousbo), spring oil seed rape	stream	0 h	93.717		133.650	
		24 h	90.683	92.234	133.618	133.648
		2 d	91.905	91.582	133.524	133.644
		4 d	86.462	91.190	133.157	133.628
		7 d	83.019	90.732	132.050	133.552
		14 d	75.299	89.240	129.629	133.123
		21d	63.976	87.451	127.043	132.410
		28 d	64.607	84.598	124.226	131.595
		50 d	65.925	77.688	116.393	128.520
		100 d	38.912	66.761	n.c.	123.693
D4 (Skousbo), spring oil seed rape	pond	0 h	185.381		349.769	
		24 h	185.346	185.378	349.764	349.768
		2 d	185.242	185.369	349.751	349.767
		4 d	184.850	185.333	349.698	349.763
		7 d	183.856	185.225	349.594	349.751
		14 d	180.769	184.712	n.c.	349.699
		21d	177.261	183.883	n.c.	349.634
		28 d	173.525	182.830	n.c.	349.449
		50 d	161.661	178.699	n.c.	347.973
		100 d	n.c.	171.136	n.c.	333.413
D5 (France), spring oil seed rape	stream	0 h	47.618		66.063	
		24 h	46.961	45.759	65.940	66.058
		2 d	44.363	45.580	65.882	66.054
		4 d	39.841	45.026	65.747	66.045
		7 d	34.979	43.851	65.374	66.024

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		14 d	30.714	41.478	n.c.	65.935
		21d	27.957	39.014	n.c.	65.774
		28 d	25.869	37.318	n.c.	65.506
		50 d	34.467	35.869	n.c.	63.197
		100 d	n.c.	34.110	n.c.	56.593
D5 (France), spring oil seed rape	pond	0 h	114.400		236.977	
		24 h	114.379	114.398	n.c.	236.816
		2 d	114.326	114.392	n.c.	236.648
		4 d	114.118	114.368	n.c.	236.297
		7 d	113.652	114.295	n.c.	235.735
		14 d	112.134	114.007	n.c.	234.239
		21d	110.267	113.747	n.c.	232.452
		28 d	n.c.	113.362	n.c.	230.335
		50 d	n.c.	111.700	n.c.	222.345
		100 d	n.c.	102.139	n.c.	196.281

n.c. Not calculable.

PEC (groundwater) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter)

For FOCUSgw modelling, values used –
Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance.

Model(s) used: FOCUS PEARL 3.3.3

Scenarios for vines: Chateaudun, Hamburg, Kremsmünster, Piacenza, Porto, Sevilla, Thiva

Scenarios for non-crops: Chateaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiva

Crop: vines and non-crops

Average parent $DT_{50 \text{ lab}}$: 40.5 d

Average K_{OM} parent: 137.5 L/kg

$1/f_n = 0.9$

Metabolites: 2,6 dichlorobenzamide (BAM)

Scenarios for vines: Chateaudun, Hamburg, Kremsmünster, Piacenza, Porto, Sevilla, Thiva

Scenarios for non-crops: Chateaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiva

Crop: vines and non-crops

Average metabolite $DT_{50 \text{ lab}}$: 125.0 d

Average K_{OM} metabolite: 24 L/kg, average K_{OC} metabolite: 41 L/kg

$1/f_n = 0.9$

Application rate

Application rate: 5400 g/ha.

No. of applications: 1

Time of application (month or season): May

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

FOCUS PEARL 3.3.3 Vines	Scenario	Parent (µg/L)	2,6-dichlorobenzamide (BAM) (µg/L)
	Chateaudun	0.288	340.961
	Hamburg	0.191	380.348
	Kremsmünster	0.107	302.933
	Piacenza	2.693	290.500
	Porto	< 0.001	84.149
	Sevilla	0.180	278.559
	Thiva	0.3174	262.178

FOCUS PEARL 3.3.3 / Non-crops	Scenario	Parent (µg/L)	2,6-dichlorobenzamide (BAM) (µg/L)
	Chateaudun	< 0.001	284.050
	Hamburg	0.061	364.929
	Jokioinen	< 0.0012	324.477
	Kremsmünster	0.033	293.002
	Okehampton	0.0742	287.690
	Piacenza	0.327	284.115
	Porto	< 0.001	80.079
	Sevilla	< 0.001	180.728
	Thiva	< 0.001	183.314

PEC_(gw) From lysimeter / field studies

Not applicable, not used for the risk assessment.

