CYPRODINIL

(4-cyclopropyl-6-methyl-pyrimidin-2-yl)-phenyl-amine
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## CYPRODINIL

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DISCLAIMER¹

FAO specifications are developed with the basic objective of promoting, as far as practicable, the manufacture, distribution and use of pesticides that meet basic quality requirements.

Compliance with the specifications does not constitute an endorsement or warranty of the fitness of a particular pesticide for a particular purpose, including its suitability for the control of any given pest, or its suitability for use in a particular area. Owing to the complexity of the problems involved, the suitability of pesticides for a particular purpose and the content of the labelling instructions must be decided at the national or provincial level.

Furthermore, pesticides which are manufactured to comply with these specifications are not exempted from any safety regulation or other legal or administrative provision applicable to their manufacture, sale, transportation, storage, handling, preparation and/or use.

**FAO disclaims any and all liability for any injury, death, loss, damage or other prejudice of any kind that may arise as a result of, or in connection with, the manufacture, sale, transportation, storage, handling, preparation and/or use of pesticides which are found, or are claimed, to have been manufactured to comply with these specifications.**

Additionally, FAO wishes to alert users to the fact that improper storage, handling, preparation and/or use of pesticides can result in either a lowering or complete loss of safety and/or efficacy.

FAO is not responsible, and does not accept any liability, for the testing of pesticides for compliance with the specifications, nor for any methods recommended and/or used for testing compliance. As a result, FAO does not in any way warrant or represent that any pesticide claimed to comply with a FAO specification actually does so.

¹ This disclaimer applies to all specifications published by FAO.
INTRODUCTION

FAO establishes and publishes specifications* for technical material and related formulations of agricultural pesticides, with the objective that these specifications may be used to provide an international point of reference against which products can be judged either for regulatory purposes or in commercial dealings.

Since 1999 the development of FAO specifications follows the New Procedure, described in the 5th edition of the “Manual on the development and use of FAO specifications for plant protection products” (FAO Plant Production and Protection Page No. 149). This New Procedure follows a formal and transparent evaluation process. It describes the minimum data package, the procedure and evaluation applied by FAO and the Experts of the FAO/WHO Joint Meeting on Pesticide Specifications (JMPS). [Note: prior to 2002, the Experts were of the FAO Panel of Experts on Pesticide Specifications, Registration Requirements, Application Standards and Prior Informed Consent, which now forms part of the JMPS, rather than the JMPS.]

FAO Specifications now only apply to products for which the technical materials have been evaluated. Consequently from the year 2000 onwards the publication of FAO specifications under the New Procedure has changed. Every specification consists now of two parts namely the specifications and the evaluation report(s):

**PART ONE:** The Specification of the technical material and the related formulations of the plant protection product in accordance with chapter 4, 5 and 6 of the 5th edition of the “Manual on the development and use of FAO specifications for plant protection products”.

**PART TWO:** The Evaluation Report(s) of the plant protection product reflecting the evaluation of the data package carried out by FAO and the JMPS. The data are to be provided by the manufacturer(s) according to the requirements of Appendix A, Annex 1 or 2 of the “Manual on the development and use of FAO specifications for plant protection products” and supported by other information sources. The Evaluation Report includes the name(s) of the manufacturer(s) whose technical material has been evaluated. Evaluation reports on specifications developed subsequently to the original set of specifications are added in a chronological order to this report.

FAO specifications under the New Procedure do not necessarily apply to nominally similar products of other manufacturer(s), nor to those where the active ingredient is produced by other routes of manufacture. FAO has the possibility to extend the scope of the specifications to similar products but only when the JMPS has been satisfied that the additional products are equivalent to that which formed the basis of the reference specification.

Specifications bear the date (month and year) of publication of the current version. Dates of publication of the earlier versions, if any, are identified in a footnote. Evaluations bear the date (year) of the meeting at which the recommendations were made by the JMPS.

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<td>CYPRODINIL WATER DISPERSIBLE GRANULES (JUNE 2009)</td>
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</table>
CYPRODINIL

INFORMATION

ISO common name
Cyperdine (ISO 1750 published)

Chemical name(s)
IUPAC (4-cyclopropyl-6-methyl-pyrimidin-2-yl)-phenyl-amine
CA 4-cyclopropyl-6-methyl-N-phenyl-2-pyrimidinamine

Synonyms
None

Structural formula

\[
\text{\begin{array}{c}
\text{\includegraphics[width=0.5\textwidth]{structural_formula.png}}
\end{array}}
\]

Molecular formula
\( \text{C}_{14}\text{H}_{15}\text{N}_{3} \)

Relative molecular mass
225.3 g/mol

CAS Registry number
121552-61-2

CIPAC number
511

Identity tests
Retention times of cyprodinil in reversed phase HPLC or in GC using a widebore capillary column with flame ionization detection, respectively, and IR spectroscopy.
This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (511/2009). It should be applicable to relevant products of these manufacturers but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (511/2009) as PART TWO forms an integral part of this publication.

1 Description
The material shall consist of cyprodinil together with related manufacturing impurities, in the form of white to yellow flakes and shall be free from visible extraneous matter and added modifying agent.

2 Active ingredient
2.1 Identity tests (CIPAC 511/TC/M/-, Note 1)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.2 Cyprodinil content (CIPAC 511/TC/M/-, Note 1)

The cyprodinil content shall be declared (not less than 990 g/kg) and, when determined, the average measured content shall not be lower than the declared minimum content.