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

Direct photolysis in air ‡	Studied with xenon light. Results converted to natural light: Latitude: 50° North Season: not applicable DT ₅₀ : 1.4 d
Quantum yield of direct phototransformation	0.06 mol/Einstein
Photochemical oxidative degradation in air ‡	DT ₅₀ of 62.78 days derived by the AOPWIN program (version 1.90) based on the methods of Atkinson. OH (12 h) concentration assumed = 1.56E6
Volatilisation ‡	Not applicable
Metabolites	2,6-dichlorobenzamide

PEC (air)

Method of calculation	Expert judgement, based on DT ₅₀
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PEC_(a)

Maximum concentration	Negligible; DT ₅₀ is 1.4 d
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Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology)	Soil: dichlobenil, 2,6-dichlorobenzamide; the metabolites 4-chloro-2(3H)benzoxazolone and 2-chlorobenzoic acid could not be assessed, data is required Surface water: dichlobenil, 2,6-dichlorobenzamide (entry route through soil) Groundwater: dichlobenil, 2,6-dichlorobenzamide Sediment: dichlobenil, 2,6-dichlorobenzamide (entry route through soil) Air: dichlobenil
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Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	No data provided - none requested
Surface water (indicate location and type of study)	No data provided - none requested
Groundwater (indicate location and type of study)	Dichlobenil concentrations in samples taken from 65 relevant wells in the south and south-east of the

Air (indicate location and type of study)

Netherlands were determined. The concentrations were below the LOQ of 0.05 µg/L.

No data provided - none requested

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

R53

Chapter 2.6 Ecotoxicology

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

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Mallard duck	a.s.	Acute	LD ₅₀ : > 50 ¹	
Bobwhite quail	a.s.	Acute	LD ₅₀ : 698	
Mallard duck	a.s.	Short-term	LD ₅₀ : > 470	LC ₅₀ : > 5200
Bobwhite quail	a.s.	Short-term	LD ₅₀ : ca. 598	LC ₅₀ : ca. 5200
Bobwhite quail	2,6-dichlorobenzamide (BAM)	Short-term	NOEL ² : 876	NOEC: 1780
Bobwhite quail	a.s.	Long-term	NOEL: 14.1	NOEC: 150
Mammals ‡				
Rat	a.s.	Acute	LD ₅₀ : > 2000	
Rat	2,6-dichlorobenzamide (BAM)	Acute	LD ₅₀ : 500	
Rat	a.s.	Long-term	NOAEL: 4	
Rat	2,6-dichlorobenzamide (BAM)	Long-term	NOAEL: 6.5	

¹ No mortality observed in any of the treatment groups. LD₅₀ was set at the lowest dose where birds did not vomit.

² NOEL instead of LD₅₀, because the LD₅₀ could not be accurately calculated because of food avoidance. According to SANCO/4145, the NOEL may then be used as a starting point for the risk assessment.

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

Vines and non-crop at 5.4 kg a.s./ha.

Indicator species/Category	Time scale	ETE (mg/kg bw/d)	TER	Annex VI Trigger
<u>Tier 1 (granivorous birds)</u>				
Active substance				
One granule	Acute	1.08	> 46	10
Grit, intentional consumption	Acute	10.0	> 5	10
Grit, accidental consumption	Acute	2.55	> 20	10
Grit, intentional consumption	Short-term	10.0	47	10
Grit, accidental consumption	Short-term	0.51	922	10
Grit, intentional consumption	Long-term	10.0	1.4	5
Grit, accidental consumption	Long-term	0.51	27.5	5
<u>Tier 1 (earthworm eating bird)</u>				
earthworms	Long-term	8.8	1.6	5
<u>Tier 1 granivorous mammals)</u>				
Active substance				
One granule	Acute	1.08	> 1852	10
Soil ingestion, accidental consumption	Acute	0.61	> 3278	10
Soil ingestion, accidental consumption	Long-term	0.12	32	5
<u>Tier 1 (earthworm eating mammal)</u>				
earthworms	Long-term	8.8	0.45	5

Non-crops at 5.4 kg a.s./ha.

Indicator species/Category	Time scale	ETE (mg/kg bw/d)	TER	Annex VI Trigger
<u>Tier 1 (small birds) – exposure via drinking water</u>				
Active substance	Acute	0.012	> 4100	10
2,6-dichlorobenzamide	Acute	0.0432	20278	10
<u>Tier 1 (small mammals) – exposure via drinking water</u>				
Active substance	Acute	0.0075	> $2.7 \cdot 10^5$	10
2,6-dichlorobenzamide	Acute	0.0265	18868	10

Vines

Indicator species/Category	Time scale	ETE (mg/kg bw/d)	TER	Annex VI Trigger
<u>Tier 1 (small birds) – exposure via drinking water</u>				
Active substance	Acute	0.056	> 893	10
2,6-dichlorobenzamide	Acute	0.0168	52143	10
<u>Tier 1 (small mammals) – exposure via drinking water</u>				
Active substance	Acute	0.0344	> $5.8 \cdot 10^4$	10
2,6-dichlorobenzamide	Acute	0.0103	48544	10

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 (Test type)	End point	Toxicity ¹ (mg/L)
Laboratory tests ‡				
Fish				
rainbow trout (<i>Oncorhynchus mykiss</i>)	a.s.	96 hr semi-static	LC ₅₀	7.2 (mm)
rainbow trout (<i>Oncorhynchus mykiss</i>)	a.s.	96 d (flow-through)	Growth NOEC	0.66 (mm)
rainbow trout (<i>Oncorhynchus mykiss</i>)	2,6-dichlorobenzamide (BAM)	96 h (semi-static)	LC ₅₀	240 (nom)
Aquatic invertebrate				
water flea (<i>Daphnia magna</i>)	a.s.	48 h (flow-through)	LC ₅₀ ²	6.2 (mm)
mysis shrimp (<i>Mysidopsis bahia</i>)	a.s.	96 h (flow-through)	LC ₅₀	2.37 (mm)
water flea (<i>Daphnia magna</i>)	a.s.	21 d (flow-through)	Reproduction NOEC	1.2 (mm)
water flea (<i>Daphnia magna</i>)	2,6-dichlorobenzamide (BAM)	48 h (static)	Mobility EC ₅₀	180 (nom)
Sediment dwelling organisms				
There are no studies available, not required				
Algae				
green alga (<i>Selenastrum capricornutum</i>)	a.s.	120 h (static)	Biomass 72h-EC ₅₀	> 3.2 (mm)
green alga (<i>Pseudokirchneriella subcapitata</i>)	2,6-dichlorobenzamide (BAM)	96 h (static)	Growth rate 72h-EC ₅₀	111 (nom)
Higher plant				
duckweed (<i>Lemna gibba</i>)	a.s.	14 d (semi-static)	Biomass, EC ₅₀	0.0279 (nom)
duckweed (<i>Lemna gibba</i>)	2,6-dichlorobenzamide (BAM)	7 d (static)	Biomass, EC ₅₀	75 (mm)
Microcosm or mesocosm tests				
There are no studies available, not required				

¹ Based on nominal (nom) or mean measured concentrations (mm).

² RMS assumes that the LC₅₀ determined using mortality as effect parameter can be read as EC₅₀ for mobility.

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Only the TER values below the Annex VI trigger are included. For dichlobenil, the acute trigger is not reached for 6 out of the 15 scenario's and the chronic trigger is not reached for 10 out of the 15 scenario's. For BAM, all TER-values are above the relevant trigger value.