Note 1 Methods for the identification and determination of cyprodinil content in TC, EC and WG formulations were presented at the CIPAC Meeting in 2008 and provisionally adopted as CIPAC method. Prior to their publication in Handbook N, copies of the methods may be obtained through the CIPAC website, https://www.cipac.org/index.php/methods-publications/pre-published-methods
This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (511/2009). It should be applicable to relevant products of these manufacturers but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (511/2009) as PART TWO forms an integral part of this publication.

1. Description

The material shall consist of technical cyprodinil, complying with the requirements of FAO/WHO specification 511/TC (2009), dissolved in suitable solvents, together with any other necessary formulants. It shall be in the form of a clear to slightly hazy, stable homogeneous liquid, free from visible suspended matter and sediment, to be applied as an emulsion after dilution with water.

2. Active ingredient

2.1. Identity tests (CIPAC 511/EC/M/-, Note 1)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.2. Cyprodinil content (CIPAC 511/EC/M/-, Note 1)

The cyprodinil content shall be declared (g/kg or g/l at 20 ± 2°C, Note 2) and when determined, the average content measured shall not differ from that declared by more than the following tolerances:

<table>
<thead>
<tr>
<th>Declared content, g/kg or g/l at 20 ± 2°C</th>
<th>Permitted tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>above 250 g/l up to 500 g/l</td>
<td>± 5% of the declared content</td>
</tr>
</tbody>
</table>
3. Physical properties

3.1. Emulsion stability and re-emulsification (MT 36.3)

The formulation, when diluted at 30 ± 2°C with CIPAC Standard Waters A and D, shall comply with the following:

<table>
<thead>
<tr>
<th>Time after dilution</th>
<th>Limits of stability</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 h</td>
<td>Initial emulsification complete</td>
</tr>
<tr>
<td>0.5 h</td>
<td>‘Cream’, maximum: 0.5 ml</td>
</tr>
<tr>
<td>2.0 h</td>
<td>‘Cream’, maximum: 0.5 ml</td>
</tr>
<tr>
<td></td>
<td>‘Free oil’, maximum: trace</td>
</tr>
<tr>
<td>24 h</td>
<td>Re-emulsification complete</td>
</tr>
<tr>
<td>24.5 h</td>
<td>‘Cream’, maximum: 2 ml</td>
</tr>
<tr>
<td></td>
<td>‘Free oil’, maximum: trace</td>
</tr>
</tbody>
</table>

Note: tests after 24 h are required only where the results at 2 h are in doubt

3.2. Persistent foam (MT 47.2) (Note 3)

Maximum: 60 ml after 1 minute.

4. Storage stability

4.1. Stability at 0°C (MT 39.3)

After storage at 0 ± 2°C for 7 days, the volume of solid and/or liquid which separates shall not be more than 0.3 ml.

4.2 Stability at elevated temperature (MT 46.3)

After storage at 54 ± 2°C for 14 days (Note 4), the determined average active ingredient content must not be lower than 95%, relative to the determined average content found before storage (Note 4) and the formulation shall continue to comply with the clause for:
- emulsion stability and re-emulsification (3.1).

Note 1 Methods for the identification and determination of cyprodinil
content in TC, EC and WG formulations were presented at the CIPAC Meeting in 2008 and provisionally adopted as CIPAC method. Prior to their publication in Handbook N, copies of the methods may be obtained through the CIPAC website, [https://www.cipac.org/index.php/methods-publications/pre-published-methods](https://www.cipac.org/index.php/methods-publications/pre-published-methods).

**Note 2**  If the buyer requires both g/kg and g/l at 20°C, then in case of dispute the analytical results shall be calculated as g/kg.

**Note 3**  The mass of the sample to be used in the test should be specified at the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D.

**Note 4**  Samples of the product taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.
1 Description
The material shall consist of a homogeneous mixture of technical cyprodinil, complying with the requirements of the FAO/WHO specification 511/TC, together with carriers and any other necessary formulants. It shall be in the form of cylindrical granules with approximate diameter of 0.4 – 1.2 mm and length 2 – 8mm, for application after disintegration and dispersion in water. The formulation shall be dry, free-flowing, essentially non-dusty, and free from visible extraneous matter and hard lumps.

2 Active ingredient
2.1 Identity tests (CIPAC 511/WG/M/-, Note 1)
The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.2 Cyprodinil content (CIPAC 511/WG/M/-, Note 1)
The cyprodinil content shall be declared (g/kg) and, when determined, the average content measured shall not differ from that declared by more than the appropriate tolerance, given in the table of tolerances.

<table>
<thead>
<tr>
<th>Declared content</th>
<th>Permitted tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Above 250 up to 500 g/kg</td>
<td>+/- 5% of the declared content</td>
</tr>
<tr>
<td>above 500 g/kg</td>
<td>± 25 g/kg</td>
</tr>
</tbody>
</table>

Note: In each range the upper limit is included

3 Physical properties
3.1 Wettability (MT 53.3)
The formulation shall be completely wetted in 30 sec.

3.2 Wet sieve test (MT 185)
Maximum: 0.2% retained on a 75 µm test sieve.

3.3 Degree of dispersion (MT 174)
Dispersibility: minimum 60% after 1 minute of stirring.

3.4 Suspensibility (MT 168, MT 184) (Notes 2 & 3)
A minimum of 60% shall be in suspension after 30 min in CIPAC Standard Water D at 30 ± 2°C

3.5 **Persistent foam** (MT 47.2) (Note 4)
   Maximum: 30ml after 1 minute.

3.6 **Dustiness** (MT 171) (Note 5)
   Essentially non-dusty.