Refined aquatic risk assessment using higher tier FOCUS modelling.**FOCUS Step 3**

Vines in applications at 5.4 kg a.s./ha:

Test substance	Scenario ¹	Water body type	Test organism	Time scale	Toxicity end point (mg/L)	PEC ² surface water (µg/L)	TER	Annex VI trigger
a.s.	D6	ditch	Fish	Acute	7.2	240	30	100
a.s.	D6	ditch	Fish	Chronic	0.66	240	2.7	10
a.s.	D6	ditch	Aquatic invertebrates	Acute	2.37	240	10	100
a.s.	R3	stream	Aquatic invertebrates	Acute	2.37	49.3	48	100
a.s.	R4	stream	Aquatic invertebrates	Acute	2.37	55.5	43	100
a.s.	D6	ditch	Aquatic invertebrates	Chronic	1.2	240	5.0	10
a.s.	D6	ditch	Aquatic plants	Chronic	0.0279	240	0.1	10
a.s.	R1	stream	Aquatic plants	Chronic	0.0279	16.3	1.7	10
a.s.	R2	stream	Aquatic plants	Chronic	0.0279	10.6	2.6	10
a.s.	R3	stream	Aquatic plants	Chronic	0.0279	49.3	0.6	10
a.s.	R4	stream	Aquatic plants	Chronic	0.0279	55.5	0.5	10

¹ drainage (D1-D6) and run-off (R1-R4)

² maximum (initial PEC values) were used for all assessments

Non-crops in applications at 5.4 kg a.s./ha.

Test substance	Scenario ¹	Water body type	Test organism	Time scale	Toxicity end point (mg/L)	PEC ² surface water (µg/L)	TER	Annex VI trigger ⁵
a.s.	D1	stream	Aquatic invertebrates	Acute	2.37	39.2	60	100
a.s.	D1	ditch	Aquatic invertebrates	Acute	2.37	53.6	44	100
a.s.	R1	stream	Aquatic invertebrates	Acute	2.37	36.6	65	100
a.s.	D1	stream	Higher plants	Chronic	0.0279	39.2	0.7	10
a.s.	D1	ditch	Higher plants	Chronic	0.0279	53.6	0.5	10
a.s.	D4	stream	Higher plants	Chronic	0.0279	6.05	4.6	10
a.s.	D4	pond	Higher plants	Chronic	0.0279	4.18	6.7	10
a.s.	R1	pond	Higher plants	Chronic	0.0279	36.6	0.8	10

¹ drainage (D1-D6) and run-off (R1-R4)² maximum (initial PEC values) were used for all assessments

Bioconcentration		
	Active substance	2,6-dichlorobenzamide (BAM)
logP _{ow}	2.70	0.38 0.51
Bioconcentration factor (BCF) ¹ ‡	in bluegill sunfish, the BCF ranged between 18 (fish fillet) and 110 L/kg (viscera)	
Annex VI Trigger for the bioconcentration factor	100	
Clearance time (days) (CT ₅₀)	< 1	
(CT ₉₀)	< 1	
Level and nature of residues (%) in organisms after the 14 day depuration phase	< 4	

¹ only required if log P_{ow} >3, based on radioactivity (calculated as dichlobenil)

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

Statement available, no data required.

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

Statement available, no data required.

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

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha) ¹	End point	% effect ²	Trigger value
<i>Poecilus cupreus</i>	adult	Casoron G quartz sand 14 d	8100	mortality	3.3	30 %
<i>Pardosa spp.</i>	adult	Casoron G sand 14 d	8100	mortality consumption	3 14	30 %
<i>Aleochara bilineata</i>	adult	Casoron G sand 10 – 12 wk	8100	parasitism	100	30 %
<i>Aleochara bilineata</i>	adult	Casoron G sandy soil loamy sand soil 66 d	8100	mortality parasitism mortality parasitism	47 88 52 55	50 %
<i>Aleochara bilineata</i>	adult	Casoron G	4050	mortality parasitism	56 50	50%

¹ expressed in units of a.s.² positive percentages relate to adverse effects

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

Field or semi-field tests

Species	Life stage	Test substance, substrate and duration	Dose (g/ha) ¹	End point	% effect ²	Trigger value
<i>Aleochara bilineata</i>	adult	Casoron G Sandy loam soil 28 d	4050 fresh residu	parasitism	65	50 %
			28-d old residu		25	
			96-d old residu		3	

¹ expressed in units of a.s.² positive percentages relate to adverse effects

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point (mg a.s./kg dw soil)
Earthworms			
<i>Eisenia foetida</i>	a.s. ‡	Acute, 14 d	LC _{50, corr} ¹ : 135
	Casoron G ² ‡	Acute, 14 d	LC _{50, corr} ¹ : > 33.8
No chronic data with the a.s. are available, no data required			
<i>Eisenia foetida</i>	BAM ‡	Acute, 14 d	LC ₅₀ : 750
<i>Eisenia foetida</i>	BAM ‡	Chronic, 56 d	NOEC : 250
Other soil macro-organisms			
<i>Soil mite</i>			
No data submitted, not required			
<i>Collembola</i>			
<i>Folsomia candida</i>	Casoron G ²	Chronic, 28d	NOEC ¹ : ≥ 33.8
Soil micro-organisms			
Dichlobenil:			
No effects > 25% on C-mineralisation on day 28 at 7.2 and 36 mg a.s./kg.			
No acceptable data submitted on N-mineralisation, data required			
BAM:			
No acceptable or useful data submitted, data required			
Field studies			
No data submitted, not required			

¹ As the log P_{ow} of dichlobenil is > 2, the LC₅₀ was divided by 2 to correct for the difference in organic matter content between artificial test soil and natural soil.

² Test substance Casoron G = 67.5% dichlobenil

Toxicity/exposure ratios for soil organisms

Vines and non-crops in applications at 5.4 kg a.s./ha.

Test organism	Test substance	Time scale	Soil PEC (mg a.s./kg)	TER	Trigger
Earthworms	a.s. ‡	Acute	7.2	19	10
Earthworms	BAM ‡	Acute	5.52	136	10
Earthworms	BAM ‡	Chronic	5.52	45	5
Earthworms	BAM ‡	Chronic	6.88 (plateau)	36	5
Springtail	Casoron G ²	Chronic	7.2	≥ 9.4	5

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

Not required for herbicides as ER ₅₀ tests should be provided
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Laboratory dose response tests

Most sensitive species	Test substance	ER ₅₀ (g/ha) vegetative vigour	ER ₅₀ (g/ha) emergence	Exposure (g/ha)	TER	Trigger
<i>Avena sativa</i>	Casoron G		100.31 (a.s.) (fresh weight)	not applicable		-
Not applicable	Casoron G	above maximum application rates (127 – 72900 (a.s.))		not applicable	-	-
<i>Lycopersicum esculentum</i>	2,6-dichlorobenzamide (BAM)		29 mg metabolite/L (root growth)	not applicable	-	-

The exposure assessment for terrestrial plants is based on emission via drift. However, dichlobenil enters the terrestrial compartment via drainage and run-off. Therefore, the risk assessment of dichlobenil for terrestrial plants is not relevant.

Additional studies (e.g. semi-field or field studies)

No data submitted

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	end point
Activated sludge	3h-EC ₅₀ : > 21 mg a.s./L (respiration inhibition)

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	Dichlobenil
water	Dichlobenil; the metabolites 4-chloro-2(3H)benzoxazolone and 2-chlorobenzoic acid could not be assessed, data is required
sediment	-
groundwater	Dichlobenil

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

Active substance

RMS/peer review proposal

N, R51

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APPENDIX 4

DICHLOBENIL

ASSESSMENT OF RELEVANCE OF ENVIRONMENTAL METABOLITES

WARNING: This document forms part of an EC evaluation data package and should not be used in isolation. Registration must not be granted on the basis of this document.

Relevance of the environmental metabolites of chlothalonil according to the Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC (Sanco/221/2000, rev.10, 25/02/2003)

The aim of this document is to sequentially assess the potential relevance in terms of pesticidal activity, genotoxic potential and toxicological effects of the environmental metabolites of dichlobenil. The draft working document "Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC" issued on 25 February 2003 as Revision 10 was applied.

Step 1: Exclusion of degradation products of no concern

Could not be excluded

Step 2: Quantification of potential groundwater contamination

PEC_{gw}

Based on chapter B.8.6 the PEC_{gw} for all relevant scenarios for 2,6-dichlorobenzamide (BAM) are given in the next table and will be used for the assessment of the relevance of this metabolite.