3.7 **Flowability** (MT 172)
   100% of the formulation shall pass through a 5 mm test sieve after 20 drops of the sieve.

3.8 **Attrition resistance** (MT 178.2)
   Minimum: 85% attrition resistance.

4 **Storage stability**

4.1 **Stability at elevated temperature** (MT 46.3)
   After storage at 54 ± 2°C for 14 days (Note 6), the determined average active ingredient content must not be lower that 95% relative to the determined average content found before storage (Note 6) and the formulation shall continue to comply with the clauses for:
   - wet sieve test (3.2),
   - degree of dispersion (3.3),
   - suspensibility (3.4),
   - dustiness (3.6),
   - attrition resistance (3.8).

---

**Note 1** Methods for the identification and determination of cyprodinil content in TC, EC and WG formulations were presented at the CIPAC Meeting in 2008 and provisionally adopted as CIPAC method. Prior to their publication in Handbook N, copies of the methods may be obtained through the CIPAC website, [https://www.cipac.org/index.php/methods-publications/pre-published-methods](https://www.cipac.org/index.php/methods-publications/pre-published-methods)

**Note 2** The formulation should be tested at the highest and lowest rates of use recommended by the supplier, provided this does not exceed the conditions given in methods MT 168 and MT 184.

**Note 3** Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, the simpler gravimetric method, MT 168, may be used on a routine basis provided that it has been shown to give equal results to those of chemical assay. In case of dispute, chemical assay shall be the "referee method".
Note 4  The mass of sample to be used in the test should be specified at the highest rate recommended by the supplier. The test is to be conducted in CIPAC standard water D.

Note 5  Measurement of dustiness must be carried out on the sample "as received" and, where practicable, the sample should be taken from a newly opened container, because changes in the water content of samples may influence dustiness significantly. The optical method, MT 171.2, usually shows good correlation with the gravimetric method, MT 171.1, and can, therefore, be used as an alternative where the equipment is available. Where the correlation is in doubt, it must be checked with the formulation to be tested. In case of dispute the gravimetric method shall be used.

Note 6  Analysis of the formulation, before and after the storage stability test, should be carried out concurrently (i.e. after storage) to reduce analytical error.
PART TWO

EVALUATION REPORTS

CYPRODINIL

FAO/WHO evaluation report based on submission of information from Syngenta (TC, EC, WG) 12
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Recommendation

The Meeting recommended that:

- The cyprodinil specifications for TC, EC and WG proposed by Syngenta, as amended, should be adopted as FAO specifications.

Appraisal

The meeting considered data submitted in 2007 by Syngenta Crop Protection AG, for the development of new FAO specifications for cyprodinil TC, EC and WG. The data and proposed specifications submitted were in accordance with the requirements of the revised 1st edition of the Manual on development and use of FAO and WHO specifications for pesticides (FAO/WHO Manual, 2006) and supported the draft specifications.

Cyprodinil is currently under patent in many countries.


Technical cyprodinil is a solid, and crystallizes in two different modifications which are designated as “modification A” and “modification B”, respectively. In the technical material, both forms may exist. These modifications show somewhat differing physical-chemical properties like melting point etc. (see Table 1). The crystallization taking place at the end of the manufacturing process is controlled in such a way that predominantly the B modification is formed. This modification shows better stability on storage in the bulk material.

Cyprodinil shows a rather low vapour pressure (crystal modification A: 5.1x10^-4 Pa crystal modification B: 4.7x10^-4 Pa at 25°C). It is moderately soluble in water; the solubility is influenced by pH in the range between 5 and 9. Its octanol/water partition coefficient (log P_{ow}=4.0) is not significantly pH dependent and shows that the molecule is lipophilic, with possibility of bioaccumulation. Cyprodinil is hydrolytically stable in the pH range 4 to 9. The estimated/extrapolated half-life in water under sterile conditions and in the dark is longer than 1 year at 25°C at pH 4, 5, 7 and 9, respectively.

However, cyprodinil is rapidly degraded in water when exposed to UV light with a half life of 13.5 days. The pK_a (base) is 4.44, leading to protonation at pH below this value and being present as a free base at pH above pH 4.4. This explains the weak pH dependence of the P_{ow} with pH at 5, 7 and 9.

The main formulation types available are emulsifiable concentrate (EC) and water dispersible granules (WG).

The Meeting was provided with commercially confidential information on the manufacturing process and five batch analysis data on all impurities present at or
above 1g/kg and their manufacturing limits in the TC. Mass balances ranged from 1001-1007 g/kg in the five batch data. None of the manufacturing impurities considered are, on the basis of information available, of toxicological or environmental concern. These data were declared to be identical to those submitted for registration in Switzerland. The question of the formation of nitrosamines in the manufacturing process was discussed by the Meeting. Based on information provided by the company, the presence of nitrosamines in the TC at levels above 0.5 µg/kg can be excluded. Nitrosamines are therefore not considered as being relevant impurities in cyprodinil TC and formulations.

Residual water in the TC may become a relevant impurity when the material is to be used for EC formulations. However, the manufacturing process leads to a TC with very low water content so the water clause becomes obsolete.

The analytical method for determination of cyprodinil in TC, EC and WG relies on reversed phase HPLC with UV detection at 254 nm. The method and its collaborative validation were presented at the 2008 CIPAC Meeting in Braunschweig, Germany, and adopted as provisional CIPAC Method. Three different identity tests for cyprodinil are provided: retention time in HPLC, in GC and comparison of IR spectra.

Methods to elaborate the physical-chemical properties of the formulation were CIPAC, and all other methods were EU, OECD and EPA.

Issues relating to TC only

A clause for water content was considered unnecessary despite of the TC being used for preparation of EC formulations as the manufacturing process leads to low water content. Similarly, clauses for pH or acidity/alkalinity were considered unnecessary as cyprodinil is not prone to rapid hydrolysis catalysed by excess acid or base.

Issues relating to WG only

The WG is produced with a technology (extrusion) leading to a low dustiness but the limit of the attrition resistance is 85 %, which is considered rather low but may be associated with the production process. On the other the limits for the degree of dispersion and suspensibility are at minimum of 60 which may be attributed to the fact that cyprodinil is often coformulated calling for a certain compromise to guarantee acceptable limits for all actives in the WG formulation.

Issues relating to EC only

No clauses on pH or alkalinity/acidity were considered necessary. The Meeting noted that the limit for persistent foam at maximum value of 60 ml but justified by the company due to the fact that cyprodinil is coformulated with other fungicides.
Uses
Cyprodinil, a member of the anilinopyrimidine group, is a systemic foliar broad spectrum fungicide. It acts as an inhibitor of methionine biosynthesis and interferes in the fungal life cycle by inhibition of penetration and by disruption of mycelial growth in the plant. It has registered uses in many countries on many crops (e.g. agriculture, horticulture, viticulture).

Identity of the active ingredient

ISO common name
Cyprodinil (ISO 1750 published)

Chemical name(s)
IUPAC
(4-cyclopropyl-6-methyl-pyrimidin-2-yl)-phenyl-amine
CA
4-cyclopropyl-6-methyl-N-phenyl-2-pyrimidinamine

Synonyms
none

Structural formula

\[
\text{Molecular formula}
\]
\[C_{14}H_{15}N_3\]

Relative molecular mass
225.3 g/mol

CAS Registry number
121552-61-2

CIPAC number
511

Identity tests
Retention times of cyprodinil in reversed phase HPLC or in GC using a widebore capillary column with flame ionization detection, respectively and IR spectroscopy.
**Physico-chemical properties of pure cyprodinil** (Table 1)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value(s) and conditions</th>
<th>Purity %</th>
<th>Method reference (and technique if the reference gives more than one)</th>
</tr>
</thead>
</table>
| Vapour pressure | Crystal modification A: 5.1 x 10^{-4} Pa at 25 °C  
Crystal modification B: 4.7 x 10^{-4} Pa at 25 °C | 99.9 % | OECD 104, EEC A.4 by extrapolation |
| Melting point, boiling point and/or temperature of decomposition | Melting point: 75.9 °C  
Melting point of crystal mod. A: 71.3 °C  
Melting point of crystal mod. B: 76.4 °C  
Boiling point: >360 °C at 101.325 kPa (at a reduced pressure of 1.96 Pa cyprodinil boils at 100.9 °C)  
Decomposition temperature: No decomposition between room temperature and 150 °C (with and without air) | 99.9 % | OECD 102, EEC A.1  
99.9 % | OECD 103, EEC A.2  
99.2 % | OECD 113 |
| Solubility in water | In buffer solution:  
20 mg/l at 25 °C at pH 5.0  
13 mg/l at 25 °C at pH 7.0  
15 mg/l at 25 °C at pH 9.0  
In pure water:  
16 mg/l at 25 °C at pH 7.6 | 99.9 % | OECD 105, EEC A.6 |
| Octanol/water partition coefficient | log P_{OW} = 3.9 at 25 °C at pH 5.0  
log P_{OW} = 4.0 at 25 °C at pH 7.0  
log P_{OW} = 4.0 at 25 °C at pH 9.0 | 99.9 % | OECD 107 |
| Hydrolysis characteristics | Pyrimidyl ring ^14C-labelled cyprodinil: No degradation at 25 °C in buffered sterilised solutions at pH 5, 7 and 9 within 32 days (in the dark)  
Phenyl ring ^14C-labelled cyprodinil: No degradation at 50 °C in buffered sterilised solutions at pH 4, 7 and 9 within 5 days (in the dark)  
Estimated/extrapolated half-life > 1 year at 25 °C at pH 4, 5, 7 and 9 | 98.7 % | EPA 161-1  
99.2 % | EPA 161-1, OECD 111 (radio-chemical purity) |
### Photolysis Characteristics

Ref. CGA219417/0268 (1994) and CGA219417/0292 (1994)

The photolytic half-lives of cyprodinil were determined at 25 °C in various sterile aqueous solutions using xenon arc light irradiation. The findings were quite variable and sometimes a lag phase was observed. The selected results given below are representative overall values, expressed in Florida (at latitude 30°N) Summer Sunlight Equivalent (FSSE) days.

- **Half-life:** 13.5 days (FSSE) for pyrimidyl ring \(^{14}\)C-labelled cyprodinil in aqueous buffer at pH 7.3 (c\(_o\) = 4.7 ppm).
- **Half-life:** 21.5 days (FSSE) for phenyl ring \(^{14}\)C-labelled cyprodinil in bi-distilled water (c\(_o\) = 4.0 ppm).
- Dark control experiments showed only negligible degradation of cyprodinil.