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

FOCUS PEARL 3.3.3 / Vines	Scenario	Parent (µg/L)	2,6-dichlorobenzamide (BAM) (µg/L)
	Chateaudun	0.288	340.961
	Hamburg	0.191	380.348
	Kremsmünster	0.107	302.933
	Piacenza	2.693	290.500
	Porto	< 0.001	84.149
	Sevilla	0.180	278.559
	Thiva	0.3174	262.178

FOCUS PEARL 3.3.3 / Non-crops	Scenario	Parent (µg/L)	2,6-dichlorobenzamide (BAM) (µg/L)
	Chateaudun	< 0.001	284.050
	Hamburg	0.061	364.929
	Jokioinen	< 0.0012	324.477
	Kremsmünster	0.033	293.002
	Okehampton	0.0742	287.690
	Piacenza	0.327	284.115
	Porto	< 0.001	80.079
	Sevilla	< 0.001	180.728
	Thiva	< 0.001	183.314

Step 3: Hazard Assessment: Identification of relevant metabolites

Stage 1 of Step 3: Screening for biological activity

“The goal is to identify metabolites, which have a comparable target activity as the parent active ingredient, and to deal with cases where the parent molecule is the precursor of the active substance. Efficacy testing should be focused on this question on comparing the activity against the biological target. However, for parent compounds with a known range of activities, or for a compound belonging to a totally new group, it may be necessary to test a metabolite in a more extensive screening assay.”

Dichlobenil is the active substance. There are no metabolites or degradation products known which exert the herbicidal effect.

Stage 2 of Step 3: Screening for genotoxicity

“All metabolites that have passed step 1, step 2 and stage 1 of step 3 should be screened for their genotoxic activity by at least the following package of in vitro genotoxicity studies: Ames test, gene mutation test with mammalian cells, and chromosome aberration test. Equivocal results in in vitro studies should be substantiated by in vivo experiments. Mutagenic metabolites (any category) are considered relevant.”

2,6-dichlorobenzamide (BAM)

Several *in vitro* and *in vivo* genotoxicity studies were performed with BAM. All studies, including two Ames tests, a gene mutation test with Chinese hamsters V79 cells, an unscheduled DNA synthesis test with rat primary hepatocytes, and a micronucleus tests *in vivo* (mice) were negative. Overall it is concluded that BAM is non-genotoxic.

Stage 3 of Step 3: Screening for toxicity

“Stage 3 of Step 3 is aimed at the question whether a metabolite has certain toxicological properties, which – from a regulatory perspective qualify for considering it relevant. Reflecting the general concept of this document, a metabolite is considered relevant if it has a similar or a more severe inherent toxicological properties than the parent substance. For pragmatic reasons, the toxicity classification of the parent active substance as determined according to Directive 67/548/EEC is used as a starting point to focus the screening activity.”

The parent active substance dichlobenil is classified as category 3 carcinogen (Carc. Cat. 3; R40). The metabolite BAM is also classified as category 3 carcinogen (Carc. Cat. 3; R40) and is therefore considered a relevant metabolite.

Although the metabolite BAM does not pass stage 3 of step 3, also the ADI for young children might be exceeded (step 4).

Step 4: Exposure assessment - threshold of concern approach

“Metabolites which have not been identified as being relevant according to the hazard screening outlined in Step 3, should be further tested in an exposure assessment to make sure that any contamination of groundwater will not lead to unacceptable exposure of consumers via their drinking water.”

Refinement of the intake of BAM due to consumption of potable water

A worst case intake of BAM through the consumption of BAM-containing drinking water derived from ground water is 0.38 mg/L. By consuming 1L water/day, the ADI for young children might be filled for 101%. By consuming 2L water/day, the ADI might be filled for 202%. Since BAM is classified as a category 3 carcinogen (Carc. Cat. 3; R40) and is considered a relevant metabolite, an unacceptable risk for young children consuming this water was identified.

Conclusion:

Following the criteria outlined in revision 10 “Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC”:

2,6-dichlorobenzamide (BAM) cannot be qualified as non-relevant metabolite of dichlobenil.