### Dissociation Characteristics

Ref. CGA219417/0108 (1992) and CGA219417/0878 (1998)

**pKa = 4.44 at 20 °C**

This constant describes the protonation of cyprodinil (neutral form) in aqueous solution. Thus the neutral form is predominantly present at pH above 4.44, the protonated form of cyprodinil at pH below 4.44.
**Chemical composition and properties of cyprodinil technical materials (TC and or TK) (Table 2)**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value/Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturing process, maximum limits for impurities ≥ 1 g/kg, 5 batch analysis data</td>
<td>Confidential information supplied and held on file by FAO. Mass balances were 100.1 – 100.7 %.</td>
</tr>
<tr>
<td>Declared minimum [a.i.] content</td>
<td>990 g/kg</td>
</tr>
<tr>
<td>Relevant impurities ≥ 1 g/kg and maximum limits for them</td>
<td>None.</td>
</tr>
<tr>
<td>Relevant impurities &lt; 1 g/kg and maximum limits for them:</td>
<td>None.</td>
</tr>
<tr>
<td>Stabilisers or other additives and maximum limits for them:</td>
<td>None.</td>
</tr>
<tr>
<td>Melting temperature range of the TC</td>
<td>73 - 76°C</td>
</tr>
</tbody>
</table>
ANNEX 1

HAZARD SUMMARY PROVIDED BY THE PROPOSER
Note: the proposer provided written confirmation that the toxicological data included in the following summary were derived from cyprodinil having impurity profiles similar to those referred to in Table 2, above.
Table 3. Toxicology profile of the cyprodinil technical material, based on acute toxicity, irritation and sensitization

<table>
<thead>
<tr>
<th>Species</th>
<th>Test</th>
<th>Duration and conditions or guideline adopted</th>
<th>Result cyprodinil technical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat (m,f)</td>
<td>Acute Oral LD₅₀, (OECD 401)</td>
<td>14d observation period; purity= 99.5%; one dose level= 2000 mg/kg bw.</td>
<td>LD₅₀ &gt;2000 mg/kg bw</td>
</tr>
<tr>
<td></td>
<td>Ref. CGA219417/0020</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rat (m,f)</td>
<td>Acute Dermal LD₅₀, (OECD 402)</td>
<td>14d observation period; purity= 99.5%; limit dose= 2000 mg/kg bw.</td>
<td>LD₅₀ &gt; 2000 mg/kg bw</td>
</tr>
<tr>
<td></td>
<td>Ref. CGA219417/0021</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rat (m,f)</td>
<td>Acute Inhalation (4h) LC₅₀, (OECD 403)</td>
<td>4h exposure, 14d observation period; purity= 99.5%; nominal concentration= 1684 mg/m³, analytical concentration= 1203 mg/m³</td>
<td>LC₅₀ &gt; 1200 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Ref. CGA219417/0026</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rabbit</td>
<td>Skin irritation, (OECD 404)</td>
<td>1-72 h; purity= 99.5%; dose= 0.5g/animal</td>
<td>Non-irritating</td>
</tr>
<tr>
<td></td>
<td>Ref. CGA219417/0022</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rabbit</td>
<td>eye irritation, (OECD 405)</td>
<td>1-72 h; purity= 99.5%; 40 mg/eye</td>
<td>Non-irritating</td>
</tr>
<tr>
<td></td>
<td>Ref. CGA219417/0023</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Guinea – pig</td>
<td>skin sensitization (maximization test), (OECD 406)</td>
<td>48h; purity= 99.2%; dose= 50% ;see study for details</td>
<td>Sensitization of 45 % of test animals. “May cause sensitisation by skin contact”</td>
</tr>
<tr>
<td></td>
<td>Ref. CGA219417/0746</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Cyprodinil is not classified as dangerous if swallowed, in contact with skin or by inhalation, and is not irritating to skin or eyes. The substance is classified as “may cause sensitisation by skin contact”.
Table 4. **Toxicology profile of technical cyprodinil based on repeated administration (sub-acute to chronic)**

<table>
<thead>
<tr>
<th>Species</th>
<th>Test</th>
<th>Duration and conditions or guideline adopted</th>
<th>Result cyprodinil technical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Short term toxicity Ref. CGA219417/0045</td>
<td>3m dietary; OECD 408, Tif:RAIf, (SPF) rat; purity= 99.5%; dose levels: 0, 50, 300, 2000, 12000 ppm</td>
<td>NOEL = 50 ppm (3.14/3.24 mg/kg bw/d)</td>
</tr>
<tr>
<td>Dog</td>
<td>Short term toxicity Ref. CGA219417/0044</td>
<td>3m dietary; OECD 409; FIFRA 82-1, Beagle dog; purity= 99.5%; dose levels: 0, 200, 1500, 7000, 20000 ppm</td>
<td>NOAEL = 7000ppm (210/232 mg/kg bw/d)</td>
</tr>
<tr>
<td>Dog</td>
<td>Short term toxicity Ref. CGA219417/0122</td>
<td>1 year dietary; FIFRA 83-1, OECD 452, Beagle dog; purity= 99.6%; dose levels: 0, 25, 250, 1500, 20000 ppm</td>
<td>NOEL = 2500ppm (65.5/68.0 mg/kg bw/d)</td>
</tr>
<tr>
<td>Mouse</td>
<td>Carcinogenicity Ref. CGA219417/0239</td>
<td>18m dietary; FIFRA 83-2, OECD 451; animals: Tif:MAGf; purity= 99.6%; dose levels: 0, 10, 150, 2000, 5000ppm</td>
<td>No carcinogenic effects NOEL = 2000ppm (212.4/196.3 mg/kg bw/d)</td>
</tr>
<tr>
<td>Rat</td>
<td>Chronic toxicity / Carcinogenicity Ref. CGA219417/0252</td>
<td>2 year dietary, FIFRA 83-5, OECD 453, 1981; animals: Tif:RAIf; purity= 99.6%; dose levels: 0, 5, 75, 1000, 2000 ppm</td>
<td>Not carcinogenic NOEL =75 ppm (2.70/3.22 mg/kg bw/d)</td>
</tr>
<tr>
<td>Species</td>
<td>Test</td>
<td>Duration and conditions or guideline adopted</td>
<td>Result cyprodinil technical</td>
</tr>
<tr>
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</tr>
<tr>
<td>Rat</td>
<td>Reproductive toxicity Ref. CGA219417/0162</td>
<td>2 generation, dietary; OECD 416, FIFRA 83-4; animals: Tif:RAI rat; purity= 99.5%; dose levels: 0, 10, 100, 1000, 4000 ppm</td>
<td>No effects on reproductive parameters NOAEL reproductive, parental,offspring =1000 ppm (51.0-144.6 /70.6-153.5 mg/kg bw/d)</td>
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<tr>
<td>Rat</td>
<td>Developmental toxicity Ref. CGA219417/0027</td>
<td>Gavage feeding; OECD 414, FIFRA 83-3; animals: Tif:RAIf rat; purity= 99.5%; dose levels: 0, 20, 200, 1000 mg/kg bw/day</td>
<td>Not teratogenic NOEL for maternal toxicity = 200 mg/kg bw/d NOEL for developmental toxicity = 200 mg/kg bw/d</td>
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<td>Rabbit</td>
<td>Developmental toxicity Ref. CGA219417/0039</td>
<td>Gavage feeding; OECD 414, FIFRA 83-3; animals: Russian Chbb:HM (SPF); purity= 99.5%; dose levels: 0, 5, 30, 150, 400 mg/kg bw/day</td>
<td>Not teratogenic NOEL for maternal toxicity = 150 mg/kg bw/d NOEL for developmental toxicity = 400 mg/kg bw/d</td>
</tr>
<tr>
<td>Species</td>
<td>Test</td>
<td>Conditions / Dose levels</td>
<td>Result cyprodinil</td>
</tr>
<tr>
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<tr>
<td>Bacterial gene mutation</td>
<td>Salmonella/E.coli in vitro (OECD 471) Ref. CGA219417/0025</td>
<td>0 to 5000 µg/plate, +/- activation; purity= 99.5%</td>
<td>Not mutagenic</td>
</tr>
<tr>
<td>Chinese hamster</td>
<td>Gene mutation in V79 cells in vitro (OECD 476) Ref. CGA219417/0028</td>
<td>0 to 30 µg/ml, - activation</td>
<td>Not mutagenic</td>
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<tr>
<td></td>
<td></td>
<td>0 to 150 µg/ml, + activation; purity= 99.5%</td>
<td></td>
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<tr>
<td>Chinese hamster</td>
<td>Cytogenetic test in Chinese hamster cells in vitro (OECD 473) Ref. CGA219417/0040</td>
<td>0 to 200 µg/ml, - activation</td>
<td>Not clastogenic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0 to 200 µg/ml, + activation; purity= 99.5%</td>
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<tr>
<td>Rat hepatocytes</td>
<td>DNA repair on rat hepatocytes in vitro (OECD 482) Ref. CGA219417/0058</td>
<td>0 to 4800 µg/ml; purity= 99.5%</td>
<td>Not genotoxic</td>
</tr>
<tr>
<td>Species</td>
<td>Test</td>
<td>Conditions / Dose levels</td>
<td>Result cyprodinil</td>
</tr>
<tr>
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<td>----------------------------------------------------------------------</td>
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<tr>
<td>Mouse somatic cells</td>
<td>Micronucleus test mouse bone marrow in vivo (OECD 474) Ref. CGA219417/0029</td>
<td>0, 1250, 2500, 5000 mg/kg bw; purity= 99.5%</td>
<td>Not clastogenic</td>
</tr>
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</table>

Cyprodinil was tested for different endpoints including gene mutation, chromosome aberration and DNA-damage in bacteria in vitro and in mammalian cells in vitro and in vivo. No mutagenic effects were noted in any test in vitro and in vivo.
Table 6. Ecotoxicology profile of cyprodinil