References relied on

Annex point / reference no.	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data protection claimed Y/N	Owner
	-	2003	Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC (Sanco/221/2000 –rev.10, 25 February 2003)	-	-

LEVEL 3

Dichlobenil

PROPOSAL FOR THE DECISION

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3 Proposed decision with respect to the application for inclusion of the active substance in Annex I

3.1 Background to the proposed decision

Dichlobenil (2,6-dichlorobenzonitrile) is the active substance of Casoron® G, a ready-to-use granular formulation containing 6.75% (w/w) Dichlobenil.

Casoron® G is proposed for use as a selective herbicide in grapes and as herbicide for total weed control on non-crop land (e.g. industrial sites, roadsides, railway tracks, along fences).

An ADI for dietary exposure of 0.005 mg/kg bw/day was established. A systemic AOEL of 0.005 mg/kg bw/day can be set. For dichlobenil no ARfD is derived. Based on the AOEL and exposure assessments, for Casoron G safe uses have been identified for operators without PPE for mechanical application of Casoron G in grapes, and also alongside paths and roads, under fence lines and hedges, around buildings and on industrial sites, and around well established trees and shrubs in parks and recreational areas. No risk assessment was performed for bystanders and workers, as it is assumed that no bystander exposure will occur and that no re-entry exposure will occur.

The parent active substance dichlobenil is classified as category 3 carcinogen (Carc. Cat. 3; R40). The metabolite 2,6-dichlorobenzamide (BAM) is also classified as category 3 carcinogen (Carc. Cat. 3; R40) and is therefore considered a relevant metabolite.

The provided residue data and dietary exposure estimates will prevent the inclusion of dichlobenil in Annex I. A worst case intake of BAM through the consumption of BAM-containing drinking water derived from ground water is 0.38 mg/L. By consuming 1L water/day, the ADI for young children might be filled for 101%. By consuming 2L water/day, the ADI might be filled for 202%. Since BAM is classified as a category 3 carcinogen (Carc. Cat. 3; R40) and is considered a relevant metabolite, an unacceptable risk for young children consuming this water was identified.

The use of dichlobenil, consistent with good plant protection practice, will not have any unacceptable effects on the environment (fate and behaviour). However a potential for leaching is demonstrated for the metabolite 2,6-dichlorobenzamide in all scenarios.

At this stage no safe use can be established for ecotoxicology.

3.2 Proposed decision concerning inclusion in Annex I

[REDACTED]

[REDACTED]

3.3 Rational for the postponement of the decision to include the active substance in Annex I, or for the conditions and restrictions to be associated with a proposed inclusion in Annex I, as appropriate

[REDACTED]

The information in sections 3.2 and 3.3 has been removed upon request by the EU Commission as it relates to risk management recommendations or proposals.

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LEVEL 4

Dichlobenil

DEMAND FOR FURTHER INFORMATION

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4 Further information to permit a decision to be made, or to support a review of the conditions and restrictions associated with the proposed inclusion in Annex I

4.1 Identity of the active substance

No further information required.

4.2 Physical and chemical properties of the active substance

No further information required.

Physical and chemical properties of the plant protection product: CASORON G

No further information required.

4.3 Data on application and further information

No further information required.

4.4 Classification, packaging and labelling

Sufficient data available. No further information required.

4.5 Methods of analysis

Analytical method for the determination of impurities in the technical material:

Confidential information - see Volume 4.

The study is not considered suitable for the overall evaluation, due to the shortcomings in the documentation of the method validation (see volume 4, C1.2.4).

Analytical methods for products of animal origin:

Depending on the outcome on the requested animal metabolism and/or feed intake studies, a validated analytical method for the determination of the relevant residues in the relevant animal matrices has to be submitted.

4.6 Toxicology and metabolism

Active substance

Sufficient data available. No further information required.

Plant protection product

Sufficient data available. No further information required.

4.7 Residue data

Residues in plants

Based on the soil degradation data for Dichlobenil and BAM, an accumulation of especially the metabolite in the ground over more than one growing season is likely and has to be investigated. The performance of a study with repeated application in successive growing seasons is therefore required. The outcome of that study can influence the view on the MRL setting as performed based on the currently available data of only one growing season per trial site as well as the necessity of waiting periods.