<table>
<thead>
<tr>
<th>Species</th>
<th>Test</th>
<th>Duration and conditions</th>
<th>Result cyprodinil</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Anas platyrhynchos</em> (mallard duck)</td>
<td>Acute oral</td>
<td>Observation: 14 days; EPA Pesticide Assessment Guidelines, E, 1982; purity: 99.5%; Treatment levels: 125, 250, 500, 1000 and 2000 mg a.s./kg bw</td>
<td>LD\textsubscript{50} = &gt; 500 mg/kg bw Vomiting at dose levels of 1000 mg/kg and above</td>
</tr>
<tr>
<td></td>
<td>Ref. CGA219417/006</td>
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<tr>
<td><em>Colinus virginianus</em> (Bobwhite quail)</td>
<td>Acute oral</td>
<td>Observation: 14 days; EPA Pesticide Assessment Guidelines, E, 1982; purity: 99.5%; Treatment levels: 125, 250, 500, 1000 and 2000 mg a.s./kg bw</td>
<td>LD\textsubscript{50} = &gt; 2000 mg/kg bw</td>
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<tr>
<td></td>
<td>CGA219417/006</td>
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<tr>
<td><em>Anas platyrhynchos</em> (Mallard duck)</td>
<td>Short term</td>
<td>Treatment 5d / observation 3 d; EPA Pesticide Assessment Guidelines, E, 1982; purity: 99.5%; Treatment levels: 163, 325, 650, 1300, 2600, 5200 mg/kg feed</td>
<td>LC\textsubscript{50} = &gt; 5200 mg/kg feed</td>
</tr>
<tr>
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<td>CGA219417/006</td>
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<tr>
<td><em>Colinus virginianus</em> (Bobwhite quail)</td>
<td>Short term</td>
<td>Treatment 5d / observation 3 d; EPA Pesticide Assessment Guidelines, E, 1982; purity: 99.5%; Treatment levels: 163, 325, 650, 1300, 2600 and 5200 mg/kg feed</td>
<td>LC\textsubscript{50} = &gt; 5200 mg/kg feed</td>
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<td>CGA219417/006</td>
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<tr>
<td><em>Colinus virginianus</em> (Bobwhite quail)</td>
<td>Reproduction</td>
<td>EPA Pesticide Assessment Guidelines Section 71-4 (1982); purity: 99.2%; Treatment levels: 100, 300, 600 mg/kg diet</td>
<td>NOAEC= 600mg/kg diet</td>
</tr>
<tr>
<td></td>
<td>CGA219417/047</td>
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</tr>
<tr>
<td>Species</td>
<td>Test</td>
<td>Duration and conditions</td>
<td>Result cyprodinil tech</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-------------------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------</td>
</tr>
<tr>
<td><em>Anas platyrhynchos</em></td>
<td>Chronic reproduction test</td>
<td>EPA Pesticide Assessment Guidelines Section 71-4 (1982); purity = 99.2%; Treatment levels: 100, 300, 600 mg/kg diet</td>
<td>NOAEC = 600 mg/kg diet</td>
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<tr>
<td><em>(mallard duck)</em></td>
<td>CGA219417/0477</td>
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</tr>
<tr>
<td><em>Oncorhynchus mykiss</em></td>
<td>Acute</td>
<td>96h static exposure/ freshwater; OECD 203; purity = 99.2%; dose = 0.28, 0.511, 0.86, 1.48, 2.72 mg/l</td>
<td>$LC_{50} = 2.41$ mg a.s./l</td>
</tr>
<tr>
<td><em>(Rainbow trout)</em></td>
<td>CGA219417/0486</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Lepomis macrochirus</em></td>
<td>Acute</td>
<td>96h static exposure/ freshwater; OECD 203; purity = 99.2%; dose = 0.285, 0.445, 0.922, 1.35, 2.55 mg/l</td>
<td>$LC_{50} = 2.17$ mg a.s./l</td>
</tr>
<tr>
<td><em>(Bluegill sunfish)</em></td>
<td>CGA219417/0507</td>
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<tr>
<td><em>Lepomis macrochirus</em></td>
<td>Acute</td>
<td>96h flow-through exposure/ freshwater; OECD 203; purity = 99.8%; dose = 0.631, 1.00, 1.64, 2.70, 4.68 mg/l</td>
<td>$LC_{50} = 3.2$ mg a.s./l</td>
</tr>
<tr>
<td><em>(Bluegill sunfish)</em></td>
<td>CGA219417/0651</td>
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<td></td>
</tr>
<tr>
<td><em>Pimephales promelas</em></td>
<td>Early-life-stage</td>
<td>Early-life-stage toxicity; 36d flow-through exposure, US-EPA FIFRA 72-4(a); purity: 99.2%; dose = 0.114, 0.231, 0.455, 0.940 and 1.91 mg/L</td>
<td>NOEC = 0.231 mg a.s/l</td>
</tr>
<tr>
<td><em>Fathead Minnow</em></td>
<td>CGA219417/0653</td>
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<tr>
<td><em>Daphnia magna</em></td>
<td>Acute</td>
<td>Static freshwater, 48h exposure; US-EPA FIFRA 72-2(2) 1982; purity: 96.2 radiolabelled material; dose = 0.022, 0.034, 0.061, 0.081 and 0.126 mg/l</td>
<td>$EC_{50} = 0.033$ mg a.s./l</td>
</tr>
<tr>
<td><em>(Water flea)</em></td>
<td>CGA219417/0461</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>Test (observed Endpoints)</td>
<td>Duration and conditions</td>
<td>Result cyprodinil</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>---------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><em>Daphnia magna</em> (Water flea)</td>
<td>Chronic</td>
<td>Flow-through, 21 days exposure; US-EPA FIFRA 72-4(b) 1982; purity: 92.8%; dose= 0.0082, 0.019, 0.040, 0.079 and 0.147 mg/l</td>
<td>NOEC = 0.0082 mg a.s./l</td>
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<tr>
<td><em>Pseudokirchneriella subcapitata</em> (Freshwater Green Algae)</td>
<td>Growth inhibition</td>
<td>72h exposure; OECD 201; purity: 99.4%; dose= 0.41, 0.94, 2.00, 4.41 and 9.47 mg/l</td>
<td>$E_{C50} = 5.2$ mg a.s./l ; $E_{B50} = 2.6$ mg a.s./l</td>
</tr>
<tr>
<td><em>Chironomus riparius</em></td>
<td>Spiked sediment exposure, emergence rate &amp; development of midge</td>
<td>27 days exposure; OECD proposal of 1998; BBA Guideline 1995, purity: 99.4%; spiked sediment 20, 40, 80, 160, and 320 mg/kg</td>
<td>Sediment exposure: NOEC = 80 mg a.s./kg sediment</td>
</tr>
<tr>
<td><em>Apis mellifera</em> (Honeybee)</td>
<td>Contact; Mortality / behaviour</td>
<td>48 hours exposure; EPPO 170 (1992); purity: 99.4%; Contact doses: of 54, 89, 196, 396, and 784 µg/bee</td>
<td>Contact $LD_{50} = &gt; 784$ µg a.s./bee</td>
</tr>
<tr>
<td><em>Eisenia foetida</em></td>
<td>Acute toxicity, Mortality /</td>
<td>14 days exposure; OECD 207; purity: 99.6%;</td>
<td>$LC_{50} = 192$ mg a.i./kg soil</td>
</tr>
</tbody>
</table>
The results of extensive tests demonstrate the low acute and short-term toxicity of cyprodinil to birds.

Based on acute toxicity tests in the laboratory cyprodinil is classified as toxic to fish and algae and very toxic to crustaceans. Toxicity to the midge *Chironomus riparia* was low after application to sediment. In experiments in freshwater ponds a rapid dissipation of cyprodinil from the water phase was observed and toxicity to aquatic organisms was significantly reduced compared to laboratory results. Various assessments demonstrate that the risk to aquatic organisms is acceptable after recommended use in agriculture.

Cyprodinil has a low acute toxicity to honeybees and earthworms.
Cyprodinil was evaluated by the FAO/WHO JMPR in 2003.
Toxicity Class WHO (cyprodinil, proposed): III
Cyprodinil is classified by Xi; R43; N; R50/53; S-2; S-24; S-37; S-46; S-60; S-61 by the Directive 67/458/EEC 31st ATP.

Formulations and co-formulated active ingredients
The main formulation types available are WG and EC.
These WG formulations are registered and sold in many countries throughout the world.
The EC formulation is registered and sold in the United Kingdom. It is in the registration process in various other European countries.

Methods of analysis and testing
The analytical method for determination of cyprodinil is based on reversed phase HPLC with external standardisation and UV detection. The method including three identity tests based on retention time comparison in HPLC, in widebore capillary GC and comparison of IR spectra was presented at the 2008 CIPAC Meeting in Braunschweig, Germany and accepted as provisional CIPAC Method.
Test methods for determination of physico-chemical properties of the technical active ingredient were essentially OECD, EU and EPA methods, while those for the formulations were CIPAC methods, as indicated in the specifications.

Physical properties
The physical properties, the methods for testing them and the limits proposed for the WG and EC formulations, comply with the requirements of the FAO/WHO Manual (revised 1st edition, 2006).

Containers and packaging
No special requirements for containers and packaging have been identified.

Expression of the active ingredient
The active ingredient is expressed as cyprodinil.
**ANNEX 2: References**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CGA219417/0268</td>
<td>1994. Aqueous photolysis of pyrimidyl-labelled CGA 219417 under laboratory conditions.</td>
</tr>
<tr>
<td>CGA219417/0292</td>
<td>1994. Aqueous photolysis of phenyl labeled CGA 219417 under laboratory conditions.</td>
</tr>
<tr>
<td>CGA219417/0878</td>
<td>1998. CGA 219417 - Dissociation constant.</td>
</tr>
<tr>
<td>CGA219417/0020</td>
<td>1990. Acute oral toxicity in the rat.</td>
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<tr>
<td>CGA219417/0021</td>
<td>1990. Acute dermal toxicity in the rat.</td>
</tr>
<tr>
<td>CGA219417/0022</td>
<td>1990. Acute dermal irritation/corrosion study in the rabbit.</td>
</tr>
<tr>
<td>CGA219417/0023</td>
<td>1990. Acute eye irritation/corrosion study in the rabbit.</td>
</tr>
<tr>
<td>CGA219417/0746</td>
<td>1996. Skin sensitization test in the Guinea pig - Maximization test.</td>
</tr>
<tr>
<td>CGA219417/0045</td>
<td>1991. 3-Month oral toxicity study in rats (administration in food).</td>
</tr>
<tr>
<td>CGA219417/0044</td>
<td>1991. 3-Month subchronic oral toxicity study in Beagle dogs.</td>
</tr>
<tr>
<td>CGA219417/0122</td>
<td>1992. 12-Month chronic dietary toxicity study in Beagle dogs.</td>
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<td>CGA219417/0025</td>
<td>1990. Salmonella and Escherichia/Liver-Microsome Test</td>
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<td>CGA219417/0028</td>
<td>1990. Gene mutation test with Chinese hamster cells V 79 (OECD CONFORM)</td>
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<td>CGA219417/0040</td>
<td>1991. Cytogenetic test on Chinese hamster cells in vitro (EC-conform)</td>
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<td>CGA219417/0029</td>
<td>1990. Micronucleus Test, Mouse in vivo study.</td>
</tr>
<tr>
<td>CGA219417/0239</td>
<td>1994. 18-months carcinogenicity study in mice.</td>
</tr>
<tr>
<td>CGA219417/0252</td>
<td>1994. 24-Months carcinogenicity and chronic toxicity study in rats.</td>
</tr>
<tr>
<td>CGA219417/0162</td>
<td>1993. Two-generation reproduction toxicity study in rats with CGA 219417 technical (dietary administration).</td>
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<tr>
<td>CGA219417/0027</td>
<td>1991. Developmental Toxicity (Teratogenicity) Study in Rats</td>
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<tr>
<td>CGA219417/0039</td>
<td>1991. Developmental Toxicity (Teratogenicity) Study in Rabbits with CGA 219'417 tech. (Oral Administration)</td>
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<td>CGA219417/0062</td>
<td>1992. Acute oral toxicity (LD50) to mallard duck</td>
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<tr>
<td>CGA219417/0067</td>
<td>1992. Acute oral toxicity (LD50) to bobwhite quail</td>
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