Livestock metabolism and feeding studies

No information about metabolism, distribution and expression of residues in livestock is available. However, based on the intended use of Dichlobenil in grapes, intake of residues by livestock can occur due to feeding of dry/wet grape pomace to dairy and beef cattle. In the residue trials relevant levels ($>LOQ$) of the metabolite BAM were found in grapes and the results of the processing study indicate an concentration of these content in fruit pomace. Based on theses results, relevant intake levels >0.1 mg/kg dry feed were calculated for cattle. Therefore, data on the metabolism, distribution and expression of residues of BAM in ruminants have to be submitted.

In case these data indicate that significant residues (≥ 0.01 mg/kg) may occur in any edible part of the animal after intake of the residue levels in potential feeding stuff at the 1x dose rate, a feeding study with BAM in ruminants will be required as well.

Storage stability

All plant extracts in the study of Gillis 2004 were stored over a considerable amount of time at $-18^{\circ}C$. Data which allow the assessment of the influence of these storage conditions on the residue levels as measured and documented in the report have to be submitted.

Notifier already stated that 4 further trials are being performed. Probably this question can be answered by performing the right controls and/or using shorter storage times. Furthermore, depending on the outcome on the requested animal metabolism and/or feed intake studies, data on the storage stability of the relevant residue(s) in the relevant animal matrices may have to be submitted.

Processing – nature of residue

No information on the effects of processing on the nature of residue is submitted. It has to be investigated if the chemical nature of the residue in wine is likely to be different from that in the raw agricultural commodity. Information on the effects of processing on the nature of residue during fermentation has to be submitted.

Refinement of the intake of BAM due to consumption of potable water

A worst case intake of BAM through the consumption of BAM-containing drinking water derived from ground water is 0.38 mg/L (see B.8.2). By consuming 1L water/day, the ADI for young children might be filled for 101%. By consuming 2L water/day, the ADI might be filled for 202%. Since BAM is classified as a category 3 carcinogen (Carc. Cat. 3; R40) and is considered a relevant metabolite, an unacceptable risk for young children consuming this water was identified.

It is recommended to make an overview of clearing methodology of processing of ground water and surface water into potable water, throughout the European Union, to make a refinement of this intake calculation.

4.8 Environmental fate and behaviour

No further information required.

4.9 Ecotoxicology

Birds

A refined risk assessment is required for the long term risk assessment for birds exposed to dichlobenil via intentional grit consumption.

A refined risk assessment is required for the long term risk assessment for earthworm eating birds for the intended uses of dichlobenil. RMS would suggest that data on measured residues in earthworms after exposure to Casoron G according to the appropriate dose rates are submitted for this purpose. Further the notifier is requested, if they still want them to be used, to submit the relevant parts of the public literature references as used in their refined risk assessment*. As one of the references is in French, an English summary should be submitted as well for this reference.

* Reference 1:

Cramp, S et al -1988 – Handbook of the Birds of Europe and the Middle East and North Africa, The birds of the Western Palaearctic Volume V Tyrant Flycatchers to Thrushes – Oxford University Press.

Reference 2:

Géroudet, P. – 1998 – Les Passereaux d'Europe – Tome 1: Des coucous aux Merles and Tome 2: De la Bouscarle aux Bruants 4th edition, updated by M. Cuisin – Delachaux et Niestlé Ed.

Mammals

A refined risk assessment is required for earthworm eating mammals for the intended uses of dichlobenil. RMS would suggest that data on measured residues in earthworms after exposure to Casoron G according to the appropriate dose rates are submitted for this purpose.

Soil non-target macro-organisms

The notifier is requested to submit data on the effects of soil metabolite BAM on the decomposition of organic matter in soil (e.g. a litterbag study).

Soil micro-organisms

The notifier is requested to provide new data on the effects on soil microflora for dichlobenil (N-mineralisation) and soil metabolite 2,6-dichlorobenzamide (BAM) (C- and N-mineralisation).

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